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Science**

*Socio-Legal Perspectives on Biobanking: The Case  
of Taiwan*

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## **Declaration**

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## **Abstract**

This thesis investigates in depth the phenomenon of biobanking from an anthropological and socio-legal approach. In recent years there has been an ever-tighter alliance formed between discoveries in life sciences and capital accumulation. The rapid advances in genomics introduce a new form of capital in the development of technoscience. In order to find biomarkers for genetic association studies in the susceptibility of common complex diseases, the generation of large-scale population resources is deemed to be an important step to support the development of genomics which now transforms its imagery from informatics to therapeutics. Biobanks - collections of human biological materials linked through genetic information - have attracted considerable attention across the globe. These global assemblages of capital and vital politics have led to innovative institutions and arrangements in fields of technoscience and ethics. Though biobanking is an apparently global phenomenon, diverse political innovations and ethical configurations emerge from the specific social and cultural milieux, in which its establishment and operation are situated. This thesis uses recent developments of a longitudinal population-based research resource in Taiwan as a specific instance to analyse the delicate entanglement between politics, capital and life sciences. It explores not only the legal and ethical issues posed by biobanks, such as consent, privacy and property, but also the political and economic aspects of the biobanks that are embedded in the broader global bio-economies. This emphasis, focusing on the way in which biovalue is produced, politico-scientific decisions are made and ethical configurations are framed, allows an opportunity to reassess law and ethics, capital and politics, as well as the role of the state and its populations in this new form of biotechnology.

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## Chapter 1 Introduction

### 1. 1 A Political Economy of Biobanks

#### 1.1.1 The Production of Biovalue

In recent years there has been an ever-tighter alliance formed between discoveries in life sciences and capital accumulation. The rapid advances in genomics introduce a new type of capital in the development of technoscience. In his book *Biocapital*, Kaushik Sunder Rajan studies the entanglement between scientific and economic growth by examining the co-production of the life sciences and political economy.<sup>1</sup> The term 'biocapital' has been used to analyse the constitutive facts of biopolitics in processes of global capitalism that lay the ground for the market frameworks within which genomics emerge.<sup>2</sup> Biocapital, according to Sunder Rajan, refers to sets of systems and practices related to the production and exchange of biovalue on the global stage. Compared to other traditional arenas of accumulation under global capitalism, such as industrial and commercial capital, biocapital derived from advances in genomics remains relatively juvenile. The discovery of the molecular structure of DNA - the double helix - in 1953 was only a few decades ago and the application of this idea to genetic engineering had not yet been fully developed until the early 80s.

Since the announcement of the working draft sequence of the human genome in June 2000, the rapid development of population genomics has brought the new form of capital and socio-politics into the terrain of the life sciences. After the initial attempts to sequence and map human genomes, scientific enquiries propel further analysis of genetic variation between individuals and populations. In order to find biomarkers for genetic association studies in the susceptibility of common complex diseases, the generation of large-scale population-based research resources is deemed to be a preliminary but important step to support the development of genomics which now transforms its imagery from informatics to therapeutics.<sup>3</sup> The scientific shift to postgenomics opens up

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<sup>1</sup> Kaushik Sunder Rajan, *Biocapital: The Constitution of Postgenomic Life* (Duke University Press, 2006). P. 4

<sup>2</sup> *Ibid.*, pp 33-34

<sup>3</sup> Kaushik Sunder Rajan, "Two Tales of Genomics: Capital, Epistemology, and Global Constitutions of the Biomedical Subject," in *Reframing Rights: Bioconstitutionalism in the Genetic Age*, ed. Sheila Jasanoff (MIT Press, 2011). P. 198

the opportunity for further development of personalised medicine so that diagnostic and therapeutic tools based on genomics could be tailored to individual genetic profiles.<sup>4</sup> On the other hand, this aspiration to consumer genomics influences the development of pharmacogenomics which aims to tailor prescriptions based on individual genetic variation in drug response in order to optimise drug therapies by ensuring maximum efficacy with minimal side effects.

Biobanks - collections of human biological materials linked through genetic information - have therefore attracted considerable attention across the globe. Following the mapping of genetic variation which made it easier to link genes and disease, biobanks have been recognised by many scientists and geneticists as the next logical step to translate genomics knowledge into clinical applications. Many countries have joined in this emerging global trend to set up their own large-scale population biobanks to support the application of genomics research. With the goal of capitalising on a state's genetic resources, biobanking turns into a new technique for a state to incorporate the biological existence of its population into a series of political and economic concerns. The dual investment in public health and economic growth characterises biobanks as both generators of pioneering scientific knowledge and a new technique for the advancement of the health and wealth of modern states, which may now take its stewardship responsibility for generating technologies of government by rearranging its resources in the name of collective security and the public good.

This thesis examines how the initiative and practice of biobanking is shaped through its entanglement with political economy and how theoretical engagement with biocapital and biopolitics may contribute in a meaningful way to reassess the role of bioethics and the notion of the individual and the collective within the context of biobanking. The thesis uses recent developments of a longitudinal population-based research resource in Taiwan as a specific instance to analyse the delicate entanglement between politics, capital and life sciences. It demonstrates how bioethical configurations may have failed to challenge the influence of global capitalism when they are positioned within the context of Taiwan's biocapital formation. It further analyses the relations between the state and the people and how the notion of citizenship may assist in turning population into resources when

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<sup>4</sup> Ibid.

the state has transformed its role from a steward to an investor in global bioeconomic competition.

The French philosopher Michel Foucault had argued that modern sovereign power is manifested in the management of life by a set of procedures and mechanisms through which human beings become the object of political strategy.<sup>5</sup> Unlike classical sovereignty, which was characterised by its power to 'take life or let live', the modern operation of biopower emphasises taking charge of life and turns modern politics into an innovative apparatus for the administration of the life of each and all.<sup>6</sup> For Foucault, the genealogy of the modern welfare state can be traced back to various state strategies invented in eighteenth-century Europe as a means to govern the naturalness of the population such as birth, disease and mortality. These strategies should not be understood separately, according to Foucault, from the development of statistics as the technique for numerical calculability of subjects and the emergence of risk calculation on which modern states relied to manage their administration of demographics and to measure the economy for prosperous continuity.<sup>7</sup> From this Foucauldian perspective, the welfare state may be viewed as an innovative political form of mutual risk pooling.<sup>8</sup> It emphasises the individual's relation to the collective by the state's intervention with techniques to protect the life of each and all through redistributing national wealth to its citizens in exchange for a reciprocal obligation on citizens to render their lives to the governance of the state.<sup>9</sup>

Like genomics, national population biobanks have become prolific sites at which scientific knowledge and its derived value and hope are closely entangled. Biobanks act vigorously as assemblages of vital politics and capitalism on the global stage. On the one hand, biobanking demonstrates modern states' stewardship responsibility to address the wellbeing of their populations by managing diseases and improving health. On the other hand, however, biobanking is a technique for states to increase their competitiveness in the global bio-economy. As Sunder Rajan recognises, biotechnologies such as genomics

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<sup>5</sup> Michel Foucault, *The History of Sexuality, Vol. 1: An Introduction* (Penguin, 1981). pp 137-139

<sup>6</sup> Nikolas Rose, "The Politics of Life Itself," *Theory, Culture, & Society* 18, no. 6 (2001). pp 1-2

<sup>7</sup> Graham Burchell et al., *The Foucault Effect : Studies in Governmentality ; with Two Lectures by and an Interview with Michel Foucault* (Chicago: University of Chicago Press, 1991).

<sup>8</sup> Melinda. Cooper, *Life as Surplus : Biotechnology and Capitalism in the Neoliberal Era* (Seattle: University of Washington Press, 2008). P. 7

<sup>9</sup> *Ibid.*, P. 8

have transformed life into a calculable market unit; biobanks set up a similar strategic terrain on which states may operate as agents and investors negotiating in global markets.<sup>10</sup> By studying modes and relations of production in biotechnologies, Sunder Rajan turns to Karl Marx's *Capital* as a supplement to Foucault's conceptions of biopower and biopolitics. In doing so, Foucault's influential notions of knowledge and power may be reconceptualised in the context of market forces.<sup>11</sup>

For Marx, capital is not a thing but a social relation between persons that was established through industrial capitalist production and exchange by the instrumentality of things. Compared to industrial capital, surplus value generated from merchant's (commercial) capital has a speculative nature as it is mainly created through the circulation of capital rather than relying on production. Emerging as a result of the rapid technoscientific changes in the life sciences, biocapital involves the production and circulation of capital and commodities which are composed of human biological materials and genomic information.<sup>12</sup> As political theorist Melina Cooper has argued, life science technologies and neoliberalism share a commonality in their ambition to overcome limitations on growth associated with the decay of industrial production and as a result, they both need to rely on finding new resources through a speculative reinvention of the future in order to create surplus value.<sup>13</sup> By analysing the link between biocapital and the drug development value chain, Sunder Rajan suggests that biotech and pharmaceutical industries represent two distinct forms of capital.<sup>14</sup> Biotechnologies, like industrial capital, focus more on upstream drug discovery and production; pharmaceutical industries, on the other hand, are more like speculative commercial capital, regulating the distribution of commodities and capital flows by deciding whether to invest in upstream technologies in the process of drug development.<sup>15</sup>

Furthermore, the rapid development of biotech and pharmaceutical industries in the field of genomics has transformed populations into fertile sources of biotech innovation and

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<sup>10</sup> Supra note 6, P. 34

<sup>11</sup> Supra note 7, P. 194

<sup>12</sup> Supra note 6, P. 17

<sup>13</sup> Melinda. Cooper, *Life as Surplus : Biotechnology and Capitalism in the Neoliberal Era* (Seattle: University of Washington Press, 2008). P. 11

<sup>14</sup> Supra note 6, P. 21

<sup>15</sup> Ibid., pp 23-24

biocapital accumulation. In order to constitute a prospective cohort for facilitating the study of multiple diseases, it requires very large numbers of participant enrolment to give ongoing access to donated samples and prospective health information for at least 20 to 30 years. Compared to small tissue and genetic information collections, a large-scale population biobank is characterised by the specific goal of providing long-term access to information, such as participants' lifestyle and health records. As a result, a national biobank may provide the statistical power necessary to identify gene-environment risk factors for common complex diseases.<sup>16</sup>

In a recent study discussing the economic aspects of biobanks, Catherine Waldby and Robert Mitchell point out that a population contributes a significant portion of the 'clinical labour' required for the creation of biovalue through the establishment of population biobanks, and that participation in biobanks' activities has been conceptualised as 'gift' rather than a form of embodied labour work that produces economic value.<sup>17</sup> The population is nurtured as a resource so the value it generates can be added through a process of biobanking by the technicians who collect and process samples. In this context, national populations may be viewed as 'economically productive participants', as their enrolment into biobanking is expected to bring a commercial potential for states.<sup>18</sup> As Waldby and Mitchell rightly observe, even though populations' participation in biobanks is often under civic discourses of public good, their enrolment is, in fact, formulated in profitable way and is closely linked to the creation of biovalue that demonstrates the economic aspect of population biobanks.<sup>19</sup>

The notion of biovalue here denotes how the productivity of living entities may be produced as a valuable resource useful for human projects.<sup>20</sup> As it has been argued that the production of biovalue is associated with the development of bio-economies, modern articulations of citizenship have been reconfigured with neoliberal techniques by viewing the constitution of a population as a living resource for satisfying a state's economic

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<sup>16</sup> Ibid., P. 2

<sup>17</sup> Robert Mitchell and Catherine Waldby, "National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue," *Science Technology Human Values* 35, no. 3 (2010). P. 7

<sup>18</sup> Ibid., P. 13

<sup>19</sup> Ibid.

<sup>20</sup> Cathy Waldby and Robert Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Duke: Duke University Press, 2006).

demands.<sup>21</sup> New debates over what it means to be a citizen in the postgenomics era is gradually being framed by interrelationships between biopolitics, neoliberal logics and governmentality. The traditional elements constituting citizenship such as sovereignty, rights and entitlements have been linked to techniques of optimisation adopted by the state. This includes not only technologies of subjectivity, as anthropologist Aihwa Ong argues, such as techniques of capital accumulation and optimisation of health regimes, but also *technologies of subjection*, so national populations may be governed for optimal productivity through citizenship projects and practices that engage market forces.<sup>22</sup> In addition, as contemporary sovereignty providing the territoriality of citizenship has embedded in the territoriality of global capitalism,<sup>23</sup> the articulation of civil rights, benefits and obligations in the age of postgenomics is inevitably influenced by forces set into motion by global technoscience and global markets.

Moreover, even though an important aim for population biobanks is to improve public health (so biobanks may be viewed as national projects for achieving a public good), these biobanks have been associated with various types of biocapital formation generated mainly by the genomic and pharmaceutical industries.<sup>24</sup> As Sunder Rajan has recognised, the distinction between public and private is blurred when most pharmaceutical industries are consumers rather than generators of genomic data in the public domain. When a state itself starts acting analogously to a biotech company to conduct upstream research and development in the drug production process,<sup>25</sup> population biobanks produce and reproduce a similar entanglement between public and private in terms of the allocation of resources in health regimes and the mobilisation of potential participants from the perspective of citizenship. As preserving citizens and enhancing the biovalue produced from them extends the stewardship responsibilities of the state, the notion of biovalue has also been expanded from economic and political meanings, such as enhancement of health and wealth, to an ethical endeavour. In the process of transforming national citizens into a potential resource for the production and accumulation of health and wealth, the conception of citizenship helps generate clinical

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<sup>21</sup> Supra note 16, P. 5

<sup>22</sup> Aihwa Ong, *Neoliberalism as Exception : Mutations in Citizenship and Sovereignty* (Duke University Press, 2006). pp 5-6

<sup>23</sup> Ibid.

<sup>24</sup> Supra note 16, P. 6

<sup>25</sup> Supra note 6, pp 45-46

labour in the context of biobanks which can produce both long-term benefits to public health and short-term incentives to intellectual property rights as well as their derived commercial profits.

Nikolas Rose and Carlos Novas have used the term biological citizenship to illustrate how national citizenship projects may form contemporary citizens as not only individuals with entitlements to national healthcare and welfare but also potential generators of biovalue for the development of the state.<sup>26</sup> Traditionally, the notion of citizenship presupposes an individual's particular awareness of rights and duties of the self and its relations with others that forms the moral attributes of a community. Contemporary biological citizens, according to Rose and Novas, have also learned to use life - the very fundamental desires of survival - to negotiate the practices of health policies and regulation as well as the population's economic and social inclusion.<sup>27</sup> In other words, a new form of ethics which makes life into a marketable asset for the political economy of hope has taken shape and become a desirable good in order to facilitate the production of clinical labour by which citizens are being built up as both consumers for the products of genomics and subjects of autonomy and responsibility.<sup>28</sup>

By emphasising the safeguard of individual autonomy, for instance, ethical discourses such as informed consent and privacy have been placed in the forefront for the creation and operation of biobanks. These bioethical mechanisms may be viewed as techniques of ethical formation for the management of the individual and the collective from the perspective of governmentality and biopolitics. According to Foucault, governmentality is an array of technologies proposed by governing authorities to regulate individuals' decisions and choices so the governed subjects may act out of their own will in accordance with authoritative criteria.<sup>29</sup> Similarly, the mechanism of informed consent acts as advanced liberal rule to construct populations as 'empowered citizens' who are able to make rational choices based on given information with regard to their

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<sup>26</sup> Nikolas Rose and Carlos Novas, *Biological Citizenship*, ed. Aihwa Ong and Stephen Collier, *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems* (Oxford: Blackwell Publishing, 2005).

<sup>27</sup> *Ibid.*, p. 441

<sup>28</sup> *Ibid.*, p. 457

<sup>29</sup> Nikolas Rose, "Governing "Advanced" Liberal Democracies," in *Foucault and Political Reason : Liberalism, Neo-Liberalism and Rationalities of Government* ed. Andrew Barry, Thomas Osborne, and Nikolas Rose (London Routledge, 1996). pp 41-42

participation in biobanks.<sup>30</sup> As a result, these bioethical mechanisms should not be treated simply as politically neutral premises; rather, their practices and trajectories need to be understood when the bioethical arrangements are re-embedded in the political economy structure in which biobanks were born and operate.

From a political economy perspective, neoliberal logics of economic growth stimulate states to take biobanking as a technoscientific approach to find niches in global competitiveness and to restore national pride. For these states, biobanking is not only a biotech innovation to improve public health and the quality of life but also the materialisation of expanding national aspirations in global competition. In addition, even though biobanking appears as a global phenomenon and its initiative is closely linked with the flow of global capital, it reflects diverse political innovation and ethical configuration when its establishment and operation are situated in specific social and cultural milieux. Characterised as heterogeneous and contingent, these national biobanks have revealed different civic epistemologies in various localities. As Stephen Collier and Aihwa Ong argue, even though technoscience and ethics may have global forms and qualities, they shape novel values of individual and collective existence and reconstitute the classic abstractions such as economy, society and culture when they are articulated in specific situations.<sup>31</sup> Anthropologist Michael Fischer has also suggested a recombinant anthropology of science and technology is moving into public futures that call for engagement across cultural difference on the global stage.<sup>32</sup> According to Fischer, the public future refers to an emergent phenomenon in the context of cosmopolitics in which articulations about politics, new knowledge and ethics can be generated and assembled in culturally and socially contested sites.<sup>33</sup>

### **1.1.2 Biobanking in Taiwan**

In April 2005, the Taiwanese government launched a Biomedical Technology Island Plan in

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<sup>30</sup> Oonagh Corrigan, "Informed Consent: The Contradictory Ethical Safeguards in Pharmacogenetics," in *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* ed. Richard Tutton and Oonagh Corrigan (London Routledge, 2004). P. 86

<sup>31</sup> Aihwa Ong and Stephen J. Collier, "Global Assemblages, Anthropological Problems," in *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*, ed. Aihwa. Ong and Stephen J. Collier (Oxford: Blackwell Publishing, 2005). P. 4

<sup>32</sup> Micael Fischer, "Four Genealogies for a Recombinant Anthropology of Science and Technology," *Cultural Anthropology* 22, no. 4 (2007).

<sup>33</sup> *Ibid.*, pp 539-540



which a large-scale population biobank was proposed as a governmental project to upgrade Taiwan's bio-economies and to support health and medical research in Taiwan. From the 1960s to the 1980s, Taiwan fitted well into the model of a capitalist developmental state described by Chalmers Johnson. By analysing Japan's postwar economic reconstruction, Johnson argued that the rapid economic recovery in Japan was exemplary in a state-guided market economy that was characterised by the state's leading role in overall economic development and the closer collaboration between the public and private sectors.<sup>34</sup> The Japanese experience was taken up as a model to be widely replicated by the newly industrialising states of East Asia, such as Taiwan, South Korea, Singapore and Hong Kong, the so-called semi-peripheral parts of an interconnected global economy compared to the established core economies in North America and Western Europe during the 60s to 70s.<sup>35</sup> Unlike liberal policies and laissez-faire capitalism, a developmental state relies on a strong state apparatus to take on developmental functions so it is mainly based on technocratic macroeconomic planning to lead the state's industrialisation drive. In a nutshell, a key quality that makes a state developmental is that it relies on state agencies rather than market forces to determine the optimal allocation of resources.<sup>36</sup>

Strong state autonomy supported by competent bureaucratic technocrats provided state capacities not only to design and implement developmental policy but also to penetrate markets and mobilise society. From the 60s to 80s, the combination of domestic capacity and external environment provided Taiwan with opportunities to emulate the Japanese model and direct the course of its economic development. Having retreated from mainland China to Taiwan after the defeat of the Chinese civil war in 1949, the Kuomintang (KMT, Nationalist) government had remained a single-party state in Taiwan until the lifting of martial law in 1987. Consensus on developmentalism demonstrated the regime's survival imperatives as a response to the security threat from mainland China as well as the KMT's initial military plan to 'recover the mainland' by constructing its base on

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<sup>34</sup> More info, see, Chalmers Johnson, *Miti and the Japanese Miracle : The Growth of Industrial Policy, 1925-1975* (Stanford University Press, 1982).

<sup>35</sup> Mark Beeson, "The Rise and Fall (?) of the Developmental State: The Vicissitudes and Implications of East Asian Interventionism " in *Developmental States. Relevancy, Redundancy or Reconfiguration?* , ed. Linda Low (New York: Nova Science Publishers, 2004). P. 29

<sup>36</sup> Mark Beeson, "Developmental States in East Asia: A Comparison of the Japanese and Chinese Experiences," *Asian Perspective* 33, no. 2 (2009). P. 9

the island. Furthermore, Taiwan's particular geopolitical location - proximate to China, right at the intersection of Southeast Asia and East Asia - and its anti-communist political stance made it a crucial element in the United States' containment strategy during the Cold War Era.<sup>37</sup> Even though the cold war ended a few decades ago, the rise of China and India as new powers in Asia has influenced the international division of labour that also impacts on Taiwan's developmental strategies.

The rapid growth of newly industrialised economies depended mainly on resource accumulation, especially that of capital. Taiwan's industrial development leading to capital aggregation was mainly attributable to the contributions of its small and medium-sized enterprises (SMEs), which had been greatly supported by the state due to their flexibility in product lines, which allowed these enterprises to quickly adapt skills and imitate products of many innovative entrepreneurs.<sup>38</sup> In contrast with South Korea, which borrowed from the Japanese zaibatsu to form a highly conglomerated industrial structure composed of large-scale corporations (Chaebol), Taiwan's economic development was based on the state's cooperation with and support of vigorous SMEs, which were mainly export-oriented and more flexible than large enterprises in adjusting to changing world market conditions.<sup>39</sup> In Taiwan, the share of the large conglomerates in overall economic production is relatively smaller than that in Korea and Japan and such conglomerates were mostly concentrated in the state-owned enterprises (SOE), such as the China Steel Corporation and the China Petroleum Corporation.<sup>40</sup> Robert Wade has therefore pointed out that the function of state intervention in Taiwan was not to encourage domestic firms to maximise their long-run profitability; rather, it was for the state to control and manage the composition of national investment so that an integrated but flexible structure for production could be established.<sup>41</sup>

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<sup>37</sup> Robert Ash and J. Megan Greene, "Introduction," in *Taiwan in the 21st Century : Aspects and Limitations of a Development Model*, ed. Robert Ash and J. Megan Greene (London; New York: Routledge, 2007). pp 1-2

<sup>38</sup> Erik Thorbecke and Henry Wan, "Taiwan's Development Experience Stability with Growth, 1950-2002," in *Taiwan in the 21st Century: Aspects and Limitations of a Development Model*, ed. Robert Ash and J. Megan Greene (London; New York: Routledge, 2007). P. 61

<sup>39</sup> Ibid., P. 57

<sup>40</sup> Huck-ju Keon, "Transforming the Developmental Welfare State in East Asia," in *Working Paper No. 40 (ST/ESA/2007/DWP/40)* (United Nations/ DESA (Department of Economic and Social Affairs), 2007). P. 6

<sup>41</sup> Robert Wade, "State Intervention in Outward-Looking Development: Neoclassical Theory and Taiwanese Practice," in *Developmental States in East Asia* ed. Gordon White and Jack Gray (Basingstoke: University of Sussex, 1988). P. 54

Another factor was the evolution of a more market-friendly environment and institutional framework in order to increase competitiveness by cutting transaction costs and enhancing the process of capital accumulation. Due to the relatively limited size of its domestic market for sustained growth, Taiwan did not adopt an inward-oriented strategy in its overall development. Its import-substitution phase lasted for a short period in the 1950s before its transition to a phase of export promotion (1962-80) followed by a new phase of development characterised by a science and technology orientation since the early 80s.<sup>42</sup> At the beginning of the 1960s, export expansion became an essential factor contributing to domestic agricultural and manufacturing growth that shaped a closer nexus between exports and the growth of domestic productivity in Taiwan's development history.<sup>43</sup> Since the 80s, Taiwan's exports have gone through another structural adjustment, moving from a labour-intensive industrial structure to a capital- and technology-intensive one that increasingly replaces exports of non-durable consumer goods with final products such as electronic machinery and machine tools, etc.<sup>44</sup>

Due to the deepening of global economic integration, Taiwan has faced increasing challenges for its developmental strategies since the country became exposed to globalisation in the early 1990s. Considering that Taiwan's economic growth from the 60s to 80s was mainly based on export expansion underpinned by cheap labour costs, the increases to the general minimum wage in the early 90s raised a serious question for Taiwan's labour-intensive industrial structure when it faced the increasing loss of price competitiveness to other developing countries with abundant supplies of low-cost labour. Some Taiwanese enterprises started to move production lines to mainland China for export competition and since 1993, China has become the biggest recipient of Taiwan's outward foreign direct investment (FDI)<sup>45</sup>, leading to the shrinking of its domestic manufacturing base and employment opportunities in Taiwan. Given the threat of global competition and the rise in the unemployment rate, the Taiwanese government saw that it would need to adjust the industrial structure by upgrading Taiwan's manufacturing economy to a knowledge-based one, developing sectors such as information technology

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<sup>42</sup> Supra note 39, pp 58-59

<sup>43</sup> Ibid., P. 59

<sup>44</sup> Ibid.

<sup>45</sup> Chen-Yuan Tung, "Trilateral Economic Relations among Taiwan, China, and the United States. ," *Asian Affairs* 25, no. 4 (1999). P. 220

(IT) and biotechnologies which generally require a more sophisticated labour force so that the country could maintain its comparative advantages under the trend of globalisation.

On the other hand, in domestic politics, Taiwan experienced its democratic transition after the mid-1980s with the legitimising of a newly-formed opposition party - the Democratic Progressive Party (DPP) - in 1986 and the lifting of martial law a year later in 1987. Following the full election of the Legislative Yuan (Parliament) in 1992 and then the first direct presidential election in 1996, Taiwan has peacefully transitioned from a one-party political system to an electoral democracy. Democratisation undermines the constituent elements of a developmental state, which relies on a strong, autonomous state apparatus to deliberately intervene in overall economic decisions. In 2000, the DPP marginally won the presidential election due to a substantial split inside the KMT, and during its two-term, eight-year administration from 2000 to 2008, biotechnology and pharmaceutical industry had been treated by the government as the flagship industry for Taiwan's next stage of economic transition. In addition, democratic political competition has triggered welfare state construction in Taiwan as a response to electoral promises delivered by both parties.

By contrast with Western welfare states which view welfare expenditures, such as healthcare, pensions and public health policy, as a growing burden on economic growth, especially in the context of an integrated world economy as the states need to raise production costs via higher taxes for social welfare, the welfare state system in Taiwan has been established and incorporated in the state's overall strategy of economic development.<sup>46</sup> In other words, social and public health policies in Taiwan have been instrumentalised to promote economic growth that subordinates the policies to economic efficiency in order to maintain the state's developmental credentials.<sup>47</sup> In this context, the role of the state becomes complicated. Even though it needs to take a stewardship responsibility to ensure its citizens' rights and entitlements, as an actor and investor in global markets, the state relies on its population to produce resources and generate surplus value for the state's long-term sustainability and perpetual growth through the revenue it can draw from the economy of which it is steward.

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<sup>46</sup> Supra note 39

<sup>47</sup> Ibid., pp 1-2

Biobanking blurs the traditional distinction between concepts of citizens and population by generating a collective mode of biovalue from subjected population through discourses of common good based on the notion of citizenship. As a new type of biovalue generator, it manifests a novel form of biopolitics in Taiwan when biobanking is re-embedded in the specific context of biocapital formation in which the future of life science research is being rerouted towards economic applications. What is at issue here is the extension of the speculative logic of capital into genomics research and personalised medicine so the classic growth cycles of production, reproduction and capital accumulation is rejuvenated by introducing the “biological turn” in the neoliberal era.<sup>48</sup> In so doing, the state may facilitate a neoliberal rationale to capitalise not only its own population but also the intrinsic value of the welfare state, such as collective wellbeing, social justice and redistribution. As Melinda Cooper argues, neoliberalism projects its strategy of capital accumulation into a speculative future by “installing speculation at the very core of production”.<sup>49</sup> Population biobanks materialise this kind of rationale in the life sciences by producing a prospective life surplus<sup>50</sup> in biotech application in the hope of overcoming the limits to growth associated with industrial production.

Despite rapid economic growth from the 60s to 80s, Taiwan’s developmental strategy confronted a series of challenges of domestic democratic transition and global competition. As a result, establishing a population biobank may be viewed as a response not only to an economic downturn but also to the increasing demand for forming a welfare state in Taiwan. The idea of setting up a population biobank has been particularly welcomed and supported by biotech and pharmaceutical industries in the island as they will be the major beneficiaries from using the data of the biobank. As the ultimate goal of biobanking in Taiwan is for the development of personalised medicine, considering that Taiwan’s overall population is dominated by Han Chinese, if Taiwan could take an advanced position in pharmaceutical design for Han Chinese genes, it would bring the

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<sup>48</sup> In the language of Melinda Cooper, See: Cooper, *Life as Surplus : Biotechnology and Capitalism in the Neoliberal Era*. P. 75

<sup>49</sup> Supra note 12, P. 10

<sup>50</sup> For Cooper, life surplus refers to the shift in production mode of capitalism from labour to biological life so life can be viewed as a source of surplus and once value is rooted in labour force, it is rooted in biological life (as biological life is presupposed by labour force) and its spheres of production and reproduction. However, what seems to be missing in Cooper’s interpretation is the demonstration that the exploitation of biological life in order to create surplus value is subject to the same contradictions as the production of surplus value from labour. More info, see: Miguel E Vatter, "Biopolitics: From Surplus Value to Surplus Life," *Theory & Event* 12, no. 2 (2009).

country tremendous commercial benefits for drug invention specifically targeting Han Chinese around the world.

In addition, as an important function of a large-scale population biobank is to discover gene-environment risk factors by searching biomarkers, such as single nucleotide polymorphisms (SNPs) or haplotype (a set of SNPs), across the complete set of human genome for identifying affected genetic association in DNA sequences, the biobanks create a distinctive form of biocapital grounded in the identification of risk categories that opens up a market for DNA-based risk factor diagnostic devices and products. These lucrative commodities allow individuals to realise their susceptibility to certain diseases given the presence of certain conditions and environmental exposures. Without continued access to a biobank which can provide stored biospecimens and genetic information that remains traceable to the particular individuals, the biovalue generated would not have been possible.<sup>51</sup> However, when more and more emphasis has been placed on the function of the biobank to produce and reproduce biovalue than on its duty of redistribution of wealth, biobanking in Taiwan has become a specific strategy of neoliberal life politics by reconfiguring the very meaning of life.

## **1.2 Research Approach**

### **1.2.1 An Anthropological and Socio-Legal Approach**

This thesis adopts anthropological and socio-legal approaches. It attempts to present research findings which combine empirical and theoretical viewpoints. Compared to traditionally doctrinal methods undertaken in studying law and relevant legal phenomena, carrying out research in law from a humanistic and social scientific standpoint is still relatively new in legal scholarship. However, rather than viewing law as a system of rules and doctrines, law may also be understood as a reflexive social institution so it requires a special research method besides those already developed by mainstream legal research. In their paper discussing the study of law in society in Britain in the mid-70s, English scholars Wiles and Campbell made a methodological distinction between the approaches taken by socio-legal studies and the sociology of law. For them, the so-called socio-legal studies seemed to focus more on employing social sciences as a research tool than adapting it in a theoretical way for substantive analysis of law, so sociology in this sense

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<sup>51</sup> Supra note 16, P. 12

was treated as a technique for data collection.<sup>52</sup> Nevertheless, the further development of socio-legal studies since then has put this stereotypical distinction into question. Not limiting methods to empirical research, contemporary socio-legal research is captured in a more recent attempt to employ interdisciplinary perspectives to challenge classical doctrinal studies of law.<sup>53</sup> In so doing, a legal system may no longer be taken for granted as the way it appears; nor are the existing legal norms, rules or definitions the system encompasses. Rather, the legal system needs to be comprehended thoroughly under the wider political-economic and social structures within which it forms and operates, so the system itself and its purpose may be challenged from an exogenous standpoint.<sup>54</sup>

To a certain extent, this kind of research concern is not unfamiliar to social anthropologists who seek to keep themselves exogenous from their research subjects so a space and liberty can be created to generate new insights in the substantive contents of their research topics. An anthropological perspective can provide a holistic and contextual analysis of law that draws attention to the effects of political economy and social conditions within which law become a set of relations. Such a perspective, according to Anne Griffiths, generates an alternative vision of law from formalist legal discourses by incorporating views of "law as process" in the study of what constitutes a legal domain.<sup>55</sup> In addition, as the anthropological approach adopts an actor-oriented perspective, it supplements conventional legal doctrines and sources, such as cases and rules, with subtle and essential elements, for instances, class, ethnicities, gender and power relations which are often missing in the traditional study of legal system.<sup>56</sup> As it has been argued that individuals are located within kin and social networks to which they belong, an anthropological approach helps situate law in relations to agencies and their situated networks that opens up for a more sophisticated analysis of law with regard to how it may be reconfigured through social processes that frame its constitution and transformation over time.<sup>57</sup>

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<sup>52</sup> C M Campbell and P Wiles, "The Study of Law in Society in Britain," *Law and Society Review* 10(1976).

<sup>53</sup> Reza Banakar and Max Travers, "Introduction," in *Theory and Method in Socio-Legal Research* ed. Reza Banakar and Max Travers (Hart Publishing 2005). xi

<sup>54</sup> Ibid.

<sup>55</sup> Anne Griffiths, "Using Ethnography as a Tool in Legal Research: An Anthropological Perspective," in "Introduction." In *Theory and Method in Socio-Legal Research Edited by Reza Banakar and Max Travers*, ed. Reza Banakar and Max Travers (Hart Publishing, 2005). pp 113-114

<sup>56</sup> Ibid., pp 115-116

<sup>57</sup> Ibid., P. 130

The empirical data collected from qualitative research methods such as interviewing, focus group and observation in this research has been used to constitute theoretical sides of the thesis. In other words, research findings derived from empirical data have been situated in relations to debates in the existing literature. In doing so, the thesis aims to show that socio-legal studies may not only address the effects of law in society but also the constitution of law itself. However, due to the nature of this research, the anthropological approach involved here does not refer to a long period of fieldwork and participatory observation anthropologists rely on to produce their ethnographic knowledge. Rather, it is constituted of several short-term fieldtrips encompassing observation and interviewing carried out during a three-year period from 2008 to 2011. In anthropological methodology, a long period of fieldwork (at least a year) provides researchers an opportunity to observe the annual cycle of important behaviour and events emerging from the fieldwork setting. However, compared to most anthropological research design which focuses more on a specific territory or area, rather than a research problem itself, the research method adopted here is a deliberate choice to reflect the difference between the nature of this research and traditional anthropological study. In addition, in terms of building up theories, the anthropological approach here refers to an exploration of the rich literature of ethnographies including concerns, conceptions and narratives that have been produced and reproduced by social anthropologists.

With an attempt to reconcile structure and agency, French anthropologist Pierre Bourdieu argued that the system of the legal universe, like the social universe, is constituted by the dual spaces of social structures and mental structures.<sup>58</sup> The former refers to objective systems of position such as the system of distribution of resources, whereas the latter concerns the subjective systems of dispositions of the agents. By putting the agents back to the legal system, law may be viewed not merely as a matter of techniques but as symbolic power systems which are constituted by economic and cultural capital in relation to the reproduction of the power of the state and the economy.<sup>59</sup> An anthropological approach reflects the symbolic structures presented in the legal field, so rather than focusing on its formal characteristics, this thesis plans to

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<sup>58</sup> Mikael Rask Madsen and Pierre Bourdieu, "Pierre Bourdieu: From Law to Legal Field " *Retfaerd* 114 (2006).

<sup>59</sup> Ibid.



explore the vision of law from its constitution, trajectory, power structures and its relations with social conditions and political economy.

### **1.2.2 Empirical Viewpoints**

The central empirical questions in this thesis relate mainly to formulating ways to observe how biobanking operates within the context of Taiwan. As the pararegulatory and ethical regime with regard to biobanking in Taiwan may be traced to a diverse set of social and economic processes, the scope of this empirical research includes studying the biobank's initiatives, research designs, institutional coordination, agencies, sample collections, confronted ethical dilemmas and governance frameworks, as well as Taiwanese aborigines' participation in the biobank, such as their concerns about stigmatisation, their political and economic rights and their perception about the implementation of the so-called 'group consent'. The biobanking project in Taiwan was still in its very early development from 2008 to 2011 and therefore it was very difficult to ascertain precisely the future evolution of the biobank. As a pilot study project, the biobank's operation fluctuated because of compromises of various different interests of the involved actors and agencies - the government, scientists, social scientists, the Institutional Review Board (IRB), the Ethics and Governance Council (EGC), potential participants, human rights organisations and biotech industries. The trajectory of the project demonstrated a mixture of aspirations and anxieties about health and economics which provided a valuable opportunity to observe the dynamics of the emergence of the biobank within the Taiwanese context.

Since the aim of the study is to investigate in depth the practice of biobanking in Taiwan, this research adopts multi- qualitative research methods such as semi-structured interviews, participant observation and a focus group. In order to ensure that the whole image of the biobanking may be faithfully presented, a purposive sampling strategy was taken which means that in the research design, the interviewees were not randomly chosen but purposely covered a broad range of actors who had constituted the biobanking phenomenon in Taiwan one way or another. For example, they included scientists who were responsible for the research design and the preliminary operation of the pilot study of the Taiwan Biobank project; geneticists and epidemiologists engaged with research on population genomics; medical doctors and pathologists collecting

various types of small-scale biobanks; legislators, scholars and governmental officials who had once been involved in the enactment of the recently passed Human Biobank Management Act, human rights advocates opposed to the pilot study project, members of the original Ethics and Governance Council of the biobank, ordinary Taiwanese aborigines and aboriginal medical doctors for their responses to the inclusion of Taiwanese aborigines into the original biobanking research design.

In order to identify and approach participants, a snowball sampling was adopted for the recruitment of potential respondents. It means that extended interviewees were mainly referred by existing study subjects who were requested to provide the names of the people to whom they were acquainted that might be relevant to this research project. The initial contacts at the start of this snowballing strategy were identified biobank stakeholders such as the PIs of the Taiwan Biobank and the relevant ELSI people who were involved in the design of the governance framework of the biobank. The samples of respondents were then expanded when the information flow about research targets increased throughout the target group. Semi-structured interviews were chosen in data collection so a fairly open framework allowed for both focused and flexible communication for giving and receiving information. The interview process started with general and open-ended questions prepared beforehand but the majority of the subsequent questions were created during the interviews that enabled both respondents and the researcher to probe further. The formulated questions phrased ahead of time allowed interviewees to express their experiences, opinions and attitudes toward the biobanking project. The interviews took place between April of 2008 and January 2011. Among the total of 23 interviews, 21 were audio-recorded with the permission of the respondents and were then transcribed verbatim. Each of the interviews were carried out face-to-face lasting for about one to two hours so plenty of time was allowed to discuss issues and topics that were particularly important to the respondents. In order to keep updated the development of the project, some respondents were also invited to have second or third interviews during the period of the data collection.

The observational participation referred to observed recruitment, sample collection and short interviews and discussions with research nurses who were involved in the forefront operation of the pilot study of the biobank at sample collection sites. In addition, a focus

group with ordinary aborigines (six Taroko youth with ages of 23-30) was carried out in Taipei in January 2010. The main purpose for choosing a focus group for data collection was to spot issues that might concern aboriginal people about biobanking once they were included in the population biobank project. In the beginning of the focus group research, each of the participants was given a test about their knowledge of biobanks. After the knowledge test, the formal discussion began. The discussion covered four big topics about biobank dilemmas – privacy and data exchange, informed consent, commercialisation and benefit sharing, and law. Each dilemma was briefly explained and was followed by several detailed questions for further discussion. Each participant was then given a red and a green card in order to answer some of the detailed questions. Raising the red card means they don't agree, and the green card means they agree. After the participants showed their cards to some yes/ no questions, they were asked to explain the reasons to their answers.

The deliberative decision to use this focus group and a snowballing sampling strategy in in-depth interviews unavoidably introduces a range of methodological limitations. A common concern is about the issue of representative and the researcher's interpretive judgments made about the data collected from the interviews. However, as described above, the main reason for carrying out the focus group is for the purpose of "issue-spotting". As a result, the research findings should not be further interpreted as the general perception of the Taroko group or the Taiwanese aborigines in general. Nor may the research results be taken to represent the general public's perception about the biobank plan in Taiwan. The same concerns may also challenge the issue of generalisation from interpreting research results derived from snowballing samples that may be relatively limited in size. Nevertheless, the main purpose for carrying out interviews in this research is to explore the practice of the biobanking within the Taiwanese context. Though the research findings may form a basis for theorising the development of the biobank in Taiwan, the researcher makes no claims to generalise what had been observed from the Taiwanese biobanking phenomenon as a regular pattern existing elsewhere around the world.

This thesis plans to present its findings as a modest attempt to combine empirical and theoretical viewpoints.<sup>60</sup> The further analysis of the research findings in the subsequent chapters seeks to engage with both theoretical frameworks and empirical examples. For instance, empirical evidence will be used to discuss the issues of the biobank initiative drawn out in Chapter 3 and complement the background information of the biobank governance discussed in Chapter 4. In Chapter 5, empirical data will be used as a way to challenge existing bioethical discourses about informed consent and provide a supplement for further discussions about group consent within the Taiwanese context.

This research followed the ethics code of the LSE Research Ethics Policy issued in 2008 and the general ethical guidelines in the conduct of anthropological research. Participants in the interviews were given a description of the project and the background of the researcher when they were initially contacted by email requesting their willingness to take part in the research. The respondents who showed their interest in joining in the research were then given more information verbally about the purpose of this study and the way to deal with the collected data. All respondents were given the opportunity to withdraw their participation at any time during the research period. Except for the PIs of the Taiwan Biobank and some prominent scientists whose opinions about biobanking in Taiwan had been published and who also agreed to disclose their identities, all other respondents have been anonymised and have been labelled according to their occupation or ethnic categories.

### **1.2.3 Theoretical Perspectives**

The on-going biobanking project may be viewed as an ideal prism to reflect the dynamic and complex entanglement of the life sciences, politics and capital as it brings together in one site a number of the essential assemblages that have constituted Taiwan's modernity (and postmodernity). What is at stake for this thesis is therefore to locate Taiwan's

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<sup>60</sup> Prior to this research, there had been no studies that have analysed biobanking from a theoretical engagement with political economy and combined this with empirical analysis within the field of Taiwan. Even though there have been studies that have focused on biobanks in particular and combined empirical and theoretical analysis, these studies had been conducted on biobanks in the UK or within Europe. The most recent one is a study about the interplay between law and practice in biobank governance in the UK. The study draws from theoretical perspective on regulation and combined this with empirical analysis to understand the view of researchers in the field of biobanking. See, Kaye, Jane, Susan M C Gibbons, Catherine Heeney, Michael Parker, and Andrew Smart. *Governing Biobanks : Understanding the Interplay between Law and Practice* Oxford: Hart Publishing, 2012.

biobanking practices in a broader context of political economy as it helps illustrate the specific national aspiration and neoliberal reasons that propel the country to join in the global biobanking trend (See Chapter 2 and 3). In other words, rather than simply proposing a legal analysis of legal and ethical issues about biobank governance, the thesis attempts to explore *how* regulatory and ethical configurations related to the biobanking practice in Taiwan have come into being when the issues are re-embedded in the broader context to reflect Taiwan's geopolitics, ethnicities, and its socio-economic reality (Chapter 3, 4, and 5).

In Chapter 4, the thesis argues that the ethics involved in the biobank project in Taiwan entails a wider politics of organisation, decision-making and accountability in democratic societies to political subjects self-organised as citizens. As a result, the ethics involved in the discussion are not limited to the narrow bioethics and codified norms for biomedical practices on which most lawyers and ethicists focus. Rather, they involve wider political innovation and joint decision-making of potential research that also demonstrates why democratic transition in Taiwan has challenged the traditional technocrat decision model so a technocrat-based policy now needs to go through scrutiny from society in order to obtain its own legitimacy. In addition, analysing biobanking from the perspective of biopolitics, in Chapter 5 and 6, this thesis illustrates how bioethical configurations such as consent and privacy may be regarded as a technique of governance in Taiwan while taking into account the emergence of modern welfare states in which the state's intervention to redress social problems for national wellbeing becomes a legitimate technique of governance "at a distance."<sup>61</sup>

The original plan to include Taiwanese aborigines in the biobank project in Taiwan highlights an inner tension between the interests of the individual and the collective. This thesis further demonstrates how such a contrast may have been extended from a general discussion on the conflicting interests of individual rights and common good to a more specific consideration of the inclusion of minority populations in the biobank project within the Taiwanese context (paragraph 5.3). The possibility of the inclusion of Taiwanese aborigines in the biobank project triggers questions about stigmatisation and the implementation of consent at a collective level. This thesis shows that even though

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<sup>61</sup> Supra note 28.

group consent is necessary to safeguard the interests of minority populations in biobanking, its implementation concerns group identification, representation, and how to reach consensus by joint decision making, all of which involve deeper political implications with regard to the recognition of aboriginal status and its related economic and social inclusion (paragraph 5.3.1). By placing ethical governance frameworks and group consent in the broader political and social context of Taiwan, the thesis has linked the relation between bioethics and accountabilities in a democratic society.

The influence of modernity along with the transitional role the state plays make Taiwan a distinctive case for reflecting on the distinction between public and private in the context of biobanks (paragraph 6.3). In order to mitigate the inner tension between the interests in biobanks between the individual rights and the benefits of the collective, this thesis adopts the principle of the moral economy developed by social anthropologist Marcel Mauss whose perceptions of the morality of exchange based on the gift relationship in a total society provides insights into the justification of redistributive exchange and reciprocal altruism (paragraph 6.2). Since the increasing association of global capital and life sciences gradually transforms human tissue and genetic data into commodities whose value can be created by exchange, a moral economy of biobanks is proposed in this thesis as an ideology to acknowledge the importance of the recognition of participants' co-production of biovalue in the market economy (paragraph 6.1 and 6.2).

For Mauss, gifts are deemed to be a mode of exchange that helps establish the bonds of reciprocity between givers and recipients. The grand cycles of exchanges observed by Mauss constitute the whole society that maps all the obligations between its members whose permanent commitments articulate the dominant institutions. As the main purpose behind Mauss's concept of gift-exchange was to support social democratic redistribution, a new form of ethic has been created when individuals are organized as collective subjects to produce mutual interests based on their positive obligations to the greater totality. By referring to Mauss, this thesis further argues that the legitimacy of biobanks may be consolidated by treating both participants and the whole society as stakeholders in a greater totality in which they are parts of a division of labour.

### **1.3 Overview of Chapters**

This thesis contains five substantive chapters that move from the macro to the micro. Chapter 2 and 3 are based on macro analysis of biobanking as a global phenomenon in the postgenomics era. They aim to illustrate the development of genomics, the notion and rise of biobanks in cosmopolitical technoscience and the driving forces and symbolic implications for the formation of biocapital and ethical configuration within the context of Taiwan. Chapter 4 discusses the political-scientific decision to establish the population biobank in Taiwan. It analyses the biobank's initiatives, agencies, ethical puzzles and the dilemmas with regard to the complicated framework of ethical governance for the biobank's pilot study. Chapter 5 and 6 are micro analyses of key legal and ethical issues about biobank governance, such as consent, privacy, property and benefit sharing. Rather than focusing on legal and ethical analysis, these bioethical configurations are deployed in a broader context of Taiwan's biopolitics and biocapital formation.

This section provides an overview of the remaining chapters of the thesis. Chapter 2 conceptualises biobanks by introducing their notions, forms and driving forces. It asks what a biobank is and how biobanks have become a phenomenon across the globe in recent years. It then introduces the cases of the national biobank projects in Iceland, the United Kingdom, Estonia and Tonga to analyse different factors leading to or impeding the establishment of these biobanks as well as their entanglement with global capital and local politics. Biobanks provide a useful resource for scientists to study the causes of common complex diseases and to translate biomedical research into diagnostic and therapeutic applications through pharmacogenomics and personalised medicine. The successful completion of the Human Genome Project was an important scientific breakthrough as it makes possible the study of human genome, namely the entirety of human hereditary information. The term "genomics" refers to this kind of study so its focus was no longer on single genes or its disorders but on interactions of those genes with each other and with the environment as well. However, the information from the genome project mainly shows the structure and function of the complete set of human genes. As it is generally believed that every individual has his or her unique genome, further scientific efforts have moved into studying genetic variants by comparing the genetic sequences of different populations and individuals.

Biobanks as a new research tool and supporting technology can facilitate the study of genetic variation across whole populations. In recent years, many countries have joined in the global trend to set up their population biobanks to support the application of genomics research with the goal of capitalizing on the states' untouched genetic resources.<sup>62</sup> Even though medical and commercial incentives seem to be promising and scientists are largely convinced that biobanks offers a powerful technology for mining the riches of the human genome, the success and failure of a biobank, as this chapter demonstrates, depends largely on how willing people are to continue contributing their tissue samples and personal health information and how this newly invented infrastructure can sustain its operation for a longer period of time.

Chapter 3 discusses the deployment of biotechnologies in Taiwan's biocapital formation and examines the social and symbolic effects of biobanking in Taiwanese political economy and geopolitical analysis. Technology and capital are two crucial elements to demonstrate a biotech revolution in Asian modernity. In order to transform Taiwan from a manufacturing economy to a knowledge based economy, the government has identified biotechnologies as a useful tool to produce value. Biotech echoes the government's neoliberal rationale of value accumulation and how it plans to position Taiwan in the map of global capitalism. As the rise of China and India as two emerging economic powers has changed the international division of labour in the world system, it urges Taiwan to recapitalise its geopolitical location in the regions. In addition, Taiwan's withdrawal from the United Nations has prevented it from participating in the international system. This chapter illustrates how the official exclusion from the international stage has driven Taiwan to experience a series of domestic political transformation from an authoritarian state to a transitional democracy. This questions the idea of Taiwan as a developmental state and influences Taiwanese civic epistemologies toward technocratic policies which have faced increasing challenges from an emerging social sphere of different opinions and voices.

This chapter also argues that Taiwanese DNA has become a symbol of showing Taiwan's anxiety about being excluded from the international health management system and its eagerness to return to the global stage by promoting its biotech capacity. In addition, the

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<sup>62</sup>Bijal Trivedi, "Betting the Bank" *Nature*, 23 April 2008.



state's developmental strategy to use biotech to upgrade its economy and enhance its international visibility has attracted global venture capital and pharmaceutical companies to establish partnership with Taiwanese local biotech industry. This chapter further explores the influence of the private sector in the formation of Taiwan's biocapital. It illustrates the enthusiasm of the government of Taiwan to encourage private start-ups to play a leading role in transmitting innovative technologies and in bringing inward investment for Taiwan to be reconnected to the global trend of biotech development. Through mechanisms such as technology transfer and research collaborations, regulatory infrastructures and capacity building have gradually blurred the distinctions between public and private.

As the government of Taiwan identifies biobanks as a new form of biotech for Taiwan's common good and future citizens, ethical configurations have emerged in Taiwan's biopolitical narratives that illustrate the ambiguous and paradoxical role the state plays in biobank practices. Since the biobank project is intertwined with Taiwan's governmentality and the formation of Taiwan's bioeconomy, the chapter argues that it is not appropriate to treat the project as simply a scientific research plan; rather, the biobank should be viewed as a public policy and social enterprise which needs to be fully scrutinised by the public. In the end, this chapter argues that current ethical configurations with regard to biobank governance in Taiwan may not be thoroughly responsive to the commercial challenges for the biobank. Approaching the issue of biobank governance from a bioethical viewpoint may ignore the influence of global capitalism on the activities of biobanks.

Chapter 4 explores the politics of science and technology behind the biobanking story in Taiwan by analysing the initiatives, agencies, ethical puzzles, and the complexities of the governance framework of the biobank pilot study. Taiwan Biobank is designed as a prospective cohort study which plans to collect about 200,000 blood samples and personal health information from voluntary Taiwanese participants aged 30-70. The pilot study was proposed by the Department of Health as a sub-project under the scheme of the Biomedical Technology Island Plan, which aims at building Taiwan into a centre of genomics research and clinical trials in Asia. Given several strengths of biobanking in Taiwan, establishing a large-scale population biobank becomes a beneficial idea for some

supporting scientists, industries and the government in order to secure Taiwan's niche in the global bioeconomy for biomedical and pharmaceutical innovations. However, the biobank pilot study has staggered along the way in its early development. Much criticism of the project comes from human rights groups and some social scientists who questioned the transparency and trust in the project.

This chapter studies how biomedical issues have become bioethical problems by linking the relation between bioethics and accountability in Taiwan's modern democracy. By extending discussions from bioethics to a broader politics of decision-making among the public, this chapter analyses the trajectories of the biobank project by asking how the innovative framework of the dual-track governance operated by the Institutional Review Board (IRB) and the Ethics and Governance Council (EGC) made the supervision of the biobank project prolonged and complex. In addition, this chapter studies the mutual interaction between science and society in Taiwan's biobanking reality. By introducing the notion of "co-production" of Sheila Jasanoff, this chapter demonstrates how the existing political and cultural structures in Taiwanese society may feed back into the production of scientific knowledge in a process of legislative formation by social mobilisation and political narratives. In addition, through the prism of technocrat governance, this chapter observes the deeper relationships among politics, S&T policy formation, and the emerging civil society and public sphere in Taiwan. It argues that the inclusion of public engagement in biobanking in Taiwan may legitimise the biobank project, which was formed on the basis of the technocrat-decision model. However, when both science and society seek to reach a consensus (if any) about the project, they need to be aware of the limit of rational communication given the information asymmetry among the variety of actors and agencies involved in the biobank.

Chapter 5 critically examines the role of consent in biobanking in Taiwan. By studying how consent has been conceptualised and positioned in the forefront of Taiwanese biobank governance, this chapter argues that the mechanism of consent has been constructed not only as a matter of ethics but also as a legal endeavour for the establishment of the biobank. In so doing, consent was instrumentalised by the state as a technology of power to legitimise various agendas in the politics of life. This chapter argues that by setting aside other essential issues in the context of biobanking, such as access and ownership,

the consent mechanism may satisfy the general expectation of 'good ethics' at the expense of substantive deliberation of the rearrangement of rights and benefits related to biobanks. It demonstrates that an overemphasis on consent has meant that biobank governance in Taiwan has failed to challenge the neoliberal rationality that focuses on individual autonomy but leaves the underprivileged on an unequal footing in the development of modern life sciences.

In addition, as the potential risks of genetic research are normally of a collective nature, biobank governance opens up an arena of power reconfiguration between the individual and the collective. The original idea of involving Taiwanese aborigines in the population biobank questions the rationale of individual consent that overlooks the significance of collective involvement in decision making in aboriginal cultures. This chapter presents empirical findings in response to questions related to Taiwanese aboriginal involvement in the practice of group consent, such as how to identify a group (by whom and by what criteria) as well as who may legitimately represent the group to give consent. In Taiwan, as the status of aborigines and its associated rights and entitlements are embedded in law, genetic information could be used to challenge an existing aboriginal status or prevent a group from asserting its legal claims to be recognised as aborigine. This chapter suggests that rather than viewing consent as a contract or an event, consent should be regarded as a process of reciprocal exchange so that research subjects, especially when they belong to minority populations, can have a certain amount of bargaining power to decide how their samples and the derived information will be processed and interpreted.

Chapter 6 focuses on issues concerning property, privacy and commodification in the context of biobanks. The development of genomics and modern biotechnologies has given rise to serious debates regarding property as human tissue and genetic information have been transformed into useful resources of biovalue. This chapter explores the circumstances and conditions by which human tissue may be viewed as commodities for exchange. By adopting anthropological theories developed by Karl Polanyi, the chapter argues that while considering the exposure of nature to a market economy, human tissue and genetic materials have been deemed to be fictitious commodities as they are not produced for sale but regarded as commodities for exchange in order to organize the market system. Such commodification of bodies has formed a new discourse in scientific

and biotech development by creating a space for the speedy flow of technologies and capital across the globe. In addition, by analysing the *John Moore* case, this chapter criticizes the adequacy of using consent and privacy to replace property as it neglects the limits on these ethical arrangements in terms of empowering research subjects by providing them continuing control over their samples and data stored in biobanks.

This chapter also examines the notion of the gift relationship proposed respectively by anthropologist Marcel Mauss and sociologist Richard Titmuss. Even though altruistic gift-giving developed by Titmuss has been favourably adopted as a policy model to govern the relationship of researchers and research subjects, such a free gift model, as the chapter points out, implies a tendency to avoid the recognition of participants as stakeholders and the rearrangement of entitlements for a share of profits related to biobanks. In contrast, for Mauss, gifts are not given for free but deemed to be a mode of exchange that helps establish the bonds of reciprocity between givers and recipients. This chapter argues that Mauss's moral economy of redistribution based on gift circles, which focuses mainly on the larger collective benefits, provides a justification to mitigate the tension between an ethic of individual rights and a utilitarianism which prioritises the public good and the interests of the community at large. In addition, in the total social phenomenon constituted by the gift-exchange, a new form of ethic may be created in which individuals are organized as collective subjects to produce mutual interests based on their positive obligations to the greater community. This chapter suggests that in order to form a trust relationship in biobanking, the moral ideal of an alliance of participants and the biobank (and its commercial extensions) needs to be acknowledged with reference to their joint interest and their co-dependent relations in a greater totality in which they are parts of a division of labour.

In addition, this chapter challenges the legal mechanisms focusing on personal data protection in biobanks which have switched the issue of property to a concern with privacy. By analysing the *Source Informatics* case, this chapter distinguishes the notion of confidentiality from privacy and illustrates how the narrow conception of privacy being adopted in Taiwanese biobank governance has mistakenly suggested that so long as the samples and data are anonymised and encoded, privacy would no longer be an issue of concern. In addition, through a discussion of Foucault's theories on surveillance and

governmentality, this chapter argues that the boundary between the private and public is subject to negotiation, especially when the individuals are viewed as autonomous agents whose choices and freedom have real effects on the greater interests of community. As biobanking is a project involving groups, the discussion of privacy and its public interest defence needs to reconsider how this technique of governance may have influenced the scope of privacy.

## Chapter 2 Biobanking as a Global Phenomenon: the Co-Production of Life Sciences and Capitalism

### Introduction

A recent *TIME* magazine article featured biobanks as one of the “10 Ideas Changing the World Right Now.”<sup>1</sup> In the article, biobanks were introduced as an “organic bank account” to safeguard people’s most valuable assets. Rather than depositing money in a personal bank account, it is a repository for people to put in their biomaterials - blood, tissue samples and DNA - in order to earn medical interest some later day in the form of new knowledge and therapies for diseases.<sup>2</sup> As most complex diseases and cancers that affect large populations are typically caused by a combination of genetic and environmental factors rather than by individual genes, scientists generally recognise that studying the population genome, namely the entirety of a person’s genes across whole populations, is necessary to fully understand the complex and subtle interaction between the incidence of disease, genes and environment.<sup>3</sup> This kind of population studies in genomics requires large sample sizes with high-quality tissue samples and it has fuelled the drive for the establishment of large-scale population biobanks.<sup>4</sup> Even though the collection and storage of human tissue samples for medical research has a decades-long history, biobanks as a sophisticated new technology can facilitate continuous collection of samples and linkage with associated epidemiological, clinical and research data.<sup>5</sup>

In recent years, the idea of creating biobanks has become a global phenomenon. Many countries in the West, such as Iceland, Britain, Norway, Sweden, Estonia, Canada and the United States, either already have or are building national biobanks in response to the demands of science and commerce.<sup>6</sup> In East Asia, Biobank Japan was launched in 2003 with initial three-year funding of about USD 200 million from the Japanese government and it has collected more than 200,000 blood samples and medical records from over

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<sup>1</sup> Alice Park, "10 Ideas Changing the World Right Now," *TIME*, 12 March 2009.

<sup>2</sup> Ibid.

<sup>3</sup> More info, see: National Human Genome Research Institute. <http://www.genome.gov/19016904> (Last visit: 10 March 2012)

<sup>4</sup> Mark Stranger and Jane Kaye, "Governing Biobanks: An Introduction," in *Principles and Practice in Biobank Governance*, ed. Jane Kaye and Mark Stranger (Ashgate, 2009). P. 2

<sup>5</sup> Ibid.

<sup>6</sup> Bartha Maria Knoppers, Ma'n H Abdul-Rahman, and Karine Bédard, "Genomic Databases and International Collaboration " *King's Law Journal* 18(2007). P. 301

170,000 patients in three years.<sup>7</sup>In China, the first population biobank was launched in Guangzhou - capital of Guangdong Province in southern China - in 2004. Even though it is not a national biobank and has only collected samples from Guangzhou, it aims to create profiles for 50,000 people in four to five years.<sup>8</sup> In South East Asia, the Singapore government approved a grant of USD 8.7 million in 2002 to set up the facility over three years for the establishment of the Singapore Bio-Bank. Located at the research centre Biopolis, Singapore Bio-Bank was then the region's first national biobank and it gave scientists and researchers free access to samples and data critical in studying diseases.<sup>9</sup> Inspired by the cases of Iceland and the United Kingdom, the government of Taiwan has been heading up an effort to establish its own population biobank.

