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CONSENT PRACTICES AND BIOMEDICAL KNOWLEDGE PRODUCTION IN TISSUE ECONOMIES

ACADEMIC DISSERTATION
Helsinki 2008

University of Helsinki
Department of Sociology
Research Reports No. 256

Cover image: David Fairfield / The Image Bank / Getty Images
Layout: Teea Laitio

ISSN 0438-9948
ISBN 978-952-10-5007-7 (paperback)
ISBN 978-952-10-5008-4 (PDF)
http://ethesis.helsinki.fi

Printed by Helsinki University Print
Helsinki 2008

For Kersti

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TIIVISTELMÄ

Ihmiskudoksen lääketieteellisestä käytöstä on muodostunut merkittävä osa biolääketieteellistä tutkimusta viime vuosina. Näytteiden kerääminen, käyttö ja tehokkaampi hyödyntäminen ovat samalla herättäneet paljon poliittista mielenkiintoa kudoskokoelmia ja niihin liitettyjä terveystietoja kohtaan sekä kansallisesti että kansainvälisesti. Lääketieteellinen tutkimus perustuu suurilta osin tutkittavan ja tutkijan väliseen suhteeseen. Tätä suhdetta voidaan pitää sosiaalisena suhteena sillä se perustuu suostumukseen, yksityisyyden vaalimiseen sekä tutkittavan autonomiaan. Tutkittaville annetaan tietoa siitä mihin tutkimus liittyy ja he voivat täten tehdä tietoisen suostumuksen osallistumisestaan. Jälki-genomisella aikakaudella käsityksemme suostumuksesta, yksityisyydestä sekä autonomiasta ovat kuitenkin muuttumassa suhteessa meistä kerättyihin näytteisiin ja terveystietoihin. Tämä kuvastaa yksilön oikeuksien muutoksia tieteen ja yhteiskunnan tarpeiden varjossa.

Hyödyntäen kudostalouden ja bioarvon käsitteitä (Waldby, 2002) tutkimuksessa tarkastellaan kudosnäytteiden luovuttajien ja käyttäjien välistä suhdetta biolääketieteellisessä tutkimuksessa katsomalla erilaisia tapauksia joiden yhteydessä kudosnäytteitä ja niihin liitettäviä terveystietoja kerätään ja hyödynnetään Suomessa. Tutkimus tarkastelee miten tulkinnat yksilön oikeuksista, eritoten suostumuksesta, ovat muuttumassa suhteessa tieteellisen tiedon tuotannon tarpeisiin sekä poliittisiin paineisiin suomalaisissa kudostalouksissa 1990-luvun taitteesta tähän päivään. Tätä tarkastelua tehdään poliittisen kontekstin analyysin avulla, sekä kolmen tapaustutkimuksen kautta, joissa tarkastellaan leikkausjätteen käyttöä, suurien epidemiologisten kokoelmien hyödyntämistä sekä periytyvän paksusuolisyövän tutkimukseen liittyviä haasteita Suomessa.

Tutkimus osoittaa miten suostumuksen tulkinnoista on tullut eriäviä sekä tuo esiin ne tekijät jotka ovat vaikuttaneet näihin eroavaisuuksiin. Tarkastelussa ilmenee miten suhde yksilön oikeuksien ja tieteellisten ja yhteiskunnallisten intressien välillä on muuttumassa siten että enenevässä määrin yhteiskunnalliset ja tieteelliset intressit painavat päätöksenteossa. Yhteiskunnallisissa ja tieteellisissä argumenteissa taas painottuvat yhä enemmän taloudelliset, kaupalliset ja ennaltaehkäisevät odotukset, joita liitetään kudosnäytteistä saatavaan hyötyyn. Tämä muutos voidaan nähdä perustavanlaatuiseksi muutokseksi länsimaisessa käsityksessä yksilön oikeuksista absoluuttisina ja luovuttamattomina oikeuksina.

ABSTRACT

The use of human tissue sample collections has become an important tool in biomedical research. The collection, use and distribution of human tissue samples, which include blood and diagnostic tissue samples, from which DNA can be extracted and analyzed has also become a major bio-political preoccupation, not only in national contexts, but also at the transnational level. The foundation of medical research rests on the relationship between the doctor and the research subject. This relationship is a social one, in that it is based on informed consent, privacy and autonomy, where research subjects are made aware of what they are getting involved in and are then able to make an informed decision as to whether or not to participate. Within the post-genomic era, however, our understanding of what constitutes informed consent, privacy and autonomy is changing in relation to the needs of researchers, but also as a reflection of policy aspirations. This reflects a change in the power relations between the rights of the individual in relation to the interests of science and society.

Using the notions of tissue economies and biovalue (Waldby, 2002) this research explores the changing relationship between sources and users of samples in biomedical research by examining the contexts under which human tissue samples and the information that is extracted from them are acquired, circulated and exchanged in Finland. The research examines how individual rights, particularly informed consent, are being configured in relation to the production of scientific knowledge in tissue economies in Finland from the 1990s to the present. The research examines the production of biovalue through the organization of scientific knowledge production by examining the policy context of knowledge production as well as three case studies (Tampere Research Tissue Bank, Hereditary Non-polyposis Colorectal Cancer and the Finnish Genome Information Center) in which tissues are acquired, circulated and exchanged in Finland.

The research shows how interpretations of informed consent have become divergent and the elements and processes that have contributed to these differences. This inquiry shows how the relationship between the interests of individuals is re-configured in relation to the interests of science and society. It indicates how the boundary between interpretations of informed consent, on the one hand, and social and scientific interests, on the other, are being re-drawn and that this process is underscored, in part, by the economic, commercial and preventive potential that research using tissue samples are believed to produce. This can be said to fundamentally challenge the western notion that the rights of the individual are absolute and inalienable within biomedical legislation.

ACKNOWLEDGEMENTS

The road to completing and publishing this work has been long and winding. Thankfully there have been many people along the way who have aided and guided me along this path. My entry into academia came about somewhat unsuspectingly in 1999 when I was looking to begin writing my masters thesis. I was very lucky to have the opportunity to begin work on issues on the commercialization of academic research at the University of Helsinki within the project Commercialization of University Activities (1999–2001). For this I am grateful to my supervisor, professor Marja Häyrinen-Alestalo who gave me the opportunity to come and work in the Research Group for Comparative Sociology and helped to secure funding for my work. To be able to work in a research group and get paid to write ones master's thesis was a privilege which ultimately led me to commence my doctoral studies.

The research that is presented here has to a large extent been made possible by funding that I have received from the Finnish Funding Agency for Technology and Innovation, Tekes from 2002 to 2006. My doctoral research began within a research project entitled Rights and Responsibilities in Biotechnology which was part of the ProACT research program on advanced technology policy. This research has subsequently led me to other projects which have examined questions related to biobanking in Finland from different perspectives. Once again the role of my supervisor, professor Marja Häyrinen-Alestalo has been important in securing the funding for this, not to mention the role of Tekes for its continued and long-term support and interest in these issues. Such long-term funding has provided an important framework within which to conduct my research and develop my networks. I am also grateful to the Helsinki Institute of Science and Technology Studies (HIST), which has graciously also provided me with funding during my doctoral research.

My supervisor, professor Marja Häyrinen-Alestalo, has also played a central role in opening many doors for me. Most notably by securing a position for me as Assistant editor of the Science Studies journal and helping me gain a position in the European Sociological Associations (ESA) Sociology of Science and Technology Network (SSTNET). Working

with Science Studies allowed me a rare glimpse into the inner workings of international scientific publishing and provided me with invaluable insight into the publication process. Over the years I have also had the opportunity to work with some excellent editors and guest editors, namely Henrik Bruun and Raymund Werle, who have led by example and given me the opportunity to participate in a highly stimulating academic environment. Both Science Studies and SSTNET continue to bear fruit in my academic life and have contributed greatly to my development as a researcher. I am also grateful to Marja for her tireless support and willingness to read and comment on my work and thesis over the years. She has been instrumental in nurturing my career and introducing me, at a very young age, to the international research community.

During the past nine years I have had the pleasure of sharing an office space with numerous colleagues within the Research Group for Comparative Sociology. Although a challenge at times, the benefits of sharing space and time with people far outweigh the cons. Two people in particular, Antti Pelkonen and Karoliina Snell, deserve great thanks for their friendship over the years. We have endured many challenges and hardships over the years in our quest to complete our 'never ending' studies. If it weren't for their support, friendship and humor over the years I am sure this task would have been much harder to bear. I am also indebted to them for their willingness to read, comment and correct much of my academic output. I would also like to extend my special thanks to Karoliina for her excellent comments on my thesis during its final preparatory phase. Several other people have also played an important part in fostering a lively academic environment in the research group, namely Tuula Teräväinen, Suvi-Tuuli Waltari and Terhi Tuominen. In addition, several people have worked in the group over the years leaving many fond memories of times spent together, in particular Ulla Peltola, Sampo Villanen, Emilia Pöyhönen, Saara Kupsala, Marjaana Väisänen and Kalle Sinivuori.

During my doctoral studies I participated in two post-graduate seminars which were important in the development of my work. The first, at the Department of Sociology, was the STEP seminar where I was able to present many of my research interests and receive constructive feedback on the sociological dimension of my work. I am especially thankful to the directors of the seminar, professors Risto Alapuro, Arto Noro, Risto Eräsaari, Keijo Rahkonen and Anssi Peräkylä for their excellent guidance and suggestions over the years, as well as my fellow doctoral students for their insightful comments on my work. The second seminar which I have attended has been organized by the Finnish Post-graduate School in Science and Technology Studies (TITEKO) which has also provided a fruitful environment for incubating and developing my work. The directors of the school, professors Reijo Miettinen and Marja Häyrinen-Alestalo deserve my gratitude for all their efforts and input towards my work over the years and their work towards fostering the field of STS in Finland. I am also grateful to the coordinators of the seminar, Petri Ylikoski, Mika Nieminen and Tuula Teräväinen for all their hard work over the years to make the seminar insightful and stimulating.

During 2003 I also had the opportunity to spend six formative months at the Science and Technology Studies Unit (SATSU) at the University of York. This stay was made possible by a Marie Curie Fellowship grant that I received from the EU. The direction of my work and my interest in biobanking took a decisive turn during my visit and I am indebted to my supervisor Graham Lewis, as well as Andrew Webster and Nik Brown for their support and encouragement during my stay. I have also been deeply touched by the friendships that have emerged out of the Marie Curie Fellowship program since these are friendships which continue to prosper and remain productive to this day.

Having completed the manuscript, I received excellent feed-back from my two external examiners professors Osmo Kivinen and Herbert Gottweis. Their comments and the subsequent discussions which I was able to have with them were crucial in revising my manuscript into the form which it has taken today. I am also grateful to Ilpo Helén and Juha Tuunainen for their careful reading and instructive comments on my manuscript, which helped me to solidify my arguments and discard those elements which were not central to my thesis. I also must give thanks to all those people who were willing to be interviewed over the years. Many of these people have read and commented on my texts and I have been able to return to them time and again for advice. I am especially grateful to Immo Rantala for his comments and professor Lauri Aaltonen and Sini Marttinen for their willingness to let me into the world of hereditary cancer research.

As I mentioned above, the path to complete this work has been long. During this time my family and friends have played an instrumental part in keeping my spirits high and encouraging me along the way. I wish to thank my father, Veikko for his never-ending efforts to train me in the art of forestry and organizing extra-curricular activities in the country side to counter-balance my intellectual work. My sister Seija and brother Juha also deserve a warm thank you for all their support over the years, it has not gone unnoticed. My brother Juha also deserves a great thanks for his excellent work in proofreading the final version of the thesis. I also wish to thank my friends Sami Vallinkoski and Vesa Lempiö and their families for keeping me occupied during my free time. I would especially like to extend a warm thank you to Teea Laitio for her work in designing and executing the layout of this book. Finally, my warmest and most heartfelt gratitude goes out to my wife Kersti Liber, who over the years has endured my uncertainties and vicissitudes in the production process. Her warmth, love and guidance have been a constant source of energy and encouragement in my life and it is to her that I wish to dedicate this book.

Aaro Tupasela
Helsinki, 18 September 2008

1 INTRODUCTION

> "In any research on human beings, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail. The subject should be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal. After ensuring that the subject has understood the information, the physician should then obtain the subject's freely given informed consent, preferably in writing."
> (World Medical Association, 2002: Art. 22)

The foundation of medical research rests on the relationship between the doctor and the research subject. This relationship is a social one, in that it is based on informed consent, privacy and autonomy, where research subjects are made aware of what they are getting involved in and are then able to make an informed decision as to whether or not to participate (Manson and O'Neil, 2007; Lötjönen, 2004). Informed consent is a contract between two actors; the source of the sample and its collector/user. Consent practices are seen to respect the moral authority of the research subject (Hansson, 2005: 415). Donation, gift-giving and altruism (Titmuss, 1970) have been seen as an integral part of this contractual process, which is also seen to constitute an economic exchange (Arrow, 1972).

Within the post-genomic[1] era, however, our understanding of what constitutes

[1] The term post-genomics increasingly includes a broader and broader list of activities. Generally speaking it can be said to refer to activities in which higher biological meaning (eg. what causes certain diseases) and function is gained from sequences of data. Such higher understanding is thought to lead to the development of new diagnostics, treatments and medicines

informed consent, privacy and autonomy is changing in relation to the needs of researchers, but also as a reflection of policy aspirations which emphasize the more efficient use of biobanks, the commercial benefits that may someday come about through their use, as well as the preventive capacity that research brings with it. The politics of knowledge production have, therefore, become a central feature in evaluating and contextualizing individual rights as they relate to consent practices. The management of these resources is no longer limited to the question of how a physical sample is acquired, but has become more a question of how to manage information on the human body and the ways in which this information is made productive in society (Manson and O'Neil, 2007: 23). As a consequence, however, what emerges are diverging interpretations of individual rights over the control of personal information. This divergence can be seen particularly clearly in the management of human tissue samples and the information that can be gained from them.

The research that I present here explores the changing relationship between sources and users of samples in biomedical research by examining the contexts under which human tissue samples and the information that is extracted from them are acquired, circulated and exchanged in Finland. I seek to enquire how individual rights, particularly informed consent, are being configured in relation to the production of scientific knowledge in tissue economies. I am interested in how interpretations of informed consent have become divergent and what elements and processes have contributed to these differences within biomedical research using human tissue sample collections. This inquiry, therefore, seeks to examine how the relationship between the interests and rights of individuals are reconfigured in relation to the interests of science and society. I show that the boundary between interpretations of informed consent, on the one hand, and social and scientific interests, on the other, are being re-drawn and that this process is underscored, in part, by the economic, commercial and preventive potential that research using tissue samples are believed to produce. In this sense the social impact of research is increasingly framed within the context of economic and commercial interests, as opposed to prophylactic, diagnostic and therapeutic procedures alone. This is an important transformation since almost all documents pertaining to medical research emphasize that the interests of science and society shall not prevail over the interests and rights of the research subject (cf. World Medical Association, 2002). Despite this, current discussions surrounding interpretations of informed consent are increasingly contextualized by looking at why the interests of science and society should outweigh the rights of the individual. This represents a shift in the power relationship between the rights of individuals in relation to the interests of science and society.

The collection, use and distribution of human tissue samples, often referred to as

biobanking or tissue banking[2], and which include blood and diagnostic tissue samples, from which DNA and genetic data[3] can be extracted and analyzed, has become a major political preoccupation, not only in national contexts, but also at the transnational level (Gottweis, 1998) in that, increasingly, such sample collections are expected to produce commercial value (Tupasela, 2006c). Sociologically, studies of the biomedical collection and use of human tissue sample collections has developed into its own distinct rubric under both the sociology of science and technology studies (STS) and medical sociology as well[4]. These approaches have provided important extensions to the seminal study of gifts as a central component of exchange (Mauss, 2004), and Marx's materialist analysis of production and capital accumulation (see Sunder Rajan, 2006; Marx, 1977).

The productive and potential capacity of biobanks and genetic data, however, is also the product of the *information* that can be gained from the samples themselves. Therefore, the classical approaches to the analysis of exchange and value production using biobanks have become inadequate and limited. Some commentators have noted that the increased production of information from tissue samples can be characterized as an *informational turn* in the biomedical sciences (Beaulieu, 2004; Thurtle and Mitchell, 2004). Recent work done by Waldby (2002; 2000; see also Waldby and Mitchell, 2006) on the development of *tissue economies* and the forms of *biovalue* that they produce has opened up new perspectives and opportunities in analyzing the supply systems associated with human tissue, its use and the types of value that it produces.

According to Waldby and Mitchell (2006: 31) a tissue economy is a system for maximizing productivity and the creation of biovalue. Tissue economies are systems of circulation which are formed through the acquisition, storage, handling and distribution of tissue samples and the information that can be produced from them. Biovalue denotes the different categorizations of value that can be attached, attributed to and created from tissue samples. These can be abstract values, such as knowledge, health and potential values, which have yet to be realized, and they can also be monetary or financial values that can be created through the sale of therapeutic treatments or medicines for example. Forms of biovalue can also overlap each other.

Recently, however, the maximization of commercial forms of value in biomedical

[2] In this research I use the terms interchangeably depending on how it is used by the informants or documents that are being analyzed. In addition, I use the term biomedical use of tissue collections since in many cases researchers themselves do not see their collections as biobanks or tissue banks, but rather emphasize the scientific practices that are associated with the collections (see also Anderlink and Rothstein, 2001: 411 for a definition of biobanks).

[3] The OECD has defined genetic data as 'all data, of whatever type, concerning the hereditary characteristics of an individual or concerning the pattern of inheritance of such characteristics within a related group of individuals.' (OECD, 2006: 10; see also Austin *et al*., 2003: 37).

[4] Philosophy and ethics have also provided central pillars in this discussion. Here, however, I seek to contextualize such discussions on biobanking within the political and practice-based context instead of getting into the ethical and philosophical discussions surrounding this field (cf. Manson and O'Neil, 2007).

research has become an important component of science and technology policies, as well as corporate strategies globally (Thacker, 2006). Concomitantly, research on the biomedical collection and use of tissue sample collections, has produced an increasing body of literature on the ethical, legal and social implications of such activities (Hansson and Levin, 2003; Knoppers, 2003; Andrews and Nelkin, 2001), as well as discussions on the relationship between the source of samples (patients and donors) and the way the benefits and profits from such collections are used and shared (Simm, 2005). Although this body of research is often centered around particular countries as case studies, such as the Icelandic Health Sector Database (Pálsson and Harđardóttir, 2002) or The Estonian Genome Project (Kattel and Anton, 2004), there is clear evidence that a critical issue in these debates is the relationship between the source of samples and the ways in which they are collected and used (see also OECD, 2006).

The policy discourse surrounding the acquisition, circulation and exchange of these samples and the information that is derived from them is an important element in this analysis in that the policies on biobanking and research practices are interrelated and dependent on one another. Both informed consent and personal privacy are social in their nature in that they entail interactions and mutual agreements between the source of the samples and its collector/users. At the same time they are activities that are legally defined and sanctioned through national and international regulations and statutes. This social element in consent practices also represents power relations between actors and the resources that are being collected and mobilized.

In relation to informed consent and personal privacy, the autonomy of the research subject has always been emphasized in legal documents pertaining to medical research (World Medical Association, 2002). Indeed, autonomy of the individual is considered a cornerstone of western legal philosophy (Rouvroy, 2008). Anderlik and Rothstein (2001: 412) note, for example, that the opt-out structure used in the Icelandic Health Sector Database can be seen as inadequate and cite Greely (2000) in arguing that

> "against the unusual breadth of the information to be gathered, the potential social benefits of the information are entitled to some weight. But the medical benefits are speculative and the commercial benefits would accrue mainly to a private corporation. More importantly, there seems no special reason to believe that informed consent would be unusually difficult or expensive to obtain."

The main concern of the argument is whether the social and commercial interests of science and society are important enough to allow for a re-interpretation of consent practices and thus diminish the autonomy of the research subject in relation to the management of those samples.

Weldon (2004: 161) has suggested, however, that although informed consent is seen as a central feature of medical research practice through which autonomy is exercised, we should start to think about different types of participatory relationships as they relate

to biomedical research using tissue sample collections (see also Manson and O'Neil, 2007; Haimes and Whong-Barr, 2004a). Similarly, Soini (2007) has argued that personal privacy laws extend too far in terms of medical research. Recent literature on informed consent and the biomedical use of tissue collections has, therefore, brought under questions the validity of existing informed consent procedures and set forth suggestions to develop new ways of interpreting informed consent (Manson and O'Neil, 2007; Hansson, 2005; Eriksson and Helgesson, 2005a; Helgesson *et al.*, 2005; Vähäkangas and Länsimies, 2004). More recently it has also been suggested that donors be allowed to give 'broad consent', particularly in large international biobank studies, where the future uses of the samples and related information are still unclear (Hansson *et al.*, 2006). Such studies indicate that what we are witnessing is a re-interpretation of the content and form of informed consent as it relates to biomedical research using tissue sample collections (see also Berg, 2001), but also that there are emerging diverging interpretations of individual rights over the control of personal information.

Policy narratives which emphasize efficiency in the use of tissue collections, as well as finding a balance between individual rights and social and scientific benefits have come to bear upon discussions surrounding the legal and ethical status of samples and information on the body (Eriksson and Helgesson, 2005b) and reflect an increasing tension between the protection of the rights of the individual in relation to social, scientific and economic interests. Although the use of human tissue in biomedical research is not in itself new (Strong, 2000), some (von Versen, 2000: 2) have argued that recent biomedical research practices using tissue sample collections constitute a new object of study within biomedical research. This change in the context of policy, use and application of collections warrants a better analysis of the conditions surrounding such interpretive changes and their consequences.

The context of this research is located in Finnish biomedical research from the early 1990s to the present. This is a period in Finland when biotechnology emerged as a new source of economic expectations (particularly after the ICT boom in Finland), and has been a point of policy emphasis for some Finnish ministries – namely the Ministry of Education and the Ministry of Trade and Industry – and the funding agencies that operate under them since the mid-1980s for long-term funding and development (see Academy of Finland, 2003a; 2003b; 2002; Tekes, 2002a; 2001;)[5].

The period from the 1990s is also important because of the emergence and development of new technologies that are used to analyze sample collections in large quantities, such as bioinformatics, high-throughput micro-array technologies, DNA chips and process automation, as well as the completion of the mapping of the whole human genome

[5] In 2002, for example, out of a budget of 176,4 million euros, a total of 63% (111,7 mil. Euros) were allocated to the natural and medical sciences (Academy of Finland, 2003b: 21). The Academy of Finland is responsible for funding basic research, although more recently there has been increased pressure for it to increase the impact of its funding through commercialization and links with the industrial sector (see Academy of Finland, 2002: 50).

(cf. Rabinow and Dan-Cohen, 2005). Together these technological changes have increased the speed and accuracy with which research can be done and are thus shortening the potential distance between basic research and its application and possible commercialization.

Given the fact that biomedical research using tissue sample collections is strongly based within the public university research system in Finland, the context of scientific knowledge production invariably touches on university and science policies as well. The biomedical use of human tissue collections has important connections with the emergence and analysis of the increased commercialization of academic research (Kankaala *et al.*, 2007; Häyrinen-Alestalo and Peltola, 2006; Häyrinen-Alestalo, 1999; Etzkowitz *et al*., 1998; Etzkowitz and Webster, 1995). Although university-industry interaction is not a new phenomena (see Tuunainen, 2004; Kleinman, 2003; Hietala, 1992), during the past two decades, there has been an intensification of the process of transforming scientific discoveries and knowledge into commercial applications (Webster and Rappert, 2000; Tupasela, 2000a). At the same time, however, ideological dependencies have begun to develop between political expectations and theoretical explanations relating to the role that knowledge plays in economic development (Häyrinen-Alestalo, 2006). The commercialization of discoveries and applications based on tissue sample collections play an increasingly important role in how tissue collections are appropriated and configured in relation to the production of scientific knowledge (Tupasela, 2006a) and invariably relate to the ways in which individual rights, namely consent, privacy and autonomy, are interpreted.

The increase in research policies to bolster the commercial application of academic research has significantly increased the commercial expectations and hopes that are attached to knowledge production in academia. Biomedical research is one such area that has garnered and produced hopes and expectations at the policy level (Academy of Finland, 2002; OECD, 2001). Theoretically, such forward looking expectations have come to be studied under the rubric of sociology of expectations (see Brown and Kraft, 2006). According to Borup *et al*. (2006: 285-286), 'expectations can be seen to be fundamentally 'generative', they guide activities, provide structure and legitimation, attract interest and foster investment. They give definition to roles, clarify duties, offer some shared shape of what to expect and how to prepare for opportunities and risks.'

Within this context, it is important to examine the process by which tissue sample collections have increasingly become a site of political and scientific interest and necessitated a reconsideration of their status both in legal and ethical terms, but also activated predictions and expectations of their potential scientific, health and commercial value. These considerations play an important part in exploring the changing relationship between individual rights and the interests of science and society as they relate to the management of personal samples and information in Finnish biobanks. Although the focus here is on Finland these issues and concerns can be seen to be international in scope since biobanking is an increasingly transnational activity.

2
RESEARCH QUESTIONS

According to the World Health Organization (2003: 8) 'body samples, and information derived from them, represent two of the most intimate aspects of us. Accordingly, we have a very strong claim to control these elements and their uses. Indeed, in ethical terms, that claim is akin to a property right, in that the primary control should always remain with the individuals who can stake a claim to samples or the information generated from them.' Waldby and Mitchell (2006: 33, 59) note that the circulation of tissues in tissue economies constitutes and presupposes social and power relations between actors and that conflicts can arise between different regimes of value. The tensions between individual rights and social and scientific interests is one such area of conflicting perspectives.

Taking this as a starting point, my main interest in this research concerns how different research practices and policies have given rise to diverging interpretations of individual rights, particularly informed consent. In policy documents, scientific literature and medical practice there appear to be diverging interpretations of individual rights and thus the conditions under which tissue samples and the information derived from them are managed legally and ethically are also different. This divergence gives rise to different types of tissue economies which both presuppose and produce different forms of biovalue, as well as power relations between actors and resources. I examine these divergences from three perspectives: conceptual and theoretical, policy and legal perspectives, as well as the practice perspective.

— I begin this examination by looking at the concept of tissue economies theoretically and conceptually in chapter 3. My research question in this chapter addresses how the categorization of tissues according to different conceptions have contributed to diverging notions of individual rights as they pertain to tissue samples and personal information. I begin by linking tissue economies to the production of scientific knowledge or epistemic cultures (Knorr Cetina, 1999) to identify the way in which the

organization of resource relationships plays an important role in the way tissues are acquired and used. I then explore three different types of biovalue (*biovalue as scientific knowledge, biovalue as health and biovalue as commercial value*) which arose from the research material, as well as the scientific literature on the subject. I will then contextualize these three types of biovalue within four conceptions of tissues; *tissue as gifts, property, waste and information*. These conceptions operate as central perspectives in the way tissues are seen to relate to the forms of biovalue that are produced and concomitantly the ways in which rights are interpreted.

— In chapter 4, I examine the notion of personal rights from a policy and legal perspective. I ask how individual rights have come to be understood and framed in relation to the interests of science and society. I play particular attention to the way in which scientific knowledge production has garnered increased political attention, particularly as it relates to the idea of knowledge-based and knowledge-based bioeconomies. This in turn has introduced new social and scientific interests into the ways in which tissue sample collections are mobilized politically and legally. What emerge from these policy discourses are moral imperatives for the broader use of tissue sample collections which appear to contradict the notion of the primacy of the individual as a fundamental western legal doctrine (cf. Rouvroy, 2008). This divergence in the interpretation of individual rights has an important impact on the way in which tissue economies operate.