In addition, some transnational infrastructures have also been established to respond to this global biobanking phenomenon. For instance, the Public Population Project in Genomics (P<sup>3</sup>G) was founded in 2003. Headquartered in Montreal, Canada, P<sup>3</sup>G is a non-for-profit international consortium aiming to build a network for sharing and harmonization of infrastructures, research methods and governance framework for the population genomics community across the globe.<sup>10</sup> One important goal of the consortium is to optimize the benefits of collaborative research for the interests of all affected biobank stakeholders, including not only scientists and research sponsors but also research participants and their communities. In 2005, the consortium created its platform website - P<sup>3</sup>G Observatory - to facilitate comparison and sharing of information between studies. The Observatory provides an overview of biobanking activities around the world covering information about operational procedures for sample collection and storage conditions.<sup>11</sup> In Europe, a pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) finished a 28 month's preparatory phase in January 2011.<sup>12</sup> Funded by the European Commission (EC), the BBMRI has grown to a 53-member

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<sup>7</sup> Robert Triendl and Herbert Gottweis, "Governance by Stealth : Large-Scale Pharmacogenomics and Biobanking in Japan " in *Biobanks : Governance in Comparative Perspective* ed. Herbert Gottweis and Alan Petersen (Routledge, 2008). P. 123

<sup>8</sup> The biobank was jointly funded by the the Guangzhou No. 12 People's Hospital, the University of Hong Kong and the University of Birmingham, based in the UK. More info, see: "China Launches First Biobank ", *Xinhua News Agency* 10 March 2004.<http://www.china.org.cn/english/China/90031.htm> (Last visit: 30 December 2011)

<sup>9</sup> "National Biobank to Close," *The Straits Times* 4 June 2011. More info, see: <http://newshub.nus.edu.sg/news/1106/PDF/BIOBANK-st-4jun-D6&D7.pdf> (Last visit: 10 March 2012)

<sup>10</sup> More info, see the P<sup>3</sup>G official website: see: [www.p3g.org](http://www.p3g.org) (Last visit: 10 March 2012)

<sup>11</sup> Ibid.

<sup>12</sup> More info, see the BBMRI official website: <http://www.bbmri.eu> (Last visit: 10 March 2012)

consortium in less than two-and-half year's time. Its scientific partners cover more than 30 countries, including 280 associated organizations, most of which are biobanks of various types.<sup>13</sup> This federated network aims to provide a sustainable legal and financial conceptual framework to benefit European research in life sciences and increase the scientific efficacy of biomedical research in Europe.<sup>14</sup>

However, will biobanking really change the world? Even though medical and commercial incentives seem to be promising and scientists are largely convinced that biobanks offers a powerful technology for mining the riches of the human genome, the success and failure of a biobank depends largely on how willing people are to continue contributing their tissue samples and genetic information. In addition, how this newly invented infrastructure can sustain its operation for a longer period of time remains questionable. In November 2009, deCODE Genetics, the operator of the Health Sector Database in Iceland, filed for bankruptcy protection and announced the sale of its drug discovery and development subsidiary, which includes its population genetics resources.<sup>15</sup> In Asia, the Singapore government announced the decision to close its national biobank in June 2011, about only a decade after the establishment of the Singapore Bio-Bank, much less than the time required for biomedical research to bear fruit. Though the biobank was recognised as a significant resource for the country's biomedical research community, the operation of the biobank cost around USD 1 million a year and its capacity to process about 10,000 samples had been deemed to be under-utilised.<sup>16</sup> After the closure of the biobank, the new challenge the Singapore government faces is how to find appropriate solutions to deal with the precious 230,000 samples (about 1.2 million vials) stored in the biobank when other similar facilities in the country are reaching their maximum capacities.<sup>17</sup>

Although biobanks have potential to transform the ways we see the development of disease, biobanking initiatives should not be seen as limited to only a scientific inquiry. Rather, they need to be embedded in a broader context of political economy. This chapter explains how biobanking has become a phenomenon across the globe. It first

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<sup>13</sup> More info, see: <http://www.bbmri.eu/index.php/about-bbmri/background> (Last visit: 10 March 2012)

<sup>14</sup> Ibid.

<sup>15</sup> "Decode Genetics Files for Chapter 11; Seeks Sale of Assets," *GenomeWeb Daily News* 17 November 2009

<sup>16</sup> Supra note 9

<sup>17</sup> Ibid.



introduces the rise, notions and norms of biobanks. It then analyses several biobanking cases around the world - Iceland, the United Kingdom, Estonia and Tonga - in order to better understand how biobanks have become global assemblages of life sciences and capitalism.

## 2.1 What is a Biobank?

Even though certain shared characteristics of biobanks may be identified, there is no consensus about what constitutes the term “biobank” in the current literature. Different names have been given to describe a collection of human biomaterials, such as “genetic databases,”<sup>18</sup> “biospecimen repositories,”<sup>19</sup> and “tissue banks,”<sup>20</sup> etc. For instance, an earlier working definition given by Mats Hasson describes a biobank as “collections of human biological material within the health care system and the medical sciences.”<sup>21</sup> Such a definition, however, ignores the fact that information linkage is the key feature of biobanks by which they can be distinguished from a collection of biospecimens, such as a tissue bank, which stores tissue samples only, without collecting and banking associated genealogical and personal health data. In the recent OECD Guidelines on Human Biobanks and Genetic Research Databases (HBGRD) (2009), biobanks are viewed as “structured resources that can be used for the purpose of genetic research, and which include: a) human biological materials and/or information generated from their analysis; and b) extensive associated information.”<sup>22</sup> It has been recognised by the OECD that even though the Guidelines were intended to be applied as broadly as possible, they may not be fully applicable to all kinds of human biobanks, given their diversity of purpose and

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<sup>18</sup> For example, Richard Tutton and Oonagh use “Genetic Database” as the name of their book discussing social and ethical issues with regard to the collection and use of DNA. See, Richard Tutton and Oonagh Corrigan, *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (London: Routledge, 2004).

<sup>19</sup> The term often refers to repositories of fluid and human tissue biospecimens, but whether it functions like a human genetic database depends on whether these repositories also collect personal health data for the purpose of genomics research.

<sup>20</sup> Usually tissue banks refer to the collections of human tissue samples only without genetic information linkage. This kind of collection of human biological materials has a long history in medical research, especially in hospital and clinical centres where doctors and researchers have easier access to patient samples, so these collections appear much earlier than the emergence of “biobanks” for genomics studies in recent years.

<sup>21</sup> Mats Hansson, ed. *Introduction, The Use of Human Biobank: Ethical, Social, Economical and Legal Aspects* (Uppsala: UppsalaUniversity, 2001).

<sup>22</sup> OECD, “Guidelines on Human Biobanks and Genetic Research Databases,” (2009). P. 1 See: <http://www.oecd.org/dataoecd/41/47/44054609.pdf> (Last visit: 10 March 2012)

operation, especially for those established for non-research purposes, such as for diagnostic, therapeutic, treatment or forensic uses, etc.<sup>23</sup>

According to the *Best Practices for Biospecimen Resources* (2007) published by the US National Cancer Institute, which has headed up an effort to establish the first national biobank - the cancer Human Biobank (caHUB) - in the United States, a “biospecimen resource” is defined as “a collection of human specimens and associated data for research purposes, the physical structure where the collection is stored, and all relevant processes and policies.”<sup>24</sup> Even though the Institute uses a different term to refer to the collection of human samples and genetic data, the definition it uses is similar to that used to define a biobank. In addition, in the earlier report published by the OECD on Creation and Governance of Human Genetic Research Databases (2006), the term “genetic databases” rather than “biobanks” was used to cover the same type of collections described by the OECD in its later Guidelines on Human Biobanks and Genetic Research Databases (HBGRDs) published in 2009. According to the earlier report, human genetic research databases (HGRDs) are described as databases containing “data, information and biological samples from populations” that are used to contribute to scientific understanding of the complex multi-factorial basis of diseases.<sup>25</sup>

The wide use of “biobank” to cover all types of collections of human specimens and associated data creates difficulties as the different types of collections with different structures and purposes may raise different technological, ethical and legal considerations.<sup>26</sup> According to the OECD Guidelines, the extent and types of consultations about the establishment of human biobanks need to take into consideration the biobanks’ nature, purpose and scope as the greater the breadth of targeted participants, the more extensive the tissue samples and data to be collected that may cause risks involved in sharing the samples and data.<sup>27</sup> Even though a number of

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<sup>23</sup> Ibid.

<sup>24</sup> National Cancer Institute Office of Biorepositories and Biospecimen Research, National Institutes of Health, U.S. Department of Health and Human Services, “Best Practices for Biospecimen Resources,” (2007). P. 58, see: <http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf> (Last visit: 27 February 2012)

<sup>25</sup> OECD, “Creation and Governance of Human Genetic Research Databases” (2006). See: <http://www.oecd.org/dataoecd/61/29/37647338.pdf> (Last visit: 27 February 2012)

<sup>26</sup> National Health and Medical Research Council Australian Government, “Biobanks Information Paper,” (2010). P. 9

<sup>27</sup> Supra note 22, P. 1

significant variables, such as size, scale and nature will influence a range of biobank activities, including recruitment, practices of consent and governance arrangements, etc, human biobanks typically share a number of common features.<sup>28</sup> For instance, they usually involve unspecified research in the future so they have an ongoing and open-ended nature that challenges the traditional practice of informed consent. Furthermore, in order to link collected biospecimens with phenotypic data, the banked samples and data need to remain potentially re-identifiable by biobank custodians even though the data may have been anonymised, and because it is not possible to make the samples and data completely de-identified, appropriate mechanisms need to be set for data management to minimise the risk of individuals being identified.<sup>29</sup> In addition, as the biobanks are more concerned with the public benefit for future generations than with the individual benefit of participants themselves, they have a common good focus and as a result, their governance needs to call for balancing individual and collective interests.

Beyond these shared features, however, a number of significant variables may further categorise human biobanks by their size and scale, participants' health status, the scope of potential research, the extent to which data linkage is possible, the nature of the collection and business models and founding sources, etc.<sup>30</sup> For instance, in terms of biobanks' differences in size, they can be distinguished between large-scale and smaller-scale collections. While the former are being established at regional, national or international levels to support large-scale longitudinal genetic research, the latter are generally small-scale collections restricted to particular population groups and particular research projects.<sup>31</sup> Besides, a biobank may target healthy people by collecting samples and data from a healthy population or target those with a specific disease to establish a diseased-oriented biobank. Most current large-scale population biobanks collect samples from healthy people; the biobanking projects in Iceland, the United Kingdom, Estonia, mainland China and Taiwan<sup>32</sup> are all biobanks of this type. An example of a

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<sup>28</sup> Supra note 26, P. 7

<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

<sup>31</sup> Ibid., pp 8-9

<sup>32</sup> The pilot study for the Taiwan Biobank was designed as a population biobank but along its development scientists have been discussing whether the biobank could also follow the model in Japan to form a biobanking network to make some existing disease-oriented biobanks to be included into the Taiwan Biobank project. These existing disease-oriented collections are commonly set up in some large hospitals and research centres in Taiwan and are created mainly for specific research uses, such as studies of rare disease, like liver cancer and breast cancers, etc.

disease-oriented biobank may be found in Biobank Japan, which mainly collects samples and data from diseased individuals for medical research covering a total of forty-six diseases.<sup>33</sup> In terms of the scope of potential research, a biobank may be limited to a particular field of research with a particular disease or it may be intended for unlimited or multi-disease research that may be unspecified at the time of data collection for the biobank.<sup>34</sup>

In addition, as for the nature of the collection, biobanks can be distinguished between a purely prospective collection and an integration of a pre-existing collection or a combination of both. In terms of the extent to which data linkage is possible, types of biobanks may be categorised depending on the coding system or anonymization procedures the biobank uses for its data protection. If funding sources and business models are taken into account, the categorization may be further refined into distinctions between public or private, commercial or non-commercial biobanks. Different types of biobanks require different governance frameworks for issues regarding consent and privacy. For instance, whether a biobank is commercially oriented may have a significant influence on people's willingness to participate, as the business model of profit maximization may not be accepted by a participant who might otherwise like to contribute her or his samples to a public and non-commercial biobank. Biobanks may also be distinguished from other collections of biospecimens created for research purposes or for other purposes but also used for research even though the boundaries between the biobanks and these kinds of collections may not be easily drawn.<sup>35</sup> For instance, the genetic research database used for the HapMap Project stored de-identified genetic information compiled from multiple donors. Even though the samples and cell lines used by the project could be identified as coming from one of the four populations taking part in the study, they were not linked to any individual participant. This is very different from a biobank in which re-identification and data linkage are necessary. Making these distinctions helps to clarify the term biobank. When it is used in this thesis, it refers to large collections of human biological materials that may be linked with personal and

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<sup>33</sup> Robert Triendl and Herbert Gottweis, "Governance by Stealth : Large-Scale Pharmacogenomics and Biobanking in Japan," in *Biobanks : Governance in Comparative Perspective* ed. Herbert Gottweis (Routledge, 2008).

<sup>34</sup> *Supra* note 26 (Australian Government Biobank Information Paper)

<sup>35</sup> *Ibid.*, P. 10

health information for use in health and medical research as in the definition given by the OECD.

## **2.2 Why Biobanking?**

### **2.2.1 Human Population Genomics**

Biobanks provide an important resource to scientific research in two main areas. One is to find out the interaction between genetic factors underlying common complex diseases and the environment. The other is to translate biomedical research into diagnostic and therapeutic applications through pharmacogenomics to achieve personalised medicine and improve public health. Since the announcement of the completion of the Human Genome Project (HGP) in 2003, the creation of large-scale biobanks for population studies in genomics has expanded rapidly. The HGP was an international scientific collaborative program aiming to understand and map the entirety of human genes. Launched in 1990, the project involved 18 countries, headed by the United States, the United Kingdom, Germany, France, mainland China and Japan but mainly funded by the National Institute of Health (NIH) in the US and the Wellcome Trust in the UK.<sup>36</sup> The successful completion of the project was an important scientific breakthrough. Prior to the HGP, scientists studied genes and their roles in inheritance in order to realise how certain inherited disorders were passed down from one generation to another. The information coming from the HGP makes possible the study of human genome, namely the entirety of human hereditary information. The term “genomics” refers to this kind of study so the focus of genomics was no longer on single genes or its disorders but on interactions of those genes with each other and with the environment as well.<sup>37</sup> Scientists have gradually recognised that cancers and several common diseases, such as asthma, diabetes and heart disease, are complex diseases because they are caused by a combination of genetic variants and environmental factors rather than by individual genes.<sup>38</sup> The study of genomics is therefore expected to open up opportunities for new therapies and diagnostic methods for some complex diseases.

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<sup>36</sup> More information about the Human Genome Project, see: [http://www.ornl.gov/sci/techresources/Human\\_Genome/home.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/home.shtml) (Last visit: 10 March 2012)

<sup>37</sup> More information about genetics and genomics, See: <http://www.genome.gov/19016904> (Last visit: 10 March 2012)

<sup>38</sup> Ibid.

The completed human sequence means that about 20,500 human genes can now be identified by determining their orders and mapping their locations.<sup>39</sup> However, the data announced by the HGP represents the combination of genomes of projects participants, rather than the individual's genome. In other words, such information mainly shows the *structure and function* of the complete set of human genes that does not represent the exact sequence of the entirety of every individual's genes.<sup>40</sup> As it is generally believed that every individual has his or her unique genome, the data published by the HGP makes possible further efforts in identifying differences among individuals. For instance, the HapMap project started to focus on identifying genetic similarities and differences in human beings. The project was another effort of multi-country collaboration, starting officially with a meeting from October 2002 and lasting for about three years.<sup>41</sup> Its primary goal was to identify genetic variants by comparing the genetic sequences of different individuals so researchers can use this freely available information to find genes involved in diseases and individual responses to medications and environmental factors.<sup>42</sup>

The HapMap project consisting of scientists, funding agencies, public and private organisations from six countries—Canada, China, Japan, Nigeria, the United Kingdom and the United States—gathered genetic information from populations with Asian, African and European ancestry.<sup>43</sup> In genomics, the term “HapMap” is a catalog of common genetic variants that is used to describe what these variants are, their locations in the DNA in human cells and how they are distributed within and among various populations across the world.<sup>44</sup> Even though the HapMap project claimed that their purposes was not to identify disease-related genes directly but to provide a tool for researchers to link genetic variants to the incidence of diseases for new methods of diagnosis and treatment, the project had raised concerns about connections established between particular genetic variants and specific illnesses.<sup>45</sup>

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<sup>39</sup> Ibid.

<sup>40</sup> Ibid.

<sup>41</sup> More information about the HapMap project, See: <http://hapmap.ncbi.nlm.nih.gov/> (Last visit: 10 March 2012)

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> More information about the term “HapMap”, see: <http://hapmap.ncbi.nlm.nih.gov/whatishapmap.html.en> (Last visit: 10 March 2012)

<sup>45</sup> Ibid.

Existing in a human cell, the DNA contains long chains of four chemical building blocks that can be abbreviated by their first English letters—A, T, C and G— strung together in 23 pairs of chromosomes.<sup>46</sup> The information contained in these genetic sequences influence people’s physical traits and our bodies’ responses to substances encountered in the environment. However, it has also been recognised that the genetic sequences of different people are remarkably similar, comparing the chromosomes of two different individuals, the difference of genetic sequences of the two people occurring only about one in every 1,200 bases.<sup>47</sup> Therefore, for geneticists, the most common type of genetic variation they can find out is differences in individual bases which are known as SNPs— single nucleotide polymorphisms.<sup>48</sup> SNPs can be used as markers to locate and identify genes in DNA sequences. For instance, even though an affected gene is known to increase the risk of suffering from a certain disease, researchers still need to find out where that gene is located in our chromosomes for the purpose of treatment. A way to locate genes is to compare the SNPs in people who have this disease with the SNPs of those who do not (the controls). If a particular SNP is found more frequently among the diseased group, then that SNP can be used to locate the gene involved in the disease.<sup>49</sup>

As it is extremely expensive to test all of the common SNPs in an individual’s chromosomes, the HapMap project aims to identify the basis for a large fraction of the genetic diversity in the human species and provides researchers with this resource to discover the genetic variants involved in disease and individual response to therapies.<sup>50</sup> A basic assumption behind the HapMap project is that medical treatment could be customised based on individual’s genetic makeup. So more knowledge about genomics, namely understanding of the interactions between genes and the environment, could help researchers to find better ways to cure and prevent disease. The samples gathered for the HapMap project came from a total of 270 people of multiple populations.<sup>51</sup> With

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<sup>46</sup> The four letters stand for adenine, thymine, cytosine, and guanine.

<sup>47</sup> More info, see: <http://hapmap.ncbi.nlm.nih.gov/whatishapmap.html.en> (Last visit: 10 March 2012)

<sup>48</sup> Ibid.

<sup>49</sup> Ibid.

<sup>50</sup> Ibid.

<sup>51</sup> According to the HapMap project, 30 sets of samples were from the Yoruba people of Ibadan, Nigeria. Japan provided 45 samples collected from unrelated individuals from the Tokyo area. The samples from China were 45 unrelated individuals collected from Beijing. Thirty U.S. trios (two parents and an adult child) provided samples, which were collected in 1980 from U.S. residents with northern and western European ancestry by the Centre d’Etude du Polymorphisme Humain (CEPH). More information about which population were being sampled in the HapMap project, see: <http://hapmap.ncbi.nlm.nih.gov/hapmappopulations.html.en> (Last visit: 10 March 2012)

samples from more than one population, researchers worldwide can have opportunities to access the genetic contributions to diseases that are prevalent in different populations. The blood samples provided for the project had been converted into cell lines for making DNA. Even though these samples and cell lines cannot be linked to any individuals, they can certainly be identified as coming from one of the four populations participating in the project. As a result, it raised ethical issues concerning stigmatisation with conducting genetic research in named populations.

In order to address these ethical issues, the HapMap project incorporated the consideration of bioethics into its samples collection. For instance, all samples were anonymous, no medical and phenotype information were collected and no individual personal information can be linked to any samples.<sup>52</sup> Besides, the project collected more samples from each population than they were used so no any particular person's DNA can be identified by knowing whether it was included in the study or not.<sup>53</sup> However, even though the infringement of individual privacy seemed to be minimal, as each sample was identified as coming from a particular population, the HapMap project raised new ethical issues about stigmatization and discrimination in a collective level. For instance, a research finding may show that a genetic variant associated with an incidence of a disease is more frequent in one population than another. But this finding may be interpreted incorrectly to indicate that each individual in this higher risk group has a higher-than-average risk of the disease, even though the higher risk may apply only to those who have the genetic variant, whether they are members of the group or not.<sup>54</sup>

In addition, genetic findings might also be misinterpreted to suggest that constructed biological category such as "race" is precise and meaningful.<sup>55</sup> Being aware of this ethical issue associated particularly with genetic study, the HapMap project made an announcement on its official website that the information emerging from the project was helping to illustrate that common perceptions about race are "loosely connected to biological ancestry" but largely from social and cultural interactions.<sup>56</sup> In fact, genetic findings could undermine established cultural or religious traditions set up from groups'

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<sup>52</sup> More information about how ethical issues were been addressed, See: <http://hapmap.ncbi.nlm.nih.gov/ethicalconcerns.html.en> (Last visit: 10 March 2012)

<sup>53</sup> Ibid.

<sup>54</sup> Ibid.

<sup>55</sup> Ibid.

<sup>56</sup> Ibid.



firm beliefs about their lineage or conflict with the methods the groups have developed to determine their membership, so such findings also have significant implications on legal or political status of a group and its members. To address these concerns, the HapMap project initiated a process of community engagement before seeking individual consent from each of its participants. Though the engagement process varied from country to country, it provided an opportunity for community members to discuss the issues raised by the project and then feedback their input into research designs about how to collect samples and what information should be covered in the consent form.<sup>57</sup> In most cases, the process is involved a combination of several forms of consultation, such as focus group discussions, community meetings, public surveys and interviews on individual basis.<sup>58</sup>

This community engagement process helped create a more transparent climate in which trust could be developed between researchers and participants by not only informing the participants about the nature and goals of the project but also for researchers to understand and respond to participants' concerns. In addition, a special agency - Community Advisory Group (CAG) - was established in each participant community to function as a liaison between the community participating in the project and the Coriell Institute in New Jersey, in which samples will be stored.<sup>59</sup> The Coriell Institute was required to distribute quarterly report and periodic newsletters about how samples were being used to the Community Advisory Group in each participating community. Unlike other population biobank studies, as the HapMap did not collect medical data and no personal identifiers were included with samples, it is not possible for researchers to re-contact individual participants to obtain their re-consent for each new study and the participants would not be able to withdraw from the project based on the same reason. However, it is possible for an entire community to withdraw their samples from the repository if they wished to do so after careful discussion and consultation with researchers.<sup>60</sup> As the purpose of the HapMap project was mainly to improve health of all people, no commercial products and drugs would be developed as part of the project, however other studies can still use the information produced from the HapMap to find

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<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

<sup>59</sup> More information about HapMap project's community advisory group, see: <http://hapmap.ncbi.nlm.nih.gov/cag.html.en> (Last visit: 10 March 2012)

<sup>60</sup> Ibid.

genetic variants involved in diseases and then translate such findings into diagnostic and therapeutic products.<sup>61</sup>

### **2.2.2 Personalised Medicine and Pharmacogenomics**

The idea of customisation of medical treatment has been further developed by the advancement of the study of genetics. It leads to a new field - personalized medicine - in healthcare, namely all medical decisions and treatment, including preventive and therapeutic care being tailored to adapt to each individual's particular genetic makeup. In the past, medical care was unable to take into account individual's genetic variability as it has centered on standards of care based on epidemiological studies of large cohorts. Traditionally, clinical diagnosis and treatment was mainly based on patients' symptoms and their medical and family history so the medical treatment was reactive rather than prospective. In other words, medication in clinics started only after the symptoms appeared. Recent advances in genomics introduced a new way to know certain diseases, especially the functions of genes and its impact on the development of complex diseases. The HapMap project has laid the groundwork for the further understanding of the similarities and differences of genetic makeup between individuals and it made possible for the application of the new tool, GWAS - Genome-Wide Association Studies - to examine how genome may affect a person's susceptibility to diseases.

A genome-wide association study is a new method for scientists to strategically search genetic markers that involves rapidly scanning SNPs across the complete set of human genomes to find genetic variations associated with a particular disease.<sup>62</sup> The purpose of this tool is to efficiently identify genetic associations so researchers can use the information to better detect, treat or even prevent the disease.<sup>63</sup> The potential impact of medical care from the studies could be significant, especially for the development of personalized medicine as the studies have been recognised as particularly useful in searching genetic variations that contribute to common, complex diseases.<sup>64</sup> The studies are expected to benefit health management when it widely applies to medical care with

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<sup>61</sup> Ibid.

<sup>62</sup> More information about what a genome-wide association study is, see, <http://www.genome.gov/20019523> (Last visit: 10 March 2012)

<sup>63</sup> Ibid.

<sup>64</sup> Ibid.

other innovative technologies, so health professionals can provide individual with information about their susceptibility of developing certain diseases or even tailor prevention programs to them according to their genetic makeup.<sup>65</sup> In addition, in therapy, the information produced from the GWAS is expected to be used to select most likely effective treatments with less likely adverse reactions. Since 2005, the application of the GWAS has been reported to successfully identify genetic variations that are associated with prostate cancer, type 2 diabetes and heart disorders, etc.<sup>66</sup>

The recent advancement in the study of genetics has greatly influenced pharmaceutical development. For example, a new field – pharmacogenomics - has been developed to study the impact of genetic variations on the response to medications. The primary goal of such study is to tailor drug therapy for the increase of the efficacy and safety of medications. For instance, the chemotherapy drug Purinethol was recommended by the Food and Drug Administration (FDA) in the United States to carry out drug testing before its use as some patients with acute lymphoblastic leukemia had been reported to have problems with processing this drug that can cause severe side effects unless the standard dose is adjusted to adapt to the patients' genetic makeup.<sup>67</sup> In fact, the systematic collection of samples has been closely linked to the study of pharmacogenomics. Many large multinational pharmaceutical companies have made considerable investment in this area by sponsoring clinical drug trials or building extensive biobanks to support genomic-based research.

In addition to studying an individual's response to particular drugs, pharmacogenomics may also examine genetic variations among populations, namely to see how different drugs might affect different racial or ethnic groups.<sup>68</sup> Biobanks as a new research tool and supporting technology can facilitate the study of genetic variation across whole populations. In recent years, many countries have joined in the global trend to set up their population biobanks to support the application of genomics research with the goal of capitalizing on the states' untouched genetic resources.<sup>69</sup> Biobanks as a substantial

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<sup>65</sup> More information about the application of the genome-wide association studies, see: <http://www.genome.gov/20019523#gwas-3> (Last visit: 10 March 2012)

<sup>66</sup> Ibid.

<sup>67</sup> More information, see: <http://www.genome.gov/27530645> (Last visit: 10 March 2012)

<sup>68</sup> Ibid.

<sup>69</sup> Bijal Trivedi, "Betting the Bank " *Nature*, 23 April 2008.

facility could turn a society into a promising region for gene hunting, drug testing and health management. Following the HGP's completion of human genome sequence in 2003, the HapMap's mapping human genetic variation in 2005 and the rise of the genome-wide association studies which makes it easier to link genes and disease, biobanking has been recognised by some geneticists and pharmaceutical industries as the next logical step to translate genetic data into clinical applications.<sup>70</sup> According to interview material published by *Nature* magazine in April 2008, a statistical geneticist has pointed out that they "found more genes for complex disease in 2007 than in the entire history of the field."<sup>71</sup> The discovery boom not only demonstrated a revolution in gene hunting but also produced a great amount of useful genomic data and information.

## **2.3 The Rise and Fall of Biobanks**

### **2.3.1 The Icelandic Health Sector Database**

Iceland was the first country in the world to initiate a national biobank for population genetics research. The idea of biobanking was proposed by deCODE Genetics, a US incorporated private company founded in 1996 with its headquarters located in Reykjavik. Describing itself as a "global leader in analysing and understanding the human genome," deCODE aims to conduct population genetics research to discover genetic risk factors of common diseases and develop technologies for DNA-based tests and personal genome scans.<sup>72</sup> Its business includes providing services of sequencing and genotyping analysis to research institutes and licensing its intellectual property, analytical tools and tests to partner companies.<sup>73</sup> Its recent product, deCODEme provides individuals with a comprehensive genome scan by analysing one million genetic variants to explore genetic risks for health investment.<sup>74</sup> The product can now be purchased on-line for under USD 1,000.

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<sup>70</sup> Ibid.

<sup>71</sup> Ibid., according to Lon Cardon, a statistical geneticist and the newly appointed leader of the genetics division at GlaxoSmithKline (GSK).

<sup>72</sup> Garðar Arnason, "Icelandic Biobank: A Report for Genbenefit" (2007). Information available at [http://www.uclan.ac.uk/schools/school\\_of\\_health/research\\_projects/files/health\\_genbenefit\\_icelandic\\_cas\\_e.pdf](http://www.uclan.ac.uk/schools/school_of_health/research_projects/files/health_genbenefit_icelandic_cas_e.pdf) (Last visit: 27 February 2012)

<sup>73</sup> Information from the website of deCODE Genetics. Inc: <http://www.decode.com/products/> (Last visit: 27 February 2012)

<sup>74</sup> Ibid.

From 1996-98 deCODE actively negotiated with the Icelandic government to set up an Icelandic Health Sector Database (HSD) to collect medical records from the entire Icelandic population. The aim was to establish a population database for the entire nation and for data linkage with databases containing complete Icelandic genealogies. Unlike most genealogical data already computerised and accessible in the public domain, medical records in Iceland had been confidentially kept in regional hospitals and health care centres. Therefore, in order to establish the HSD, it needed to have a legitimate basis for the hospitals and centres to transfer their medical records to this health database. After successful negotiation, deCODE Genetics obtained support from the Icelandic Prime Minister, David Oddsson, to establish the database. On 17 December 1998, the Icelandic parliament passed the *Act on a Health Sector Database* permitting the establishment of the health database by a vote of 38 to 23.<sup>75</sup>

Furthermore, the Act also granted an exclusive operating license to deCODE for the management of the HSD for 12 years. An agreement set between the deCODE and the Icelandic Ministry of Health was that the company would pay the government its 6% profits up to the amount equivalent to the annual fee (about 800,000 EUR) for securing the position as a monopoly licensee.<sup>76</sup> In addition to the arrangement of monopoly control, the Act adopted presumed consent as an arrangement for the HSD to efficiently collect patients' medical data from hospitals and clinical centres around the nation. According to the Act, the hospitals and clinical centres were presumably to have obtained consent from their patients so they could negotiate with deCODE directly to decide whether or not to transfer their clinical data into the HSD. If individual patients did not want their records to be included in the HSD, they needed to follow a separate opt-out procedure within six months, namely before mid-June 1999 as stipulated by the Act.

Many concerns arose about consent, privacy and confidentiality. For a country of a small population (about 275,000 people), it remained questionable whether coding and competence of computer security of the HSD was sufficient to protect the privacy of individuals and families. Furthermore, an anxiety emerged with the ambition of deCODE to use Iceland's population to create a commercial laboratory. Such an attempt worried

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<sup>75</sup> Chadwick, Ruth. "The Icelandic Database—Do Modern Times Need Modern Sagas?" *British Medical Journal* 319, no. 7207 (1999). pp 441-444

<sup>76</sup> Ibid.

those who treated genealogies and genetics as cultural elements constituting Icelandic personal and national identity.<sup>77</sup> For that reason, debates about patients' rights appeared in society especially with regard to issues about confidentiality, ownership and commodification of clinical data. For the medical profession, maintaining confidentiality of patients' clinical records was their legal and professional responsibility. As a result, most of Icelandic physicians refused to submit their records to the HSD unless requested by patients. Furthermore, based on the right to opt out, about 11,000 Icelanders had opted out from the HSD by mid-June 1999 so their data would not be included in the health database before the HSD was formed.<sup>78</sup>

However, despite the opt-out option, this concession was ethically inadequate as it was not yet clear whether patients would have a right to withdraw their already entered data from the HSD after the database was created. In addition, according to the Act, only adults, namely those who were over 18 by mid-June 1999, could have legal rights to opt out; as a result, data of deaths would have been automatically included in the HSD, leaving children and the dead as the two categories without adequate privacy protection.<sup>79</sup> In 2003, an Icelandic Supreme Court's decision on the case *Guðmundsdóttir v. the State of Iceland* (No.151/2003) rendered the Act unconstitutional based on the 1<sup>st</sup> paragraph of article 73 of the Icelandic Constitution about the freedom from interference with privacy.<sup>80</sup> The case was filed by Ms. Guðmundsdóttir against the Icelandic Ministry of Health in February 2000 to exclude her deceased father's clinical record from the HSD. The Reykjavik District Court first dismissed the case on the ground that Ms. Guðmundsdóttir did not have legal standing to file the lawsuit as the legislation only conferred the right to opt out on adult individuals rather than extending the right to their family members. The Supreme Court's decision granted Ms. Guðmundsdóttir a personal interest in the case on the grounds that the one-way encryption system of the HSD could not ensure data anonymity.<sup>81</sup> Furthermore, the nature of genetic data concerned not only the individuals from which they are derived but also descendants and family

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<sup>77</sup> Hilary Rose, "The Commodification of Bioinformation: The Icelandic Health Sector Database," (London: The Wellcome Trust, 2001). pp 9-10

<sup>78</sup> Ibid., P. 20

<sup>79</sup> Ibid., P. 25

<sup>80</sup> "Icelandic Supreme Court Holds That Inclusion of an Individual's Genetic Information in a National Database Infringes on the Privacy Interests of His Child. — *Guðmundsdóttir V. Iceland*, No. 151/2003 ". *Harvard Law Review* 118 (2004), pp 810-817

<sup>81</sup> Ibid.

members of the individuals.<sup>82</sup> After the legislation was struck down by the Supreme Court, the probability of resuming the establishment of the HSD declined dramatically. Even though deCODE Genetics has continued operating its business since then, without support from Icelanders, the idea of building a centralised health database for population genetics research turned out to be futile. On 24 November 2008, a press release announced that the company was removed from the NASDAQ Biotechnology Index and a year later, deCODE Genetics filed for bankruptcy in the US with debts of \$313.9 million.<sup>83</sup>

### 2.3.2. The UK Biobank

The UK biobank is a prospective cohort project aiming to recruit 500,000 British participants aged 40-69 to form a genetic database for a wide range of medical research uses. As a national research resource, the biobank was funded by the Wellcome Trust, Britain's largest public charity sponsoring biomedical research<sup>84</sup> and the UK government through agencies of the Department of Health, the Medical Research Council (MRC), and the Scottish Executive and the Northwest Regional Development Agency.<sup>85</sup> In 2003, the biobank was incorporated and registered as a charity in England and Wales; about 61 million GBP had been secured for its initial phase for recruitment and assessment.<sup>86</sup> Recruitment started in April 2007, about eight years after the idea of the biobank was initiated, and it was scheduled to reach the final goal of recruiting 500,000 participants by August 2010.<sup>87</sup>

Even though the biobank was registered as a charitable company, its link with commercialisation was not invisible. In fact, the earliest initiative of setting up the biobank for linking to electronic medical records retained by the NHS can be traced back to 1999 when Sir George Poste proposed the idea to ministers to discuss.<sup>88</sup> Poste then worked for a global pharmaceutical company - SmithKline Beecham - ,<sup>89</sup> a firm later

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<sup>82</sup> Ibid.

<sup>83</sup> Jeanne Whalen, "Genomics Pioneer Decode Seeks Bankruptcy Protection " *The Wall Street Journal*, 18 November 2009.

<sup>84</sup> The Wellcome trust is also the world's second richest medical charity, with net asset over £13.4 billion in 2006, see GeneWatch UK, "Bioscience for Life? Appendix A: The History of UK Biobank, Electronic Medical Records in the NHS, and the Proposal for Data-Sharing without Consent," (London 2009). P. 19

<sup>85</sup> Ibid.

<sup>86</sup> Sarah Hall, "£61m Medical Experiment Begins," *The Guardian*, 22 August 2006.

<sup>87</sup> Keith Doyle, "Uk Biobank 'Close to Signing up 500,000 Participants' " *BBC News*, 24 April 2010.

<sup>88</sup> Supra note 84 (GeneWatch UK, "Bioscience for Life?")

<sup>89</sup> Ibid.

merged with Glaxo Wellcome, another healthcare company to form Glaxo SmithKline (GSK)<sup>90</sup>, a global drug firm with business focusing on invention and marketing of medications. In April 1999, Poste published an article in *Science* as co-author noting the potential use of NHS electronic medical data to link with DNA samples for exploring the association between genes and disease.<sup>91</sup> Considering the decode controversy about commercialisation of medical records, Poste proposed an idea of a “public-private partnership (PPP)” as a model for the creation and management of the biobank.<sup>92</sup> In May 1999, the Wellcome Trust organised a workshop to discuss the possibility of creating the UK Population Biomedical Collection, a national DNA database for Britain. In the same year, the Wellcome Trust and the Medical Research Council agreed in principle to co-fund the project and later, in January 2000, the MRC called for proposals for establishing a large genetic database as a national resource accessible to biomedical researchers in the UK.<sup>93</sup>

Learning from the Icelandic lesson, in order to have adequate social legitimacy to ensure the biobank’s success in Britain, the funding agencies have carried out a series of public engagement activities since the early stage of the project. The first public consultation began in 2000<sup>94</sup> and it has continued as the project develops as a way to receive updated feedback and obtain trust from the public. In addition, in order to increase public confidence, the project upholds the principle of openness and transparency. It has made accessible the information about the management of the biobank online such as minutes of meetings, reviewers’ reports on the protocol, etc. Even though several methods to generate public engagement have been adopted, for instance, focus groups, panel discussion and surveys, criticism remains especially with regard to the lack of serious debate in society about the scientific aims and approaches of the biobank and the inadequate legal safeguards to prevent genetic discrimination and protect personal genetic information.<sup>95</sup> For instance, GeneWatch, a pressure group in the UK, has challenged the necessity to build a national DNA database like this and called for more

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<sup>90</sup> In the proposal of the pilot study of the Taiwan Biobank, the previous experience of collaboration between the GSK and the Institute of Biomedical Science at the Academia Sinica has been mentioned as an advantage for the establishment of the biobank in terms of its industrial application. .

<sup>91</sup> Robin Fears and George Poste "Health Care Delivery: Building Population Genetics Resources Using the UK NHS." *Science* 284, no. 5412 (1999). pp 267-268.

<sup>92</sup> Ibid.

<sup>93</sup> Supra note 84

<sup>94</sup> Mairi Levitt, "UK Biobank: A Model for Public Engagement?," *Genomics, Society and Policy* 1, no. 3 (2005). P. 78

<sup>95</sup> Helen Wallace, "A UK Biobank: Good for Public Health?," *openDemocracy*, 23 July 2003.



democratic mechanisms to be involved in the biobank project, especially more debates about the research design and agenda.<sup>96</sup> Furthermore, despite public involvement in every stage, the engagement has been criticised as an “upstream” ethics,<sup>97</sup> namely the public is entitled to have their voices heard on the existing arrangement of the biobank so the obstacles to the project can be smoothed. However, the public cannot really control the direction of the project throughout its development or even stop it when there is a need to do so.

In addition, in order to ensure the biobank acts for the public good, an independent committee - the Ethics and Governance Council (EGC) - has been set up by the Wellcome Trust and the MRC since November 2004 in order to monitor the biobank management and keep the use of the biobank resource under review.<sup>98</sup> One of the important functions of the EGC is to advise the biobank on the interests of donors and the public in general based on the Ethics and Governance Framework (EGF) under which the biobank operates. The framework acting as an ethical standard for the operation of the biobank was drafted in 2003 by the biobank founders with the advice of the Interim Advisory Group consisting of multidisciplinary experts. It is expected that the Ethics and Governance Framework can be evolved throughout the development of the project. The latest version which is the third draft of the EGF agreed by the ethical committee and the Board of Directors of the biobank was published in October 2007.<sup>99</sup>

In the framework, the ethical standards are discussed according to the three relationships associated with the biobank - relationship with participants, relationship with research users, and relationship with society.<sup>100</sup> The first category covers issues about recruitment, namely consent and confidentiality with regard to participants’ enrolment in the biobank project. The second category focuses on stewardship of and research access to data and samples. In addition to stipulations regarding decisions on access and use, the section also covers principles on sharing of data and findings as well as licences for specific use.

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<sup>96</sup> Ibid.

<sup>97</sup> Supra note 94, P. 80

<sup>98</sup> Information at the Ethics and Governance Council website: <http://www.egcukbiobank.org.uk/> (Last visit: 27 February 2012)

<sup>99</sup> "UK Biobank Ethics and Governance Framework Version 3.0," (2007).<http://www.ukbiobank.ac.uk/wp-content/uploads/2011/05/EGF20082.pdf> (Last visit: 27 February 2012)

<sup>100</sup> Ibid.

The last category emphasises the management and accountability of the biobank. Besides the internal governance arrangements such as the Board of Directors, the Ethics and Governance Council, the Steering Committee and International Scientific Advisory Board, the framework lists the plan for external governance that includes an ethics approval review by relevant ethics committees and compliance with the Research Governance Framework for Health and Social Care in England and the corresponding frameworks in Wales and Scotland.<sup>101</sup> More to the point, this section acknowledges the principle of benefit sharing by requesting dissemination of new knowledge produced from research to benefit public health not only in the UK but also in the rest of world.<sup>102</sup> As the biobank is positioned as a common resource, in order to ensure it is not improperly exploited by non *bona fide* users, terms of access and intellectual property procedures are separately developed and expected to be embodied in legal agreements that are compliant with the project's aims and purposes.<sup>103</sup>

However, despite the ethical framework stating clearly that the biobank does not expect itself to lead to significant income returns from patentable inventions, it does not exclude the opportunities that the biotech and pharmaceutical industries may use the biobank resource for inventions that make a profit. According to the governance framework, commercial companies are allowed access to the biobank so long as their research application falls within the biobank purposes.<sup>104</sup> Such arrangement of access has been criticised; even though the internal ethical committee was set up as a guardian of the biobank to review the uses of data, it has no veto power over such decisions as the power to decide on types of research belongs to the Board of Directors.<sup>105</sup> Furthermore, although the Ethics and Governance Council and all interested parties including participants and members of the public may propose amendments to the governance framework, whether to adopt such advice on revisions still rests with the Board of Directors. The board, acting as company directors and charity trustees, includes one member from the scientific committee but no members from the ethical committee.<sup>106</sup>

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<sup>101</sup> Ibid.

<sup>102</sup> Ibid.

<sup>103</sup> Ibid.

<sup>104</sup> Ibid.

<sup>105</sup> Supra note 94, P. 79

<sup>106</sup> Ibid.

Besides the anxiety about commercialisation, a further concern is about how to safeguard privacy without compromising freedom of research. Even though the data are collected for the biobank with the consent of participants, it is not clear whether such consent would be extended later on to allow the linkage between electronic medical records retained in the NHS and the genetic data of the biobank. The UK government's recent forced withdrawal of the data sharing provisions from the Coroners and Justice Bill 2009 reflected the worries from the public that the government would allow personal data to be shared with third parties, including police and private companies, without proper consent.<sup>107</sup> Clause 152 of the Coroners and Justice Bill 2009 obviates privacy protection of individuals by inserting a new section 50A into the Data Protection Act 1998 that confers designated authority, which is further defined in 50A (2) as an order-making power to share information consisting of or including personal data.<sup>108</sup> The Clause 152 initiative came from a review of the Data Protection Act proposed by Dr. Mark Walport, Director of the Wellcome Trust, to remove unnecessary legal barriers on data sharing for creating new mechanisms that enable population-based research.<sup>109</sup> However, many concerns that patients' personal data would be misused and inappropriately disclosed to third parties triggered a campaign organised by more than 30 groups<sup>110</sup> to stop the legislation, including the British Medical Association (BMA), Royal College of Psychiatrists and British Computer Society.<sup>111</sup> The abandonment of Clause 152 illustrated the influence of British public opinion giving an abstract concept like privacy a concrete meaning in its implementation in reality. It also shows that the creation of biobanks needs to obtain its legitimacy from society. Questions such as what constitutes personal data and how it may be used in an ethically and legally acceptable way would be a question to be decided by the public.

### 2.3.3 The Estonian Genome Project

The Republic of Estonia, lying on the eastern shores of the Baltic Sea and bordered to the north by the Gulf of Finland, is one of the Baltic Rim countries of the northwestern part of

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<sup>107</sup> David Barrett, "Government Abandons Data-Sharing Scheme " *Telegraph*, 7 March 2009

<sup>108</sup> Clause 152, *Coroners and Justice Bill 2009*

<sup>109</sup> Richard Thomas and Mark Walport, "Data Sharing Review Report," (2008). <http://www.justice.gov.uk/reviews/datasharing-intro.htm> (Last visit: 10 March 2012)

<sup>110</sup> Henry Porter, "Yesterday Saw the Birth of a Great Movement for Liberty," *The Guardian*, 1 March 2009.

<sup>111</sup> "Straw Drops Secret Inquest Plans," *BBC News*, 15 May 2009. <http://news.bbc.co.uk/1/hi/uk/8051953.stm> (Last visit: 10 March 2012)

East Europe. Estonia has a population of 1.34 million. According to Andres Metspalu, the main initiator of the Estonian Genome Project (EGP), Estonians are representative of all Caucasian populations in Europe.<sup>112</sup> Whereas the Icelandic Health Sector Database focused on the homogeneity of the Icelandic population, scientists in Estonia stressed the heterogeneity of Estonians as representative of the European gene pool as a whole. The main idea of the genome project was to set up a national gene bank in Estonia so the research carried out on the basis of the Gene Bank can be generalised for other Europeans. This was expected to not only improve Estonian health care but also bring an enormous benefit from the development of personalised medicine in the future. In addition, the genome project aimed to support the further development of existing biotechnology industries in the country. Compared to its Baltic neighbours, Estonia's economy has grown rapidly after the country's independence from the Soviet Union in 1991. The country is listed as an advanced economy by international organisations and it has the highest GDP among former Soviet republics and the lowest ratio of government debt to GDP among EU countries at the end of 2010.<sup>113</sup>

The planning of the Estonian Genome Project began in March 1999. It was mainly developed by the Estonian Genome Foundation (EGF), a private and non-profit organisation founded by a group of scientists to support Estonia's genetic research. In December 2000, the Estonian Parliament passed the Human Genes Research Act laying out ethical and security principles for the establishment and use of the Gene Bank, which aimed to be established during a period of five years and to collect blood samples of up to 1 million Estonian people, with 70-80% of the participants being included during the first three years.<sup>114</sup> In order to coordinate and govern the genome project, a non-profit institution - the Estonian Genome Project Foundation (EGPF) - was established under the Ministry of Social Affairs in March 2001.<sup>115</sup> In the same year, the EGPF founded a private Estonian based company EGeen Ltd to form the public-private partnership between the foundation and the company in order to finance and commercialise the results of the Estonian Genome Project. As the foundation acted not only as a privacy shelter but also the owner of the Gene Bank, it granted EGeen a 25 years' exclusive commercial licence

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<sup>112</sup> The Estonian Genome Project, See: <http://www.genomics.ee/files/menu/egp.pdf>, P. 10 (Last visit: 27 February 2012)

<sup>113</sup> European Commission, *Eurostat newsrelease* 21 October 2011.

<sup>114</sup> Supra note 112

<sup>115</sup> Ibid.

access to the EGP in return for EGeen's annual payment of about 300,000 Euros to the EGPF and an unlimited annual profit payment of 0.5% as well as 3% of the turnover depending on the financial success of the EGeen Ltd.<sup>116</sup>

The EGPF and its exclusive commercial licensee EGeen Ltd, in turn, founded another private company EGeen International Inc (EGI Inc) registered in the United States to enable the involvement of private funding from international venture capital firms and private individuals without many regulatory restrictions.<sup>117</sup> However, this public-private funding set-up lasted only for three years from 2001 until late 2004 when the contract between the EGeen Ltd and the EGP terminated. In fact, the contradiction between the EGP and the EGI Inc started from an early stage when the EGI Inc was reported to be dissatisfied with the way the samples were gathered by the EGI Inc and would prefer to have a significantly narrower approach to the Gene Bank to focus on a few specific diseases, so that marketable results could be delivered much sooner, which would add more incentives for private capital to invest in the project.<sup>118</sup> Both EGPF and EGeen Ltd were reluctant to change the method of sample gathering from a broader population-based one to a narrower disease-based one, and since the contract was terminated, foreign capital flows underpinning the EGP had also stopped. Even though, from a scientific perspective, it is still arguable whether sample gathering on a broader basis would produce better scientific results in medical research, EGI Inc as venture capital seemed to be more interested in the short-term financial returns than the long-term research results and their impact on public health in general. During the contractual period from 2001 to 2004, EGI Inc totally financed the EGP with 4.3 million Euros while the funding from the public sector was little over 60 thousand Euros in 2001 for initiating the project and a few thousand Euros for covering the operation cost of the EGP for maintaining the DNA samples after the contract was terminated.<sup>119</sup> The termination of the contract also meant that EGeen Ltd was no longer obligated to finance the genome project which had collected about 10,000 samples from Estonian participants.<sup>120</sup>

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<sup>116</sup> Rainer Kattel and Margit Suurna, "The Rise and Fall of the Estonian Genome Project," *Studies in Ethics, Law, and Technology* 2, no. 2 (2008). P. 7

<sup>117</sup> *Ibid.*, pp 6-7

<sup>118</sup> *Ibid.*, P. 8

<sup>119</sup> *Ibid.*, P. 10

<sup>120</sup> *Ibid.*

The activity of the EGP was frozen from 2004 to 2007. During this period, several political debates about the future of the EGP emerged but the only related on-going substantial project was cooperation with Latvia about cancer prevention measures that enabled the EGP to collect 5,000 additional samples by the end of 2006.<sup>121</sup> In 2007, the Estonian Parliament passed the Amendment of the Human Genes Research Act that provided a legitimate basis for the EGP to continue as a structural unit of the University of Tartu, the oldest public university in Estonia. The EGP was turned back into a public-funded scientific venture with direct funding from the state budget. In 2007, according to the State Budget Law, the government of Estonia financed the EGP with around 1.15 million Euros and later, about 7.7 million Euros of public funding was guaranteed for the years 2007-2009.<sup>122</sup> The EGP had collected 13,500 samples in 2007 and expected to continue its collection to 100,000 samples for the Gene Bank by 2010.<sup>123</sup> The case of the EGP demonstrated that in the public-private partnership, when different expectations about the research benefits occurred, the collaboration was threatened to be brought to breakdown, and that added many uncertainties in the development of the project. In addition, like the Icelandic Health Sector Database, the exclusive commercial licence created a monopoly for the use of scientific results that could have a potentially severe impact on the overall scientific and innovative environment for the country's long-term scientific and biotech development.

In order to create public support, the genome project was presented to the public by discourses associating with 'Estonia's return to Europe' and framed as the 'Estonian Nokia' by means of technoscience and innovation to demonstrate the quality of Estonian biomedical development.<sup>124</sup> Even though the passage of special legislation for the establishment of the Gene Bank may be viewed as a deliberate effort to create legitimacy for the Gene bank and mediate between science and society, it has been argued that the heavy involvement of private funding in the early phases of the EGP had not yet been fully disclosed to the public nor had it been seriously discussed in the Estonian Parliament in the enactment process of the Human Genes Research Act.<sup>125</sup> According to the Act,

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<sup>121</sup> Ibid.

<sup>122</sup> Ibid.

<sup>123</sup> Rain Eensaar, "Estonia : UPs and Downs of a Biobank Project," in *Biobanks: Governance in Comparative Perspective* ed. Herbert Gottweis (Routledge, 2008). P. 56

<sup>124</sup> Ibid., P. 57

<sup>125</sup> Supra note 116 (The Rise and Fall of the Estonia Project) pp 6-7

participants had the right to decide whether they would like to be informed of their genetic data and personalised information, but samples and data collected are the property of the Gene Bank.<sup>126</sup> In addition, a special Ethics Committee composed of appointed members from the Supervisory Board of the EGP was legitimised by the Act, according to which the committee played a decisive role in evaluating the pertinence of the establishment of the Gene Bank and assisted in ensuring the protection of privacy and other rights related to research subjects in biobanking. Even though a coherent governance structure seemed to be created for the establishment of the EGP, the Estonian case illustrated that a feasible business model plays a key role, one as important as a legal and ethical framework for the sustainability of a biobank.

#### **2.3.4 The Case of Tonga**

The Kingdom of Tonga is an archipelago state in the South Pacific Ocean, comprising 176 islands, about 36 of which are inhabited.<sup>127</sup> The state has a population of 101,000 who are mainly descendants of Polynesians who inhabited the islands thousands of years ago.<sup>128</sup> In November 2000, an Australian-based biotech company, Autogen, informed the Australian Stock Exchange (ASX) that it had reached an agreement with Tonga's Ministry of Health to establish its own private genetic database with the population of Tonga to study the genes behind common diseases, such as obesity, diabetes, certain cancers and cardiovascular diseases.<sup>129</sup> According to Greg Collier, director of research and development of Autogen, Tonga offered a powerful resource for identifying genes associated with common diseases to develop disease-specific drugs as it was still relatively homogeneous in its genetic background.<sup>130</sup> Under the terms of the agreement, Autogen would have exclusive access to the database even though samples and data gathered for the database remained the property of Tonga. In return for access to the exclusive use rights, Autogen agreed to provide annual research funding to the Ministry of Health in Tonga and net royalties on revenues derived from discoveries which were

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<sup>126</sup> Supra note 123 (Estonia in Biobanks Governance) pp 60-61

<sup>127</sup> More info, see the website of the Government of Tonga: <http://pmo.gov.to/general-/about-tonga> (Last visit: 25 February 2012)

<sup>128</sup> Ibid.

<sup>129</sup> Kim Griggs, "Tonga Sells Its Old, New Genes," *The Wired News* 27 November 2000.

<sup>130</sup> Ibid.

commercialised.<sup>131</sup>Autogen would also give Tonga pharmaceutical drugs free of charge that were produced based on the Tonga database.<sup>132</sup>

In fact, the database project was an alliance between Autogen and a subsidiary of Merck, the German pharmaceutical giant, which held a 15% stake in Autogen and funded a six-year research project at the International Diabetes Institute located in Melbourne to discover genes associated with obesity and to develop new drugs for a potentially lucrative market as well as the diagnostic tests to predict the susceptibility of the disease.<sup>133</sup> Merck was the major manufacturer of metformin, the top selling drug for the treatment of Type 2 diabetes, which produced sales of around 1.3 billion USD per year.<sup>134</sup> The Melbourne-based Institute had a database established over decades which stores blood samples coming from many places across the world, such as Europe, China, India, Melanesia and Polynesia.<sup>135</sup> Autogen was also reported as a biotech company with good political connections as its chairman and managing director, Joseph Gutnick, was a leading businessman from the Australian Jewish Community and, according to media reports, a confidant of former prime minister of Israel, Benjamin Netanyahu, who had attended a forum on biotech hosted by Autogen in August 2001.<sup>136</sup>

Autogen's agreement faced strong opposition from church and human rights groups in Tonga and this stalled the Tonga database project. According to Lopeti Senituli, director of the Tonga Human Rights and Democracy Movement, the main reason they opposed the Tonga proposal was because that there was no public discussion either through the media or in Tonga's Legislative Assembly on the agreement.<sup>137</sup> In addition, the Tonga National Council of Churches held a consultation conference on bioethics in March 2001 bringing together church and community leaders from the Pacific region that resolved to oppose conversion of life forms into corporate property through patent monopolies as it is "counter-productive to the interests of the people of the Pacific."<sup>138</sup> The consultation also

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<sup>131</sup> Ibid.

<sup>132</sup> Ibid.

<sup>133</sup> Bob Burton, "Proposed Genetic Database on Tongans Opposed " *British Medical Journal* 324, no. 7335 (2002).

<sup>134</sup> Lopeti Senituli and Margaret Boyes, "Whose DNA? Tonga and Iceland, Biotech, Ownership and Consent," in *Australasian Bioethics Association Annual Conference* (Adelaide, 14-16 February 2002).

<sup>135</sup> Ibid.

<sup>136</sup> Bob Burton, "Opposition Stalls Genetic Profiling Plan for Tonga," *South Pacific* 18 February 2002

<sup>137</sup> Ibid.

<sup>138</sup> Ibid.



recognised that the ideal way to address common diseases, such as obesity and diabetes, was through education to change people's dietary habits and lifestyles. Even though Autogen stated that it would follow the procedure of prior informed consent for its sample collection and the project would not involve the whole population in Tonga, such a statement, according to the churches, neglected the family-centred values in Tonga's cultural norms and that blood samples donated from individuals would also reflect the extended kinship and group's genetic makeup.<sup>139</sup> In addition, it had been reported that the statements on ethics contained in the Autogen agreement were "unacceptably vague"; nor did they have enforcement mechanisms.<sup>140</sup> The economic benefits from the agreement were also argued to be heavily weighted in favour of Autogen, as the promised royalties from any invented drugs and new therapies were conditional on Autogen's future revenues, but the agreement could immediately attract capital for Autogen from global pharmaceutical conglomerates.<sup>141</sup>

Stung by the regional opposition, the Minister of Health in Tonga denied having signed the agreement with Autogen and the company also stressed that it had no immediate interest in carrying out research in Tonga. Rather, it would put more resources into studying the Tasmanian population in Australia.<sup>142</sup> However, human rights groups in Tonga were still concerned whether Autogen would really retreat from Tonga as the company had not removed its reference to the state from its website; nor had the Australian Stock Exchange been informed of the withdrawal of this Tonga project.<sup>143</sup> For these opposition groups, the secretly negotiated agreement between Tonga and Autogen demonstrated that the state was prepared to cooperate with foreign commercial interests to sell its own resources, including the genes and genetic information of Tongan people, so they were concerned that other biotech and pharmaceutical companies would also follow Autogen's footsteps to exploit their genetic resources and therefore it was necessary to advocate a more accountable government in Tonga, the Pacific's only remaining monarchy.<sup>144</sup>

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<sup>139</sup> Supra note 133

<sup>140</sup> Supra note 134

<sup>141</sup> "The Gene Hunters," *New Internationalist Magazine* 349 (September 2002). <http://www.newint.org/features/2002/09/05/hunters/> (Last visit: 27 February 2012)

<sup>142</sup> Supra note 136

<sup>143</sup> Ibid.

<sup>144</sup> In 2010, Tonga started its legislative reform to become a fully functioning constitutional monarchy and had its first fully representative elections for its legislative members and Prime Minister.

The opposition groups urged the Tongan government to reconsider what Autogen offered, given that existing international intellectual property frameworks favoured those with the technology and capital but what Tongan provided was the raw materials - blood. On the company's website, Autogen had already claimed 35 genes related to obesity and diabetes which were in different phases of patent protection.<sup>145</sup> For Autogen, the alliance with the Tonga government continued the company's growth as a world-class biotech enterprise, especially in the field of gene discovery, by complementing the unique samples from Tonga.<sup>146</sup> In addition, the groups also called on the Tonga government to put in place national regulations to review any proposal like the one of Autogen before it could be seriously considered for Tonga. On 13 February 2002, the Tonga government approved the establishment of the National Health Ethics and Research Committee to take charge of this supervision role.<sup>147</sup>

## **Conclusion**

This chapter explains the notion, norms and driving forces of biobanks and introduces the cases of biobanks in Iceland, the UK, Estonia and Tonga to illustrate various reasons behind the rise and fall of biobanks and the entanglement between life sciences, politics and capitalism. In order to support genomics research and to capitalize on states' genetic resources, many countries have joined in the global trend to set up their own national biobanks. Following the completion of the human genome sequence and the mapping of human genetic variation, biobanks have been recognised by supporting geneticists, governments and pharmaceutical industries as the next logical step to translate genetic data into clinical applications.

The four cases have illustrated that the lack of public cooperation may finally lead to great controversy and even failure of biobank projects. It also shows that commercialisation and the arrangements for consent and privacy influence the legitimacy of the establishment of a biobank. Since every agency involved in the creation and operation of biobanks comes with different expectations and interests, for instance, freedom of

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<sup>145</sup> Supra note 141

<sup>146</sup> Ibid.

<sup>147</sup> Ibid.

research for scientists, protection of personal rights for participants, improvement of public health and the growth of bioeconomy for the states, it is essential to guarantee a procedure which is ethically acceptable and can create enough space for adequate public engagement in order to reach a balance among these different and sometimes conflicting interests. The cases also show that how the development of life sciences has been closely connected to global capital and how capital needs to be seriously considered in biobank governance. In Taiwan, even though its population biobank is still in an early phase of development, the idea of biobanks has been introduced as an international trend to follow that ignores various essential elements in the successful establishment and operation of a biobank. These examples may provide a valuable point of reference to Taiwan for its biobanking project and for the sustainability of a healthy biobank.

## Chapter 3 Taiwan in the Global Bio-Economies: Biocapital Formation, Taiwanese DNA and Ethical Configuration

### Introduction

Since 1982, Taiwan's government has identified the potential of biotechnology and systematically schemed for several large-scale programs in order to upgrade the country's capacity from a manufacturing economy to a knowledge-based economy using knowledge resources such as technology and know-how as a tool to produce value. In addition, the neoliberal rationale of value accumulation dominates the state's overall development policy that echoes the government's recent ambitious plan to propose Taiwan as a "global operations centre."<sup>1</sup> By continually respecting market logics, the government is fully aware that in terms of better use of production factors such as capital, technology, land and manpower, Taiwan needs to find its own edge, especially compared to other Asian countries, in global competitiveness. Considering nearly 23 million people, which is equivalent to twice the population of Shanghai in 2010<sup>2</sup>, living in a land area of approximately 36,000 square kilometres, two thirds of which is mountains, the government recognises that in order to lead the country to build its own niche on the global stage, it should make the most of capital and technology, since these two factors, compared to limited manpower and limited land resources, are relative advantages for Taiwan's long-term development.

As a distinct feature of modernity, technology has been viewed by some scholars and anthropologists in the field of Science and Technology Studies as a useful indicator to understand the process of modernisation and to interpret and reconstruct the notion of modernity in different regions. It can illuminate, for example, how technology has been projected by individual countries as a valued tool for their transformation from the pre-modern to the modern era. The term "modernity" thus captures a sense of revolutionary change when it entangles with the idea of technology. A parallel attempt can be found in *Asian Biotech*, a recent collection of several ethnographic studies on biotech innovations in Asia. In the book, Aihwa Ong used the term "biotech revolution" to introduce how Asian states make biotechnologies a "mechanism of regeneration" to

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<sup>1</sup> "Introduction to Biotechnology & Pharmaceutical Industries in Taiwan, Republic of China," (Taipei: Biotechnology & Pharmaceutical Industries Program Office, Ministry of Economic Affairs 2009).

<sup>2</sup> "Shanghai Officially Just Got a Bit More Crowded", *CNN International* January 19 2011.

create a new form of knowledge, ethical configurations and value generation.<sup>3</sup> She proposed that a biotech modernity seems to have emerged in some Asian regions that demonstrated the endeavours of Asian countries to catch up with the West when biotechnologies articulated not only the scientific imagination but also the nationalist aspirations of these modern states.<sup>4</sup> As Charis Thompson shows in her ethnographic studies of stem cell research in South Korea and Singapore, the hope of building a modern nation turns biotechnologies into state-led enterprises that are allied to the milieu of postcolonialism in the region in order for the former occupied countries to restore national identity and a competitive niche on the global stage.<sup>5</sup>

Similarly, Michael Fischer identifies convergence across diversities by deploying development of science and technology in a global context in which he points out that “a cosmopolitical technoscientific world”<sup>6</sup> is emerging and it is becoming ever more “diverse, distributed and dependent on a heterogeneity.”<sup>7</sup> Even though for the global context, such as connections, networks, the flowing of expertise, materials, capital and technologies may be transnational, he argues that the grounded ethnographic concerns are mainly local and it is because of the local inputs to global assemblages<sup>8</sup>, a space has been created to realise the reconfiguration of social and ethical norms, politics and regulation in this technoscientific world.<sup>9</sup> Indeed, the contribution of local knowledge enriches the cosmopolitical world by creating a space for recognition and comparison. According to Ong and Fischer, such a space is an ethical terrain for which different civic epistemologies<sup>10</sup> and their entangled frames on the issues of new technologies in the life sciences can be better understood and represented.

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<sup>3</sup> Aihwa Ong, "Introduction: An Analytics of Biotechnology and Ethics at Multiple Scales," in *Asian Biotech: Ethics and Communities of Fate* ed. Aihwa Ong and Nancy N. Chen (Duke University Press, 2010). pp 2-16

<sup>4</sup> Ibid, pp 5-6

<sup>5</sup> Charis Thompson, "Asian Regeneration? Nationalism and Internationalism in Stem Cell Research in South Korea and Singapore," in *Asian Biotech : Ethics and Communities of Fate* ed. Aihwa Ong and Nancy N Chen (Duke University Press, 2010). pp 95-117

<sup>6</sup> Michael Fischer, "Four Genealogies for a Recombinant Anthropology of Science and Technology," *Cultural Anthropology* 22, no. 4 (2007). pp 578-79

<sup>7</sup> Ibid.

<sup>8</sup> For the notion of “global assemblages,” see, Aihwa Ong and Stephen J Collier, eds., *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems* (Oxford: Blackwell Publishing, 2005).

<sup>9</sup> Fischer, "Four Genealogies for a Recombinant Anthropology of Science and Technology." P. 574

<sup>10</sup> Ibid.

By the same token, locating a pragmatic case study under the context of cosmopolitical technoscience may enliven ethical and legal discussions of practical issues for biobanks. As a result, before directly moving into discussions with regard to ethical configurations on biobanking practices in Taiwan, the chapter first contextualises the role of biotechnologies in Taiwan's bioeconomy in order to realise the state's strategies in shaping its own niche according to the logics of cosmopolitics that is formed by both geopolitics and global capitalism. It then locates ethical practices with regard to commercialisation into the map so the issues may be addressed not only from the single viewpoint of biobank governance but also from a broader framework that hopes to contribute to a better understanding of a more dynamic and intricate entanglement with Taiwan's sovereign reasons, biocapital formation, technoscientific imagination and collaboration of public and private entities based on which the ethical configurations emerge.

### **3.1 Biotech Aspirations and Neoliberal Logics**

Taiwan's genomics study has been embedded in the broader context of the development of biotechnology in Taiwan. The rationale behind it is to use this innovative scientific research to foster industrial applications by developing new technologies and medicines. Associating life sciences with engineering, biotechnology is a cross-disciplinary field addressing research on applied biology. The scope of biotech applications is vast including genetic engineering as one of its modern uses. Taiwan's biotechnology development can be traced back to 1982 when the government first listed biotech as one of the eight key technologies to promote for Taiwan's industry.<sup>11</sup> Two years later, the Ministry of Economic Affairs (MOEA) established the Development Centre for Biotechnology (DCB) to further assist in biotech research and encourage its applications.<sup>12</sup> Since then, biotechnology has been prioritised and placed at the centre of the state's high-tech development plan.

For nearly 30 years, the government nurtured the biotech industry by launching national programmes and forming institutes to provide an amicable environment for attracting foreign investment. For instance, an advisory committee for promoting biotechnology

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<sup>11</sup> "Taiwan Biotechnology Industry Overview," (Taipei: Development Centre for Biotechnology, 2008).

<sup>12</sup> Ibid.

industry was set up under the Executive Yuan (the cabinet) in 1995. In the same year, the cabinet approved the "Promotion Plan for the Biotechnology Industry," which is a road map document listing the nation's development guidelines, goals, growth targets and needs to be revised biannually to meet the industry update.<sup>13</sup> The plan allows the government to promote the biotech industry and provides bureaucratic bodies with a clearer direction about their action tasks. At the same time, the private sector can also benefit by having a better idea about the state's prospective development strategies. According to the recent amendment to the guideline, the government planned to attract USD 4.5 billion as new investment in local pharmaceutical and biomedical companies by 2010.<sup>14</sup>

Like many other East Asian countries, Taiwan faced the new development challenges brought by globalisation during the 1990s. Advance in the Internet and information technology enhanced the division of labour across the globe. Outsourcing became a feasible way for firms and companies worldwide to reduce costs emerged in the process of manufacturing and distribution. This new economic pattern diminished the original competitive advantages of cheap labour costs in dragon countries and put more pressure on these East Asian newly industrialising economies to upgrade their local industries.<sup>15</sup> At the same time, as the average product cycle had been shortened due to the overall market reduction, the competitive pressure from innovation and R&D became fiercer in the high-tech industries.<sup>16</sup> Developing location-specific advantages, such as human capital and science and technology policies, has become critical for Taiwan to transform itself from original equipment manufacturer (OEM) suppliers to own-brand manufacture (OBM).<sup>17</sup> However, the process Taiwan relied on to upgrade its economy in the age of globalisation was more adaptive than revolutionary and the evolution of the state's industrial policy apparatus had been understood as a path-dependent development, namely learning by doing.<sup>18</sup>

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<sup>13</sup> Ibid.

<sup>14</sup> Ibid.

<sup>15</sup> Yun-han Chu, "Re-Engineering the Developmental State in an Age of Globalization: Taiwan's Quest for High-Tech Industries " in *Taiwan in the 21st Century: Aspects and Limitations of a Development Model*, ed. J. Megan Greene and Robert Ash (Routledge, 2007). pp 157-158

<sup>16</sup> Ibid.

<sup>17</sup> Ibid. pp 158-159

<sup>18</sup> Ibid. P. 160

### 3.1.1 The Developmental State and Its New Challenges

Chalmers Johnson has used the term “developmental state” to characterise fast-growing economies in East Asia that had followed Japan’s post-war state-led growth strategy.<sup>19</sup>

The developmental state model can be understood as an alternative capitalism, contrasting to the dominant model of laissez-faire capitalism. The four little dragons - Taiwan, Hong Kong, Singapore and South Korea - were categorised by Johnson as core examples of the developmental state for their fast track economic growth from the 1960s through the 1980s.<sup>20</sup> A developmental state can be primarily characterised by its high degree of state autonomy and the state’s penetration into the economy based on the idea of developmentalism. In this model, the state usually steers the industrialisation drive in order to take on developmental functions. Compared to a regulatory state, such as the United States, which governs the economy through regulatory agencies’ enforcement of rules, a developmental state relies on governance through technocrats. As bureaucratic governmental elites are not elected officials, they are usually less subject to interest groups’ lobbying. It renders the technocrats more freedom and space to plan the economy for the state’s long-term interest without being interrupted by short-term political forces.

Policies formed in these developmental states usually reflect technocrats’ consensus on developmentalism so high economic performance can be used as a way to consolidate the legitimacy of the governing regime. Even though local elections were instituted early in the 1950s, Taiwan was mainly a one party regime governed by the K.M.T. (Kuomintang, Nationalist) party so no genuine opposition was allowed to exist and this rendered society relatively inert and weak.<sup>21</sup> The KMT’s defeat in the Chinese Civil War made the party more aware of the issue of class antagonism after it retreated to Taiwan in 1949. The party’s state-building process started from a sweeping land reform, which was already envisioned but failed to be implemented on the mainland until later. The influence of the landowners was largely curtailed after the reform so it could not form a powerful social group to challenge the regime. In addition, a highly penetrative state operated by the K.M.T was gradually established by forming networks with local factions and taking over

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<sup>19</sup> Chalmers Johnson, *Miti and the Japanese Miracle : The Growth of Industrial Policy, 1925-1975* (Stanford University Press, 1982).

<sup>20</sup> Ibid.

<sup>21</sup> Yu-Shan Wu, "Taiwan's Developmental State: After the Economic and Political Turmoil", *Asian Survey* 47, no. 6 (2007). P. 980



associations of farmers and fishermen, and the organisations representing labour and commerce became more state transmission belts than autonomous agencies representing social interests.<sup>22</sup>

Strong state autonomy is a precondition for implementing industrial policy. However, because the developmental state is also a modern mercantilist state, it relies on a world market for export expansion. In fact, the state's capacity to export and accumulate foreign exchange reserves is usually taken as an important measure to evaluate its economic performance. As a result, technocrats need to correctly evaluate the strength of the state and then direct national resources to locate world market niches for locally designed industries. Since the 1980s, the rapid expansion of the information technology industry has fuelled Taiwan's export drive. This demonstrates that Taiwan's industrial policy set during the 60s to 80s had been successfully linking domestic strengths with world market niches.<sup>23</sup> However, the domestic democratisation in the late 80s has greatly changed the original structures that buttressed Taiwan's developmental state. The impact of democratisation on the autonomy of the state was noticeable. Since the Parliament (Legislative Yuan) election of 1992 and Taiwan's first presidential election of 1996, the state's developmental policies have been gradually transitioned to its electoral democracy.<sup>24</sup> Even though many industrial policies<sup>24</sup> are still formed through the consensus of technocrats, these policies need to face supervision from an emerging society and to satisfy various social interests.

On the other hand, globalisation has brought new challenges to Taiwan's developmental state model. As the income level and labour cost of domestic economies rises, Taiwan needs to upgrade its industry in order to maintain its export competitiveness.<sup>25</sup> However, which direction the country plans to move is no longer just a decision for technocrats. Rather, the allocation of national resources is now greatly influenced by the global market and global capitalism. Besides, Taiwan's past experiences of following international trends for its industrial development may not be useful anymore. As the state has gradually reached manufacturing maturity, it now faces similar challenges as its forerunners, such

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<sup>22</sup> Ibid. P. 981

<sup>23</sup> Ibid. pp 981-982

<sup>24</sup> Ibid.

<sup>25</sup> Ibid.

as Japan and other established core economies in North America and Western Europe, in designing its path ahead. As a result, in the 1990s, Taiwan faced the problem of designating the country's future strategic industries. It then chose biotechnology as a major strategic policy for upgrading Taiwan's economy.

Due to the government's concentration on the development of high-tech industry, since the late 80s onward, Taiwan has successfully transformed itself from a traditional manufacturing state to a knowledge-based economy. The strong state-driven approach to economic growth may be found primarily in various strategic policies offering investment incentives, such as tax benefits, R&D subsidies and grants programmes, low interest preferential loans,<sup>26</sup> industrial park rent discounts (zero rent for the first two years), stock listing, and joint investment from the National Development Fund (NDF), etc.<sup>27</sup> The National Development Fund is an investment scheme proposed by the Executive Yuan to encourage the private sector in Taiwan to take part in R&D and the biotech Venture Capital business. Announced in 2001, more than USD 0.62 billion of the development fund has been set aside for investment in the biotech industry.<sup>28</sup> Even though the government still focuses on how much it will spend to promote industry development, it ignores the fact that the big environment of political economy has changed. Before the 90s, Taiwan's knowledge-based economy primarily concentrated on information technology (IT). Biotechnology did not become a strategic industry for Taiwan until the late 1990s. After the Democratic Progressive Party (DPP) won the presidential election in March 2000, in its eight years' administration, biotechnology had been regarded as the flagship industry for Taiwan's future economic development. Nonetheless, because of the structural changes in the international market influenced by globalisation and the nature of the biotech industry, this strategic policy has proved problematic in its implementation in Taiwan.

Unlike manufacturing or previous strategic industries developed in Taiwan such as IT and microelectronics, biotechnology is a highly innovation-driven industry that relies heavily

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<sup>26</sup> There are two kinds of banks – state-owned banks and privately-owned banks – in Taiwan. These government loans are usually issued by state-owned banks, which hold the majority of total market assets in Taiwan's banking system and are tightly regulated by the government.

<sup>27</sup> "The Biotechnology Industry Investment Incentives in Taiwan," (Taipei: Industrial Development Bureau, Ministry of Economic Affairs 2007 ). P. 19

<sup>28</sup> Ibid.

on R&D and a long-term investment. For instance, it usually takes more than a decade from the innovation of a drug to the completion of several stages of clinical trials before the drug can be permitted for sale in the market. In order to thrive in the biotech industry, the government needs to provide long-term prospective plan and support rather than relying on traditional short-term incentives such as tax breaks and loans to motivate investors. Since the late 90s, the original structure supporting Taiwan's developmental state has greatly changed. The autonomy of the state is increasingly limited so rather than penetrating into the economy as in the 60s to 80s, the state has gradually lost its capacity to exercise control over the market, which has been influenced by globalisation and the ideology of neoliberalism.

### **3.1.2 Infrastructures**

Since the early 90s, the pharmaceutical industries prioritise the government's development agenda. Influenced by global ageing and the rise of living standards in the Asia Pacific region, the business opportunities of the drugs and disease-finding technologies has grown rapidly as a promising market prospect. In 1993, the Academia Sinica set up the Institute of Biomedical Science (IBMS) for fostering basic biomedical research. The institute later became the major executive body for the biobank project in Taiwan. Two years later, the Department of Health formed the National Health Research Institute (NHRI), a non-profit public foundation which aims at enhancement of innovative research in biomedical science and improvement of healthcare in Taiwan. In 1996, the Biotechnology & Pharmaceutical Industries Program Office was founded under the Ministry of Economic Affairs in order to assist promoting Taiwan as "an Asia-Pacific bio-manufacturing centre."<sup>29</sup> Later, the Department of Health set up the Centre for Drug Evaluation (CDE) and started to implement the Good Clinical Practice (GCP) which provides rules and standards for clinical trials in Taiwan.<sup>30</sup>

In addition, the government also established several science-based industrial parks. The coalition of the parks forms the four major "Bio Clusters" around the country. Among them, the cluster in Northern Taiwan mainly focuses on the biopharmaceutical industry, medical and clinical-trial related services.<sup>31</sup> The investment incentives provided by the

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<sup>29</sup> Ibid.

<sup>30</sup> Ibid.

<sup>31</sup> "Introduction to Biotechnology & Pharmaceutical Industries in Taiwan, Republic of China," (Taipei:

industrial parks attract global and domestic biotechnology companies starting their enterprises in Taiwan and investing in several gene-related technologies and products, such as biochips, bioinformatics, new drug invention, gene diagnosis and gene therapy, etc.<sup>32</sup> In terms of human resources, according to a recent governmental report, in 2008, there were 168 life science-related academic departments set up in Taiwan; about 8,000 among 36,352 university graduates had a life science related background.<sup>33</sup> In addition, the government launched plans for recruiting overseas Taiwanese high tech professionals returning back home to upgrade domestic industries and enhance international cooperation. A guideline prescribed by the Ministry of Economic Affairs listed the definition of high tech personnel, who are further classified in three detailed categories (Levels I, II, III) based on their qualifications, academic and practical experience.<sup>34</sup>

Several laws and regulations are also enacted to help provide a friendly environment for biotech invention. For instance, a Statute for the Development of Biotechnology New Drug Industry was announced in 2007 and will be in force until the end of 2021. During these 15 years, the statute is expected to upgrade new domestic drug companies, to make them more capable of competing with their international counterparts.<sup>35</sup> The government's commitment to the protection of intellectual property rights, such as emphasising the implementation and enforcement of related laws and regulations, is expected to gain investment for Taiwan in biotech and pharmaceutical industry.<sup>36</sup> This series of government actions aims to give Taiwan an edge over its competitors in the Asia Pacific region. With the dense Han Chinese population and a strategic geopolitical location - proximity to China, as a transportation hub of Northeast and Southeast Asia - the government introduces Taiwan as an ideal "springboard" to tapping the Asian market, especially the greatest one in mainland China for biotechnology investment.<sup>37</sup> However,

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Biotechnology & Pharmaceutical Industries Program Office, Ministry of Economic Affairs 2009). P. 14

<sup>32</sup> Ibid.

<sup>33</sup> "Diamond Action Plan for Biotech Takeoff," (Taipei: Science and Technology Advisory Group, Executive Yuan, 2009 ).

<sup>34</sup> According to the guidelines, the overseas high tech personnel are defined as individuals who can "assist in solving key problems faced in the upgrading of domestic industries." The industries here include technical, research and development, management control, market development and science and technology services, etc. See, "The Biotechnology Industry Investment Incentives in Taiwan," (Taipei: Industrial Development Bureau, Ministry of Economic Affairs 2007 ). pp 22-25

<sup>35</sup> Ibid., pp 7-10

<sup>36</sup> For mainland China, for example, poor protection of intellectual property rights up to now is a weak point for its strategies to attract foreign direct investment in high tech products and innovations.

<sup>37</sup> "Introduction to Biotechnology &Pharmaceutical Industries in Taiwan, Republic of China," (Taipei:

up to this point, Taiwan's biotech industry is still in its very early development. All the efforts have only led to a small percentage of world biotech production. The slow development of biotech in Taiwan not only demonstrates the difficulty in implementing this strategic policy in Taiwan but also Taiwan's gradual transformation from a developmental capitalist state to a neoliberal economy.

### **3.1.3 A Political Economy of the Human Genome Race**

The idea of biobanking was regarded by the government as a way to equip Taiwan with a substantial niche in international biotech competition. When considering a long-term investment, the government hopes to look for a plan that can be positioned at the forefront but also satisfying domestic requirements so that Taiwan may distinguish itself with its own uniqueness. The project of the population biobank fits well into this consideration. In fact, before the emergence of the idea of biobanking, Taiwan already had a good start in genomics research. Due to its international political status, Taiwan was not able to be formally invited to join the Human Genome Project (HGP), which was initiated as a cross-national cooperation that the People's Republic of China (P.R.C.) has been a consortium member state. However, in September 1999, when one of the cooperative labs based at Stanford University planned to withdraw itself from the ongoing sequencing work due to the heavy workload but unsatisfied progress, it started looking for other research labs to carry on its task. The Rong-Yang Team, a genome research lab from Taiwan, seized this opportunity.

Set up by a group of researchers and medical geneticists from Veterans General Hospital and National Yang Ming University, the Rong-Yang Team is a publicly-funded joint venture based in Taipei. In early 2000, roughly about six months before the draft sequencing report was announced by the HGP, the Rong-Yang Team was informally invited to replace the Stanford lab and took part in this international cooperation for the task of sequencing one part of human chromosome 4.<sup>38</sup> In fact, what lay behind this opportunity is a personal relationship between the two leading scientists in charge of their research labs in Taipei and Palo Alto, respectively. Unlike other participators in the HGP project as formal consortium members, the Rong-Yang Team's participation in the HGP is significant but

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Biotechnology & Pharmaceutical Industries Program Office, Ministry of Economic Affairs 2009). P. 4

<sup>38</sup> Interview with the Rong-Yang Team, Taipei, 2010

invisible.<sup>39</sup> Chromosome 4 has around 200 million base pairs of which the Rong-Yang Team focused on sequencing a segment of around 10 million bases.<sup>40</sup> The team successfully completed its task, locating over 200 genes from the bases about six weeks in advance of its original timetable, though it has not received due international recognition for its work on the HGP.<sup>41</sup>

Even though the Rong-Yang Team did not benefit much from international cooperation, its efforts demonstrated its capability. As gene sequencing is a tangled and repetitious process, it requires extreme precision to sort out useful information from a huge volume of repetitive data produced in the sequencing process. The scientist who was in charge of the sequencing work claimed that the Rong-Yang Team repeated each step ten times in the sequencing process for each base, so for every 100 bases sequenced by the team, there was only 3-5 breaks in the data, compared with a figure of 10-20 breaks sequenced in the United States.<sup>42</sup> The contribution of the Rong-Yang Team to the HGP was about 3% of its total data that had ranked Taiwan seventh in the world in terms of its capability of gene sequencing and put it on a par with the contributions from other HGP consortium member states, such as Germany and mainland China.<sup>43</sup> Even though the data produced from the HGP is required to be registered internationally so it can be used as a common resource worldwide, subsequent discoveries of newly located genes and their association with diseases may be privatised as the subjects of the intellectual property for patent. It makes biomedical research and biotechnology prospective fields of immense commercial opportunities.

Despite the accomplishments made by the Rong-Yang Team, the participating scientists started to be concerned that the pace of research in Taiwan was slowing down and that it might already be losing out in the race for genomics research. A leading scientist of the team published an article in the *China Times* calling for more attention by the government to Taiwan's genomics research.<sup>44</sup> The article pointed out that the major difficulty Taiwan

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<sup>39</sup> Ibid.

<sup>40</sup> Chang Chiung-fang translated by Christopher MacDonald, "The Gene Genies Gene Sequencing Brings a Breakthrough," *Taiwan Panorama* (July 2000).

<sup>41</sup> Ibid.

<sup>42</sup> Ibid.

<sup>43</sup> Ibid.

<sup>44</sup> Shih-feng Tsai, "The Pride and Worry of the Gene Research Team," *China Times*, 25 May 2000.

faced with its genomics study was not due to the insufficiency of research resources but due to the lack of a coherent government plan. Even though the government has developed many strategic policies to improve Taiwan's biotech environment, most of the schemes are simply task-oriented so the budgets allocated for them are only for a limited period of 3-5 years, not enough for basic biomedical research. In addition, because Taiwan was not a member of the HGP, it had limited opportunities to cooperate with other international consortium states. Even though the government recognised the importance and the necessity of developing genomics study, it did not fully realise that the timing for such development was extremely urgent for Taiwan as many other countries had already prepared well to join in this genome race.<sup>45</sup>

It is estimated that the cost of the Human Genome Project for the sequencing draft was at least USD 300 million. Currently the biggest project supported by the Taiwanese government - the Advanced Plan for Genomics Medicine and Health - started as late as 1998 was under a budget of only NTD100 million each year. For the past two years, the total money the government putting into the genome sequencing was about USD 2 million or so. To put it simply, the effort that the government put into this area was too little and the speed was too slow.<sup>46</sup> (*China Times*, 15 May 2000)

The article further mentioned that even though mainland China started its race of genome sequencing in 1999, a few years later than Taiwan, it had equipped itself with over 40 cutting-edge capillary electrophoresis sequencing machines one year later in 2000 while Taiwan only had one. It showed that Taiwan was losing its original strength which had been built up with great efforts over the past few years.<sup>47</sup> Scientists in Taiwan hoped the government would pay more attention to basic scientific research as it is a field demanding a long-term investment but cannot easily find a short-term return. For the supporting scientists, the completion of the DNA sequence has made personal genomics study a prospective field. However, what concerned them is the fierce competition with their counterparts worldwide, especially the competitive pressure caused by mainland China. After all, time is the most essential element in distinguishing success or failure in

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<sup>45</sup> Ibid.

<sup>46</sup> Ibid.

<sup>47</sup> Ibid.

the field of genomics research.<sup>48</sup> For instance, Shen Cheng-Yang, a professorial research fellow at the Institute of Biomedical Science at the Academia Sinica, Taiwan, and a co-principal investigator for the biobank project, mentioned his concerns on the cross-strait genomics race:

What I observed from mainland China is that it has already started its sample collection for a population biobank. If the Taiwan Biobank finally fails, it will be a big loss for Taiwan.. (because) the cost of obtaining the most suitable medicine for the Taiwanese people will be much higher and it also means that we still need to buy medicine designed by the Western clinics. If the biobank in China is successful and the medicine invented from its research is allowed to be patented, then Taiwan of course can use such medicine but it is not invented in particular for Taiwanese people and it is a pity because Taiwan is more advanced than the Mainland in biomedical research in terms of our experience and we have computerised our national population's household registration data and health insurance data. " (Interview with Shen Chen-Yang, Taipei, 2010)

The fundamental issue needs to be addressed is perhaps what kind of role Taiwan could play in the field of biomedical research and biotech industry in the context of global bio-economy. For scientists, they hoped that the government can realise Taiwan was dropping behind in their particular fields so related authorities can come up with a plan for catching up. Even though relying on government funding is an important factor for scientists to achieve a breakthrough, it had also been suggested that the current approach taken by the National Science Council (NSC) - mainly providing funding for researchers freely carrying out their individual projects - was not an ideal strategy to support basic science and biotech development for Taiwan.<sup>49</sup> Rather, scientists hoped that the government could consolidate resources to concentrate on one particular area of research and set up a clearer goal for long-term biomedical development. In addition, unlike the development pattern in some other countries in which investment from the industry and joint ventures have played an important role in biotech development, Taiwanese industry is rather conservative as most of them are still small-and-medium-sizes enterprises (SMEs), which cannot afford hugely investing in R&D.

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<sup>48</sup> Paul Rabinow and Talia Dan-Cohen, *A Machine to Make a Future* (Princeton: Princeton University Press, 2006). P. 189

<sup>49</sup> Supra note 40



For government, the potential commercial interests the biobank would bring to Taiwan are tremendous. Taking into account that 98% of the Taiwanese population has Han Chinese ancestry, it is hoped that in the future, the research findings from the biobank can be applied to the great population of Chinese around the world. As one purpose of the establishment of the biobank is for reaching the goal of personalised medicine, if Taiwan can seize this opportunity to have an advanced position in pharmaceutical design for Han Chinese genes, enormous commercial returns will be expected. In the pilot study proposal, it is also stated that the biobank can be used as a necessary “shortcut” for pharmaceutical and biotech companies to enter the market for medications in mainland China and for the development of pharmaceuticals designed for Chinese people.<sup>50</sup> Furthermore, the biobank is expected to be able to attract funding and technology from multinational pharmaceutical companies that can make Taiwan’s biotech industries prominent in cross-strait competition and also create a tremendous business opportunity.<sup>51</sup> A consultant for the biobank pilot study has mentioned that because the ethnic groups in Taiwan come from various areas of mainland China, the country can position itself as the centre for Han Chinese gene study in the world.<sup>52</sup> In order not to lose this astonishing potential market, setting up a population-based biobank for Taiwan has been prioritised by the government in its biotech development plan.

### **3.2 Biocapital formation in Technoscientific Cosmopolitics**

#### **3.2.1 Geopolitical Reasons**

The State has played an active role in shaping and promoting Taiwan’s biotech development. In the past 30 years, it adopted many strategies to make Taiwan an important destination for overseas investors. In addition to the endeavors made in building capacity and improving regulatory and human resource infrastructure as discussed earlier, the government proactively capitalises on Taiwan’s geographical location. Official reports and introductory brochures for investment in Taiwan emphasise Taiwan’s geographic advantages: “Taiwan is located at the hub (or “heart”) of the

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<sup>50</sup> The Proposal for the Pilot Study of the Taiwan Biobank, P. 10

<sup>51</sup> Ibid.

<sup>52</sup> *Pei-ru Chao and Pei-ru Ho, "Government Promoting the Establishment of the Biobank for Personalised Medicine and New Drug Invention," Economic Daily News,, 19 March 2004.*

Asia-Pacific region.”<sup>53</sup> Adjacent geographically to several large economic entities of the world, such as Japan (north), China (west), India and the Association of Southeast Asian Nations (south), the government’s strategy is to promote Taiwan as an ideal logistics centre for investors to make use of abundant production resources and marketplace in the region.<sup>54</sup>

Beyond the economic sense, however, Taiwan’s location has another significant layer of meaning. During the Cold War Era, Taiwan was a crucial element in the United States’ containment policy. In order to build a protective shield to maintain peace in the Pacific with a minimum military effort and expense, the US strategic frontier was to extend its power control to a chain of islands off the shores of mainland Asia so the prior allies could dominate air power in the region to prevent hostile aggression in the Pacific basin.<sup>55</sup> In this strategy, Taiwan was viewed by the US as a critical element of this arc-shaped island chain as it is located at the very centre of the defensive perimeter. General MacArthur had compared Taiwan to an “unsinkable aircraft carrier and submarine tender” considering that it was easier for the US air force to take off from Taiwan to the adjacent friendly segments of the island chain, ie., Okinawa and the Philippines, than from any point in continental Asia.<sup>56</sup>

Although the Cold War ended in the early 90s after the Soviet Union collapsed, the spirit of the cold war seems to have revived as a result of the rise of China and India. The two emerging major powers in Asia challenge the US dominant status during the post-Cold War period. Geo-strategic policies appear again in Eurasia and the Asia Pacific, although the new form of containment may not be simply reduced to the ideological confrontation of the Cold War. In his book, *The Grand Chessboard*, the former US national security advisor Zbigniew Brzezinski analysed the importance of Eurasia as a geopolitical axis. In his analysis, this biggest continent of the world covers two thirds of world’s population and 75% of energy resources, including nuclear power, so a power that dominates the region can control the majority of economic production and initiatives.<sup>57</sup> Interestingly, when the

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<sup>53</sup> "Introduction to Biotechnology & Pharmaceutical Industries in Taiwan, Republic of China." Taipei: Biotechnology & Pharmaceutical Industries Program Office, Ministry of Economic Affairs 2009.

<sup>54</sup> Ibid.

<sup>55</sup> "National Affairs: An Unsinkable Aircraft Carrier," *TIME* 4 September 1950

<sup>56</sup> Ibid.

<sup>57</sup> Zbigniew Brzezinski, *The Grand Chessboard: American Primacy and Its Geostrategic Imperatives* (New

Obama administration sought to improve US relationships with countries in Eurasia by taking a new Afghanistan-oriented foreign policy, China at the same time emphasises its cooperation with the region, for example, launching the China-Eurasia Expo 2011, a platform established for multi-field exchange and cooperation between China and Eurasia.<sup>58</sup>

Another instance of power balance can be illustrated by China's recent decision to tighten the long-term partnership with Pakistan by selling it two nuclear reactors.<sup>59</sup> Such a decision was deciphered broadly as a counterweight to the cooperation between the US and India as the two formed a civilian nuclear deal which was approved by the US Congress under the Bush administration in 2008.<sup>60</sup> Certainly, "a new policy of containment"<sup>61</sup> may not be an ideal view to see the dynamics of the emerging power in "the Modern World System," in the language of Immanuel Wallerstein.<sup>62</sup> However, the rise of China and India has influenced the international division of labour that inevitably impacts on Taiwan's economic strategies and its development policy on biotech industries.

### **3.2.2 Mine for Gold on the East Side of the World**

The release of the initial working draft sequence by both the Human Genome Project (HGP) and Celera Genomics has opened up various opportunities for genomic research and the development of biotech industries. Scientists are optimistic that the data produced from the human genome sequence will provide new insights into inherited disease that may lead to innovative methods of disease prevention and genetic therapies. At the same time, international pharmaceutical companies and biotech venture capitals have also sought to explore the commercial potential of inventing new drugs. Some of them have tried to establish partnerships with East Asian biotech companies in order to expand their business maps and to mine genetic gold in the Asian region. For example,

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York: Basic Books, 1997).

<sup>58</sup> "China Upgrades Urumqi Trade Fair, Eyes Broader Eurasia Prosperity", *Xinhua News Agency* 6 September 2010.

<sup>59</sup> Geoff Dyer and Farhan Bokhari, "China-Pakistan Reactor Deal to Open Fresh US Rift," *Financial Times* 23 September 2010.

<sup>60</sup> Peter Baker, "Senate Approves Indian Nuclear Deal " *The New York Times* 1 October 2008.

<sup>61</sup> Demetri Sevastopulo and Jo Johnson, "Gates Denies Hedge Strategy against China," *Financial Times* 27 February 2008.

<sup>62</sup> Immanuel Wallerstein, *World-Systems Analysis: An Introduction* (Duke University Press, 2004).

Celera Genomics announced in January 2000 its acquisition of a 47.5% equity in Shanghai GeneCore Bio Technologies Co., Ltd. which was formerly held by Axys Pharmaceuticals.<sup>63</sup> Shanghai GeneCore is a genomics service company selling products of DNA sequencing, mutation detection, nucleotide synthesis and bioinformatics analysis.<sup>64</sup> Celera hopes the acquisition can help expand its genomic information globally as Shanghai GeneCore has established a large customer base in China and has collaborations with several Chinese government agencies.<sup>65</sup> For Celera, building a partnership in China means it would have access to an abundant resources of genetic diversity located in the region. On the other hand, for GeneCore, using the information and software capability provided from Celera is expected to have a significant impact on its genomics research pace. Both parties anticipate having certain benefits from the collaboration.

In Taiwan, there is a similar but slightly different story. A new Taiwanese genomics company - Vita Genomics, Inc. - was launched and opened its office in Taipei in March 2001. The company aims to study the patterns of single-nucleotide polymorphisms (SNPs, pronounced *snip*)<sup>66</sup> among East Asians and hopes to find the genes related to diseases common among people in the region so it would have new insights into drug responses in East Asian populations. In order to reach the goal, the company's first step is to compile a database that includes disease-relevant SNPs prevalent in Asian populations.<sup>67</sup> Such a database is expected to help researchers to improve drug efficacy as they believe genetic variability may have an influence on adverse drug reaction since some diseases are reportedly more common among Asians than among Caucasians.<sup>68</sup>

In order to achieve this ambitious goal, Vita Genomics plans to first explore genes related to diseases common to people in Taiwan and China, such as hepatitis, asthma and some

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<sup>63</sup> Celera Press Releases, "Celera Acquires Equity in Shanghai Genecore Biotechnologies," (13 January 2000).

<sup>64</sup> Ibid.

<sup>65</sup> Ibid.

<sup>66</sup> A single-nucleotide polymorphism, occurring at a specific site in the DNA sequence, is a genetic variation between human beings that can be used as an enabler in personalized medicine to hunt for correlations between genotype and phenotype. In addition, since some SNPs may predispose individuals to have a trait to react to a drug in different ways, their analysis is often useful in drug discoveries and pharmacogenomics. More info, see: Carlson, Bruce. "SNPs - a Shortcut to Personalized Medicine." *Genetic Engineering & Biotechnology News*, 15 Jun 2008

<sup>67</sup> "Taiwanese Genomics Startup to Research Population Genomics among Asians," *GenomeWeb Daily News* 14 March 2002.

<sup>68</sup> For example, liver and stomach cancer rates are higher among Asians than among Caucasians; on the contrary, however, rates of breast cancer seem to be lower in Asia than in Europe and in the United States.

forms of cancers like oral, liver and nasal.<sup>69</sup> The CEO and founder of the company, Ellson Chen, had commented: "Almost every race you find in China you can find somewhere in Taiwan, so I thought this was a good place where it is not that big and difficult to handle as China."<sup>70</sup> Ellson Chen, born and educated in Taiwan,<sup>71</sup> was a former principal scientist at Celera Genomics. Before moving back to Taiwan, he was involved in sequencing the human genetic code during his time at Celera and his lab had built Celera the famous sequencer, which made this private company able to compete with the publicly-funded Human Genome Project in the sequence race.<sup>72</sup>

When Ellson Chen worked at Celera Genomics, the company was still part of Perkin-Elmer (PE) Corporation, which later changed its name to Applied Biosystems Corporation. The name Applied Biosystems refers to a combination of the company's two operating groups and business models - the Applied Biosystems Group and the Celera Genomics Group.<sup>73</sup> The former was responsible for manufacturing machines and therefore it provided tools and instruments by developing new sequencers; the latter, Celera Genomics, was formed mainly as a way to market the sequencer invented by the former. When the new sequencer was successfully invented in 1998, Applied Biosystems decided that rather than sell this new tool to the Human Genome Project, it would be better to use the technology to sequence the genetic code by itself. As a result, Applied Biosystems formed Celera Genomics with an investment of USD 300 million that was equivalent to selling 1,000 units of the new sequencer at USD 300,000 each and then the company successfully approached its balance of investment within a year by selling the new machine to the Human Genome Project.<sup>74</sup>

Although the business strategy was successful it was not sustainable due to the increasing criticism of Celera Genomics' intention to privatise and commercialise the human genomic information. The shotgun method applied by Celera led to a rapid acceleration of the sequencing efforts used by the HGP, which was officially initiated in 1990 and was

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<sup>69</sup> "Taiwanese Genomics Startup to Research Population Genomics among Asians."

<sup>70</sup> "Vita Genomics Ready to Mine Genetic Gold in Asia," *Biotech East* 8 October 2001

<sup>71</sup> He received a degree of Bachelor in Science from National Taiwan University and then a PhD from the United States.

<sup>72</sup> Supra note 70

<sup>73</sup> Celera Press Releases, "Pe Corporation to Change Name to Applied Biosystems Corporation," 13 January 2000.

<sup>74</sup> "Vita Genomics Hopes for Biotech Stardom," *Taipei Times* 13 July 2001.

originally planning to complete the genome sequence within 15 years with a total budget of USD 3 billion.<sup>75</sup> Even though the private company Celera Genomics may be able to complete genetic code sequencing much earlier than the Human Genome Project and cost only a fraction of the HGP, critics claimed that when Celera started its sequencing race, a large portion of the human genome had already been sequenced and published by the HGP at its freely accessible database - GenBank. Therefore, Celera had benefited from the public information with no extra costs. Scientists were also concerned that privatizing human genomic data for commercial exploitation would hinder scientific progress in the end, and for that reason they urged the US and UK governments to get involved in the process of mediation and to persuade Celera to give up its intention to privatize the human genome. The initial working draft sequence was finally released by both the HGP and Celera in February 2001. It illustrated the triumph of public efforts and the prevailing view that the human genome should be treated as a public resource and a common good.<sup>76</sup>

On the other hand, in order to dig for gold on the East side of the world, Celera Genomics considered addressing the needs of Asian countries. Its management team initiated a project with the code name Celera Asia and thought of the possibilities to make the project a fully owned subsidiary of Celera.<sup>77</sup> Ellson Chen was then a representative of Celera so he travelled extensively in East Asia to seek for the right environment to set up a regional company. However, rather than establishing a fully owned subsidiary for Celera, Ellson Chen finally split out with an agreement with Celera's management team to form his own company - Vita Genomics - in Taiwan, in which Celera held only 5 % shares but was still a strategic partner. In a newspaper interview, Chen emphasised the importance to have local people and local officials' acceptance of a biotech company of this magnitude to make it successful. He called it "local input" and viewed this element as significant for a biotech company to adopt changes.<sup>78</sup> Ellson Chen explained the term using a practical case of Celera's subsidiary in China. He then concluded that seeking

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<sup>75</sup> J. Craig Venter et al, "The Sequence of the Human Genome," *Science* 291, no. 1304 (2001).

<sup>76</sup> More information about the human genome sequencing race, see, John Sulston and Georgina Ferry, *The Common Thread: A Story of Science, Politics, Ethics, and the Human Genome* (National Academy Press 2002); James Shreeve, *The Genome War: How Craig Venter Tried to Capture the Code of Life and Save the World* (New York: Ballantine Books, 2004).

<sup>77</sup> "Vita Genomics Hopes for Biotech Stardom," *Taipei Times* 13 July 2001.

<sup>78</sup> Ibid.

partner collaboration in East Asia would be more appropriate for a global biotech company like Celera Genomics to expand its business in the East since it may prevent local countries from viewing the foreign company as an invader similar to delivering democratic values from an “enemy nation.”<sup>79</sup>

### **3.2.3 Localisation of Genomics Research**

Compared to China, Taiwan’s liberal political milieu and stronger protection of intellectual property provides Vita Genomics with a friendlier environment for investment. In addition, the company can easily establish local collaborations with other biotech industries as well as public academia and research institutes in Taiwan. However, among all of these stated advantages, the most helpful one is the enthusiastic attitude from the Taiwanese government. Ellson Chen’s idea to form a company to secure Taiwan’s place on the global biotech stage echoes the government’s development plan to use biotech industries to upgrade its economy and boost Taiwan’s international competitiveness. For that reason, fundraising in Taiwan was relatively easier than in other countries of East Asia. Back in 1996, Taiwan’s Ministry of Economic Affairs (MOEA) had established a specific office to promote the development of biotech and pharmaceutical industries in Taiwan that aimed to promote the country as an “Asia-Pacific bio-manufacturing centre.”<sup>80</sup> A year later, a five-year investment plan with a budget of NTD 20 billion (about USD 600 million) was promulgated from the Executive Yuan’s Development Fund in order to help biotech industries carry out R&D research.<sup>81</sup> Facing the emerging economic power of China and India, Taiwan’s government had planned to use biotech industries to move from a centre of manufacturing to an operations centre focusing more on R&D and invention so Taiwan may keep its competitive advantage compared with the two emerging powers, both of which have surplus population to provide cheaper labour.

With its management and business centre in Taipei but main lab located in the Tainan Scientific Industrial Park in southern Taiwan, Vita Genomics planned to recruit up to 40 employees in the first year of its operation and then expanded its personnel to 100 a year after.<sup>82</sup> Its estimated corporate capital is about NTD 3.5 billion (about USD 100 million)

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<sup>79</sup> Supra note 70

<sup>80</sup> Supra note 53

<sup>81</sup> Ibid.

<sup>82</sup> Supra note 70

and almost half of the amount had been secured when the company was launched in March 2001.<sup>83</sup> During that time, most Asian countries had not yet completely recovered from the Asian Financial Crisis of 1997 so the successful capital recruitment for Vita illustrated Taiwan's optimistic attitudes toward biotech industries, especially about genomics research and its related services.<sup>84</sup> Many high profile officials attended the company's launching ceremony, including Taiwan's Minister of Economics and the president of the Academia Sinica. It symbolised an anticipated collaboration between industries, government and academic institutes in Taiwan. However, on the other hand, it precluded a more intricate and complicated entanglement of public and private sectors in Taiwan's biotech development.

Since the company launch, Vita Genomics has been promulgated by the government as a successful start-up to attract more overseas Taiwanese experts returning home to bring back capital and technology. Many Taiwan-born scientists like Ellson Chen had been working overseas for more than two decades. They usually went abroad for a higher education after finishing their bachelor degrees in Taiwan and then stayed abroad to work until they established their own niches overseas. These professionals have been important agents of reconnecting Taiwan to international development trends. However, such knowledge and know-how transplants are sometimes at the risk of one-way transmission and it can mean that the needs of the local society may not be easily fed back. Such a gap usually becomes wider if these agents have been absent from Taiwan during the period of its most dynamic social transformation. As Taiwan was under martial law for a long period from 1947 to 1987 and its presidential direct election had not been possible until 1996, Taiwan's society has experienced a dramatic transition from an authoritarian regime to democracy. Without recognising this important context, it would not be easy to grasp the civic epistemology behind Taiwan's biotechnologies and biotech policies.

In 2003, the government listed the biotech industry in its Two Trillion and Twin Stars programme<sup>85</sup> and about a year later, the idea of "Biomedical Technology Island Plan" was

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<sup>83</sup> Ibid.

<sup>84</sup> In addition, compare to other East Asian countries, especially South Korea, Taiwan proved relatively insulated from the 1997 Asian Financial Crisis because of its abundant foreign exchange reserves.

<sup>85</sup> This is a four-year project proposed by the Ministry of Economic Affairs in 2002. The "Two Trillion" refers



born, in which building up a biobank for Taiwan was formally proposed by the government. Ellson Chen of Vita Genomics was appointed as a consultant for the Taiwan Biobank Preparatory Office. However, the biobank pilot study had experienced an unexpected delay since the project commenced. This prolonged delay involving intricate ethical review procedures illustrates the situation the biobank study faced in Taiwan. In addition, the social resistance to a technocratic scientific plan represents a kind of “local input” from Taiwan that may have been out of Ellson Chen’s original consideration when he decided to return back to establish his Vita Genomics due to the Taiwanese government’s full support.

In order to put Taiwan on the global biotech map, Vita Genomics was keen to establish partnerships with public research institutes and academic R&D centres in Taiwan as Chen believed such collaboration would save a great amount of time and capital for his company to reach its goal. Both Academia Sinica and the National Health Research Institutes (NHRI) were potential partners of interest to Vita Genomics. The NHRI, a non-profit foundation, was established by the government in 1995 in order to improve health care in Taiwan. It carries out research on basic biomedical science, including developing drugs for several of Taiwan’s common diseases. In a print media interview, Ellson Chen expressed his interest in collaborating with the NHRI as it had worked on some of the diseases that Vita might have a sight on.<sup>86</sup> For example, the NHRI had been developing a medicine treating Hepatocellular carcinoma, which has a high incidence especially in East Asia due to the prevalence of chronic hepatitis B in the region but not enough attention had been paid by global pharmaceutical companies to it.<sup>87</sup>

Since hepatoma is very common in China, it is believed that the potential consumer for the drug is nearly 350 million people in Asia.<sup>88</sup> In 2001, the drug invented by the NHRI was already in the process of clinical trials and it was expected by the institute to finalise the medication within 5 years but Ellson Chen believed that if Vita Genomics joined in the

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to the desire of the government to drive the production value of the semiconductor and the flat-panel display industries in Taiwan to NTD 1 trillion (USD 29.6 billion) each by 2006. The “Two Stars” means to promote the digital content and biotechnology sectors into star industries for Taiwan’s economic development. More information about the project, see: <http://www.cepd.gov.tw/m1.aspx?sNo=0012498> (in Chinese) (Last visit: 10 March 2012)

<sup>86</sup> Supra note 70

<sup>87</sup> Ibid.

<sup>88</sup> Ibid.

finalisation, it would be able to shorten the process.<sup>89</sup> It is a similar market logic to the one followed when privately-owned Celera Genomics jumped in at a later stage to compete with the publicly-funded HGP in the human genome sequence. However, the most difficult part of this kind of “collaboration” is not only about how to split up the workload but also how to make a fair share arrangement if there are any profits when the drug is finally patented and marketed. For a biotech start-up like Vita Genomics, one of its goals is to seek to identify biomarkers and new drug targets and obtain intellectual property in order to sell it to major pharmaceutical firms for mass production.<sup>90</sup> A profit-driven logic like this is in conflict with views supporting the common good although the boundary between public and private gets blurred when the collaboration between industries and public research and academic institutes becomes more and more common in Taiwan.

### **3.2.4 The Implementation of Neoliberalism**

In order to connect upstream R&D with downstream product manufacturing, the government has improved Taiwan’s regulatory infrastructure to foster the biotech industry. In 1999, the Legislative Yuan passed the Fundamental Science and Technology Act that is similar to the Bayh-Dole Act passed by US Congress in 1980 which allows the transfer of intellectual property rights from the government to private industries. According to the Act, the IP rights derived from a scientific and technological project which is funded, subsidised or commissioned by the government may now be retained by implementing research institutes. This precludes the application of the National Property Act under which the IP rights would be treated as national property.<sup>91</sup> As a result, publicly-funded research institutes can transfer their technology to industries for commercialisation of their research results. In addition, the Act requires the government to formulate development plans for science and technology every four years and such plans need to be discussed in the National Science and Technology Conference held by the Executive Yuan.<sup>92</sup> The plans approved through the conference will become national policy for implementation. In 2006, the Executive Yuan amended another regulation which clearly states that the ownership of publicly-funded research results belongs to the implementing

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<sup>89</sup> Ibid.

<sup>90</sup> Ibid.

<sup>91</sup> Articles 5 and 6, the Fundamental Science and Technology Act, 2000, Taiwan

<sup>92</sup> Article 10, the Fundamental Science and Technology Act, 2000, Taiwan

institutes although its transfer to a third party needs to be approved by the funding agency.<sup>93</sup>

In June 2007, Taiwan passed the Biotech and New Pharmaceutical Development Act aimed at helping to promote biotech and new pharmaceutical industries for the country's economic transition. The Act, effective for 15 years until the end of 2021, provides many incentives such as tax benefits for the industries for a total of five years. It plans to strengthen Taiwan's biotech market, which has been growing since 2000 due to the government's full support. According to statistics, from 2002 to 2007, the government's annual investment in the pharmaceutical industry had risen from less than USD 300 million to almost USD 700 million, and the average growth for the biotech and biomedical market was 13%.<sup>94</sup> In addition to the tax relief, another major change the Act brings is to open another possibility for collaboration of public and private sectors. According to the Act, with the permission of the original employer, certain researchers in government research institutes, such as the Academia Sinica, are now allowed to help privately-owned industries with R&D by serving as founders, executives or acting as consultants to private companies.<sup>95</sup>

In an interview with *Nature News*, the president of the Academia Sinica, Wong Chi-Huey, optimistically predicted that with the help of the Act, Taiwan will have at least 5% of the world biotech market within 10 years.<sup>96</sup> The Academia Sinica is Taiwan's top academic institution, originally established in mainland China in 1928, and then relocated and reestablished in Taipei in 1954. Like Ellson Chen of Vita Genomics, Wong had been working in the United States for nearly 30 years before he returned back to take over Taiwan's most eminent research institute in 2006. Wong's previous experiences as a professor of Chemistry at the Scripps Research Institute at San Diego and also a co-founder of Optimer Pharmaceuticals made him keen on helping the government establish its biotech industry. His message introducing Academia Sinica on its official

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<sup>93</sup> Government Scientific and Technological Research and Development Results Ownership and Utilization Regulations, 2006, Taiwan

<sup>94</sup> "Taiwan's Biotech and New Pharmaceutical Development Act," *Asia Medical eNewsletter* 05 October 2007.

<sup>95</sup> Article 10, the Biotech and New Pharmaceutical Development Act, 2007, Taiwan

<sup>96</sup> David Cyranoski, "Taiwan's Hopes for a Biotech Revolution: The President of the Country's Top Research Institute on Growing the Knowledge Economy," *Naturenews* 10 July 2009.

website shows an increasing commitment by the institution to strengthen the cooperation between research and industry by “assuring the protection of intellectual property rights, encouraging patent applications, increasing technology transfer, and holding joint conferences on research achievements with other domestic research institutions.”<sup>97</sup>

The 1928 established institution, which had been expected to act as an opinion leader in the society<sup>98</sup> has gradually been transformed to an agency of neoliberalism. The Institution was extended rapidly during the term of its former president Lee Yuan-Tseh, who is the first Taiwanese Nobel Prize laureate and is also a chemist. Lee served at the Academia Sinica for 12 years from 1994 to 2006 during the period when life science and genomic research had witnessed a revolutionary development on a global scale. When the human genome sequence draft was released, Lee thought that so long as Taiwan could take this opportunity to start its life science research and enter the field at the right time, it would be able to catch up with this international trend in genomics research.<sup>99</sup> At the launching event of Vita Genomics, Lee re-emphasised the importance for Taiwan to keep up with the international genomics research standard and it would have to be done as soon as possible due to insufficient funding up to that point of Taiwan’s R&D.<sup>100</sup> In order to rapidly integrate resources to improve Taiwan’s life science research platform, Lee helped found the Genomic Research Centre at the Academia Sinica in January 2003. In addition to emphasis on understanding genomic functions and developing therapeutic strategies, the centre established a Bio-tech incubator for the purpose of pursuing

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<sup>97</sup> More info, see the Academia Sinica website: <http://home.sinica.edu.tw/en/about/message.html> (Last visit: 10 March 2012)

<sup>98</sup> Due to the prestigious status of the institution, the President of the Academia Sinica also had a social symbolic meaning of an independent intellectual who was expected to act to form public opinions. Some previous presidents, like Tsai Yuan-Pei, (on his term from 1928-1940) and Hu Shih (1958-1962), were influential Chinese philosophers in modern Chinese history. Both Tsai and Hu were leading intellectuals during the May Fourth Movement, a patriotic movement growing out of student demonstrations in Beijing on 4 May 1919 in order to protest the Beiyang government’s concessions to imperialism by their weak response to the Treaty of Versailles. The legacy of the movement was profound. It was later viewed as a prelude for Chinese modernisation as since then, the Western ideas of science and democracy had been introduced and promoted in China.

<sup>99</sup> Chen Chang-Yu " Lee Yuan-Tseh Would Like to Have a Conversation with Life Sciences," *Great View Magazine (in Chinese)* November 2002

<sup>100</sup> Din Wan-Ming, "The Launch of Vita Genomics: Lee Commented: Taiwan Would Be Hopeless If It Could Not Catch up with the World within Three Years Due to Its Limited Reserach Budgets," *United Daily News* 17 April 2001. (in Chinese)

technology transfer in order to help advance the development of Taiwan's biotech industry.<sup>101</sup>

A year before the Genomic Research Centre was set up, the National Science Council launched a National Research Programme for Genome Medicine (NRPGM). The industry and academic collaboration was one of the major parts of this national priority project. The Programme was directed by two Academicians and its research division focused on disease-oriented topics dedicated to Taiwan's common diseases, such as lung and liver cancers and some highly heritable diseases with a hope to add to Taiwan's competitive edge.<sup>102</sup> As Taiwan has a small domestic market compared to China, it is important for it to strategically integrate resources among government, industry and academics. Although its biotech development had not yet started until the late 90s, the government optimistically thought that Taiwan's previous success in information and computer technologies would be able to help with biotech growth. What needed to be done immediately is to improve Taiwan's research capacity, for example to build up infrastructure such as a biobank for research and for boosting Taiwan's biotech and pharmaceutical industry. This idea is especially welcomed by a start-up company like Vita Genomics as it may save a great amount of capital to establish its own genetic database but can still access to crucial data for its research purpose. Also, the company may rely on government's credibility to avoid the difficulties in collecting samples if it had to form its own biobank.

### **3.3 Governmentality and Biosovereignty**

Although the biotech and pharmaceutical industry has a cosmopolitical character, some Asian countries have used their sovereign powers to protect their bioresources from being consumed by global market forces. An emerging "biosovereignty" seems to have challenged the global biotech thinking and practices dominated by Western interests.<sup>103</sup> Taking China as an example, it adopts a more rigorous attitude than India toward international scientific collaborations with global pharmaceutical companies in order to

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<sup>101</sup> More information about the Centre, see, <http://www.genomics.sinica.edu.tw/> (Last visit: 10 March 2012)

<sup>102</sup> More information about the project, see, <http://nrpgm.sinica.edu.tw/en/index.php> (Last visit: 10 March 2012)

<sup>103</sup> Ong, "Introduction: An Analytics of Biotechnology and Ethics at Multiple Scales." P. 40

protect Chinese genetic materials from piracy and unauthorised use.<sup>104</sup> Moreover, in seeking overseas collaborations, China inclines to establish partnerships with overseas Chinese experts. It shows “an explicit norm of ethnic trust” which has made genomics manifest a deeper layer of meaning of nationalism and its territoriality.<sup>105</sup> Similarly, in Paul Rabinow’s *French DNA*, he shows how the civic epistemologies of France as to the inseparability of body and personhood caused the failure of scientific collaborative efforts with an American biotech start-up in order to prevent French DNA being profited from Americans.<sup>106</sup> Indeed, through technological intervention, life itself has created a new space for exclusive ownership and commercialisation.<sup>107</sup> For a nation state, genomics research reinforces the concept of sovereignty that forms a new kind of identity based on biological facts.

By further extending Rabinow’s notion of biosociality,<sup>108</sup> Wen-Chin Sung used the concept of “bionation” to examine how China adopts genomic research to recapitulate the notion of Chinese ethnicity in order to engage in debates over sovereignty with its fifty-six nationalities (“minzu”) and with Taiwan and Tibet.<sup>109</sup> The concept of *Chinese DNA* shows the “imagined communities”<sup>110</sup> have been consolidated through the introduction of genomics that contributes to the discourses and practices of China’s ethno-political narratives as “unity in diversity.”<sup>111</sup> It also illustrates how science may help form a new identity that makes room for the power of sovereignty to assert its will. China’s story demonstrates not only how politics can be scientific but also how science can be political; as Bruno Latour argues, science and politics are fully intertwined in the process of knowledge production.<sup>112</sup> Paradoxically, even though claiming the solidarity of the state, China skilfully views its various ethnicities as national treasure and has utilised its

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<sup>104</sup> Ibid., P. 41

<sup>105</sup> Ibid.

<sup>106</sup> Paul Rabinow, *French DNA: Trouble in Purgatory* (Chicago: University of Chicago, 1999).

<sup>107</sup> Sarah Franklin, "Life Itself: Global Nature and the Genetic Imaginary," in *Global Nature, Global Culture* ed. Sarah Franklin, Jackie Stacey, and Celia Lury (London: SAGE, 2000).

<sup>108</sup> See, Paul Rabinow, "Afterword: Concept Work," in *Biosocialities, Genetics and the Social Sciences : Making Biologies and Identities*, ed. Sahra Gibbon and Carlos Novas (London, New York: Routledge, 2008).

<sup>109</sup> Wen-ching Sung, "Chinese DNA: Genomics and Bionation," in *Asian Biotech: Ethics and Communities of Fate*, ed. Aihwa Ong and Nancy N Chen (Duke University Press, 2010). P. 264

<sup>110</sup> Benedict Anderson, *Imagined Communities: Reflections on the Origin and Spread of Nationalism* (London: Verso, 1991).

<sup>111</sup> Regarding the narrative of “Zhonghua Minzu”, see, Sung, "Chinese DNA: Genomics and Bionation." P. 270

<sup>112</sup> Bruno Latour, *We Have Never Been Modern* (Hemel Hempstead: Harvester Wheatsheaf, 1993).

abundant genetic resources to build a modern nation in terms of adding its competitiveness in the global biotech industry and pharmaceutical markets.