— Finally, in chapter 5 I examine the operation of tissue economies through three case studies which I relate to the theoretical discussions in chapter 3 and the policy analysis in chapter 4. With the case studies I ask how research practices related to the biomedical use of tissue sample collections contribute to diverging interpretations of individual rights? The three forms of biovalue and four conceptions of tissue play differing roles in the processes and practices that lead to such diverging interpretations and thus different types of tissue economies. The three cases examined in this research – the Tampere Research Tissue Bank, the Genome Information Center and Hereditary Non-polyposis Colorectal Cancer (HNPCC) – are used to clarify the following questions relating to interpretations of consent (respectively):

1. Donation and gift-giving has traditionally been seen as a central feature of tissue acquisition (Titmuss, 1970). How has the collection and use of surgical waste and diagnostic samples become an increasingly important conduit for tissues in Finnish research and how is this reflected in consent practices? The acquisition of surgical waste and diagnostic samples circumvents the need for donation and informed consent which is considered an important cornerstone of medical practice (cf. Manson and O'Neil, 2007). How does this circumvention redefine the limits of personal autonomy and consent in relation to tissue sample

use in biomedical research and what is its role within the political landscape of knowledge production? Why is research using diagnostic samples afforded a different status from research using donated samples and what types of a tissue economy arises from such practices?

2. Collections of large tissue samples, particularly epidemiological sample collections, pose new types of information management challenges, but have also become a site of political interest in the possibility that they provide in the production of new scientific knowledge. How are large tissue sample collections activated and managed nationally and transnationally and how do these practices re-define interpretations of informed consent in relation to existing sample collections? The structural features of such large tissue collections is identified as a practical challenge that is leading to a more liberal interpretation of consent (cf. Aromaa *et al.*, 2002). Expectations of possible future commercial value have also come to play an important role in these arguments.
3. The study of hereditary disease raises many issues relating to interpretations of personal privacy and autonomy (Laurie, 2002). Questions related to prevention are not individual, but relate to relatives and family members as well. Interpretations of consent and privacy in relation to samples and other healthcare records serve to open the possibilities of mapping and preventing disease in whole families. How do privacy, autonomy and the preventive imperative operate within an age when these categories are up-held as fundamental individual rights? The tension between privacy in research and prevention is examined in relation to Hereditary Non-polyposis Colorectal Cancer (HNPCC).

The analysis of tissue economies, biovalue and the different conception of tissue has, therefore, important implications for the way in which the rights of individuals are understood and interpreted in relation to the interests of science and society. The production of scientific knowledge using biobanks has a fundamental bearing on the formation of rights as it relates to informed consent, but also reflects more broadly the changing power relationship between individuals and society. The analysis of tissue economies and biovalue helps to highlight the way in which research practices and policy discourses give rise to new and diverging interpretations of the rights of individuals in relation to the tissue samples that have been removed from them and also helps to identify weaknesses in the traditional assumptions related to donation as serving as the foundation of tissue sample acquisition. Furthermore, the politics of knowledge production have an important bearing on the ways in which rights of individual citizens are interpreted and contextualized within biomedical research legislation. Interpretations of informed consent and how samples and information are used within tissue economies relates directly to the practices of how scientific knowledge is produced within scientific communities or epistemic cultures as Knorr Cetina (1999) refers to them.

Policy discourse and personal interview material serve to highlight how knowledge

production, as a scientific and political ambition, is reflected in the way tissue economies are organized and activated. Emerging configurations with which tissue sample collections are mobilized are increasingly premised on what can be described as a commercial paradigm that is generated through the creation of hope and expectations in science and technology policies, as well as the way in which researchers describe the significance of their work (Tupasela, 2007a; Tupasela, 2006a; Helén, 2004; Brown, 2003).

The case studies, in turn, explore the changing interpretations that are given to informed consent, privacy and autonomy as they relate to tissue sample collections and the scientific knowledge that can be produced from them. Since the focus is on practices in the research field, this necessarily involves questions related to epistemic cultures and how scientific knowledge production is organized in relation to tissue sample collections (Knorr Cetina, 1999). The re-evaluation of the content and form of informed consent reflects, in a fundamental way, the power relationship between the source of tissues and its collector and user since these practices are also legally and ethically regulated.

2.1 DATA AND METHODS

Data

The empirical research material used in this research is based on work done since 2001 on the biomedical collection and use of human tissue sample collections and other population information registers in Finland, including genetic databases. The research has been part of a larger research project entitled *Rights and Responsibilities in Biotechnology* that was funded by the Finnish Funding Agency for Technology and Innovation (Tekes)[6] as part of a research program on advanced technology policy in Finland (ProACT) between 2001–2005. During 2003, I also spent five months working and studying at the Science and Technology Studies Unit (SATSU) at the University of York during which I was able to collect background material on biobanking in the UK. My analysis has looked less at the public side of biotechnology and more at the opinions and discourses of experts in Finland, as well as national and international research policies, particularly in Europe[7].

[6] Tekes is a public research and development funding organization under the Ministry of Trade and Industry. Traditionally it funds applied research that involves partners from both the public and private spheres. The ProACT research program was a large, four-year research program that was a joint venture between Tekes and the Ministry of Trade and Industry and in which the social sciences were also strongly represented.

[7] We are currently undertaking a research project entitled *Re-thinking Public Participation in Biomedical Research* in which we are studying the attitudes of Finns towards the biomedical use of tissue sample collections, as well as the conditions under which they would like to donate and have tissue samples used by the medical community (see Sihvo *et al.*, 2007; Tupasela *et al.*, 2007)

The decision to focus and draw my cases from Finland, as well as support and compare this material with European policies was based on a number of reasons:

First, although Finland is relatively small, it has large collections of tissue samples and health register data. Indeed, more samples have been used to date in Finland than have been collected and used in both Iceland and the UK Biobank projects put together (see chapter 5). Tissue samples have been collected both for research projects, as well as diagnostic samples. Increasingly, however, the distinction between research and diagnostic samples is being blurred since diagnostic samples are collected specifically for research purposes as well. The large number of registers is based on a tradition of collecting population data which in some cases, such as the cancer registry, is also legally mandated. Population data and tissue collections form an important research axis within the biomedical research community.

Second, Finland, as a Nordic country, has a comparatively (cf. USA and the UK) liberal policy on the use of personal data (data that is based on social security numbers and can be linked to individuals and their healthcare records) in scientific research. Scientific research has been afforded a special status within personal data laws that allows for this. The Nordic countries also form an important test bed for population studies in molecular genetics. In addition, Finnish collections are argued (by Finns) to be of high quality, not only in terms of the lifestyle information that they have collected, but also in terms of the follow-up studies that have been done as well. Many also argue that the homogeneity of the population and its various population isolates is an important factor in making Finnish collections special (Palotie and Peltonen-Palotie, 2004).

Finally, despite its relatively small size, Finnish researchers maintain numerous international contacts and actively participate in international research projects, particularly in Europe, due to funding structures which support such networking. This has also been true in the biomedical use of tissue sample collections and has made the use of Finnish collections in European research quite common. Finland is also relevant at the European level, since it is a signatory to many European directives which regulate medical research.

The research presented here focuses on the non-therapeutic use of tissue sample collections, as opposed to *in vitro* and therapeutic use of tissues (such as stem cell research and tissue engineering[8]), which forms its own rubric, both legally, and in terms of scientific practices themselves. Most commonly, scientific disciplines associated with the non-therapeutic use of tissue sample collections include epidemiology, as well as pathology, but also include molecular genetics and increasingly bioinformatics and statistics (Fujimura and Fortun, 1996). Although connections do exist between therapeutic research and non-therapeutic, such as with stem cell research and therapies, it is nonetheless important to

[8] This distinction is by no means a clear cut one since many tissues that are used for therapeutics are used only within the non-therapeutic research context as well. There are, however, several disciplinary distinctions that demarcate differences between these sets of activities.

maintain this distinction, since the practices are in many instances governed by different sets of legal regulations, both at the national and international levels (cf. Norden, 2006).

The research material on biomedical research policies and legislation, as well as the three cases, can be categorized in the following general groups: 1) personal interviews, 2) official written policy and legal documents (both national and international), 3) unofficial documents (un-published), 4) personal communications, 5) publications, 6) public lectures and presentations, 7) site visits, as well as 8) material available on the internet.

The cases that were chosen came about through a general study of biobanking in Finland. The Tampere Research Tissue Bank was the first case I looked at when I came upon it in 2002 through a newspaper article. The researchers involved in it were interested in developing a structured system through which surgical waste would be collected and made available to research. The HNPCC case was chosen after I had had a discussion with a colleague who worked in the research group. She was able to provide me with a detailed description of how the research group collected different sources of information and tissue and how they were used. She also helped me get in touch with the research group leader. Both people read and commented on my later work. In addition, the research administrator at the Tampere Research Tissue Bank read and commented on my thesis chapter on the tissue bank, providing valuable feedback and validation of my work. The case of the Finnish Genome Information Center became of interest to me through interviews with administrators and researchers who were involved with the project. Although it has only recently begun its operations, the run-up to its founding has provided a good example of the way in which tissue economies are expanding and the rhetorical strategies that are employed to legitimate its funding. Although all cases represent different institutional settings, research goals and methods, they provide a good scope of the variance of the ways in which tissue economies operate and the problems they raise in terms of privacy, autonomy and informed consent. I will discuss the cases in some more detail shortly below.

Interviews

The most important source of information has come from personal interviews. Early on in the research, interviews emerged as the main source of information. Many of my contacts were gained through previous interviewees who made useful suggestions in terms of the people who I should seek out and interview as well. This supplemented my original list of people who I had identified early on in my searches as playing important roles in government policy or conducting important research in biomedicine.

Given that the field of biomedical research is quite broad (including the bioinformatics and policy aspects), yet at the same time quite small in Finland, personal interviews proved very informative and useful. Interviews using a thematic, open-ended question structure provided the best source of up-to-date information on the events that were taking place in a given research field, as well as the opinions of the people who were active in it. In addition, the choice to interview researchers and administrators also helped to

triangulate many issues, such as interpretations of informed consent from different perspectives and levels.

A total of 42 personal interviews were conducted in which the discussions were taped and transcribed. Interview excerpts that are used here are printed in italics to distinguish them from longer quotations from published material. The make-up of the interviews can be categorized in the following general groups:

- Researcher scientists in Finland and the UK (9),
- Research administrators (7),
- Clinical doctors (4),
- Officials in the EU (2),
- Data protection ombudsmen (1),
- Officials from the Ministry of Social Affairs and Health, the Ministry of Trade and Industry and the Ministry of Education (8),
- Members from the National Advisory Board on Healthcare Ethics, the Sub-Committee on Medical Research Ethics (TUKIJA) and the National Advisory Board on Research Ethics (TENK) (3),
- University technology licensing officials (3),
- The patients union (2),
- Other experts involved in various aspects of the use of human tissue and the 'products' developed from them, including a representative of the Medical Research Council (MRC) in the UK (3).

Some of the categories overlap and many of those interviewed held several positions which would place them in two or even three categories. I have, however, simplified their roles for the sake of clarity and defined them according to their main tasks.

Policy Documents

Interview material was supplemented with official government documents and policies – national and international – from the EU, the Organisation for Economic Co-operation and Development (OECD), the World Health Organization (WHO) and the World Medical Association (WMA) for example. Both EU and OECD policies are reflected in Finnish science and technology policies. Finland has also been active in promoting policies developed by the OECD. The use of the national innovation system concept, for example, reflects such up-take of international policy discourses in Finnish policy (cf. Hallituksen Esitys, 2008). The policy documents and other statistical data that have been used are listed separately at the end after the references. The policy documents can be categorized into two general groupings: general policy documents on biotechnology and its future (see for example OECD, 1999; Opetusministeriö, 2005b) and policy documents that deal more specifically with biobanks or tissue collections (see for example OECD, 2001; Opetusministeriö, 2005a). Policy

documents on biobanking were searched for on the databases of various organizations such as the OECD, Council of Europe, the EU, national ministries, as well as with a general internet search.

Legal Documents

Legal documents[9] and guidelines pertaining to biobanking were collected and analyzed both nationally and internationally, such as the Act on the Use of Human Organs and Tissues for Medical Purposes (2001/101), the Act on Personal Data (523/1999) and the Act on Medical Research (986/1999). Legal documents are integral to the development of tissue economies because they represent a codification of accepted and sanctioned social activity. They are also the frameworks in which actors operate. National legal documents refer increasingly to international agreements and laws to which Finland is a signatory, which helped to identify the relevant international documents (cf. Council of Europe, 1997). Legal documents and their explanatory texts (see HE 93/2000; Hallituksen Esitys, 2008), were analyzed with reference to the issues and themes that were raised in interviews, and the policy documents, such as informed consent. Interviews of government officials who had prepared various laws were also used to highlight and clarify issues in those documents. Statistics and technical documents (see for example Eurobarometer, 2002) on public attitudes and tissue collections and their biomedical applications were also collected and used as supporting material in the research.

Scientific and Review Articles

In addition to the interviews, review articles and popularizing articles published by researchers (see Palotie and Peltonen-Palotie, 2004) and administrators were also collected and analyzed. These documents provided good material for the textual analysis which was complemented by the interview and policy material. The articles, some short commentaries (Portin, 2005), while others longer articles (Käpyaho *et al.*, 2004), provide a good picture of the sometimes opposite opinions in this research area, as well as textual material on the arguments that are set forth by the actors. These arguments often complemented those given in interviews and thus served as a good way of validating interview material.

Other Material

Material has also been collected and analysed from the Finnish National Authority for Medicolegal Affairs on permits from research groups on the use of diagnostic samples for research purposes. This material is presented in Section 5 where I discuss the ways in which tissue samples are used in Finland at a general level and reflect on the way in

[9] For an overview of biotechnology legislation in Finland and the Nordic countries, see Norden (2006).

which diagnostic samples are an important source of non-donated tissue samples in Finland. Data was collected on computing in biomedical research, namely from statistics in the annual reports of the Finnish Center for Scientific Computing (CSC), which is a national computing centre maintained by the Ministry of Education and major Finnish universities. This material has provided supporting data on the informational turn in genome research using tissue sample collections and indicates a trend in the increase and intensity of research activities.

In order to explore the ways in which consent and privacy are interpreted in concrete settings, three case studies are presented in detail to provide insight into the variability of tissue economies and the ways in which this bears upon the management of those tissues. The three cases are the *Tampere Research Tissue Bank, the Finnish Genome Information Center* and *Hereditary Non-polyposis Colorectal Cancer* (HNPCC).

— The Tampere Research Tissue Bank is part of the Pirkanmaa hospital district in central Finland and operates in conjunction with the University Hospital of Tampere, which offers medical expertise in 34 different medical disciplines. The roots of the tissue bank go back to the early 1990s, when various researchers began to collect diagnostic samples for their own research. Since then, however, these activities have been taken over by the hospital administration to try and consolidate all the activities under one operation. The Pirkanmaa hospital district, to which the university hospital belongs to, covers a population of approximately 460 000 people. The idea behind the research tissue bank is to collect samples of both diseased and healthy tissue in conjunction with surgical procedures in which tumors or other tissue is removed. The case is analyzed because it identifies an important source for the acquisition of tissues which falls outside of the informed consent framework and draws our attention to the way surgical waste can have value.
— The official development of the Finnish Genome Information Center emerged from a commissioned study by the Finnish National Technology Agency (Technomedicum, 2003) on the possibility to utilize the extensive sample collections, as well as other population data already collected and available in a number of databases. The goal of the center is to act as a hub for other databases through which existing sample collections and other public healthcare registers can be connected to each other. The Genome Information Center has helped to identify new ways of organizing tissue economies and the arguments used to support these activities, as well as the consequences this has for interpreting informed consent.
— Research on Hereditary Non-polyposis Colorectal Cancer (HNPCC) began in the early 1980s. Institutionally, the clinical work on HNPCC involves two hospitals, one in Helsinki and the other in Jyväskylä (central Finland). The genetic research, however, has taken place in Helsinki, particularly in the research group of professor Lauri Aaltonen. The HNPCC case is useful in understanding how the problematic nature of personal genetic information has important consequences for family members and

relatives. The mapping of hereditary disease in families confronts physicians with the prospect of re-interpreting the significance of informed consent and privacy in relation to the duty to warn family members of a life-threatening condition within the context of prevention.

In Table 1 I summarize the research problems, data and main concepts that are associated with the policy analysis and each case.

Table 1. RESEARCH PROBLEMS, DATA SETS AND CONCEPTS ASSOCIATED WITH THE EMPIRICAL MATERIAL

Empirical material	Research problem	Data	Main concepts
Policy and legislation	How are the rights of individuals perceived in relation to interests of science and society. What role does knowledge production play in this process?	Both national and international policy and legal documents. Personal interviews with administrators and government officials.	Politics of knowledge production. Individual rights vs interests of science and society. Moral imperatives.
Tampere Research Tissue Bank	How is informed consent interpreted in relation to surgical waste? What elements and processes make up tissue economies? How are tissues activated?	Personal interviews with researchers, administrators and government officials. Scientific articles. Unpublished documents and presentations Laws, statutes and regulations. Personal communication	Tissues as waste vs gifts. Informed consent. Epistemic cultures.
Genome Information Center	How is informed consent interpreted in relation to old sample collections? What elements and processes make up tissue economies? How are tissues activated?	Personal interviews with researchers and clinicians, administrators, data protection ombudsmen, legislators and government officials. Scientific and popular articles. Laws, statutes and regulations. Unpublished documents and presentations. Personal communication.	Tissues as information. Personal privacy. Epistemic cultures. Sociology of expectations.
HNPCC	How is informed consent interpreted in relation to prevention in hereditary disease? What elements and processes make up tissue economies? How are tissues activated? What type of biovalue is produced?	Personal interviews with researchers and clinicians, administrators, data protection ombudsmen, legislators and government officials. Scientific articles. Laws, statutes and regulations. Personal communication.	Tissues as information. Personal privacy. Epistemic cultures.

In light of my choice of cases to approach this subject it is necessary to say a few words on the limitations of my work. The biomedical use of human tissue samples is by no means a homogenous activity within the medical research community. The vast array of uses and processes by which samples are acquired, stored and utilized reflects the myriad of scientific disciplines and sub-disciplines which exist, ranging from organ transplants (see Huhtamies and Relander, 1997), anatomy (see Niemi, 1990), pathology to molecular genetics. This also places limitations on generalizations of the results from a study of the biomedical use of non-therapeutic tissue samples to other areas of use, which include therapeutic applications and quality control, for example. The cases, however, represent different aspects of banking in Finland and also have relevance internationally by raising important issues relating to the interpretation of consent practices associated with the use and re-use of sample collections.

In addition, each country has, to one degree or another, varying legal frameworks which govern the conduct of their research community in relation to the collection, storage and use of tissue samples. Tissue economies are, however, transnational in character and therefore many of the issues, such as legal consideration, are echoed throughout legal texts in the Western world. In this sense, Finland represents a particular legal and social policy perspective that differs from other countries, such as the UK and the USA. By focusing on only one country, one loses sight of the transnational character of scientific research and tissue economies. Such a research project was, however, outside the scope of my resources.

By conducting interviews with a range of actors, I have been able to improve the validity and reliability of my research results by confirming specific points in other interviews, as well as matching them to policy issues that have been identified in documents. In addition, I have also returned to many of those who I interviewed to consult on texts that I had written, and also conducted more than one interview in some cases to clarify issues. This process has allowed for a type of triangulation of issues (Kvale, 1996: 229) through the use of different methods and empirical material.

Research Process

The research material that has been collected and presented here has focused on the perceptions and opinions of the users of tissue sample collections (i.e. researchers) and the government officials who develop policies, as opposed to the way research participants, patients or the public view these practices in Finland[10]. The rationale behind this decision stems from the fact that in Finland the process of organizing the production of scientific knowledge and the infrastructure needed for it is essentially guided by the interests of researchers and policy-makers (Tupasela, 2007a), who also have to take into consideration

[10] Studies of public opinion are currently under way, but are outside the scope of this study (see Sihvo *et al.*, 2007; Tupasela *et al.*, 2007; Tupasela and Snell, 2006).

international agreements and ethical guidelines which Finland has signed. In addition, the discussions that have surrounded the biomedical use of human tissue sample collections have not included the public to the extent that it has in countries, such as Iceland (namely through media coverage and public debate) and the UK. The public is also seen to have a different role in comparisons between EU and Finnish science and technology policies (Snell, 2002). Although there have been a number of seminars and workshops relating to issues of informed consent, biobanking and the re-use of sample collections, these events have for the most part been attended by experts and not the public (see Järvi, 2006), although the reasons for this are difficult to gauge.

The interview themes remained quite general at the beginning of the research project, relating to the development of the biomedical research sector and the challenges that it faced both commercially, as well as from a legal perspective. This period served as an orientation period into the field, during which site visits were also conducted. As my research focus became more specific relating more to biobanks, I was able to narrow my questions and interview themes to more specific points. Some of these included the role of informed consent and research, the way researchers saw the value of their work, major challenges faced in the management of biobanks, as well as their future. In the case of people who were involved with one of the three case studies that I looked at, I was able to go even further to ask how their research was organized, how was their scientific knowledge was produced and how they managed the information that they used?

What became evident in the interviews, however, was a general concern and interest in the translation of scientific knowledge into health and commercial forms of value. Indeed, most of the legal documents in Finland relating to biobanking explicitly mention the Finnish research infrastructure as playing a central role in the production of innovations and wealth (Hallituksen Esitys, 2008).

The interviews and the questions that were asked were chosen based on a number of different criteria, such as whether they were a knowledge producer (research scientist or clinician), an administrator or a government official or an expert in a related field. Government officials and administrators were interviewed earlier on in the research when the research questions were still quite general, relating to changes in the regulation of biomedical research. Later on in the specific cases, and when my research interests had become more focused, questions also became more specific. Experts on computing, for example, were asked about the role of processing, databases and data mining in biomedical sciences, whereas technology transfer experts were asked questions relating to intellectual property rights, university technology licensing and the role of universities in knowledge production.

In some instances, when the person had several roles, they were asked to comment on a broader range of topics and the relationship of one area to another. Some people had had long careers as research scientists or clinicians, but had become more involved in administrative tasks. They were, therefore, asked, not only about their research, but also to reflect on research in general from an administrative perspective. Researchers were

asked questions related to the ways in which research practices had changed in relation to tissue sample collections, the way in which they viewed commercialization, as well as whether they considered the current legal framework as adequate to govern the biomedical use of tissue sample collections. In contrast, government officials were asked to reflect on the way science, technology and innovation policy played a role in the organization of research activities and funding in relation to tissue sample collections.

The interviews remained quite open and flexible to allow for the interviewee to take the discussion in the direction that they wanted it to go in, after which I would return to the themes that had been outlined. The outlined themes had been selected from official policy documents and publications by researchers where important issues had been raised, such as the commercial applications of genome research and its requirements on the research system in general. Some of the interviewees were identified based on their position in government administration or the research group (group leaders), others were chosen through recommendations by those who had been interviewed. Research scientists were chosen on the basis of whether they used tissue sample collections and other health registers in their work. Some researchers, such as with the Tampere Research Tissue Bank case, were directly involved in the setting up of a bank.

In other cases, such as the Hereditary Non-polyposis Colorectal Cancer case, the researchers were involved in using a multitude of different types of tissue and register resources, as well as the clinical aspects of the work. Government officials were chosen based on their role in decision making and their expertise in fields that related to the collection and use of tissue sample collections. Many had been involved in committees that had prepared various legislations pertaining to biomedical research or were aware in some way of the international legal framework. In some cases, people held several posts as both researchers and experts in a particular committee, such double roles were important, since the people could provide perspectives from both an administrative, as well as a scientific perspective. Material from university licensing officials was collected to supplement existing material that had been collected for an earlier research project on the commercialization of university research (see Tupasela, 2000a; 2000b; Häyrinen-Alestalo and Peltola, 2006).

Analytical Approach

In my analysis I have sought to identify the policy discourses, themes and the content of texts which have been employed by various actors in their everyday dealings with different aspects of biobanking. I seek to draw connections between policies, statements and legal documents on the one hand, and interview material on the other. Despite being different types of texts in terms of analysis, they nonetheless draw upon one another repeatedly. Policy documents and legislation are constantly referred to by those who were interviewed, whereas, the needs and material conditions (computers, software, samples) available and used by researchers are constantly referred to in policy documents. The issues raised by

actors and the way they choose to frame, sometimes contentious, subjects, such as how to interpret informed consent from a legal and practical standpoint, provide a frame of reference within which the development of tissue economies and the production of biovalue can be placed.

Several discourses and themes became apparent in the readings of the policy and interview material: one such narrative relates to the relationship between genome research and economic development in Finland, a narrative that is not new in itself (cf. Gottweis, 1998: 34), but relates directly to the ways in which tissue economies are being organized and the types of biovalue that they are hoped to produce. What struck me as novel within this narrative, however, was how the role of research subjects was being de-emphasized from a legal standpoint and the way in which the benefits gained from commercialization and privatization could be seen as a form of reciprocity. Yet at the same time, the case studies indicated how difficult it was to translate the knowledge and health value gained from research into commercial forms of value.

The research material has, therefore, been analyzed in light of increasing commercial expectations associated with value and their relation to the contexts in which new biomedical knowledge is being produced (Brown, 2003; Brown and Michael, 2003; Väliverronen, 2007; 2004). Another important narrative which emerged related to the preventive capacity that research was seen to have.

It is here that Waldby's (2002) idea of biovalue is useful for my analysis. Increasingly, the expectations associated with the development of molecular genetics play an important role in the way discussions and arguments are framed in what has been called an economy of hope[11] (Novas, 2007; Helén, 2004: 16; Franklin, 2003). An economy of hope refers to the hopes and expectations which are built through the narratives of new technologies which purport to produce new innovations and cures for diseases and ailments, for example. This economy is based on belief and expectations as opposed to fact or something that already exists. In this sense, hope and expectations serve a performative task of mobilizing support and resources. The notion of an economy of hope moves the attention of analysis beyond epistemic questions (i.e. how is scientific knowledge produced) within the sociology of scientific knowledge, and extends the analytic framework of studies of expertise and experience (SEE) (Collins and Evans, 2002) to what I have called studies of expectations and visions (SEV) (see Tupasela, 2007a). What differentiates SEV from SEE is the extension of expertise to the creation of visions of hope and a culture of expectations.

As Helén (2004: 16) notes 'the objects of profit seeking, are not primarily certain drugs or medical devices, but prospects of hope. The production, exchange and, to some extent, also consumption is entirely oriented toward the future. Therefore, this economy is virtual and, in fact imaginative, based essentially on expectations.' Although hope and expectations can be said to be virtual they also have concrete manifestations in the policies and actions which are employed in the present. Expectations play an important role in defining

[11] Also referred to as the sociology of expectations.

value because they help to structure and create markets and possibilities that do not yet exist. In relation to this temporal flexibility, my analysis has played close attention to how personal interviews and policy documents reflect the hopes and expectations that are often associated with biomedical research and highlights the strategies used to shape and order the information that is deemed important by experts (see Myers, 1991; Douglas, 2005).