### 3.3.1 Taiwanese DNA

Compared to China, Taiwan's attempt to relate biological identity to national building seems to be much trickier. Jennifer Liu argued in her article "Making Taiwanese" that some scientists of Taiwan had turned stem cell and genetics research into vehicles to help define a "distinctive Taiwanese ethnicity" as opposed to Han Chinese.<sup>113</sup> The main purpose of doing so is to counterbalance China's discourse of making sovereign unity out of ethnicity. For example, a study suggested that Taiwanese aborigines are genetically linked to Maori in New Zealand and over centuries of interbreeding between the aborigines and Han immigrants had contributed the Taiwanese genome of aboriginal mixture that may further differentiate the people of Taiwan from Han Chinese.<sup>114</sup> Even though only 2% of the Taiwanese population comes from the group of Taiwanese aborigines, this ethnic group has turned into a specific research target in terms of its genetic traits, which are relatively unique compared with most of the Han Chinese gene pool that covers 98% of the population in Taiwan. The original inclusion of aborigines in the population biobank provides an opportunity to form discourses on the uniqueness of Taiwanese DNA. A geneticist in Taiwan has even suggested that the genetic variant HLA-B46 may have caused susceptibility to the SARS virus and because Taiwanese aborigines do not have this kind of genes, no aborigines are reported to have suffered from the epidemic of SARS when the disease was prevalent in Southeast China.<sup>115</sup>

The biobank story in Taiwan shows the entanglement of identity configuration, sovereign reasons and governmentality within the context of biocapital formation. The biobank initiative enhances the formation of identity that makes people of Taiwan a distinct category for scientific research. When addressing the importance of setting up a biobank with Taiwanese genetic characteristics, the supporting scientists emphasised the project will ensure the people of Taiwan not be excluded in the therapeutic promise of

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<sup>113</sup> Jennifer A. Liu, "Making Taiwanese (Stem Cells): Identity, Genetics, and Hybridity," in *Asian Biotech: Ethics and Communities of Fate* ed. Aihwa Ong and Nancy Chen (Duke University Press, 2010). P. 246

<sup>114</sup> Marie Lin et al, "Heterogeneity of Taiwan's Indigenous Population: Possible Relation to Prehistoric Mongoloid Dispersals." *Tissue Antigens* 55, no. 1 (2000). pp 1-9

<sup>115</sup> Marie Lin, *We Have Different Bloodhound: Disclosing the Myth of Taiwan's Ethnicities by Scientific Evidence of Genes* (Taipei: Chien Wei, 2010). (in Chinese)

personalised medicine. Wu Chen-Wen, the founder of the National Health Research Institute, had commented Taiwan needs to have its own genetic database to study diseases common to people in the region so it will help Taiwan develop suitable medicines for the diseases that might have been ignored by Western markets.<sup>116</sup> In an Academician Conference held by the Academia Sinica in 2000, Academician Tsuang Ming-Tseh proposed to build up a population-based genetic database for Taiwan to collect genetic samples from Hoklo, Hakka and Aborigines according to the relative proportion of their population in the country.<sup>117</sup>

These narratives suggested that a category of ethnicity which presupposed a genetic distinction has been adopted by scientists and may have existed before any new genetic studies were embarked upon. At the same time, it reflects the logic of population genetics adopted by the Taiwan Biobank project, namely to infer degrees of relatedness among populations by comparing their genetic markers with the hypothesis presupposing that an individual within a population is more compatible genetically with other individuals from the same population than with individuals from different populations. However, as categories may not be ontological, they do not necessarily reflect distinctions among groups but are often reflective of power and knowledge for which the categories themselves are invented.<sup>118</sup> As it has been rightly pointed out, scientific categories used by Taiwanese scientists for genetics and stem cell research are determined largely by historical and cultural ways of reckoning identity; as a result, the categories themselves require examination.<sup>119</sup>

Since “Taiwanese” is not a stable designator, in order to collect samples which can better represent the genetic compositions of all the people in Taiwan, the original research design for biobank’s population sampling followed the four ethnic categories of Hakka, Hoklo, Mainlander and Taiwanese Aborigine. As both Hakka and Hoklo, referring to the offspring of the earlier immigrants coming to Taiwan about 400 years ago mainly from

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<sup>116</sup> Lee Se and Yang Yu-Ling, "From Economic Power to Health Power," *Health Magazine (in Chinese)* 1 May 1999

<sup>117</sup> Lu Ling-Ling and Huang Hsu-Hui, "Academician Conference: Considering Ro Set up a National Biobank Like Iceland to Preserve DNA," *United Daily Night News* 05 July 2000. (in Chinese)

<sup>118</sup> Ian Hacking, "Making up People," *London Review of Books* 28, no. 16 (2006).

<sup>119</sup> Jennifer A. Liu, "Making Taiwanese (Stem Cells): Identity, Genetics, and Hybridity," in *Asian Biotech: Ethics and Communities of Fate* ed. Aihwa Ong and Nancy Chen (Duke University Press, 2010). P. 261



Fujian and Guangdong provinces, can be viewed as dialect groups from Southern China and the category of mainlander which refers to the group who migrated from mainland China to Taiwan after the Chinese Civil War in 1949 and their descendants who are born and raised in Taiwan, such categories are not completely biological.

In fact, the slogan of the “four great ethnicities” was first proposed by a legislator candidate during one of Taiwan’s electoral campaigns in the early 90s. The primary goal of the category was to converge a fragmented society due to the political confrontation between local Taiwanese and mainlanders in Taiwan’s ethnopolitics. Since then, the four categories have been used as a common description of Taiwan’s ethnicities. Nevertheless, the original inclusion of aborigines into the scheme shows that not only different languages, social structures, or even migration times may constitute ethnicities in Taiwan, but also biological appearance, skin colours and body figure, which are what physical anthropologists have mainly used to identify the components of ethnicity. Although some genetics research may hope to substantiate a scientific basis to claim that there is *Taiwanese DNA* which can be distinguished from Chinese genetic composition, a question as to whether and how Taiwanese are Chinese depends on which categories have been used in differentiation. Are they cultural, biological, national or political? The complicated naming practices make Taiwan Biobank a useful prism to observe the entanglement of identity formation within the biopolitical and biocapital context of Taiwan.

Interestingly, for the biotech and pharmaceutical industry, Taiwanese DNA may be viewed as a concentration of genetic variations of fifty-six ethnicities in China. As the main purpose of the biobank plan is for personalised and tailored medicine, if Taiwan can take an advanced position in pharmaceutical design for Chinese genes, great potential commercial benefits will be expected. As Ellson Chen of Vita Genomics has mentioned, because Taiwanese ethnicity comes from various areas of mainland China, Taiwan can position itself as the centre for Chinese gene study in the world. In order not to lose this opportunity and the potential market, setting up a national biobank for Taiwan has been a priority for the government that is also promoted, welcomed and greatly supported by the industry. Interestingly, even though the biobank was planned to back up personalised medicine targeting Chinese and Asian populations, it needed to call for Taiwanese people’s participation and support. In addition, under the administration of the

Democratic Progressive Party (DPP), “localisation” had become a trend for reviving Taiwanese identity, which was deemed to have been suppressed for the past 50 years under authoritarian rule. Since the transfer of political power in 2000, the term “Taiwan” was used much more frequently than its official name the “Republic of China (R.O.C.)” in various official and governmental documents. In this milieu, the project was also given the name “Taiwan Biobank” to justify its local characteristics.

While it might be an unconscious choice, a subtle signal of the identity influence appears. After the name “Taiwan Biobank” was given, all the advertisements of the project revolve around Taiwan and the Taiwanese population only. The concept of the four ethnic groups was proposed for population sampling but neither the Han Chinese nor the Taiwanese aborigines has been singled out in the project as a special gene pool for study. The Taiwanese aborigines as a key minority group have played an important role in all of these identity debates. They stand out as unique in order to satisfy the requirement of local characteristics. However, the aborigines hope to call more attention to their own characteristics and the practical issues that are relevant to aboriginal health conditions at present.<sup>120</sup> What matters for the Taiwanese aborigines is not only whether the biobank will bring any promising results in terms of improving their public health environment but also whether they are well considered in the whole research design. Paradoxically, even though obtaining knowledge of the genetic makeup of Taiwanese aborigines is an important component of biopolitics, the biobank plans to act as an ethnic melting pot that may form a Taiwanese identity transcending ethnicities, kinship and ethno-political divisions. According to a scholar in charge of the ELSI group of the biobank project, the biobank is expected to create a new form of identity that is not necessarily based on scientific facts but also on participants’ voluntary actions which contribute to a sense of solidarity for citizens’ future needs.

### **3.3.2 Biosafety**

The desire to ensure the Taiwanese population as a whole is included in the therapeutic promise of personalised medicine calls for a further biopolitical analysis. The biobank project funded by the Department of Health aims at identifying Taiwanese genetic

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<sup>120</sup> More discussion of these arguments can be found in the section 3 of the Chapter 5 of this thesis. Interviews with Taiwanese aborigines in Hualine, Taiwan, 2010.

makeup for drug targets of therapeutic purposes, which served a basis for the government to form policies of health, bioeconomy and biotech industry for Taiwan. This governance of population is a product of scientific governmentality that substantiates Foucault's biopolitics to promote forms of life by noncoercive exercises of power in modern states.<sup>121</sup> From this angle, the biobank project may be considered as an execution of biopower although the mode of the power is distinct due to its connection with new genomic knowledge and its entanglement with global pharmaceutical biocapitalism. At the same time, the project provides an opportunity to scrutinise how a new genomic technology like a biobank is able to be used by sovereign reason to govern its population.

On the other hand, even under the significant influence of global biocapitalism, the biobank initiative in Taiwan may not be simply reduced to a commercial undertaking. In fact, genomics research has been viewed by the government as a way to provide biosecurity and reconnect Taiwan to its long absent international health management system. Taking the outbreak of severe acute respiratory syndrome (SARS) as an example, the spread of the SARS epidemic created a sense of crisis of health in Taiwan. However, Taiwan was forbidden to participate in the World Health Organisation (WHO) due to Beijing's insistence. Despite timely reporting of the situation to WHO during the prevalence of the SARS epidemic, Taiwan did not receive any official advice and assistance from the international system. The lack of efficient communication with the WHO caused delay in the handling of the disease. Taiwan's failure to argue for its own seat in the WHO unfavourably excludes Taiwan from the mechanism of global public health monitor that triggers the government's awareness to safeguard the life of the nation. From this viewpoint, life science and the biotech industry have become the solution for Taiwan to the threat of the rise of China as both an emerging economic power and a military and health policy's deterrence. Becoming a biotech operating centre in East Asia seems to be a geopolitical strategy for Taiwan to redefine its distinct identity on the global stage. A biobank for Taiwan substantiates the notion of Taiwanese DNA as it echoes the government's enthusiasm to raise Taiwan's international visibility and it shows that citing Taiwanese genetic uniqueness has both scientific and political significance. Furthermore,

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<sup>121</sup> More information about the notion of biopolitics, See, Michel Foucault, ed. *Governmentality*, vol. 3 Power, Essential Works of Foucault, 1954-1984 (New York: New York Press,1994).

under the Democratic Progressive Party (DPP)'s national building discourses, putting the country's interests in the forefront means exercising name rectification, namely using "Taiwan" instead of the "Republic of China" to bring the country necessary international attention.

In order to better understand these complicated naming practices, it would be helpful to zoom back again to geopolitics in the Asia Pacific. Taiwan has been a "hot" issue even during the Cold War period. The Sino-American Mutual Defence Treaty signed in 1954 between the United States and the Republic of China (R.O.C.) government was a part of the US containment policy against the People's Republic of China (P.R.C.) led by the Chinese Communist Party, which won in the Chinese Civil War on mainland China in 1949. After the Civil War, the R.O.C. government led by the Chinese Nationalist Party (Kuomintang, the KMT) under the rule of Chiang Kai-shek retreated with troops and civil officials from mainland China to Taiwan. However, even though the R.O.C. Constitution went into effect in 1947, it was later suspended by martial law and therefore it had not been applied to the region of Taiwan until 1987 when martial law was lifted. For that reason, despite being known in the West as a "free China" in contrast to the "Red China" ruled by the Communist party in the mainland, the Republic of China on Taiwan was under martial law and was in fact a single party state from 1947 until 1987.

Even though retreating to Taiwan, Chiang continued to claim sovereignty over the mainland of China according to the constitution and claimed that the R.O.C. government was the only legitimate government of the whole of China. This position had been recognised by the West and the United Nations until 1971 when the R.O.C. government finally withdrew from its U.N. China seat as a result of a gradual loss of international support for the R.O.C. statehood. The withdrawal from the United Nations was a historic turning point for Taiwan as it led to the country's subsequent isolation from the international system and has had significant impacts on Taiwan's foreign relations and its domestic politics.

In 1979, the US Congress passed the Taiwan Relations Act by which the US recognised an unofficial relationship with Taiwan, namely establishing government-to-government interaction (in contrast to state- to- state) as a result of its normalised relations with

Beijing. A year later, the Mutual Defence Treaty signed with the United States was terminated unilaterally by the Carter administration. Since 1979, the US-Taiwan has maintained a *de facto* diplomatic relationship. Such an unofficial diplomatic model later became the major means for Taiwan to establish its relations with other foreign countries as a result of Beijing's insistence on its "One China Principle" and use of it as a diplomatic strategy to suppress Taiwan's international space. The One China principle proposed by Beijing asserted that there is only one China and that Taiwan is a part of China. This principle is different from the so called "One China Policy" which was formalised in the 1992 Consensus. The policy refers to the consensus between the R.O.C and the P.R.C. governments that there is only one China, one sovereign state called China that encompass the territories of both mainland China and Taiwan, even though there are two existing governments claiming to be the legitimate representative of the whole of China. For the R.O.C. government, for example, the One China refers to the Republic of China, which was founded by Dr. Sun Yat-Sen in 1912 after overthrowing the Qing Dynasty in the Xinhai Revolution, and it continues to exist on the island of Taiwan. Because the K.M.T government has not yet formally recognised the legitimacy of the People's Republic of China established by Mao Zedong in 1949 after the end of the Chinese Civil War, it has aroused an increasing identity crisis in Taiwan as the government needs to face domestic challenges for its ruling legitimacy, especially after it withdrew from the United Nations.

In 1986, the first opposition party - the Democratic Progressive Party (DPP) - was established in Taiwan. It supports Taiwan's independence as a separate country, a sovereign state separate from the territory of China. According to the DPP, claiming Taiwan's official name as the Republic of China has prevented Taiwan from participating in the international system and this produces no benefits to the people of Taiwan. As a result, the DPP supporters have been demanding name rectification for the country. For example, they called for a referendum to use the name of "Taiwan" to apply for membership of the United Nations in order to avoid UN General Assembly Resolution 2758, which was passed in 1971 and recognised the PRC as the sole legitimate representative of the China seat in the UN.<sup>122</sup> The referendum was held by the DPP administration in 2007 under DPP President Chen Shui-bian. Chen won the 10<sup>th</sup> term's

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<sup>122</sup> It includes both the seat in the UN General Assembly and the membership of the United Nations Security Council.

Presidential election in 2000 because of the split of the KMT party and it was the second direct election for the President of the Republic of China on Taiwan since prior to 1996 the presidency of the R.O.C. had been elected by the National Assembly.

The referendum proposed by the DPP administration caused tension across the Taiwan Straits as Beijing viewed it as a preliminary action for Taiwan's independence by planning to change the state's name from the "Republic of China" to "Taiwan". The Chen administration explained the necessity of the referendum as only to deepen Taiwan's identity and promote the recognition of Taiwanese statehood by the international community. However, the DPP had also been severely criticised for using the referendum as a way to help its party win domestic elections and to affect political campaigns by creating a wave of Taiwanese nationalist sentiment.<sup>123</sup> In order to oppose the DPP referendum, the KMT proposed another version of referendum emphasising that its standing is to make the country "re-join" the United Nations rather than apply for a new membership in the UN with the name of "Taiwan." For the KMT, the "Republic of China on Taiwan" has undoubtedly been an independent sovereign state from the P.R.C. regime so the main issue for the party turns out to be how to maintain the status quo in the Taiwan Straits for the best interests of people in Taiwan. The KMT views the name rectification and formulation of a new constitution as impractical and especially not moderate at the current stage since it would threaten and destabilise peace in the Western Pacific, breach mutual trust in the Taipei-Washington relationship and finally damage Taiwan's credibility in East Asia as a responsible citizen. Nevertheless, the DPP administration considered a referendum to be a pragmatic and necessary way to increase Taiwan's international visibility.

On the other hand, since Beijing never gives up the threat of armed force to solve the issue over the Taiwan Straits if Taiwan claims independence, the DPP's strategy for national security is to make Taiwan an international issue and then request support from the international community, particularly from Japan and the US, for the latter, based on the Taiwan Relations Act passed by the US Congress in 1979. However, even though

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<sup>123</sup> The text of the DPP referendum reads as follows: "In 1971, the People's Republic of China replaced the Republic of China as a member of the United Nations, thus making Taiwan an international orphan. In order to strongly express the will of the Taiwanese people, and to elevate Taiwan's international status and international participation, do you agree with the government to use the name "Taiwan" to enter the United Nations?"

Washington acknowledged its political commitment<sup>124</sup> made in the Act that includes providing Taiwan with arms of a defensive character, it reclaimed its recognition of the one China principle in response to Taiwan's independence claim. Nevertheless, in Taiwan's domestic milieu, the suppression of an international space for the country drives and consolidates forces to form an emerging Taiwanese consciousness. Despite the lack of consensus with regard to the issue of name rectification, such consciousness has been reconfigured as a form of Taiwanese identity through domestic political campaigns. For the DPP, such identity is mainly constructed in its nationalism-based discourse to promote Taiwan's independence; for the KMT, on the contrary, identity formation signified its endeavours in localisation in order to obtain recognition from Taiwanese society and regain its legitimacy in Taiwan's democratic transition.

In the 2008 Presidential election, the KMT regained executive power in Taiwan. It reclaimed the acceptance of the 1992 Consensus and maintained the status quo by declaring no reunification and no independence in its cross-strait relations. Later, regular direct flights between mainland China and Taiwan resumed for the first time since 1950 and the Chinese mainland has become the largest market for Taiwan's exports and outward investment. In June 2010, Taipei and Beijing signed the Economic Cooperation Framework Agreement (ECFA) which aims to have tariff concessions over 807 products. As Taiwan has been prevented from signing free-trade agreements with its neighbouring economic powers by Beijing, the government hopes that ECFA will benefit Taiwan's overall economic development although the opposition DPP has concerns that ECFA may make Taiwan be overly economically dependent on mainland China.

The historical context illustrates the complexity of how political components and market forces may have influenced the constitution of Taiwanese identity and why identity formation is not necessarily inherent but fluid and full of flexibility. It also shows that for Taiwan, obtaining international recognition has geopolitical significance for its national security. Taiwanese DNA in these biopolitical discourses has a sense of national distinctiveness that represents Taiwan's anxiety about being excluded from the international system and its eagerness to return back to the global stage by using its economic power. However, on the other hand, the uniqueness of Taiwanese genes has

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<sup>124</sup> For example, it is permitted to sell arms of defensive characteristics to Taiwan.

also been promoted by the government as a comparative advantage for Taiwan to attract global investment which targets the potential of the Greater China market. In the public imagination, although biobanking in Taiwan causes many ethical concerns among the human rights groups, it is recognised by the government as an innovative technology for the common good and for Taiwan's future generations. These public interest oriented discourses constitute ethical configurations in Taiwan that cast the state as both a guardian of its population and also an investor in terms of turning the population into a resource for the purposes of forming a bioeconomy.

The paradoxical role the state plays makes biobank governance in Taiwan a challenging task and it explains the necessity to deploy the practical governance issues in the context of cosmopolitics in order to realise the social and symbolic effects of applying biobanking as a new form of biotechnologies in Taiwan's modernity. However, behind the paradox is the complicated intertwining of governmentality and the logic of value accumulation that shows a kind of biopower has been exercised through the configuration of ethics. In addition, the huge Chinese population has turned to be an advantage claimed by Taiwan's government to carry out the development of cures for Chinese-exclusive diseases. It is like reliving the territorial boundary cited in the R.O.C. constitution in the realm of genomics research that unlocks the potentialities of Chinese populations as values to be harvested.

In addition, even though the KMT and the DPP have different policies toward the status of Taiwan's statehood, both parties have seriously complied with the logic of neoliberalism and taken it as the fundamental principle for Taiwan's economic development. In contrast to other postcolonial countries in East Asia, such as South Korea, for example, the leftist influence against capitalism and globalisation is relatively weak in Taiwan. In fact, Japanese colonisation not only brought capitalism to Taiwan by creating a system of colonial mercantilism but also formed the hierarchical class differentiation in Taiwanese society. Even though there was some strong resistance to imperialism from some local Taiwanese elites during Japanese colonial rule (1895-1945), these left-wing legacies encountered major historic ruptures first by the repression from Japan's colonial power and later from the KMT's authoritarian rule by using martial law to systematically clean up communist ideas and left wing ideas in Taiwan. The influence of these political



interferences is not only a long period of White Terror in Taiwan but also a tacit mentality of compliance with the logic of capitalism.

### **3.4 Ethical Configurations in Biocapitalism**

The expectation of biotechnology in improving public health and the treatment of diseases enhances the logic for ethicalisation of the biobank practices in Taiwan. Building an adequate regulatory infrastructure has become a priority of the government in order for Taiwan to be more easily reconnected to the global biotech and pharmaceutical market. As Kaushik Sunder Rajan has argued in his ethnographic study of genomics research in India, the fundamental structural violence of technoscientific production in global capitalism cannot be mitigated by the forms that ethics takes in the region.<sup>125</sup> Both human rights groups and the actors supporting biobanking in Taiwan are drivers of an ethical regulatory environment. However, the national biobanking initiative is more complicated than just executing biopower for improving the quality of life for a nation state. The biobank project involves analysing the enthusiasm of Taiwan's government to make the state a crucial niche for genomics study in the Asia Pacific. As a result, rather than protecting research subjects from possible exploitation, a formal attentiveness to ethics, on the contrary, helps turn Taiwan into a site of sample collections for global biotech investment and commercialisation.

In Taiwan, the executing scientists for the national biobank are also concerned with ethics as they would like a clearer boundary between what is allowed and what not. For that reason, the Human Biobank Management Act passed on 7 January 2010 focuses mainly on the issues of good practice such as collecting informed consent and implementing confidentiality. Little attention is paid to substantive proprietary issues, for example, the ownership of samples and genetic information and the operational and business model of the biobank. Consider, for example, Celera's business strategy in racing for the human genome sequence with the HGP. The legally enshrined proper protocol can nonetheless lead to consolidating the existing profit-oriented structures of global biocapitalism that may risk Taiwan becoming an attractive site of "genetic colonialism" for the global pharmaceutical industry. In addition, the distinction between public and private sectors has been blurred by mechanisms such as technology transfer and research collaboration

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<sup>125</sup> Kaushik Sunder Rajan, *Biocapital* (Duke University Press, 2006).

that further complicate the role of state in the biobanking in Taiwan. Under the influence of global capitalism, many publicly-funded research institutes and labs of Taiwan have become aggressive market players like biotech companies in seeking patenting of their research results. However, those participants who decide to voluntarily take part in the biobank project because of their trust in the credibility of the government and executive agency - the Academia Sinica - may turn out to have a more reserved attitude toward biobanking if they know their samples and data collected from the institution would be used for profits and marketing in the end.

Confronting mainland competition in genomics research, Taiwan wants to privilege biotechnology as a springboard into the potential market of Sinopathology. In contrast to China, Taiwan's democratic political milieu and its more established regulatory infrastructure are competitive advantages. The state can claim it is geographically adjacent to the large Chinese populations but is more interested in protecting intellectual property by complying with the rule of law than the mainland. Interestingly, most of the concerns in Taiwan about the establishment of the national biobank had revolved around the lack of ethics to regulate this kind of innovative technology. Since the biobank project is still in its early development, informed consent and privacy have occupied most of the regulatory efforts in the ethical configurations. However, such configurations may have sent a hazardous signal to the public in a way that so long as some ethical safeguards are in place the biobank can carry on without too many worries left. It also illustrated why the critical voices from the human rights groups in Taiwan seem to have been weakened since the biobank Act was passed by Taiwan's Legislative Yuan in early 2010. Ethics and regulation have turned out to be an agency to localise global biocapitalism. They consolidate the invisible structural violence of commercialisation by internalising opposition forces and transforming their concerns into sovereign reasons by configuring ethics through a process of legislation.

According to the proposal for the pilot study for the Taiwan Biobank, the Development Centre for Biotechnology (DCB) is responsible for planning the future industrial application for the biobank. The DCB, a non-profit organisation established in 1984, is co-sponsored by both government grants and private donations. The centre's purpose is to serve as a bridge between the upstream R&D and downstream industrial application so

publicly funded academic research institutions and private biotech-pharmaceutical industry can be coordinated in a more efficient way. In addition, the centre positions itself as a value-adding partner for the industry that means it adds values to new developed drugs by filing Investigational New Drug (IND) Applications to the US Food and Drug Administration for approval and then licenses out drug candidates to down-stream biotech and pharmaceutical companies for clinical trials and eventually for product commercialisation. Even though the possible business models of the biobank, such as patent licensing, technology transfer or strategic alliance, etc, are still under discussion in the DCB, the centre's objective is for commercialisation and help business expansion into the global biotech pharmaceutical market.

As Sunder Rajan has argued, the global harmonization of ethics and intellectual property regimes constitute the structural violence of global capitalism.<sup>126</sup> In Taiwan, this violence is exacerbated by the fact that a patriarchal state has gradually transformed itself from a protector of to an investor in the biotech industry so biopolitical purposes are easily intertwined with the underlying logics of neoliberalism. Recently, Taiwan's Ministry of Economic Affairs has launched a Biotechnology Takeoff Action Plan aiming to identify opportunities for further commercialisation of biotech and pharmaceutical R&D research results. According to the plan, a biotech venture capital scheme will be set up so the government will work with private capital to invest in some local research projects. In addition, the Department of Health has planned to establish a Food and Drug Administration similar to the FDA in the United States to regulate medical and pharmaceutical products in line with international standards. As one of the purposes of the Takeoff Action Plan is to promote Taiwan as a R&D partner for the international biotech community, international alliance has been emphasised through putting extra efforts into the harmonisation of regulations. Taiwan's eagerness to be compatible with international standards also represents its geopolitical mentality to act as a springboard for multinational companies to enter the Chinese market when the global economic centre is moving from the West to the East. Taiwan's recent efforts to link itself with the international value chain have opened an opportunity for the country to be integrated

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<sup>126</sup> Kaushik Sunder Rajan, "The Experimental Machinery of Global Clinical Trials: Case Studies from India," in *Asian Biotech: Ethics and Communities of Fate* ed. Aihwa Ong and Nancy N. Chen (Duke University Press, 2010). P. 74

into the Greater China economic sphere that further shows how Taiwan's relations with China can be competitive as well as cooperative.

However, when the state and public sector act more and more like a profit-driven corporation or an investor, the structural violence of biocapitalism, as Sunder Rajan argues, turns to be more consolidated and hard to discern. For example, in terms of collecting informed consent, the public face of biobanking recruitment suggests the project is a public good for realising the causes of diseases common to the people of Taiwan. Nevertheless, the project's underlying link to commercialisation has not yet been properly disclosed and as a result it is difficult for individuals to consider whether commercial involvement would be a factor to influence their willingness to take part in the project. In addition, the biobank's technocratic purpose such as promoting Taiwan's biotech industry in its international competitiveness has been covered by public health related discourses in the biobank's recruitment of participants. As the government has managed well to locate the biobank project inside a narrative of both scientific development and Taiwanese genetic distinctiveness, the general public may view the biobank simply as a research infrastructure and neglect to challenge its possible commercial linkage and ensure if there are any benefits derived from the research results in which the public would be entitled to share as voluntary participants. DeCode Genomics portrayed the Icelandic population as highly educated but "cooperative." However, in Taiwan, perhaps the question is not simply to ask whether Taiwanese population is cooperative or not. Rather, it is to examine under what narratives and context the population of Taiwan may have been viewed as cooperative by the biotech industry and government as an ideal population for pharmacogenomics research.

## **Conclusion**

This chapter discusses the deployment of biotechnologies in Taiwan as a valued opportunity for its national building, economic growth and the formation of identity and biosecurity. It also examines the social and symbolic effects of biotech innovations, such as biobanking in Taiwan's geopolitical analysis. Biobanking may be viewed here as a useful indicator to interpret and reconstruct the notion of biotech modernity in the Taiwanese reality. It demonstrates the Taiwanese government's endeavours to catch up with the

international trend in genomics research and pharmaceutical development when biobanking articulated not only the scientific imagination but also nationalist aspirations to end the exclusion of the country from the international system. Such hope of building a modern nation has turned the biobank project into a state-led enterprise that is allied to the milieu of neoliberalism in Taiwan in order for the state to restore national identity and a competitive niche in the Asia Pacific.

Taiwan's sovereign reasons to use biotechnologies to revolutionise its industry and enhance its international visibility has attracted global pharmaceutical companies to establish partnership with Taiwan's local industry to explore the commercial potentials by mining genetic gold in East Asia. Because of this, the influence of the private sector significantly increases in Taiwan's formation of biocapitalism. The story of Vita Genomics illustrates the Taiwanese government's enthusiasm to encourage private start-ups to play a leading role to bring capital and transmit innovative technologies in order for the country to be reconnected to the global trend of genomics research and biotech development. Regulatory infrastructures and capacity building have gradually blurred the distinctions between public and private by mechanisms such as technology transfer and research collaborations in the hope to integrate resources for Taiwan's biotech development.

Even though for a nation state, genomics research may reinforce the concept of sovereignty that forms a new kind of identity based on biological facts, the case of Taiwan demonstrates the formation of identity is fluid and subject to change. Furthermore, the Taiwan Biobank illustrates that ethnic categories may be consequential as the elements used in differentiation are not necessarily biologically true. In addition, the chapter argues that the Taiwanese government identifies biobanking as a new form of biotech for Taiwan and its future citizens' common good. Relevant ethical configurations have emerged in Taiwan's biopolitical narratives that illustrate the ambiguous and paradoxical role the state plays in biobank practices in Taiwan. Since the biobank project is intertwined with Taiwan's governmentality and the formation of Taiwan's bioeconomy, it is not appropriate to treat the project as simply a scientific research plan. As a result, the current ethical configurations with regard to biobank governance may not be thoroughly responsive to

the commercial challenges for the biobank, considering its close association with the biotech development but unclear arrangements of proprietary interests.

In addition, this chapter points out that holding a bioethical view to discuss biobank governance may ignore the influence of global capitalism on its application to biobanking practices in Taiwan. The case of Taiwan shows that how regulation and ethics may be used as a helpful way to legitimise sample collections but leave substantial issues such as access, ownership and intellectual property unattended. It also demonstrates how the idea of neoliberalism has prospered in Taiwan's modernity and seems to keep leading Taiwan's overall development. The Taiwanese biobanking case may act as an important input to contribute to global assemblages by deploying the country's development of biotechnologies in a cosmopolitical context. It also helps create a space to realise different civic epistemologies and their entangled frames in this emerging technoscientific world.

Finally, the chapter hopes to enliven the current literature with regard to commercialisation of biobanks by locating Taiwan's practical experience in the context of cosmopolitical technoscience. In so doing, the force of global capitalism might be easier to be recognised and discerned from the covering biopolitical discourses.

## Chapter 4 Biobanking in Taiwan: the Politics of Science and Technology

### Introduction

This chapter introduces the biobanking story in Taiwan by analysing its initiatives, agencies, ethical puzzles and governance framework from a perspective of science and technology studies. In 2005, the Executive Yuan of Taiwan announced the start of the Biomedical Technology Island Plan with the aim of building Taiwan into a centre for genomics research and clinical trials in Asia. Several government agencies worked out this great scheme in synergy: the Ministry of Economic Affairs (MOEA), the National Science Council (NSC), the Department of Health (DOH), the Academia Sinica, and the National Health Research Institute (NHRI). The initial agenda for establishing this integrated biomedical infrastructure was five years, within which the government was planning to call for the investment of NTD 15 billion (equivalent to USD 457 million).<sup>1</sup> It is hoped that this scheme may greatly improve Taiwan's environment for biomedical and pharmaceutical research and attract more overseas investment in local health service-related industries. In the future the scheme is expected to generate significant resources of biovalue for genomic research and biotechnology development in Taiwan. According to the government, the scheme was expected to boost investment of about NTD 40 billion from both public and private sectors over the five-year period.<sup>2</sup>

For the government, Taiwan has many strengths that make it ideal for the development of biomedical technology and pharmacogenomics. For instance, during the period of 2002-04, international medical organizations had conducted 337 clinical studies in Taiwan<sup>3</sup> and roughly around the same time, the National Science Council launched the National Research Programme for Genomic Medicine (NRPGM).<sup>4</sup> This collaborative, national-level scheme aims to carry out genomics research and capitalise knowledge acquired through it. In April 2005, the idea of establishing a large-scale population biobank as a biomedical research infrastructure was first initiated in the National Science

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<sup>1</sup> "Biomedical Technology Island Plan to Spur Investments of NTD 40 Billion over 5 Years," *Central News Agency* 20 April 2005. see: <http://dois.pristine.com.tw/en/news/200504/2005042001.html> (Last visit: 08 March 2012)

<sup>2</sup> Ibid.

<sup>3</sup> Ibid.

<sup>4</sup> More information about the NRPGM can be found in its website: <http://nrpgm.sinica.edu.tw/en/content.php?cat=agtc> (Last visit: 08 March 2012)

and Technology Conference (NSTC). The NSTC is a national-level meeting held every four years under the supervision of the Science and Technology Advisory Group. Unlike usual ministerial meetings, the NSTC provides a significant platform for both government officials and representatives from industries and academia to express their ideas of how to design Taiwan's science and technology blueprints. After the promulgation of the Fundamental Science and Technology Act in 1999, each consensus reached in the NSTC is required to be documented and therefore its policies can be integrated into the National Science and Technology Development Plan. Proposed under the broader scheme of the Biomedical Technology Island Plan, the Taiwan Biobank project aims to provide a supportive platform to help promote Taiwan's biomedical research and biotechnology development. With the advantages of well-developed medical centres for clinical trials and over 99 % of the population participating in the National Health Insurance Scheme,<sup>5</sup> it is acknowledged by the government that establishing a large-scale population biobank in Taiwan is beneficial and can help Taiwan secure its niche in the global bioeconomy for biomedical and pharmaceutical innovations.

In addition to this biobanking project, the broad scheme covers two other core facilities - the National Health Information Infrastructure (NHII) and an integrated system for clinical research and trials. The goal of the NHII is to establish an electronic system for rapid image transmission of health information among regional medical centres and hospitals. This system planned to simplify the complicated data transfer procedures in clinical trials that used to rely on a tremendous amount of documents and paperwork for applications. After the NHII was founded, the expected time for health information transfer will be significantly shortened from a period of two weeks to three working days. The integrated clinical trial system aims to support domestic pharmaceutical companies undergoing the clinical trial procedure requested by the Department of Health for drug invention and production.<sup>6</sup> An executive agency - the Clinical Trial and Research Programme Office - was accordingly established by the Department of Health about four months after the announcement of the Biomedical Technology Island Plan. In the future, according to the government's plan, the NHII was expected to support the realisation of the personal

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<sup>5</sup> Founded in 1995, this is a government-run health insurance scheme, financed through a mix of premiums and taxes. The enrolment is mandatory to ensure the adequate risk pooling.

<sup>6</sup> Supra note 1



health care system and to save about NTD 10 billion annually in national health insurance expenses for the state.<sup>7</sup>

#### **4.1. Biobanking Conditions**

##### **4.1.1. Pharmacogenomics**

The prospects for the study of pharmacogenomics and genetic epidemiology have made biobanking attractive to many scientists in Taiwan. For them, creating a large-scale prospective cohort can overcome the shortcomings of a case-control study which is frequently shown in their research as a result of ineffective statistics from inadequate samples. In fact, collecting large sample sizes for establishing a cohort for medical research is not unfamiliar to epidemiologists in Taiwan. Several hospitals, medical centres and universities have had their various-sized sample collections for research and therapeutic uses. For instance, a few decades ago, a famous cohort for the study of hepatitis B was established by Dr. Palmer Beasley and his Taiwanese colleagues at the US Naval Medical Research Unit No. 2 in Taipei. The cohort consisted of 22,707 Taiwanese male government employees who were traced forward for over 15 years.<sup>8</sup> The research findings demonstrated that carriers of hepatitis B are about 265 times more susceptible to liver cancer than average and the use of vaccines may effectively prevent a newborn baby whose mother was carrying hepatitis B from becoming infected by it.<sup>9</sup> Based on the successful experience of using a large-scale cohort in epidemiology research, launching a population biobank motivates the supporting scientists in Taiwan to continue exploring the scientific unknown.

In addition, since Taiwan has a relatively small population (23 million), in practice it is rather difficult for it to request that every new drug invented outside of the country goes through the process of local clinical trials before the drug can be permitted to be sold openly in the domestic market. Even though some multinational pharmaceutical companies have also carried out regional studies, which may take into account different racial groups as a factor affecting the efficacy of medications, the results from these clinical trials are not necessarily useful for people in Taiwan. According to Chen

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<sup>7</sup> Ibid.

<sup>8</sup> RP Beasley et al., "Hepatocellular Carcinoma and Hepatitis B Virus: A Prospective Study of 22,707 Men in Taiwan," *The Lancet* 318, no. 8256 (1981).

<sup>9</sup> Ibid.

Yuan-Tsong, the Director of the Institute of Biomedical Science (IBMS) at the Academia Sinica and also a co-principal investigator of the biobank project, Taiwan needs to have its own population biobank designed especially for Taiwanese people.

When I returned back (in Taiwan), I had heard from many physicians that the side-effects of medications in Taiwan is extremely serious. Even though many countries have started to create biobanks, since every different races has different genes, so are environmental factors, we couldn't say that because they have already started doing this, we (Taiwan) don't have to do so. The best example is that we often see many multinational pharmaceutical companies inventing pharmaceuticals targeting only white people. Although the FDA in the United States has mentioned that in clinical trials, it is necessary to profile people from different racial groups, the finding results have not yet been sufficient because those pharmaceutical companies' major markets remain in the US or in Europe.

[T]hen we started to do research on the Stevens-Johnson syndrome and to see why there were very few cases with this symptom in Caucasians but so many among people in Taiwan and also in South East Asian countries. Later, we found out that there is a gene found in people from the South East that cannot be found in Caucasians. Even though the drug carbamazepine was already out of patent during that time, I have told my students in class that if this drug had ever gone through its clinical trials in Taiwan, it would not have been able to be passed. (Interview with Chen Yuan-Tsong, Taipei, 2009)

After the publication of this research finding, carbamazepine was requested to be relabelled for its possible pharmaceutical side-effects especially for the gene marker of HLA-B\*57:01 which is frequently seen in East Asian populations (especially Han Chinese and Thai).<sup>10</sup> Due to the different genotypes of the Taiwanese population, about 5% of Taiwanese are severely allergic to carbamazepine which was originally designed for Caucasians.<sup>11</sup> Another similar example may be found in Iressa, a drug for target therapy in lung cancer. According to the study, it shows that the efficacy of Iressa for Europeans and Americans is lower than for East Asians.<sup>12</sup> The reason is that Iressa has a significant

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<sup>10</sup> Chung WH et al., "Medical Genetics: A Marker for Stevens-Johnson Syndrome," *Nature* 428, no. 6982 (2004).

<sup>11</sup> Ibid.

<sup>12</sup> J. Guillermo Paez et al., "Egfr Mutations in Lung Cancer: Correlation with Clinical Response to Gefitinib Therapy" *Science* 304, no. 5676 (2004).

therapeutic effect on people with the EGFR mutation and, like people in other East Asian countries, many people in Taiwan have this kind of genetic mutation. As a result, it has been proven that the responding efficacy of Iressa, mainly for tumour regression, works much better in Taiwan than in most Western countries.<sup>13</sup>

According to Shen Chen-Yang, a professorial research fellow at the Institute of Biomedical Science and a co-director of the biobank project, setting up a long-term cohort study is in the best interests of the next generation because it helps immensely in discovering the causes underlying common complex diseases by examining innate genetic composition and acquired lifestyle and environmental factors.<sup>14</sup> Taking lung cancer as an example, according to Shen, even though most people believe that smoking increases the chance of developing lung cancer, in Taiwan, only one in every nine women diagnosed with lung cancer is a smoker and this shows that one of many unknown variables here may very well be genetic.<sup>15</sup> Viewed as a platform to support long-term cohort tracking studies, the idea of establishing a national-level biobank has been supported by some scientists in Taiwan. As establishing a population biobank helps in developing personalised medicine, the hope is high that in the future when a doctor prescribes a medicine, she or he will take into account patients' individual genetic makeup in order to manage side effects in medications. Analogous to biobanking projects launched all over the world, the invention of the biobank in Taiwan will have significant implications for Taiwan's biomedical research and public health. In addition, this biobanking project has become an important medium for the government to manage the health of its population.

#### **4.1.2. Genetic Diversity among Taiwanese Populations**

In order to push Taiwan's biomedical research to a new height, some scientists view the population biobank project as a powerful infrastructure, especially for genomics research to take into account Taiwanese unique genetic makeup. Wu Cheng-Wen, the former president of the National Health Research Institute, has suggested that Taiwan needs to establish its own genetic database for better research on local prevalent diseases, such as liver cancer and nasopharyngeal carcinoma because of the genetic variations existing

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<sup>13</sup> Interview with Chen Chien-Jen, Taipei, 2010

<sup>14</sup> Chang Chiung-fang translated by Phil Newell, "Making a Deposit in Taiwan Biobank: How Safe Are Your Secrets?," *Taiwan Panorama* (2008).

<sup>15</sup> Ibid.

among different ethnic groups.<sup>16</sup> In the biobank proposal, genetic diversity is introduced as a major strength for the establishment of a population biobank in Taiwan.<sup>17</sup> Even though the goal of the Human Genome Project was to map the entire human genome, for the development of population genomics more attention has been paid to the study of genetic variation among different populations and even individuals. Unlike the Icelandic Health Sector Database which values the genetic homogeneity of the Icelandic population, the genetic diversities among Taiwanese populations encourage geneticists and epidemiologists in Taiwan to discover the association between genes and a wide range of data relating to human phenotypes and Taiwanese environment.

Following the significant reduction in the cost of genotyping after sequencing the human genome, it is now feasible for scientists to study factors contributing to common diseases by discovering genetic polymorphisms. For some scientists, even though many Taiwanese may trace their ancestral origins back to Han Chinese, as a migrant society, the expression of their genes may have been developing through changes induced by local environments, customs and diet habits. In addition, Taiwan's migrant history enriches its genetic diversity. The specific character of Taiwanese migrant history may be illustrated by the old saying: "there are *Tangshan* fathers, no *Tangshan* mothers." The term *Tangshan* refers to mainland China and the saying explains that about four hundred years ago most people who came to Taiwan from Fujian and Guangdong provinces were male immigrants. So the descendants of these immigrants would be through intermarriages with Taiwanese aborigines, particularly with the plain aborigines who inhabited the lower mountain areas and western plain lands in Taiwan during that time. The intermarriage between indigenous and non-indigenous groups enriches the genetic diversity of the Taiwanese population.

Since genetic variation is significant in genomics research, genetic diversity turns to be a strength in the establishment of a population biobank in Taiwan. The importance of ethnic difference to biobanking lies in the possibility of looking into what combination of different genes relates to which diseases. Therefore, setting up a population biobank for searching genetic variation among different ethnic groups enables scientists to detect the correlation between genetic variation and diseases and carry out a comparison of cross

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<sup>16</sup> Ibid.

<sup>17</sup> The Proposal for the Pilot Study of the Taiwan Biobank, (Academia Sinica, October 2005), pp 9-10

ethnic groups. According to Chen Chien-Jen, a distinguished epidemiologist and an Academician at the Academia Sinica, the genetic diversity of the Taiwanese population is very vast and that enriches the biobank as a valuable tool to understand the risk factors that underlie common complex diseases in Taiwan.

In Taiwan, one of the strengths for the population biobank is that we have a population with a high genetic diversity. The Taiwanese ethnicities are much more complicated than we might have ever expected. For instance, in terms of Taiwanese aborigines, there are many original traits that make their genetic makeup very diversified. Even for the offspring of Han Chinese immigrants, there are many of them through intermarriage related to plain aborigines. In addition, the immigrants who came to Taiwan after 1949 may cover 56 different ethnic groups in mainland China, so generally speaking, the population diversity in Taiwanese ethnicities is very vast. If everyone had the same genetic makeup, there would be not much of research interest here. (Interview with Chen Chien-Jen, Taipei, 2010)

In the early planning stages of the Taiwan Biobank, scientists used the general term “the four great ethnic groups” - Hoklo, Hakka, Mainlanders and Taiwanese Aborigines - as a criterion for the project’s research design and population sampling. However, this approach of genetic sampling had been criticized in that it failed to recognise that the categories themselves are not intrinsically biological. As mentioned in the earlier chapter, such ethnic category was socially constructed and initiated by a political figure as a slogan during a domestic electoral campaign in the 1990s. The original purpose of constructing the term is to diffuse the tension between the local Taiwanese - Hoklo and Hakka (referring to the offspring of the earlier immigrants coming to Taiwan about 400 years ago from Fujian and Guangdong provinces) - and Mainlander (the later immigrants and their offspring who retreated from the Mainland to Taiwan after the end of the Chinese civil war in 1949).<sup>18</sup> According to population geneticists, both Hoklo (70%) and Hakka (15%) may be broadly categorised as subgroups from Southern Han<sup>19</sup> and the category of Mainlander (13%) may reflect genetic traits of both Han Chinese and the rest of other ethnic groups (*Minzu*) in China. Since, except for Taiwanese aborigines (2%), the other three ethnic categories - Hakka, Hoklo and Mainlander - may more or less trace their

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<sup>18</sup> A-Chin Hsiao, *Contemporary Taiwanese Cultural Nationalism* (London: Routledge Press, 2004).

<sup>19</sup> Geographically divided by the Yangzi River in China, Han Chinese can be categorised broadly as Southern Han and Northern Han. Interview with a medical geneticist, Taipei, 2009.

ancestral origins back to the Han Chinese gene pool, the implication of their genetic variation on the population sampling for the biobank is not without controversy.

An argument focuses on Taiwanese Austronesian roots emphasising that even though only 2% of the population in Taiwan are aborigines, the aboriginal groups have the most unique genetic traits compared with the majority Han Chinese gene pool that covers 98% of the population in Taiwan.<sup>20</sup> However, for some scientists, even among the subgroups of Han Chinese, the genetic differences between Hoklo and Hakka would have been developed as a result of genetic evolution influenced by different environmental exposures. According to Chen Yuan-Tsong, since every specific ethnic group has unique characteristics in the gene pool, even though the 1.5 billion Chinese around the globe may all trace their genetic roots back to the same source, the genetic makeup of people in Taiwan may have been through changes induced by different historical paths and circumstances such as local customs and habits that could have impacted on variations in gene expression.<sup>21</sup> This viewpoint is echoed by Chen Chien-Jen, who has explained the reasons why there is a genuine need to establish a biobank devoted to Taiwan and why using the category of the four ethnic groups for population sampling seems to be acceptable.

We know that even though Hakka and Hoklo speak different dialects and perhaps their living habits are quite different as well, in terms of genetic composition, they may be broadly categorised into the Southern Han Chinese gene pool. But would it be possible that we might find some particular genes which associate with a specific disease among them? At least, from the research by far we have found out that the susceptibility to nasopharyngeal carcinoma is about two times higher in Hakka than in Hoklo. I would say it may still be useful to adopt the category of the four great ethnic groups to sample the population as for geneticists, their difference may not be reduced to language and culture. Besides, even for people within each group, their ethnic backgrounds might be slightly different, not completely the same. (Interview with Chen Chien-Jen, Taipei, 2010)

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<sup>20</sup> Peter Bellwood, "Formosan Pre-History and Austronesian Dispersal," in *Austronesian Taiwan: Linguistics, History, Ethnology and Prehistory*, ed. David Blundell (Berkeley, CA: University of California Press, 2000).

<sup>21</sup> Supra note 14

In the biobank project, neither the Han Chinese nor the Taiwanese aborigines was singled out as a special gene pool for the project's research design. It demonstrates that the biobank in Taiwan plans to address not only the genetic distinction between Han Chinese and Taiwanese aborigines but also among the subgroups of Han Chinese gene pool, or even within the subgroups, namely to study the genetic variation among individuals themselves. Since every ethnic group and even each individual has its own uniqueness in its gene pool, a population biobank designed for Taiwan is regarded by the supporting scientists as a valuable facility for supporting genomics research for the ultimate goal of personalised medicine.

Nevertheless, even though the population biobank aims to represent the genetic composition of the population in Taiwan, throughout history, who the *Taiwanese* are has never been an easy question to answer. The complexity derives not only from the ambiguous international political status of Taiwan but also due to fluid self-identification criteria influenced by daily Taiwanese social and political experiences.<sup>22</sup> For instance, a traditionally-categorised Hakka or Hoklo might be willing to be self-identified as not only local Taiwanese but also Han Chinese in a broader sense. By the same token, a second or third generation Mainlander may choose to identify her or himself as Taiwanese and Chinese. Since the "four ethnic groups" is a socially constructed criterion, it is inevitably influenced by people's self-identification that does not necessarily correspond to their biological traits. As a result, a question such as whose genes may represent the Taiwanese population and its sub-divisions turns out to be an open one as it is unavoidably influenced by various factors outside the scientific arena.

Nevertheless, such an identity configuration inevitably influences the biobank's research design and researchers' perceptions about the diversity of the Taiwanese population. For instance, for sampling recruitment, in order to know if a participant belongs to a specific ethnic group, it needs first to rely on that participant's self-identification about his or her ethnicity before any further research on genetics in biobanking can formally start. In practice, this self-identification is presented as an ethnic option for box-ticking on the questionnaire form which needs to be filled out by participants at sample collection sites.

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<sup>22</sup> More information about this argument, see: Melissa J. Brown, *Is Taiwan Chinese? The Impact of Culture, Power, and Migration on Changing Identities* (Berkeley and Los Angeles, California: University of California Press, 2004).

As a result, a participant's biological trait is not necessarily being fully reflected as the ethnic identity she or he claims or chooses to have. Despite the appeal of the genetic diversity of the Taiwanese population to some scientists, to what extent this strength may be presented effectively through the research design remains a question. At the same time, it challenges the feasibility of using the biobank to study the interaction of gene and environment among different ethnic groups as the scientists originally planned.

### **4.1.3 Household Registration and National Health Insurance Databases**

#### **4.1.3.1 The Household Registration System**

In addition to genetic diversity, the family data and medical history of all the nationals provides another favourable condition for establishing a population biobank in Taiwan. A pedigree or family tree can be used to trace gene transmission and biological characteristics from one generation to another. Unlike rare single gene disorders, common chronic disorders such as diabetes, cancers and heart disease are not controlled by single genes but by multi-factorial conditions that are often found to run in families.<sup>23</sup> Even though genes may not be easily changed, it is easier to impact their expression by controlling other factors such as lifestyles and environment. As a result, linking family history with data of these common chronic disorders will especially empower a biobank and it is also the first step toward preventive medicine.

In Taiwan, obtaining a national ID card requires proper household registration. However, unlike the hukou system in China, the household registration does not function as a tool of government to control and manage residents' movement within the country. The system of household registration (hukou) in Taiwan can be traced back to the Japanese colonial period (1895-1945). The system was established in 1906 by categorising residents into two broad groups - local residents and temporary residents.<sup>24</sup> Even though the household survey was the responsibility of the police during that time, the household registration was mainly carried out by clerks of local Baojia authorities.<sup>25</sup> Invented in the Song Dynasty (960-1279) in the Imperial China, Baojia was a community-based system

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<sup>23</sup> More info, see: <https://www.migeneticsconnection.org/genomics/Family%20History/family%20history.htm> (Last visit: 08 March 2012)

<sup>24</sup> The system was introduced by Wang Anshi in his implementation of the seven-year New Policies reform.

<sup>25</sup> See, Frederick W. Mote, *Imperial China 900-1800* (Harvard University Press, 2003). pp 918-920



designed for law enforcement and civil control. The system gave “bao”, which was composed of several families, authority to maintain local order and organise civil projects so it could reduce central government’s financial burden of reliance on mercenaries by transferring responsibility of law enforcement from the central government to civil societies.<sup>26</sup>

The Baojia system was in operation in Taiwan even during the period of Japanese colonisation. Later, the Household Registration Act was enacted by the government of the Republic of China (R.O.C.) in 1931 but it had not been implemented in Taiwan until 1946 after Taiwan was restored to the R.O.C. government after World War II. According to the Act, household registration was governed by the civil administration authority. But in reality, since 1973 until 1992, household registration was under the supervision of the police authority in Taiwan.<sup>27</sup> In 1985 the computerisation of the household registration was initiated as a trial and after a decade the household registration data was fully computerised and it has been online nationwide since 1997.<sup>28</sup> The computerisation ensures that the household registration data can be archived in an electronic database that makes data sharing and linkage possible, even though it also causes anxieties about the infringement of privacy.

#### **4.1.3.2 The National Health Insurance Database**

In addition, Taiwan’s well-established national health care system covers about 99% of the population.<sup>29</sup> The National Health Insurance (NHI) scheme retains complete medical records of each registered national. As a single-payer social insurance scheme mainly funded by collective premiums, enrolling in the scheme is an obligation for all nationals in Taiwan who have household registration. The coverage of the system is broad enough to include various forms of medical treatments, from preventive checks, physical

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<sup>26</sup> Ibid. In Song Dynasty, the basic unit of a “bao” consisted of ten families. In the Ming Dynasty (1368-1644), the family was relabelled as a “Jia” and a “bao” usually consisted of ten Jia or one hundred families. Even though the structure of the system changed over time, the Baojia had been an important way of governance in Imperial China to hold the Chinese society altogether.

<sup>27</sup> More information about the history of the household registration in Taiwan, see: <http://www.ris.gov.tw/18;jsessionid=404867C80733D790AE07D6E6CC122FAD> (Last visit: 08 March 2012)

<sup>28</sup> Ibid.

<sup>29</sup> The National Health Insurance Statistics, see: [http://www.nhi.gov.tw/English/webdata/webdata.aspx?menu=11&menu\\_id=290&webdata\\_id=2974&WD\\_ID=290](http://www.nhi.gov.tw/English/webdata/webdata.aspx?menu=11&menu_id=290&webdata_id=2974&WD_ID=290) (Last visit: 08 March 2012)

examinations, laboratory tests to surgeries, medications, nursing and palliative care.<sup>30</sup> The health care system was established in 1995 and about 10 years later the Bureau of National Health Insurance (BNHI), which is under the supervision of the Department of Health, adopted the use of an electronic IC card to replace the previous paper-based health insurance card.

The chip embedded in the IC card stores the card holders' medical records that include data of medical test, treatment and prescription. As the card serves as the authoritative record of treatment under the National Health Insurance system, it records medical history data of all doctors' visits. The medical history information can be updated at any location where a card reader is available, such as any branches of the Bureau of National Health Insurance, city, town, village, or regional administrative office. However, access to a card reader is controlled in a way that it can only be operated after installing a security authentication module. A mutual recognition system requires doctors to use their health professional card to access the data stored in the readers.<sup>31</sup> Like the system of household registration, the computerisation of the national health insurance scheme provides Taiwan with a well-established health sector database that stores a comprehensive medical history of each individual national. Associated with genetic diversity, the two electronic databases of household and medical history offer a competitive condition for Taiwan to establish its population biobank. Because of these advantages, some scientists and pharmaceutical industries started to lobby the government that a population biobank will be a worthwhile investment that can help Taiwan improve its scientific research and biotechnology development by mining its abundant genetic resources.

#### **4.1.4 Bioinformatics**

The progress of research on bioinformatics in Taiwan is reflective of Taiwan's biotechnology development. With a hope to make use of biotechnology industries to propel Taiwan's economic growth, the government has systematically supported education in bioinformatics since 1990. In addition to setting up the Bioinformatics

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<sup>30</sup> Ibid.

<sup>31</sup> More information, see: [http://www.nhi.gov.tw/English/webdata/webdata.aspx?menu=11&menu\\_id=594&WD\\_ID=594&webdata\\_id=3173](http://www.nhi.gov.tw/English/webdata/webdata.aspx?menu=11&menu_id=594&WD_ID=594&webdata_id=3173) (Last visit: 08 March 2012)

Research Centre at Yang-Ming University in 2001 which was then the largest bio-computing resource in Taiwan,<sup>32</sup> the National Science Council (NSC) founded about 50 short-term granted programmes to encourage incentives for bioinformatics research in the same year. Several undergraduate programmes were established with the funding support of the NSC in 2002.<sup>33</sup> Furthermore, a coalition research network was established together by the National Health Research Institute (NHRI), the National Centre for High Performance Computing (NCHC) and three national universities.<sup>34</sup> This consortium aims mainly to coordinate resources and collaborate to build up a bioinformatics infrastructure for Taiwan. Even though the mature IT environment is beneficial for the establishment of a biobank, the biobank itself can also stimulate related industry growth.

For biobanking, it also requires a sophisticated IT system to support its operation. The IT system in biobanks is generally composed of two major parts. One is the core computing system designed for the management of sample collection and storage. It includes an information system for data transportation and software programs supporting anonymity of data and long-term tracing of coded samples. The other is a peripheral software that supports management of documents, standard operating procedures (SOP) and systematic automatic operation etc.<sup>35</sup> Taiwan's strength in information technology manufacture effectively backs up bioinformatics - the application of statistical knowledge and informatics in life sciences. As a biobank produces useful genetic information, the government hopes to make the most use of the biobanking project not only for the improvement of public health in Taiwan, but also for the advance of the country's competitive edge in the global bio-economies.

## **4.2 Building the Biobank**

### **4.2.1 Agencies and Facilities**

Taiwan Biobank is designed as a prospective cohort study which plans to collect about 200,000 blood samples and personal health information from voluntary participants aged 30-70. Although a consensus was reached in the National Science and Technology

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<sup>32</sup> Sara Harris, "Biotechnology: The Next Engine of Growth for Taiwan's Economy?" (European Molecular Biology Organization (EMBO) Reports, 2002).

<sup>33</sup> Ibid.

<sup>34</sup> Ibid.

<sup>35</sup> Supra note 17, P. 17

Conference that there is a need to build a large-scale population biobank, the term “Taiwan Biobank” had never appeared as an official name for the project until the Department of Health started to request implementation proposals and to use this term on its documents. However, two years before this biobank project was formally proposed by the Department of Health in April 2005, the National Science Council, one of the eight ministries under the Executive Yuan which is responsible for promoting S&T research, had already proposed a feasibility study to establish a genetic database for Taiwanese genes and disease. This feasibility study which aimed to collect about 1,000 human samples during a period from August 2005 to 2007 is a sub-project under the National Research Program for Genomic Medicine (NRPGM), a national priority program launched by the NSC in 2002.

The goal of this NRPGM project is to act as an “initiator” for Taiwan’s biomedical research and to increase Taiwan’s competitive advantages by capitalizing knowledge acquired through the studies of genomics and bioinformatics.<sup>36</sup> As a result, several core facilities have been set up by the project. For example, the National Clinical Core for Genetic Medicine (NCC) is an infrastructure for research on pharmacogenetics in Taiwan.<sup>37</sup> In order to understand the drug responses on the complex diseases, the NCC established a Han Chinese Cell and Genome Bank which collected 3,380 samples from voluntary non-aboriginal Taiwanese citizens.<sup>38</sup> The sample collection for this small-scale database was completed in 2005. Used as a control group in comparative studies with diseased people, this small-scale population database planned to map single-nucleotide polymorphism (SNP) markers of Han Chinese in Taiwan for gene-disease association.<sup>39</sup> Even though the database sampled only Han Chinese and so was not reflective of the entire genetic profile of the Taiwanese population, it commenced a preliminary experiment for the establishment of a population biobank for genomics research in Taiwan.

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<sup>36</sup> See, <http://nrpgm.sinica.edu.tw/en/content.php?cat=agtc> (Last visit: 08 March 2012)

<sup>37</sup> See, <http://db1n.sinica.edu.tw/textdb/nrpgm/webFile/1193392689.pdf> (Last visit: 08 May 2012)

<sup>38</sup> As the database aims to collect samples from Han Chinese, one of the sampling criteria is that participants, aged above 20, need to have “no parents and/or grandparents of aboriginal or foreign descent” See, [http://ncc.sinica.edu.tw/han-chinese\\_genomebank/about03\\_e1.htm](http://ncc.sinica.edu.tw/han-chinese_genomebank/about03_e1.htm) (Last visit: 08 March 2012)

<sup>39</sup> More information, see: [http://ncc.sinica.edu.tw/han-chinese\\_genomebank/about01\\_e1.htm](http://ncc.sinica.edu.tw/han-chinese_genomebank/about01_e1.htm) (Last visit: 08 March 2012)

In 2003 the Institute of Biomedical Sciences (IBMS) at the Academia Sinica was commissioned by the National Science Council (NSC) to formally execute the feasibility study for the biobank project funded under the NRPGM. Even though no real samples had been collected, scientists at the IBMS took this opportunity to plan out the whole operating procedures involved in sample collection for the subsequent establishment of the Taiwan Biobank. With this earlier experience obtained in participating in the feasibility study, when the Department of Health announced this biobanking pilot project two years later, the scientists of the IBMS started to organise a preparatory team and submitted a joint proposal for bidding for the project. The team won the bid as the sole bidder and this preparatory group acted later as the biobank cooperative team responsible for designing and executing the whole pilot study. Even though both the feasibility and the pilot studies were executed by the same group of scientists at the IBMS, Academia Sinica, the two projects appear in different formats. The feasibility study is more like a research project funded by the NSC; so strictly speaking, it had not yet become a formal plan of the government. In Taiwan, researchers and academics are encouraged to propose their plans of study to the NSC for grant application. If a plan is approved, the NSC will support the requested funding for research. Compared to the feasibility study, the pilot study announced by the Department of Health is a preliminary government plan, the budget of which comes from its upper scheme - the Biomedical Island Project. As it was a pilot government plan, an open bidding procedure set by the Government Procurement Act needed to be followed in order to decide who the executors were.

The original plan held by the IBMS was to implement this biobanking project by making the most use of the resources at the Academia Sinica.<sup>40</sup> Therefore, in addition to the expertise in molecular biology and epistemology that the IBMS already holds, other institutes at the Academia Sinica would be expected to provide assistance in the overall project design. For example, the Institute of Jurisprudence might help in planning out a regulatory framework and the Institute of Information Science could assist in setting up a sophisticated information and management technology which is crucial in biobanking. However, in the end, the project did not really follow this original plan. On the contrary, rather than unified execution by the Academia Sinica, the pilot study of the biobank

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<sup>40</sup> Interview with scientists at the IBMS, Academia Sinica, Taipei, 2009

project divided itself into four subdivisions - the Medical Genetics, the ELSI (Ethical, Legal, and Social Implications), the Information Technology and the Industrial Application. Except for the Medical Genetics group which is under the IBMS, the other three divisions were in charge of the following organizations and institutes respectively: the Medical Professionals Alliance in Taiwan (MPAT) for the ELSI group, the Institute of Information Industry (III) for the IT group, and the Development Centre for Biotechnology (DCB) for the group of industrial application. A preparatory office is set on the 8<sup>th</sup> floor of the IBMS building in order to coordinate these four groups.

This fragmented framework design has made the coordination of the project complicated. In addition, not every division has equal power in the overall decision making process. The Medical Genetics group of the IBMS has been in fact the main unit responsible for the major project design and its operation. The Taiwan Biobank Operational Office was established in 2005 in order to coordinate these four divisions. Even though the four divisions were responsible respectively for setting up operational frameworks involved in their own tasks, when different opinions existed, it was up to the Operational Office to reach resolutions and made final decisions. Chen Yuan-Tsong is the leading director of the Operational Office. Other members in the Office include Shen Chen-Yang, a co-director of the biobank project, a PI from the ELSI division, two representatives from IT and biotech industries, and two other members with the background of management of information technology.

According to the pilot study proposal for the biobank, the Medical Genetics division is mainly responsible for planning out the operating procedures concerning recruitment, sample collection and storage, and questionnaire design. The expectation was that after completing this pilot study in four years (2005-2009), approximately 15,000 (out of 200,000) samples would have been obtained. In addition, in terms of facilities, there are two laboratories located in the IBMS specially prepared for this biobanking pilot study. One is a laboratory for sample storage that includes eight freezers set at -80C and four vats of -196C liquid nitrogen, the current lowest temperature equipment for sample storage at the IBMS. As to capacity, one freezer can store about 28,800 samples and one vat of liquid nitrogen 58,968 samples. As a result, in order to reach the final goal of collecting 200,000 samples from Taiwanese people, the biobank will need to have at least

86 freezers and 40 vats of liquid nitrogen. Besides the storage equipment, the other lab is equipped with a DNA extractor through which DNA can be extracted from blood. However, in addition to basic quality check (QC exam), no further DNA analysis is allowed to be conducted at the pilot study stage.

As for the personnel, about 25 to 30 staff members have been recruited to work full-time for the project. Most of them are research nurses and medical technologists responsible for sample collection. Even though at the current stage, no full-time researchers and scientists are recruited specially for the project, the scientists at the IBMS have provided a large amount of assistance to the project, especially for questionnaire design and data standardisation. Moreover, even though the IBMS has the necessary equipment, it has also considered the possibility of transferring the operation of the biobank to other research institutes, for instance, the National Health Research Institute (NHRI), after the biobank was established. For this reason, the IBMS has tried to keep the pilot study project as independent as possible in terms of both its personnel and key facilities.

Another concern came from the challenge that questioned the initiatives of the biobank project. It was said that the project was designed particularly for the scientists at the IBMS who need this large-scale biobank to support their own research projects which require an adequate amount of samples for analysis.<sup>41</sup> In order to ease such worries, especially when the two principal investigators of the biobank project are also leading scientists at the IBMS, the biobank office guaranteed that this pilot study will be operated independently from any other research projects under the IBMS.<sup>42</sup> The attitude of the IBMS toward the biobank, according to the project directors, is to provide service for the government.

We all have our own regular research work to do so that is why I said it is just like providing service. It is a task “demanding a great deal of efforts but cannot even please the public.” (there is a Chinese proverb: “吃力不討好” *Chi Li Bu Tao Hao*.) We do this because we truly

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<sup>41</sup> Interview with an anonymous informant, Taipei, 2009

<sup>42</sup> For this reason, the pilot study has its own independent set of facilities. A specific operating office was set up in particular for the pilot study. The office recruited six full-time staff members working for matters of operation preparation - two of them are responsible for laboratory work, two for sample collection and the other two for questionnaire design. Each of them has a background in microbiology or epidemiology in graduate level.

think and hope that this project will benefit future generations and will lead to improvements in developing preventive medicine. Some social scientists criticize that the biobank seems to be a project designed tailoredly for Director Chen<sup>43</sup>, but just as he (Chen) has been saying that one day when the results of this research finally come out, we (refers to Shen himself and Chen) even don't know where we will be then. (Interview with Shen Chen-Yang, Taipei, 2009)

Shen had used the term “providing service” to explain the relationship between the IBMS and the execution of the biobank project. Even though the Taiwan Biobank was originally intended to run for 20 years, the budget and capacity has remained a challenge. The budget (about NTD 300 millions) funded by the DOH could only sustain the pilot study for four years from 2005 to 2009. After September 2009, whether the budget from the DOH would continually be granted was still not certain during that time. As the budget needs to go through reviews at the Legislative Yuan (Parliament), one condition for continuing the budget also depended on whether the pilot study executed by the IBMS had complied with the ethical norms and standards set up by the Institutional Review Board (IRB) of the Academia Sinica. In addition, according to Chen, the IBMS might not be able to keep running the biobank in the long run because of the project's ambitious goal of collecting 200,000 samples. One reason for this is due to the spatial capacity. The IBMS now has only two buildings (called “Old Building” and “New Building”) at the campus of the Academia Sinica but they need to accommodate over 800 personnel, including 56 full-time and adjunct principal investigators, 61 postdoctoral fellows, 472 administrative and technical staff, and 282 graduate students.<sup>44</sup>

#### **4.2.2 Ethical Puzzles**

The Taiwan Biobank is expected to revolutionise Taiwan's public health system and the biomedical research environment. However, rather than being merely a repository of bio-specimens and genetic data, this biobank had also provoked anxiety, confrontation and even distrust in Taiwanese society. Much criticism of the project was particularly concerned about issues of inadequate consent, privacy infringement and the lack of

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<sup>43</sup> Director Chen Yuan-Chong is a leading scientist in the area of pharmacogenetics. Chen returned back to Taiwan in 2000 from the United States where he obtained his doctorate in Genetics from the Columbia University and thereafter had been working for the Duke Medical Centre over 30 years.

<sup>44</sup>See, <http://www.ibms.sinica.edu.tw/pages/intro/index.php?id=04> (Last visit: 08 March 2012)



public deliberation. At the beginning of 2006, a few months after the IBMS formulated its proposal for implementing the biobank pilot study, an article published in a Taiwanese newspaper by a lawyer from the Taiwan Association for Human Rights (TAHR) severely challenged the initiatives and purposes of establishing this large-scale biobank in Taiwan and claimed that the pilot study had severely violated due process in its sample collection.<sup>45</sup>

However, this condemnation was later proved to be a false charge as the writer confused the biobank project with another cohort research operated earlier by the IBMS that required blood collection from participants as well. Although some clarification was given by its two principal investigators, the biobank plan was for the first time exposed under the spotlight. For the executing scientists, since the project was still at its very preliminary stage that limits the degree of transparency to a certain extent, they thought that this article had a negative influence on the public perception of the project. However, for the human rights association and some opposing social scientists, this approach toward setting up a large-scale population biobank provoked their doubts about the project from the very beginning as it had never gone through public debate and serious discussion among the public. In addition, all the relevant rules and regulation about the biobank were still absent in Taiwan. This caused distrust in the project and further deteriorated relations between the project and the groups who opposed it.

The major problems lay in the issue of transparency and the potential commercial interests behind this ambitious project. According to the critics, the project should make itself more transparent about these issues and initiate public engagement to obtain its own legitimacy even if such an attempt would not be an easy task.<sup>46</sup> For the human rights advocates, the key issue is whether there is a way for the public to be involved in every process of decision making.<sup>47</sup> According to them, whether this biobank is a “must-do” project has never been seriously discussed and debated among society in Taiwan. However, as this project is funded completely by the government and has made use of a great amount of public resources, it should be viewed as a public issue in society

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<sup>45</sup> Chao-Chun wang, "Taiwan Biobank Project Beat the Gun? Taiwan Association for Human Rights Call for the Halt," *Yam News*, 23 January 2006.

<sup>46</sup> Interview with an EGC member, Taipei 2009

<sup>47</sup> Interview with human rights lawyers, Taipei 2009

rather than simply a research plan that can only be understood and discussed among a group of scientists in their labs.<sup>48</sup>

Debates over the issue of transparency and public trust had suspended the pilot study project right at the beginning and it was not able to resume until after approval from the Institutional Review Board (IRB) of the Academia Sinica. Since the IBMS - the executing agency of the biobank - is an institute of the Academia Sinica and the biobank project involves research on human subjects, according to the guideline stipulated by the Department of Health, this pilot study needed to obtain permission from the Academia Sinica's IRB before commencing its sample collection. The IRB of the Academia Sinica was formed in October 2004, comprising 16 members. It is a mechanism planned to review, approve, and supervise biomedical and clinical research involving human research subjects in order to make sure research does not violate bioethics.

The pilot study proposal was first proposed by the biobank team to the IRB for review on 14 May 2007. Nevertheless, an unexpected delay occurred and a decision had not yet been made by the IRB until a year later. At its sixth meeting on 19 May 2008, the IRB ultimately made an approval decision on the pilot study with a condition that an Ethics and Governance Council (EGC)<sup>49</sup> needed to be set up.<sup>50</sup> On the IRB's conditional approval it stated that in order to seek a greater social legitimacy of the biobank, an EGC should be established and be responsible for the supervision of the biobank project. The rationale behind this decision is that compared to the EGC, the IRB itself is still a review board of the Academia Sinica, so it is not an ethical review mechanism designed mainly for the biobank supervision. According to the contents of the conditional approval, the EGC has a duty to report back to the IRB about its operation every six months. However, whether the pilot study project is allowed to commence and start its sample collection is a decision which remains to be decided by the EGC.

Nevertheless, another issue being raised was regarding how and by which procedures this EGC could be set up. An important rationale concerning forming the EGC is based on the idea of modern democracy. That is to say, who decides by which standards the rights

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<sup>48</sup> Ibid.

<sup>49</sup> This Ethics and Governance Council was also funded by the Department of Health from its original budget for the pilot study of the Taiwan Biobank.

<sup>50</sup> Interview with an ELSI scholar, Taipei, 2010

of access of the biobank can be granted is a question that needs to be justified. Unlike the IRB which is an institutional supervision mechanism, the EGC is composed of members selected from among society with different backgrounds so it may be regarded as a representative of “the public” and therefore its decision seems to be more legitimate than that be made by the IRB. Even though a consensus was reached that the EGC should be set up, its forming process opened another prolonged journey. In fact, it took about eight months for the Selecting Committee of the EGC to nominate and vote for the final 19 members to form this governance council.<sup>51</sup> According to the original plan supported by the IRB, the members of the EGC should be nominated together by the Academia Sinica and the Department of Health. Because the department is the funding agency of the biobank project, its responsibility of supervising the execution of the project is a way to fulfil the requirement of political accountability. However, this original plan was not carried out and it was finally replaced by another selection process of “two-stage nomination,” namely it was the IRB who initially nominated a group of people who would serve as a search committee and from which the final 19 members of the EGC was later recommended and selected.<sup>52</sup>

In fact, after the IRB released its conditional approval in May 2008, in order to meet the requirement of setting up the EGC, the ELSI group of the biobank pilot study had suggested a list of candidates to be nominated as the members of this EGC. The original idea supported by the ELSI group was to invite some principals of universities to set up an association called the Principal League and then use this League to act as the EGC to supervise the pilot study as well as the biobank’s operation later on.<sup>53</sup> In the view of the ELSI group, the Principal League which was composed of five university principals and one former Minister of Education should have been able to reach a required reputation to call for the public’s attention to monitor the project and therefore to assure the check and balance function. But this idea was not accepted by the IRB and the Department of Health. Wishing to follow the governance framework developed by the UK Biobank, the IRB required that the EGC should have at least some kind of independence and only by which it could function well on its own responsibility.

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<sup>51</sup> Interview with IBMS scientists, Taipei, 2009

<sup>52</sup> Ibid.

<sup>53</sup> Interview with an ELSI scholar, Taipei, 2009

As far as the IRB was concerned, in order to win the public trust, the selection process of the EGC should be transparent and open. In addition to supervising the project, the EGC is also expected to play a role in communicating with the public in order to bridge the gap between science and society. However, the ELSI group of the project have demonstrated its concerns that the EGC may become a terrain for human rights groups to accumulate social capital by boycotting the project completely.<sup>54</sup> Such concern reflects the fact that the communication between the biobank and society has not been ideal. For human rights advocates, if the biobank has become a project which will be carried out in any event, there seems to be not much space for further discussion with scientists.<sup>55</sup> As direct communication seems not to make sense, the human rights groups have turned their attention to the media and hope to use public pressure to supervise the project. For scientists, this kind of reaction may have made public trust in the project become even more vulnerable. Once the feeling of distrust emerges, it will make the project more difficult to fulfil in the end.<sup>56</sup>

In order to set up the EGC, a representative board was initially created. The board consisted of three members from the IBMS and four members from the IRB and it recommended and appointed the Selecting Committee of 12 members.<sup>57</sup> The Committee then voted for the 19 members to form the EGC on 21 January 2009. The EGC members had their first meeting a month later in March 2009. Since the forming process had been slow, the biobank team and the Department of Health requested the IRB of the Academia Sinica to temporarily act in place of the EGC to supervise the pilot study until the EGC had been established.<sup>58</sup> At its meeting in June 2008, the IRB reached a decision agreeing to temporarily execute the duty of the EGC. However, the detailed ethical review for the biobank project, including whether or not to permit genetic analysis still waited for the decision made by the EGC after its formation. Five months later, at its meeting in November 2008, the IRB reviewed and permitted the biobank pilot study to start its sample collection of 1,000 participants at its already established two sample collection sites - one in Chia-yi city and the other one in Tainan, both of which are in the southern part of Taiwan. Before this approval, in order to test the whole design of the process for

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<sup>54</sup> Ibid.

<sup>55</sup> Interview with human rights lawyers, Taipei 2009

<sup>56</sup> Interview with IBMS scientists, Taipei, 2009 and 2010

<sup>57</sup> Ibid.

<sup>58</sup> Ibid.

sample collection for the project, collection sites had been set up but no blood was allowed to be taken.<sup>59</sup> These collection sites were located in hospitals even though the nature of their work (sample collection) is not really affiliated with these hospitals.

This decision later caused much criticism as during that time the relevant governance framework of the biobank was still absent and the EGC was not yet set up. Because of the prolonged ethical review procedure, the pilot study originally designed as a four year project running from 2005 to 2009 had been forced to delay its execution. The period of execution was later extended a year until the end of October 2010. However, the amount of the budget allocated by the Department of Health remained the same. Since the budget for the four year study now needed to be used for the execution period for five years, this hampered the biobank plan from the beginning of its pilot study stage.

After the EGC was established, several meetings were held to review and discuss the biobank project.<sup>60</sup> A question remained whether any further sample collection could be allowed in addition to the 1,000 samples permitted to be collected by the IRB before the EGC was formed, taking into account the original goal of collecting 15,000 samples for the pilot study. At the meeting on 3 May 2009, the EGC reached a decision to permit sample collection in the areas of Yunlin, Chiayi and Tainan by a vote decision of 11-7. This decision was criticised heavily by some EGC members as a violation of the consensus-based decision-making they agreed on in their earlier meetings.<sup>61</sup> In addition, some controversies about substantial issues of biobanking were still unsolved. For instance, some EGC members criticised that there were still around 30%-50% of the participants who misunderstood the project as a health check which demonstrated the inadequate endeavours of the biobank team to communicate with the public.<sup>62</sup>

After the EGC reached this decision, a press conference was organised by an EGC member and a legislator in order to call for more public awareness and attention on the biobank project. A website was consequently set up as a means of pursuing “the national people’s

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<sup>59</sup> Ibid.

<sup>60</sup> The meetings were held on 19 March, 3 May and 28 June in 2009. More info, see: Control Yuan Report released on 15 October 2009.

<sup>61</sup> Interview with an EGC member, Taipei 2009

<sup>62</sup> Supra note 60.

supervision of the Taiwan Biobank.”<sup>63</sup> Influenced by the press meeting, the attitude of the Department of Health toward the establishment of the biobank project turned to being more cautious and concerned when its minister was questioned at the meeting of the general enquiry at the Legislative Yuan. In responding to a legislator’s enquiry about the biobank project, the head of the Department of Health made a clear statement that so long as the project violated human rights, the department would not continue supporting this biobanking project. The biobank plan was therefore put into the public spotlight again and it now undoubtedly needed to move out from the laboratory to go through scrutiny from society in order to obtain its own legitimacy.

#### **4.2.3 The Complexity of the Governance Framework**

The dual-track governance by the IRB and the EGC made the supervision of the biobank in Taiwan prolonged and complex. Controversies emerged due to the vague and unclear relationship between these two institutions. For example, it was not obvious whether a decision made by the EGC was binding for the IRB, or in case the two institutes held different opinions on their ethical reviews, which institute should have a final say in terms of the biobank governance. Because the EGC was formed solely based on the request of the IRB, its position remains ambiguous. Divergent opinions existed even among the 19 EGC members. For some members, the EGC should act independently to supervise the biobank and safeguard participants’ rights. For the others, the EGC should not play a role in hindering the project but help the biobank to reach its necessary ethical and legal requirements to move forward. A consensus was hard to reach based on these fundamentally divergent viewpoints. Since it had never been an issue to be publicly debated and discussed whether Taiwan needed a biobank, the debates unavoidably revolved around the essential issues of the biobank legitimacy, whenever the EGC reviewed and decided whether to commence the pilot study. This caused the project’s development to become unpredictable. Furthermore, it postponed the progress of the biobank pilot project.

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<sup>63</sup> More info, see the website: <http://biobankforum.blogspot.com/> (Last visit: 07 March 2012) However, there has been no more updates on the website since the latest article posted in April 2010. In fact, after the Human Biobank Management Act was promulgated in February 2010, there have been very few discussions about the biobank project in the Taiwanese society. The Taiwan Association for Human Rights seems to have switched its attention from the biobank project to other more appealing and important social issues in Taiwan based on the reason that the biobank project is now being able to be regulated by the newly-enacted Act.

The unclear relationship between the IRB and the EGC was later clarified in a Control Yuan report. Since the pilot study was a governmental plan but it had been delayed seriously in its execution, the Control Yuan initiated an investigation in 2009 to check whether the biobank team had any administrative defaults in its execution. The report released on 15 October 2009 expressed that in terms of the status, the EGC was not superior to the IRB because the EGC was requested to be set up to execute the IRB's own duty and it needed to report back to the IRB about its operation every six months. Based on this viewpoint, the EGC is not an independent agency but can only be regarded as a mini-IRB and therefore whenever there are conflicting opinions between the two institutions about the biobank supervision, the IRB still has the final power to decide. For some EGC members, this interpretation infringed the independent position of the EGC. Three months after the release of the Control Yuan report, the Legislative Yuan passed the Human Biobank Management Act on 7 January 2010.

The Act was enacted to regulate the establishment and operation of all types of biobanks in Taiwan. Even though the Act was initially proposed for specifically regulating the Taiwan Biobank, it can now be applied to all types of biobanks with a purpose to legitimise some already existing small-scale biobanks in research institutes and hospitals in Taiwan. Since the passage of the Act, the complex puzzle of the dual-track governance has temporarily been solved. According to the Act, the establishment of biobanks should be governed by an EGC set up from the biobanks' supervisory authority which needs to comply with certain criteria to be set up. For that reason, the EGC formed in January 2009 will not be expected to continue supervising the biobank project but another EGC needs to be established by the Department of Health according to the stipulation of the law. However, it also implies another prolonged process in terms of implementing this ethical review requirement.

Since the initiative of the pilot study in 2005, the main issue that has been raised and discussed about the biobank project has been how to set up a suitable governance framework for the establishment and management of the biobank. Because the biobank plan was designed to ultimately collect 200,000 samples from Taiwanese populations, this great amount of sample collection and storage requires a well-established governance framework for its long-term sustainability. In Taiwan, however, when the

idea of the biobank was initiated, relevant rules and regulations were still absent. The only rule about sample collection was the Ethical Guidelines for Research on Human Subjects released by the Department of Health in 2007. But these guidelines are only an administrative order so they have no imposing sanction on the enforcement. In addition, since the blood and samples contain genetic information that is not only personally identifiable but can also be identifiable to a research subject's family and ethnicity, the requirement of data protection on the biobanking was deemed to be urgent and imperative.

The Human Biobank Management Act was enacted under this background. It is designed as a specific regulation on biobanks with the purpose of conducting genetic-related biomedical research. Like the biobanking project itself, the Act represents an image of power negotiation and compromise among a variety of actors and agencies in order to reach a balance between the production of scientific knowledge (and biovalue) and the protection of research subjects. For example, the scientists of the IBMS, human rights advocates of the TAHR, indigenous participants, the IRB of the Academia Sinica, the EGC of the pilot study, and ELSI groups both inside and outside of the biobank team all participated. These different agencies constitute a governance framework with Taiwanese characteristics. It shows that even though self governance such as the mechanisms of IRB and peer reviews among scientist groups may be effective in some countries, in Taiwan, formal legal rules are still placed at a paramount position in terms of biomedical governance. How does this respond to Taiwanese culture and milieu?

Looking in depth into the formation process of the Human Biobank Management Act, it illustrates that an emerging social energy from the bottom-up is gradually strong enough to challenge and transform the formation of a top-down biotech plan. This also explains Taiwanese democratic transition to some extent, and therefore, a government policy has to go through the scrutiny from the public in society in order to obtain its own legitimacy. Even though that whether the biobank project will be successful or not depends on many factors, the support from the public should be placed at the foremost. Without a trust relationship, a biobank is threatened to fail as several cases around the globe have illustrated. In Taiwan, as the biobank is a solely government funded project, the Department of Health needs to face seriously all the challenging voices from society. In the four year pilot study, however, who should be responsible for the biobank plan has



been a mystery. The government holds itself back based on the position that the plan is still in its pilot stage. For that reason, most of the time, the executing scientists are pushed to respond to critical enquiries from the society. However, for the scientists, they seemed to have held a view that the requirement for public communication is also beyond their remit. Since no agency was willing to stand up and tell the public in a responsible way why Taiwan needed a biobank and why now; then openly call for the public's discussion about the plan, the biobank pilot study has staggered along the way in its early four year development.

### **4.3 A Co-Productive Perspective on Biobanking**

As Sheila Jasanoff argues in her book *Designs on Nature*, the notions of modern democracy, such as deliberation, citizenship and accountability can only be better understood in a broader context of the politics of science and technology.<sup>64</sup> She uses the notion of “co-production” to describe the mutual interaction between science and society. Although the development of science may bring significant implications to society, the existing political and cultural structures in the society will feedback to science in a process of policy formation and by political narratives. For Jasanoff, the notion of co-production provides a perspective which may be used to comprehend the dynamic interface of scientific knowledge and social order. In so doing, a new discourse of the politics of science and technology may be produced that will provide an opportunity to represent identities and institutions which are embedded in the narratives of the science and technology policies.

Jasanoff adopts this co-production perspective to explain in detail how the US, British and German governments and their people are coping with several biotechnology innovations, such as embryonic cell research and genetically modified food, etc.<sup>65</sup> Although the governments in these three countries are in favour of promoting biotechnology advances, the perceptions of the public in these three nations toward the S&T policies have been very different because the historical and cultural contexts vary. In the United States, based on its constitutional tradition and Congress' support of scientific and technological development, biotechnology has been reframed as a “product” which is regulated mainly

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<sup>64</sup> Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton, NJ: Princeton University Press, 2005). pp 7-9

<sup>65</sup> *Ibid.*, pp 152-155

by scientists' self-governance and technocrats' risk assessment. The result of this is the privatization of the decision making process and the narratives concerning S&T policies are easily framed by interest groups. On the contrary, biotechnology in the United Kingdom has been regarded as a "process" of public concerns. In order to promote public communication, the British government has been trying to make institutional innovations. However, due to the background of respecting British elite culture, the real practice of public participation in S&T decision making remains to be seen. Finally, Jasanoff argues that in Germany, biotechnology has been deemed to be a "program" by which the government and scientists work together in order to avoid the danger that the development of science will be used as a way to infringe human rights. It reflects Germany's deliberate and cautious attitude toward scientific research based on the successful strategy used by Germany's Green Party and the historical context of the lessons of the Nazi era. In order to ensure rational decision making, the German government adopts expert committees drawing up specific laws to regulate biomedical research. However, the government's conservative attitude toward scientific and technological development reflects the public's silence about the S&T policies in Germany.

For Jasanoff, even though the three governments have different attitudes toward biotechnology development, they all fail to propose a new discourse by which the opportunity of public involvement into the S&T policy formation can be reinforced. She further develops the term of "civic epistemology" to argue that in the process of knowledge formation, in particular of scientific knowledge, the public should not only be acceptors.<sup>66</sup> In addition, neither is scientific knowledge absolute and definite. To conclude, the public's perception toward new scientific and technological policies is influenced by various factors and elements which are embedded deeply in a broader historical and cultural context. Following this discussion, it may be worthwhile to ask: what are the politics of science and technology in Taiwan? Or the question may be further formulated in this way: what political and socio-economic contexts may be outlined in a theoretical way that provides a broader network of meanings where the observation of public attitudes toward the biobank project in Taiwan can be anchored? In the language of Paul Rabinow, it is to ask: what national characteristics can be delineated

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<sup>66</sup> Ibid., pp 249-256

to show “a reflection on the forms” of important events?<sup>67</sup> To answer these questions, technocrat governance seems to be a proper prism by which the deeper relationships among politics, S&T policy formation, and the Taiwanese society may be observed. Even though deliberative democracy and public engagement have been proposed by the ELSI group of the biobank project, these notions have not yet been fully materialised in the biobanking practices in Taiwan. The major obstacle to involving the public into the process of policy making lies in that Taiwan still lacks a strong tradition for public consultation in its development of science and technology policies. In addition, it is also worth exploring the role of the emerging society in Taiwan.

#### **4.4 The Politics of Trust**

##### **4.4.1 Public Engagement**

Public engagement is an essential ingredient in the process of biobanking. The rationale for public involvement in S&T policy formation is usually in two parts. One is for achieving ideal outcomes in rules and policy implementation; the other is for expression of rights of individuals and groups participating in the policy-making process.<sup>68</sup> Even though the establishment of the biobank in Taiwan may be viewed as a way to meet the common good, in this pluralist-values modern society it seems more and more difficult to keep an objective standard to decide what the common good of the society would be. For that reason, some mechanisms have to be deployed for making sure that different viewpoints on any matter can be fully expressed. A mechanism of public engagement is expected to be an ideal option to guarantee public trust and make sure that different voices may be taken into account. Participatory democracy has been proposed by the ELSI group of the biobank project as an important principle for the engagement of the public. Contrary to the traditional representative democracies that tend to rely on decisions made by politicians and limit citizens’ participation to voting, participatory democracy creates an opportunity for a bottom-up decision-making model as it creates the legitimacy of decision making coming from the participation of the citizenry. In Hannah Arendt’s words,

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<sup>67</sup> Paul Rabinow, *French DNA: Trouble in Purgatory* (Chicago: University of Chicago, 1999). pp 17-25

<sup>68</sup> D.J. Galligan, "Citizens' Rights and Participation in the Regulation of Biotechnology" (paper presented at the International Workshop: The impact of Biotechnology on Human Rights, European University Institute, Florence, 2004). P. 5

such participation is significant because this is not only a way for men to be heard and be seen, but also to excel and be remembered.<sup>69</sup>

The antiquity, especially the Greek polis, is the model for Arendt. She uses Greek experience as both the exemplar of her political dream and a standard by which postclassical experiences are judged. For ancient Greek citizens, citizenship meant first of all to be present at the citizen assembly (courts or clubs) since in these occasions they could talk, discuss, and make decisions.<sup>70</sup> The ultimate source of the Greeks' enthusiasm for the public came from their agony of death and their pursuit of immortality.<sup>71</sup> As argued by Arendt, the ability to act is the "exclusive prerogative" left by God to men that makes immortality somewhat possible.<sup>72</sup> Actions - or one can say "participation" in the current context - are very basic in the sense that they not only make men immortal, but "insert men into the human world" and make men be reborn.<sup>73</sup> Arendt's views of the political depict her ideal of participatory democracy. That provides us a profound platform for a review of public engagement in biobanking nowadays.

However, before further analysis, there is a need to clarify the notion of "public engagement" itself. As Sue Weldon has mentioned in her report for the UK North-West Genetics Knowledge Park (NOWGEN), the term "engagement" is often used interchangeably with such other terms as "dialogue" and "consultation."<sup>74</sup> However, she fails to argue that these three terms actually bear very different purposes. Like the practical guidelines that the Research Councils UK suggests, "public engagement" in the context of genomics research is stimulating interest in, and raising awareness of, science among the public. Under this definition, "engagement" is more like an informal, two-way interaction while the "dialogue" is being portrayed as an informal but multi-way one, and the "consultation" implies being formally instigated for a policy outcome.<sup>75</sup> These

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<sup>69</sup> Hannah Arendt, *The Human Condition* (Chicago: The University of Chicago Press, 1998). P. 49

<sup>70</sup> On the other hand, the private sphere seems to have been forgotten by the Greeks, and only been barely cared about by the Romans. The citizens, both Greek and Roman, were not expected to spend most of their time in the private sphere, for example, housekeeping and trades, and so on.

<sup>71</sup> Supra note 69, P. 18

<sup>72</sup> Ibid., P. 19

<sup>73</sup> "Word and deed "insert" men "into the human world, and this insertion is like a second birth."" Supra note 69, P. 18

<sup>74</sup> Sue Weldon, "Public Engagement in Genetics: A Review of Current Practice in the UK (a Report for Nowgen)," (Institute for Environment, Philosophy and Public Policy, Lancaster University, 2004).

<sup>75</sup> Research Councils UK, "Dialogue with the Public: Practical Guidelines," (2002). pp 41-42

definitions help us to understand that there are at least three different approaches to perform the interactions between the public and professional experts, who are often decision makers in law or related policies.

However, once the requirement of “public engagement” has been lifted to a higher standard, such as “participatory democracy” as the ELSI group of the biobank puts it, public engagement here seems to imply the possibility of creating something new. In this sense, public engagement is more like a formal process of policy creation rather than an informal mutual understanding between the experts and the public in its narrowest literary interpretation. This reminds us again of Arendt’s “second-born” reference and where her aspiration of freedom comes from.<sup>76</sup> For Arendt, the polis is an abstract concept that depicts a sphere wherein the people are acting and speaking together.<sup>77</sup> So, what matters for men who live in a polis is their “speech and act.” Participatory democracy presupposes the capability of the public and people’s willingness to take part in public matters. In John Dryzek’s words, participatory models of engagement imply that there is an opportunity for all parties to negotiate and reevaluate their position in the society.<sup>78</sup> Therefore, the fulfilment of participatory democracy is mainly based on people’s voluntary involvement, people’s speech and acts.

Another important aspect in public engagement involves the term “the public.” As addressed by Weldon, the public is no longer one homogenous entity.<sup>79</sup> The public constitutes a range of “publics,” which may share different interests and may not be mutually exclusive. For that reason, it may be worthy to discuss which “publics” in what capacity one needs to consider in evaluating engagement. In the case of Taiwan, however, individuals have been addressed as unitary users in the whole biobanking process rather than being addressed as members of wider social groups. For example, while talking about the basis of public engagement in the biobank, “local community” had been proposed as the basic unit in the process of enhancement of public trust. But even

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<sup>76</sup> Arendt’s idea of freedom designates the capability to participate rather than mere liberation. Arendt thought that the notion of liberty implied in liberation can only be negative. Therefore, the purpose of liberation should never be regarded the same as the aspiration for political freedom. See, Hannah Arendt, *On Revolution* (New York: The Viking Press, 1965). P. 29

<sup>77</sup> For Arendt, the polis is far from the “city-state in its physical location.” Rather, the political is born in the polis, among the acting people who share the words and deeds.

<sup>78</sup> Supra note 74

<sup>79</sup> Ibid.

though the idea recognizes the need to engage with representatives of local residential communities, it fails to justify such awareness while the target local community is particularly described as the “model community.” In fact, by doing so, an outcome of preference might have been “framing” the interactions with the public in particular ways while emphasizing the importance of joining the biobank project.<sup>80</sup> Such participatory design has kept itself away from appreciation of the freedom Arendt claims. While the “speech and act” are reframed, the freedom is limited — at most it could be the freedom of choice (yes/no option for the biobank), rather than the freedom of creation one pursues.

#### **4.4.2 Public Sphere and Civil Society**

The major obstacle to public engagement in the biobank case in Taiwan lies in the fact that Taiwan lacks a long tradition of community consultation in its development of laws and policies. In addition, it has been arguable whether a mature public sphere or civil society has been developed and functions well in Taiwan. Even though “public sphere” and “civil society” have been used interchangeably in a great amount of literature, strictly speaking, these two terms are not equivalent. To some extent, “civil society” is connected to the discourses of modern liberal democracy, but various meanings of this term are still deeply embedded in the historical context. But what is meant by civil society today? In general, modern discourses of civil society can be understood by three crucial components. The first perspective pays attention to the cultural dimension of civil society by which civil society is seen as a site of social contestation wherein collective identities, ethical values, and alliances are forged.<sup>81</sup> Under this perspective, the meaning of civil society is to form various values and identifications rather than repeating the established beliefs.<sup>82</sup>

The second view of civil society, however, arises from the observation of the radical part of social movements and informal networks. Initiative social movements respond to social concerns by generating new values and identities. The ultimate goal of this radical approach is not to seek reform within the polity but to reform “the institutions of civil

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<sup>80</sup> Ibid.

<sup>81</sup> Ted Fleming, *Habermas, Democracy and Civil Society: Unearthing the Social in Transformative Theory.*, ed. C. Wiessner, S. Meyer, and D. Fuller, *Challenges of Practice: Transformative Learning in Action* (New York: Columbia University, 2000).

<sup>82</sup> Ibid.

society itself.”<sup>83</sup> The last, but also the most influential perspective of civil society, comes from the discourse theory of Habermas. For him, the institutional core of civil society comprises those “nongovernmental and non-economic connections and voluntary associations that anchor the communication structure of the public sphere in the society of the lifeworld.”<sup>84</sup> Here, Habermas distinguishes between the concepts of “civil society” and “public sphere.” According to him, the public sphere is located in civil society and is where people can openly discuss matters of mutual concern with a status of equality.<sup>85</sup> Following this discussion, one may further ask: is there a civil society in Taiwan? Or we may put the question in this way: to what extent can this western-born notion be applied to Taiwan to explain its state and society relationship? Is there any limit of such adaption? What is the real implication when connecting discourses of civil society to the public engagement requirement of the biobank project in Taiwan? If civil society can be described as a confrontation of the power of the state that derives from the desire of individual protection, a civil society seems to have been emerging in Taiwan along with Taiwan’s democratic transition since the 1990s. However, this society has its own characteristics, one of which is its relationship with the concept of “public sphere.” For Habermas, public sphere refers to a public space that constitutes “a network for communicating information and points of view,” which finally transforms themselves into a public opinion.<sup>86</sup> Under this definition, public sphere presupposes an ideal speech situation in which consensus is possible and each individual is recognized as an equal and rational participant whose “communicative action” forms public discourse.

However, in Taiwan, which witnesses its democratic transition in an early stage, public opinion, in fact, still relies heavily on a formal legislative procedure in order to constitute a power of communication. The very difference lies in that, in the ongoing process of democratic transition, the existence of public sphere cannot guarantee that its outcome of consensus (if any) can necessarily become the basis of public policy or legislation. Therefore, the bottom-up voice may not be strong enough to legitimately transform itself to the status of a given right or entitlement which constitutes the core of the individual

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<sup>83</sup> More info, See: Partha Chatterjee, *The Politics of the Governed: Reflections on Popular Politics in Most of the World* (Columbia University Press, 2004).

<sup>84</sup> Jürgen Habermas, *Between Facts and Norms: Contributions to a Discourse Theory of Law and Democracy* (Cambridge: Polity Press, 1996). pp 366-367

<sup>85</sup> Supra note 81, P. 53

<sup>86</sup> Jürgen Habermas, *The Structural Transformation of the Public Sphere: An Inquiry into a Category of Bourgeois Society* (Cambridge, MA: MIT Press, 1989).

protection. A similar dilemma appears in the biobank case in Taiwan. Even though the concept of “public engagement” or even “participatory democracy” has been introduced to supplement the possible challenges of the technocrat-decision model, there is still a lack of formal mechanism that is capable of presenting the function of public sphere within the policy and legal regime. If the existing gap between rules formation and public opinion is an outcome not only of institutional design but also of a historical heritage, what does civil society really mean in Taiwan’s future implementation of its biobank project?

#### **4.4.3 Technocrat-Decision Model and Its Challenges**

The requirement of public engagement in the establishment of the biobank seems to have projected an important signal that the traditional technocrat-decision model may not be appropriate in today’s biotech era. In order to achieve public trust in biobanking, scientific experts are expected to tear down an invisible wall built between the public understanding of science and the scientific rationality held by experts. Public engagement presupposes the possibility of rational communication through which different opinions may be discussed and finally a consensus (if any) may be formed.<sup>87</sup> However, in reality, rational communication does not necessarily lead to a consensus formation. At most, rational communication refers to only a process but nothing beyond. Such process, in Arendt’s words, is a process trying to get rid of violence. But under what conditions can rational communication really relate itself to a consensus formation? For Habermas, consensus will be possible if and only if an ideal communicative situation exists. Several principles underpin this ideal situation, one of which is that each individual is entitled to an equal right to participate in dialogue. In addition, each participant should be able to sincerely express her or his opinions and be willing to rationally accept the “better argument” presented by others.<sup>88</sup>

However, this ideal situation ignores the existence of “information asymmetry” among communicators while the emphasis is focused on the “rationality”. Rationality itself may include “mutual understanding” that makes an objective evaluation of arguments become possible. Nevertheless, mutual understanding may not mitigate the problems of

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<sup>87</sup> Supra note 68, P. 9

<sup>88</sup> Jürgen Habermas, *Moral Consciousness and Communicative Action*, ed. trans., Christian Lenhardt, and Shierry Weber Nicholsen (Cambridge MA: MIT Press, 1990). pp 65-66



information asymmetry because, although open attitudes might be helpful to alleviate institutional infringement, it is eventually helpless in changing the underlying structure that contributes such infringement. Unfortunately, information asymmetry in terms of biobanks arises directly from the knowledge gap that is the core obstacle in public engagement. Knowledge itself, especially professional scientific knowledge, has its own power and authority. Such authority is by no means unchallengeable, but it may be easily legitimized by the modern technocrat-decision model. Public engagement will be possible if scientific experts and the public speak the same language in describing the unknown biotech future. However, one may find the limits of language under this scenario. Technocrat governance is not new to the modern era since the bureaucracy emerged in which one-man rule has transformed into no-man rule. In the case of biobanking in Taiwan, scientific rationality has been lifted to a somewhat irrational height wherein scientific experts are responsible for all the governance, including the initial decision of establishing the biobank. Public engagement has never played a crucial role in the biobank project even though it was proposed and discussed by the ELSI group of the project.

This policy reminds us to rethink Taiwan's technocrat governance. Since martial law was lifted in 1987, Taiwan's public sphere has been growing rapidly. Since 1949, when the KMT government came to Taiwan from mainland China, the major national policy in Taiwan has been evolving the core principle of "development." In the early years, the main purpose of such development was aiming to fight for an opportunity to return to the Mainland. However, since 1972, the year when the government of the Republic of China (R.O.C.) formally withdrew itself from the United Nations, the KMT government has not been able to legitimately claim its sovereignty over the Mainland. Since then, the purpose of the development plan switched its interests to local construction. Generally speaking, this development principle contains almost every aspect of the process of modernization, but the main focuses are in three interdependent schemes: infrastructure establishment, economic (land) reforms, and industrialization.<sup>89</sup> With a limited support of inner market and natural resources, the KMT government pays its major attention to the promotion of human resources.

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<sup>89</sup> *Taiwan's Economic Success since 1980*, ed. Chao-Cheng Mai and Chih-Sheng Shih (Cheltenham, UK Northampton, MA: Edward Elgar, 2001). pp 215-217

Obtaining higher education allows professional experts the opportunity to perform civil service in the governmental administration. To a certain extent, Taiwan's economic and industrial development has greatly benefited from this technocrat-governance model that covers from the beginning of policy formation to the later supervision of policy implementation. The Taiwanese government also enjoys the general advantages this technocrat-governance brings. The most obvious one is that the technocrat-decision model can form a national scheme in a very efficient way. Nevertheless, even though Taiwanese society had been used to this kind of governance, along with democratic transition in Taiwan since the early 90s, technocrat-governance has increasingly been challenged by scrutiny from society. Hopefully, public engagement for the biobank will be able to mark its significance in Taiwan's participatory democracy, even though the engagement scheme has not yet ripened during the current stage. After all, public engagement is valued not only for its instrumental effect in formation of the public good, but also for building a trust relationship between the state and society.

## **Conclusion**

For scientists, building a biobank seems to be a straightforward idea; nevertheless, along with the criticism that has grown among society, the scientific rationale has been forced to confront challenges coming from society. The puzzle at the heart of the biobanking story in Taiwan, as this chapter has argued, lies in how to find a way to transform the invectives into an acceptable mechanism which can fulfil democracy and not hamper scientific development. Here, a co-productive perspective of biobanking might support this way of reflection. As co-production implies the importance of inter-subjectivity, science and the social are expected to move forward at the same pace as they are rowing the same boat. In addition, public opinions formed through the engagement of the public may ease social distrust as it forms the bond on which the social relies to live. Biobanking in Taiwan could therefore be an opportunity for the government and Taiwanese society to re-imagine together what the nation stands for, what the core value of the society remains and how to pass on the hope, as both science and society have delineated, to the next generation.

## Chapter 5 Consent

### Introduction

Many discussions of governance of biobanks focus on the issue of informed consent. Since the conclusion of the Nuremberg trials after the World War II, informed consent has been developed by ethicists and lawyers as a mechanism to protect human subjects in medical research and human experimentation. However, the emergence of biobanks challenges the practice of fully informed consent because the details of specific future research are still unforeseen at the time of consent. Manson and O'Neill recognise that there is a need to rethink classical informed consent requirements as the scope of consent has been extended from clinical treatment and medical research to the secondary use of specimens and personal data over time.<sup>1</sup> Bartha Knoppers also suggests that the rigorous standards which require explicit and written informed consent as recommended by the Declaration of Helsinki have caused many difficulties to biobanking in the post-genomic era.<sup>2</sup> In order to facilitate biomedical research and make possible international networking and cooperation, the principles of informed consent need to be refocused away from its rationalities of autonomy and individualism towards an emphasis on reciprocity, mutuality and citizenship.<sup>3</sup>

This chapter aims to examine critically the role of consent in biobanking in Taiwan. Rather than engaging in a philosophical discussion that focuses on the principles of consent in Western liberal political theories, the chapter looks at how informed consent have been conceptualised and positioned in the forefront of Taiwanese biobank governance. Various standards and modalities have been developed to deal with the mechanisms of informed consent in biobanking. They vary from self-governance to external legally binding instruments. In Taiwan, ethical configuration introduces a framing process through which

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<sup>1</sup> Neil Manson and Onora O'Neill, *Rethinking Informed Consent in Bioethics* (Cambridge Cambridge University Press, 2007). P. 4

<sup>2</sup> Bartha Maria Knoppers and Ma'nH. Abdul-Rahman, "Biobanks in the Literature," in *Ethical Issues in Governing Biobanks* ed. Bernice Elger, et al. (Hampshire: Ashgate, 2008).

<sup>3</sup> Bartha Maria Knoppers and Ruth Chadwick, "Human Genetic Research: Emerging Trends in Ethics," *Nature Reviews Genetics* 6 (2005).

consent was constructed not only as a matter of ethics<sup>4</sup> but also as a legal and judicial endeavour for the establishment of the Taiwan Biobank. By inserting the consent requirement into the national legislation, the mechanism of consent was instrumentalised by the state to legitimise various agendas in the politics of life.<sup>5</sup>

This chapter analyses the dynamic relations among individual and collective, state and society, culture and identity that are involved in the practice of consent in biobanking in Taiwan. As biobanks generate issues concerning intervention into an individual's private sphere, the governance of biobanks opens up an arena of power rearrangement between the individual and the collective. At the same time, the commercial potential of biobanking has influenced the consent requirement. When consent is mainly constructed as an ethical discourse, it leaves other essential issues such as access and property aside since obtaining consent provides biobanks with a justification for turning human specimens into the property of a biobank whose ownership is not yet clear.<sup>6</sup> In addition, this chapter argues that an overemphasis on consent has meant that biobank governance in Taiwan has failed to challenge the neoliberal rationality that focuses on individual choices but leaves the underprivileged on an unequal footing in the development of modern life sciences.

Moreover, the inclusion of Taiwanese aborigines in the biobank project in Taiwan questions the rationale of the individual consent model which overlooks the significance of collective involvement in the process of decision making in aboriginal cultures. As a result, how to respect aboriginal groups' interests needs to be seriously considered in the practice of informed consent for biobanking in Taiwan. This chapter further argues that the configuration of consent depicts a contradiction in the Taiwanese reality. Even though the national legislation attempts to consolidate the protection of human subjects in biobank research, the consent mechanism risks being "demoralized" in its practice as a

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<sup>4</sup> For instance, Alan Petersen had drawn on the Scandinavian biobanking as a case study for arguing how the governance framework of biobanks in these countries had been framed as a matter of ethics. See Alan Petersen, "Biobanks: Challenges for 'Ethics' " *Critical Public Health* 15, no. 4 (2005).

<sup>5</sup> More discussions with regard to turning ethics into regulation may be found in Klaus Hoeyer, "Biobanks and Informed Consent: An Anthropological Contribution to Medical Ethics" (Umea University, Sweden, 2004). P. 10

<sup>6</sup> Kaushik Sunder Rajan, *Biocapital* (Duke University Press, 2006). pp 71-72

way to feed the process of “turning populations into resources”<sup>7</sup> under the global biocapital trend of commodification of human tissue samples.

### **5.1. A Technique of Governance**

Policies may be viewed as instruments of governance or even social institutions as some anthropologists have suggested in the sense that they shape people’s ways of thinking and acting and form relations between the different agencies involved.<sup>8</sup> Even though such processes of formation are not static, so that the policies themselves may also be challenged and modified by the relevant actors, what needs to be noticed is how the construction of policies represents existing power structures that may be further consolidated by legal instruments to endorse political agendas. The strategic legislation for the governance of the biobank in Taiwan illustrates how law may operate through various governmental agencies as an instrument to serve underlying agendas even though it is apparently neutral. In this context, consent is instrumentalised as a technology of power that serves the state’s policies in the name of individual autonomy.<sup>9</sup>

#### **5.1.1 Embedding Consent in the National Legislation**

The recently enacted Human Biobank Management Act in Taiwan provides the general legal basis for the construction, management and operation of biobanks. Before the Act entered into force on 3 February 2010, there had been no legislative initiative in Taiwan to regulate the procurement and storage of human specimens for research use. However, the increasing demand for human samples for biomedical research encouraged the Department of Health to amend its administrative rules - the Guidelines for Collection and Use of Human Specimens for Research - in August 2006 in order to ensure that the procedures of sample collection were ethically adequate. The Guidelines set concrete contours for the process of sample collection by adopting a model of explicit and written informed consent.<sup>10</sup> Even though the Guidelines regulate human subject research in

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<sup>7</sup> Ibid. P. 102

<sup>8</sup> Cris Shore and Susan Wright, eds., *Anthropology of Policy: Critical Perspectives on Governance and Power* (London: Routledge,1997). pp 15-16

<sup>9</sup> Some studies of medical anthropology view ethics as a discourse of power for unjust systems. This kinds of arguments can be found in, for example, Leslie Sharp, "The Commodification of the Body and Its Parts," *Annual Reviews of Anthropology* 29 (2000).

<sup>10</sup> In the Guidelines, it specifies the matters research subjects require to be informed. It further stipulates consent needs to be put in a written agreement accompanied by an oral notification for making sure donors have a clear understanding of the contents informed.

general and may therefore apply to the case of biobanking, they do not deal with issues concerning the use of human genetic information for the purposes of biomedical study. In addition, whether a traditional doctrine of informed consent is suitable for the case of biobanking had been a main issue considered among the biobankers in Taiwan.

The Department of Health - the funding body of the Taiwan Biobank - was the governmental agency in charge of drafting the Human Biobank Management Act. However, in reality, it was the experts of the ELSI group at the biobank team who were responsible for initiating the first few drafts of the Act that were subsequently submitted to the Department of Health for reviews and revisions.<sup>11</sup> Since the drafting process started in early 2007, the space for public engagement was fairly limited. Even though the Legal Office of the Department of Health had organised several meetings for reviewing the drafts of the Act, most of the discussions were carried out among a few selected groups of experts. Only one “public hearing” was held by the Department of Health in 2008 to gather responses about the drafts from the interested biobank stakeholders. As a result, in reality, there have been few opportunities for the public to be involved in the formation of the biobank legislation and not enough government research was carried out to gather adequate information about the public’s concerns on the Taiwan Biobank.<sup>12</sup>

The final draft of the Human Biobank Management Act was proposed to the Legislative Yuan (the Parliament) for approval on 21 July 2009 after it went through the process of internal reviews in the Department of Health and in the Executive Yuan (the Cabinet) respectively. The Act subsequently moved through a fairly smooth voting process in the Legislative review— it took only about a week from sending the draft from the Committee of Social Welfare and Environmental Hygiene to the General Meeting for a vote, and it was passed on 7 January 2010. The passage of the Act in such a speedy way was not very common in Taiwan. Normally the process of legislation is expected to be delayed if the

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<sup>11</sup> It would be meaningful to do more analysis on the revision of the drafts in order to have a better understanding how the Human Biobank Management Act is developed in Taiwan. However, due to the limits on accessibility to the documents, my focus is on the broader social context for the enactment of the biobank Act rather than on the detailed comparison of various versions of the drafts or of the difference between the final draft and the Act.

<sup>12</sup> For example, there is no research like focus group study ever being carried out in Taiwan. This kind of study can especially apply to issues which may not be familiar with ordinary people, such as biobanks, in order to spot issues and to know what would really concern potential participants from their questions and their discussions on the topic.

legislation is politically controversial.<sup>13</sup> The Human Biobank Management Act was listed as one of the urgent laws for review and voting in the Legislative Yuan even though it was not politically sensitive.

Several reasons may explain this particular phenomenon. First, informed consent raised most difficulties since recruitment for the pilot study of the biobank started. In fact, right after the idea of the Taiwan Biobank was initiated, there had been a few scandals reported in the news media about researchers' collection of samples from Taiwanese aborigines without proper informed consent.<sup>14</sup> In order to rebuild trust from the general public, the government had planned to use the Taiwan Biobank as a special niche to trigger a unification of regulations on human subject research. This attempt was supported by the human rights groups even though they had taken a rather conservative attitude towards the biobank project in Taiwan. For the human rights advocates, enacting national legislation for biobanking in Taiwan is necessary. As the groups had planned to call for the public's supervision of the Taiwan Biobank, they pushed hard for the enactment of the Human Biobank Management Act in the expectation that Taiwan might prevent itself from becoming a target of sample collection for global pharmaceutical companies to carry out drug invention and clinical trials.<sup>15</sup>

Besides, the unclear relationship between the Institutional Review Board (IRB) of the Academia Sinica and the later, elected, Ethics and Governance Council (EGC) had made the supervision of the Taiwan Biobank prolonged and complicated. The enactment of law is thus expected to be a more suitable way for the management of the Taiwan Biobank. In terms of the governance of a biobank, an external supervision model such as the enactment of national legislation is not a universal model. In some jurisdictions, for example in the United Kingdom, governing biobanks is mainly based on self-governance or an independent supervision mechanism, such as relying on research ethics committees or an Ethics and Governance Council. In Taiwan, the authority of the EGC had been challenged by the biobank team on the grounds that the formation of the EGC was only a

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<sup>13</sup> Even though a legislation is of less political significance to be debated by the parties, it moves slowly in a queue for scrutiny, party negotiation and then voting in the general meeting due to the accumulation of legislation.

<sup>14</sup> Chao-Chun wang, "Taiwan Biobank Project Beat the Gun? Taiwan Association for Human Rights Call for the Halt," *Yam News*, 23 January 2006.

<sup>15</sup> "No Legal Rules for the Taiwan Biobank," *Central News Agency* 11 May 2009.

decision made by the IRB of the Academia Sinica. For that reason, the EGC was regarded by the executing scientists of the biobank team and the Department of Health - the biobank sponsor - as a mini-IRB which was set up to function as a model of internal supervision. This point of view had not yet been accepted by some EGC members who viewed the EGC as an independent institute. For these members, the IRB had no capacity to supervise the Taiwan Biobank because the biobank project in their views was no longer a research plan. Rather, the project is more like a public policy that will have a significant impact on society.

Nevertheless, even among the 19 selected members of the EGC, their opinions were very diverse. Some members highly valued the independence of the institute and held the view that the decision made by the EGC should prevail against the contrary decision made earlier by the IRB. These members challenged the social legitimacy of the Taiwan Biobank. They claimed that due to the lack of legitimacy, the sample collection should not have been permitted. The decision to permit sample collection was made by the IRB on 19 May 2008, about eight months before the EGC was formally set up. For this reason, opponents in the EGC insisted that the sample collection should be halted until the relevant legislation was enacted. As for the samples which were already collected, they could only be stored for DNA extraction, and no further DNA analysis should be allowed. Later, the function of the EGC was further clarified by the Control Yuan in Taiwan.<sup>16</sup> In its investigatory report on 15 October 2009, the Control Yuan echoed the viewpoint taken by the biobank team, viewing the role of the EGC as a mini-IRB. For that reason, the samples which had been collected could continue to be used for research; however, the report also recommended that a specific law should be enacted as soon as possible in order to help clarify the supervisory mechanism for the biobank and to make the relevant regulations on sample collections clearer. Ironically, even though the desirability of the biobank project remained questionable in Taiwan, a consensus had been formed about the enactment of a specific law for governance of the biobank.

On the other hand, as the biobank project had raised many concerns, the Legislative Yuan made a decision in December 2008 to freeze half of the budget allocated for the biobank

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<sup>16</sup> The Control Yuan, set by the Constitution, is a central-level governmental agency in charge of impeachment and audit for all government officials and government branches in Taiwan.



until the passage of the required legislation. This decision slowed down the process of recruitment for the pilot study that was originally planned to reach the goal of collecting 15,000 samples from Taiwanese people by September 2009. According to the administrative contract, the delay in the collection of samples imposed a penalty on the biobank executive team. The penalty was charged according to the total shortage of samples calculated on a daily basis. As a result, both the Department of Health and the scientists involved expected that the passage of the Human Biobank Management Act would allow the Taiwan Biobank project to keep moving on.

In addition, in order to ease the ethical controversies caused by the Taiwan Biobank, the Department of Health made an administrative order to impose a halt on sample collection for all biobanks in Taiwan, right after the draft of the Human Biobank Management Act was proposed to the Legislative Yuan in July 2009. In the administrative order, the term “biobanks” was given a broad definition, so it included the archive collections of human specimens in hospitals and laboratories if the collections had been used to link with the donors’ phenotypic data for the purpose of biomedical study. Due to this broad definition, several biomedical research projects were forced to be interrupted. This led to great pressure from scientists and pathologists on the government to speed up the legislation, so the lack of regulation would not continue impeding their research.

When the draft was in the final review process in the Legislative Yuan, the Head of the Department of Health made a presentation to the legislators emphasizing the importance of the biobank project for Taiwan and pleaded for support from the legislators to approve the draft. The presentation introduced the current international trend of biobanking and recognised that the government had tried to improve ethical mechanisms such as informed consent and data protection in order to fulfil the requirement of good ethics for biobanking. The Taiwan Biobank was presented as a key infrastructure for Taiwan to develop research on personalised medicine in order to catch up with the international trend and to improve public health by discovering the causes of local common diseases. In the end, the Act was passed by the Legislative Yuan as a way to ease all the controversies regarding biobanking in Taiwan. The Human Biobank Management Act is expected by the biobankers to play a role in helping to position Taiwan’s biobank initiative in the context of the global health economy. In addition, it has transformed the mechanism of consent from a notion of ethics to a technology of power for serving various policy agendas.

### 5.1.2 Compromise Legislation

Unlike formal regulation in some other jurisdictions such as the Norwegian law that defines a biobank as sample storage without reference to data,<sup>17</sup> or the governance framework of the UK Biobank which relies on separate legislation - the Human Tissue Act 2004 and the Data Protection Act 1998 - to regulate samples and data respectively, the Human Biobank Management Act serves as specific legislation for biobanks in Taiwan by prescribing rules on human biological samples and associated data together.<sup>18</sup> A respondent from the biobank sponsor indicated that such a legal strategy is deliberate as it aims to avoid a prolonged law-making process. In addition, it makes the legislation successfully escape from a sophisticated yet unsolved puzzle with regard to the application of a data protection law to human samples. In the current literature, it is still unsettled whether a specific law regulating data and information may apply to tangible biological samples which contain DNA information.<sup>19</sup>

Even though in the drafting process, there had been several discussions about the need for the enactment of two separate laws for regulating human biological samples and associated data respectively, we later decided to have a specific law to regulate biobanks so that it would save us a great deal of time in dealing with all the details of the rules with regard to complicated issues on samples and databases. As a result, we can have a law to be used immediately for the Taiwan Biobank project and all other biobanking activities can keep moving on. (G1, Governmental official, Taipei, 2010)

However, as compromise legislation, the newly enacted Human Biobank Management Act raises more questions than it can probably answer. The main difficulty lies in the unclear scope of the Act that turns consent into a loaded notion waiting to be further interpreted. Even though there are great variations in the definitions of biobanks, what is included in

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<sup>17</sup> Act on Biobank No 12, February 21, 2003 (Norway); see [http://www.europa.eu.int/comm/research/biosociety/pdf/norwegian\\_act\\_biobanks.pdf](http://www.europa.eu.int/comm/research/biosociety/pdf/norwegian_act_biobanks.pdf)

<sup>18</sup> Before the latest revisions of the Personal Data Protection Act approved by the Legislative Yuan on 27 April 2010, the Data Protection Act in Taiwan applied only to eight specific industries. After revisions, the revised Act applies to all industries and every individual. In addition, and genetic information is enumerated in the revised Act as personal information to be protected.