Structure of Thesis

The rest of this thesis can be divided into four main sections. In *Tissue Economies and Epistemic Cultures* I will first look at tissue economies and biovalue in more detail. I will discuss three types of biovalue which I identified in the research material. These concepts will then be connected to the production of scientific knowledge using the concept of epistemic cultures (Knorr Cetina, 1999). I will then locate the collections of tissue samples within four different perspectives: *tissues as gifts*, *property*, *waste* and *information*. These concepts have emerged as central analytical perspectives in my research, as well as within recent studies on the biomedical use of tissue sample collections (cf. Waldby and Mitchell, 2006; Mitchell and Thurtle, 2004). Given the significance that tissues have gained in biomedical research and policy discourse, these concepts are important in understanding the ways in which tissues are being activated, as well as the way in which they can be translated from one category to the other. They are also foundational in relation to the way in which consent practices are understood in relation to the samples and the information that can be derived from them. The concepts also relate to the theoretical discussions on the character of tissue economies in that the processes associated with the collections and use of tissues rely on such differences to draw distinctions on the nature of the tissue sample that is at hand.

In *Policy, Laws and Tissue Collections* I will present a major axis of discussion on the scope of informed consent and the use and collection of tissue samples. This discussion is set amidst policy discourse on the knowledge-based economy and knowledge-based bio-economy. From a policy perspective the role of scientific knowledge gained from human tissues is seen to play an important role in maintaining and building social solidarity and cohesion, because the research and knowledge that it produces is seen to legitimate public expenditure into scientific research and build trust between science and the public. The role of scientific knowledge in policies is characterized as an important component of economic development. In this sense, it is important to examine the relationship between biomedical research policy and economic development in that it helps to identify the interdependence of the two areas and its relation to interpretations of informed consent. It is also an important source of analytical material for the way expectations are written into policy documents and the interplay these expectations have with the way resource relations are conceptualized. I will examine the ways in which policies, legal texts, researchers, administrators and government officials alike seek to legitimate their activities using various arguments and rhetorical strategies. Many of these arguments

rely on notions of reciprocity and social solidarity.

In *Building Tissue Economies*, I will first present the Finnish tissue collection context in more detail paying particular attention to the ways in which diagnostic tissue sample collections have been collected and used recently. I then go on to examine the way in which the production of scientific knowledge using tissue sample collections and other research registers is increasingly being organized using input/output models drawn from industry. Subsequently, I will look at the three case studies to provide concrete examples of the ways in which tissues are acquired, stored and utilized and the ways in which informed consent, privacy and autonomy operate in everyday research practices. The case studies are important in understanding the different ways in which tissue economies are formed and operate, as well as the ways in which scientific knowledge production is related to the production of biovalue.

In *Dissecting Tissue Economies*, I start by analyzing the relationship between the three types of biovalue in relation to the four conceptions of tissue and the way this is reflected in diverging conceptions of consent. I then look at the increasingly transnational character of tissue economies followed by a discussion of the way trust and moral imperatives play an important role in the operation of tissue economies. I conclude by looking at the ways in which actors who utilize tissue sample collections reflect on their activities in relation to notions of hope and expectation, and the way this forms an important factor in the development of the social significance of tissue collections. It is argued that despite increased pressure to commercialize research results, many actors reflect on their activities in a way that emphasizes social significance and responsibility, as opposed to individual interests, while at the same time noting many of the possibilities that their research will open up in the future. This is seen as a way of developing trust between actors, but it also creates moral imperatives in the collection and use of tissue sample collections.

3
TISSUE ECONOMIES AND EPISTEMIC CULTURES

The use of large human tissue sample collections has become an important tool in biomedical research because of the versatility in providing new information about, not only the human body and disease, but also populations (Collins *et al.*, 2003). Given the significance that commercialization has been given in relation to the production of scientific knowledge (Jacob, 2003) and its perceived role in economic development, it is important to recognize the connection between tissue economies and the scientific production of knowledge, since politically, scientific knowledge production is seen as the basis for economic development (cf. European Commission, 2007b). In this section I begin by drawing a connection between *tissue economies* and *biovalue* (Waldby, 2002) and Knorr Cetina's (1999) notion of *epistemic cultures*. According to Knorr Cetina (1999: 1), epistemic cultures are scientific cultures which 'create and warrant knowledge'. Tissue sample collections play an important role in this knowledge production process in biomedical research. I then identify three types of biovalue which are associated with the production of scientific knowledge since these typologies have emerged as important outputs of epistemic cultures. It is, therefore, necessary to examine the theoretical relationship between tissue samples and knowledge production in more detail since they also have a bearing on the way the rights of the individual come to be interpreted.

I then continue by examining four different conceptions of tissue: *tissues as gifts, property, waste* and *information*. These conceptions are continuously attached to tissue sample collections in varying configurations and relate directly to the ways in which tissue resources are acquired and organized. Given that the information gained from tissue samples is playing an increasingly important role in scientific knowledge production, it is important to understand how different conceptions of tissues are used and deployed, because these concepts have a bearing on the ways in which informed consent is being

interpreted in biomedical research. The traditional gift paradigm as suggested by Titmuss (1970) is only one framework in which tissues are acquired.

Tissue Economies, Biovalue and Scientific Knowledge Production

The donation, acquisition and use of tissue samples can be characterised as a tissue economy, where human tissue and health information acts as a type of object that is not just circulated and exchanged, but transformed as well. In trying to characterise the emergent biomedical use of human tissue in its different forms and contexts, Waldby (2002; 2000) has developed the term tissue economies to help explain different ways in which human tissues are collected, organized, the way they come to have value and the way they can be used to generate new value. According to Waldby and Mitchell (2006), tissue economies represent:

> "a system for the maximization of [...] productivity, through strategies of circulation, leverage, diversification and recuperation. An economy is also a system for the adjudication of value; hence, a tissue economy involves the hierarchization of the values associated with tissue productivity." (Waldby and Mitchell, 2006: 23)

Tissue economies are systems where 'the exchange of biological substance is simultaneously a technical/material and social act' (Waldby, 2002: 309). Following Marx, Waldby and Mitchell (2006: 33) note that economies are always forms of social relationship and the 'different forms of economic exchange constitute the social fabric in different ways.' Tissue economies, therefore, also touch upon the relationship between individuals and collectives, in that individuals serve as the sources of samples and collectives (science and society) use and benefit from these samples in different ways. Tissue economies also represent, therefore, power relations between actors and the resources that are acquired, exchanged and used.

In addition to the policy analysis, the three cases presented in this research are examples of acquisition, exchange and circulation and are therefore examples of tissue economies. The policy analysis, in turn, examines the discourses and context within which these economies operate. The use of human tissue samples can, however, also take place without the social act of donation or gift-giving, such as with pathology samples taken from patients during the course of surgery or diagnosis and the re-use of existing sample collections. This practice, in my opinion, adds yet another dimension to the ways in which tissue economies can develop and illustrates changing relationships between the sources of the samples and their users. Tissue economies also give rise to a further dimension in terms of circulation that relates to health and lifestyle information, which are non-physical entities. Interviewed researchers noted that a sample without accompanying

health and lifestyle data on whom it is from is essentially worthless. Health and lifestyle data forms an important information component that can be linked to genetic data. The health information is as important an asset as the samples themselves and forms a central element in tissue economies alongside the samples and the information that is gained from the samples. Many of the tensions surrounding already collected sample collections centre on the extent to which they can be used for different purposes than what they were originally collected for. These discussions are based on developing and devising new ways of maximizing the productive capacity of these collections in terms of use and, therefore, refer to issues of efficiency in the circulation of materials and information.

The collection of tissues and their associated medical and lifestyle information, such as healthcare records, forms the basis for the production of biovalue. Biovalue refers to the different forms of value that can be created from tissue samples themselves. Most commonly, biovalue can be understood and measured in commercial terms, as profits gained from the production and sale of various products and services derived from tissue sample collections. These include diagnostic tests, new medications or therapeutic treatments, for example. The production of scientific knowledge from tissue economies is in this sense a transformative process where value is created from raw materials (tissue samples and information) and deployed in a multitude of ways which include scientific publications, tacit knowledge, as well new treatments, medicines and commercial products.

The systems of exchange surrounding human tissue economies are, however, somewhat different from traditional economies in that 'the human body and its parts shall not, as such, give rise to financial gain' (Council of Europe, 1997: Art.21). Despite such guidelines, human tissues are central to the production of wealth. Several authors and organizations have developed and used terms, such as technocapitalism (Suarez-Villa, 2001), bio-economy (OECD, 2005), biocapital (Sunder Rajan, 2006) and bio-wealth to describe the forms of value that biotechnological processes produce (see also Rose, 2001; Franklin, 2006). The emphasis on the commercial forms of value production has been perhaps a more recent phenomenon, replacing more traditional forms of indicators for value, such as scientific and the health value that tissue collections are also instrumental in giving rise to.

My choice to use the notion of tissue economies and biovalue, as opposed to other concepts listed above, in my research derives from its focus on the interaction and exchange aspects of tissue acquisition, as well as the forms of circulation that become possible through the maintenance of tissue collections. Many of the other notions listed above focus too heavily on only the commercial aspects related to biomedical research and less on other forms of value that are also simultaneously created. Although the tissue economies concept places too much emphasis on the social and interactive aspect associated with donation, it nonetheless provides the most comprehensive and flexible approach which is available to study the biomedical use of tissue sample collections.

The collection and storage of human tissue sample collections themselves also represents the production of a type of biovalue in that the collection itself is a valuable resource that can be used and distributed (although it is not to give rise to financial

gain in itself). The collection itself, therefore, comes to have exchange value and gains productive potential. Defining the scope of biovalue is, however, difficult in relation to biobanks in that biobanks, once created, become the sites of not just existing value, but also potential value (see Novas, 2007; Sunder Rajan, 2006) in that they can be used for currently unknown purposes. Theoretically and practically, this poses a problem in terms of trying to determine what types of biovalue can be attached to and created from bodily fragments, as well as defining for research participants the future uses of their samples. This characteristic has also been a challenge for regulators in trying to determine the legal status of sample collections and their related information (see Lehtonen, 2006: 131).

Much of western medical practice in relation to informed consent has been based on the supposition that informing the donor is based on the ability to describe the use and significance of those samples. Donation of samples has also assumed a certain amount of knowledge on the part of the donor, as to what the donation will be used for, such as with blood or organ donation. Yet as literature on biobanking, particularly large epidemiological studies, has indicated, the consent procedure itself has become contentious as the definition and function of informed consent has come under question (Helgesson *et al.*, 2007; Godard *et al.*, 2002; Berg, 2001; Deschênes *et al.*, 2001). I raise the issue of informed consent in conjunction with the discussion of biovalue, because it specifically addresses the issue of the prospects, hopes and expectations that are attached to tissue sample collections, as well as the uncertainty of their value in future use (see Tupasela, 2007a).

Although the possible list of forms of biovalue is essentially limitless, the interviews and literature on the biomedical use of tissue sample collections in biomedicine generally refer to one of three general dimensions of biovalue: *biovalue as scientific knowledge*, *biovalue as health* and *biovalue as commercial value*[12].

The three categorizations of value presented themselves time and again in interviews, as well as policy documents (scientific knowledge, health value and commercial value). There are no clear boundaries between these categories in that knowledge value can also have considerable commercial value, such as with the case of patents, and health value can also have considerable commercial benefits in terms of improved health of a population. These categories are important, however, in that arguments for the collection, use and re-use of tissue sample collections are increasingly premised on the potential biovalue that they might produce.

Biovalue as scientific knowledge refers to the value that is created through discovering and understanding biological processes in more detail, as well as in a broader systemic context. This perspective is best characterized through the traditional conception of basic science as providing the basis for our understanding, but also for new applications. The category can therefore include publications, tacit knowledge, as well as proprietary objects of knowledge such as patents, which are in effect public. Biovalue as scientific

[12] It should be noted here that I am aggregating numerous activities under the term commercial, including venture capital investment, valuation and returns, as well as marketing, distribution and sale of goods.

knowledge refers, therefore, to the general epistemic goal of knowledge production and the value that it has in itself.

Biovalue as health refers to the application of scientific knowledge to promote health. Health promotion can take place through a multitude of avenues, such as the promotion of individual health (e.g. individual choices), the promotion of the health of the population (e.g. through national or regional health programs), as well as preventive strategies and programs, which include vaccinations, screenings, as well as regular health checkups. Biovalue as health has important connections to biovalue as commercial value in that health promotion in the population also has considerable impact on costs of healthcare in general.

The third form of biovalue which I reflect upon in this research is *commercial biovalue*. Commercial value has become a major driver of biomedical research during the past two decades. Several reasons can be seen as drivers of this trend, namely increased private investment into biomedical research, public expenditure into research and training programs in higher education, the willingness of universities to participate in public-private partnerships (Tupasela, 2000b; Grit, 1997: 4) and the development of a favourable regulatory environment that promotes the commercialization of biomedical inventions (see Sunder Rajan, 2006: 6; Owen-Smith and Powell, 2002). In addition, besides biovalue as health, biovalue as commercial value encapsulates perhaps the greatest degree of hope and expectations as to the promissory value of biomedical research (see Helén, 2004).

One shortcoming of the notion of biovalue is that it draws heavily on the biomedical use and development of therapeutic tissues, especially stem cells. This results in the creation of a special category 'bio' which is added to the term value. Biomedical and medical research, however, has been producing forms of value for centuries, and one must ask whether the addition of the term 'bio' to value is also a reflection of the popularity of biomedicine both scientifically and politically. This is not to say that stem cell research does not offer novel possibilities in terms of treatment, but the same can be said for vaccines and antibiotics when they were developed.

In evaluating claims related to commercial value production, Waldby argues that one needs to examine the situatedness of tissues in new biomedical systems utilising new technologies. Such an examination would require 'a reconsideration of the kind of social and corporal economy the new technology might imply, and what kinds of economies it might be situated in' (Waldby, 2002: 309). In terms of Finland, it is important to note that research takes place, for the most part, in public universities and university hospitals. Although private healthcare is available, and its share is growing in Finland, the most significant provider of healthcare is the public healthcare system. This contextualization is significant in understanding the situatedness of tissue collections in Finland, in that the state is not only the major source of research funding, but also the major consumer of products as well, and has an inherent interest that existing resources are used efficiently. This includes re-imbursement for medications through the public healthcare system, the up-take of different types of treatments in the hospitals and clinics, as well

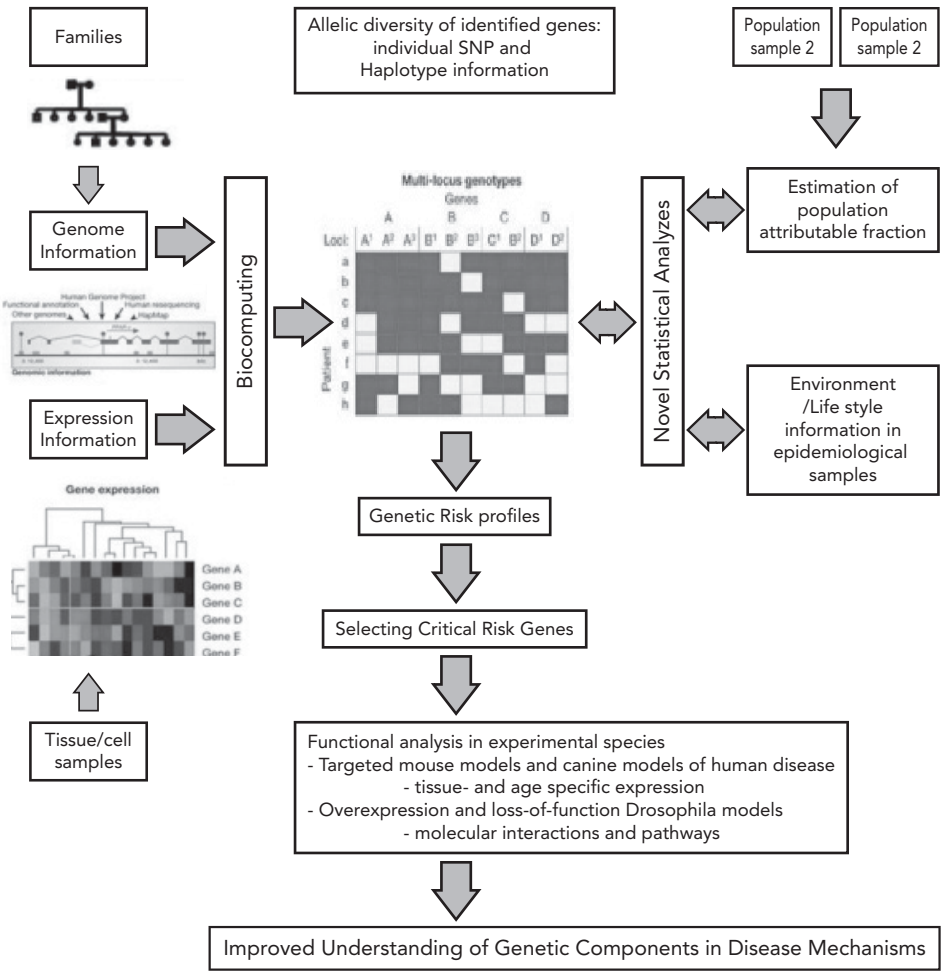
as an important source of information on health itself through prevention programs and screening. It is, therefore, important to consider, that the state plays a significant role in the process of knowledge productions and consumption (see Tupasela, 2006c). For example, an important research area in Finland has been epidemiology and molecular genetics, which emphasise the value of large tissue sample collections and accurate lifestyle information in the production of information on the human body, its related diseases and populations. These collections are, therefore, also seen to play an important role in national research on prevention, but increasingly expected to produce new innovations for the private sectors (cf. Sosiaali- ja terveysministeriö, 2007).

In this sense, tissue economies and the biovalue that can be produced from them are closely aligned with the production of scientific knowledge and the structures and practices that are developed to foster such production. These structures and practices of scientific knowledge production can be said to form epistemic cultures (Knorr Cetina, 1999). The connection between tissue economies and epistemic cultures is a central one, in that epistemic cultures are scientific communities which produce and warrant scientific knowledge (Knorr Cetina, 1999). In her analysis of scientific knowledge production, Knorr Cetina (1999: 3) identifies the 'construction of the machineries of knowledge construction' as a central task, whereby the architectures involved in such processes become increasingly visible. In this sense, the production of knowledge and knowledge cultures has a specific context and relationship to economic dynamics if knowledge is increasingly seen as a driver of economic development, as so many science and technology policy documents have argued time and again (see Häyrinen-Alestalo, 2001). Knorr Cetina (1982: 103) points out that what is at stake with knowledge production is not what traditionally has been understood as social organization of scientists (see Merton, 1973), but rather the organization of research activities based on *resource-relationships*. She argues, therefore, that 'what is of interest is the acceleration and expansion of the reproductive cycle which produces new and credible information' (Knorr Cetina, 1982: 105). For biobanks, the extraction of information from physical samples and its connection with other health-related data plays a central role in this process in that the re-interpretations associated with informed consent, privacy and autonomy relate directly to the ways in which resource relationships are re-organized. Furthermore, the organization of resource relationships is directly linked to the relations of power which emerge in tissue economies through the changing contexts under which tissues are collected and used, and the concomitant development of the legal and ethical frameworks which surround these practices. The context of knowledge production dynamics has a close relationship with the practices, structures and mechanisms in biomedical research and the resources that are made and become available to them.

To illustrate how this operates in practice, we can examine the ways in which research groups, for example, organize their resource relationships. In Figure 1, the tissue economy of the Research Group for Molecular Medicine in Helsinki provides a detailed graphical outlay of the resources, methods and 'products' that the group uses and produces. The

figure shows that there is no such thing as a tissue economy, but rather a multiple array of different tissue economies and associated data resources that are organized in a type of architectural outlay. For example, information and samples collected from families and population samples come about through different research processes, yet through the organization of these resources the information that can be collected from them is brought together through statistical analysis and biocomputing. Similarly, information on lifestyle in epidemiological samples forms another component of the tissue economy represented here.

Figure 1. A TISSUE ECONOMY OF A FINNISH RESEARCH GROUP



Source: http://research.med.helsinki.fi/molmed/ (30.1.2007). Re-printed with permission.

In terms of the three classifications of biovalue, one can say that the primary form of biovalue produced in this tissue economy relates to biovalue as scientific knowledge. Although this can be later translated into biovalue as health and commercial value, within this representation of the activities of this particular research group, scientific knowledge is seen and defined, however, as the primary form of biovalue. In this sense, this organizational model represents the transformative process which takes place in converting information gained from tissue samples and other information resources into biovalue in the form of scientific knowledge. Such organizational architectures therefore represent the productive process, therefore, of transforming biovalue from raw materials.

Figure 1 also highlights the dual nature of tissue economies as physical economies of samples, but also as information economies that are easily transferable and analyzable. The sample collections form, therefore, only a basis or source, while the information that is gathered from them forms the major part of the research process. It is, therefore, pertinent to ask to what degree does the idea of a gift economy of gift exchange reflect the purpose and goals of the whole research process itself? Certainly gaining access to the samples is an important component of the process, but since samples can be used time and again (recycled), and they can be compared to other, non-donated tissues, as well as information, it is useful to question the role and significance of the notion of gift-giving in tissue economies.

The language of scientific knowledge production that is employed in the chart also highlights and entails power relations between the users of the samples and information and the sources. The production of 'Genetic risk profiles', 'Selection of Critical Risk Genes' and the 'Functional analysis' is an expression of the ability of researchers to have access, control and produce scientific knowledge based on these resources. Here we see tissue economies penetrating the lives of people and population by producing risks and profiles through analysis. Tissue economies come to have a much broader impact on the lives of the people and their lifestyles as well.

The tissue economy presented here also represents the way in which researchers seek to organize their research activities to produce scientific knowledge. The purpose and use of connecting epistemic cultures with tissue economies and biovalue is three-fold. *First*, the production of biomedical knowledge and the organization of the material and information resources that are required to produce it form an important structural and cognitive framework in relation to knowledge production. I look at this in the flowcharts that represent knowledge production in the three case studies. *Second*, the connection is useful in that it identifies the use of tissue collections as, not only a process and set of practices within research groups, but rather as a broader political process of constructing machineries of knowledge production that are related to the emergence of knowledge societies. This connection also has relevance to ongoing discussions on the role of biobanks in providing new healthcare technologies, as well as commercial opportunities and contributes to theoretical discussions concerning the notions of knowledge societies, biovalue and tissue economies (EU Workshop, 2003; Lewis, 2004). *Third*, in considering

how the significance of tissue collections has changed, the transformation of tissues to information (indeed their very classification as information) and the uncertain potentialities which they contain has important consequences in the scope of the interpretation of informed consent. This re-interpretative process is derived from a need to produce scientific knowledge, and has implications for individuals as research participants and patients since the information is derived from them and touches upon some of the most fundamental issues relating to privacy and autonomy. It also has implications as to the way in which individual rights are defined in society in general.

Given that the production of biovalue entails a transformative process, we can also ask, how the process of knowledge production is governed in relation to biotechnology (Stehr, 2004). Stehr (2003: 644) has argued that knowledge politics or knowledge governance:

> "is about attempts to channel the social role of knowledge; to generate rules and sanctions pertaining to relevant actors and organizations; to affix certain attributes (such as property restrictions or legal prohibitions) to knowledge. […] The essence of knowledge politics consists of strategic efforts to move the social control of new scientific and technical knowledge, and thereby the future, into the centre of the cultural, economic, and political matrix of society."

In the analytical framework of socio-economic perspectives of recent decades, the field of biotechnology has emerged as a fruitful source of empirical material through which the development and complexities of new research areas can be analyzed in relation to their role in economic development and the ways in which the public is engaged in decision-making processes. As I discussed earlier, I see informed consent to represent an important and central feature of engagement within biomedical research that uses tissue sample collections because it remains to date the most effective way for individuals to exercise their rights over their bodily fragments and personal information that is derived from them.

Häyrinen-Alestalo (2007: 2), however, has argued that ideological dependencies have begun to form between political expectations and theoretical explanations, noting that 'increasingly the political system takes the initiative and formulates concepts and theory-like ideas that the scientific community is afterwards eager to adopt.' With biobanking, informed consent is seen as the foundation of social interaction and legitimacy of research activities because it is through informed consent that researchers gain their mandate and permission to do research on research subjects, as well as the samples and information that are gained from them. Increasingly, however, the discussions that surround informed consent are coloured by interests relating to the expectations associated with biomedical research. These expectations derive in part from political expectations, but also from expectations created by scientists. As a result the rules and regulations that emerge are situated within this context of expectations.

To understand the situatedness of tissue sample collections and how they relate to their source (research patients), it is necessary to look at the different ways in which

tissues are conceptualized. The classifications which I will discuss below (gifts, property, waste and information) are key concepts which are deployed in policy and interview materials and play an important role in the way in which tissue economies are conceptualised and the way in which the rights of the individual are interpreted. They are also strongly represented in the scientific literature which discussed the biomedical use of tissue sample collections.

Tissues as Gifts

Within the sociology of giving, Berking (1999: 139-143) has explored the moral and cultural foundations of the liberal-capitalist market economy and its supposed degrading influence on pre-modern systems of meaning and obligation in relation to giving. He argues that individualization and de-traditionalization have been seen as a threat to forms of socialization and community building, but the influence of modernization in the decay of community is not straightforward, and cannot be dichotomized simply in terms of market and social relations or equivalence and reciprocity. Instead there are also signs of an intensification of collective interests. Such interests have been characterized in different activities that people increasingly take part in, such as volunteering in the community and financial donations to charities and can be extended to donation of blood and other tissue samples for biomedical research.

Nelkin and Andrews (1998: 7) have noted that 'the norms that guide the disposition of body tissue reflect community ideals and social priorities.' Following this connection between norms and social priorities, it is possible, therefore, to argue that the emergence of market economy ideals within biomedical research does not necessarily entail an opposition between donation and commercialization, but rather one can ask whether commercialization can serve to foster collective interests and bolster socialization. It is important, therefore, to develop an understanding of the ways (if any) in which forms of giving, solidarity and reciprocity that have traditionally been associated with notions of common welfare come to be expressed within the context of increased neoliberal policies, and tendencies that emphasize market forces as they apply to the biomedical use of tissue sample collections. This will help us to contextualize gift-giving and commercialization in relation to consent practices. Interestingly, Berking notes that rather than receding the boundaries of community, individualization is creating new avenues through which community is expanded and created.

> "This form of interaction runs like a red thread through the everyday life of modern society: it initiates and authenticates relationships, fosters trust, develops mutual recognition, and ensures that generosity still finds a legitimate place in the moral vocabulary of a society which is structurally dedicated to profit-maximization behaviour."
> (Berking, 1999: 144)

Whether individualization and its expression through commercialization creates new forms of trust and mutual recognition equally across society is not at all straightforward. Berking's argument, however, raises an interesting point concerning the development of reciprocity in tissue economies, in that it challenges traditional assumptions concerning the role of modernization in the development of social relations. Following Berking's argument, it is possible to identify elements in society that can be interpreted as being both individualizing and socializing at the same time. How these forces act upon the interpretations that are given to informed consent therefore has important consequences on the organization of resource relationships.

Any analysis of tissue samples and their significance requires, however, an understanding of the nature of tissue samples as objects. Frow (1997: 124) has shown how in relation to objects, a traditional way of seeing the exchange of objects has been a dichotomy between commodity exchange and gift exchange. The former is characterized by alienable objects, reciprocal independence and a quantitative relationship between objects. The latter is characterized by inalienable objects reciprocal dependence and a qualitative dependence between subjects. This opposition sets up a distinction between two types of social relations. In gift economies, the object serves as a vehicle or mediator of social bonds that creates indebtedness, whereas with commodity economies, the objects themselves are what is being exchanged and there exists a quantifiable value for this exchange. With tissue economies, therefore, the donated tissue sample (gifted sample) would serve as a vehicle of social bonds, whereas if the sample were to be paid for then the sample would serve as the exchange in return for payment.

The traditional dichotomy between commodity and gift, described above, derives from Marcel Mauss' (2004) analysis of gift giving as a means of, not only the transfer of goods, but more importantly, as a form of social structuring and community building in which the gift serves to build solidarity between individuals and groups. In this sense there is no such thing as a 'free' gift, or a gift that does not obligate the recipient to reciprocate. In her forward to Marcell Mauss' *The Gift*, Mary Douglas (1990: xiii) notes that 'the theory of the gift is a theory of human solidarity' in that it seeks to criticize the notion of individualism. This approach has many connections to the use and re-use of tissue sample collections without re-gaining informed consent. The relationship between individualism and social solidarity are tested to see whether the use of tissue samples for commercial purposes and without consent or re-consent undermines the incentive or will of people to participate in research. In interpreting Mauss, Douglas notes that:

> "The gift cycle echoes Adam Smith's invisible hand: gift complements market in so far as it operates where the latter is absent. Like the market it supplies each individual with personal incentives for collaborating in the pattern of exchanges." (Douglas, 1990: xviii)

The distinction between gift and market has been a central theme that has emerged from Mauss' work on what he called archaic forms of contract. Although gift giving presents itself as voluntary, Mauss (2004: 9) argued that what in fact was involved in gift giving, receiving and reciprocating was a *system of total services* where there was an obligation on the part of the person who received a gift to reciprocate it. The act of giving, therefore, has an important social structuring component to it in that it inherently involves obligations to those who receive the gift to give in return. Using the example of the potlatch, Mauss drew attention to the ways in which gift giving, receiving and reciprocating was a phenomenon of social structure where there emerged an obligation to give. The work of Mauss has had an important impact on contemporary analyses of forms of social relations as they relate to gift giving and can be applied to the use and re-use of tissue samples in biomedical research.

Perhaps the most important influence on recent research involving gift relations and biobanks remains, however, Richard Titmuss' (1970) *The Gift Relationship*, where he compares blood donation in several different countries. Titmuss argues that in those countries where there is a non-commercialized market for blood, i.e. donors do not receive financial compensation for donating, the system of acquiring blood remains far more efficient and safer as opposed to those countries, such as the US, where the donation of blood is premised on a commercial market model. According to him, altruism plays an important role in the donation process and that commercialization has a tendency to repress such tendencies. Titmuss (1970: 223) argues that 'no money values can be attached to the presence or absence of a spirit of altruism in a society'. For him altruism was 'taking part in the creation of a greater good transcending the good of self-love' (Titmuss, 1970: 269). In many ways Titmuss' work reflects that of Mauss in trying to conceptualize gift giving and the conditions under which it operates.

The work of Mauss and his contemporaries, including Titmuss, on the dichotomy in market structures raises an interesting problem in relation to the status of the body and its parts in the context of tissue economies (Beyleveld and Brownsword, 2000; Schepher-Hughes, 2001). The gift model remains difficult to apply in many of the practices that are associated with tissue acquisition and use today, most notably in that tissues are not always acquired through gift giving and when they are, there may be other reasons besides reciprocity which influence such decisions. Thus the model of the 'gift relationship' may provide only a partial picture. The assertion by Titmuss that donation is premised on altruism has been shown to be greatly problematic and idealized in that people have been shown to attach all types of different meanings and significance to why they choose to donate and participate (see Tutton, 2002; Busby, 2004; Haimes and Whong-Barr, 2004a). In addition, as Berking (1999) has noted, individualization does not necessarily run counter to the idea of community or socialization, but rather expresses itself in different ways.

In his critique of Titmuss, Kenneth Arrow (1972: 350) has also aptly pointed out that when the possibility of selling blood is added to the voluntary system of blood donation, one is merely expanding the range of choices made available to the individual. Arrow

continues that although Titmuss asserts that giving may actually increase efficiency in the operation of a market system, there is very little evidence provided by Titmuss to show that commercial systems decrease the amount of altruism in a society, especially when the type of altruism that Titmuss is referring to remains a 'diffuse expression of confidence by individuals in the workings of society as a whole' (Arrow, 1972: 360).

Here lies one of the main challenges that the notion of altruism comes up against in terms of the biomedical collections and use of tissue sample collections: *first*, there appears to be critical evidence to show that donation is not premised on altruism alone. *Second*, despite this fact, many researchers evoke the idea of responsibility and reciprocity when talking about the collections and use of samples. *Third*, there are other sources for the acquisition of samples, which do not rely on the gift-giving system of sample acquisition. *Finally*, the systems that are created and maintained for the acquisition of tissue samples are to a great extent based ethically and legally in western countries on the donation principle which is framed within the consent procedure. This principle, it is argued, maintains the safe and efficient operation of these acquisition systems.

Gifted samples also come to occupy a somewhat awkward position as objects as they age. It is becoming increasingly difficult to determine the status of old samples taken from donors who have, for example died, and donated the sample for one type of research. Many years later, researchers have come to realize that the sample could be used for something else than what it was originally donated for. If the sample has been donated for one purpose, can it be used for another? What are the values associated with this sample? It is in no way clear whether the intentions of the donor are that it be used only for a particular type of research or whether the common good of society has a more important status (cf. Helgesson *et al.*, 2007). Titmuss' conceptualization of a gift relationship in terms of blood donation, although useful in some ways, says nothing concerning the possible conflicts of interest inherent in genetics research using old tissue samples, nor of the collection of samples without donation or permission. It is in no way evident whether the interests of science and society, through research and then possibly commercialization, are more important values for a society as a whole, as opposed to the right of the individual, which also hold an important role as social values. The issue of commercial value has been particularly challenging in relation to the biomedical use of tissue sample collections and will be discussed in more detail in the next section. The use of the idea of donation and gift, however, plays an important linguistic role in the languages that are deployed in legal and policy documents and merits, consideration in relation to the ways in which tissue economies operate. Furthermore, it is essential to consider how the role of donation and gift giving changes as the content of consent practices change. Donating samples for yet unknown and commercial purposes is becoming increasingly common. It is important to explore, therefore, what role these practices, if any, have on the willingness of people to donate their samples.

Tissues as Property

In relation to the biomedical use of human tissue sample collections, there has emerged a large body of literature and case law that has explored the role of patients, as well as citizens and their rights over samples that have been taken from them (cf. Boyle, 1996). The case of John Moore, who began treatment for his leukaemia in 1976 at the University of California Medical Center, has been one such landmark case. The doctors treating Moore realized very early on that his particular type of leukaemia and the products that they could produce from it were commercially very valuable. Over the years that Moore received treatment, his doctors collected numerous tissue samples from his body including the removal of his spleen. In 1981 the doctors were able to establish a cell line and consequently the University of California proceeded to patent Moore's T-lymphocytes, whereby his doctors were listed as inventors (see Boyle, 1996: 22). Moore felt that he had certain rights to the samples that had been removed from him and proceeded to take legal action against the university.

The significance of the case is reflected in the ensuing US court decision whereby it was ruled that Moore did not have property rights in the cells and genetic information that had been removed from his body. The court argued, among other things, that by agreeing to take part in treatment and provide samples, Moore had 'abandoned' his cells. Another major argument put forward by the courts was that the provision of property rights in bodily fragments would in due course hinder scientific research in such a way that it would become prohibitively expensive in the future (see Moore v. The Regents of the University of California, 1990).

Waldby (2002) has argued that despite technical attempts to detach bodily fragments from the donor by denying property rights (see also Beyleveld and Brownsword, 2000), there is a large body of evidence which illustrates how, in many cases, these fragments 'retain values of personhood' for donors (Schepher-Hughes, 2001). I would argue, however, that Moore argued his case on the wrong premises. Instead of attempting to gain property rights in his tissues, he should have challenged the right of the researchers to collect and develop a cell line from his samples without gaining the appropriate consent. If he had been made aware of the commercial interests of the researchers, he would not have had reason to challenge their patent application. This would have changed the nature of the argument from one where a principle was tested to one where the procedure came under question.

Biomedical research that relies, to an increasing degree, on the availability of different types of fragments of the body would appear, according to some authors (Schepher-Hughes, 2001), to have to account for a retention of values in some way in order to avoid conflict and encourage future access and availability of such resources. This would mean that consent practices would be a necessary passage to ensure this. Here again we see how a relationship between samples and their sources is framed within a context of a relationship between the interests of individuals and collectives, as well as the way in

which the source of the sample continues to figure in the discussion surrounding the use of samples even after they have been removed. Issues of ownership also touch upon the power relationship over the control of the samples and related information.

Tutton (2002: 537) has suggested that in analysing motives for participating and donating to research, it is important to note the outcome and use for which samples are taken for. Blood donations, for example, tend to relate to a 'corporeal economy' where donors know what the use of the donation is for, whereas, blood taken for DNA analysis in research is more connected with an 'informational economy', where the uses and outcomes of research may be less apparent to the participants. The sample can be used and re-used for multiple purposes which might be different than from what was originally expressed to the participant when donating the original sample. In addition, it is highly unclear what the end products will be from the information that is analyzed. Therefore, tissue samples can retain differing forms of significance depending on their use and purpose. Waldby (2002: 310) aptly argues that biotechnology produces a margin of *biovalue* that can be measured both in terms of the production of health, as well as increasingly in the production of commercial value.

Yet, following Tutton's line of argument, one can say that biovalue can remain highly unspecific and indeterminate. Commercial value within scientific knowledge production has, however, become increasingly tied to information about the body and populations themselves, as opposed to physical entities. Since the possible uses of the information gained from the samples remains uncertain, this extends the scope of biovalue to an open-ended economy of production. What becomes the focus of commercial interest, therefore, is the information that is and can be produced on the body. At the same time this is making it increasingly difficult to define to research participants in consent forms the significance and use of that information in the future, as well as who has ownership rights over it. The control of information derived from physical samples as a form of property, however, remains problematic, since individuals retain rights, under certain legal jurisdictions, to control private information. Here we can see how, even if we can be denied the right to control our samples to some degree, it still remains possible to control the information derived from it in other ways. Such rights of control are, however, different from property rights, but the possibility to control one's information emerges as a result of tissue donation and its subsequent use. Although donation is said to entail the transfer of property rights, it is clear that this transfer is an incomplete one to a certain extent, in that there exists evidence to show that attempts are made to allow the donor to maintain a say in the way the samples are used and whether or not they are destroyed at some point in time. The right to control also changes over time, since in some instances in Finland the transfer of old epidemiological tissue samples to national collections has taken place without consent due to the old age and large size of the sample collections. This indicates that different consent criteria are applied divergently depending on the age and size of collections.

Rose (2001: 5) has noted that the rise of information as an important nexus in

biomedical research can be attributed to the fusion of two large technosciences of the 21st century, namely biotechnology and informatics, whereby bioinformation becomes increasingly a tradable commodity. The so-called commodification of bioinformation in the Icelandic Health Sector Database, for example, represents only one approach in the production of biovalue by setting up an information monopoly for deCode Genetics. The production of commercial value from biomedical knowledge is dependent on a number of factors, one of which is the way in which knowledge is assembled using different information resources.

Commercialization and ownership have also been a central theme in more recent discussions concerning the knowledge economy, and its role in the interaction of individuals within communities. Häyrinen-Alestalo (2001: 206) has noted that the policy changes that have accompanied new ideological perspectives, such as the information society, carry with them normative assumptions on the role of technology in improving the conditions of social interaction and equality. She notes that both EU and Finnish policies have begun to blur the earlier boundary between science and innovation, where the foundation of knowledge and development is no longer vested in academic knowledge that has traditionally been seen as communitarian (cf. Merton, 1973: 270), but increasingly in terms of innovations, which are considered commodities and property. The main thrust of such political 'super-utopias' has been that a new 'joint social effort' emerges, where innovation becomes a social phenomenon that allows both individuals and collectives to express and attain their creativeness, needs, wishes and values.

The act of participating and belonging to a social system, therefore, becomes increasingly framed, according to such policies, on a neoliberal market model where innovations and the conditions for their production play an important role in justifying the conditions under which resources are organized and made available. Whether these models are successful in building and maintaining community bonds and social relations is highly unclear, but the exploration of various arenas where their interplay has emerged is a central task in this research as it relates to the biomedical use of tissue sample collections in that innovations are invariably property rather than common goods. Tissues which have been donated or gained through other means from people need to become property in order for them to have productive power (see Waldby and Mitchell, 2006), yet at the same time there remains a great deal of ambiguity as to the legal status of tissue sample collections in many cases despite the fact that consent has been sought.

Within the market model, the currency that needs to be created and exchanged is no longer simply a public or common good, but rather an entity that is transformed, owned and exchanged using quantifiable (patents) and monetary values as the measure of success (see for example Mayer *et al.*, 2003). Donated tissues, however, do not fit neatly into this system of exchange and production. Given that biomedical research utilizes tissue samples that are acquired through a non-commercialized system of acquisition (voluntary donation or diagnostic samples), it is important to explore the social conditions and mechanisms that emerge and are created to support the continuity of such activities. This effort to

maintain continuity and emphasize the notion of community and reciprocation is an important feature which would appear to undermine the assertion that the development of neoliberal markets is unilaterally undermining notions of solidarity. The attempt to maintain continuity and a form of reciprocity through commercialization represents a new way of framing solidarity within the neoliberal context and can be seen to enter consent practices, as well in that it is also possible to donate samples for commercial purposes. Therefore, it might be more fruitful to explore what types of social relations and solidarity are emerging within this context of tissue acquisition, exchange and use.

According to Strathern (1999: 21), 'the last twenty or thirty years has seen an unprecedented development not just of new things to own but of things which suggest that Euro-Americans need to devise new ways of laying claim.' The organization of scientific knowledge production using human tissue sample collections in Finnish biomedical research from the early 1990s to the present is undoubtedly a reflection of this process to devise, not only new ways of laying claim, but also new 'substances' to which to lay claim. The re-interpretation of the scope of informed consent as a form of re-organizing resource relationships is a reflection of this process as well.

At the end of the 1990s, biomedicine in Finland, as a part of biotechnology in general, began to gain interest in science and technology policy as an important strategic instrument that needed to be developed because of the scientific and economic possibilities that it brought with it (Academy of Finland, 1997; see also Gottweis, 1998). This is well illustrated by an international evaluation panel on Finnish biotechnology which noted on the commercialisation of knowledge that 'basic research is to generate new knowledge and understanding that can provide the basis for applied research to create significant commercialisation opportunities' (Academy of Finland, 2002: 50). The panel went on to note that efforts should be made to engage researchers in the *translation* of research findings into economic gain. This policy assertion suggests that tissue economies encompass a much broader set of activities, besides the technical and material act of collecting and exchanging physical material. At the same time, the boundaries between what is proprietary, who can lay claim to it and in what ways resources can be mobilized are being re-drawn and negotiated. I would argue, however, that this process of re-drawing is still unfinished and that there remains a great deal of ambiguity as to the legal status of sample collections. The above comment also touches upon the transformative process which is expected to take place in converting basic scientific knowledge to other forms of biovalue, namely economic gain, which also remains highly unstable since many of the commercialization attempts in Finland remain very limited (see Valtiontalouden tarkastusvirasto, 2008).

The transformation of tissues and the information gained from them into property has, therefore, become a major political preoccupation in relation to biomedical tissue sample collections, since it is seen as the basis for converting scientific knowledge into economic gain. Waldby and Mitchell (2006: 71) have argued that 'informed consent is the mechanism that transforms a gift into property' by formalizing the transfer process between donor and recipient. According to Waldby and Mitchell (2006: 72), informed consent acts

as a 'surrogate property contract' which helps to 'disentangle' objects from their owners (see Callon, 1998). The OECD (2006: 123), however, has recently noted that most of the population database initiatives lack policies on intellectual property, commercialization or benefit-sharing. An interesting observation since it is exactly these goals that biobanking is supposed to be fulfilling according to policy documents. The processes associated with disentanglement are not, however, always straightforward; tissues sometimes resist attempts to disentangle them from their source, thus impeding some forms of claim and proprietorship. This can be seen in the ways in which the interests of the sources of samples are reconfigured into legislation on the use of tissue sample collections. I will discuss this in more detail in section 4 when I look at the way individual interests are reconfigured into a new proposal for biobanking in Finland.

Non-donated tissues also problematize such distinctions and disentanglements since donors are never in a position to form such contracts. Instead, decisions of whether or not to use samples and information are based on other criteria, such as social interests and commercial potential. The use of tissues that are acquired outside of the informed consent and donation paradigm shows yet another mechanism through which claim can be laid on objects derived from the human body. At the same time, such practices subvert any possibility for the source of that sample from having an influence over its use.

Such practices are important given the emphasis that recent science and technology policies, as well as guidelines, have placed on autonomy, engagement with the public and gaining the public's trust in research practices (see for example World Health Organization, 2003) and brings forth the tension that is evident between involving the public and individuals in decision-making, on the one hand, and the research practices which circumvent these forms of engagements in the name of efficiency, on the other.

Tissues as Waste

The case of John Moore is interesting in that it raises an important question relating to the use and significance of tissue samples that have been removed from a patient. In the case of Moore, it was said that Moore had no right to claim property rights in his sample, because it was seen to be 'abandoned', yet at the same time the case made it possible for someone else – the researchers and the company involved – to lay claim and thus have property rights in those very same samples (see Waldby and Mitchell, 2006). This would appear to support Stratherns' (1999) claim that there has been an increase in the past three decades of devising new ways of laying claim to objects. With waste, claim and property is acquired through the possibility of future technical and intellectual work, and the prospect of productivity. The status of tissue samples in the Moore case is very similar to tissue samples which are collected as surgical waste during operations in that samples are seen to have no value for the patient (except for diagnostic purposes), but great value for the researchers collecting them.

Hospitals have always maintained large collections of diagnostic samples (i.e. not

collected for a specific research purpose), which are commonly stored in paraffin blocks. Most countries maintain laws which require hospitals to do so. The samples are seen as part of the patients medical record and can be referred back to later on if needed. These samples are also used regularly in teaching. Diagnostic tissue samples are not given to the hospital as a donation or gift, they are taken as part of routine medical procedures and are stored for an indefinite period of time. Yet the tissues themselves are a valuable source of information on the body. As a result, many research groups regularly use diagnostic tissue samples for research purposes.

Samples collected during surgery are only one source of waste. Waste material is also collected during other procedures, such as childbirth, where cord blood can be collected and used for research, as well as therapeutic treatments. Nelkin and Andrews (1998) note that cord blood is used in shampoos, cosmetics and skin care products, which make it of great value commercially. Hair is often collected during haircuts for use in wigs for cancer patients who have lost their hair during treatment. Waldby and Mitchell (2006: 85) note that 'the strategic work of any economy involves relocating waste to other regimes of value where it does productive work.' In this sense, 'abandoned' tissues, surgical waste and diagnostic samples are relocated into more productive systems, such as scientific knowledge production.

In many such instances, informed consent is sought from mothers or the donor themselves for the use of the waste, which would in one sense make the waste itself a gift. Waldby and Mitchell (2006: 115) discuss waste or abandoned tissue in the context of those samples being de-linked or anonymised[13]. Research practices in Finland, however, particularly those associated with epidemiological and cancer research, rely to a great extent on the fact that tissues can be linked to other information related to the patient through social security numbers. Although this data might be coded or protected through other privacy protection measures, the possibility of linking it to other personal information is of central importance to researchers. The cases of the Genome Information Centre and HNPCC research, which I will discuss later, highlight the ability to connect different types of personal data.

What is important in relation to the acquisition of the tissue itself, however, is the status that is given to particular samples before they are donated or extracted. Giving samples the status of waste is important in that it highlights to the donor that they will have no use for the samples themselves. The sample in itself would therefore not be productive. In addition, samples that are not being used can also be classed as being wasted since their potential value is not being maximized. The discourse and narratives surrounding the collection and use of waste highlights a powerful ethos of efficiency in scientific research, an activation of use and possible future values which is a powerful

[13] Anonymisation and de-linking refers to the process by which samples cannot be connected to other information on the source of the samples. Such samples are usually exempt from the requirements of informed consent and their use usually requires only that an ethics review board has given permission for their use.

tool for motivating decision-making. It also sets certain normative standards for the use of information on the human body in that not using such resources becomes classed as inefficient and wasteful, which in economic terms is non-desirable. Decisions of using or not using resources, no longer is a question of autonomy or personal choice, but rather economic calculus.

The collections and use of waste which can be linked to other personal information extends the scope of tissue economies well beyond the scope of the gift relationship that Titmuss (1970) describes in blood donation. The tissue economies of surgical waste operate outside of gift practices and informed consent practices in that researchers are not required – at least in Finland – to gain consent from the patient to study the sample or use patient information. Instead they are only required to get the permission of an ethics review board and the permission of the National Authority for Medicolegal Affairs. Here an expert authority stands in for the individual and interprets their interests and can be said to represent an institutional replacement of autonomy. This process of replacement also carries with it normative assumptions on the part of those institutions that are making decisions for individuals as to the significance of those decisions. I am not arguing here, that this practice is necessarily problematic, but rather that the scope of individual autonomy to act and make decisions on samples and information taken from oneself is changing in a way which supplants institutional or expert decision-making for that of the individual's personal choice. At the same time, those normative interests that are attached to scientific knowledge production, namely commercialization, come to act upon those very same decisions. This process reflects the social criteria which are viewed as legitimate in re-interpreting the extent of autonomy and personal privacy in any given society.

Surgical waste tissue economies are also outside the scope of any exchange system, since no form of exchange takes place when the sample is collected, stored or re-used. It can certainly be argued that the surgery itself is a form of payment that the patient benefits from. The collection and storage of the diagnostic sample, however, is more a technical/bureaucratic process than what can be understood as an exchange in the classical sense, where patients/donor would receive a financial compensation or some other reciprocation for the sample. In many cases patients do not even know that such a sample has been stored. On the other hand, this has been standard practice for decades and there have been very few problems with it ethically or legally. This practice indicates that tissue economies are able to extend themselves beyond standard economic models in which either exchange or philanthropy play a role in the operation of that system (cf. Arrow, 1972: 344-345). The increased interest in the commercial applications associated with this waste, however, has brought to light the need to reconsider the forms of engagement that are necessary in their procurement.

While it is possible to give waste as a gift, it is also possible to waste gifts. Most of the large biobank collections in Finland have been collected through various large national research projects that have relied on participation and donation of samples

through informed consent. Some of these studies are decades old and took place when consent procedures and standards were different from today. Recently in Finland, there has arisen a concern over research sample collections or cohorts that have become either 'homeless' or the collections could be used for something other than what they were originally intended for. 'Homeless' collections mean that the researchers who have originally collected them have retired or moved on to other jobs leaving the sample collection and its related data without a custodian or user. Although one might think that sample collections and their related data can be used by anyone, there is evidence to show that a great deal of tacit knowledge about sample collections and their management is required in order to successfully or fully use such collections (see Hoeyer, 2004). In a sense, one could argue that these collections could be seen as wasted gifts since the tacit knowledge associated with them has decreased or become unavailable. Both homeless and old tissue sample collections can, however, be re-used or applied in the study of new research questions. Many researchers in interviews argued that these samples should be used and not forgotten or destroyed since this would be effectively wasting the gifts and constitute an inefficient practice. This concern over homeless and old tissue sample collections reflects once again a concern over efficiency and the possibility of wasted productivity or capacity within the national research context.

According to Titmuss (1970: 220), the fact that the notion of waste can be applied to blood signifies that it is in effect an economic good. Following this argument then, it is possible to say that tissue samples, be they of any kind, are also economic goods to which cost figures can be applied. This assertion, more than perhaps any other, is significant when considering the collections of human tissue, the formation of tissue economies and the production of biovalue, in that it directs attention to the use values and expectations that are applied to tissue samples and, therefore, the expected health and commercial value that they might have. The tissues themselves have value not just as physical objects, but also for the information that can be extracted from them. Value is also gained through the processing of the samples themselves so that they meet specific standards. This, most often, involves the attachment of a whole host of metadata to the sample, as well as its handling according to specific technical standards. In this sense, physical tissues also form an important part of an information economy. I will discuss the significance of information drawn from tissue samples in the next section in more detail.

What emerges as an important question relating to the use of surgical waste in biomedical research is whether or not consent should be sought before surgery or the removal of that tissue. Clearly there are instances when this is done, but this is by no means standard practice. The knowledge that surgical waste will be collected for the purposes of research also means that there is an opportunity to gain consent. Interestingly, however, we can see in these practices diverging interpretations over the role of consent and autonomy as to the future uses of removed tissue samples.

Thus far I have focused more on tissues as a physical entity. In the following, however, I will look at the relationship between tissue collections and the production of

information and knowledge as it relates to biomedical research. Given that tissues are increasingly transformed into information and that this information is seen as the basis for economic development, it is important to understand the function that information plays in tissue economies and the production of biovalue.

Tissues as Information

> "Linking the biological data contained in samples with the background information on the donors of the material in question is fundamental to the biobank concept."
> (Pitkänen and Hassinen, 2007: 32)

Earlier in this chapter, I described the process through which a research group in Finland transformed scientific knowledge from tissue samples and other population data resources. This transformative process in knowledge production is seen as a central feature in the creation of biovalue and links physical samples with the information that can be gained from them, as well as the other information resources that they can be connected to. Thurtle and Mitchell (2004: 2) have argued that the study of the body and its related information forms its own general rubric known as 'materialistic information studies' where information and its various forms becomes the object of analysis and interrogation. Tissue economies invariably form an important zone between the physical (samples) and information itself (see also Parry, 2004).

Within the context of materialistic information studies, Beaulieu (2004: 367) has characterized the production of large amounts of data based on physical specimens as the 'informational turn.' New imaging technologies, computerized tools, informatics and electronic networks have contributed, therefore, to the development of a new object of analysis (see also Waldby, 2000; Silverstein, 2001). Fields, such as molecular biology, are becoming dependant on tools from mathematics, statistics and information and computer sciences (Fujimura and Fortun, 1996: 166). Knowledge production in the biomedical sciences, as they relate to the collection of human tissue samples, can be located directly within political attempts to develop new knowledge-intensive economies. Castells (1996: 78) notes that 'the emergence of a new technological paradigm organized around, new, more powerful, and more flexible information technologies makes it possible for information itself to become the product of the production process.' Given the economic importance that science and technology policies place on scientific knowledge, it is clear that information is seen politically to be an economically productive force. This political position has given rise to terms such as knowledge-based economies (OECD, 1996) and knowledge-based bio-economies (European Commission, 2005; OECD, 2005). Such terms reflect the political aspiration that knowledge in general and knowledge derived from the understanding and manipulation of biological processes will help produce applications and innovations that will help produce economic gains. I will discuss these terms in more detail in the next section.

Politically, the biomedical sector is seen, therefore, as an important source of information that is considered an economically productive force. Lenoir (1998: 27) has argued that 'sometime in the mid-1960s biology became an information science,' where information technology tools became increasingly integrated into the everyday work of biologists. This process has increased and intensified and has indeed had the same impact within biomedicine as well. According to Hagen (2000: 231-232), three factors gave rise to this development: expanding collections of amino-acid sequences, the idea that macromolecules carry information, and high-speed digital computers.

Kay (2000: 28) has noted how information, as a metaphor in the life sciences, emerged through an amalgam of disciplines, including linguistics and philosophy, and that the notion of metaphor functioned as a medium of exchange between the domains of *intra-scientific* and *extrascientific* activities (emphasis in original). In this sense, the translation of physical tissue samples into information has required the extension of biomedicine, not only within its own discipline, but also outside its traditional boundaries to begin using new information technology tools. The materiality of the samples themselves is an important element in the information and knowledge that is derived from them and plays a pivotal role in the knowledge-based economy. The transformation of tissues to information has also had an important impact on the way that individual rights are interpreted in that it introduced new legal domains which touch on personal privacy into the equation. No longer are the legal and ethical questions related to how to act on the human body, but rather how to manage information on the human body.