<sup>19</sup> Relevant arguments may be found, for example, in Heather Widdows and Caroline Mullen, eds., *The Governance of Genetic Information: Who Decides?* (Cambridge University Press, 2009). P. 8

regulations defining the term has ethical consequences.<sup>20</sup> Originally, the Act was specifically enacted for the Taiwan Biobank; however, it later carried another functional task assigned by the Department of Health to unify regulations of sample collection and to provide a general rule for governing all existing biobanks in Taiwan. As a result, the draft was revised extensively in the internal review process in the Department of Health. By expanding its scope of application, the Act was finally expanded from a specific law designed for the Taiwan Biobank to a general regulation applying to all types of biobanks in Taiwan. However, since how to interpret consent remains ambiguous, the Act raises a great deal of difficulties for its practical application.

For instance, Article 7 of the Act adopts a specific consent model that requires biobankers to inform participants of the objectives and duration of research, the manner in which tissues will be collected, the mechanisms for data protection, the expected associated health data to be linked in the future, etc.<sup>21</sup> However, it has been generally recognised that a classical model of informed consent which requires consent to be “informed and explicit” may cause difficulties for population biobanks as researchers cannot identify future research uses at the time of consent. So, how the Taiwan Biobank could fit itself into this consent requirement remains to be seen. Unfortunately, even though the scope of the Act was expanded, the basic definition of the terms in the legislation remained the same. According to Article 3, the term “biobanks” was defined as “the collection of human biological samples which are stored for the linkage of associated data and

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<sup>20</sup> A. Cambon-Thomsen, E. Rial-Sebbag, and B.M. Knoppers, "Trends in Ethical and Legal Frameworks for the Use of Human Biobanks," *EUROPEAN RESPIRATORY JOURNAL* 30, no. 2 (2007).

<sup>21</sup> Article 7 of the Human Biobank Management Act: As set forth in the preceding Article, a participant shall be informed of the following matters: 1. The legal authorities and their contents governing the establishment of the biobank. 2. The identity of the biobank operator. 3. Information regarding the identity and the service unit of the biological specimen collectors. 4. The reasons why a particular participant was selected. 5. The rights and direct benefits the participant is entitled to pursuant to this Act. 6. The purposes of collection and the range and duration of the use of the collected biological specimens; collection methods; types and quantities of specimens to be collected; and regions where specimens are collected. 7. Any complications and hazards that might possibly occur during and as a result of a collection(s). 8. Any possible impacts of the genetic information derived from the biological specimens on the participant, and his/her relatives or an ethnic group. 9. Any reasonable risks or inconvenience which the participant may anticipate. 10. The rights which are excluded by this Act. 11. The mechanism designed to safeguard personal privacy and other rights and benefits of the participant. 12. The Operator's organizational structure and operating principles. 13. Specific type of health information of the participant that is expected to be linked in the future. 14. Relevant regulations governing the applications of the biobank. 15. Anticipated commercial applications. 16. The participant may choose whether upon his/her death or incapacity, his/her biological specimens and related data and information will continue to be stored and used. 17. Other important matters related to the biobank.

information based on population or specific groups for the purpose of biomedical research.”<sup>22</sup> Due to the lack of a clear definition of “population” and “specific groups” which constitute the fundamental elements for defining a population biobank, the application of the Act turns out to be complicated and problematical.

The Act neglects the fact that the Taiwan Biobank uses a prospective population-based long-term cohort, and as a result, it requires not only collecting a massive amount of samples and linking them with associated personal health databases for follow-up application, but also re-contacting participants again and again for updating their health data and additional information over a long period of time. These features make the Taiwan Biobank different from other types of biobanks, such as biobanks for diagnosis or therapy of specific diseases which generally do not have a longitudinal nature and therefore are easier to define in terms of their research purposes. In addition, even though Article 7 enumerates the matters participants need to be informed of, it is not yet clear whether re-consent is required for future research uses of samples and data, and whether the consent requirement could be waived when certain safeguards are ensured, such as anonymisation of samples and data or the approval for future use from research ethics committees, etc. Due to the unclear definitions, the Act fails to respond appropriately to the distinction between various types of biobanks considering their different functions and purposes. Such uncertainty makes the interpretation of the Act exceptionally difficult in the biobank practice in Taiwan that includes finding an appropriate interpretation of the consent requirements.

## **5.2. Framing Consent**

### **5.2.1 Consent Models**

Numerous discussions in the literature revolve around the applicability of informed consent to biobanking.<sup>23</sup> The general argument points out that it seems to be inadequate to apply a classical doctrine of informed consent to biobanks, especially to a population

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<sup>22</sup> Article 3, the Human Biobank Management Act (Taiwan)

<sup>23</sup> In the recent literature about biobanks, consent has been a major issue to be touched upon. See, for example, *Principles and Practice in Biobank Governance*, ed. Jane Kaye and Mark Stranger (Surrey, England: Ashgate Publishing Limited, 2009).; Bernice Elger et al., eds., *Ethical Issues in Governing Biobanks: Global Perspectives* (Hampshire: Ashgate, 2008).

research biobank of a longitudinal nature. Since research questions for such a biobank evolve over time, it is difficult to anticipate future projects when a sample is taken at a certain moment. Given that the contents of future research are unforeseen for both researchers and participants, in reality, it is impractical to obtain participants' specific and explicit consent, even though in bioethics, such consent is normally required for human subject research. Besides, among current international guidelines, there is a lack of consensus on what types of consent are suitable for biobanking. A variety of modified consent requirements emerge between the two extremes of strict consent and broad consent. For instance, a multi-layered consent was proposed as a compromise between the two. Introduced by the Medical Research Council of Canada, this consent arrangement requires a comprehensive consent form, which allows participants to choose among the listed options they would like to be kept informed about for secondary use of their donated samples.<sup>24</sup>

In addition, a hybrid consent model has also been projected. In this model, specific consent needs to be obtained for the collection and storage of samples but broad consent for presently unspecified research.<sup>25</sup> The model emphasises respect for the core rationalities of consent even though all future research projects cannot be specified at the time when consent is obtained. As a result, in order to obtain broad consent for presently unspecified research, researchers need to inform participants sufficiently for them to understand what the research is generally about.<sup>26</sup> New legislation in Spain on biobanks adopts another consent model that requires individuals to give explicit consent for one kind of research use and then broad consent to further unspecified uses so long as the new research projects are related to the original uses.<sup>27</sup> Under this model, a Research Ethics Committee, on the donor's behalf, has the power to make the decision on the unspecified research.<sup>28</sup>

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<sup>24</sup> There are some options on the consent form for participants to choose, for example, whether they permit biobanks to reuse samples under certain conditions of irreversible anonymization, or if they permit coded use for identified study, etc. See Medical Research Council of Canada 1998, Art 8.7.

<sup>25</sup> Margaret Otlowski, "Developing an Appropriate Consent Model for Biobanks: In Defence of 'Broad' Consent," in *Principles and Practice in Biobank Governance* ed. Jane Kaye and Mark Stranger (Ashgate, 2009).

<sup>26</sup> Ibid.

<sup>27</sup> Antonio Casado da Rocha and Ismael Etxeberria Agiriano, "Consent by Research Ethics Committees: The New Law on Biomedical Research in Spain," in *Principles and Practice in Biobank Governance*, ed. Jane Kaye and Mark Stranger (Ashgate, 2009).

<sup>28</sup> Ibid.

Aiming to avoid a costly process of re-contact and re-consent, broad consent has been supported by several international institutions, such as the World Health Organisation (WHO),<sup>29</sup> the Human Genome Organisation (HUGO),<sup>30</sup> and the European Society of Human Genetics (ESHG),<sup>31</sup> etc., provided certain considerations are met. The UK Human Genetics Commission and UK Biobank also favour a broad consent model in order to prevent impediments to scientific research from the application of a strict informed consent.<sup>32</sup> A broad consent (or so-called “general consent”) allows investigators to use samples and data for the future research without the need to re-contact original participants for obtaining their re-consent. Inspired by the consent model taken from the experience of the UK Biobank, the pilot study of the Taiwan Biobank adopts similar broad consent requirements. It is worth noting, however, that even though the later enacted Human Biobank Management Act in Taiwan adopts a specific consent model, broad consent has been used for the pilot study since the project started its recruitment in 2008. Therefore, it still remains to be seen how the Taiwan Biobank, if it is enacted successfully in the future, would be able to cope with the new legislation that requests a stricter requirement of obtaining consent.

It has also been argued that consent should not be treated as the sole basis of safeguarding participants’ autonomy and broad consent generally operates best in an environment of a strong governance regime.<sup>33</sup> On the consent form of the Taiwan Biobank, it states that samples and associated data are permitted to be used for future medical research, which needs to be approved by the project’s ethics committee and relevant institutional review board. However, unlike the UK Human Tissue Act 2004 that permits the secondary use of identifiable samples whenever reasonable efforts have been made to re-contact donors, the consent requirements for the Taiwan Biobank do not specify that non-identifiability of samples and data are also a necessary condition for the waiver of consent. The rationale of broad consent in biobanking reflects the need to

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<sup>29</sup> "Genetic Databases: Assessing the Benefits and the Impact on Human & Patient Rights," (World Health Organization (WHO), 2003).

<sup>30</sup> "Hugo Ethics Committee:Statement on Human Genomic Databases," (Human Genome Organisation (HUGO), 2002).

<sup>31</sup> "Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues," According to the guidelines, consent may be waived if samples are anonymised. (rec.9) (European Society of Human Genetics (ESHG), 2003).

<sup>32</sup> "Inside Information Balancing Interests in the Use of Personal Genetic Information," (London: UK Human Genetics Commission, 2002). P. 94

<sup>33</sup> Supra note 25

balance the freedom of research and participants' rights. For that reason, it is important to consider if the waiver of consent involves no more than minimal risk for the interests of the participants and if research may be impeded by the extra effort and cost of obtaining re-consent.

In Taiwan, this kind of independent evaluation is completely left to ethics committees to decide. Even if participants still have the right to withdraw from the biobank project at any time without liability, it raises questions such as whether the broad consent requirements may be justified in the Taiwanese context and for what reasons the decision made by ethics committees may legitimately replace the individual's decision. In the recent literature, a "co-determination" structure has been introduced to supplement broad consent in order to uplift participant autonomy in the consent arrangement.<sup>34</sup> Inspired by German labour law on co-determination, the idea requires researchers to keep participants updated on present and prospective future use of samples and data. As the framework asks for a greater degree of transparency, it allows participants to be perceived as partners of biobanks rather than simply sample suppliers. In addition, the model makes possible transferring decision-making from biobankers to participants who will then have more opportunities to decide how they would like their samples and data to be used in a biobank, especially a population biobank which requires a long-term follow-up of participants' health data.<sup>35</sup>

Nikolas Rose had used the term "ethico-politics"<sup>36</sup> to introduce a field of "technologies of responsabilization"<sup>37</sup>, arguing that an increased freedom of choice has turned out to be a politics of enrolling citizens in government whose choice will have to be influenced by experts. This perspective offers a useful angle to analyse the broad consent practice in Taiwan. Any arguments made to support broad consent seem to concede that even if individual autonomy needs to be respected, other values such as communitarianism and reciprocity are also significant in modern society, so they have to be equally weighted in the process of evaluation of the knowledge production of the causes of diseases. The

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<sup>34</sup> Lukas Gundermann and Ulrich Stockter, "Co-Determination of Donors in Biobanks," in *Principles and Practice in Biobank Governance*, ed. Jane Kaye and Mark Stranger (Ashgate, 2009).

<sup>35</sup> Ibid.

<sup>36</sup> Nikolas Rose, *Powers of Freedom: Reframing Political Thought* (Cambridge: Cambridge University Press, 1999). P. 188

<sup>37</sup> Ibid. pp 74-83

project itself might thus be regarded as a social asset so long as its research promotes certain values which most citizens in the society would like to support.<sup>38</sup> As Graeme Laurie, the former Chair of the UK Biobank Ethics and Governance Council, has argued, adopting broad consent does not necessarily make the UK Biobank ethically deficient if other adequate governing mechanisms exist.<sup>39</sup> However, the public engagement process which the UK Biobank relies upon to build its own legitimacy has been omitted from the practice of biobanking in Taiwan. For the case of the Taiwan Biobank, a fundamental prerequisite to adopting a broad consent model is perhaps to enable the public to join a wider discussion and debate concerning the necessity, the research design and governance framework of the biobank in order to ensure that participants' opinions have been properly represented. As a result, the legitimacy of the ethics committee will have to be recognised by the public in order to distinguish the institute from other possible instruments of policy legitimatisation.

Salter and Jones point out that biobanks are not innovative in terms of the collection of samples and data for the purposes of research, diagnosis or medical treatment. Nevertheless, what is new in this technology is the political sensitivity of linking genetic data with health information for the study of whole populations.<sup>40</sup> In Taiwan, such sensitivity makes the creation of the population biobank a socio-political activity. At the same time, it constructs the consent process as a discourse of political utility. In order to call for the public's support, "creating a biobank for the health of our next generation" has been deployed by policy makers as a policy discourse. The rationale behind this appeal is the doctrine of altruism, under which participation in the biobank has been formulated by the biobank team as an act of donation. Such a rationale provides a distinct perspective of further observation on the role of informed consent in biobanking. Even though consent has been viewed by bioethicists and lawyers as a mechanism to secure individual self-autonomy, when examining its embedding context, what seems to be ignored is the possibility that the informed consent may have been used unintentionally as a political

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<sup>38</sup> Erik Christensen, "Biobanks and Our Common Good" in *The Ethics of Research Biobanking* ed. Jan Helge Solbakk, Soren Holm, and Bjorn Hofmann (London: Springer, 2009). P. 2

<sup>39</sup> Graeme Laurie, "The UK Biobank Ethics and Governance Council: How Valuable Is an 'Ethics+' Approach to Governance?," in *New Challenges for Biobanks: Ethics, Law and Governance*, ed. Kris Dierickx and Pascal Borry (Intersentia, 2009). P. 242

<sup>40</sup> Brian Salter and Mavis Jones, "Biobanks and Bioethics: The Politics of Legitimation," *Journal of European Public Policy* 12, no. 4 (2005).



technology whenever ethics becomes another terrain for power negotiation between actors who are on an unequal footing. Therefore, it is worth noting that how easily the practice of informed consent procedures in Taiwan may encourage and then transform participation in the biobank from a voluntary action to an ethical conduct. For instance, as an interviewee in Taiwan pointed out, what matters to her was not what types of consent were used for the biobank project. Rather, it was whether she had been convinced from the information given that the biobank is the kind of research she would like to support.

I would be glad to participate as it seems to me this (referring to Taiwan Biobank) is research that can help many people... I am not really worried about if there is a fully informed consent so long as I think it is a project through which I can help others and the research itself is good for society, I would be willing to support. Other issues would not really matter and won't bother me that much. (P1, Taiwanese Aborigine, Focus Group, Taiwan, 2010)

However, the procedure of consent should not be regarded as requiring communication or conviction. Rather, it is a process of comprehension for which trust needs to be embedded to prevent the consent requirement from being a merely formal endorsement. Corrigan and Tutton have argued that for sample collection more attention should be paid to research participants since interpretation of consent in a broader sense has to re-entangle individuals within their communities, under which the notion of solidarity can replace individualism.<sup>41</sup> Waldby has also used the term “imagined communities” to describe how discourses of reciprocation may be established from sample donations in which trust is framed.<sup>42</sup> According to Waldby and Mitchell, informed consent represents a form of social relationship by which biological samples formally enter into a process of tissue economies.<sup>43</sup> Such economies are associated with not only actions and decisions relating to scientific progress but also great commercial potentials arising from genetic research on personalised medicine. As a result, it is worthwhile examining critically not only what kind of information is created for the process of consent, but also how such

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<sup>41</sup> Oonagh Corrigan and Richard Tutton, eds., *Introduction: Public Participation in Genetic Databases, Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (Routledge, 2004). pp 1-19

<sup>42</sup> Cathy Waldby and Robert Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Duke: Duke University Press, 2006). P. 76

<sup>43</sup> *Ibid.*, P. 33

information is constructed as well as in which ways it has been delivered, acknowledged, understood and interpreted by the consenters.

In terms of broad consent requirements for biobanks, since participants are not expected to be re-contacted for each new research project in the future, biobanks' purposes and aims are regarded as essential information to be communicated when consent is sought. In practice, how such information is formed and delivered normally has a direct impact on participants' willingness to take part. Nevertheless, a statement about the purposes of biobanks is of a normative nature. Rather than a scientific truth waiting to be proven, the statement essentially is a discourse of anticipation of the future. Since such entanglement may be difficult for a consenter to discern, the information delivered for the informed consent is easily entangled with the underlying policy agenda set for the biobanks. For instance, an inner document of the Taiwan Biobank indicates that it normally takes about 23 minutes for each participant to complete the required consent procedure at a sample collection site.<sup>44</sup> Even though participants are encouraged to ask questions when consent is sought, in practice, there are usually no more significant questions to be raised during the consent procedure. Among the participants, about 45.7% had attended the recruiting events organised by the biobank team before they visited the collection sites where they gave their consent.<sup>45</sup> Therefore it could be inferred that quite a few participants who had joined the recruiting activities made their decisions to take part in the biobank project thereafter. For these participants, their knowledge about the biobank primarily came from the information provided by the biobank team.

For the pilot study of the Taiwan Biobank, research nurses are mainly responsible for organising the recruiting events. The nurses are staff recruited particularly for the biobank project so they are full-time employees on a contract basis with the Institute of Biomedical Science (IBMS) of the Academia Sinica. They usually have nursing or related degrees and need to pass the exams on their training for sample collection. Such training is provided by the biobank team and includes necessary techniques of carrying out sample collection, obtaining consent and some basic knowledge about ethical issues associated with biobanking. The purpose of the training is to equip the nurses with

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<sup>44</sup> An unpublished document, released by the biobank team, IBMS, Academia Sinica, Taipei, 2009

<sup>45</sup> Ibid.

needed knowledge for answering questions raised by participants in the recruitment and in the consent procedures.

Currently, there are six collection sites operating in Taiwan—three in Chiayi and three in Tainan—all of them are in the Southern part of the country. Generally, about seven to nine research nurses are assigned to a collection site where they are divided into two groups responsible for sample collection and recruitment respectively. The recruiting activities are normally task-oriented, namely the venue for recruitment is not completely chosen by chance. In contrast, the recruiting venue needs to be adjusted according to the research need. For instance, when the samples collected in a particular area are donated mostly by women, the research nurses will arrange to have their recruiting events aimed at male audiences, for example, holding events for staff working in fire stations or police stations, etc. In a recruiting event, research nurses mainly introduce the audiences to what the biobank is - its functions and purposes.

Usually, a recruiting event lasts for about half an hour depending on the time allocated and the reaction from the audience. Though the contents introduced include the possible risks and harms associated with the biobank, the main focus is on how much effort the biobanking had made and will continue to make to ensure that the biobank is ethical. Issues such as informed consent, the right of withdrawal, coding, anonymity, and the ethics committee are all mentioned briefly to emphasize that a high standard of ethical governance is a central consideration to the biobank operator. Nevertheless, the recruiting process itself is in a lecture style, so it is mainly a one-side information delivery, not a discussion or consultation in which the information may be further examined, challenged or reformulated by the audience. Certainly, there is not much space for the creation of new knowledge about biobanking that may be fed back in to the biobank governance framework from this type of recruitment.

In Taiwan, according to the Medical Law, sample collection for medical purposes needs to be carried out in a hospital or health clinic. Even though it is arguable whether this rule may apply to sample collection for a research biobank, in order to avoid controversies, the biobank team separates recruitment from the formal sample collection procedure. Currently, all six collection sites are set in hospitals. They are either a converted patient

chamber or a similar size rented office to make it more accessible to the interested participants. At the end of the recruiting activities, the audiences who showed interest in taking part in the biobank project are invited to leave their contact information with the research nurses. Then, the nurses will contact them by phone to further check on their willingness and arrange appointments to visit a collection site nearby.

The formal consent procedure starts at the collection sites. Before any samples are taken, participants will be given a consent form with a 13-page introductory booklet that covers all the needed information about the biobank project: its functions, purposes, aims, operators, research scope and duration, the methods of recruitment, the use of samples and data, privacy protection, potential risks and harms it may entail, potential benefits (none of pecuniary benefits, but there is reimbursement of a coupon of 300 NT dollars for the transportation expenses), the right of withdrawal, the consent procedure, the governance framework, the supervision institute, waiver of any rights for any commercial benefits derived from the research, the accessible data from the participation and the circumstances for re-contact etc. In the form, there is a separate statement for the participants to decide whether they permit their samples and data to continue to be used when they become diseased or lack the ability to consent.

The participants are expected to read thoroughly the booklet together with research nurses, who sit beside them. After ensuring all the information is understood, the participants are asked to tick beside each statement in the consent form to indicate that they now have a preliminary understanding about the project and they permit the biobank to use their samples and data for medical research purposes, which need to be approved by the project's ethic committee or relevant institutional review board. In addition, the participants need to specify if they permit the biobank to keep in contact with them (every two to four years) for follow-up purposes. A separate statement on the consent form requests participants to indicate that they understand that their samples and data will be transferred to the Taiwan Biobank if it is set up successfully in the future. If the Taiwan Biobank is not established, their samples and data will be destroyed under the supervision of relevant institutes, provided that there is no contrary agreement from the participants to allow their samples and data to be used for other purposes.<sup>46</sup>

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<sup>46</sup> See, the Taiwan Biobank Pilot Study Introductory Booklet and Informed Consent Form, released by the IBMS, Academia Sinica. The booklet was approved by the IRB of the Academia Sinica on 19 May 2008.

### 5.2.2. Framing Consent for the Taiwan Biobank

In Taiwan, the creation of the biobank is regarded by policy makers as a project for the common good. For instance, on the cover of the consent booklet, there is a cartoon drawing showing several characters of different ages in various costumes making a circle standing hand in hand on the island of Taiwan. Below the drawing is the statement—“To build the new healthy Age, it requires you and me.” In order to have the public’s support for the project, common good and altruism are the two themes for justifying the biobank. Though what the term common good refers to needs to be further defined, it is largely deemed to be a utilitarian appeal for the achievement of the greatest possible benefits for the maximum number of people. Nevertheless, a very key issue is *who decides* what the common good is so that the rationale may be used appropriately to support the creation of the biobank in the Taiwanese context. A specific good that is regarded as something common and important by policy makers may be at the expense of citizens of the state. Even though in civil society, it is ordinarily problematic to reach consensus in the formation of public opinion, what is essential here is whether a decision concerning public policy is able to be fully discussed before it is made.

Certainly, improving health for the coming generation is a valid public interest. It is also a significant purpose for the creation of the population biobank for Taiwan. However, what has not yet been disclosed properly to the public is the project’s potential for commercialisation. According to the biobank proposal and the structure of the biobank’s executive preparatory team, industrial application has been anticipated by the project. Even though the biobank is still in its pilot study phase, in the proposal, the project is expected to rely on its own earnings for continuous operation if it is successfully set up in the future. Since the project’s current funding is solely from the Department of Health and its executive agency is the IBMS of the Academia Sinica, when participants are informed about the project, they are easily convinced that the biobank is a government related public asset and their participation is a meaningful action that can do something good for society.

Discussion of the current governance framework of the Taiwan Biobank focuses mainly on the issues of consent and data protection. Controversies with regard to the potential for

commercialisation have not yet been fully touched upon. This partial framework has influenced the recently enacted Human Biobank Management Act. According to this legislation, the establishment of biobanks in Taiwan needs to be approved by the Department of Health.<sup>47</sup> In addition, biobank operators are restricted to certain organisations, such as governmental agencies, medical or academic institutions and research institutes.<sup>48</sup> Therefore, who is allowed to set up biobanks in Taiwan has become a matter of administrative discretion. Relevant rules with regard to the review standard and qualifications for such applications are for the Department of Health to further prescribe. For that reason, whether a pharmaceutical company or any other commercial entity would be allowed to establish biobanks in Taiwan remains ambiguous. Even though Article 21 of the Human Biobank Management Act concedes the principle of benefit sharing for profits derived from commercial uses<sup>49</sup>, other related issues with regard to commercialisation remained untouched by the Act. For instance, it is still unclear who has access rights to biobanks, whether the Taiwan Biobank is permitted to be jointly operated by commercial partners after it is set up, or if it is allowed to be transferred to a private entity for its future management, and if so, whether a re-consent needs to be obtained from participants, etc. In addition, if the biobank is forced to cease operation in the future, how to deal with the existing samples and data remains an important but unsettled issue.

According to the Human Biobank Management Act, when the participants are deceased or become incapable, so long as there are no other contrary instructions, Article 9 permits biobank operators to continue using their donated samples and data based on the original scope of the consent.<sup>50</sup> Nonetheless, under the unclear definition of biobanks and

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<sup>47</sup> Article 4 of the Human Biobank Management Act: A biobank operator must be a governmental agency, medical or academic institution, research institution, or legal person (hereinafter collectively referred to as “organization”) and shall apply to the Competent Authority for a permit. The Competent Authority shall stipulate rules and regulations to govern matters related to the permit applications mentioned in the preceding paragraph, such as applicant qualifications, application procedures, and conditions for the establishment approval, review standards, regular inspections, relevant managerial matters, and other matters of compliance.

<sup>48</sup> Ibid.

<sup>49</sup> Article 21 of the Human Biobank Management Act: Any profits derived from the commercial use and received by an operator and biobanks shall be given back to the human population groups or specific population groups to which the respective participants belong. The Competent Authority shall stipulate regulations governing the distribution of profits mentioned in the preceding Paragraph.

<sup>50</sup> Article 9 of the Human Biobank Management Act: In the event of a participant’s death or incapacity, except as otherwise agreed herein, the biobank may, in accordance with the original agreement, continue the storage and use of the biological specimens and related data and information.

biomedical research prescribed by the legislation, what the scope of consent refers to would be difficult to interpret in its application. In addition, whether the deceased person's offspring is able to request withdrawal of biobank samples considering the shared nature of genetic information remains unsolved. Even though Article 17 indicates the principle of fairness and equality to be applied for a third party's access rights to biobanks if the biobanks are publicly-funded or established in the public interest,<sup>51</sup> there are no more regulations in the Act to clarify proprietary interests in biobank samples and genetic information produced from them. As a result, how to apply the principle fairly remains questionable. If a third party is a pharmaceutical company, under what criteria would it be considered fair and equal for the company to access biobank samples, data and information? To what extent does the current trend of international data sharing need to be taken into account in interpreting third party access rights? Undoubtedly, these issues will have to be discussed in a much more sophisticated way that is beyond the research scope of this chapter. Nevertheless, such discussion needs to be grounded in the Taiwanese social context to consider how biobanking has been reconfigured as a bio-economic and bio-political activity in Taiwan.

Since the biobank project bears various economic and political agendas, in Taiwan, it has become a special enterprise. As a result, the major issue that needs to be clarified is not whether any "good ethics" exist for sample collection and storage in terms of the governance of the enterprise. On the contrary, more awareness needs to be invested in examining cautiously how ethics was formally embodied in national legislation and how it is used to legitimise the underlying agenda. For a longitudinal research biobank, the practice of consent is doomed to be difficult since the information about future research is yet unknown even to researchers and biobank operators themselves. As Onoagh Corrigan has observed, the term 'informed consent' is tautological because it creates the misleading impression that there is explicit and specific information with which to inform.<sup>52</sup> In order not to make the practice of consent turn into an "empty ethics,"<sup>53</sup> it is

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<sup>51</sup> Article 17 of the Human Biobank Management Act: In the event that a Biobank that is established for the purpose of public interests or subsidized by the government should provide its biological specimens and relevant data and information to a third party, the principle of fairness and equality shall apply.

<sup>52</sup> Onoagh Corrigan, "Empty Ethics: The Problem with Informed Consent," *Sociology of Health & Illness* 25, no. 7 (2003). pp 768-92

<sup>53</sup> Ibid.

necessary to bring the consent procedure back to its social and cultural context. At the same time, it is essential to scrutinise the possible implications when informed consent, introduced as an ethical principle, becomes a legal and judicial criterion of regulation in the governance of biobanks in Taiwan.

### **5.3 Group Consent**

#### **5.3.1 Aboriginal Participation in Biobanking**

The current informed consent mechanism is based mainly on the rationale of individualism, considering its emphasis on autonomy and self-determination. According to the ethical guidelines released from the Council for International Organisations of Medical Sciences (CIOMS), consent can only be made by the individual even though a group can authorise research involving human subjects by permitting its implementation.<sup>54</sup> However, in genetic research, such as biobanking, the potential risks carried out from research results are normally of a collective nature. Taking stigmatisation as an example, consent obtained from individuals of a specific group is regarded as inadequate to safeguard the interests of the entire group on which the detrimental social impact occurs. Under this circumstance, an individual consent needs to be supplemented by other mechanisms, such as group consent made from the related group or community.

However, group consent still receives little attention in the current international guidelines on biobanks. The HUGO statement recognises that the choice of communities regarding the use of their data should be respected but leaves open the possibilities of implementation of such principle. The European Society for Human Genetics (ESHG) points out that additional group consent may be required for population studies, but it does not further specify the criteria for applying group consent.<sup>55</sup> In terms of group involvement in consent procedures, the main issues are how to identify a group, by whom and by which criteria, and who may legitimately represent the group in order to give consent. Since “group” and “community” are open-loaded notions, the meaning of these

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<sup>54</sup> "International Ethical Guidelines for Biomedical Research Involving Human Subjects," ed. the Council for International Organizations of Medical Sciences (CIOMS) (Geneva2002). See, [http://www.cioms.ch/publications/layout\\_guide2002.pdf](http://www.cioms.ch/publications/layout_guide2002.pdf)

<sup>55</sup> See, the European Society of Human Genetics, "Data Storage and DNA Banking for Biomedical Research: Technical, Social and Ethical Issues: Recommendations of the European Society of Human Genetics," *European Journal of Human Genetics* 11, Suppl 2, S8–S10 (2003).



terms needs to return back again to its embedding context. In Taiwan, even though the recently passed Human Biobank Management Act intends to safeguard the welfare of human research subjects, several bewildering contrasts remain between the concerns of law makers and potential participants. The most controversial one is about how to protect Taiwanese aboriginal group interests when the aborigines are recruited in the Taiwan Biobank.

### **5.3.1.1 Taiwanese Aborigines**

Recently, genetic research on Taiwanese aborigines had caused many disputes. Even though only 2% of the Taiwanese population comes from the aboriginal groups, this ethnic group has turned into a specific research target for genetic-related studies in terms of its genetic traits, which are relatively unique compared with most of the Han Chinese gene pool that covers 98% of the population in Taiwan. In addition, studies of Taiwanese aboriginal genetic origins are regarded as politically sensitive due to the special role the aborigines play in Taiwanese ethnic politics. Although it is still arguable whether the ancestors of the aborigines originated in Taiwan or migrated from southern China or from the Malay archipelago 6,000 years ago, it is generally believed that they belong to the Austronesian race and were once the majority of the inhabitants in Taiwan before a massive Han Chinese migration from mainland China in the 17<sup>th</sup> Century.<sup>56</sup> As a result, the aborigines have become an expressive symbol under the trend of localisation to present a distinct identity for Taiwan that enables it to be distinguished from mainland China.

However, within Taiwanese society, the aborigines have been culturally and economically marginalised and also politically and socially underrepresented. In fact, obtaining aboriginal status in Taiwan requires government recognition. According to the Basic Law of Indigenous People promulgated in 2005, a group which regards itself as aboriginal needs to apply for approval from the central authority - the Council of Indigenous Peoples in the Executive Yuan. Although the Basic Law is regarded as of the same status as the Constitution and it was enacted for the purpose of protecting the fundamental rights of

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<sup>56</sup> More arguments about the creation story of the Taiwanese aborigines, See, Robert Blust, "Subgrouping, Circularity and Extinction: Some Issues in Austronesian Comparative Linguistics," in *Selected Papers from the Eighth International Conference on Austronesian Linguistics* ed. E. Zeitoun and P.J.K Li (Taipei: Academia Sinica., 1999). pp 31-94

the aborigines, it has been criticized by aboriginal rights advocates as a violation of their self-determination and self-governance.<sup>57</sup> Viewing themselves as the descendants of Taiwan's original inhabitants, the aborigines hold a distinct identity from Han Chinese. They usually use their group to self-identify who they are. For instance, rather than using the term *Taiwanese*, they prefer calling themselves Amis, Atayal, Paiwan, Taroko, etc by direct referring to their groups' names. In some cases, they also use the term *Taiwanese aborigines* to self-identify, when they have to be distinguished from Han Chinese. Currently, there are 14 ethnic groups that have been recognised by the Executive Yuan. Each of the groups has its own distinct language, customs, social structure and cultural features.<sup>58</sup>

Nevertheless, it is also worth noting that the Taiwanese aboriginal groups have not been categorised according to their biological traits. In the Qing Dynasty of the mid-eighteenth century, the aborigines were broadly categorised into two groups - cooked *savages* and *raw savages* - according to their degree of civilisation,<sup>59</sup> namely acculturation to the Chinese settlers' culture and their relationship to the state.<sup>60</sup> This cultural-political classification was followed by the Japanese colonial regime (1895-1945) and since then the two groups have come to form a larger subdivision - the aborigines of Taiwan.<sup>61</sup> During the Japanese colonial period, the cooked savages were given the name *plain aborigines* as they practiced agriculture and lived on the western plains of Taiwan. The raw savages were called *mountain aborigines* who inhabited the hills and mountains. The ethnic categories in Taiwan were changed again after World War II by the KMT regime. In 1956, the category of plain aborigines was dropped. The aborigines belonging to this category was merged into the larger subdivisions of Hoklo and Hakka based on the belief

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<sup>57</sup> Tsai Wen-ting, "From the Streets to the Villages - the Indigenous Peoples' Movement Turns 20," *Taiwan Panorama* (March 2006).

<sup>58</sup> See the website of the Council of Indigenous Peoples, Executive Yuan, R.O.C. <http://www.apc.gov.tw/main/> (Last visit: 10 March 2012)

<sup>59</sup> It is interesting to see how the evaluation of cooking techniques has been used as a symbol to distinguish culture and nature in the interpretation of the degree of "civilisation." For example, French anthropologist Claude Lévi-Strauss used a similar pair in his book *The Raw and the Cooked* published first in 1964. He analysed the myths of certain South American Indians by exploring the evaluation of cooking rules, namely to see cooking as a language that can be structured as a cultural agent and transformed into a cultural process. More information see, Claude Levi-Strauss, *The Raw and the Cooked* (New York: Octagon Books, 1979).

<sup>60</sup> Antonio C. Tavares, "The Japanese Colonial State and the Dissolution of the Late Imperial Frontier Economy in Taiwan, 1886-1909," *The Journal of Asian Studies*, 64, no. 2 (2005). P. 364

<sup>61</sup> *Ibid.*

that they had been acculturated into Han society.<sup>62</sup> At the same time, mountain aborigines were recognised by their groups' names. From 1956-1980, the central government recognised 9 aboriginal groups. Since then, the numbers of groups have been gradually increasing as a result of the aboriginal renaming movements. In 1990, the notion of the "four great ethnic groups" was invented by a politician of the Democratic Political Party during an electoral campaign.<sup>63</sup> The notion broadly divided the Taiwanese people into four ethnic groups and the Taiwanese aborigine is one of them with the other three subdivisions of Hoklo, Hakka, and Mainlanders.

### 5.3.1.2 Concerns about Stigmatisation

In terms of potential risks associated with biobanking, stigmatisation of aboriginal people concerns most human rights advocates, social scientists and lawyers in Taiwan. For instance, due to the emergence of genetic technology, some scientific papers regarding genetics research on Taiwanese aboriginal alcoholism have been published in international medical journals since the 90s.<sup>64</sup> Nevertheless, this kind of research has also encountered serious criticism for violation of aboriginal rights. Several commentators claimed that the interpretation of the research findings has formed a state discourse of alcoholism that helps reproduce the imbalance in power relations between the aborigines and Han Chinese.<sup>65</sup> The critics further pointed out that such discourse involves a repetition of negative stereotypes that creates a public perception of social pathology for the Taiwanese aborigines but not enough attention had been paid to the social and

political conditions contributing to the phenomenon or the cultural meaning of alcohol for some aboriginal groups.<sup>66</sup> This viewpoint is shared by an aboriginal interviewee who mentioned his concerns about the impact of the research results:

For scientists, ethnicity is a valued label in research, but I am concerned about the impact of the research results...Just like a few earlier scientific studies have published

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<sup>62</sup> Fu Chang Wang, *Dang Dai Taiwan She Hui De Zu Qun Xiang Xiang* 當代台灣社會的族群想像 *Ethnic Imagination in Contemporary Taiwan* (Taipei Qun xue 2003).

<sup>63</sup> Ibid.

<sup>64</sup> See, Mark Munsterhjelm, "Alcoholism Related Genetics Research Involving Taiwan Aborigines as a New Terrain of Settler Colonialism," in *Canadian Sociology and Anthropology Association Conference* (2005).

<sup>65</sup> Liu Shao-hua, "Genes, Ethics and Aborigines," *Taipei Times*, 29 August 2000.

<sup>66</sup> Ibid.

that aboriginal people seem to have a genetic predisposition to the illness of gout or to alcohol drinking. It seems to me that a research result presented in a way like this has made society think that aborigines are more vulnerable to have a particular kind of illness or inclined to have drinking problems due to our genetic markers. Of course, it is an unfair judgement to us. (A1, Taiwanese Aborigine, Taiwan, 2010)

In fact, informed consent procedures had been poorly enforced for most genetics research on Taiwanese aborigines. In some cases, obtaining consent was under the name of a free health check with the help of local health authorities.<sup>67</sup> However, once consent was obtained, blood samples were completely detached from the living aborigines. Even though blood is regarded as sacred for some aboriginal cultures, the informed consent procedure has “secularised” the samples so they can be easily transported without boundaries, be processed in labs and then transformed into data and information for scientific analysis. Such a process of secularisation echoes the western concept of dualism that separates an individual into mind and body and treats the body as a morally neutral item so it may be objectified and even commoditised.<sup>68</sup> Current informed consent discourse reinforces this kind of separation as it legitimates the detachment of blood from personhood and further transforms human samples into valuable resources of biocapital under the name of autonomous and self-determined donation. Arguing further from this perspective, informed consent acts ironically as a “waiver” of true autonomy as it is normally based on choices but often ignores how limited the space of negotiation could be for individuals to make their own “choices.” The situation usually deteriorates when research subjects come from a minority population. As was often pointed out during the interviews, uncertainty about how research results will be published worried most aboriginal interviewees.

What concerns us here is that we do not really understand how researchers will present their research results. In the past, some researchers just took our blood to do analysis and published their research findings in international journals in English but we have no idea at all what the content is... (A1, Taiwanese Aborigine, Taiwan, 2010)

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<sup>67</sup> Ibid

<sup>68</sup> Kerry Bowman and Maxwell Smith, "Culture, Identity and Consent for Genomic Research," in *New Challenges for Biobanks. Ethics, Law and Governance*, ed. Kris Dierickx and Pascal Borry (Intersentia, 2009).

An aboriginal respondent indicated that she would consider her consent to be valid only when some preconditions exist. One of them is the necessity to obtain group consent from her tribal group before any research findings were published in order to appropriately redress the detrimental impacts from genetics studies.

We all know that there are so many ways in terms of interpreting research results. Even if I already gave my consent, it should not be inferred that I had agreed with you to carry out research that would eventually bring harm to my group. If I had known that your research findings would bring us this kind of harm, I would not have agreed to sign the form and give my samples. (A3, Taiwanese Aborigine, Taiwan, 2010)

Due to such concern, whether individual informed consent is able to safeguard aboriginal groups from the risks of stigmatisation is highly arguable. Taking genetics research on aboriginal alcoholism as an example, the critics have challenged that the increase in alcoholism reflects Taiwan's rapid modernisation. Due to the rapid social transformation, it has disrupted aboriginal social structures fundamentally by converting their territories and land into resources for Taiwan's economic development.<sup>69</sup> However, this basic historical and social context was generally disproportionately evaluated in the interpretation of research findings. As a result, it is worth noting whether genetics research has in fact reproduced a hegemonic narrative regarding health and welfare for the Taiwanese aborigines as some critics claim.<sup>70</sup> If so, some interpretation of genetic research findings may reinforce the social impact of stigmatisation that cannot be easily justified by legal instruments such as individual consent before the research started.

Additionally, even if the Biobank Act stipulates the right of withdrawal, such rights concentrating on individuals still fail to address risks associated with biobanks as genetic data. Information in biobanks is of a collective nature and is usually analysed statistically. Although a population-based biobank relies on the use of individual samples and data for

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<sup>69</sup> Supra note 56

<sup>70</sup> More arguments can be found in Mark Munsterhjelm's doctoral thesis, "Living Dead in the Pacific: Racism, Sovereignty, and Biopolitics in Genetics Research Involving Taiwan Aborigines and Maori " (University of Windsor 2010).

genetics analysis, it is essentially a kind of research on the group itself, so the risks and harms associated with such biobanks may be imposed on the entire group not on individuals only.<sup>71</sup> Consequently, it is worth discussing whether a collective form of decision-making is required to supplement traditional individual consent especially when the research subject group is a minority population such as the Taiwanese aborigines for the biobank project in Taiwan. Some respondents suggested the necessity to have not only prior group consent for research but also further group agreement before any research findings were published in order to better safeguard aboriginal group interests.

I think that it is irrelevant whether or not I have given my consent earlier because if research results are detrimental, I would not have been willing to let researchers do a project like that, so if researchers say that I cannot say anything at this stage because a consent has been given, I would feel that I have been used (by them)...Besides, once research results have been manipulated, it will take at least another ten or twenty years to overcome the wrong impression from the whole society so even if an interpretation about genetics is proven later to be wrong, it has caused a disaster for the generation that is affected. (A3, Taiwanese Aborigine, Taiwan, 2010)

Because we are an ethnic minority, even if scientists already have our group consent (before research starts), if they are going to publish something in the future that is relevant to our group, it is still possible to cause the risk of stigmatisation for us, so they need to request another consent from our whole group before the publication. (P2, Taiwanese Aborigine, Focus Group, Taiwan 2010)

### **5.3.1.3 Economic and Political Rights of Taiwanese Aborigines**

In addition to the issue of stigmatisation, genetics research may bring tangible harms to aboriginal groups' economic and political rights. In Taiwan, since the status of aboriginal people and its associated rights' protection are embedded in law, genetic information could be used to challenge an existing aboriginal status or preventing a group from asserting its legal claims to be recognised as aborigine based on research findings.<sup>72</sup> For

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<sup>71</sup> Agomoni Ganguli-Mitra, "Collective Consent," in *Ethical Issues in Governing Biobanks: Global Perspectives* ed. Bernice Elger, Nikola Biller-Andorno, and Alexander M. Capron (Ashgate, 2008). P. 121

<sup>72</sup> Supra note 64

example, the Kavalan dispute in Taiwan demonstrated that what most worried the Kavalan aborigines was not only the lack of adequate informed consent for genetics studies, but also the concerns about recasting Kavalan's historical identity that had been shared by the entire group members. Kavalan is a recently recognised aboriginal group which had been categorised in a larger group of *plain aborigines* before its new name Kavalan was approved by the Executive Yuan in 2004. The dispute arose in April 2007 when a geneticist was requested by the Kavalan Development Association<sup>73</sup> to openly destroy the 29 saliva samples she collected for interdisciplinary research studying the migratory routes and the origins of Taiwanese aborigines. According to the claims asserted by the Association, since the sample collection was carried out in one of the Kavalan villages, it had violated Article 21 of the Indigenous Peoples' Basic Law that requires consultation and consent from aboriginal people when academic research is conducted in the aboriginal regions.

Although the implementation rules still remain to be developed, Article 21 of the Basic Law of Indigenous People was recognised as a legal ground for Taiwanese aboriginal group consent. After the samples were collected, the Association found out that some of the geneticists' earlier publications had implied that the origins of Taiwanese plain aborigines were not distinctive enough to be indigenous so this group was in danger of being declassified. Such research interpretations threatened the Kavalan as most of its population (about 3000 or so) are descendants of the plain aborigines. After complaining to the National Science Council, the funding body of the interdisciplinary research, on the grounds of violation of research ethics, the Association reached an agreement with the geneticist to withdraw completely from the research. The 29 saliva samples were returned to the village and later destroyed in public in a traditional Kavalan ceremony.

The Kavalan dispute and the ceremony made the headline in *China Times* next day and have made Taiwanese aborigines more cautious about participating in genetics studies and giving their blood or samples for academic and research uses. What often concerns them is the impact of genetics research on their historical identities based on which their sense of belonging and memories are grounded. As some respondents mentioned during

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<sup>73</sup> The association itself is a non-government organisation set up for promoting Kavalan's community works and rights movements.

the interviews, they do not need scientific research to tell them their own history and for them identities are not formed completely by biological traits. However, publication of genetic findings that contradict existing historical identities will bring more harm than benefit for aboriginal groups, especially when the aborigines have little power and limited abilities to argue against such claims made by research.

In genetics studies, you may define whether he or she is aboriginal by genetic markers, but for indigenous ourselves, ancestry or lineage is only one factor in forming our identities, it is however, not an absolute one... (A2, Taiwanese Aborigine, Taiwan, 2010)

As long as you don't have such feeling of belonging, there is not much sense to say which genes you have.. Aborigines put heavy emphasis on interrelationship and partnership.. So kinship is important but there are also many other factors we use to build up our historical identities.. I would say it is more like a cultural image, because of the collective memories we have been sharing together, we are families. Because we have lived together in this specific region for such a long time in which we establish our belongings so we feel that we belong to this group. (A1, Taiwanese Aborigine, Taiwan, 2010)

Even though the purpose of the biobank in Taiwan is not for defining ethnicity, what needs to be noticed is how to avoid the data and findings resulting from the biobanking initiative being used to form historical narratives that may contradict the aborigines' beliefs. As a result, a prior individual consent should not be interpreted as a contractual relationship from a pure legal perspective. Rather, it has to be a process of reciprocal exchange so research subjects, especially when they belong to minority populations, can have a certain amount of bargaining power to decide how the data will be processed, interpreted, and presented. A respondent recognised that even if he had been informed about the research purposes and given his consent, a potential threat to his group's identity and culture may still exist if he cannot be informed again how research findings will be published.



As for their scientific findings, you know, many of us just cannot accept their conclusions. We do not know exactly if what they are saying is correct or not. But if they didn't tell us what their research purposes are or even if they have said so but didn't inform us again about their research findings before publishing their research results, it could cause a big catastrophe for us and for our culture. (A1, Taiwanese Aborigine, Taiwan, 2010)

The concerns of the respondents indicate the limits of prior individual consent when it is applied to the aborigines in the Taiwanese context. As the aboriginal people are an ethnic group to be included in the Taiwan Biobank's sampling design, it is indispensable to re-evaluate the current consent mechanism in order to protect aboriginal groups' interests in the biobanking process in Taiwan.

### **5.3.2. Aboriginal View's on Informed Consent**

Before further discussing the mechanism of group consent, it is necessary to first explore Taiwanese aborigines' views on informed consent so their concerns with biobanking may be analysed more appropriately from a culturally specific perspective. Since culture provides an epistemological system for communication and understanding, it is a crucial factor to be considered in examining the practice of consent.<sup>74</sup> For example, the results of the interviews show that some Taiwanese aboriginal groups may hold different explanatory models of genes and illness based on their cultures and cosmological outlook.<sup>75</sup> In order to have an adequate comprehension of the informed consent requirements, these cultural aspects need to be taken into account. In addition, even though an important goal for the Taiwan Biobank is to find the causes of illness and to improve health, health and illness are both experience- loaded notions and therefore in terms of evaluations of and beliefs about these concepts, they may not be always universal. Culture provides a fundamental setting to comprehend values and beliefs shared by members of a particular social group.<sup>76</sup> It can also form a sense of belonging and identity that may redefine the boundaries of groups and communities.

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<sup>74</sup> Supra note 68. P. 66

<sup>75</sup> Arthur Kleinman, "Concepts and a Model for the Comparison of Medical Systems as Cultural Systems," *Social Science and Medicine* 12(1978). P. 85

<sup>76</sup> More explanations about the term "culture" can be found in, for example, Roger Keesing, *Cultural Anthropology : A Contemporary Perspective* (Fort Worth: Harcourt Brace College Publishers, 1998).

Sometimes, culture influences the way in which health information is configured, transmitted and comprehended by the Taiwanese aborigines. As an aboriginal interviewee indicated, due to different cultures, aboriginal groups have developed different configurations of health knowledge from the ones established for modern Western medicine. However, he took “taboo” as an example to show how similar this traditional aboriginal value is to modern knowledge of preventive medicine.

Each (aboriginal) group has its own explanation about health. In some cultures, we develop the notion of taboo. Namely, from elders we know what to do and what not to do. These taboos prevent us from being ill in our daily lives. They are developed as a way for us to maintain our health and safety in our specific environments. Now this kind of knowledge can be transferred to modern medicine to operate. The main difference is about the terminology. In fact, we already have this kind of notion (referring to health-related notions in Western medicine). But when staff from local health authorities came to our villages to teach us these things, we felt that we did not really understand what they said (referring to the terms they use). But if you knew our cultures, you could express these ideas in a different way, for example, talking to aborigines about taboos, then we can easily follow up because these are something we already have in our own cultures. (A3, Taiwanese Aborigine, Taiwan, 2010)

A similar example may be found in aboriginal views of genes and genetic research. As another aboriginal respondent suggested, in consent transactions, what needs to be avoided is use of scientific or biomedical terms to explain research purposes, its applications and goals. Rather, these ideas should be delivered in a way corresponding to the aboriginal health knowledge configuration.

Many indigenous people have a different perception about genetic-related diseases from modern western medical knowledge. They might not understand what genes are but they would connect their inherited illness to a moral or value judgement. If one suffers from a kind of genetic disease, they frequently think that it is because in their families there is someone who had violated an ancestral taboo. (A1, Taiwanese Aborigine, Taiwan, 2010)

These examples help to recognise that the practice of informed consent should be able to reflect these kinds of cultural differences in order to achieve real respect and autonomy. In the process of informing and comprehending, sample collectors and research subjects need to be able to communicate with the same language. The language here refers not only to the literal meaning of aboriginal dialects but also the underlying backdrop of aboriginal epistemology in which a culturally specific knowledge configuration may be identified. For instance, in terms of obtaining consent from Taiwanese aborigines, local people associated with aboriginal groups might be the agency to carry out recruitment and sample collection. As an aboriginal medical doctor pointed out during the interview, informed consent should be regarded as a process or, borrowing his own words, - “an encounter of the traditional and the modern” embedded in the aboriginal context in order to make the consent requirement morally justifiable. He used a twisted ankle as an instance to illustrate how the aboriginal knowledge configuration put more emphasis on the process rather than on the results.

A non-aboriginal, modern trained physician usually ignores that in aboriginal cultures we form health knowledge in a very different way. We put more emphasis on the process rather than on the result. So when an aboriginal patient comes to seek your medical advice, she might spend much time in explaining what happened to her. She puts emphasis on the process.. For informed consent, we should also treat it as a process, rather than a single event. But are sample collectors aware of this? Or they may think it is just a routine procedure they have to follow? (A3, Taiwanese Aborigine, Taiwan, 2010)

Finally, the interviewee pointed out that in consent transactions, it is necessary to identify the connotations and emotional coloration used in aboriginal communication in order to trace their feelings and implied value judgements. Due to different modes of expression and linguistic reasoning, for some aboriginal groups, even an apparently positive sentence may imply a conservative attitude that is sometimes hard to be discerned from someone not familiar with this kind of communication. It also demonstrates why it is important to cooperate with local aboriginal communities when consent is sought.

You have to get used to the way we speak... Sometimes it may sound like we agree with something as we express something in a positive way, but in reality, we have negative feelings about it. That's because we translate the sentence from our mother language to mandarin in our mind before we speak. So for informed consent you got to take into account our feelings, attitudes at that specific moment. (A3, Taiwanese Aborigine, Taiwan, 2010)

### 5.3.3 The Notion of “Group” and Its Representatives

Even though collective consent has been little discussed in the international guidelines with regard to the storage and use of human samples and data, it has been associated with the protection of indigenous rights by the Convention on Biological Diversity (CBD). Entering into force on 29 December 1993, the CBD was the first international treaty to recognise that biological diversity is a global asset and to commit to its conservation and sustainable use.<sup>77</sup> The initiative of the CBD was relevant to the international debate on extending intellectual property protection to genetic resources.<sup>78</sup> The quick expanding IP scope on genetic resources which has mostly occurred in developed countries consolidates the Northern countries' economic power and increases their political and economic influence.<sup>79</sup> It also changes the status of genetic resources that were traditionally regarded as a common heritage. However, as Stenson and Gray argued, since most biodiversity is distributed in the Southern countries, patent protection has resulted in commercialisation of genetic resources that create more value for pharmaceutical industries in the developed countries than benefits returning back to developing ones.<sup>80</sup> In order to redress this disparity, the CBD was proposed to recognise several fair and equal principles such as benefit sharing and group consent obtained from indigenous communities, etc.

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<sup>77</sup> More info, See, the CBD website: <http://www.cbd.int/history/> (Last visit: 10 March 2012)

<sup>78</sup> See, Susan Bragdon, Kathryn Garforth, and John E. Haapala Jr, "Safeguarding Biodiversity: The Convention on Biological Diversity (CBD)" in *The Future Control of Food: A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*, ed. Geoff Tansey and Tasmin Rajotte (Earthscan, 2008).

<sup>79</sup> Anthony J. Stenson & Tim S. Gray, "An Autonomy-Based Justification for Intellectual Property Rights of Indigenous Communities," *Environmental Ethics* 21, no. 2 (1999). P. 15

<sup>80</sup> Ibid.

In Taiwan, even if Article 21 of the Basic Law of Indigenous Peoples<sup>81</sup> is regarded by some aboriginal rights advocates as a legal basis for aboriginal group consent, how to implement it remains questionable. The current debates about group consent revolve mainly around its implementation rather than its principle. Even though there is recognition in the literature<sup>82</sup> of the limits of individual informed consent for biobanks, how to adequately protect group interests is still unresolved. The greatest difficulty lies in the equivocal definition of the term "group." In terms of aboriginal group consent, does "group" refer to the whole aboriginal population or their specific tribal groups or communities? Where are the boundaries drawn for a group and by which criteria are these boundaries being made? Are the criteria based on biological traits, such as blood and kinship, or on cultural ideas such as identity and memories? In addition, who may represent aboriginal groups to decide if group consent will be given or not - representative elders or chiefs of their groups or other significant figures based on their administrative tasks assigned by their groups? Certainly, all of these important questions will influence how group consent is to be implemented.

In Taiwan, aboriginal group consent has been embedded in a broader narrative of Taiwanese aboriginal autonomy. However, more concrete rules regarding how to implement this higher principle remain to be discussed. On 23 September 2010, the Executive Yuan proposed a draft of the Aboriginal Autonomy Act to the Legislative Yuan for review and approval. Nevertheless, this draft was criticised heavily by aboriginal commentators for its violation of the Basic Law's principles and failure to fulfil real aboriginal self-autonomy.<sup>83</sup> According to the draft, the creation of aboriginal autonomous regions needs to be approved not only by aboriginal group leaders but also city and

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<sup>81</sup> It stipulates as follows: I. The government or private party shall consult indigenous peoples and obtain their consent or participation, and share with indigenous peoples benefits generated from land development, resource utilization, ecology conservation and academic researches in indigenous people's regions. II. In the event that the government, laws or regulations impose restrictions on indigenous peoples' utilization of their land and natural resources, the government shall first consult with indigenous peoples or indigenous persons and obtain their consent. III. A fixed proportion of revenues generated in accordance with the preceding two paragraphs shall be allocated to the indigenous peoples' development fund to serve as returns or compensations.

<sup>82</sup> See, for example, Jane Kaye, "Abandoning Informed Consent: The Case of Genetic Research in Population Collections " in *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA*, ed. Oonagh Corrigan and Richard Tutton (Routledge, 2004).

<sup>83</sup> See, Chiou Kuo-rong and Lydia Ma, "Aborigines Protest against Illusive Aboriginal Autonomy Act," *Taiwan Church News* October 2010.; Loa lok-sin, "Aborigines Fight for Autonomy," *Taipei Times* 20 November 2010.

township councils.<sup>84</sup> Since many aboriginal groups still inhabit regions where Han Chinese are the majority, the designed mechanism would make the setting up of aboriginal autonomous regions extremely difficult.

The challenge of seeking group permission lies in the fact that the traditional social structure in Taiwanese aboriginal cultures for group consent has gradually disappeared. It makes the concept of group and community in the Taiwanese aboriginal context “fluid and porous.”<sup>85</sup> In fact, group and community are both meaning-loaded notions though they may refer to different kinds of human associations.<sup>86</sup> When asking aboriginal respondents what ‘group’ means to them during the interviews, many of them pointed out that for the case of biobanking, they think their tribal groups or the aborigines as a whole should be able to give consent. In addition, such consent should prevail over individual consent since the group may be exposed to harms and risks such as stigmatisation associated with genetic research. At the same time, some respondents also mentioned that they do not see there is a specific person, entity or organisation that may speak for all aboriginal people in Taiwan. Although they offered their opinions from aboriginal perspectives, many respondents recognised that their viewpoints may not be regarded as representative of their groups or Taiwanese aborigines as a whole.

I think group consent is necessary, but the point is how do we implement it? I doubt that we can find an organisation or entity to be representative of all aboriginal people in Taiwan. To this point, we still have no consensus about the issue of representation. If it is individual consent, there is no such problem. But for group consent, there is always an issue like that. (A4, Taiwanese Aborigine, Taiwan, 2010)

Since it remains arguable who can legitimately represent aboriginal group interests to give their consent for taking part in the biobank project, the Taiwan Biobank team had reached a decision to halt the sample collection from the Taiwanese aborigines until relevant rules are enacted. However, according to the ELSI group of the biobank team, in their original

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<sup>84</sup> Ibid.

<sup>85</sup> Here, I borrow this term to illustrate how difficult a boundary can be made to describe ‘group’ and ‘community’. See, Marshalla, Patricia, and Jessica Bergb. "Protecting Communities in Biomedical Research." *The American Journal of Bioethics* 6, no. 3 (2006). P. 25

<sup>86</sup> Ibid.

design, they would have liked to use the notion of “community” to carry out the required group consent. In this sense, community is mainly based on location and place that transcends ethnic relationships of kinship and ancestry. The proposed idea was to use the biobank project to build communities so a partnership may be established between communities and the Taiwan Biobank. It is the communities which will be responsible for recruiting individual aboriginal participants in the biobank project. These communities are located in aboriginal regions and their boundaries may have been defined as a result of a series of community development or community name rectification movements. Since several kinds of group consent mechanisms have already been developed at the community level, the biobank team hopes to use the existing collective decision structures to implement the obscure group consent requirement for recruiting Taiwanese aborigines. For instance, group consent may be obtained based on decisions made in elders’ or cadres’ meetings. Even in modern society where the traditional social structures have gradually disappeared, elders still play important symbolic roles for some aboriginal groups, especially in the groups’ ceremonies and traditional rituals. On the other hand, in some aboriginal groups, decisions with regard to ordinary administrative matters are generally made by cadres, who are usually school teachers or secretaries of local administrative officials.

Even though the biobank team would like to use the notion of community to replace the sub-divisions of the aboriginal groups, in order to create a collective entity that transcends the notion of ancestry, it ignores the fact that the biobanking data is of a collective nature so the aboriginal groups will be analysed as the Taiwanese aborigines as a whole. For that reason, even though the proposed community consent is based on the principle of group consent made by aboriginal people, it cannot be equivalent to a mechanism representing the Taiwanese aborigines when they are aggregated as an ethnic entity compared with other ethnic groups in Taiwan. It also demonstrates the current complicated situation with regard to defining the boundaries of “group” for the Taiwanese aborigines. Since most Taiwanese aboriginal people have their collective identities based on their own tribal groups, the existing collective decision mechanisms have not yet been developed to go beyond their groups’ level. However, in terms of the representation of the Taiwanese aborigines as a whole, currently there is not yet any organisation or individual that may be entrusted to fulfil this role. For instance, for some aborigines, the

Council for Indigenous Affairs is an organ of government so it is regarded as a representative of the governing class rather than a legitimate representative of the aboriginal people. As for group consent of the Taiwanese aborigines, a respondent suggested that it should be for aboriginal self-determination to decide.

The issue of representation finally needs to be solved by aboriginal self-determination. As it is not only about consent for biomedical research but also regards our collective permission and decision for land rights and name rectification, etc.. I don't see the Council for Indigenous Affairs can represent us legitimately. It is a government branch but what we ask is real autonomy that is to say let aborigines decide what we want by means of our own mechanisms... (A5, Taiwanese Aborigine, Taiwan, 2010)

Even though the issue remains unsolved in terms of how to decide who can be suitable representatives of the Taiwanese aborigines, most respondents recognise that such decisions should only be made by the aboriginal people. This viewpoint echoes the opinions of the respondents that there has to be a member of aboriginal status in ethics committees of biobanks to safeguard aboriginal rights, especially when broad consent is adopted as the consent mechanism for biobanks in Taiwan. However, this viewpoint has not yet been well reflected in the recently enacted legislation. Although Article 5 of the Human Biobank Management Act stipulates the required types of professions such as legal experts and social workers to act as members of the ethics committee, it fails to enumerate that at least aboriginal status has to be a selection criterion for satisfying the requirement of legitimate representative if the aborigines are recruited in biobanks.