According to Waldby (2000: 33) 'currently the most productive forms of biovalue emerge from the calibration of living entities as code, enrolling them within bio-informatic economies of value which converge with capital economies.' Bio-informatic economies are systems of information acquisition, production and exchange, where the information that is in question is produced from tissue samples and related health and lifestyle information. This information is then, in turn, translated into other forms of value, such as commercial value through the development of innovations, for example. In this sense, they are extensions of tissue economies. Tissue samples, and indeed any other plant- or animal-based biological material, are considered to have a dual nature either as 'wet' or 'dry'. By this scientists mean that research takes place in two different locations in terms of the lab. On the one hand there is the physical sample itself, which is said to be located in the 'wet' lab. On the other hand, there is the information that can be acquired from the sample by using micro-array analysis, for example, and this data or information is said to make up the 'dry' lab or *in-silico*. Both form distinct epistemic objects, but are intimately connected to one another in that researchers need to move between the two to first gain the information from the tissue and also later to return to either the samples, the patient or the model organisms to apply the know-how that has been gained through the research (see for example Kleinman, 2003 on wet and dry labs).

Beaulieu (2004) reminds us that the informational turn is not a revolution, but rather represents a change in the production methods associated with scientific research. These

technologies include the development of the polymerase chain reaction (PCR) technology, micro-pipets and chips onto which thousands of small samples can be placed, computer software for the analysis of information, as well as the connection of various information infrastructures, which allows for the combination of different types of data (see Rabinow and Dan-Cohen, 2005). One can say, however, that the information turn created the possibility of producing knowledge at an increasingly high through-put rate. At the same time, it has allowed for the possibility to re-organize the production methods associated with knowledge creation. The re-organization of knowledge production in turn, emerges as an important component of the appeal behind the commodification and commercialization of knowledge, in that knowledge production becomes an increasingly industrial process. By industrial I mean calculable, scaleable and increasingly controllable using management techniques originally developed for traditional industry, such as paper and pulp.

In terms of the development of tissue economies this is important because it draws attention to the structural changes associated with knowledge production, as well as the epistemic changes associated with the ways in which researchers are able to analyze data itself. The epistemic changes, for example, can be seen in the way researchers themselves talk about genetics research. One epidemiologist noted in an interview:

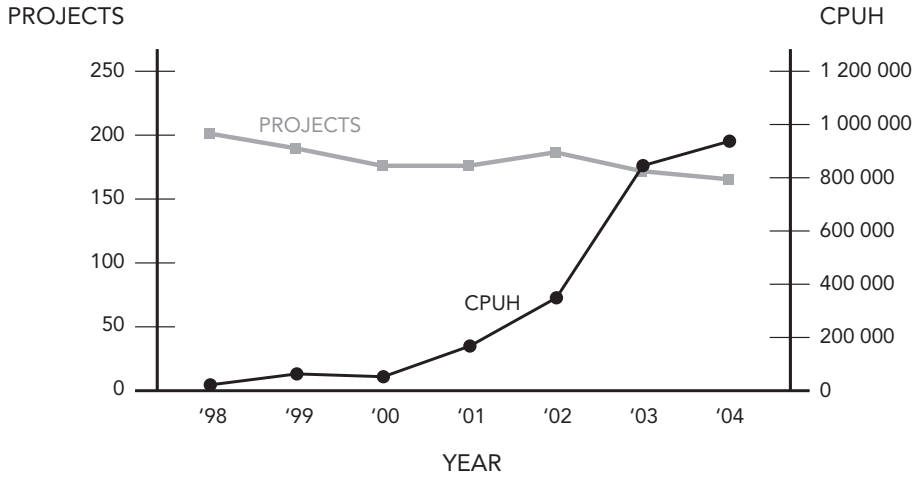
> **Epidemiologist:** *"When we talk about genetic information we are talking about polymorphisms or genetic variance across the genome, so it tells us what area regulates what. Next summer we have a 500 000 polymorphism set coming out."*
>
> **AT: "***You're talking about SNP's (single nucleotide polymorphisms)."*
>
> **Epidemiologist:** *"Yes, and I'm starting to have an interest in them. These earlier high-throughput methods, where we're talking about 10 Kb or 100Kb – this 100Kb is more recent – are too sparse for one to do credible science, in my opinion. This is currently a very delicate topic in genetics and people are almost having fist fights over what is reliable. I'm a purist, which means I want the whole sequence, which of course is not currently possible, and even then one couldn't be certain, but 500 000 snips would be something worth investing in."*
> (Interview with epidemiologist, 2005)

Here again we see the way in which genetic information is referred to in information technology terms (Kb – kilobytes), at the same time, the researcher notes that the current data accuracy in genetics is insufficient to draw reliable conclusions from. The informational turn, therefore, can not only be seen in the technologies that are used, but also the way in which interpretations are drawn from them. There is no one event that can be ascribed to have given rise to such a turn, but rather a host of technologies that have allowed for the more efficient and intense production and processing of information.

To illustrate the transformative process that is taking place in terms of the acquisition of information from biomedicine we can look at statistics on computer usage at Finland's Center for Scientific Computing (CSC). The CSC is owned by the Ministry of Education and it is part of a national research system that develops and supports information technology services. These services include the use of numerous software packages for various scientific disciplines, as well as the provision of computing time for calculations on its various mainframes. As such, the CSC statistics on computing time usage is one indicator of the changes in the amount of information that is being produced and analysed within the scientific community in Finland.

As Figure 2 indicates, since 1998 there has been an increase in the amount of central processing unit hours (CPUH) used by the processors at CSC for the biomedical sciences. Particularly after 2001, the CPUH increased rapidly, which means a concomitant increase in the amount of information that is being analysed. This increase has taken place despite the fact that the amount of research groups using the services of CSC has somewhat decreased over the years. It should be noted that these statistics reflect only the CPUH at the CSC and does not reflect the computing hours that take place in university research groups on a normal desktop computer or a smaller server. Therefore, the actual amount of data that is being analyzed and produced is far greater. These figures, however, are meant as an indication of the informational turn that Beaulieu is talking about in the biomedical sciences. They represent a dramatic shift in the amount of information that is being produced and analyzed.

Figure 2. CENTRAL PROCESSING UNIT HOUR (CPUH) USAGE IN THE BIOMEDICAL SCIENCES AT THE CENTER FOR SCIENTIFIC COMPUTING (CSC) 1998–2004.



Source: CSC Annual Reports, own calculations.

Another indicator for the increase in the amount of data that is being extracted from tissue samples can be gleaned from the Finnish Genome Center in Helsinki, which specializes in the use of micro-array analysis and provides genotyping services to research groups all over Finland. In 2001, the center genotyped 400 000 samples, whereas in 2003 the number had risen to over one million (Muilu, 2004: personal communication; see also Tupasela, 2004: 4163). This change in the amount of genotyped samples and the amount of data that is being analyzed represents a change in the availability of physical technologies, such as micro-array machinery, as well as new computational bioinformatics software that allows for the analysis of the information that is being produced. An important aspect of the data that is produced is that it can be further analyzed by combining it with other population data registers. This means that the increase in the output of genomic data is also accompanied by an increased demand for other (non-biological) data sources as well. From a policy perspective the informational turn in biomedicine is particularly important in that the knowledge-based economy is seen as an important frame for commercialization. Tissues and the data that can be derived from them, therefore, are an important element, in policies that try to foster economic development using such resources.

From the perspective of personal rights the increase in the ease with which analysis can be done poses challenges in the ways in which personal information can be managed and the role that consent plays in this process. As information on the body has become easier to analyze and link with other data sources, there has also emerged a strong interest to re-interpret consent in a way that would allow researchers to re-use samples and other data without having to re-gain consent. Here we see a movement away from a policy where people are seen to have a strong right in controlling how samples and information from them are used. The role of tissues as information in transforming the power and resource relationship between the source and user become apparent in this context.

Alongside the increase in the pace at which tissues are transformed into information has emerged the interest to control it through property rights. This has, in part, been fuelled by developments in the United States regulatory framework, which has fostered the patenting of university innovations, for example, through the Bayh-Dole Act, as well as the interests of venture capitalists to invest in new start-up companies. A pre-requisite for investment is, however, the securing of property rights in the substances that are in question (cf. Cooper, 2008). This movement, however, is not a unified one, and is witness to different factions pulling in different directions. The Human Genome Organization (HUGO), for example maintains that 'genomic databases are global public goods' (HUGO, 2002). These factions, however, have different interests in terms of the types of biovalue that they wish to produce. A further problem with proprietorship as it relates to information is that although people may relinquish their property right to tissues when it is abandoned or donated, they still have, under some legal jurisdictions, the right to control how that information is used and demand that it also be removed to a certain extent. This indicates that the property rights that are afforded to physical samples are not translatable directly into the information that can be derived from them.

This would also seem to indicate that there are limits to the legal claims that can be made on some types of information that are derived from tissue samples. It is important to note that donating samples, does not remove this problem either, in that people are still, after donation, afforded some rights as to the way in which tissues are handled and can demand that they be destroyed.

The extension of tissue economies to encompass the production of new data, as well as the possibility of connecting this data with other population registers, represents an aspect of tissue economies that has been neglected. In their work on tissue economies Waldby and Mitchell (2006) pay close attention to the physical aspects of tissue economies, but leave open the broad range of activities that epidemiologists and cancer researchers, for example, participate in when they collect clinical data from research subjects. In these tissue economies, the physical samples represent only the starting point in the transformative process of producing scientific knowledge and products which can be translated to the market. In these economies, information, more than the tissues alone, play a crucial and central role.

The notion of tissues as information also appears to complicate the disentanglement of tissues from their source through consent procedures. It is clear that individuals maintain some rights to the control and management of their personal information in tissue economies despite the fact that they have given consent. This is, however, more problematic with surgical waste, since in many cases people are not even aware that a sample is being used for research. Here we can see how diverging notions and practices of consent in different research contexts give rise to different regimes of tissue economies and thus different types of epistemic cultures. Tissue acquisition and knowledge production become based on different legal and ethical frameworks of acquisition, use and circulation. This can be seen as a challenge in attempts to harmonize the legal and ethical field surrounding the biomedical use of tissue sample collections.

I began this chapter by taking a closer look at tissue economies and biovalue and linking these concepts to the idea of epistemic cultures in order to highlight the ways in which scientific knowledge production in tissue economies is related to the creation of value through a transformative process. I identified three different types of biovalue which have emerged from the research material. I then examined the main theoretical aspects surrounding the status of tissues in tissue economies: namely tissues as gifts, property, waste and information. I have argued that the gift cycle that has been a predominant model in the work of Titmuss (1970), for example, is inadequate to characterize the multitude of ways in which tissues are collected, stored and used today. The use of informed consent as a process of transforming tissues into property was also shown to be an inadequate model of disentangling samples from their source since tissues are acquired through several other means which do not rely on consent procedures. I also discussed the significance that tissues as waste serves in articulating narratives of efficiency within the use of tissue sample collections. The concept of waste serves as a normative perspective in mobilizing tissue samples for scientific knowledge production. Finally, I looked at the way in which

tissue economies extend into forms of information. The concept of the informational turn was suggested as marking an important turning point in the biomedical sciences when the production of scientific knowledge emerged as an increasingly important political aspiration since it is also seen to serve as the basis for economic development.

From these discussions it is important to look at the way in which tissue use is framed within the policy and legal contexts. In the following section I will look at the way in which interpretations of the scope of informed consent has changed and relate this to the policy discourse surrounding the biomedical use of human tissue sample collections. Interests related to privacy, autonomy and informed consent are increasingly weighed against social and scientific interests. These social and scientific interests are, in turn, defined through policy discourse and narratives which are increasingly permeated by commercial aspirations and expectations. This discussion is an important element in the way research resources are organized and thus provides the basis for the ways in which tissue economies are developing in Finland.

4
POLICY, LAWS AND TISSUE COLLECTIONS

In the previous section I discussed how gifts of tissue have been traditionally seen as the basis of exchange in the acquisition of human tissues and how other models of acquisition and collection operate alongside these traditional forms. From a policy perspective on scientific knowledge production, however, the role of knowledge from human tissues is seen to play an important role in maintaining and building social solidarity and cohesion because the research and knowledge that it produces is seen to legitimate public expenditure into scientific research and build trust between science and the public. Increasingly, social cohesion and solidarity among citizens is seen, from a policy perspective, to be based on economic development and commercial prospects which rely on the development and maintenance of a common vision of the future. The rhetorical texts that are deployed to support these beliefs help to formalize social relations between different actors, particularly those of donors and users of samples.

In this section, I will present a major axis of discussion on the scope of informed consent and the use and collection of tissue samples. This discussion is first, however, set amidst policy discourse on the knowledge-based economy and knowledge-based bio-economy as they have become pervasive terms influencing the role of scientific knowledge production in economic development (cf. Birch, 2006). The interpretation of the scope of informed consent is seen as the major challenge in the collection, as well as re-use of existing samples, in biomedical research – and thus a challenge to economic development – and can also be seen as the basis of social interaction in the acquisition of samples. It also reflects, however, the introduction of political aspirations and interests into legal formulations surrounding the extent to which individuals can control and influence the way personal information derived from them can be used by others. These political aspirations are normative in nature and thus represent the introduction of normative assertions

into legislation on the biomedical use of human tissue collections. These interpretations also touch on central aspects of privacy and autonomy in Europe.

The Politics of Knowledge Production

> "Life sciences and biotechnology are widely recognized to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies."
> (European Commission, 2002a: 7)

I have discussed how the informational turn reflected the way in which tissue samples and the information that can be gained from them has become an important feature in producing scientific knowledge from biobanks. Indeed it is a central aspect of how resource relationships are being organized in epistemic cultures. The informational turn has concomitantly been paralleled with a political interest in the way scientific knowledge is managed and translated into economic gains. As a result, it is also possible to identify the emergence of policy discourses which specifically focus on the productive capacity of scientific knowledge. The identification of such discourses is important in that they enter and configure in the arguments behind new laws and statements on the biomedical use of tissue sample collections and help to formalize the normative assumptions and basis of tissue acquisition and circulation. It is, therefore, important to look at the main policy discourses on knowledge production and then move on to a closer examination of the way they relate to interpretations of informed consent.

After the mid-1990s, the Finnish Science and Technology Policy Council (1996) began to incorporate the idea of knowledge-based economy into its policy framework where the production of scientific knowledge became a central component of economic development. This concept was 'imported' from international organizations, such as the Organization for Economic Co-operation and Development (OECD)[14], as well as European policies (see for example European Commission, 2002a). According to the OECD (1996: 3), knowledge-based economies are 'economies which are directly based on the production, distribution and use of knowledge and information.' Economic development was, therefore according to these policies, no longer primarily based on the use and refinement of raw materials such as wood and steel, but was becoming increasingly dependant on the development of new ideas and innovations, which required investment into research and development.

The idea of knowledge-based economy has been extended even further in relation to biotechnology, where new research intensive areas have been seen as the basis of new commercial activities. The OECD has defined the bioeconomy 'as that part of the economic

[14] According to Godin (2006: 23) 'the OECD is a think tank, not an advocacy think-tank looking for media exposure, but a research think-tank that feeds policy makers.' It uses two strategies to disseminate its ideas: institutional (conferences, books, committees etc…) and rhetorical (packaging ideas into conceptual frameworks and creating buzzwords).

activities which captures the latent value in biological processes and renewable bioresources to produce improved health and sustainable growth and development' (OECD, 2005: 9). The bioeconomy, however, differs, according to the OECD from other technologies in that

> "Most biotechnologies involve the human element in development, production, and consumption. […] Individual and societal values will play an important role in decisions as to which technologies are explored and exploited. Public opinion will be a key determinant in this innovation wave (security, safety, privacy, ethics)."
> (OECD, 2005: 5)

Here we see how at a policy level, economic development in biotechnology is linked with public and individual values and the way in which public opinion is seen to have a bearing on acceptance. Individual and social values are identified as key determinants of technological research. The human element is considered to play a role though-out the process, from development to consumption. This policy discourse of public and individual input into science policies plays an important role in many supra-national policies involving biotechnology and reflects a more general interest in involving the public in decision-making (see European Commission, 2007a). What the reference does not do, however, is identify the means by which these values are determined or measured.

Since the 1980s, policies have also been looking at the commercial successes and expectations associated with biotechnology as a whole. For example, in an early OECD report it was noted that 'already some of the greatest successes of new biotechnology are tied to the commercial introduction of the growing number of immunodiagnostic tests based on monoclonal antibodies, biosensors and gene probes' (OECD, 1989: 65). The interests between individuals, the public and the commercial expectations related to biotechnology have, therefore, been explicit in science policies and have become even more pronounced in more recent policy documents on biotechnology. For example, in its life science and biotechnology strategy, the European Commission noted:

> "The potential of life sciences and biotechnology is being exploited at an accelerating rate and is likely to engender a new economy with the creation of wealth and skilled jobs. […] Some estimates suggest that by 2005 the European biotechnology market could be worth over EUR 100 billion. By the end of the decade, global markets, including sectors where life sciences and biotechnology constitute a major portion of the new technology applied, could amount to over EUR 200 billion. […] But to manage this development, to give us options, to project our values and policy choices internationally, and to reap the benefits of a new emerging economy, Europe should also command the knowledge base and its transformation into new products, processes and services."
> (European Commission, 2002a: 12)

The above quotation from the European Commission policy on life science and biotechnology is interesting for several reasons. *First*, it suggests that those sciences related to life science and biotechnology will give rise to a new economy. This new economy is in later policy documents defined or categorized as the bioeconomy or the knowledge-based bio-economy. Therefore, the statement is future-oriented by containing a vision of what is expected. *Second*, in contrast to the previous OECD quotation which discusses already achieved benefits, the policy document employs this forward looking predictive strategy to estimate the future commercial value produced by the life sciences and biotechnology. Here we see how expectations of potentialities are expressed within policy documents to motivate and enrol readers into this policy and strategy, even though there is little evidence to support such claims. Furthermore, biovalue is defined in commercial terms. *Third*, the development of the new economy, as it is referred to, is based on the management and projections of 'our' values in relation to the transformation of the knowledge base into new products and services. In the previous reference it was noted that public and individual values serve as the basis of decision making, whereas here, values are already defined collectively by policy makers themselves. The clarification of what these values are, however, remains unclear. The predictive stance taken in the policy document emphasises the *potential*, rather than actual, commercial biovalue that will be created from biotechnology. Such policies can be said to be based on expectations. The passage also constitutes a social relation that is based on the productive capacity of biotechnology and its direct link to knowledge.

It is not surprising, however, that other policy labels have been developed in relation to biotechnology and economic development. For example, the knowledge-based bio-economy (KBBE) (European Commission, 2005) has more recently been put forward as a new policy rubric under which the economic, social and environmental potential can be reached through a more focused policy agenda. As such, there are connections between tissue economies and biovalue in relation to the idea of a knowledge-based bio-economy. It is difficult to ascertain whether the knowledge-based bio-economy represents anything new or whether it is merely a policy term used to organize disparate activities in different sub-fields, such as plant biology and biomedicine. There are also questions as to its relevance as a new economy at all, since many of the industries which utilize such technologies have existed before such policy rubrics. Despite such uncertainties, these policy discourses are reflected in R&D investments, which serve as an engine for the production of scientific knowledge.

The identification of biotechnology and its related economic activities as forming a new analytical object can also be related to scientific knowledge production using human tissue sample collections in that it identifies the broader impact that tissue collections and the knowledge gained from them are thought to have in relation to national economies (see OECD, 2006). It is here that we can see an important connection emerging between tissue economies and epistemic cultures and the possibilities that are seen from a policy perspective in capturing biovalue from research.

In line with the idea that the production of knowledge and information is an important element in the development of new industries, Finland began to increase the share of its GDP into public R&D during the mid-1990s in the hope that the strategy to produce scientific knowledge would help to further economic development through new commercial opportunities and innovations. The role of the Science and Technology Policy Council in bringing together representatives from the government, important ministries, such as the Ministry of Trade and Industry and Ministry of Education, as well as industry and labour organizations has been important because it serves as a conduit through which policy is channelled (Pelkonen, 2006) and also entails the enrolment of support from different actors.

Since the mid-1990s, Finland invested heavily into developing emerging technology areas, such as biotechnology, in the hopes that this will foster the formation of new high-tech industries. In 2006, Finland invested 3.41% of its GDP into R&D (Tilastokeskus, 2007). This follows an increased interest in the outputs and impact of research investments (Husso, 2001) and follows a similar approach which was taken with the information and communication technology sector (see Pelkonen, 2003a). In addition, a number of measures and strategies were undertaken to develop the role of universities as sources of new innovations (Ministry of Education, 1998; Ministry of Trade and Industry, 2002), including changes in the intellectual property legislation that has governed university research (see Opetusministeriö, 1998), as well as directing research funding towards critical areas, such as biotechnology. Allardt (1998; 1995) has noted how innovation and technology policy rhetoric have spilled over into other Finnish policy areas, particularly science policy. Such spillage has helped to increase the influence of innovation policy over others.

The problem of translating knowledge production into commercial successes is, however, a major challenge to assumptions that are written into policy documents on the role of biotechnology in economic development (see Kivinen and Varelius, 2003: 159; 2000; Tupasela, 2006c; 2000a). Despite such problems, biomedical research is still seen as a major source of new innovations and commercial opportunity. Within this context, the analysis of the biomedical use of human tissue sample collections in Finland has been fruitful for a number of reasons. *First*, unlike many other countries, the role of the Finnish public in biomedical research has been somewhat limited (Tupasela, 2007a; Järvi, 2006; Häyrinen-Alestalo and Snell, 2004), at least in its role in developing and influencing policy decisions. Some have noted that in part this can be explained by the strong role that corporatist modes of governance have played in the Finnish decision-making process, which have integrated major actors, but left out others, such as the public (Häyrinen-Alestalo *et al*., 2005; Helander and Anckar, 1983).

Second, it has been suggested that Finnish government officials and policy formulations perceive the role of the Finnish public and its engagement in a different light in comparison to the EU. For example, it has been noted that official policy documents in Finland ascribe the role of the public as more passive than in EU documents, which reflects the perception that officials understand the public to be receivers of guidance, as opposed

to drivers of change and decision making (Snell, 2002).

Third, Kettunen (2001: 232) has noted that unlike other Nordic welfare countries, such as Sweden, the dominant strategy in Finland has been to depoliticize social policies, whereby social reforms and policy decisions have been discussed as functional needs requiring pragmatic steps. This has tended to restrict the domain of public discussion and conflict between different actors. In terms of the development of knowledge economies and the significance of human tissue collections, the issues have been framed more in terms of practical steps that can be taken by government officials and legislators to facilitate biomedical research and the benefits that it is seen to provide in the future, both in terms of healthcare and commercial development. Interestingly though, this strategy would seem to contradict recent national and international initiatives to increase the participation of citizens in the political decision-making process. In a similar vein, Miettinen (2002: 76) has argued that, in relation to the homogeneous rhetorical language of Finnish science and technology policy that surrounded the emergence and development of the Finnish national innovation system during the 1990s, there was a lack of discussion surrounding political alternatives. This, according to Miettinen, gave rise to a kind official world view, where the success of the country's economic development was closely tied to the development of technology. Given that current supra-national policies emphasize the role of engagement and dialogue with the public concerning policy issues, the Finnish approach appears to represent somewhat of an anomalous approach to the formulation of science policy.

In the following sections, I will examine the relationship between policies relating to science and technology on the one hand, and discussions relating to the scope of informed consent and autonomy in biomedical research involving human tissue samples on the other. This discussion highlights many of the tensions surrounding the relationship between the role of the individual and the samples taken from them in relation to the interests of science and society. The interpretations that are afforded informed consent reflect to a great extent the relationship that exists between notions of individual rights, on the one hand, and social interests on the other. These social interests, in turn, are gauged through public engagement and discussions.

Individual Rights in Science and Society

> *"The biggest challenge has been with informed consent because in the majority of these large longitudinal studies the samples have been collected already in the 1980s when there were no guidelines for what people were giving their samples for and in what ways the samples could be re-used."*
> (Interview with member of The National Advisory Board of Healthcare Ethics, 2003).

From a science and technology policy perspective, legal and ethical formulations and texts are significant in relation to informed consent because legislation and ethical guidelines

are an important mechanism through which state and social interests are enacted both on the public and private arenas of technological development. Legislation and ethical guidelines represent an effective codified form of social control in which explicit limits are placed on possible forms of action. At the same time, however, legislation and ethical guidelines can serve as a conduit through which interests can be effectively protected and legitimated. Therefore, these documents not only have a forbidding component, but a consenting component as well.

As new technologies develop within certain areas, such as genetics, there invariably rises a need to organize activities in a way that is considered generally acceptable and efficient. At the same time, however, this process can raise criticism as to the ways in which resources are made available and regulated. The role of informed consent plays a fundamental role in the medical, legal and ethical traditions and is considered a cornerstone in research involving human subjects (Helgesson *et al.*, 2005). The World Medical Associations' (WMA) *Declaration of Helsinki* is perhaps one of the most definitive medical documents that sets forth the principle of informed consent and the rights of the patient in relation to medical research (World Medical Association, 2002).

As Carlson *et al.* (2004) have noted however, the cornerstone of medical ethics itself is not without its controversies and poses several challenges in the way the text can be interpreted. Although relatively short, during the past 40 years, from when it was originally written in 1964, the text itself has grown from about 700 words to almost 2000. This increase reflects the need for clarification, as well as the need to introduce new aspects that the WMA has seen as important in protecting. In its 2000 revision, for example, paragraph 21 has been explicitly modified to include the protection and confidentiality of information concerning the patient (Carlson *et al.*, 2004: 704). This indicates that what is at issue with protecting the patient can also be extended into information on the patient as well. As one of the authors of the 2000 version of the declaration noted in an interview:

> *"It [Declaration of Helsinki] has changed quite a bit when you think that it started in 1947 from the Nürenberg code to the 1948 Geneva Declaration and then to the Helsinki document. Until then you only spoke of the individual, the living individual. Since then our discussions have been permeated with issues relating to the rights of the fetus, research on the fetus, then fertilized eggs to the acquisition and sale of eggs and sperm. Finally we have new concerns over tissue trade and commerce, where whenever a mole is removed it can be preserved in a tissue bank.*
>
> *We used to have a concept called anonymity and you could attach a number to a patient file where there was no name or social security number and it was considered anonymous unless there was a coding scheme. Now that genetics has advanced so much we know that you can identify someone on the basis of DNA in hair or a cell and so we have arrived at data protection. You can see*

> *in the 2000 declaration that we have added identifiable human tissue which is quite a huge change and this is what we've been accused of in that some feel that the idea of protecting the living individual has gone too far because now we are also trying to protect information."*
> (Interview with WMA official, 2003)

The interview quotation reflects the tensions which have arisen through attempts to protect new areas related to personal privacy and genetic information. Such tensions also give rise to narratives related to evaluating the relationship of the individual within the broader context of social interests. The excerpt indicates the way in which the protection of DNA, alongside the protection of human beings taking part in research, has been seen as controversial and reflects the question of whether this has gone too far in interpreting personal rights. Yet it is clear that the question of the relationship between the individual and the information that can be gained from them through DNA has emerged as a pivotal point which is at stake in the interpretation of consent, personal privacy and issues of autonomy.

The narratives related to personal rights also provide a good example for comparing science and technology policy and laws, in that legal and policy documents draw on each other for reference and context. What is important to note, however, is the ways in which legal documents are increasingly drawing on narratives in policy documents related to the knowledge-based economy. These documents, however, tend to be imbued with normative assumptions on the role of scientific knowledge in society.

Although the Declaration of Helsinki is seen as a cornerstone of medical research practice, more recently a number of other international organisations have elaborated their own guidelines for biomedical research and the biomedical use of human tissue sample collections in light of the technological advancements in the field and provide good examples for comparison. Some of the most notable examples are the Council for International Organizations of Medical Sciences' (CIOMS) *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (2002) and UNESCO's *Universal Declaration on the Human Genome and Human Rights* (1997). These documents serve as the foundation on which national legislation concerning biomedical research is founded, but also reflect emerging policy concerns in scientific knowledge production.

The starting point for these legal documents and ethical statements is the primacy of the individual and the respect for their rights. In the following we can see four notable examples drawn from international documents on research practices involving human research subjects:

> "…considerations related to the well-being of the human subject should take precedence over the interests of science and society."
> (World Medical Association, 2002: Article 5)

> "The interests and welfare of the human being shall prevail over the sole interests of society and science."
> (Council of Europe, 1997: Article 2)

> "…respect for autonomy, which requires that those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination…"
> (CIOMS, 2002: 10)

> "The interests and welfare of the human being whose biological materials are used in research shall prevail over the sole interests of society or science."
> (Council of Europe, 2006: preamble)

Besides drawing attention to the fact that the primacy of the individual should be respected in relation to decisions on their well being and interests, the above citations establish a relationship between the interests of the individual, on the one hand, to those of science and society on the other. The statements tend to refer to these interests as counterpoints to one another, as if they could be separated from one another; the individual and their rights, therefore, stand outside and above the interests of science and society. The important point remaining within these documents, however, is that social and scientific interests should not prevail over those of the individual. It should be noted, however, that the World Medical Association's statement remains more general, stating that what is at the heart of research involving human subjects is their 'well being' rather than their interests alone. This is somewhat different from the other statements which include individual interests as also being important in considering the individual's relationship with medical research and thus science and society.

As discussed above, the legal process through which the interests and autonomy of the patient or the research subject is gauged has been the act of informed consent, which is also a contractual agreement and an important form of engagement. The act of donation, gift-giving and altruism (Titmuss, 1970) has been seen as an integral part of this contractual process, which also constitutes an economic exchange (Arrow, 1972). This process, according to Waldby and Mitchell (2006: 71), not only serves the function of gaining the permission of the research subject to participate, but also 'formalizes the transfer of possession from donor to recipient.' What is at stake, therefore, is the acquisition of ownership rights to the samples through a contractual procedure. This is significant in relation to the organization of resource relationships in biomedical research, in that legal texts also highlight how biological materials should not give rise to financial gain on the part of the donor.

The Council of Europe's (2006: Art. 7) recommendation on research on biological materials of human origin, for example, states that 'biological materials should not, as such, give rise to financial gain.' This is also similarly stated in the Council of Europe's

(1997: Art 21) *Convention on Human Rights and Biomedicine* and UNESCO's declaration on the *Human Genome and Human Rights* which states that 'the human genome in its natural state shall not give rise to financial gains' (UNESCO, 1997: Art. 4). The CIOMS ethical guidelines go even further, stating that 'payments or rewards that undermine a person's capacity to exercise free choice invalidate consent' (CIOMS, 2002: 29). Here it is argued that payment would distort a person's ability to exercise free choice. This argument makes a strong normative claim in relation to the role of commercial payment in undermining one's ability to make free choices, but also brings under question the relationship between financial gain and personal choice by placing the profit motive in relation to one's own body under question. Such a position is also interesting in relation to Waldby and Mitchell's (2006) point of informed consent formalizing the transfer of possession, in that financial reward, other than small, acceptable re-compensations according to CIOMS, would serve to invalidate the transfer process altogether. The CIOMS position highlights the gift giving and altruistic nature of the donation process itself and the way in which financial exchange is excluded from such resource acquisitions. Gift-giving, therefore, should be based on a non-commercial transaction, which nonetheless results in proprietorship being given to those who are seeking to acquire the sample (cf. Frow, 1997). The transfer of ownership or proprietary rights would also appear to indicate the relinquishment of control over these donations.

This position can, however, be contrasted to that taken by a report by the World Health Organization which makes the following statement on the nature of individual claims to body parts:

> "Body samples, and the information derived from them, represent two of the most intimate aspects of ourselves. Accordingly, we have a very strong claim to control these elements and their uses. Indeed, in ethical terms, that claim is akin to a property right, in that the primary control should always remain with the individuals who can stake a claim to samples or the information generated from them. It should be irrelevant where, or how, these elements are gathered or stored."
> (World Health Organization, 2003: 3.1)

Here we see a position being taken where we are seen to have property rights in ourselves, as well as a strong interest and right in determining how our body parts and the information gained from them are used. Having property rights in ones body, however, is contrary to what was highlighted in the case of John Moore which I discussed earlier, where the point of the United States Supreme Court was precisely that we cannot make property claims to our samples once they have been removed from our body, noting that this would undermine the ability of the scientific research establishment to acquire tissue samples in the future. What is at question then, at least in the Moore case, is setting up a system of resource acquisition which places as little expense or cost on the acquisition of

samples while allowing for commercial gain to be made from them in the future through innovations. This acquisition scheme, however, is set amidst the normative language of non-commercialized gift giving and donation. Yet as the WHO report notes, individuals can stake claims to samples and information generated from them.

The WHO report is interesting in another aspect also, in that it brings forth an important element which similar reports, legal documents and ethical statements make concerning the interests of individuals in relation to those of science and society. As I mentioned above, the starting point to all such documents is the primacy of the individual in relation to science and society. This primacy, however, appears to be a relative one, in that individuals are also seen to have obligations towards science and society. The WHO report, for example, approaches this issue in the following way in relation to genetic databases:

> "The value of databases derives from the collective nature of their data. Often, the prospect of direct individual benefit is minimal. Thus, the justification for a database is more likely to be grounded in communal value, and less on individual gain. And, while this is not to say that individual protection should be ignored, it leads to the question whether the individual can remain of paramount importance in this context."
> (World Health Organization, 2003: 2.3)

A similar approach is also employed by UNESCO in its declaration, where it states:

> "In order to protect human rights and fundamental freedoms, limitations to the principles of consent and confidentiality may only be prescribed by law, for compelling reasons…"
> (UNESCO, 1997: Art. 9)

Here we see an interesting policy narrative which brings forth both the notion of 'communal values' and 'compelling reasons' for re-interpreting the primacy of the individual in informed consent. The first excerpt frames the decision to donate or participate in relation to direct personal benefit and positions them in relation to what it calls 'communal values'. What these communal values are remains, however, unclear and undefined. At the same time, the notion of the primacy of the individual is also brought under question in relation to these communal values. It could be argued here that communal values represent interests of science and society, which as we saw earlier should never take precedence over those of the interests of the individual.

The second excerpt introduces the idea of compelling reasons into interpretations of rights, but once again leaves it open as to what such reasons or the criteria for their evaluation might be. Such contradictions in the relationship between the primacy of the individual and the interests of science and society (communal values and compelling

reasons) are a common thread in other legal documents and declarations as well and represent a common tension in the discourses surrounding tissue economies. This reflects the tension in the power relations between the rights of the individual and the interests of science and society. The Council of Europe, for example, in its recommendation on research on biological materials of human origin, frames this balance between interests in terms of risks and benefits:

> "The risks for the persons concerned and, where appropriate, for their family, related to research activities, in particular the risks to private life, should be minimised, taking into account the nature of the research activity. Furthermore, those risks should not be disproportionate to the potential benefit of the research activities."
> (Council of Europe, 2006: Art. 5.1)

This risk discourse, however, is very different from the statement of the primacy of the individual because it too allows for interpretations of risks and talks about their minimization. The text discusses the question of 'proportionate risk' in the relationship between risks and benefits. This textual approach creates a discursive space for discussions of potential benefits, which, due to their nature, reflect expectations and hopes. Since such expectations and hopes in relation to potential benefits are impossible to measure, such wordings in legal texts also, in effect, create the possibility of introducing normative positions, as well as legal ambiguity, into legal documents.

Such textual tactics in legal documents and other statements and declarations help to introduce re-interpretations of the scope of informed consent, as it applies to the biomedical use of human tissue sample collections. Although the issue of re-interpretation and the creation of clauses for broader use can be understood in the context of the changing possibilities which are offered in terms of the development of new technological possibilities, my criticism relates to the way in which this process allows for the introduction of normative political ideologies related to, in this case, the role of scientific knowledge production in economic development. Such discursive tactics, however, introduce a tension between political expectations and the rights of individuals to control their personal and private information and sets up ambiguities between different legal and ethical documents as to the status of samples and individual rights. It also highlights the ways in which tissue economies are entwined within the legal and political frameworks which govern them. Since these political expectations are based on potentialities as well, this also further complicates the function and role of laws as protective instruments against over-optimistic generalizations in science and technology policies. Given such overt penetration of expectations into legal and ethical statements it is important to examine which elements of policy narratives have been allowed to enter and contribute to these texts.

In the next section I will look at the governance of scientific knowledge production and discourses of social cohesion to identify how certain elements within these discourses

have entered into legal and ethical documents pertaining to informed consent. This will help to further highlight the interdependence that has developed between narratives of social cohesion and solidarity in science and technology policies (cf. Berking, 1999), on the one hand, and rights of individuals in legal and ethical documents on the other.

Engagement and Moral Imperatives

> "Science activities need to centre around the needs and aspirations of Europe's citizens to a greater extent than at the present."
> (European Commission, 2002b: 7)

For European science and technology policy, the fostering of conditions under which scientific knowledge can be better exploited has meant the development of policies which foster a closer dialogue between science and society (European Commission, 2002b). Nowotny *et al*. (2001: 54) have described this as creating social conditions that allow, and necessitate, that 'society is able to 'speak back' to science.' As a recent European Commission report noted 'the bioeconomy is complex. It involves different sciences and technologies, different industries, and different policy areas. Achieving a common vision among such a diversity of stakeholders is no easy task' (European Commission, 2005: 1). The dialogue between science and society is seen as an important element in legitimating scientific research, but is also seen as the basis of creating a common vision for science and technology policies. In relation to re-interpreting the scope of informed consent it is also necessary and important to have dialogue in order to legitimate such activities.

Indeed, the opening up of policy making to make it more responsive to the concerns of a wider set of actors, including the public, has been one of the main goals of European governance in an attempt to develop a shared vision (European Commission, 2002b). As it was noted in a recent European Commission report on the knowledge-based bio-economy 'a coherent research strategy for the future must be developed based upon the shared vision of the diverse stakeholders' (European Commission, 2005: 10). This shared vision is achieved through increased engagement in issues related to science and society, but also through the introduction of normative assumptions as they relate to human tissue samples into policy and legal texts.

To illustrate this, several examples can be drawn from recent policy documents relating to biobanking. In a recent policy document on the creation and governance of human genetic research databases, the OECD has noted that:

> "Public engagement in the development of such databases is essential for ensuring their viability as well as community support for and participation in such undertakings."
> (OECD, 2006: 131)

The OECD report draws a relationship between public engagement, community support and the creation of databases, noting that research activities are indeed dependent on the participation of the public in order to establish and maintain such databases. Here we see a further element that relates to informed consent. If the public cannot be encouraged to participate in research, then there is no possibility of gaining informed consent from them in the first place, which as we discussed serves as the basis for the exchange of ownership rights to samples and information and also represents a central element of engagement at the personal level. At the same time, however, the supply of tissue samples is undermined. For this reason, the relationship between public engagement in science and technology policies, in general, and informed consent, in particular, is important, in that trust is a necessary condition in order for informed consent to be gained (cf. Hansson, 2005).

The Human Genome Organization (HUGO), which is an international organization of scientists involved in human genetics, has also made a similar claim in their *Statement on Human Genomic Databases*:

> "Public engagement is a prerequisite for public responsibility."
> (HUGO, 2002: Rec. 2a)

Here the statement is framed more in terms of the research scientists' responsibility towards the public and how this responsibility entails public engagement. The underlying argument here too is that research using biobanks cannot take place without public engagement. HUGO's position is also important to note in that it has maintained consistently that the 'human genome is part of the common heritage of humanity' and that 'human genomic databases are global public goods' (HUGO, 2002). This position is important in developing a common interest between the public and research in that it defines genomic databases as public goods. This position can be said to complicate the idea that informed consent serves as a contractual agreement that transfers ownership rights of tissues from donor to researcher as suggested by Waldby and Mitchell (2006) in that if human genomic databases are public resources one cannot lay individual or private claim to them. This would also further appear to complicate the idea of tissues and the genomic data that can be derived from them as forms of property. Indeed, the question of ownership of genomic databases is something that the OECD (2006: 61) has recognized as remaining unresolved in terms of issues of ownership and commercialization, noting that there is a tension between free public access and commercial exploitation. Given this dilemma, the OECD recommends that:

> "the public should be meaningfully engaged at both the design stage and throughout the life of the project. […] it should be viewed as a means of creating an ongoing and informed dialogue about the research project's benefits and risks, including a balancing of the possible scientific and health outcomes against privacy concerns."
> (OECD, 2006: 133)

This statement is interesting for a number of reasons. *First*, the excerpt highlights that biobanking requires an *ongoing* dialogue with the public which takes place at different stages of the projects, not just at its inception. This goes even further than measuring acceptance levels at a given point in time. *Second*, the question of balancing risks and benefits is also brought up here in relation to the possible benefits of the outcomes in relation to privacy concerns. Here we see how societal interests become linked with public engagement. *Third*, the biovalue of the research is seen in terms of scientific and health value as opposed to commercial value, despite the fact that it is commercial value which these collections are expected and hoped to produce. Here we also see how tissue economies and their knowledge production are closely entwined with public dialogue and acceptance which establishes the social nature of tissue acquisition.

In a similar vein, the European Commission has noted that:

> "If citizens and civil society are to become partners in the debate on science, technology and innovation in general and on the creation of the European Research Area in particular, it is not enough to simply keep them informed. They must also be given the opportunity to express their views in the appropriate bodies."
> (European Commission, 2002b: 17)

Here again, the notion of continued engagement is emphasised in contrast to simply informing the public of what is being done. Scientific knowledge production is characterized as a partnership. Public engagement has, however in my opinion, implicit implications in legitimating scientific research and knowledge production by allowing citizens to express their views and concerns. Engagement also helps to solidify a quasi-reciprocal relationship between citizens and science and technology policies and is used to introduce implicit assumptions on the responsibilities of citizens. I say that this relationship is quasi-reciprocal in that the notions of responsibilities and duties ascribed to citizens by policy and law makers are morally and normatively prescriptive. That is to say that the duties of the citizen to act and behave in certain ways are defined by policy makers themselves, as opposed to emerging through a common dialogue.

Engagement also serves another important function in relation to informed consent, in that in situations where informed consent or re-gaining it is discarded as a practice, such forms of engagement serve an important legitimating function. Although informed consent is a contractual process between individuals, doing away with it requires some form of other engagement. In this sense, social interests are gauged through public engagement.

In relation to genetic information and the obligations citizens have, this is seen in several documents. For example, the World Health Organization has framed this in the following way:

> "The generation of genetic information gives rise to both rights and responsibilities. There can be much value in genetic information beyond that which it

> represents to the individual to whom it relates. […] several public interests can be furthered by the judicious use of such information. […] an ethical case can be made that we each have a moral imperative to share our genetic information if some, or any, of these ends can be furthered. Thus duties might be owed to (i) the community, (ii) certain institutions acting in the public interest, or (iii) one's own family."
> (World Health Organization, 2003: 3.2) (italics added)

Here the role of biovalue is considered in relation to the individual and the public, once again bringing under question the primacy of the individual. The statement is also significant in that it goes even further by introducing a moral imperative that each individual has to share their genetic information if certain ends can be met. The statement even goes on to indicate that citizens have duties towards the community, institutions acting in the public interest and ones own family. This excerpt carries with it a strong normative and moral message of the role of the individual in relation to science and society, in that it obligates one towards the needs of broader interests. It would also appear to contradict the dichotomy between individual and social interests as set out in many of the legal documents I discussed above. Once again, however, it remains highly unclear what those interests are and who defines them. In this context, tissue economies become morally obligating systems of exchange and acquisition since individual rights are contrasted in relation to public interests. This narrative discourse is very different in relation to that which emphasises the rights of the individual in relation to the interests of science and society. It also indicates the variance and distribution of perspectives among international organizations in relation to the role and rights of the individual when contextualized and contrasted to those of society.

The idea that individuals are given moral imperatives in relation to interests of science and society is interesting in that it reflects the penetration of implicit assumptions contained within policy documents dealing with knowledge production. Within policy documents, the production of scientific knowledge is seen as the basis for social solidarity and cohesion within society. This indeed is one of the basic tenets of the Lisbon Agenda (see European Commission, 2007a). For example, in a European Commission document on the knowledge-based bio-economy it is stated that:

> "The knowledge-based bio-economy will help us preserve and protect Europe's coveted social solidarity and cohesion model by contributing to the creation of the necessary resources to sustain it."
> (European Commission, 2005: 8)

Here we can see how economies that are related to the production of knowledge from biotechnology are linked to social solidarity and cohesion. In this sense, the argument can also be extended to the use of human tissue sample collections and economic development.

According to the logic of these arguments, tissue economies serve to regulate both, social cohesion, as well as help to contribute to economic development in that the tissue samples and the information gained from them can be used to further the possibilities of economic development. This normative stance on the role of economic development and tissue economies can be seen in the way donation is characterized as a form of solidarity. Here we return to Titmuss' (1970) notion of gift giving and non-commercialized forms of exchange serving as the basis for social solidarity, an argument that has been shown to be problematic (Arrow, 1972; Douglas, 1990). In their recommendation on research on biological materials of human origin the Council of Europe (2006) notes that:

> "Considering that progress in medical and biological sciences, in particular advances obtained through biomedical research, including research using biological materials donated in a spirit of solidarity, contributes to saving lives and improving their quality."
> (Council of Europe, 2006: Preamble)

The phrase I want to highlight in this passage – 'donated in a spirit of solidarity' – is important in that it seeks to emphasize a common solidarity among those who have donated the tissue samples, those who decide on how they shall be used and those who will be able to capitalize commercially from them. The notion of solidarity is a powerful linguistic and normative tool that is used in this document on the biomedical use of tissue sample collections in that it makes an assumption that donation is premised on a spirit of solidarity despite the fact that individuals have many different reasons for donating and participating in research (cf. Haimes and Whong-Barr, 2004b). More importantly, there is also an implicit element in evoking the idea of a spirit of solidarity which opens up the possibility for the broader use of tissue collections if certain scientific and public interests are met. Here again, we can see how public interests are being positioned in relation to personal rights and interests, except that here it is done within the context of evoking a spirit of social solidarity. It should be noted, however, that the donation of these gifts is not related or discussed in relation to the property rights which they are also thought to convey to those who receive them.

What makes such normative statements of interest in terms of our analysis of tissue economies is that they have also been entered into legal documents pertaining to biobanking and tissue collection. Here we see how, political ideologies penetrate, not only ethical statements and declarations related to human tissue, but also the legal discourse surrounding tissue donation and acquisition. This raises a fundamental question relating to the status of such legal documents as representing a balanced account of various rights. An example of this can be found in the Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells. The directive is interesting in that it extends the scope of standardization and

harmonization of regulation concerning the biomedical collection, storage and distribution of human tissues and cells beyond technical facts and chooses to make normative claims on the status of donated tissues. In its preamble the directive notes that:

> "As a matter of principle, tissue and cell application programmes should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development."
> (Directive of the European Parliament and of the Council, 2004: 48)

The statement is important for a number of reasons. *First*, it evokes the idea of altruism in donation and further supports this by claiming solidarity, as the basis for this, between donor and recipient. This altruism in donation is limited, however, in relation to the industrial use of tissue samples, in that reciprocity is not expected from industrially manufactured products since they fall outside the scope of the directive (see preamble section 6 of the directive). It is also unclear what solidarity from the recipient entails. *Second*, the directive maintains that tissue collection activities should be encouraged to be managed within a public and non-profit sector, even though the industrial sector is seen as a major beneficiary of this tissue supply. Once again then, altruism is operationalized in an attempt to maintain a safe and secure supply of tissue samples to the public and private sector. *Third*, the statement essentially refers to the setting up, maintenance and organization of a resource relationship between the source and user of tissue samples. This relationship, however, is done within the normative context of altruism and solidarity which is one-sided since commercial interests are driven by private profit incentives and not reciprocation or altruism.

Similar discursive tactics have also been used in other policy areas. In a recent report on the knowledge society, it has been noted that such practices of introducing norms into laws, as well as their enactment in various policy discourses can be described as a form of politics of values, where the goal is to 'evoke society without involving it' and 'to control citizens' behaviour and even to allow direct intervention into their bodies, and to exempt the market from ethical criticism and debate' (European Commission, 2007a: 47). The engagement of the public in the development of science policy can be contrasted to the normative stance which is prescribed in policy and legal documents on the conditions and premises for human tissue acquisition. In this sense, such attempts to engage the public are already delimited and framed within a narrative that has been developed to ensure a steady and uninterrupted flow of tissue resources to the research system.

The reciprocating element on behalf of society and science is located increasingly, however, within the commercial gains and economic progress that such a system of acquisition system will provide. Yet, as Anderlink and Rothstein (2001) have noted, the commercial

benefits of such an exchange system would accrue mainly to private corporations. The value system which this resource relationship supports, however, attempts to argue that this exchange system is a reciprocal one, which would continue to motivate people to donate and participate. Reflecting on Berking's (1999) suggestion that commercialization may in fact help to create new forms of socialization, it remains unclear whether this policy strategy will have the intended effect.

The introduction of moral imperatives and the employment of the notion of altruism within policy and legal documents within biobanking practices is an indicator of the social significance that they are seen to have in terms of scientific knowledge production. In addition, however, in terms of the discussions on the nature of tissues as gifts, there are also further implications. It would appear from the policy narratives that there is ambiguity as to the legal status of both tissues and biobanks (cf. OECD, 2006) since some discourses relating to tissues highlight the fact that people have property rights in tissues, while others claim there are none. Despite this ambiguity, however, policy discourses and narratives appear to promote and continue to enlist notions of solidarity and altruism despite the fact, that increasingly, the biomedical use of tissue collections are seen to have commercial output. This ambiguity, however, does not appear to have diminished the one-sided expectation that donors act within the context of altruism and solidarity, while similar normative frames are not prescribed to the commercial applications derived from the use of tissues. It appears, therefore, somewhat counterintuitive – given the emphasis that is placed on the primacy of the individual – to apply from a policy and legal perspective such moral and normative imperatives in such a one-sided fashion. This also reflects the changing power relation between the primacy of the individual in relation to the interests of science and society. What emerges as an important element in this tension is the way in which political and commercial expectations come to bear upon the discussions of risks and benefits.

Given this context of policy and legal frameworks it is important to look at how this operates in practice. In the next section I will look at the ways in which the acquisition process related to tissue sample collections has become operationalized within the Finnish legal documents pertaining to tissue sample collections to identify some of the problems that are related to defining the scope of application as it pertains to the collections themselves and the ways in which they have been collected.

New Laws, Old Samples

> "In biobank research the interests of the researcher, the research subject and society are parallel."
> (Sosiaali- ja terveysministeriö, 2007: 13) (own translation)

In 2001, Finland re-wrote its legislation concerning the medical use of human organs and tissue (2001/101), replacing existing legislation that was originally written in 1985. Up

until the 2001 law, the biomedical use of tissues was largely unregulated as a practice in its own right, but rather it was regulated through other laws, such as the Law on Medical Research (986/1999) and the Law on Personal Data (523/1999). Researchers felt that the use of human tissue was becoming such an important activity that there had to be a law in place to regulate such activities more clearly. This was seen as an important measure by many researchers to legitimate their research activities which up until then were regulated by a multitude of different laws that had not been written with tissue banking and its uses in mind.

Although innovation was an important policy goal, there were clear limits as to the degree to which it was considered in revising the new law. When asked about the significance of biotechnology as a new 'national' technology that would replace ICT, one legislator who had prepared the law on tissue use noted:

> *"In addition to the national interest perspective in law-making there was a clear goal of maintaining the human rights perspective and complying with the international agreement on biomedical research, which would guarantee a level of international compliance and standards so that Finland would not become one of these ethics free zones or black holes where you can do more than in other countries. This is a risk in itself and can give you a bad reputation."*
> (Interview with legislator, 2003)

The law, however, drew a great deal of criticism from researchers claiming that it was too restrictive and placed research tissue collections and diagnostic sample collections in a different legal status. There was also no legal categorization or definition of a biobank itself. As a result the Ministry of Health and Social Affairs began to draft a new biobank law for Finland in 2006 which would give researchers a better legal basis for the use and collection of tissues within the legal context of biobanks, as well as clarify the rights of the donor in relation to their samples and personal data (see Sosiaali- ja terveysministeriö, 2007; 2006; Hallituksen Esitys, 2008). With the more recent legislative proposal, commercial and economic interests emerge as important aspects which are considered alongside the human rights issues. Both the existing law and the new proposed law bring forth the complicated nature of old tissue sample collections, collected before the enactment of these laws and the limits of how the samples can be used in present day research in relation to re-gaining consent. In this sense, information gained from tissues becomes problematic and connected to a whole host of other concerns ranging from patient rights to legal interpretations of informed consent, as well as practical issues relating to the possibility of contacting research participants and the potential value of the collections. Besides the interests of researchers to make better use of existing sample collections, a central theme in many of the discussions surrounding this debate has been the benefit the re-use of samples would have for Finns and the national economy (Palotie and Peltonen-Palotie, 2004); the debate is not therefore, just about technicalities, but also has strong political and

economic undercurrents. Notions of efficiency and waste become deployed as important linguistic tactics in mobilizing resources and support. In what follows, I will trace some of the important undercurrent related to regulating tissue collections in Finland.

Within the proposal to the Finnish Parliament on the act on organs and tissues (HE 93/2000), an interesting proposition is made concerning the nature of human tissue samples. According to the proposal

> "Tissue samples can in certain ways be compared to patient records based on the information that they contain. The difference being that with tissue samples the information is in a biological form and the samples unique."
> (HE 93/2000: 29) (own translation)

The preparatory document argued, therefore, that tissue samples are comparable to other patient documents, such as medical histories, and the information that is contained within them. This is an important clarification in that it categorizes tissue samples as objects that can be considered official documents in one sense and, at the same time, moves the question of management squarely into the domain of information management, since documents contain different types of information. Essentially, this line of argumentation exemplifies what Thurtle and Mitchell (2004:1) have noted on the relationship between physical objects and the information they contain: 'bodies and information continually graft themselves onto one another in a number of different cultural domains.' This approach is significant also because it approaches the question of ownership of tissues as physical objects from a different angle altogether. If tissue samples are documents (i.e. forms of patient information) then questions related to their ownership become framed within the context of who has the right to access and manage such information and not that of who has a right to own it. As documents, patients would also have a right to access this information.