## **Conclusion**

Even though informed consent has been a major issue to be discussed in biobank governance, its implementation varies across different jurisdictions. In Taiwan, consent has been positioned in the forefront among all other ethical and legal issues posed by biobanks. By analysing the process of the enactment of the Human Biobank Management Act in Taiwan, this chapter argues that the introduction of informed consent in national legislation has transformed the consent mechanism from ethics to regulation, from morality to power. Such a transformation opens up an opportunity to legitimise sample



collection when informed consent is framed as a due process for the conduct of biobanking in the Taiwanese reality. In addition, a broad consent mechanism adopted by the Taiwan Biobank consolidates the leeway of framing consent whenever the given information is entangled with the biobank's underlying policy agendas. Even though adopting a broad consent model for population biobanks is not necessarily detrimental to individual autonomy if the consent operates in a strong governance regime, the chapter suggests that there has to be a prerequisite for using an ethics committee to replace specific consent and the prerequisite lies in the establishment of the social legitimacy of the biobank project in Taiwan. This requires the public to be granted an opportunity to debate the necessity of the project as well as its research design so the voices from the public can be well reflected along with the development of the biobank project.

Furthermore, the chapter argues that by setting aside other essential issues of biobanking such as access and ownership, consent has been instrumentalised as an ethical and legitimate way to justify sample collection. The consent mechanism satisfies the general expectation of good ethics for biobanks at the expense of substantive deliberation of the important arrangement of rights and benefits associated with biobanking. By so doing, the practice of consent in biobanking in the Taiwanese context has difficulty fulfilling its original purpose although informed consent has been articulated as the major narrative in the bioethical discourse and in Taiwan's legislation. Besides, the current consent mechanism emphasizing individualism has failed to safeguard Taiwanese aboriginal group interests when they are recruited for the Taiwan Biobank. By analysing aboriginal viewpoints on informed consent, the chapter hopes to provide a culturally specific perspective that may contribute to the current discussions of consent requirements for biobanks, which focus only on the types of information to be delivered rather than the modes of delivery and the comprehension of such information. Since the aborigines have been in the margin of Taiwanese society, in order to avoid the potential risks and harms of stigmatisation, group consent is necessary in addition to individual consent whenever the aborigines become a target of sampling in biobanks in Taiwan.

Finally, for better respect of aboriginal group interests in biobanks, this chapter argues that consent needs to be regarded as a process rather than an event so the aborigines should be entitled to be consulted before any related research findings are to be

published. Although there is still no consensus among Taiwanese aborigines with regard to how to implement group consent, the issues of representation and the boundaries of groups should be decided by the aborigines themselves. Because Taiwanese aborigines are minority populations in the Taiwan Biobank project, the practice of informed consent in Taiwan has its own special characteristics. In such practice, individual consent needs to be supplemented by aboriginal group consent whenever the research design plans to recruit aborigines in the conduct of biobanking. In addition, in terms of qualification for the selection of members of ethics committees, aboriginal status needs to be stipulated in order to better represent Taiwanese ethnicities.

Even though informed consent has been introduced in national legislation in Taiwan, many issues remain in its practice in terms of achieving “good ethics” and the protection of participants’ interests in biobanks. Since the biobank project in Taiwan has gradually transformed from a research platform to a social and political enterprise, the Taiwanese experience may provide a distinct opportunity to reflect on the current principle and discussion of informed consent on biobanks. In the end, the chapter argues that informed consent should not be regarded as only a contractual relationship but as a relationship of trust.

## Chapter 6 Property, Privacy and Commodification

### Introduction

In the politics of the life sciences, biobanks are regarded not only as modern assemblages of human tissue and genetic information but also as unsettling relations between persons and things.<sup>1</sup> Viewing property relations as a culturally specific form of power, various social entitlements have been invented in order to meet the interests of different groups involved in the process of biobanking.<sup>2</sup> Access and ownership are two crucial but contested issues often raised and discussed in biobank governance. Even though collection and storage of human biological materials for treatment and research purposes is not a novel phenomenon, biobanks are distinguishable from the old collection by their open-ended nature and by containing biospecimens and genetic information that may be linked with phenotypic data and genealogical records. In addition, human tissue and health information have increasingly become useful resources of biovalue along with the development of biomedical innovations. As a result, biobanks bring new challenges to ownership with regard to property entitlements in stored tissue samples, personal health information and databases themselves.

A question worth further discussion is whether recognising property rights in human tissue and genetic information derived from it would be more appropriate to protect the sources of the tissue in terms of retaining control over its use once the tissue has been removed from the body. In addition, when human tissue samples are processed and transformed from gifts to commodities, whether the sources are entitled to claim for any share of benefits on the ground that they are the “owners” of their tissues? The well-documented *Moore* case opens up profound debates about ownership of the human body and body parts.<sup>3</sup> It also makes a legal distinction between property and personhood.

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<sup>1</sup> David E. Winickoff, "Partnership In. U.K. Biobank: A Third Way. For Genomic. Property? ," *Journal of Law, Medicine and Ethics* 35, no. 3 (2007). P. 440

<sup>2</sup> Klaus Hoeyer, "The Emergence of an Entitlement Framework for Stored Tissue - Elements and Implications of an Escalating Conflict in Sweden," *Science Studies* 17, no. 2 (2004). pp 63-64

<sup>3</sup> After the *Moore* case, subsequent *Greenberg* and *Catalona* cases also upheld the principle that the sources of the human bodily material hold no property rights when the material was voluntarily handed over. More discussions about the cases, see, Rao, Radhika. "Genes and Spleens: Property, Contract, or

The patenting of the cell line, Mo, transformed Moore's excised tissues through invention from "biological substances in their natural state" to the enhancement made by "added human labour."<sup>4</sup> Such enhancement is deemed to be distinct from Moore's personhood according to the legal dichotomy of nature and invention.<sup>5</sup> The decision upholds the inalienability of the human body by personifying tissue, which is treated as the essence of the person rather than as a commodity for exchange.<sup>6</sup> Even though the case tends to prevent human tissue from being commodified by refusing to recognise self-ownership of human body parts, the presumed gift model implied from using consent to replace property renders patients and research subjects powerless in a capitalist market system in which biotechnological commodification has turned human tissue from waste to resources of biovalue.

In Taiwan, the issue of property has been relatively ignored in discussions of biobank governance. Bioethical concerns have, instead, focused heavily on consent and privacy. On the one hand, this demonstrates that property in the body has not yet been *formally* recognised in the Taiwanese jurisdiction.<sup>7</sup> On the other hand, however, it illustrates that the role of capital and markets may have been insufficiently represented in the ethical configuration of biobanking practice in Taiwan. Gift relationship and solidarity constitute the main discourses of sample collection for the biobank, which has been purveyed to the public as an altruistic enterprise that will benefit public health and facilitate the production of scientific knowledge. In addition, technical safeguards have been introduced into legal frameworks in order to protect the privacy of individuals which is considered to be an indispensable fundamental right advocated by local human rights groups. Since privacy rather than property dominates the ethical concerns surrounding

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Privacy Rights in the Human Body?" *The Journal of Law, Medicine & Ethics* 35, no. 3 (2007).

<sup>4</sup> Klaus Hoeyer, "Person, Patent and Property: A Critique of the Commodification Hypothesis," *BioSocieties* 2, no. 3 (2007). P. 338

<sup>5</sup> *Ibid.*

<sup>6</sup> *Supra* note 4. P. 339

<sup>7</sup> In Taiwan, the legal status of removed human tissue is not yet clear. In civil law tradition, once human tissue is separated or removed from the human body, it is considered to be abandoned as "waste" and therefore the source of the tissue has no further property rights on it. In Taiwan, there have been no rules or adjudication to demonstrate legislative and judicial opinions about the legal status of human tissues even though the recognition of property rights on human body parts has been supported by some legal scholars in Taiwan. For instance, according to Wang Tez-Chien, there are proprietary interests on removed human body parts so the source is entitled to ownership although whether the removed tissue or body parts may become consideration of contract still depends on the principle of *ordre public* and *boni mores*. See, Wang Tez-Chien, *General Rinciple of Civil Law* (2000). (in Chinese) pp 233-234

biobank governance, issues such as commodification of human biological samples and the penetration of market forces into human tissue and personal health data seem to have not yet been seriously reflected upon in Taiwanese society.

This chapter discusses property and privacy concerns with regard to biobanking. It first analyses the Moore case and its relevant theoretical issues about the commodification of human body parts. It then studies the case of Taiwan in order to examine whether the existing legal framework is sufficient to protect research subjects and if the recognition of property interests in human tissue and health information may be an alternative supplement to bioethical practice in the Taiwanese context.

## **6.1 Property in Human Biological Materials**

### **6.1.1 Fictitious Commodities**

According to John Locke's labour theory of property, an appropriator may claim the "fruits of labour" over a resource by mixing his or her labour with it in the course of production. Locke's epistemology presupposes the distinction of subject and object and the object may become property of the subject who works on it. For Locke, ownership is a natural right which implies exclusive possession for particular individuals as a form of social control of the arrangement of resources. The justification for an exclusive right is through the individual's labour on things as that can be viewed as an expression of the self. Nevertheless, applying Locke's theory to the human body and genetic information in the post genomic era remains complex. Even though new technology has brought with it various innovative forms of potential property, such as cell lines, DNA, genome and genealogies, concerns are raised when the increasing association of market and science gradually transforms human tissue and DNA into commercial property that blurs the distinction of persons and things and makes the new creature possible to be exchanged in the marketplace in the form of commodities.<sup>8</sup>

Throughout history, the human body and its parts has been a target for commodification that can be traced through various forms such as slavery and female reproduction.<sup>9</sup>

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<sup>8</sup> Gisli Palsson, *Anthropology and the New Genetics* (Cambridge University Press, 2007). P. 173

<sup>9</sup> More info about the history of human body commodification may be found in Lesley A. Sharp, "The Commodification of the Body and Its Parts," *Annual Review of Anthropology* 29(2000). pp 287-328

Although commodification remains a controversial notion when it applies to bodies for the purpose of medical technology, issues about commodifying bodies involve the formation of a new social relationship that is increasingly challenged and governed by market rules. Anthropologist Arjun Appadurai argues that it is *politics* that focuses on the things exchanged rather than simply on the forms or functions of exchange and creates the link between exchange and value, which is embodied in commodities.<sup>10</sup> Because commodities may be defined as objects of economic value which can be created by exchange,<sup>11</sup> when objects are put into circulation in a monetary economy, they gradually lose their “social lives”, as Appadurai puts it, in the process of being commoditised.<sup>12</sup> For Appadurai, the omission of the trajectories of things is a kind of methodological fetishism since it ignores apparently that things-in-motion may illuminate their human and social settings.<sup>13</sup> By extending Marxian commodity fetishism, which denotes the mystification of commodities as if they attain independent power that are separable from social relations in which they were produced and exchanged, Appadurai argues that social life of an object may be understood by situating it within a culturally constructed context. By pushing Appadurai’s argument further, it may be worth expanding attention and analysis from things and their exchange to the *politics* itself in which social setting is embedded. In the context of commodifying bodies, this shift refers to exploring the circumstances and conditions by which human tissue may be deemed to be an economic object that can be detached from personhood and commodified for free circulation in a modern market system.

In arenas of bioethics and law, informed consent has come to play a significant role for instituting a procedural scheme in which persons may be distinguished from things by withdrawing their subjectivities from tissue samples. Moreover, by being granted the

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<sup>10</sup> Arjun Appadurai, "Introduction: Commodities and the Politics of Value," in *The Social Life of Things : Commodities in Cultural Perspective*, ed. Arjun Appadurai (Cambridge: Cambridge University Press, 1986). P. 3

<sup>11</sup> For instance, For Karl Marx, a product needs to be transferred to another to serve its social use values in order to be considered as a commodity. More info, see, Karl Marx, *Capital, Vol. I: A Critical Analysis of Capitalist Production* (International Publishers Co, 1967).

<sup>12</sup> In order to argue what constitutes commodity exchange, Appadurai contrasts this form of exchange with two other different kinds of exchange modes - barter (direct exchange) and the exchange of gifts. For Appadurai, barter may be regarded as one form of commodity exchange in which money plays an indirect role and gifts represent the spirit of reciprocity that link things to persons and also embed a drive mediated by sociality.

<sup>13</sup> Supra note 10

authority to give consent, persons are qualified as subjects of biotechnology; as Alain Pottage argues, it illustrates how the replication of contemporary bio-power is different from the traditional sovereign power which emphasizes the power over the extinction of a subject's life.<sup>14</sup> Even though the classical sovereign power is characterised by the power to 'take life or let live', in the modern biopower, according to Michel Foucault, individual autonomy has become a technique of self-governance for modern states to govern its subjects. However, due to the limits of consent, this broadly applied bioethical mechanism may only ensure a conditional autonomous decision when consent is given and no further control of the use of tissue samples for consenters may be expected without appropriately recognizing property rights in human bodies and body parts. Modern technology and molecular biology have given rise to serious debates concerning ownership in bodies as they have opened up lucrative opportunities for marketing of body parts and their derived DNA information. Even though whether somatic commodification is acceptable depends on the particular historical and social context, the influence of markets and capital on the trend of biotechnological commodification is worth further analysis.

When life becomes an object of manipulation, it turns to be a new fetish in the history of modernity. For Ivan Illich, such focus on the extension of life at any cost by the invention of medications has made life into the ultimate fetish that transforms a person into a life-as-such that may be saved and prolonged by the intervention of modern medical technologies.<sup>15</sup> By extending Illich's notion of the fetishisation of life, Scheper-Hughes argues that modern biotechnology such as organ transplants has introduced an "artificially created need", in the words of Illich, that erases the possibility of a social ethic by disguising bioethical choice as individual autonomy.<sup>16</sup> In addition, such fetishisation creates new relations between the market, technologies and human body parts that have reconceptualised the meaning of property in human bodies and at the same time, have driven the alienation of human body parts for biomedical research. In the global economy, as Margaret Lock points out, the escalation of procurement of human tissue to make

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<sup>14</sup> Alain Pottage, "Persons and Things. An Ethnographic Analogy," *Economy & Society* 30, no. 1 (2001). pp 122-3

<sup>15</sup> Ivan Illich, "The Institutional Construction of a New Fetish: Human Life," in *Ivan Illich: In the Mirror of the Past, Lectures and Addresses* (New York: Marion Boyars, 1992).

<sup>16</sup> Nancy Scheper-Hughes, "Bodies for Sale- Whole or in Parts," in *Commodifying Bodies*, ed. Nancy Scheper-Hughes and Loïc J. D. Wacquant (SAGE, 2002). P. 3

patenting of tissue samples and cells has constituted a sign of “globalised commodity fetishism.”<sup>17</sup> Such fetishism illustrates how human tissue may have been transformed into technological artifacts in the process of patenting and how patent as a legal technique may keep transgressing the boundaries between nature and artifacts. In the current age of genomics, human tissue, cells and genetic materials have been deemed to be a part of a “commodity fiction,” in the words of Karl Polanyi, while considering the exposure of nature to a market economy. The commodification of bodies now forms a new discourse in scientific and biotech advances by creating a space for the speedy flow of technologies and capital across the globe.<sup>18</sup>

By analysing social and economic changes brought about by the great transformation of the Industrial Revolution in the nineteenth century, Polanyi argues that the self-regulating market system which has emerged since then has made society separate into an economic and a political sphere.<sup>19</sup> In ancient civilisations, the market was not an institutional pattern as it later evolved but a meeting place for trade and exchange of goods. Therefore, before the industrial revolution, the economy was mainly embedded in social relationships and was operated through reciprocity and redistribution guaranteed by an environment for continued exchange of resources, either due to a symmetrical relationship between trading partners or a centrality for the rearrangement.<sup>20</sup> The market itself was a part of society, and it was subject to social relations and governed by other mechanisms such as community arrangements, moral considerations and religious beliefs.<sup>21</sup>

A new market pattern emerged when the great transformation occurred that made markets be regarded as autonomous forces separating from society. In this self-regulating market economy, as Polanyi argues, production was no longer for household use or for exchange but for gain, and the crucial elements of industrial life - labour, land and money - were treated as commodities for selling and buying. In this market system, the order of production and distribution of goods was ensured by prices alone as everyone was

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<sup>17</sup> Margaret Lock, "The Alienation of Body Tissue and the Biopolitics of Immortalized Cell Lines," in *Commodifying Bodies*, ed. Nancy Scheper-Hughes and Loïc J. D. Wacquant (SAGE, 2002). P. 65

<sup>18</sup> Supra note 16

<sup>19</sup> Karl Polanyi, *The Great Transformation : The Political and Economic Origins of Our Time* (Boston: Gower Beacon Press, 1957).

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.



assumed to act for the purpose of seeking maximum gains.<sup>22</sup> For Polanyi, such a market economy could only function in a market society, which means that all elements of industry, including the substance of society itself, needed to be included into the market mechanism and subordinated to the laws of the market. The so-called self-regulating market implied that all production was for sale and was regulated by prices. In this system, labour and land were no longer human beings and natural surroundings but also commodities for sale and purchase. Polanyi recognises that the deficiency of the market system is based on this “commodity fiction”, as a true commodity needs to be *produced* for sale, and as a result, labour, land and money are only “fictitious commodities” as they are not produced for sale but regarded as commodities in order to organize the market system.<sup>23</sup>

Modern critiques of the commodification of bodies are commonly manifested as a resistance to this self-regulating market system in which the ideal society embedded in sociability and morality is now challenged by a profit-orientation. In order to respond to the increasing desire for the enhancement of life driven by both global capitalism and biotechnology, body materials and fluids are allowed to transform into fungible commodities by removal, extraction, processing and perhaps patenting in the end as a way to create commercial value. The process of transformation constitutes a part of circulation that commodifies body samples in economic exchange which is associated with the capitalist mode of production and consumption. As Appadurai points out, in modern capitalist societies more contexts are likely to become legitimate commodity contexts, within which the standards and criteria that define the exchangeability of things may embrace a larger part of the world of things than in non-capitalist societies.<sup>24</sup> It shows that the extent to which a thing may be regarded as a commodity depends not only on its social status of exchangeability but also on the political and cultural contexts in which the thing belongs.

In anthropological writing, the contrast between primitive and modern societies is often presented as an embedded social and cultural setting for the distinction between gifts and commodities. Putting such a contrast in a very simplified way, gifts linking things to

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<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

<sup>24</sup> Supra note 10, pp 14-15

persons and relations usually represent the spirit of reciprocity that is contrasted to the nature of commodities which are relatively impersonal and are largely deemed to be free of cultural constraints.<sup>25</sup> Even though it is a very rough distinction that has been criticized for ignoring the common spirit found in gift and commodity circulation, such a mutually exclusive distinction has added a critical dimension to reflect the invisible association of politics and value in the process of commoditization. In other words, it is worth thinking over who has been benefited in terms of creating a commodity flow in a self-regulating market system or, as Appadurai enquires, - “who is permitted to exercise what kind of effective demand in what circumstances”<sup>26</sup> so that a thing may be commoditized for circulation and exchange.

The new genetics and genome research has redefined and expanded the notions of property in response to the increasing monopolies exercised by pharmaceutical industries. Since a DNA sequence is allowed to be patentable, the idea of UNESCO which proposes to treat the human genome as the common heritage of humankind in order to avoid abuse by private interests only remains a symbolic meaning. Furthermore, in the arena of law, ownership and property rights in the human body and body parts are still unsettled. Even though invention, such as cell lines, may be the subject of property by recognising Locke’s labour theory, its rights of control derive mainly from added values rather than from the sources. As a result, whether a proprietary interest may be recognised in the sources themselves remains legally complex. In some jurisdictions, privacy and informed consent have been proposed to replace property as a regulatory mode to govern the control and use of human tissue in medical research. Nevertheless, without an appropriate recognition of property rights in human body parts, it has disempowered patients and sample donors by treating their removed tissue as either waste or gift.

### **6.1.2 The *John Moore* Case**

The famous but contentious John Moore case demonstrates that in the common law tradition, property of excised tissue may be granted by patent through invention; however, such ownership has not yet been extended to the subject of the tissue by simply alleging that the subject is entitled to share the financial benefits derived from patent because she

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<sup>25</sup> Supra note 10, P. 11

<sup>26</sup> Supra note 10, P. 57

or he is the “owner” of the biological materials.<sup>27</sup> In the case, Moore, the plaintiff, was diagnosed with and under treatment for hairy-cell leukemia by Dr. Golde at the UCLA Medical Centre. In October 1976, Moore underwent a splenectomy operation. Although Moore had signed a written consent form for the operation based on Golde’s representations, he was not informed of Golde’s plan to establish a cell line from his excised tissues; neither had his permission been requested to carry out this kind of research. From November 1976 to September 1983, Moore traveled several times from his home in Seattle to the UCLA Medical Centre in Los Angeles for the follow up treatment because of the suggestions of Golde, who then took additional samples from Moore without his consent. In 1979, Golde established an immortal cell line from Moore’s T-lymphocytes that was later issued a patent in 1984, naming Golde and his assistant Quan as the inventors and the Regents of University of California as the assignee. Later, Golde made an agreement with the Genetics Institute for commercial development of the cell line. In the agreement, the Genetics Institute had exclusive access to the cell line and it agreed to pay Golde 75,000 shares of common stock and Golde and the Regents at least USD 330,000 over three years in exchange for the use of the cell line. Moore discovered the deal thereafter. He sued for a share of the financial benefits based on 13 causes of action including conversion.<sup>28</sup>

The majority of the California Supreme Court rejected the argument that Moore’s excised tissue should be protected by conversion of property in order to protect Moore’s interest in his bodily integrity and privacy. Viewing conversion as a strict liability tort and considering extending it might sacrifice the protection of innocent parties in society. The court pointed out that patients’ rights of privacy and autonomy would be better protected by existing disclosure obligations in the fiduciary duty and informed consent theories without hindering research by restricting access to or exchange of the raw materials.<sup>29</sup> In his concurring opinion, Justice Arabian identified the moral issue of the case as the plaintiff’s request for the court to recognise and enforce a right to “sell one’s

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<sup>27</sup> *Moore V. The Regents of University of California*, (1990). 51 Cal.3d 120, 793 P.2d 479, 271 Cal.Rptr. 146.

<sup>28</sup> Conversion is a tort of strict liability in common law. It refers to an act by one person that infringes another’s ownership rights even though the person’s voluntary act is without culpability. So, conversion is a civil action that is distinguishable from a criminal action such as theft, which however, requires an element of dishonesty.

<sup>29</sup> Supra note 27

own body tissue for profit.”<sup>30</sup> He argued that recognizing Moore’s claim for conversion of his body tissue was like regarding the most venerated subject in any civilized society as a “commercial commodity” and therefore commingled “the sacred with the profane.”<sup>31</sup>

According to the court, Moore did not retain a sufficient interest of possession in his excised cells to support a cause of action for conversion although under traditional common law principles, a plaintiff may recover the economic value of the right to control the use of his body parts. When considering whether to “extend” the liability of the tort of conversion to the case, the court held as a matter of policy that a patient’s continuing interest in the use of excised cells should be limited because imposing tortious liability to the use of human samples in research meant imposing on scientists a duty to investigate the pedigree of each sample they used and would have a negative influence on medical research in society.<sup>32</sup> In addition, by citing *Diamond v. Chakrabarty*<sup>33</sup>, the famous intellectual property case in the United States in 1980, the court recognised that the patented cell line in the Moore case was the product of invention since what patent law rewards was inventive efforts rather than the discovery of “naturally occurring raw materials.”<sup>34</sup> As a result, the cell line was considered by the court both “factually and legally”<sup>35</sup> distinct from the cells taken from Moore’s body that made Moore’s allegations that he “owned” the cell line because he was the subject of the cells inconsistent with the rationale of patent law.

Even though the court stated that it did not purport to hold that property can never be granted in excised tissue without considering any purposes, it claimed that in the Moore case relevant policy considerations were taken into account in order to decide if the extension of liability of conversion would be necessary. However, such policy considerations were not based only on an apparent reason to avoid judicial uncertainty as the reasoning of the adjudication explained. On the contrary, they also aimed to facilitate the market economy because uncertainty about the legal title of human

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<sup>30</sup> Ibid.

<sup>31</sup> Ibid.

<sup>32</sup> Ibid.

<sup>33</sup> In the case, the Supreme Court of the United States held that a genetically engineered bacterium was patentable as a “new and useful manufacture.” More info, see, *Diamond v. Chakrabarty* (1980) 447 U.S. 303

<sup>34</sup> Supra note 27

<sup>35</sup> Ibid.

samples might affect commercial use of medical research and companies' willingness to invest in developing a patented product, which mainly relied on samples provided by human sources.<sup>36</sup> The Moore case has made the legal status of human body parts elusive and ambiguous. After all, it was legally untenable, as Justice Mosk remarked in his dissenting opinion, that the defendants could own Moore's tissues but Moore himself could not. Despite the worries of commodification of human body parts implied by the decision, for research resulting in significant financial benefits for the researchers but almost no gain for sample donors, it was equivalent to treating the human body as a commodity, namely a means to an end.<sup>37</sup>

In addition, the court rejected a proposal to expand the notion of "joint inventor" to include the human source of biological materials used in research, so that sample donors were completely excluded from the property model.<sup>38</sup> The difficulty of the case, perhaps as Justice Arabian commented, lay in requiring a choice to be made between competing social and economic policies, namely the court was asked to decide whether treating human tissue as fungible articles of commerce would uplift or degrade the human condition in both spiritual and scientific senses.<sup>39</sup> As the implications of the decision on research and industrial development would be profound, recognizing a property interest in human tissue seemed to have involved engaging with conflicting moral and philosophical values.

The Moore case demonstrates that market and economic impact has been acting as a crucial policy reason, which, however, ignores other equally important factors such as notions of equity and distributive justice. Since the parties in the case did not have equal bargaining power, in order to prevent unjust enrichment, recognizing that the plaintiff had a property interest in his excised tissues may entitle him to an equitable share as a morally acceptable result of fairness.<sup>40</sup> Besides, the nondisclosure cause of action such as informed consent was in reality inadequate to protect Moore's interests as it gave him

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<sup>36</sup> As researchers may have no reason to know whether their use of a particular sample is infringing sample sources' rights.

<sup>37</sup> Justice Mosk's dissenting opinions, see: *Moore V. The Regents of University of California*. (1990) 51 Cal.3d 120, 793 P.2d 479, 271 Cal.Rptr 146

<sup>38</sup> For the majority view of the court, it was Congress' exclusive power to effect change in the law so the criticism of the law's present state should have no legitimate bearing on the court's disposition of the case.

<sup>39</sup> Supra note 37

<sup>40</sup> Ibid.

only a right to veto rather than entitling him to an affirmative right to consent to the commercialisation of his tissues and to request sharing in its proceeds. Moreover, by exercising consent, as the dissenting opinion already points out, it is not possible to reach potential defendants outside of the formal physician-patient relationship, such as research institutes or pharmaceutical companies, which are often major parties involved in the control and use of patients' tissues. Since the nondisclosure cause of action fails to protect Moore's affirmative rights to share in the proceeds and it may make the true exploiters escape from their liabilities, it should not be deemed to be an adequate substitute for conversion as the Court held.<sup>41</sup>

## **6.2 Gift Relationship, Reciprocity and Benefit Sharing**

Like the Moore case, the consent mechanism proposed by the pilot study of the Taiwan Biobank claims that participants retain no property rights in their donated tissue samples and therefore they are not entitled to claim any interests of intellectual property if granted in the future based on the use of the tissues in question.<sup>42</sup> Since Moore did not really consent to removal of the cells from his spleen for the purposes of research and commercialisation, whether his consent to treatment for his hairy-cell leukemia would suggest abandonment of his excised cells was not yet clear and is certainly worth discussion. However, had Moore indeed been well informed of the potential commercial use of his cells and had he also given his consent to his doctor for patenting of the cell line, the formulations of consent would have granted Moore only an illusory power in terms of exercising continuing control of his body materials. In biomedical research, in order to ensure the participation is on a voluntary basis without any undue influence, consent has been deemed to be the most important, or in some circumstances, the only appropriate ethical and legal approach to procure samples. However, once consent is obtained, the continued relationship with donors and their samples has ceased with the result that it precludes research subjects from being considered as stakeholders in the overall research project.

A recent case with regard to gene hunting in the Solomon Islands illustrates the limits on consent in terms of empowering and providing real respect for the research subjects in

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<sup>41</sup> Ibid.

<sup>42</sup> The Pilot Study of the Taiwan Biobank Informed Consent Form

the context of commercialisation of collected samples. On 1 April 2011, a Taiwanese medical researcher, Dr. Ko Ying-Chin, filed an express abandonment of his patent application entitled "Method and Kit for Assessing Risk of Gout and Hyperuricemia" to the United States Patent and Trademark Office.<sup>43</sup> The patent application was reported to use genetic samples from 192 Solomon Islanders collected in the Islands' local hospitals during a research trip led by Ko in 2006. The withdrawal of the patent application was in response to the public challenge of serious ethical breaches raised by the Network of the Indigenous Peoples- Solomons (NIPS). The NIPS' claim was supported by other local NGOs and the government of the Solomon Islands. The basis of the challenge lay in the inappropriateness of the informed consent obtained from blood donors in 2006 which stated that blood was limited to medical research uses and contained no mention of using the collected samples for patenting and commercial purposes.<sup>44</sup> According to the NIPS, even though the process of patent application was now stopped and Ko stated that he did not immortalize cell lines based on the samples and he would be willing to repatriate the samples back to the Solomon Islands, it was still not clear whether the collected samples had been shared with other researchers in Taiwan or abroad.<sup>45</sup> A similar scenario happened about a year ago when Ko and his colleague were forced to withdraw another US patent application that involved using samples from 1500 Taiwan Atayal Aboriginal donors with informed consent only for health research rather than for commercialization.<sup>46</sup>

Both cases involved biopiracy and raise serious questions about consent. Even though obtaining consent has been deemed to be a part of the official process that a researcher in Taiwan needs to go through in order to have permission to carry out medical research in Taiwan and abroad, it is far from a sufficient mechanism in terms of continued monitoring of the use of samples by research subjects. The Moore case seems to suggest that consent may sufficiently empower the plaintiff so that the recognition of proprietary rights in bodies is not necessary. Such a point of view putting consent and property in a position of mutual exclusivity has been questioned by some legal scholars.<sup>47</sup> For instance,

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<sup>43</sup> "Doctor Abandons Us Patent Application," *Solomon Times Online* 11 April 2011. More info, see, <http://www.solomontimes.com/news.aspx?nwID=6035> (Last visit: 10 March 2012)

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> "Patent Application Withdrawn in Biopiracy Dispute," *United Daily News* 24 March 2010.

<sup>47</sup> Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University

Beyleveld and Brownsword argue that the informed consent strategy presupposes that there is property in our own bodies and body parts so that, rather than denying it, the rights lying behind consent regimes are “most plausibly explained as proprietary.”<sup>48</sup> Graeme Laurie also suggests that a property model may serve as a major supplement to privacy and autonomy in protection of the personality if it can empower research subjects by providing them with continuing control over their samples or information.<sup>49</sup> Laurie further points out that the language of ‘gift’ used frequently in bioethical discourses implies ownership and property but it has been used in a way associated with altruistic behavior, so rather than being deemed to be exercises of self-ownership, in the context of donation, the concept of gift presumes the surrender of an individual’s residual interests in donated samples.<sup>50</sup>

### 6.2.1 Reassessing the Gift Relationship

In his work *The Gift Relationship*, Richard Titmuss studied the role of altruism in modern society by comparing blood donation systems on both sides of the Atlantic in the 1960s.<sup>51</sup> He argues that the commercially oriented approach of blood procurement in the United States not only led to the exploitation of socially disadvantaged groups and the production of contaminated blood but was also degrading for society as a whole by diminishing social solidarity and altruism.<sup>52</sup> Giving, for Titmuss, was the human capacity that demonstrates the individual’s conception of the needs of others and their views of external world, and to donate is to give with an altruistic motive.<sup>53</sup> Recognising that men

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Press, 2002). P. 315

<sup>48</sup> By building on the “rule preclusionary” conception of property based on Article 22 of the Council of Europe’s Convention on Human Rights and Biomedicine, Beyleveld and Brownsword argue that “a person’s own body is par excellence the kind of thing that might be treated as one’s property.” Recognising this argument might not demonstrate conclusively that a property interest exists in human bodies and body parts, Beyleveld and Brownsword point out that the argument may be used to illustrate why the mechanism of consent implies an underlying property regime. Because the post-intervention informed consent regime of Article 22 includes rights in relation to the control over the post-removal use of human body parts, insisting on the consent requirement, as the authors argue, is to accept that “the person has a protected interest in the uses to which his body parts are put.” More indo, See: Deryck Beyleveld and Roger Brownsword, “My Body, My Body Parts, My Property?,” *Health Care Analysis* 8, no. 2 (2000). pp 88-96

<sup>49</sup> Supra note 47, P. 316

<sup>50</sup> Supra note 47, P. 317

<sup>51</sup> Richard Titmuss, *The Gift Relationship : From Human Blood to Social Policy* (London: London School of Economics & Political Science, republished 1997). P. 59

<sup>52</sup> Richard Tutton, “Person, Property and Gift: Exploring Languages of Tissue Donation to Biomedical Research,” in *Genetic Databases : Socio-Ethical Issues in the Collection and Use of DNA*, ed. Richard Tutton and Oonagh Corrigan (London and New York Routledge, 2004). P. 25

<sup>53</sup> Supra note 51, P. 305



are not born to give, Titmuss argued that it is the government's responsibility to set up instruments and institutions of public policy in order to foster the individual expression of altruism because eventually this kind of moral behaviour contributes to holding a society together.<sup>54</sup> As a proponent of the welfare state, Titmuss's idea of altruism was for utilitarian purposes. For him, preserving the freedom of the individual is the potential role that social policy should play. According to Titmuss, the voluntary blood donation system operated in Britain was an important way to form a sense of community and solidarity because it mainly relied on donors' altruism to give blood to unknown strangers on whom no obligations were imposed to make a corresponding gift in return.

Titmuss's notion of gift relationship has been commonly used as a policy model to govern the relationship of researchers and research subjects. For instance, the ethical guidelines published by the Medical Research Council (MRC) of the UK in 2001 made a clear statement that "samples of human biological materials obtained for use in research should be treated as gifts."<sup>55</sup> The rationale behind the guidelines reflects the undesirability of the commodification of human body parts, so rather than viewing biological materials as commodities for sale, such materials are deemed to be altruistic gifts. Gift-giving is therefore being categorised in the context of medical research. On the one hand, it has been viewed as a legitimate way for the transfer of samples in accordance with the distinction between personhood and property so even though body parts cannot be sold, they may be given. On the other hand, the language of gift reflects an altruistic nature that is conceived as expressing the quality of human values, as Titmuss puts it, in order to benefit the greater common good. Nevertheless, as Richard Tutton rightly recognises, such a gift model may have been used as a boundary maker around the commercialisation of tissue samples that implies a tendency to avoid the rearrangement of entitlements for a share of profits and for the exercise of control over the samples.<sup>56</sup>

In order to make the provision of human biological materials for research being treated as a non-commercial transaction, the gift model precludes donors from any further claims

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<sup>54</sup> Supra note 51, P. 59

<sup>55</sup> Medical Reserach Council, "Human Tissue and Biological Samples for Use in Research - Operational and Ethical Guidelines," (May 2001 ).

<sup>56</sup> Supra note 52, P. 20

to their samples after donation and from entitlements for a share of benefit made from its commercial development. However, the increasing entanglement of science and markets has constituted a very different political and social setting from the time of the 1960s when Titmuss proposed his altruistic ideal to underpin the British blood donation system. Even though it may be true, as Titmuss argues, that the essential altruism fostered by the British National Health Service was vital to the moral health of the welfare state, there remain crucial differences between blood donation and biobanking itself. Compared to blood donation, which is more like a random one-off event except for some regular donors, biobanking relies on participants' long-term involvement for discovery research by establishing the correlations of genotype and phenotype through linking DNA information with health data.<sup>57</sup> In addition, for Titmuss, it is anonymity that makes pure gifts possible as donating blood to unknown strangers frees recipients from social obligatory returns of gifts. However, the anonymous gifts Titmuss relied on to depart from Marcel Mauss's anthropological account of gift exchange may not fit well in the context of biobanking in which recipients are no longer disinterested strangers but specific biobankers.

For Mauss, gifts are not given for free. By observing gift exchange in Polynesian culture where the exchange is governed by the notion of *mana* - a spiritual quality of supernatural origin existing in the universe - , Mauss argued that in archaic societies, gifts are deemed to be a mode of exchange that helps establish the bonds of reciprocity between givers and recipients.<sup>58</sup> Because having *mana* is to have prestige and authority, gift-giving represents a way for the givers to maintain and increase such glory, wealth and honour, and to reciprocate gifts shows the willingness of the recipients to accept the bond of alliance and commonality.<sup>59</sup> To refuse the gifts means to reject the social bond which values communal identity and may even be tantamount to the declaration of war.<sup>60</sup> In this mode of exchange, the gift is no longer a mere object but may be deemed to be a spiritual article that constitutes a part of the giver who has been indissoluble from it.

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<sup>57</sup> It is also worth considering different purposes of donation. For example, donation for the purpose of saving other people's lives may differ in important ways from donation for research or other treatment purposes. See: Nuffield Council on Bioethics. "Human Bodies: Donation for Medicine and Research ", 11 October 2011. P. 132

<sup>58</sup> Marcel Mauss, *The Gift : The Form and Reason for Exchange in Archaic Societies* (London: Routledge, 1990).

<sup>59</sup> *Ibid.*, P. 13

<sup>60</sup> *Ibid.*

Since the gift has never been separated from the giver, there is no real distinction between persons and things comparable to that which emerges in a commodity economy in which objects can be completely alienated and sold to new owners through the notion of private property.

### **6.2.2 Reciprocal Altruism and Redistributive Exchange**

Mauss's gift relationship emphasises the obligation to reciprocate.<sup>61</sup> Rather than being given for free, each gift is part of a system of reciprocity in which the subjectivities and power relations of givers and recipients are formed. The grand cycles of exchanges constitutes the whole society which can be viewed as a total system of gift or be described by "the catalogue of transfers," as Mary Douglas puts it, that map all the obligations between its members whose permanent commitments articulate the dominant institutions.<sup>62</sup> However, the challenging issue here is how to apply Mauss's theory in a different social and temporal setting, namely in a modern, industrial society in which institutions and laws of exchanges are governed by the rule of markets. The same question seemed to be not unfamiliar to Mauss when he tried to use his own ethnographic observations of primitive societies to support social democracy's redistributions and the idea of solidarity in contemporary societies. As Mauss recognized, these kinds of anthropological facts should not be taken as curiosities or serving only for the purpose of comparison. In fact, they have general sociological value and can be used to explain modern societies from a historical perspective that would allow us to understand where we are and how far we have traveled in the process of social evolution.<sup>63</sup>

Indeed, by extending Mauss's recognition, ethnographic knowledge may provide a meaningfully alternative way to reflect on how the notion of the free gift may be taken

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<sup>61</sup> However, as it has been discussed well in the Nuffield Council on Bioethics' report on "Human Bodies: Donation for Medicine and Research", donation based on altruism is not necessarily mutually exclusive from donation involving some form of payment. As a result, here, Mauss's notion of gift relationship which emphasizes on reciprocity should also be understood as a way to supplement (rather than contradict) the notion of altruism, which can be defined in various ways and is usually seen as a motivation and/or actions concerns for the welfare of others. See: the Nuffield Council on Bioethics. "Human Bodies: Donation for Medicine and Research ", 11 October 2011. P. 139-144

<sup>62</sup> Mary Douglas, "No Free Gifts: Forward" in Mauss, *The Gift : The Form and Reason for Exchange in Archaic Societies*. ix

<sup>63</sup> Supra note 58, P. 47

for granted when it is used in the context of biomedical research especially in a modern capitalist society. In addition, even though modern legal systems have created many categories by making distinctions, such as a general distinction made between persons and things, new developments in genetic research and biotechnology have urged us to think over the appropriateness of continuing with such distinctions. Even though ownership rights over removed human biological materials are still controversial in the arena of law, a complete refusal of the recognition of property rights in the human body and body parts is far from the only solution to respond to the dilemma. Instead, when commercial interests are involved, the unbalanced arrangement of benefits and risks between donors and researchers triggers a deeper reflection on issues of equality and distributive justice that have been relatively ignored in the traditional moral debates on the commodification of bodies.

Mauss's moral economy of redistribution based on gift circles which focuses mainly on the larger collective benefits may be viewed as an alternative supplement to the current unsettling debates about the recognition of individual proprietary interest in human body materials. Like consent, granting property in human tissues and the information derived from them is mainly concerned with individual rights even though genetic information is of a group nature. The shared nature of genetic information means that an individual's choice and action will have an impact on those who share genetic similarities with them. As a result, modern biotechnologies and their application of genetic information have challenged bioethics and law which put more emphasis on individual autonomy than on collective benefits. Biobanking, like health care initiatives, is an activity with an ethic beyond individual rights. On the one hand, it involves the use of genetic information of a shared nature, on the other hand, however, it relates to larger groups of participation so it needs to be further justified by values of a community of rights, such as citizen responsibilities in the emerging biosociality, in the words of Paul Rabinow,<sup>64</sup> or the stewardship responsibilities of the state.

Mauss's theory on the totality of society provides a justification to mitigate the tension between an ethic of individual rights and utilitarianism which prioritises the public good

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<sup>64</sup> Paul Rabinow, "Afterword: Concept Work," in *Biosocialities, Genetics and the Social Sciences: Making Biologies and Identities*, ed. Sahra Gibbon and Carlos Novas (London, New York: Routledge, 2008).

and the interests of the community at large. For Mauss, considering the total social facts and the whole entity of society in which individuals become aware of their own positions and their situation in relation to others is a way to the so-called 'civilized world.'<sup>65</sup> In the total social phenomenon constituted by the gift-exchange, a new form of ethic may be created when individuals are organized as collective subjects to produce mutual interests based on their positive obligations to the greater community. In the case of biobanking, even though individual agents do not have a positive duty to participate in biobanks, the state's stewardship responsibility for the general wellbeing of the community may have extended the obligation of citizens who are expected to act as responsible agents to improve conditions of public health for the common good of the community.

Rose and Novas have used the term 'biological citizenship' to explore how conceptions of citizenship have been linked with the biological existence of human beings by states' citizenship projects that encompass practical techniques to make individuals as potential citizens.<sup>66</sup> Developments in bioscience and biomedicine have reconfigured notions of citizenship by norms and practices of health. On the one hand, the biologisation of politics produces biological citizens who understand their entitlements and responsibilities in terms of their rights to health services and social welfare. Life, therefore, creates a new type of value concerning regulation and compensation which may be negotiated by citizens for their economic and social inclusion.<sup>67</sup> On the other hand, however, biological citizens may be viewed by states as potential generator to provide a valuable resource for genomics research and biotech innovation.<sup>68</sup> Such biovalue concerning the moral economy of health and national imperatives has redefined notions of what it means to be a citizen.

Since the adjudication of the *Moore* case in the early 90s, the biovalue of human tissue has increased on a dramatic scale along with the development of genomics studies. Participants' growing awareness of potential commercial entanglement with their donated samples and the derived information challenges the distinction between gifts

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<sup>65</sup> Supra note 58, pp 82-83

<sup>66</sup> Nikolas Rose and Carlos Novas, *Biological Citizenship*, ed. Aihwa Ong and Stephen Collier, *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems* (Oxford: Blackwell Publishing, 2005).

<sup>67</sup> *Ibid.*, P. 441

<sup>68</sup> Supra note 66, P. 443

and commodities because their tissue samples and personal information may now be transformed from a pure gift to a circulating commodity as a form of product with exchange value.<sup>69</sup> In the context of biobanking, the potential for commercialisation has a significant impact on participants' willingness to take part in projects. Taking Iceland as an example, even though the Icelandic Parliament endorsed the biobanking project by passing national legislation to give exclusive commercial rights to a company - deCODE genetics - for the establishment of the Icelandic Health Service Database (HSD), the lack of public support due to concerns about commercialisation finally led to deCODE filing for bankruptcy in 2009. As a cohort study monitors follow-ups on participants' health condition for succeeding years, the sustainability of a biobank requires establishing a long-term partnership between biobankers and participants. In order to obtain trust from the general public, such a partnership needs to be reciprocal by recognizing the return of "gift" as a social obligation of biobanks so that a reciprocal relationship may be expected to be established among all actors in the process of biobanking.

Even though the calculation of research benefits may not be easy for biobanks because future research results are still unknown even to researchers themselves, governing mechanisms based on the principle of reciprocity need to be proposed by biobankers at the initial stage when they procure consent from participants. In Mauss's gift relationship, in primitive societies, the chief may give proof of his *mana* by redistributing what he received to his relations so that he may sustain his own rank among the chiefs.<sup>70</sup> In biobanking, the recognition of the share of benefits by treating participants and their communities as stakeholders may eventually consolidate the legitimacy of biobanks. Furthermore, according to Mauss, the system of 'total services' is the system in which the exchange of everything among individuals and groups become possible so that the system can provide a basis on which the morality of the exchange has flowed.<sup>71</sup> By analogy, in order to form a trust relationship, it will be the biobankers' responsibility to make an initial step to construct the room of morality in which public interests may be

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<sup>69</sup> More info about relevant arguments to rethink the distinction of gifts and commodities may be found in Cathy Waldby and Robert Mitchell, *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism* (Duke: Duke University Press, 2006). Literature about the distinction of gifts and commodities in capitalist societies may be found in James Carrier, *Gifts and Commodities : Exchange and Western Capitalism since 1700* (London; New York: Routledge, 1995).

<sup>70</sup> Supra note 58, P. 75

<sup>71</sup> Supra note 58, P. 70

fostered and the contents of a common good be debated and shaped. In fact, a free gift model used in blood donation is not ideal to be transplanted into the circumstances of biobanking. Rather than empowering participants, the discourse of a pure gift-giving creates ambiguities and difficulties in the arena of law in which the status of removed human tissue is contestable and a donation has been treated as the surrender of participants' rights of further control over their samples.

For Mauss, gift-giving not only forms the basis of social relations in primitive societies but also lays the foundation for justifying a broader scheme of redistributive exchange in modern industrial economies. In his concluding remarks to *The Gift*, Mauss extended the idea of gift-exchange to enhance solidarity in modern societies based on market exchange by referring approvingly to proposals on welfare and social support such as health and unemployment insurance. By so doing, the gift cycle which was presented as a theoretical counterpart to Adam Smith's invisible hand may operate in a way of 'being visible' so the redistribution of accumulated goods and service based on political innovations of alliances may avoid the failure of market exchange by subjecting it to judgments of fairness.<sup>72</sup> Mauss's theories on the gift cycle provide an alternative response to Polanyi's analysis of the great transformation brought by the industrial revolution. Rather than being alienated, redistribution of wealth and power in the moral economy reunifies the entire social systems as the greater totality in which institutions such as law, religion and economy are not segmented but entities of the total social facts.

It is by considering the whole entity, according to Mauss, that individuals could be sentimentally aware of who they are and of their relations with others.<sup>73</sup> The ultimate goal of reciprocal altruism which suggests stable relationships and giving in return between individuals involves a new form of ethics that concerns a wider politics of organization and decision-making by which consensus about mutual interests may consequently be formed. In the case of biobanking in Taiwan, such ethics further involves accountability of commerce to biological citizenship when the citizens are constructed not only as political subjects of entitlements but also generators of biovalue for health and wealth of the state. In other words, the moral ideal of an alliance of participants and the biobank (and its commercial extensions) needs to be acknowledged with reference to

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<sup>72</sup> Supra note 62, xiv

<sup>73</sup> Supra note 58, P. 80

their joint interest and their co-dependent relations in a greater totality in which they are parts of a division of labour.

In order to protect the individual's autonomy from undue inducement and to appeal for altruism, the introductory booklet for the pilot study of the Taiwan Biobank states that no financial rewards may be given to participants; neither any property rights in donated samples or in the information derived from the samples may be claimed from the participants.<sup>74</sup> If a participant agrees to take part in the biobank project, any research results relying on his or her samples will be published as collective data and be used as a common resource for global medical research. In the future, if there is any commercial product, for example, intellectual property derived from the invention based on samples and data of the biobank, according to the booklet and the consent form, such property belongs to the inventing institutes rather than to the participants. These arrangements clearly demonstrate that in the biobanking case in Taiwan, participants have been treated as donors or free-gift providers rather than being included as stakeholders of the project who are entitled to decide how the samples and health data may be used in the future. However, the unreciprocated gift will eventually make the person who has accepted it inferior, as Mauss emphasizes, particularly when the receiver has no thoughts of returning it.<sup>75</sup> Applying the analogy of Mauss's gift model to the creation of the Taiwan Biobank, without a proper mechanism for the project to implement the principle of reciprocity, the biobank will be threatened by gradually losing its own credibility in social relations it has endeavoured to establish.

### **6.2.3 From Profit-Sharing to Power-Sharing**

In fact, the ongoing biobanking project in Taiwan may not be easily fitted into any broad categories of its international counterparts. It is not like the cases of Iceland and Tonga in which the biobanks are mainly operated by commercial companies or pharmaceutical industries but backed up by national governments through legislation for exclusive licensing.<sup>76</sup> Nor is it similar to the projects in Sweden and Estonia, both of which were initially funded by governments but later operated in cooperation with commercial

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<sup>74</sup> Taiwan Biobank Introductory Booklet and the Informed Consent Form (in Chinese)

<sup>75</sup> Supra note 58, P. 65

<sup>76</sup> Nadja Kanellopoulou, "Reciprocity, Trust and Public Interest in Research Biobanking: In Search for a Balance," in *Human Tissue Research - a Discussion of the Ethical and Legal Challenges from a European Perspective*, ed. Christian Lenk, et al. (Oxford: Oxford University Press, 2011).



enterprises even though the genetic databases are mainly based in academic and research departments.<sup>77</sup> In Norway, Singapore and Quebec, the biobanks are set up for research purposes so they are government-funded projects with no commercial involvement.<sup>78</sup> According to its purposes and the initial framework, the Taiwan Biobank may be viewed as a research platform that is wholly funded by the Taiwanese government in order to improve the health of the next generation in Taiwan and to become a common resource for medical research on the global stage. However, in the proposal for the establishment of the biobank, the potential commercialisation is hardly invisible. The idea of commercialisation has been proposed as a potential business model for the biobank's future operation so that the project can have its own niche for long-term development without continued reliance on government funding. Even though how such a commercial idea may be executed remains to be discussed - whether it will rely on cooperation with pharmaceutical or like-minded commercial companies, or whether the biobank's ownership may be allowed to be transferred to private entities for continued operation, collaboration between public and private seems to dominate the future sustainability of the biobank in Taiwan.

In September 2010, the Department of Health<sup>79</sup> in Taiwan published the implementing rules for the Human Biobank Management Act on the sharing of benefit.<sup>80</sup> Even though it is still to be seen how the rules may be implemented in practice, they may be viewed as a significant step for biobankers' recognition of the importance of reciprocity. These implementing rules echo current international guidelines which address the issue of benefit-sharing in human genetic research. For instance, in UNESCO's International Declaration on Human Genetic Data, Article 19 recommends the forms that benefits may take. In addition to provision of facilities for new treatments or drugs that directly stem

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<sup>77</sup> Ibid.

<sup>78</sup> Ibid.

<sup>79</sup> It is not only the founding body of the Taiwan Biobank but also the supervisory authority of all biobanks in Taiwan.

<sup>80</sup> The Rules on Feeding Back of Profits on the Commercial Uses of Human Genetic Databases, Taiwan, 08 September 2010 (人體生物資料庫商業運用利益回饋辦法). The rules were promulgated by the Department of Health as the implementing rules of Article 21 of the Biobank Management Act. In the Article, the legislature authorises biobanks' supervisory authority to promulgate relevant measures for implementing the principle of benefit-sharing when commercial use of biobanks is involved. However, controversies arise as the implementing rules may apply to all biobanks in Taiwan even though it was originally aimed to regulate benefit-sharing for the Taiwan Biobank. How the rules may be implemented in Taiwan, not only for the large-scale population biobank, but also to those existing small-scale disease biobanks remains to be seen.

from the research, the forms of benefits may also include capacity building, access to medical care or support for health services, etc. As a result, the recipient of the benefits, according to the article, may not be limited to the persons and groups that have taken part in the research. It may also be broadened to a population, the society as a whole or even the international community as the article recommends.<sup>81</sup>

In addition, the Human Genome Organisation (HUGO) - the international organisation involved in the Human Genome Project - released its Ethics Committee Statement on Benefit Sharing in 2000. In the statement, a benefit is described as “a good that contributes to the well-being of an individual and/or a given community.”<sup>82</sup> Even though how to define a community reflects practical difficulties in applying the principle of benefit-sharing, the statement recognises that since a benefit is not identical with profit in the monetary sense, determining a benefit depends not only on needs and values but also priorities and cultural expectations.<sup>83</sup> In Taiwan, according to the rules, the obligation for biobankers to share benefits arises only when the commercial use is involved.<sup>84</sup> As a result, although there is a power disparity between biobankers and participants, benefit-sharing may not always take place if there is no involvement of commercial gains. The measure stipulates that biobankers and users should reach an agreement by contract to decide the percentage of profits to feed back when the profits at issue are estimable.<sup>85</sup> In the circumstances when the potential profits are inestimable, biobankers may charge a set fee depending on the nature and quantity of the use when the users apply for access to biobanks. If the users and biobankers are identical, the rate of feed-back or the set fee needs to be decided by biobanks’ ethics committees.<sup>86</sup>

By observing what constitutes a fair benefit in the regulation, benefit-sharing in the context of biobanking in Taiwan may have been reduced to “profit-sharing.” As anthropologist Cori Hayden rightly points out, although intellectual property may serve

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<sup>81</sup> Article 19 of the International Declaration on Human Genetic Data, published by United Nations Educational Scientific and Cultural Organisation (UNESCO), 16 October 2003

<sup>82</sup> The HUGO Statement on Benefit Sharing, published by the Human Genome Organisation (HUGO) Ethics Committee, 2000

<sup>83</sup> Ibid.

<sup>84</sup> Article 4, the Rules on Feeding Back of Profits on the Commercial Uses of Human Genetic Databases, Taiwan, 2010

<sup>85</sup> Article 5, the Rules on Feeding Back of Profits on the Commercial Uses of Human Genetic Databases, Taiwan, 2010

<sup>86</sup> Ibid.

either as an *enabling device* for or as an *idiom* of benefit-sharing, the right itself is rarely considered “part of the package of goods” to be redistributed to benefit-recipients.<sup>87</sup> As a result, benefits are “posed as *not-rights*.”<sup>88</sup> When assessing who is entitled to benefits, a new boundary may be created in order to form a community acting as a benefit-recipient to satisfy the collective nature of biobanks. When intellectual property is used as a metaphor in defining who should be included or excluded in a benefit-sharing scheme, John Locke’s labour theory of property which emphasizes the necessity of mixing one’s labour with an object seems to have reclaimed its own title in the discussion. For instance, as Hayden illustrates, the Lockean notion has set the stage for indigenous rights activists who claimed property rights by arguing that much biodiversity was already suffused with labour that has been produced and reproduced by indigenous people over a long period of time.<sup>89</sup> On the other hand, when considering the relationship between intellectual property and benefit-sharing, it is procedurally complicated to trace back to identify who has contributed to adding value to the collected materials.<sup>90</sup> For that reason, the indigenous group as a whole may be entitled to rights of ownership or compensation as they have collectively put labour into the product.

The mechanism of benefit-sharing in Taiwan may also be viewed as an institutional response to the mobilization of local human rights groups and their criticism of the Taiwan Biobank due to a lack of consensus and of an appropriate governance framework to deal with related ethical and legal issues. In Taiwan, according to the regulation, if the profits of the use of biobanks may be attributed to the contribution of a specific population, they shall be shared with the population. Where it is difficult to ascertain the attribution, the profits shall be fed back to the population as a whole.<sup>91</sup> In order to reward participants’ contributions, the principle of benefit-sharing is mainly based on the values of redistributive justice. To some extent, such an endeavour is worth encouraging as it recognises the necessity of “giving-back” that may help complete the total system of exchange, in Mauss’s words, and forms social relations among biobankers and

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<sup>87</sup> Cori Hayden, “Benefit-Sharing: Experiments in Governance” in *SSRC Workshop, “Intellectual Property, Markets, and Cultural Flows”* (New York, NY October 24-25, 2003).

<sup>88</sup> *Ibid.*

<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> Article 6, the Rules on Feeding Back of Profits on the Commercial Uses of Human Genetic Databases, Taiwan, 2010

participants. However, benefit-sharing cannot address the fundamental problem with regard to property rights in human body parts if property is not to be recognised as a form of benefit. The very difference lies in that such form of benefit-sharing grants “profits” rather than “power” to recipients so the power asymmetry between biobankers and participants may not be abridged by merely redistributing profits derived from the use of biobanks. Ownership and property relate to the interest in control over things. Therefore, the core issue in biobanking in general and in the Taiwan Biobank in particular is whether participants may attain some degree of control over their samples after they have been given to biobankers in research through the mechanism of informed consent. In the terms of Mauss’s gift relationship, the benefit-sharing arrangement in Taiwan may serve as gesture of reciprocity but not the spirit of it because true reciprocity emphasizes forming power relations in which the subjectivities of givers and recipients are able to be restructured. When such a power relationship is formed, no one would be deemed to be inferior as even though the society itself may be archaic and hierarchical, givers and recipients are constructed as inter-subjectivities in the whole system of exchange of gifts.

By viewing biobanks as assemblages of human biological materials, genealogies and personal health information, it has been argued that the assemblages have unfolded the new distributive politics of life science.<sup>92</sup> However, within the politics, the normative unsettlement for property relations between biobankers and participants has made solutions to the governance of biobanks elusive and impractical. In the Moore case, Justice Mosk favoured a policy permitting Moore’s cause of action for conversion by claiming that property is a complex bundle of rights. According to him, a proprietary interest in the human body should be granted as such rights did not attach to all forms of property, and as a result, the limitation on or prohibition of the exercise of certain rights over certain forms of property did not entirely destroy the title.<sup>93</sup> To understand property as a bundle of rights meant to treat property as an abstract notion rather than viewing it directly as a concrete material object and therefore it referred to the rights being exercised with respect to the object, for example, the right to possess, to use or to refrain others from using it, etc.<sup>94</sup> When the same rule applies to the case, as Justice

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<sup>92</sup> David E. Winickoff, "Partnership in U.K. Biobank: A Third Way for Genomic Property?," *The Journal of Law, Medicine & Ethics* 35, no. 3 (2007). P. 440

<sup>93</sup> Supra note 37

<sup>94</sup> Ibid.

Mosk pointed out, Moore still retained property rights in his excised tissues so he should be entitled to the rights to do with his tissues as the defendants did with them, such as contracting with pharmaceutical companies to develop the tissues' commercial potentials.<sup>95</sup>

Although the majority opinions in the Moore case seem to think that granting a proprietary interest would make the human body a commodity, this perception is itself ambiguous and not completely true. Not granting property rights in human tissues and their derived information ignores the power asymmetry between sample subjects and researchers and also it may make sample providers lose their control in samples after they are excised. Although it is still unsettled in law in many jurisdictions, including Taiwan, with regard to the recognition of property in human samples in medical research, participants' interests in a better control over the use of their samples in research and the information derived from them should be prioritised. By so doing, a true reciprocity as Mauss had wished to apply in a modern industrial society, may be expected and in the context of biobanking, a long-term trust relationship may be reshaped and consolidated.

### **6.3 Privacy, Confidentiality and Public Interest**

The emergence of new technologies for collecting, processing and storing personal data has gradually reconfigured the relationships between citizens and states. As David Lyon has argued, the rapid expansion of technologies along with the development of computerization in modern bureaucracies has not only reshaped personal experiences of daily life but also influenced large-scale social processes by constituting novel social formations.<sup>96</sup> In addition, collecting detailed personal information in a systematic and comprehensive way by the mediation of new computing and digital technologies features administration in modern societies in which rational institutions and a hierarchical management order can now be formed more easily than in the past.<sup>97</sup> According to Max Weber, modern societies may be characterized by observing the growth in capitalism and bureaucracies that has transformed old types of social actions established in feudal systems based on lineage and religious relationship to systems based on rational

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<sup>95</sup> Ibid.