This approach, however, has had its limitations since the law also made a distinction between samples taken for research and those samples taken for the purposes of diagnosis and treatment of the patient. According to the legislation, diagnostic samples can be later used for research purposes provided that the research has the approval of an ethics review board and a permit from the National Authority for Medicolegal Affairs. As I have discussed earlier, the re-use of diagnostic samples for research is quite common in biomedical research. Samples that have been taken for the purposes of research, however, are not granted this status (as of yet, although a new law on biobanking is being prepared which would address this issue). Instead, if researchers want to re-use the samples which are identifiable for something other than what they were originally taken for, they must re-gain consent from the donor or make them unidentifiable. Therefore, if personal information is not included (identifiable sample), informed consent is not required of the patient that donated the tissue sample. Instead, permission for using the tissue can be given by the department that originally collected it. According to Martin

and Kaye (2000: 173) 'this has been an accepted research practice for epidemiological research in both the UK and internationally.'

The different status given to samples collected through diagnosis as opposed to research is derived from the purposes of their intended use and whether they have been gifts or not. In reference to diagnostic samples, the explanatory text states

> "Within the scope of this law, the collection of organs and tissues refers to a procedure in which a sample or an organ is removed from the patient to either diagnose their condition or provide treatment for medical purposes. The patient is not therefore a donor since the purpose of the removal is the treatment of the patient themselves."
> (HE 93/2000: 20) (own translation)

Samples taken for the purpose of treatment or diagnosis of the patient are not seen as gifts, therefore, but their use for research or purposes other than what they were originally intended for is allowed for since the samples are not seen to have been donated. The logic behind this argumentation is interesting, because it is arguing that samples not donated for research can be used for research and other purposes than what they were originally intended for, while samples donated for research can only be used for the research which they were originally donated for. This argumentation would appear to be a twist in the use of the donation paradigm that is evoked in arguing for the broader use of donated research tissue samples. The argumentation also provides an example of the way in which non-donated tissue samples are encompassed and brought into the realm of tissue samples that are usable in research without gaining informed consent and represents a good example of the ways in which research resources are re-organized to allow for their broader use. This is also significant in relation to the power relations between the source of the samples and users since with diagnostic samples the source is powerless to control the samples, while with donated samples, the source is afforded power of control.

The legislations which are written to regulate tissue economies represent the rules and conditions under which tissue exchange and acquisition take place in a given society. These conditions are by no means stable or fixed, but rather reflect the myriad of requirements which stem from research practices and political aspirations as well. For example, one cancer researcher commented on how research practices in his group had changed in 2002 when the new law on the use of human tissue came into effect in Finland:

> *"Back in 1991, when we got the research permit from the Ministry of Social Affairs and Health to do this research, we understood that diagnostic samples in paraffin would be an important resource for us. But since there was no specific law on its use in research we had to settle the matter with the heads of each pathology department to gain access to various samples. That's the way it operated back then and it worked well, but I think this new law is a good*

> *thing. It hasn't hampered our work really, but it has given it a sort of structure that only a law can give, that says this is the way the process must go. When you consider the type of sensitive information that we can gain through these samples, it is important that there is a degree of control in it and not just the permission of the local pathologist."*
> (Interview with molecular geneticist, 2003)

It is clear from the interview excerpt that some researchers feel more comfortable doing research when a particular formalized exchange system – in this case for diagnostic samples – is more structured and regulated through legislation. Yet at the same time, due to the fact that tissue economies also inhabit a territory that spans, not only the physical realm of the samples themselves, but also the information that can be gained from them, tissue economies are confronted by the legal frameworks that are applied to the regulation of personal information as well.

Many researchers noted in interviews that a tissue bank comprised of physical samples alone is a 'trash collection', indicating that the importance and significance of the samples becomes tangible and significant only if other data, such as lifestyle information that is collected with the samples is of good quality and linkable. One molecular geneticist noted the following when asked of the relationship between phenotypic and genotypic information:

> *"Connecting phenotype and lifestyle information to the genetic data is where the analytic power will come from. I'm quite convinced that schizophrenia is fifteen different diseases at the biological or molecular level and we will understand this only when we begin to connect, without restrictions, the events in a persons life as variables in the analysis that lead to it and not just an end diagnosis."*
> (Interview with molecular geneticist, 2003)

The excerpt points to the relationship that tissues have to other forms of information; the genetic information gained from samples provides only one data source. Researchers are just as interested in other variables in the lifestyle and other events during the course of one's life that could also play a role in the onset of diseases for which the use of social security numbers are often used as identifiers. This relationship is an important indicator of the fact that tissue economies are invariably information economies as well. At the same time, however, there are restrictions to the way that information can be handled and deployed in everyday life.

The mobilization of diagnostic tissue samples through legislation is only one part of organization of resource relationships. Although informed consent remains an essential part of collecting samples for research, the development of technical solutions to maintain patient anonymity have also been used as a solution to some of the problems involved in gaining informed consent from patients if the original research question or

problem changes. This is especially useful for tissue collections that have been collected in the past before the so-called post-genomic era when it became possible to study hundreds of genes at the same time. For samples that are being currently collected this is not so much a problem, because these questions are covered in the informed consent agreement by creating a broader scope for research and possible future uses (cf. Sociaali- ja terveysministeriö, 2007). Patients are made aware of the broad range of possible research questions that it may be used for and they can also decide on whether it can be used for research purposes only or if it can be used for developing commercial applications as well (Deschênes *et al.*, 2001; Hansson *et al.*, 2006). They are also made aware of the fact that they do not have any property rights in terms of their tissue and are able to opt-out of the collection at any time. The patient is also made aware of questions relating to anonymity.

Within the most recent proposal for a new biobanking law in Finland (Hallituksen Esitys, 2008) it is suggested that a new national research ethics board be established to consider the status and possible future use of existing research and diagnostic sample collections. The law would allow for this board to provide a presumed consent for those collections which were seen to be nationally significant from a research perspective. The presumed consent could be given if it was seen that the new research did not violate the privacy of individuals. The introduction of a presumed consent is a significant move in the re-use of tissue sample collections for several reasons. *First*, the law does away with the distinction that existed between diagnostic and research samples. In the new law, both old research and diagnostic samples would be open to re-use once a permit is gained from the new board. *Second*, this decision-making process would be expert-led and circumvent the necessity of having to re-gain consent. Here again, we see the way decision-making in regard to some classes of tissue sample collections become guided by experts and are taken outside the scope of personal decision making through re-consent, for example. *Third*, the presumed consent practice is problematic in that experts will necessarily have to make assumptions about the wishes of those people they represent. There is also the issue that their decisions will be imbued with expectations of the potential that lies in the re-use of the samples. These expectations are increasingly framed within commercial terms. It should be noted, however, that to counter pose presumed consent, research patients are given better opportunities to find out and influence the way in which their samples and data are used in new biobank collections. This represents a new direction in the way research patients are able to engage in the way researchers use their sample collections.

As with the international legal, ethical and policy documents which I discussed in the previous section, Finnish legislation is also increasingly being encroached upon by commercial expectations associated with tissue sample collections. These expectations derive from Finland's national innovation policy which has for a long time emphasised the role of innovations as the basis of economic development and thus social welfare as well. The penetration of innovation policies into consideration on the use of human

tissue sample collections is, therefore, quite understandable. For example, in Finland's most recent proposal for a new biobanking law, it was noted that:

> "Research sample collections collected with public funding, diagnostic sample collections and related information can be seen as being a part of the infrastructure that supports research and innovations, whose efficient utilization can be seen to benefit the whole society. […] In biobanking research, the interests of the researcher, the research participant and society are parallel. Biobank research produces significant new research findings. The translation of these findings into products and services that contribute to public health also requires partnerships with the private sector. Finland's prosperity is based on the generation of innovations, their up-take and the creation of new businesses."
> (Sosiaali- ja terveysministeriö, 2007: 13) (own translation)

A number of issues should be pointed out in regard to this reference. *First*, tissue sample collections and their related information are seen to form an integral part of the innovation system. Since, however, they have been collected and maintained using public funding, it is necessary to maximize the benefits that can be extracted from them. Here we see the discourse of waste and efficiency entering the discussions surrounding legal formulations.

Second, the excerpt takes a holistic view on commercialization as benefiting the whole society. This can be contrasted with arguments posed by authors who have suggested that commercial benefits accrue mainly to private corporations (cf. Anderlink and Rothstein, 2001). The blurring of the divide between public and private benefit and interests from biobanks is a common strategy that is employed in Finnish innovation policy narratives and follows an approach by which policies are depoliticized in Finland (cf. Kettunen, 2001; Miettinen, 2002).

Third, the above text goes even further, however, in underlining such a position by claiming that the interests of researcher, society and participants are similar. Such statements, however, are highly normative since, as we know, research participants may have many different interests for participating. In addition, it has been shown in a recent survey of the Finnish population that helping private companies develop their business is not the reason why people participate and contribute to public research (Sihvo *et al.*, 2007; Tupasela *et al.*, 2007). Instead, the innovation policy rhetoric is a political aspiration that has been set through successive governments and has penetrated the argumentation behind the broader use of tissue sample collections as well.

Fourth, the statement draws attention to the fact that value is derived through a process of translation where the findings based on tissue sample collections serves only as the starting point in a longer development process. Here we see how the production of biovalue is increased through its translation from biovalue as scientific knowledge, to biovalue as health and finally to biovalue as commercial value. Biovalue as scientific

knowledge serves only as the basis for the other two forms of value which require a process of translation in order to be actualized.

The idea of using collections efficiently was also something that emerged as a theme in many of the interviews that were conducted. For example, in an interview with a hospital administrator, the role of the state as guarantor of efficiency and collective interests was emphasised in relation to individual rights and autonomy.

AT: "*How has the role of the patient changed in medical research?*"

Hospital administrator: *"In Finland this position has probably been strengthened with the increase of regulation and introduction of limitations on medical research practices. Research has become far more formal and stricter in Finland than what it was 20 years ago when research practices were very much dependent on the opinion and outlook of the individual researcher as to what was ethically acceptable, right/wrong etc… and of course the opinions of the researchers varied a great deal from one person to another and did not always reflect the opinion of the research subject."*

AT: *"How would you compare the role of the patient in a comparative perspective, with the US for example?"*

Hospital administrator: *"It's difficult to compare because the rights are based on such different legal perspectives. In the US, the rights of the individual are arbitrated through the court system where it is possible to sue for just about anything. If it goes through you can get huge reparations. In Finland, however, our sanctions are very modest because monitoring is the role of the state. There are good and bad sides to this difference. In the US, the rights of the individual, such as consent and autonomy are emphasised perhaps more than in Finland where during the past decades we have emphasised more the collective rights, such as the right to medical treatment and care and as a result maybe be willing to give up some autonomy."*

AT: *"How strongly does the Finnish healthcare system influence this idea of collectivism vs. patient autonomy?"*

Hospital administrator: *"Very much if we think about the activities of the public sector in comparison to private practice. In private practice it is a business where there is a customer relationship which is based specifically on the agreement between the two parties. With the public sector, however, there immediately emerges the interest of society in general or as a whole. So the management of the healthcare system is directly related to the management of society as a*

> *whole as well. In a collective, not for profit or not meant for profit, healthcare system it is accepted that the information of the patient, such as healthcare information, can be used for other purposes more readily than in a (private) system where you have paid for your care directly and it is based on a contract or agreement for specific services. […] Here we see the role of the public authorities in trying to find the most efficient and economic way of operation. So if the doctor changes, the resources still remain, be they databases or patient records, which ensure that the system as a whole operates. […] With public research organisations, such as the National Public Health Institute or university hospitals, it is very difficult to draw a line between a general interest of society and infringement of individual rights since the institutions are in one sense part of the healthcare system."*
>
> (Hospital administrator interview, 2003)

The interview excerpt with the hospital administrator is telling in many ways. *First*, it shows the way in which the context of individual rights and autonomy of the patient are directly linked with broader administrative imperatives of efficiency. Here again, the function of resources is contextualized within the waste argument, where idle resources are seen to be inefficient and non-productive from a broader social perspective.

Second, the emphasis of efficiency is then connected with a collective sense of duty which in some cases overrides conceptions of personal autonomy. The considerations which relate to the interests of society in relation to personal autonomy, in turn, contribute to the broadening of the scope of informed consent as it is applied in Finland. This is also contrasted to the US where the individual is seen to have greater rights in relation to collective interests.

Finally, and ironically, the interview excerpt indicates how a supposedly not for profit system, such as public healthcare, might in fact be more inclined to find commercial applications for its resources than the private sector due to an administrative imperative that guides towards efficiency and the use of existing resources. This is significant since it indicates the way in which commercial applications based on tissue sample collections (donated and diagnostic) are seen as a continuously operating system of acquisition, use and application.

The act on the Medical Use of Human Organs and Tissue (2001/101) raised a number of important issues relating to the role of old/existing samples and research. The dichotomy between research samples and diagnostic samples was criticised by many researchers as creating inefficiencies within the research tissue economy by denying researchers the ability to re-use research samples for other purposes than what they were originally intended for. At the same time it created an asymmetry in relation to informed consent in that samples not donated for research (diagnostic samples) could be used for research, while those donated for research could not be used for other research than what they were originally taken for, except by re-gaining consent. This, however, has led to a

new law proposal for biobanking where it would be possible to re-use research samples for new purposes based on presumed consent. This consent would be given, however, by a national research ethics committee. This would resolve the asymmetry issue, but it would also mean that expert authority would replace individual autonomy in deciding whether samples could be used or not. Essentially, this would mean that in any research involving the acquisition of tissue samples and personal information research participants could only be asked to give broad consent, since anytime down the line the researchers could have the samples used for other purposes than what they were originally meant for (cf. Hansson *et al*., 2006).

The relationship between individual vs. collective rights and interests has been a pivot around which the re-interpretation of informed consent and the writing of the new law on biobanking has focused on whereby the general interest of society can be seen to take precedent over individual rights to privacy and autonomy under certain conditions (see Sosiaali- ja terveysministeriö, 2006). This position, however, places a great burden on policy makers and researchers to enact the spirit of engagement and dialogue that is emphasised in policy documents, since the possibility for personal intervention and decision making is being limited. At the same time, the increased emphasis on commercial expectations associated with tissue collections are problematic because they intertwine policy discourse with moral and normative imperatives which are then transferred into legislation and regulation. It seems suspect that within the human rights discourse, any citizen or private individual should be morally obligated or pressured to have their personal health information used in order to further commercial interests, albeit that they might have general social value as well. Such a policy position, in my view, is detrimental to issues of trust and legitimacy in the long-run since commercial interests are in the end primarily interested in the creation of profit for owners and not about reciprocation or altruism towards society.

The consideration of collective interests, the writing of regulation and inevitably the organization of tissue economies does not, therefore, take place within a narrow context of individual autonomy alone, but is reflected within a much broader social context that relates to issues of waste, management and efficiency, both from a scientific perspective, and an administrative one as well. It could be argued that legal and ethical documents contain certain misleading ambiguities in relation to the significance of personal rights in relation to information and tissue samples removed from one's body. This is highlighted by the ways in which interpretations related to informed consent are coming to terms with the practical issues of acquiring, storing and using tissue sample collections.

In the next section I will bring these various strands of discussion together and look at ways in which such collections of tissues and information systems are being brought together and used in the three case studies that I have looked at. This description is an important part of conceptualizing the way tissue economies are constructed and the way in which various national resources are activated and circulated through the research system. Before exploring the three case studies, however, I will provide a general introduction to

the way tissue collections and information systems are being organized in Finland. This is important since, increasingly, the models associated and employed in the production of scientific knowledge are utilizing production models drawn from traditional industry. Such models are helpful in identifying visually how resource relationships are managed and organized in tissue economies.

5
BUILDING TISSUE ECONOMIES

Before presenting the three cases studies of Finnish tissue economies, I will provide a general introduction to Finnish tissue collections. As discussed earlier, the production of scientific knowledge from tissue economies necessitates the organization of resource relationships in such a way that tissue samples and related information become increasingly manageable. These scientific knowledge production management processes are often described using flowcharts or input/output models through which resource relationships are visualized and presented. These models serve an important role in helping to position various tissue resources in relation to their users and serve as descriptive tools of epistemic cultures. Such resource positioning also has an important role in the way individual rights, informed consent and personal autonomy are interpreted. At the same time, the flowcharts are representations of the transformative process to convert tissue samples and their related information into scientific knowledge, health and commercial value. Here we see how the organization of resource relationships relates to the production of biovalue.

Finnish Tissue Collections and Health Registries

Structurally, tissue economies form a multifaceted network of connections to various information resources and institutions. As discussed earlier, this means that tissue economies extend well beyond the physical realm of resource management. At the same time it becomes evident that altruism, although an important component in many tissue acquisition processes, plays only a small part in the operation of tissue economies since much of the information and tissue samples are gained through other, non donated means. Due to the limited role of the sources (donors) of tissues in tissue economies, it is possible to point

to other factors which increasingly play a significant role in the production of biovalue and the operation of such economies. Within this context, therefore, biovalue is introduced as a central component within more recent discourses on the commercial significance of tissue collections, even though there still remain significant research activities that see the production of value in other ways as well.

Finland has been conducting research into national health risk factors since the 1950s and collecting DNA-samples for such purposes since the beginning of 1980s (Aromaa *et al.*, 2002: 7; see also Anttonen *et al.*, 2004). This means that these tissue economies have been developed over a long period of time. In the European context, Finnish collections have gained importance in that they are of a high standard and have been conducted on a number of important common diseases, such as diabetes and heart disease and that unlike more notable efforts, such as the UK Biobank, these collections already exist and have been followed meticulously over the years through longitudinal studies. In this sense tissue collections and the biovalue that they can produce are also connected to broader national interests in the production of scientific knowledge.

According to a recent study funded by the Finnish Funding Agency for Technology and Innovation, Tekes, Finland has over 190 000 samples within ten of its most significant epidemiological cohort studies (Technomedicum, 2004a). This represents about 3.6% of the country's population, which in comparison to the UK Biobank goal of 500 000 samples from a population of over 60 million represents only a .83% sample of the population. According to the report, these samples and the related health information could be used far more efficiently in the study of the human genome, diseases, as well in the development of pharmaceuticals and treatments. The report also sees genome research as uniting science and industry in a way that will give Finland an edge over similar competing projects elsewhere in the world. In addition to the epidemiological cohort collections, Finland has pathology collections that amount to well over 2 million samples. These sample collections are used routinely in medical practice for teaching and research, as well as for comparative purposes if patients are re-diagnosed with a new condition. Together these sample collections are seen by both researchers and policy makers as a significant national resource that should be organised to facilitate the development of new innovations and scientific discoveries (see Academy of Finland, 2003c).

The 'activation' of diagnostic samples into the research system is a significant source of tissue samples and represents a major source of human tissue that can be said to be based more on technical than social acts. As Table 2 indicates, between 2001 and 2006 the National Authority for Medicolegal Affairs granted 136 permits to various research groups to use diagnostic samples for research purposes[15]. The permits cover a total of 262 414 individual patient samples, which is considerably more than what UK Biobank and deCode

[15] The data collected from the National Authority for Medicolegal Affairs contain some data discrepancies since the permits made available for calculation did not always add up to the permits that their database reported nor the official statistics that were published by them. The figures here for permits given represent the ones I was able to calculate. For example, in 2003 my calculations were based on a total of 24 permit

Genetics in Iceland have used to date. Most of the samples are analysed and handled within research departments in Finland, with only about 10% of the permits reporting that samples will be shared with foreign research partners. This would seem to indicate that for the most part the actual handling of samples is maintained in local hands. The range for the amount of samples that are covered in one permit ranges from 1 to 200 000 with the average size being 1929 samples per permit. The majority of the applications relate to research on cancer, which is not surprising since cancer samples form a large part of diagnostic sample collections in hospitals. Cancer research is also a major research area that receives a great deal of funding, both nationally and globally.

Table 2. NATIONAL AUTHORITY FOR MEDICOLEGAL AFFAIRS PERMITS AND SAMPLES FOR TISSUE SAMPLES ORIGINALLY USED FOR DIAGNOSTIC PURPOSES IN 2001–2006

YEAR	PERMITS	SAMPLES
2001	6	6 913
2002	30	216 537
2003	24	8 514
2004	20	5 673
2005	26	12 753
2006	30	12 024
Total	**136**	**262 414**

Source: National Authority for Medicolegal Affairs, own calculations

As Table 2 indicates, research groups have been relatively active in applying for permits to utilize diagnostic samples. The use of samples should be calculated as cumulative, since the permits are often given for several years at a time and the majority of samples relate to different forms of cancer research. The patients themselves, who might be living or deceased, are not contacted by the authority, but rather the agency acts as a surrogate for decision making in this situation. The re-use of samples, therefore, is social insofar as it is a bureaucratic application process between the research group and the permit authority, but it does not involve the patients in any way, nor have there been any complaints by patient groups or patients themselves. Diagnostic samples, therefore, form an important tissue economy within the research community which circumvents the need for consent. At the same time, it can be noted that the possibility of re-using samples taken

applications that were found in the files. The database log, however, indicated that a total of 33 had been handled, while the annual report said that only 32 permits were given. These data anomalies have been present in every year of data that I have collected. The data nonetheless indicates the high degree to which diagnostic samples are used in Finnish biomedical research.

for diagnostic purposes raises the issue of efficiency in research practices. If unorganized diagnostic sample collections have proven to be such a fruitful source of research material for researchers, then what are the possibilities of re-using research samples and their related health and lifestyle information.

In considering the situatedness of diagnostic samples and their use rates, it is interesting to look at the geographical distribution of samples use according to hospital districts. In Table 3, the use of diagnostic samples indicates that the distribution coincides with the size and location of the major university research hospitals in Finland. The most important and largest university hospitals are located in Helsinki, Tampere and Turku. Although this is not surprising, it points to an important relationship between research funding and the biomedical use of diagnostic sample collections.

Luukkonen (2004: 15) has shown that the geographical location of Finnish biotechnology firms correlates with university towns. The use of tissues, according to the permits granted, also correlates with both universities and biotechnology companies. It should be noted, however, that the list of companies also includes companies other than biomedical research companies.

Table 3. REGIONAL DISTRIBUTION OF DIAGNOSTIC SAMPLE USE IN FINLAND BY HOSPITAL DISTRICT 2001–2006

HOSPITAL DISTRICT	SAMPLES
Helsinki and Uusimaa hospital district	227 842
Tampere hospital district	15 276
Varsinais-Suomi hospital district	6 731
Pohjois-Pohjanmaa hospital district	10 579
Keski-Suomi hospital district	1 338
Pohjois-Savon hospital district	490
Etelä-Pohjanmaan hospital district	158
Total	262 414

Source: National Authority for Medicolegal Affairs, own calculations

In considering the nature of tissue economies, biovalue is often associated with commercial value that is acquired through commercialization. Public expenditure in biomedical research, however, represents an important component of that value creation and can be related directly to the use rates of samples. Biovalue, therefore, also takes on a meaning at the national level as a national resource that can be harvested and developed. Public investment is also important from an epistemic perspective in that funding provides the substance or content for research within newly created infrastructures, such as population

genetics and gives rise to the possibility of transforming tissue samples into different forms of biovalue.

Health and social service registers are another important tool that is available to Finnish researchers. Most are maintained in accordance with decrees and laws and are maintained by various organizations that are governed my ministries. One of the most important registries is, for example, the cancer registry (Act on National Healthcare Registers, 556/89) which is an epidemiological database of all cancer incidence in Finland. Physicians are required by law to report all diagnosed cases of cancer and their type to the register (STAKES, 2003). The registry is an important tool in the biomedical research community that studies cancers in Finland, and it allows the extension of physical tissue economies to information on populations by allowing researchers to develop statistical models of cancer occurrence, but also identify individual diagnosis of cancer in patients. This is particularly useful for studying hereditary diseases. Here we see how physical and information tissue economies become intertwined. It also indicates, however, that the notion of tissue economies needs to be extended to include such forms of information which do not derive from physical tissue samples.

Other important registers in terms of medical research are the drug sales register (Act on Medicines 395/87) and the hospital discharge register. These are particularly important in long-term studies on chronic disorders and can also be used to calculate cost-benefit ratios of various treatment plans. Finland also has a relatively high rate of autopsies that are performed which varies between 20–25% of all deaths. Most autopsies are carried out for cases where the person has not been under the care of a physician or when there is a suspicion of a crime that has been committed. The high rate of autopsies also means that there are a number of samples that are collected in the process as well, which also form tissue banks of their own. In all registers, data is maintained using social security numbers and can therefore be easily accessed and analysed in relation to results obtained through tissue sample collections where patients provide their social security numbers as well.

The ability to combine data acquired from tissues with register data is an important extension of physical tissue economies. Not only does it emphasise the fact that tissues have a dual nature where on the one hand they are physical entities, but also on the other that they are information (that can also be considered an object), but it also extends our understanding and the role of tissue economies to areas which are not traditionally associated with tissue collections. For example, the comparison of unemployment rates with hypertension is one way of exploring the relationship between socio-economic factors and the risk of heart attack. Therefore, biovalue can be extended into new arenas of influence as it pertains to the possibility of social and economic intervention becoming an increasingly important factor in treating chronic illnesses. The impact of tissue economies and the biovalue that can be derived from them, therefore, extends far beyond the medical and can be said to penetrate a large number of social arenas of influence.

The ability to compare data between information gained from tissue samples with

other register data has also led to numerous proponents of a new biobanking law to argue that tissue banks are comparable to other healthcare registers (Aromaa *et al.*, 2002). This comparison, although useful, has a number of problems with it. Although both registers and data acquired from tissue collections both contain information that can be traced back to a person, registers do not provide the possibility to gain new information outside the data that has been collected. Tissue samples, however, offer the possibility of returning time and again back to the samples for new analysis and provide an added dimension in terms of re-use. It is the possibility to re-use samples for different research that is one of the most challenging questions that law makers are currently grappling with, and the degree to which researchers should be required to involve the research subjects from whom they have been acquired. Furthermore, there is a built-in assumption within this argument that tissues are only used for statistical research, but as many cases have shown such as with John Moore or HeLa cells derived from Henrietta Lacks (Landecker, 2007), cells and tissue samples can have biovalue beyond that which is derived from information gained from them (see also Waldby, 2002).

Whether or not this is ethically right or wrong is beyond the scope of this research, but it should be noted, however, that the re-use of samples and the ability to combine the data acquired from them with other register data is an important component of the way in which tissue economies operate in Finland and the way in which various forms of biovalue can be produced. It also constitutes a major reason why informed consent regimes are being re-thought, which concomitantly changes the power relations between the different actors.

In the next section I will further examine the relationship between sample collections and the information that can be derived from them in relation to the informational turn and industrial production models in biotechnology. The purpose is two-fold. *First*, the organization of tissue resources in relation to knowledge production is taking on increasingly industrial production models using in-puts and out-puts. *Second*, the models illustrate the material/informational character of tissue economies and are at the same time the juncture at which biovalue as knowledge, health and wealth are being created. This is an important element within the process of value creation and its transformation from one form to another and also provides an important underpinning to understanding the nature of the epistemic changes that are occurring with the biomedical use of tissue sample collections.

Input/output Models of Tissue Economies

> "Biobanks offer numerous opportunities for business and the potential for a range of new business possibilities – whether in terms of data on how well various pharmaceuticals and types of care perform and where improvements are needed, or where new diagnostic tools could be called for."
> (Pitkänen and Hassinen, 2007: 33)

It is clear that tissue collections and their related clinical information, as well as various population registries form an extremely heterogeneous group of objects, varying from the original purpose of the collections, means of collecting, the type of sample collected, the type of data collected and derived from the samples, as well as the regulatory framework that governs their use. Within the conceptual framework of tissue economies, however, it is possible to analyze the significance of these collections in the process of transforming them from one form of value to another. In this sense, tissue economies are mobilized within a type of knowledge production machinery where the input of tissue samples and related information is translated into forms of biovalue, such as scientific knowledge and commercial gain.