<sup>96</sup> David Lyon, "Surveillance Technology and Surveillance Society," in *Modernity and Technology*, ed. Thomas J. Misa, Philip. Brey, and Andrew Feenberg (Cambridge, Mass: MIT Press, 2003). pp 161-165

<sup>97</sup> Ibid.

calculation, impersonality and efficiency.<sup>98</sup> In order to effectively operate the huge bureaucratic apparatus, states have managed to develop ways to handle their detailed modes of governance involving large amounts of data connecting the daily life of citizens such as routine record keeping for the purposes of identification, tax collection, welfare and policing, etc. However, the introduction of computer technology into the processing of personal data provides modern states not only with more efficient techniques to run their bureaucracies but also with an effective mode of governance of their citizens.<sup>99</sup>

When modern information societies came into being, George Orwell's concerns about the augmented power of states by pervasive government surveillance does not only exist in his dystopian novel *Nineteen Eighty-Four* or in his imagination of the geopolitical analysis of the Oceania province of Airstrip one,<sup>100</sup> but also in people's social relations and real daily life. For instance, a report published by Big Brother Watch, a campaign group set up for defending civil liberties in the United Kingdom points out that the operation of closed circuit television (CCTV) camera on Britain's street had increased from a figure of 21,000 to at least 59,753 in 2009 in about ten years' time.<sup>101</sup> In addition to using the camera as a technique of governance, population biobanks collecting and storing human biological materials and genetic information bring the issue of privacy in the forefront. As the biobanks generally require the linkage of different databases of massive population registries and personal health information in order to know the causal interaction among diseases, environmental and genetic factors, concerns about the misappropriation of personal data and its social impact renders protection of privacy a significant issue to be discussed.

In April 2001, the Bureau of National Health Insurance (BNHI) in Taiwan introduced a health care smart card scheme in order to replace the original paper-based patient card system. The smart card is an integrated circuit (IC) card with 32 kilobytes (KB) of memory which allows it to store a cardholder's status such as personal information, health insurance related information, medical service information and the information of public health administration. As the smart card contains personal and medical data such as a

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<sup>98</sup> Max Weber, *General Economic History* (Dover Publications, 2003). P. 356

<sup>99</sup> Supra note 96, pp 167-169

<sup>100</sup> George Orwell, *Nineteen Eighty-Four* (London: Penguin, 2003).

<sup>101</sup> A report from Big Brother Watch, See:  
<http://www.bigbrotherwatch.org.uk/research-and-reports/page/2>

cardholder's name, national ID number, last six medical visits and treatments, prescriptions, history of immunisation, drug allergy and remarks for catastrophic diseases, it functions like a carryable medical record accessible to all participating health provider institutions by setting up the required interface and card readers. Furthermore, as the card includes health care related information such as accumulated medical expenditure records and the amount of cost-sharing, it has proprietary interest not only to the card holder him/herself but also to the state's health care agency - the BNHI.

The implementation of the smart card scheme has become compulsory in Taiwan since 1 January 2004. The overall electronic system requires registered hospitals and clinics<sup>102</sup> to upload their medical records to the BNHI on a daily basis so that the bureau is able to access patients' information and then to reimburse medical service providers in a more efficient way. Although compared to the paper-based patient card system, the smart card scheme helps reduce waste of resources for the BNHI by identifying fraud and excess false insurance payments claimed from registered health providers, it has caused human rights concerns that a centralised medical data storage could turn Taiwan into a police state due to mass "datavelliance", in the language of David Lyon.<sup>103</sup> In addition, who is entitled to claim ownership of the medical data stored in the smart card is still a pending question. Like human biological materials, even though personal and medical data has significant proprietary interests in a modern information society, its ambiguous legal status has challenged the notion of property in the arena of law. However, rather than clarifying titles of proprietary interest, legal mechanisms focusing on personal data protection have switched the issue of property to a concern with privacy.

### **6.3.1 Confidentiality: A Narrow View of Privacy**

In the *Source Informatics* case the England appellate court suggested that patients do not have proprietary interests in their information in prescription forms, so that they are not entitled to claim for the misappropriate use of their prescription information for commercial purposes even though the use was without obtaining the patients' consent. In the case, the appellant (Source) was a company engaged in obtaining information about doctors' prescribing habits which then could be sold to pharmaceutical companies for

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<sup>102</sup> The participation rate is over 90% so a service network for insured applicant has been created nationwide.

<sup>103</sup> Joy Su, "New Health Cards Become Compulsory Despite Fears," *Taipei Times* 2 January 2004.

marketing their products. Concerned that the practice of target marketing would increase prescriptions made by doctors and add the burden for the British National Health Service (NHS) to pay the bill, the Department of Health in the United Kingdom issued a policy document claiming that the disclosure of prescription information to third parties without patients' consent was a breach of patients' confidentiality even though the patients' identities were not revealed. Source appealed against an English High Court decision which refused to grant a declaration that the Department of Health's policy document was made in error. According to the High Court, it was a breach of confidence to use prescription information given by patients for treatment for any other purposes without their consent. However, the Court of Appeal overturned the High Court's decision on the grounds that patients' privacy was not being infringed in this circumstance because their personal information was not identifiable. For the Court of Appeal, as the patient had no proprietary claim to the prescription form and the information the form contains, he was deemed to have no right to control the use of his information as the protection of his privacy seemed to be intact.<sup>104</sup>

Clearly, what the Court of Appeal recognised is a narrow view of privacy that suggests the patient's privacy would be infringed only if the patient's prescription information was identifiable and was used unfairly against the patient. A weakness of the legal reasoning shown in *Source Informatics* lies in the fact that it treats confidentiality and privacy as identical notions. However, in terms of respecting self-control of personal information, privacy is a much broader concept since it requires no relationship characterised in confidentiality as a duty owned by confidants to confiders in order to maintain the security of confidential information.<sup>105</sup> In addition, in the ruling, the English Court of Appeal has suggested that it is a *fair use* of information to disclose anonymised data to a firm for commercial uses even without consent from patients. Such a ruling has challenged the traditional defence of public interest to the breach of confidence by obviating the competing public interest to the reassessment of the notion of fairness of use.<sup>106</sup> As a result, what the court in fact suggested seems to be that so long as there is no unfairness in the use of information to the confider, there may be no breach of confidence even though a proposed use of information is unauthorised and the use is not

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<sup>104</sup> Ibid.

<sup>105</sup> For instance, a relationship of patient and physician; more info, See Supra note 46, pp 211-212

<sup>106</sup> Ibid., pp 224-225



within the public interest defence as the duty of confidence.<sup>107</sup> Following this legal reasoning, the Court of Appeal imposed an onus on the confider to demonstrate that the proposed use is unfair even though what is supposed to be protected should be confiders' own information as confidentiality is one of patients' rights in their relationship with health care professionals.

This minimalist view of privacy taken in the judgment of *Source Informatics* ignores the argument that individual's autonomy may not be simply reduced to anonymisation of personal information. By the same token, discussions of access and management of participants' health and genetic information in the context of biobanking should not be limited to the rules relating to confidentiality such as forms of the coding and anonymisation of samples and data stored in biobanks.<sup>108</sup> On the contrary, a broader conception of privacy needs to be taken into account. By so doing, the focus may be shifted from the sensitivity of genetic information and how to maintain stricter control of its use to more fundamental aspects about the notion of privacy itself and how to balance collective and individual rights in the circumstances especially when a relevant public interest is identified.

By analyzing different approaches biobank governance adopts to deal with legal and ethical issues of consent, property and privacy, Brownsword argues that the UK Biobank has adopted a compromise model as its governance framework design mixes a regime of weak provisions on property but strong provisions on consent and privacy.<sup>109</sup> In terms of strong privacy, the UK Biobank Ethics and Governance Framework addresses the importance of protection of confidentiality of data and samples by ensuring that samples are reversibly anonymised and are linked and stored by strict measures and to high standards.<sup>110</sup> Following the UK Biobank's governance principles, a similar governance model of strong privacy can also be detected in Taiwan. For instance, Article 18 of the Human Biobank Management Act provides particulars about anonymisation to ensure

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<sup>107</sup> Ibid.

<sup>108</sup> Relevant literatures with regard to anonymization in the context of biobanking may be found in Bernice Elger, "Anonymization and Coding," in *Ethical Issues in Governing Biobanks: Global Perspectives*, ed. B Elger, et al. (Ashgate, 2008).

<sup>109</sup> Roger Brownsword, "Biobank Governance: Property, Privacy and Consent," in *Ethics and Law of Intellectual Property : Current Problems in Politics, Science and Technology*, ed. Christian Lenk, Nils Hoppe, and Roberto Andorno (Ashgate, 2007). pp 11-15

<sup>110</sup> UK Biobank Ethics and Governance Framework, P. 16

that participants could not be identified through their samples and related personal data and information in the process of biobanking.<sup>111</sup> In addition, in July 2010, the Department of Health released the implementing rules on Article 13 of the Human Biobank Management Act that stipulates electronic security measures about the management of information technology. These mechanisms demonstrate that anonymity and confidentiality are prioritised in the biobanking case in Taiwan and the biobankers have made a great deal of effort in order to ensure that the storage and processing of information would not violate participants' data protection.

However, it demonstrates that what the Taiwan Biobank adopts is also a narrow and thin conception of privacy as the biobankers take the view that so long as participants' samples and personal data have been anonymised, the protection of privacy is sufficient and there is a low realistic possibility that confidentiality could be breached or participants' identities could be revealed. For instance, the interview contents below illustrate that the scientists who are in charge of the pilot study of the Taiwan Biobank project have taken the minimalist view of privacy that reflects their beliefs in that if a person's identity is protected, the person's privacy is not put at risk.

We understand critics' concerns, so we have set the highest standards to ourselves in terms of protection of participants' privacy. We would like to be the model in bioethics for biomedical research in Taiwan. These years we have developed strict standard operating procedures for the collection, management and the storage of samples and data. For instance, samples and lifestyle information collected in every sample collection sites will be coded at the sites and the data transmitted from the collection sites to our main lab will be encrypted. Identifiable personal information such as participants' names, birth, and addresses, etc will be stored separately with their samples. Only the holder of the key may link participants' samples to their identities. Therefore, in the future, even when we need to use samples and data stored in the biobank, we are required to apply to access to the biobank through a user committee.<sup>112</sup>

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<sup>111</sup> The article stipulates that "any storage, use, or disclosure of the concerned biobankers' entire biological specimens and related data and information shall be encoded, encrypted, delinked, or transformed so that the participant's identity is unable to be determined." See, Article 18 of the Human Biobank Management Act, Taiwan, 2010

<sup>112</sup> It is worth noting, however, that the access policy with regard to the Taiwan Biobank has not yet been discussed and proposed by the biobankers at the current stage.

In science, when we talk about risk management, we would like to evaluate the possibility, namely the chance of the risk happening. Even though the public may be concerned about the sensitivity of their personal and genetic information, scientifically speaking, I would say that the chance of data leakage is very low in the current IT security system of double coding and encryption. (Interview with scientists at the IBMS, the Academia Sinica, Taipei, Taiwan, 2010)

### 6.3.2 Informational Conception of Privacy

Nevertheless, this narrowly conceived privacy ignores another valid claim that the right to privacy, to some extent, is also to respect individual autonomy and such autonomy includes a decision with regard to how individuals would like their own information to be used.<sup>113</sup> Even though privacy is a fluid idea as its content changes constantly depending on context and circumstance, the protean character of privacy, as some legal scholars suggest, may be broadly reflected in its two conceptions - spatial and informational conceptions.<sup>114</sup> The spatial conceptions of privacy refer to the state of separateness to an individual's self in a physical or psychological sense and the informational conceptions of privacy may be viewed as inaccessibility to an individual's personal information from others.<sup>115</sup> Although "the right to be let alone"<sup>116</sup> makes the right to privacy be conceived as a passive right, the notions of privacy has gradually changed along with the advent of the information age in which the right to control the use of personal information reconfigures the right to privacy from a passive right to a positive one.

In Taiwan, privacy<sup>117</sup> has not been enumerated as a fundamental right in the R.O.C. Constitution. However, it has been recognized through judicial interpretations based on Article 22 of the Constitution, a catchall provision guaranteeing the protection of people's freedoms and rights that are not detrimental to social order and public welfare.<sup>118</sup> The Council of Grand Justices composed of 15 members is the Constitutional Court in Taiwan responsible for interpreting the Constitution. In its Interpretation No. 585, the Council

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<sup>113</sup> Supra note 47, P. 225

<sup>114</sup> More info, see, supra note 46, P. 6; Supra note 106, P. 18

<sup>115</sup> Supra note 47, P. 6

<sup>116</sup> Warren and Brandeis, "The Right to Privacy," *Harvard Law Review* IV no. 5 (1890).

<sup>117</sup> Here, the meaning of "privacy" is limited to the discussions of rights to privacy in the Taiwanese reality, although the notion of privacy itself, as it has been mentioned in the chapter, is a much broader concept than being viewed as a fundamental right.

<sup>118</sup> For instance, Interpretations No. 509, 535 and 603 of the Council of Grand Justices, Taiwan, R.O.C.

formally recognised spatial and informational conceptions of privacy as a way to preserve the value of the constitutional structure of free democracy.<sup>119</sup> However, the concrete contents of the rights of informational privacy have not yet been elaborated until the release of the Interpretation No. 603 in which it is claimed to be unconstitutional to make fingerprinting a compulsory condition for the issuance of an ROC national identity card.<sup>120</sup>

In summer 2005, the Council of Grand Justices in Taiwan announced a preliminary injunction on the fingerprint policy which requires all Taiwanese nationals over 14 years of age to provide their fingerprints when applying for a new national identity card. According to an amendment to the Household Registration Act, no new ID cards will be issued unless the applicant is fingerprinted. Even though the Ministry of Interior made a statement in a press conference claiming that the collected fingerprints would be used for identification purposes only and no law enforcement agencies may use the data to investigate criminal cases, local human rights groups had launched a series of public campaigns with the concerns that the establishment of a fingerprint database would infringe people's privacy and could bring Taiwan back to a police state after the lifting of martial law in 1987.<sup>121</sup> A few months later, the Council of Grand Justices issued its Interpretation No.603 in which the relevant provisions of the Household Registration Act were deemed to be unconstitutional by conditioning the issuance of an identity card upon compulsory fingerprinting. In the Interpretation, the Council recognized that the right of informational privacy includes the rights for individuals to decide whether or not to disclose their personal information, and if so, to what extent and in what manners such information may be disclosed.<sup>122</sup> The self-control of personal information constitutes part of the right to privacy which was viewed by the Council as an indispensable right for the free development of personality and for the preservation of human dignity.<sup>123</sup> As fingerprints are a form of abstract personality characterized by

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<sup>119</sup> "[t]he right of privacy, though not clearly enumerated under the Constitution, is an indispensable fundamental right protected under Article 22 of the Constitution because it is necessary to preserve human dignity, individuality, and the wholeness of personality development, as well as to safeguard the freedom of private living space from interference and the freedom of self-control of personal information." See, Interpretation No. 585 of the Council of Grand Justices of the Republic of China, 2004.

<sup>120</sup> According to Article 8 II of the Household Registration Act, except national who is under fourteen years of age, all national who apply for an ROC identity card shall be fingerprinted for record keeping. Article 8III further provides that no ROC card shall be issued unless the applicant is fingerprinted.

<sup>121</sup> Jimmy Chuang, "Fingerprinting for I.D. Cards Halted," *Taipei Times* Jun 11, 2005

<sup>122</sup> Interpretation No. 603 of the Council of Grand Justices of the Republic of China, 2005

<sup>123</sup> *Ibid.*

biological uniqueness and lifetime unchangeability, they are deemed to be sensitive personal data by the Council to be protected under the right of informational privacy.

### **6.3.3 Public Interest: the Individual and the Collective**

However, as the right to privacy is not an absolute right, the mass collection of people's fingerprints by the state still needs to be justified by the compelling public interest and by enacting unambiguous laws in order to satisfy the principles of legal reservation. As the legislative purposes of collecting fingerprints were mainly to enhance personal identity verification in household administration, they were viewed by the Grand Justices as overly generous, broad and not compelling for the defence of the public interest in Taiwan. Furthermore, since compulsory fingerprinting and record keeping were not the least intrusive means to effectively serve the purpose of identification, it was deemed to be in violation of the principle of proportionality.<sup>124</sup> In order to protect people's right of informational privacy, the Grand Justices also required that the state shall make sure all legitimately collected personal data is reasonably used and properly secured and maintained.

In considering whether the right to privacy may have been infringed, the defence of public interest is generally viewed as a way to evaluate the balances within the tension between individual and collective. Under the tradition of Western liberal democracy, in order to encourage debates and communication of public matters and to foster the development of trust relationships in society, individuals' personal privacy is expected to be guaranteed so that not every aspect of an individual's private life could be infringed as a result of serving greater social purposes.<sup>125</sup> In the context of biobanking, the tension between the individual and the collective is much more apparent as genetic information which relates not only to its sample source but also to the group of people who share the same genetic lineage is involved. Moreover, since the purposes of the establishment of population biobanks aim to enhance understanding of the causes of diseases in order to improve preventive medicine for future generations, these expectations are mainly collective interests rather than individual ones.

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<sup>124</sup> Ibid.

<sup>125</sup> Supra note 47, pp 10-11

Biomedical development on human genetics challenges mainstream modern bioethics which puts more emphasis on the protection of individual rights than on community benefits. Even though the right to self-control of personal information is recognised in Taiwan, considering giving the individual more control over his or her personal information illustrates how the legal analysis may have been influenced by the rationale to prioritise the autonomy of individuals.<sup>126</sup> Moreover, when considering what kinds of benefits biobank research seeks to bring, such as the advancement of scientific knowledge and the improvement of public health, the boundary between public and private turns out to be negotiable. The scope of privacy becomes floating as an individual agent whose self-governance of her or his health condition may no longer be viewed as simply a personal decision made in the private sphere. The intervention of the state turns out to be much more delicate compared to the past that empowers the individuals to look after themselves by introducing health care rather than by using police to exercise the power of traditional sovereignty in order to fulfill the functions of control and discipline.

According to Michel Foucault, biopower involves a set of mechanisms and procedures through which human beings became the object of political strategy.<sup>127</sup> In eighteenth century Western Europe, governmentality changed from taking life to maintaining the sustainability of the population as a result of the threats of scarcity and the outbursts of epidemic diseases such as smallpox. As both of these phenomena could lead to a very high mortality rate, several techniques and mechanisms of security such as statistics, inoculation and vaccination were adopted by the states to safeguard population growth. In addition, the emergence of the town, which was deemed to be an exception to the power of feudalism, posed new problems of government technique. How to integrate this kind of autonomous zone that was able to govern itself within the central mechanism of power concerned the legitimacy of the sovereign.<sup>128</sup> In other words, how the power of the sovereignty could be executed effectively over the population challenged not only the validity of the governance but also the sustainability of the modern state.

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<sup>126</sup> Fingerprint, as discussed in the Judicial Interpretation No.603, is an individual characteristic for identification, so it is unlike genetic information having group effects. The compulsory collection of fingerprints may infringe only the rights of the individual rather than the rights of any other members of the groups who share the same genetic heritage with the individual.

<sup>127</sup> Michel Foucault, *Security, Territory, Population : Lectures at the Collège De France, 1977-78* (New York Palgrave Macmillan, 2007). pp 1-2

<sup>128</sup> *Ibid.*, pp 64-65

In fact, such a mechanism of security did not function in the form of the prohibition or a way to ensure the totality by sacrificing the individuals. On the contrary, it governed the individual by allowing the natural processes, namely by recognising the naturalness of the population, which was not deemed to be the simple sum of individuals, but a “datum” depending on a series of variables, such as customs, religious values, laws, material surroundings, or the intensity of commerce in the circulation of wealth, etc.<sup>129</sup> The datum, according to Foucault, could not be transparent to the sovereign as the variables on which the population depended might easily escape the sovereign’s direct action in the form of the law.<sup>130</sup> As a result, the relation between the sovereign and the population was dynamic rather than simply be “one of obedience or revolt.”<sup>131</sup> Because the population appeared as a “thick natural phenomenon” which was constantly accessible to agents and techniques of transformation, a new technique of governance emerged whose purpose was not getting the population to obey the sovereign’s will but governed far away from the population’s immediate behaviour by having a hold on a range of factors and elements through calculation and analysis and knew that an effect on the population would be expected.<sup>132</sup>

Besides, even though the population was made up of individuals with different opinions and behaviours, for Foucault, the commonality of each individual was that everyone acted out of desire - out of the pursuit of the individual’s interests - and when each individual acted following his or her spontaneous play of desire, it would allow the production of the favourable interest of the population.<sup>133</sup> As a result, the new technique for the sovereign to govern the population was simply to recognize the naturalness of the desires of the individuals and then to follow, to encourage or even to stimulate this desire, so that it would produce necessary beneficial effects on the population. By introducing “nature” into the field of governance, an effective technique of power turned to be something that may demonstrate the reflected procedures of the sovereign’s governance within this nature. From this point of view, on the one hand, the population was characterised as “the human species” in the form of the integration within biology and, on the other hand, however, it was “the public” when viewing the appearance of the population from the

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<sup>129</sup> Ibid., pp 70-71

<sup>130</sup> Ibid., P. 71

<sup>131</sup> Ibid.

<sup>132</sup> Ibid.

<sup>133</sup> Ibid., P. 73

aspects of its opinions and requirements.<sup>134</sup> A space was therefore created from the biological rootedness to the surface of the public and it was within this space, according to Foucault, that the pertinent elements for mechanisms of power became possible.<sup>135</sup>

### 6.3.4 Advanced Liberalism

The traditional distinction between public and private spheres of life is blurred in Foucault's discourses of biopower and governmentality, as recognising the space for the individuals' self-governance has become a new technique of power for the state to govern its subject population. In contemporary political economy, such a technique of governance is manifested by the practice of neo-liberalism, which proposes the view that the utilisation of the individuals' freedom of choice is to govern in an advanced liberal way.<sup>136</sup> The individual is conceived by neo-liberalism as an active social agent who can be cultivated to be responsible for his or her own wellbeing and by so doing, a space of governance may be created in which the relations between citizens and the state is reconfigured from obedience and coercion to acts of choice exercised by responsible individuals. The dominant logic underpinning this new strategy of governance is the logic of a free market which introduces new relations of power by treating autonomous individuals as consumers who can evaluate and manage risks and to make a decision to fulfill their maximum interests.<sup>137</sup> For that reason, the most effective strategies of governance are in fact those that may transplant the goals of authorities into the choices of the individuals who can govern themselves by their autonomy and by their freedom to choose.

Even though the discourses of biopower Foucault used to analyse the relations between the sovereignty and the population in Eighteenth century Western Europe were embedded in a temporal and social setting very different from contemporary Taiwan, it provides a useful theoretical perspective to observe the intermingling phenomenon of public and private in the Taiwanese reality. In fact, the privacy-related problems in Taiwan are embedded in a much broader political and economic context. The increase in the

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<sup>134</sup> Ibid., P. 75

<sup>135</sup> Ibid.

<sup>136</sup> Nikolas Rose, "Governing "Advanced" Liberal Democracies," in *Foucault and Political Reason : Liberalism, Neo-Liberalism and Rationalities of Government* ed. Andrew Barry, Thomas Osborne, and Nikolas Rose (London Routledge, 1996). P. 53

<sup>137</sup> Ibid., P. 58



elderly population combined with a declining birthrate has changed the profile of Taiwanese demographic development, and therefore, how to improve public health in order to support the aging society gradually dominates the government's welfare policy. Health and disease may no longer be treated as merely a scientific or medical concern under this broader perspective. Rather, they are closely connected to the sustainability of the state and as a result, the improvement of health for the population turns to be a crucial issue in Taiwanese governmentality. Investing in preventive medicine not only allows the state opportunities to build up its domestic biotech industries, it is also a strategy to reduce health care costs that have risen due to the increase in longevity.

This illustrates that the role of the state has changed from the threat of death to taking charge of life. According to Foucault, such intervention of modern state governmentality is no longer to control populations through rules or regulations but to manage, to recognise and to work with the population in its naturalness, namely that the population is no longer conceived as simply a collection of subjects but a set of natural phenomena for which the state needs to take responsibility.<sup>138</sup> However, when the population appears as a reality, it forms like a social body and its relation with each individual who comprises it becomes dynamic when the state's intervention has extended to the wellbeing and health of the individual. The ethical tension between considering individual rights as paramount and pursuing the common good based on maximising aggregate utility seems not to be uncommon in the formation of modern welfare states. How to balance the dilemma challenges not only the role of the state but also the individuals' self-reflections in terms of the formation of their social identity. In other words, individuals are expected to play a role as responsible citizens in a larger community as their individual autonomous choices will inevitably have impacts on the other members of the greater social to which the individual belongs.

However, scientific advances in genomics have allowed a new way for individuals to view health and diseases. For instance, the purpose of studies on pharmacogenomics is to find out new strategies for optimising drug therapy based on the correlations between the variation in drug responses and each individual's genetic make-up. This purported objective echoes the scientific goal of the establishment of the Taiwan Biobank that plans

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<sup>138</sup> Supra note 127, pp 352-353

to discover and to capitalise new therapeutic targets for the improvement of preventive medicine in Taiwan. In order to obtain the public's support for the project, one effective strategy is therefore to translate the purported goal and the possible benefits of biobanking into the Taiwanese citizens' perceptions of self and of health. This kind of indirect governance has been reflected through the discourses of altruism and solidarity proposed by the biobank project. By so doing, the relationship between the collective and the individual is more elusive and ambiguous as the intervention of the state into the private sphere of individual health management turns to be more subtle and invisible.

As a result, important questions for the privacy-related issues in Taiwan may no longer be limited to the legal and judicial ones such as whether the mechanisms of confidentiality and data protection exist, or whether an individual's self-control of personal information has been respected. On the contrary, it has turned out to be a more profound question challenging the trust relationship between the state and its citizens, namely to what extent an individual would be willing to act as a responsible social agent and to accept the neo-liberal strategy proposed by the government. Such ethical complexity between the individual and the collective highlights the issue of privacy especially in the context of biobanking as participating in the biobank project, to some extent, also means to entrust certain risks of privacy infringement to the biobankers. Even though samples and data stored in the biobank may have been encoded and made anonymous, due to the nature of the biobank research, individuals are supposed to be followed up for their health conditions and life styles throughout a certain periods of their lives. As a result, in reality, it is still questionable whether the privacy of individuals would remain intact without decoding data for tracing identified participants.

As the Taiwan Biobank is a government-funded project, citizens' attitudes towards the project are heavily influenced by their perceptions of the state. In Taiwan, the role of the state has been transformed dramatically since the lift of martial law in 1987. The old authoritarian apparatus gradually faces the challenges proposed by the burgeoning society which has increased its own autonomy and is no longer docile in its interaction with the state. Even though Taiwan has moved slowly into a welfare state since the early 90s as a result of its successful economic development and its democratic transition, the role of the state remains ambiguous in terms of its relationship with society, which keeps itself distant and skeptical from the apparatus due to the influence of a long-term

governance under the martial law. Under this context, in Taiwan, the stewardship responsibilities of the state are more complicated than the common debates between Right and Left in modern Western welfare states. On the one hand, the state has learned how to adopt the techniques of power to govern its population; on the other hand, however, the state's reactions with a free market remains unsettled as market and capital are no longer easily to be controlled and managed by the will of the state. Even though Taiwan is also generally recognised as a society influenced by Confucian philosophy which prioritizes community interests over individual ones, the influence of modernity along with the transitional role the state plays has rendered Taiwan a more vivid case reflecting on the distinction of public and private in the discussions of privacy-related issue in the context of biobanking.

### **Conclusion**

The purpose of this chapter has been to provide an alternative perspective to reflect on issues of property and privacy raised by the emergence of biobanks as a modern technology. This chapter examined the way the mechanism of consent and the legal rationality of intellectual property that recognises proprietary interests on added values rather than in the sources of human biological materials may have facilitated the commodification of human body and body parts. It argues that the *Moore* case fabricated the distinction of property and personhood that renders the legal status of human tissue samples much more ambiguous. In addition, the presumed gift model implied by using the mechanism of consent to replace property has put research subjects in a relatively powerless position especially in a capitalist market system where the innovation of biotechnologies has transformed human biological materials from waste to valuable resources. The major difference between the models of consent and property, as the chapter argued, lay in the fact that the mechanism of property grants an affirmative right for the sample sources to continuously control their removed samples after giving consent and it allows a legal standing to request a share of benefits from the related proceeds as a result of the research.

Even though the *Moore* case raised the issue of treating human biological materials as gifts, it is mainly the case of individual interest; whereas Mauss' perceptions of moral economy with greater societies based on gift-exchange provides insights into the

justification of reciprocal altruism and redistribution. This chapter questioned the ethical guidelines adopting the gift model from Titmuss' work to govern the relationship of researchers and research subjects. It suggested that it is not appropriate to treat biobank participants as simply donors who are expected to have no entitlements to a share of profits derived from research based on the differences between blood donation and participation in biobanking. In addition, Mauss' theories on viewing society as 'a greater totality' illustrates why the giving-back needs to be extended to the larger collective even though they are not participants in the biobank and the reasons why a profit-sharing may fail to satisfy the requirement of redistributive justice if it does not address the distinction between "power" and "profits" by ignoring the fundamental problem with regard to the recognition of property interest of human biological materials.

In the end, this chapter discussed the issues of privacy and confidentiality in the context of Taiwan. Rather than redefining the notion of privacy, the chapter challenged the narrow conception of privacy adopted by the biobankers in Taiwan that has inappropriately treated privacy and confidentiality as the same and has mistakenly suggested that so long as the samples and data are encoded, privacy would no longer be an issue in the practice of biobanking in Taiwan. The chapter argued that the unsettling property interests of human genetic information have rendered the legal status of the ownership of medical records and the personal information stored in the biobank ambiguous. Such ambiguity became more apparent when the legal mechanism of personal data protection smoothly switched the issue of property to the concerns of privacy.

Finally, by introducing Foucault's theories on surveillance and governmentality, the chapter argued that the boundary between the private and public spheres of life is no longer firm and stable; rather, it may be subject to negotiation especially when the individuals are viewed as autonomous agents whose choices and freedom have real effects on the greater interests of community. The role of the state has changed in this neoliberal way of governance that blurs the traditional distinction between individual rights and community benefits. As biobanking is a project involving groups, the discussion of privacy and its public interest defence needs to consider how this technique of governance may have influenced the scope of privacy in the Taiwanese biobanking reality.

## Conclusion

Even though the co-production of life sciences and capitalism is in itself not new, biobanking introduces a new form of global assemblages of capital and vital politics that leads to innovative institutions and arrangements in fields of technoscience and ethics. In current literatures, there has been much discussion about the implications and regulatory frameworks of biobanks in order to ensure that this epistemic and biotechnological innovation may proceed in the post-genomic age without compromising rights and creating new ethical problems. However, a focus on the ethical and regulatory aspect of biobanks often neglects the larger social and political-economic contexts that shape the initiatives and trajectories of these newly formed global assemblages. This thesis has tried to investigate in depth the biobank project in Taiwan by exploring issues related not only to its governance framework but also to the political and economic aspects of the biobank. This emphasis, focusing on the way in which biovalue is produced, politico-scientific decisions are made and ethical configurations are framed, allows an opportunity to reassess law and ethics, capital and politics, as well as the role of the state and its population in this new form of biotechnology.

Since Iceland initiated its population biobank in the late 90s, a number of countries have joined in this globally technoscientific trend to establish their own national biobanks in response to the rapid development of genomics and its associated demands of health and wealth. These biobanks across the globe retain their own heterogeneous and situated characteristics that make possible the global phenomenon in which biobanking conditions vary significantly according to their local settings. The case of Taiwan, as this thesis has demonstrated, contributes to this global phenomenon by presenting distinctive features in its biobanking endeavours. It reflects the formation of Taiwan's biocapital and the state's aspirations to make use of this biotech innovation to increase Taiwan's competitiveness and visibilities on the global stage. Developments in life sciences are deemed by the government of Taiwan to be a way to promote the wellbeing of its populations and materialise its sense of modernity. These sovereign incentives attract

biotech and pharmaceutical industries to form public-private collaborations through innovative arrangements for technology transfer between the government, academia and industry. Law (regulations) and the system it operates, as this thesis has argued, not only are affected by their social context but also affect in turn the broad context in which they are embedded.

This thesis has presented research findings which combine empirical and theoretical viewpoints in a modest attempt to demonstrate that theory (concept) and method (observed phenomenon) are mutual so they may connect with each other in the study of law and its related phenomenon. The case of Taiwan contributes the so-called “local inputs” to the bigger image of the developing cosmopolitical technoscience, so what this image is able to reflect is no longer a broadly encompassing and conventional phenomenon, as the terms ‘global’ and ‘cosmopolitical’ tend to suggest. Rather, as these inputs pay detailed attention to heterogeneous, contingent and situated conditions which highlight the distinctive civic epistemologies and politics of technoscience in Taiwan, they enrich an understanding of the evolution of this rapidly emerging cosmopolitical technoscientific world. Biobanking fits itself well into this particular perspective as the development of genomics and life sciences have been closely entangled with capital, technology and science, all of which are deemed to be elements of global forms given their universal and mobile nature. However, as every state’s approach to the formation and development of its technoscientific policies are varied (based on its own national politics and civic epistemologies), the manifestation and operation of biobanks in these different localities are diversified. It is because of these variations that the Taiwanese experience provides its own value in terms of enriching current literatures on the development and governance of biobanks.

### ***1. Reassessing Bioethics from the Perspective of Biopolitics***

In addition to empirical contributions, as the biobanking case in Taiwan illustrates, however, this thesis has also opened up several theoretical points which are summarised and addressed in these concluding remarks. The first theme concerns the re-evaluation of bioethics in biobank governance from a perspective of biopolitics and governmentality. As this thesis has argued that while informed consent and privacy have been placed in the forefront of biobank governance in Taiwan, such an ethical configuration has,

however, failed to challenge the influence of global capitalism. Rather, it has further consolidated a neoliberal rationality which echoes the state's transformation from its role of steward to an investor in global bioeconomic competition. Bioethics, if positioned in the context of Taiwan's biocapital formation (and its entanglement with the global flow of capital), may easily be reduced to procedures and framed as a governing mechanism to help the state turn its population into resources through discourses of citizenship in the name of individual autonomy. Even though bioethics is one of the key elements in legitimating modern biomedical research involving human subjects, they are equally useful tools to act as a procedural safeguard that in reality consolidates invisible power structures associated with capital and politics, especially when the ethics are introduced into law as a formal technique of the technology of governance.

Nevertheless, the purpose of this thesis is not to blindly question the necessity of bioethics in Taiwan's biomedical research. Certainly, in a country whose bioethical arrangements and regulation are still in the early developing stage, bioethics is an appropriate point to reflect the importance of human value and conditions in the production of scientific knowledge. However, this thesis has emphasized that bioethics should not be viewed as a neutral and sufficient mechanism, and as its configuration implies the compromise of various competing interests, the ethics itself also needs to be scrutinised for its underlying agendas through tracing its process of formation and the possible entanglement with capital and politics. As a result, Michel Foucault's notions of biopower and governmentality provide a useful angle in this thesis to detach bioethics from its moral-loaded appearance, especially when these ethical configurations are connected to a neo-liberal logic which focuses on individual autonomy as a way to justify liberal democracies. A modern governing technique can extend its liberal governance in the name of individual autonomy to the wellbeing of the population and the individuals who compose it in the interests of the state. This advanced liberal rule, as Nikolas Rose suggests, seeks to govern through the regulated choices of individual citizens, who are to be governed through their freedom as they are constructed as subjects of choices.<sup>1</sup>

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<sup>1</sup> Nikolas Rose, "Governing "Advanced" Liberal Democracies," in *Foucault and Political Reason : Liberalism, Neo-Liberalism and Rationalities of Government* ed. Andrew Barry, Thomas Osborne, and Nikolas Rose (London Routledge, 1996). P. 41

Such a technique of governance, as argued by Rose, may not be understood thoroughly without taking into account the emergence of modern welfare states in which the state's intervention to redress social problems for national wellbeing becomes a legitimate technique of governance "at a distance."<sup>2</sup> In other words, governing through individuals' self-governance becomes a more effectual way than traditional authoritarian rule using laws and bureaucracies for political purposes to seek to produce desired effects.<sup>3</sup> As a result, the state of welfare becomes a specific terrain to observe the relations between the political sphere and other domains of economy and society as the state may now take its stewardship responsibility for generating technologies of government by rearranging its resources in the name of collective security and the public good.<sup>4</sup> Social insurance and national healthcare are both exemplary of this welfare formula by addressing social solidarity and individuals' responsibilities as dutiful citizens to share the common good for the management of both individual and collective risks.

Discourses of citizenship in biobanks, as this thesis has argued, re-conceptualise national populations from biovalue generators to political subjects who are entitled to their rights and entitlements for social protection in exchange for their duties of social responsibilities, for example, their will to be healthy and to contribute to public health. This neo-liberal method of governance which guarantees individual autonomy and acts of choice has become an advanced liberal strategy for the state. National biobanks exemplify this governing technique by forming active citizens as voluntary participants of the biobanks for the public good. Rather than governing through society, this advanced liberal strategy seeks to govern through the choices of individual citizens by creating a space to recognise their freedom to pursue maximum benefits for themselves and for others. Nevertheless, this modern technique disguises the economic role of biobanks which focuses on the production of biovalue by forming biobanks for the application of genomics research. In other words, as these population biobanks have been deemed to be valuable resources in the global bioeconomy, the advanced liberal governance relying on the discourses of citizenship may effectively help states in turning their populations into resources of biovalue.<sup>5</sup>

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<sup>2</sup> Ibid.

<sup>3</sup> Ibid., P. 46

<sup>4</sup> Ibid., P. 48

<sup>5</sup> Robert Mitchell and Catherine Waldby, "National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue," *Science Technology Human Values* 35, no. 3 (2010). P. 3



Bioethics, such as informed consent and the protection of confidentiality, constitutes a crucial part of this global biocapital structure but its entanglements with relations of power and capital have not yet been fully presented in the establishment and operation of population biobanks. Even though the Iceland controversy regarding the application of presumed consent on the establishment of its Health Sector Database has been frequently discussed in the current literature, these discussions focus more on the dimension of bioethical issues associated with governance frameworks than on reflecting the political and economic roles of biobanks. Following the Icelandic project are similar biobanking plans across the globe with different scales, approaches and different forms of collaboration between the public and private sectors but all of them seem to pose similar fundamental ethical concerns from bioethical vantage point addressing consent and privacy as key issues in biobank governance.<sup>6</sup>

In addition, bioethics in the Icelandic case, as Gisli Pálsson and Paul Rabinow argue, provides a fertile ground for the Association of Icelanders for Ethics in Science and Medicine to accumulate symbolic capital in the transnational market of civic virtue.<sup>7</sup> Taiwan provides an excellent case study, as this thesis has illustrated, to observe how biomedical issues have become bioethical problems and how the ethical gaze in Taiwan is focused on some themes (consent and privacy) and blind to others (property and access rights). Like the association in Iceland, the Taiwan Association for Human Rights is also a strong ethical and political body which acts as the main platform for ethical criticism for the biobank project in Taiwan. Given the association's earlier success to put on hold a governmental plan to establish a national fingerprint database, the biobank project concerns human rights advocates in relation to the infringement of individual privacy and the lack of transparency and trust. These ethical concerns had led to the biobank project's sample collection being temporarily suspended until its Ethics and Governance Council was formed.

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<sup>6</sup> Gísli Pálsson and Paul Rabinow, "The Iceland Controversy: Reflections on the Transnational Market of Civic Virtue," in *Global Assemblages: Technology, Politics, and Ethics as Anthropological Problems*, ed. Aihwa Ong and Stephen Collier (Oxford: Blackwell Publishing, 2005). P. 92

<sup>7</sup> Ibid.

Moreover, the biobanking case in Taiwan has demonstrated that in terms of the public engagement, the public is no longer one homogenous entity. Rather, it constitutes a range of “publics”, which may share different interests and may not be mutually exclusive. For that reason, this thesis has suggested that it is worthy to discuss which “publics” in what capacity one needs to consider in evaluating the engagement of the public in the production of scientific knowledge and biovalue. The major obstacle to public engagement in the biobank case in Taiwan lies in the fact that Taiwan lacks a long tradition of community consultation in the formation and implementation of S&T policies. However, the subsequent democratic transition in Taiwan has challenged the traditional technocrat decision model, so a technocrat-based policy now needs to go through the scrutiny from society in order to obtain its own legitimacy. It also illustrates why Taiwan relies on formal legal rules rather than self-governance, such as institutional review boards and peer reviews among scientific groups, to govern biobanks and how this newly-enacted Human Biobank Management Act has become a special terrain to reflect power negotiation and social mobilisation in its forming process.

Furthermore, this thesis has suggested that public engagement should not be valued only for its instrumental effect in formation of the public good. Rather, it needs to be viewed as a way to build a trust relationship between state and society as opinions formed through the engagement of the public may ease social distrust that forms the bond that society relies to live on. In so doing, the allocation of resources may be better justified as what constitutes the common good has become a decision made by “the publics”. This thesis has also illustrated that the ethics involved in the biobank project in Taiwan entails a wider politics of organisation, decision-making and accountability in democratic societies to political subjects self-organised as citizens. As a result, the ethics involved here is not only limited to the narrow bioethics and codified norms for biomedical practices on which most lawyers and ethicists focus. Rather, the thesis argues that these ethics involve wider political innovation and joint decision-making of potential research subjects. As a result, the analysis of ethics presented by this thesis hopes to connect with empirical reality entailing the impact of politics and capital, which have been relatively neglected in current discussion of the ethical and legal issues posed by biobanks.

## ***II. Individual and Collective***

Concerns about Taiwanese aboriginal participation in the biobank project challenge the current informed consent mechanism, which is mainly based on the rationale of individualism. In the context of biobanking, as the potential risks posed by research results are normally of a collective nature, individual consent by members of a specific ethnic group is often regarded as inadequate to safeguard the interests of the entire group on which the detrimental social impact occurs. The original plan to include Taiwanese aborigines in the biobank project in Taiwan highlights this inner tension between the interests of the individual and the collective. This thesis has demonstrated how such a contrast may have been extended from a general discussion on the conflicting interests of individual rights and common good to a more specific consideration of the inclusion of minority populations in the biobank project in Taiwan.

As aborigines constitute only 2% of the entirety of the population in Taiwan, their potential to be included in the biobank triggers a more specific question about stigmatisation and the implementation of consent at a collective level. Moreover, as this thesis has mentioned, human rights advocates challenged the process of sample collection for the biobank based on Article 21 of the Basic Law of Indigenous People (Taiwan), which requires collective consent obtained from aboriginal groups in addition to the consent of the individual when academic research is conducted in the aboriginal regions. As a satisfactory mechanism for obtaining group consent from Taiwanese aborigines is still under debate, the biobank project has decided to temporarily postpone its sample collection from aboriginal groups until a proper mechanism of group consent is devised.

This thesis has linked the relation between bioethics and accountabilities in a democratic society by placing ethical governance frameworks and group consent in the broader political and social context of Taiwan. In so doing, the issue of bioethics may be connected with core questions in politics such as who decides on the question to whom a collective decision through the mechanism of ethical governance council or group consent is accountable. This thesis attempts to deepen the analysis of biobank governance frameworks and consent by moving beyond defining instances of moral certainties when new contexts of decision making arise due to the emergence of new

biotechnology such as biobanks. In addition, this thesis seeks to demonstrate that ethics involves a set of tactics which play a significant role in shaping contexts in which ethical norms may be subject to change as well.<sup>8</sup> The Taiwanese experience further shows that even though group consent is necessary to safeguard the interests of minority populations in biobanking, its implementation concerns group identification, representation, and how to reach consensus by joint decision making, all of which involve deeper political implications with regard to the recognition of aboriginal status and its related economic and social inclusion.

Furthermore, this thesis has suggested that it is necessary to take into account Taiwanese aboriginal views on genetic research and informed consent so their concerns with biobanks may be analysed from a culturally specific perspective. However, this culturally-oriented approach does not mean to evoke the notion of cultural relativism, which tends to argue that cultural differences are unbridgeable divides.<sup>9</sup> In health and medical related ethnographic research, this culturally relative view has been criticised as making research subjects more susceptible and dependent as it entrenches inequality by blindly defending local cultural traditions without thinking about their implications.<sup>10</sup> Being aware of these concerns, this thesis has sought to move beyond an emphasis on difference and demonstrated that the inclusion of the element of cultural difference can help design a more suitable consent mechanism for the best interests of Taiwanese aborigines in their practice of collective decision-making.

In fact, in the context of biobanks, the inner tension between the individual and the collective is particularly apparent as genetic information relates not only to its sample source but also to the group of people who share the same genetic lineage. As a result, biobanks have challenged bioethics and law which put more emphasis on individual autonomy than on collective benefits. Biobanking not only involves the use of genetic information of a shared nature but also relates to larger groups of participation, so it needs to be further justified by values of a community of rights. This thesis has argued that when considering what kinds of benefits biobank research seeks to bring, the boundary between public and private turns out to be negotiable. The scope of privacy

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<sup>8</sup> Adriana Petryna, "Globalizing Human Subjects Research " in *Global Pharmaceuticals: Ethics, Markets, Practices*, ed. Adriana Petryna, Andrew Lakoff, and Arthur Kleinman (Duke University Press, 2006). P. 34

<sup>9</sup> *Ibid.*, P. 35

<sup>10</sup> *Ibid.*

becomes floating as an individual agent's self-governance of her or his health condition is no longer viewed as simply a personal decision made in the private sphere from the perspective of biopolitics.

In addition, this thesis has argued that important questions for privacy-related issues in Taiwan may no longer be limited to the legal and judicial spheres. Rather, there is a more profound question challenging the trust relationship between the state and its citizens. This thesis has further illustrated that in Taiwan, the stewardship responsibilities of the state are more complicated than those of modern Western welfare states. On the one hand, the government of Taiwan has learned how to adopt the techniques of power to govern its population; on the other hand, however, the state's relations with a free market remain unsettled as market and capital are no longer easily controlled by the will of the state. The influence of modernity along with the transitional role the state plays, as this thesis has recognised, make Taiwan a distinctive case for reflecting on the distinction between public and private in the context of biobanks.

### ***III. The Moral Economy of Biobanks***

In the end, this thesis argues that the inner tension between the interests in biobanks between the individual rights and the benefits of the collective may be mitigated by the principle of the moral economy of Marcel Mauss. Compared to the free gift model proposed by Richard Titmuss, Mauss's perceptions of the morality of exchange based on the gift relationship in a total society provides insights into the justification of redistributive exchange and reciprocal altruism. Even though collection and storage of human biological materials for medical use is not a new phenomenon, the possible combination of genealogical history and health information with genetic data has made biobanks useful resources along with the development of biomedical innovations. As intellectual property protects the interests arising from enhancement made by added human labour rather than the sources of tissue samples, in order to prevent human tissues from being commodified, human body materials have been treated as either gift or waste in medical research, rather than as a commodity for exchange. However, this thesis has argued that this presumed gift model implied by using consent to replace property renders research subjects powerless in a capitalist market system in which

biotech commodification has turned human biological materials from waste to resources of biovalue.

In Taiwan, as consent and privacy rather than property dominate the ethical concerns surrounding biobank governance, issues such as commodification of human biological materials and the penetration of market forces into human tissue and personal health data have not yet been seriously reflected upon. On the contrary, altruism and solidarity constitute the main discourses of sample collections for the biobank, so proprietary control of human tissue and personal health data remains in the hands of medical researchers and it also means that the economic role played by participants in the co-production of biovalue has not been fully recognised in the operation of the biobank. This thesis has pointed out that the increasing association of capital and life sciences gradually transforms human tissue and genetic data into commodities whose value can be created by exchange. In this process of transformation, informed consent plays a significant role in instituting a procedure in which persons may be detached from their tissue samples by withdrawing their subjectivities and personhood. So being granted the authority to give consent, biobank participants are qualified as subjects of modern biotechnologies. In addition, this thesis has argued that without an adequate recognition of property in human biological materials, the formulations of consent grant research subjects only an illusory power in terms of exercising continuing control over their tissue samples and personal data.

By analysing the *John Moore* case, this thesis demonstrated that putting consent and property in a position of mutual exclusivity ignores the notions of equity and distributive justice and fails to recognise that the patient in the case did not have equal bargaining power in biomedical research. Similarly, in biobanks, once consent is obtained, the continued relationship with participants and their samples has ceased with the result that it precludes the participants from being considered as stakeholders in the project. Even though the language of 'gift' is used frequently in bioethical discourses, it has been interpreted in a way associated with altruistic behavior. So rather than being deemed to be exercises of self-ownership implied by property, the free gift model presumes the surrender of participants' residual interests in their donated samples.<sup>11</sup> By further

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<sup>11</sup> Graeme Laurie, *Genetic Privacy: A Challenge to Medico-Legal Norms* (Cambridge: Cambridge University Press, 2002). P. 317

analysing the notion of gift relationship proposed by Richard Titmuss, this thesis distinguished the differences between blood donation and biobanking and argued that an altruistic gift model may be used in biomedical research to suggest that it may avoid the rearrangement of entitlements for the exercise of control over the samples and for a share of benefits derived from the application of research results.<sup>12</sup>

On the contrary, for Mauss, gifts are deemed to be a mode of exchange that helps establish the bonds of reciprocity between givers and recipients. To reciprocate gifts shows the willingness of the recipients to accept the bond of alliance and commonality. In addition, in this mode of exchange, the gift is no longer a mere object but a spiritual article that constitutes a part of the giver who has been indissoluble from it. As the gift has never been separated from the giver, there is no real distinction between persons and things as emerges in a commodity economy in which objects can be completely alienated and sold to new owners through the notion of property. According to Mauss, the grand cycles of exchanges constitute the whole society that maps all the obligations between its members whose permanent commitments articulate the dominant institutions. As this thesis has observed, the main purpose behind Mauss's concept of gift-exchange was to support social democratic redistribution and the idea of solidarity in modern industrial economies in which the institutions and laws of exchange are governed by the rule of markets.

By extending Mauss's gift relationship to a discussion of biobanks, this thesis has argued that the morality of exchange proposed by Mauss for redistribution may be viewed as an alternative supplement to the current unsettling debates about the recognition of individual proprietary interests in human body materials. For Mauss, in the total social phenomenon constituted by the gift-exchange, a new form of ethic may be created when individuals are organized as collective subjects to produce mutual interests based on their positive obligations to the greater totality. As a result, even though individual agents do not have a positive duty to participate in biobanks, the state's stewardship responsibility for the general wellbeing of the community may have extended the obligation of citizens, who are expected to act as responsible agents to improve conditions of public health.

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<sup>12</sup> Richard Tutton, "Person, Property and Gift: Exploring Languages of Tissue Donation to Biomedical Research," in *Genetic Databases : Socio-Ethical Issues in the Collection and Use of DNA*, ed. Richard Tutton and Oonagh Corrigan (London and New York Routledge, 2004). P. 20

However, as such biological citizens may also be viewed by states as a valuable resource for biomedical research, this production of biovalue concerning the moral economy of health and national imperatives has redefined notions of what it means to be a citizen.

This thesis has further argued that participants' growing awareness of potential commercial entanglement with their donated samples challenges the distinction between gifts and commodities in a market economy because their tissue samples and the derived personal information may now be transformed from pure gifts to circulating commodities as a form of product with exchange value. As the potential for commercialisation has a significant impact on participants' willingness to take part in biobanks, in order to obtain trust from the general public, this thesis has suggested that governing mechanisms based on the principle of reciprocity need to be proposed by biobanks at the initial stage when they procure consent from participants. In addition, as the sustainability of a biobank requires establishing a long-term partnership between biobanks and participants, in order to obtain trust from the general public, such a partnership needs to be reciprocal by recognizing the return of "gift" as a social obligation of biobanks. Furthermore, according to Mauss, the system of 'total services' is the system in which the exchange of everything among individuals and groups become possible. Such a recognition of the share of benefits, by treating participants and the whole society as stakeholders, may eventually consolidate the legitimacy of biobanks.

Mauss extended the idea of gift-exchange to enhance solidarity in modern societies based on market exchange by referring approvingly to proposals on welfare such as health and unemployment insurance. In so doing, the redistribution of accumulated goods and services based on political innovations of alliances may avoid the failure of market exchange by subjecting it to judgments of fairness. As this thesis has argued, Mauss's theories on the gift cycle provide an alternative response to Polanyi's analysis of the great transformation brought by the industrial revolution. Rather than being alienated, redistribution of wealth and power in the moral economy reunifies the entire social system as the greater totality in which institutions such as law, religion and economy are not segmented but entities of the total social facts. This thesis has further illustrated that the ultimate goal of reciprocal altruism which suggests stable relationships and giving in return between individuals involves a new form of ethics which



entails the accountability of commerce to biological citizenship when citizens are constructed not only as political subjects of entitlements but also as generators of biovalue for the health and wealth of the state. As a result, the moral ideal of an alliance of participants, the biobank and its commercial extensions needs to be fully acknowledged with reference to their joint interests and their co-dependent relations in a greater totality.

## APPENDICES:

### Appendix I. Interview Subjects

#### A. Aboriginal doctors and public health officials

1. **A1**, Thao group, University
2. **A2**, Taroko group, University
3. **A3**, Ami group, Indigenous Medical Association
4. **A4**, Kavalan group, Kavalan Development Association
5. **A5**, Taroko group, University

#### B. Scientists within the biobank team

6. **Chen Yuan-Tsong**, Institute of Biomedical Sciences, Academia Sinica
7. **Shen Chen Yang**, Institute of Biomedical Sciences, Academia Sinica

#### C. Geneticists and Genomicists

8. **Wu Cheng-Wen**, Member, Academia Sinica; Founding President of the National Health Research Institutes (NHRI)
9. **Chen Chien-Jen**, Member & Distinguished Research Fellow, Genomics Research Centre, Academia Sinica
10. **S1**, Scientist, Division of Molecular and Genomic Medicine, NHRI
11. **S2**, Scientist, Division of Biostatistics and Bioinformatics, NHRI
12. **S3**, Medical Doctor & Professor, National Taiwan University Hospital
13. **S4**, Scientist, Division of Molecular and Genomic Medicine, NHRI

#### D. Government Officials

14. **L1**, legislator, Legislative Yuan
15. **G1**, Staff, Department of Health

#### E. ELSI People

16. **EL1**, ELSI scholar
17. **EL2**, ELSI scholar
18. **E1**, EGC member
19. **I1**, IRB member

#### F. Human Rights Lawyers

20. **H1**, Human Rights Lawyer
21. **H2**, Human Rights Lawyer

## Appendix II. Interview Question Outlines

### A. For Aboriginal Doctors

-- What do you think of the idea of building up a national biobank for Taiwan? Do you have any concerns about it? If so, what are they? What do you think about the informed consent requirement in the biobank? What do you think of the “group consent”? How do you define your “group”? What do you think of benefit sharing? What does the benefit mean to you? How do you identify yourself? Is your self-identity biological?

### B. For Scientists, Geneticists and Genomicists

#### 1. Questions about the Taiwan Biobank:

-- What do you think of the idea of building up a national biobank for Taiwan? What kinds of implication do you expect? What are the advantages and disadvantages for Taiwan to set up this biobank? What do you think about grouping the population in Taiwan by the four great ethnicities? What is the uniqueness of Taiwanese genes?

#### 2. Questions about biobank governance in general:

-- Before the Human Biobank Management Act is enacted, what kind of mechanisms do you use to govern your research biobanks? Would different biobank purposes influence your answers? What do you think of the new Human Biobank Management Act? Will it do any good or bad to your biobanks? How does your lab deal with remaining samples? Can other labs apply to use your samples? If so, who decides with what criterion about the access rights? How does your lab deal with international cooperation in terms of sharing samples and data?

### C. For legislators and government officials:

-- What is the background of the enactment of the Human Biobank Management Act? What are the difference between the draft and the legislative version of the Act? How does Department of Health see the biobank plan? What is Department of Health’s attitude toward the biobank? Who is responsible for the biobank and its future development?

### Appendix III. A Brief Description of the Focus Group Research

In January 2010, I did a focus group research with 6 Taroko youths discussing their concerns about the biobanking project. The purpose of doing this research is in order to spot issues that might worry aboriginal people about biobanking. Because the purpose is for “issue spotting” only, the research results should not be further interpreted as the general perception of the Taroko group or the Taiwanese aborigines in general. Nor can the results represent as the general public’s perception in Taiwan about the biobank plan.

- A. Participants: 6 Taroko youth, with ages of 23-30; 2 of them are females; 5 of them have college degrees; their backgrounds are varied; 1 person with law background; 1 person with pharmaceutical background; the other 4 people have backgrounds in art, engineering, and business management.
- B. Time: about 2 hours
- C. Procedure: Before the discussion started, each of the participants was given a test about their knowledge of what a biobank is. The Test lists 5 questions. Every question contains one item of information about the description of the Taiwan Biobank. All the 5 descriptions are true. All the information comes from the IBMS website of the biobank plan. The answer proposes 5 responses that refer to the different knowledge degrees about these sentences in questions. The choices of answers are as follows: 1. don’t know; 2. know it but not clear. 3. know it and somewhat clear, 4, know it and quite clear, 4. know it clearly.

The question sentences are follows:

- (1) The biobank collects and stores participants’ samples for biomedical research
- (2) In addition to collecting samples, the biobank keeps tracing back participants’ personal and medical information in a certain period of time
- (3) The biobank collects samples from different ethnicities in the hope of finding out the causes of diseases among different populations.
- (4) The biobank collects participants’ personal and medical data in order to know the correlation with these data and the diseases.
- (5) The biobank is a long-term research project, for at least 20 years or even longer.
- (6) To participate in the biobank is not like participating in a health check so participants will not receive a formal report about their health condition.

The responses of this knowledge test are as follows: (P refers to participant)

P1: 2, 2, 2, 2, 2, 2

P2: 5, 1, 5, 4, 5, 2

P3: 1, 1, 1, 1, 1, 1

P4: 1, 2, 2, 2, 2, 1

P5: 2, 1, 2, 2, 3, 1

P6: 2, 3, 3, 3, 1, 2

After the knowledge test, the formal discussion began. At that time, the 6 participants more or less had an idea what we were going to discuss. I introduced to them again what the biobank is, according to the information released by the IBMS team. Then I asked them to write down a positive and a negative thing about the biobank. Then I asked each of them to briefly explain what they think of the positive/negative parts. In sum, the positive things are: to know why people got sick; to improve health condition, to improve biomedical research, etc. The negative things are: the reliability of the research results; too long to know the results; privacy concerns; the result could be manipulated, like eugenic things; if the results are useless, it wastes a great amount of resources.

After everyone gave their explanations, the main discussion started. The discussion covered 4 big topics about biobank dilemmas—privacy & data exchange, informed consent, commercialisation & benefit sharing, and laws. Each dilemma was briefly explained and then it was followed by several detailed questions for further discussion. Each participant was given a red and a green card for them to answer some of the detailed questions. Raising the red card means they think it is a negative thing (or they don't agree), and the green card means they think it is positive (or they agree). After they showed their cards to some yes/ no questions, they were asked to explain the reasons to their answers.

The question outlines for each topic:

(1) Privacy & Data sharing:

What do you think about linking biobank with personal medical and household data? When would you be willing for your information to be traced down to you? When wouldn't you? What do you think of the coding system; would you trust the coding? Why, and under what circumstance would you trust the coding? What do

you think of international data sharing among biobanks? Would biobanks in different regimes be a consideration for you?

(2) Informed consent:

What do you think of general consent (for research now and in the future)? What kinds of information are the most important for you to know before you give such consent? What do you think of group consent? What does the group mean to you? What do you think of the re-contact? Would you like to have a right to withdraw from your consent?

(3) Commercialisation and Benefit sharing

What do you think of voluntary participation of the biobank (see participants as donors)? If the biobank is funded by some private companies, would that influence your answers? E.g, the government cooperates with private companies? What do you think about benefit sharing? What does benefit mean to you? How to share and who to share, by individual or group as whole?

(4) Laws:

If relevant laws were absent, would that concern you? What do you think is the best way to govern biobank? E.g, by government, or by an independent institute, by scientists' self-governance, etc.

After the discussion was completed and before the meeting was dismissed, each participant was asked whether they would be willing to take part in the Taiwan Biobank project. Six of them gave red cards for this question. Then I asked further under what circumstances, would they change their minds? Several answers were given: For example, the biobank purpose needs to be clearer; they need to be given more information about the biobank; their privacy and their groups' reputation need to be better protected; all the negative points discussed earlier must be solved, etc.

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