In order to show how biobanks are represented as engines of production, maps or flowcharts of the various actors and practices serve as examples of the ways in which tissue sample collections are organized. These flowcharts show the institutions that govern them, the way information travels between actors and the outputs that are produced. This can be characterized as a transformative process. Epistemically, tissue economies can, therefore, form their own unique entities in that they are used to organize and rationalize knowledge production into a mechanistic flow chart. Although innovation studies have certainly moved beyond mechanistic conceptions of knowledge production to include more micro-level practices, such as interactive learning (see Lundvall, 1992), the organization aspects which draw from industrial input/output models still have relevance to the way tissue economies are being organized in Finland. These charts highlight several important aspects relating to tissue economies and biovalue. Given the numerous institutional and individual actors that are involved in these processes, it becomes clear from the outset that biovalue can be interpreted in many ways. For some, it is a form of power and influence and others a practical research tool. For others it is an important way of mobilizing financial resources and networking with other actors.

Within the scope of this research, the organization and representation of research activities can generally be divided into two categories: that which takes place at the research level and is done by research groups to try and describe their activities; and that which takes place at the institutional level. Although the type of analysis may slightly differ between the two levels, both represent an attempt to describe and organize knowledge production in relation to resources and capacities (technologies). The mechanistic description of knowledge production, although somewhat crude, plays an important epistemic function in bringing together various resources under one process. Following Knorr Cetina (1999), one can argue that such charts represent a certain type of knowledge production machinery where particular inputs – in these cases tissue samples and other patient information – are put through a particular research system to produce a particular type of result. For research groups the results tend to be characterized as new knowledge or understanding, improved healthcare and treatment or patents on new discoveries. At the institutional level, the results may be characterized in relation to industry and economic development. Although we can argue that tissue economies form a technological

zone which cuts across national and political boundaries (Barry, 2001), the organization of research activities at the national level are often characterized as local in nature (although exceptions do exist[16]).

In looking at the way tissue economies are organized at an institutional level, one excellent example of the way in which various resources, including tissue sample collections, and actors are related and visually organized in relation to each other can be found in a recent strategy from the Finnish National Public Health Institute (Eskola, 2005). The Finnish National Public Health Institute is a public research organization that is directly under and funded by the Ministry of Social Affairs and Health. It also maintains the largest tissue sample collections in Finland, including several large, longitudinal population studies.

The strategy that was the outcome of result-based management negotiations with the Ministry of Social Affairs and Health in 2004, where the ministry set the National Public Health Institute with the task of more efficiently utilizing its resources, research results and competence in biomedical research for the benefit of the population. Among a broad range of recommendations made in it, was a model for the commercialization of research results at the institute (Eskola, 2005: 66). Although the institute has commercialized research results before, this was the first time that it was made an explicit part of its research strategy.

The model has a number of interesting features which highlight the way tissue economies are constructed from an institutional perspective. In particular, the model emphasizes the way in which political aspirations of efficiency and results become incorporated increasingly with tissue collections themselves and the way this is reflected in knowledge production systems. The actualization of this process, therefore, requires a political aspiration at a policy level in that these goals become incorporated into official strategy and policy guidelines. In this way, commercialization and increased cooperation with the private sector, among other policy goals, become part of the official world view that is held among the actors in these institutions. At the same time, it has an impact on the epistemic practices surrounding research in that it solidifies and encourages the creation of contact with private industry. Kleinman (2003), for example, has noted that such strategies can also have indirect effects on research practices and research culture in research groups.

As the description of the model indicates:

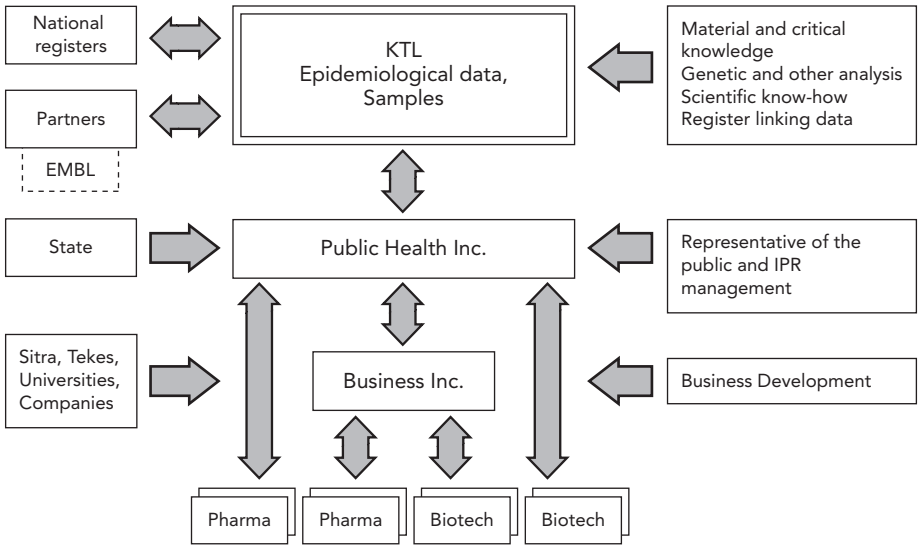
> "Connections with industry would be maintained through a friendly intermediary. A professional intermediary can guarantee that a research institute can come into a fair agreement and gains a reasonable compensation for its know-how and is not put in a position of disadvantage in relation to the negotiators of the business world."
> (Eskola, 2005: 65). (Own translation)

[16] One example where tissue economies are specifically organized as an international collaborative effort has been the GenomeEUtwin (2006) project. See http://www.genomeutwin.org/

The tissue economy model is based on the idea that in order for publicly funded institutions, such as the National Public Health Institute (NPHI), to cooperate with industry without losing their credibility in the public eye, there needs to be a buffer between the public and private sector. This model bears a strong resemblance to university licensing firms which operate at the boundary between public and private (Pelkonen, 2003b; Tupasela, 2000b).

Figure 3 represents the proposal that has been made for the commercialization of research results based on tissue sample collections at the institute. The model bears a strong resemblance to corporatist models of interaction (cf. Pelkonen, 2006; 2008) in which all the major players are linked and cooperate together towards a common purpose and goal. The purpose of this approach is to gain a high level of approval and acceptance when there is a strong representation from the major players. These actors include universities, funding agencies, such as Tekes and Sitra, as well as cooperative international partners, such as the EMBL.

Figure 3. A TISSUE ECONOMY OF THE NATIONAL PUBLIC HEALTH INSTITUTE



Source: Eskola (2005: 70). Reprinted with permission.

Perhaps the most important aspect of the model is that it clearly shows the way national registers and epidemiological data and samples are brought together and the way in which new knowledge is produced and then channeled through a company owned by the National Public Health Institute (Public Health Inc.) to pharmaceutical and biotech companies using another possible intermediary. Here we see a concrete example of the way commercial

biovalue is developed. This organization of resources in relation to scientific knowledge production, therefore, represents a transformative process in which national registers, epidemiological data and samples, as well as other materials, critical knowledge, genetic and other scientific know-how are brought together to produce scientific knowledge that can be translated into products for businesses using an intermediary. In the model, the traditional goal of science to further our understanding of phenomena also becomes intimately tied to the goals of business development and commercialization. The model of public health and prevention in its traditional sense is also seen increasingly to take place in partnership with the private sector. The translation of biovalue as knowledge to health and wealth becomes one continuous and fluid operation within a traditional public research institute through this flowchart model.

The model also has a number of other important features in it. *First*, the NPHI would not sell samples or register data itself, but the results of various analyses. Therefore, all critical data and material would remain in the control of the institute and the encryption keys used to connect samples with health data would also be managed by the institute, thus maintaining a level of security that would prevent personal information from leaking out. This also transgresses the distinction between biovalue as scientific knowledge and biovalue as commercial, since knowledge is what they would be selling. It also shows how critical the samples and original data are to knowledge production.

Second, there would be a representative of the public interests which would be associated with the management of intellectual property rights (IPR). It is not clear who this would be or how it would work. Nonetheless, the model has taken the interests of the public into account in developing this model. In this sense it shows an attempt at integrating public representation into decision making processes in some way.

Finally, there would also be a business development capability built into the model that would allow for spin-offs and innovation development. The model, therefore, tries to incorporate a broad range of interests and actors in developing a model for the commercialization of its research and scientific know-how. Although the model has not been implemented yet due to technical difficulties relating to the legal status of the collections, it is nonetheless a concrete example of the way in which knowledge production systems are being conceptualized and organized. It is also an example of the way in which political aspirations to mobilize tissue sample collections in public institutions become operationalized in practice.

The commercialization model presented here is also significant in that it is an example of the ways knowledge production models are increasingly drawing on industrial production models. In relation to the re-interpretation of the scope of personal privacy and informed consent, this is significant in that such production models tend to obscure the ethical, legal and social aspects associated with tissue acquisition, use and re-use, and focus more on the organization of resources from a production perspective. This has a number of important implications. *First*, there is an implicit assumption that the transformation of knowledge gained from tissue sample collections to products and

services that can be used and applied by businesses is a straightforward one. *Second*, the commercialization paradigm, such as the one presented here, is presented as natural and obvious, being the only possible way through which value derived from tissue can be utilized. In this sense, the commercial model that is applied here becomes the only real option that is made available for the transformation of value from scientific knowledge to health and commercial biovalue. *Third*, the model also ties political hopes and expectations associated with prospects of commercialization into the practices associated with the biomedical use of tissue sample collections. Here again we see how political aspirations help to define the knowledge production processes associated with tissue sample collections and the ways in which they are organized and mobilized. Such models are important in the governance of biobanking and its related resources in that it not only sets up new research infrastructures, but also introduces indirect commercial aspirations through institutional policies (cf. Kleinman, 2003). These institutional policies, in turn, reflect broader neo-liberal policies related to the benefits that are seen to accrue from the biovalue that is produced in tissue economies.

Thus far I have looked at Finnish tissue collections, the use of diagnostic tissue samples and the ways in which scientific knowledge production is increasingly drawing on industrial production models to organize the resources which are at their disposal. In the following, I will extend the use of flowcharts to the analysis of three examples of tissue economies in Finland. Although the cases differ in their historical background, institutional setting, purpose, as well as role and function, they exemplify a number of central aspects related to interpretations of informed consent in tissue economies and the production of biovalue. These aspects of tissue economies and the production of biovalue are relevant in that they are also reflections of political aspirations to maximize the productive capacity of biobanks.

5.1 THE TAMPERE RESEARCH TISSUE BANK – COLLECTING SURGICAL WASTE

In section 3, the notion of waste was examined as it applied to the collection and storage of human tissue samples. The idea that waste has value as possible knowledge, health and commercial value might seem paradoxical, but as research indicates, the collection of surgical waste can be put to great use in biomedical research and the value that waste can have raises a number of important issues concerning the relationship between the source and users of samples. The collection of surgical waste also links directly to the discussion surrounding the interpretation of the scope of individual rights and informed consent.

Informed consent is traditionally sought from individuals who donate their samples and information for research, but since surgical waste is collected within the context of diagnosis and treatment of disease, many practitioners have seen it to fall outside of the requirements set for medical research involving human subjects. (cf. Waldby and Mitchell, 2006: 115).

Yet as we have seen in the previous section, the use of diagnostic samples for biomedical research is quite common, and increasingly, diagnostic samples are collected with future research in mind. This process blurs the distinction and boundary between research and diagnostic samples which is commonly made in legal texts on the biomedical use of tissue sample collections. The collection of surgical waste also highlights the importance that the physical collection systems and structures play in tissue banking and the generation of value from the collection system. The institutional setting, therefore, has an important role in the way waste is mobilized as a research tool and reflects new ways in which resource relations are being organized. Finally, the collection of, not just surplus tissue, but the collection of diagnostic material in general, also shows the ways in which the donation paradigm is less and less useful when we discuss the use of diagnostic samples for research in Finland.

The Tampere Research Tissue Bank is operated by the Pirkanmaa hospital district administration. Its roots, however, are located in the consolidation of several different tissue bank operations at the hospital from the early 1990s onwards. The consolidation of these activities under one administration has also changed the role of informed consent in the acquisition of samples. In the following, however, I will focus on one collection operation which preceded the consolidation to highlight the main features of the ways in which researchers were collecting surgical waste. I will then look at the way the consolidation of collection practices changed these practices and the way in which these practices relate to discussions on tissues as waste and the interpretations of informed consent.

Setting up the Research Tissue Bank

In the late 1990s, two researchers at the University of Tampere medical school (in central Finland) began discussing the possibility of setting up a research tissue bank to provide samples to biomedical researchers. The researchers had noticed that it was becoming increasingly difficult for researchers to get their hands on tissue samples for their research, and that in the future this problem was only going to increase unless something was done about it. As noted, these researchers were by no means the only ones involved in collecting surgical waste at the hospital, but had nonetheless been very active in international workshops to develop tissue banking networks and standards. The problem, therefore, was by no means limited to Finland, but rather there was emerging an international need to coordinate the collection and standardization of processes associated with tissue collection and storage.

In late 2000 the two researchers from Finland attended the UK Human Tissue Bank Workshop (Belfry, Birmingham), which was the first research tissue bank meeting that

was organized in Europe. The purpose of the meeting was to set up a *network* of research tissue banks in Europe that would actively support the acquisition of tissue sample collections and develop collectively acceptable standards and procedures within Europe for the acquisition and use of tissues. One of the outcomes of the meeting was the establishment of the European Network for Research Tissue Banks (ENRTB). According to its mission statement, the goal of the group was

> "To establish a sustainable network for sharing information to guide in the establishment and running of human tissue banks with the ultimate goal of sharing human tissue/information derived from use of these donations across this network under harmonized guidelines and agreed best practices to promote the use of human tissue."
> (Orr *et al.*, 2002: 136)

The mission statement highlights the development of a network activity and its codification into practice, namely *sharing donations*. At this stage of the development of the tissue bank, it was assumed that samples would be donated by patients. This donation process would be mediated through the process of informed consent, which as Waldby and Mitchell (2006) have noted serves as the basis of transferring property rights from the donor to the receiver. Tissues collected as surgical waste were, therefore, at this stage still considered donations by patients and embedded within the practices of consent.

The network was not limited to research groups in public research institutions, but a number of private companies were involved as well (see ECVAM, 2002 for complete list of participants). From the beginning, therefore, the network was set up, not only to collect, store and share tissue transnationally, but also to bridge the public-private divide. Epistemically (Knorr Cetina, 1999), such network practices of sharing samples are also important because they extend the scope of research work and cooperation beyond the single lab and the resources that are available to them locally. Tissue samples become increasingly available on an international scale through a codified network with similar standards of collecting and handling of material and data. Essentially, such networks represent one facet of the construction of knowledge-producing machineries where standardization practices serve to assure that the quality of the inputs (tissue samples) remains the same across a heterogeneous set of activities and actors.

An important impetus behind the establishment of the network was, not only to improve the availability of tissue samples, but also to develop and promote alternative methods to the use of laboratory animals in biomedical research, especially in relation to programs of medical and pharmacotoxicological studies (ECVAM, 2002). In addition, the use of diagnostic samples or surgical waste is seen as a way of decreasing the need for human testing as well (Hallituksen Esitys, 2008). One of the goals and intended values, therefore, had little to do with capitalizing research results or improving the health of patients, but rather a methodological research-oriented goal of decreasing the need to use animal

models in experiments and replace them with in-vitro human tissue models. Besides decreasing the need for animal testing, it is also argued that human tissue models have greater validity for scientific experiments relating to humans and are less expensive than having to maintain animal testing facilities. Once again, the epistemic goals associated with knowledge production relate more to issues of validity and methodology than the production of commercial value alone. This interest in the technicalities of knowledge production methods and technical standards raises an important aspect of tissue economies that I will return to below.

Besides developing common collection and storage standards among European research tissue banks, the network also sought to develop a common and ethically acceptable and transparent regulatory framework. One of the goals of the ENRTB was to encourage all governments to 'regulate such services appropriately, and to work to achieve clarification and harmonization of laws concerning the use of the non-transplantable and surgical-residue human tissue' (Anderson *et al.*, 2001: 127). The network, therefore, also had a clear policy goal in relation to the development of government regulation.

In 2002, the two Finnish researchers, Heikki Helin (Department of Pathology) and Timo Ylikomi (Department of Cell Biology) at the Tampere University Hospital and Tampere University – respectively – established the Research Tissue Bank in Tampere. The purpose of the bank was to collect *surgical waste* or *residue* from operations and store it in a tissue bank. In their prospectus on the setting up of the research tissue bank, the researchers noted that the use of the tissues would cover two general sectors, university research and corporate research (Helin and Ylikomi, na).

In setting up the bank, the researchers wanted to set up a consent procedure that would allow patients to be given information on tissue banking well before they came into surgery, while they were visiting their own healthcare professional. At the same time they wanted to codify the somewhat *ad hoc* procedures that existed in the collection of different samples. The pathology department, for example, had several different types of organized collections among the millions of diagnostic samples that it had collected more or less haphazardly over the years, and no one knew exactly what types of collections there were or whether consent had been gained. The codification of collection procedures would not only give patients enough time to familiarize themselves with the documentation that was provided and allow them to ask questions if they arose, but it also set standards and procedures for the way tissues were collected. The consent procedure also allowed patients to decide if they wanted samples used only for academic research purposes or if they could also be used by private companies (Helin and Ylikomi, na). In this sense, the researchers sought to engage the patients and allow them the choice of whether their samples could be used for research or not.

This consent model, however, was later abandoned and it was decided that although tissues would be collected and stored for future research use, the act on Medical Use of Human Tissues and Organs allowed researchers to apply for a permit from the National Authority for Medicolegal Affairs to use the diagnostic samples without having to gain

consent, since the samples were used for diagnosis. This gave the sample collections a dual nature; although the samples were diagnostic samples taken in routine medical procedures, they were also collected with future research in mind. At the same time, however, this decision eliminated the decision-making possibility that patients had in whether or not to donate tissue for research or whether it could be used by private companies. The tissues, therefore, lost the possibility of being donated and became abandoned tissues whose future use was governed by expert bodies, such as ethics review boards and the medicolegal council. This dichotomy in the law between diagnostic and research samples, therefore, has proven problematic in relation to diagnostic samples that are collected for research purposes since researchers and hospitals are able to avoid consent procedures altogether.

In this sense, expert systems replaced patient autonomy over diagnostic tissue collection and use. Although it has been recently shown that surgical patients are willing to donate samples to research (Bryant *et al.*, 2008) this move by the managers of the biobank, nonetheless reflects a move to involve patients and research subjects less and less in decision making.

A Tissue Economy of Surgical Waste

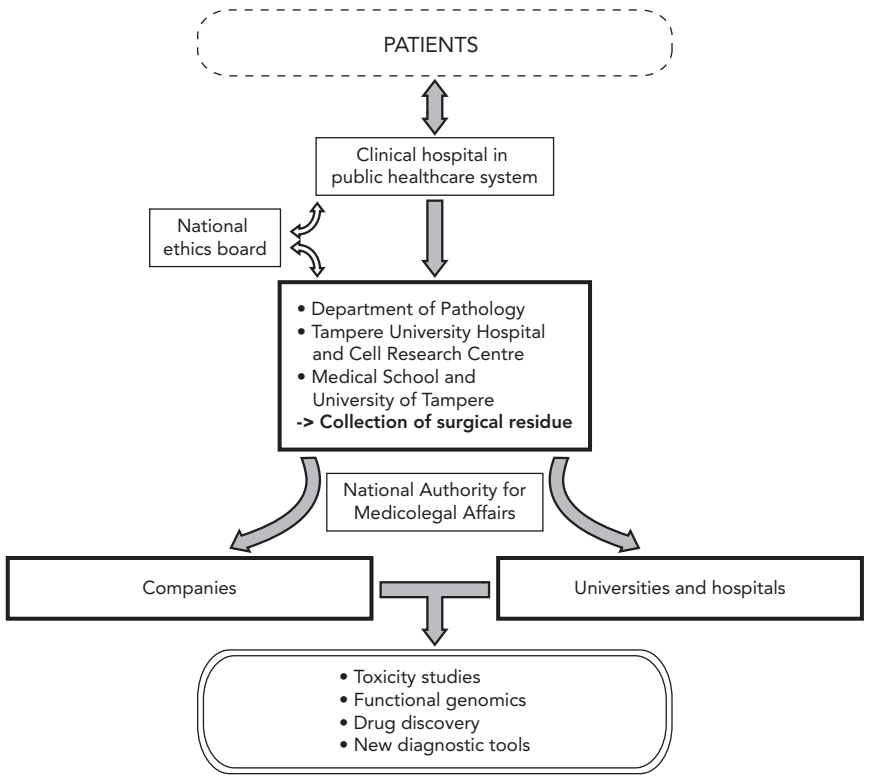
During the early years of its operation, the institutional setting of the collection of the tissue samples at Tampere was a cooperative effort between two departments: the Department of Pathology and the Cell Research Center at the Tampere University Hospital and the medical school of the University of Tampere, respectively. In this early model, informed consent served as the basis for the acquisition of tissue samples. In Figure 4, I have drawn a diagram of the general features of the tissue economy of the Tampere Research Tissue Bank, as it relates to the collection and dissemination of samples. The acquisition process begins with patients who are being treated for some condition and come into surgery. Whatever tissue is removed during the surgery is sent to the pathologist who makes a diagnosis, but also collects a sample of diseased and healthy tissue which is then prepared and stored using appropriate standardized techniques by the Cell Research Centre. These samples can then be distributed for use by companies or universities and other hospitals, where the Cell Research Centre serves as a distributor for the samples that it has collected. The research tissue bank does not do any research of its own; it simply collects, manages and stores the samples that it sees to be useful for future research. Therefore, it is a management facility rather than a research organization. It is, however, an important structure in the organization of resource relationships (see Waldby and Mitchell, 2006; World Health Organization, 2003).

The diagram does not provide a specific indication of the collaborative partnerships that exist with other research groups and private companies (this data was not available), although those networks are the core reason for its existence. Rather, I have sought to develop a schemata of the way in which the bank has tried to develop its acquisition and distribution system and its relation to research ethics boards and national legal authorities.

This collection and acquisition structure is an important element in the construction of knowledge producing machineries or epistemic cultures, which rely on tissue samples. It not only brings together various actors to collect surgical waste, but also serves as the administrative structure to manage the collection, storage and distribution of the samples themselves. At the same time, the practical goals of this process are connected to the knowledge production goals as well, which besides producing biovalue as scientific knowledge also include the development of commercial biovalue as well.

The sources of the samples are patients who are being treated at the university hospital. The source is, therefore, regionally localized, since the hospital is responsible for patients in the Tampere region, which is made up of 33 counties and a population of slightly over 460 000 inhabitants. The samples which make up the collection, however, are useful globally. In this sense the Tampere Research Tissue Bank forms a local tissue economy in terms of its acquisition practices, but is able to extend its distribution practices throughout its network, which is international. Through standardization practices, such local tissue economies are able to extend themselves beyond national borders to provide a supply of samples beyond the local scientific and commercial production capability.

Figure 4. A TISSUE ECONOMY OF THE TAMPERE RESEARCH TISSUE BANK



As I noted above, the tissue bank set up by the two researchers was, however, only one of many at the hospital. Several other groups collected and maintained their own collections. In order to systematize and consolidate these different activities, the hospital administration decided to develop one large tissue bank that would serve all researchers at the hospital, as well as its outside partners. In doing so, however, the administration also changed the processes by which tissues were acquired and decided to forego the informed consent process.

In the original informed consent model developed by Ylikomi and Helin, patients were given an information leaflet where the activities and goals of the research tissue bank were described. The leaflet also stressed to the patient that by donating they can encourage medical progress and the development of treatment methods for diseases, as well as decrease the amount of animal tests that are required in research, which reflects the altruistic side of the activities. The collection of tissue samples was compared to the collection of blood and bone marrow except that it is not used for the direct treatment of patients or production of therapeutic products. The bank also indicated that it does not pass on data that can be used to identify the patient, such as social security numbers. When the samples are transferred from the pathology department to the tissue bank, the samples are coded so that patients can ask to have their samples removed later on, the patient can enquire for what purposes that sample has been used and that the sample has to be traceable. In this sense, the researchers appealed to a model of donation as gift (Frow, 1997; Titmuss, 1970). The language that they employed in this original document appealed to the altruistic motives of patients, as well as the nature of the tissue as waste. Such techniques evoke powerful images of a necessity towards the more efficient use of existing resources and form an important strategy of motivating patients to donate and thus it can also be seen as a strategy of mobilizing resources and support.

Subsequently, however, when the university hospital took over this operation, the tissue bank changed its procedure to streamline it in a way that allowed them to continue to collect samples, but did not require them to gain consent and maintain the consent papers for an indefinite period of time. In the following I will look at this in more detail.

Changing Modes of Collection and Categorization

The consent model described above was considered and used, therefore, for only a short period of time, after which acquisition practices were consolidated and changed. Instead of asking for consent, the samples which are deemed important or interesting are collected during the diagnosis by the pathologist and then stored and maintained for research. The donation process was therefore abandoned and replaced by a technical collection procedure, thus eliminating the possibility of the patient to decide whether to donate the sample or not. If a researcher or a company becomes interested in a particular sample collection, for example on breast cancer, they can apply for a permit from the National Authority for Medicolegal Affairs to use diagnostic samples for research purposes. In this way, no consent

is needed from the patient for the use of the samples for research purposes. This change in approach substantially re-configures the theoretical grounding on which traditional notions of donation and gift giving have rested (see Titmuss, 1970), since patients are not aware of the collections and use of the samples, while the tissue bank itself is aware that it is collecting diagnostic samples specifically for research purposes. At the same time, it further distances the patient from influencing the ways in which samples removed from them are used in research. There are, however, important reasons behind this decision. In relation to the goals of the ENRTB to collect donations, however, this process averts such practices all together (see Orr *et al.*, 2002) and creates differing standards for collection practices in relation to informed consent. Here we see how tissue economies become embedded within different ethical, legal and social contexts for their acquisition procedures.

The collection, storage and dissemination process is seen as a 'life span' model where the bank not only collects the sample, but is also responsible for the permits, diagnosis, handling, use and destruction of the sample. The hospital administration seeks to bring together, under one set of practices, all collection, storage and distribution activities. In addition, they supervise that their partners utilize the samples in an ethically acceptable manner. Most importantly, in accordance with the Finnish law on the collection and use of human tissue samples, tissues are not bought or sold under any circumstances. The tissue bank, however, is allowed to recoup its expenses, which is standard practice in the utilization of human tissue, such as with blood banks.

A major question in the collection of tissue samples from patients has been the form and type of consent that is required from patients. As Deschênes *et al.* (2001: 221) note, one of the main challenges facing researchers and Research Ethics Boards (REB) is that they must identify the relevant information that must be communicated to the research subjects (see also Berg, 2001). With the advent of molecular genetics and the mapping of the human genome, it has become increasingly difficult to assess the level of information that should be passed on to the patient, and there have been attempts to broaden the interpretation of informed consent (see Hansson *et al.*, 2006). Molecular genetics has also brought under question the definition of traditional disease categories, which further complicates the work of researchers and REB's in determining how and what type of information is necessary for the patient . This was also evident in the interviews which were conducted during the research. As one researcher noted:

> *"The pathologist looks at the slide to see what type of cell structure there is, but in the future we look at each case of cancer and the whole gamut of the genome and its expression, then we can divide breast cancer into many different categories. Then there is no longer a breast cancer or one disease, but rather this or that type of molecule and a cancer with that kind of pathology […] and for a researcher this is important. Is this anomaly same in all cancer cases in Finland, Europe or the US or unique to the Tampere region?"*
> (Interview with researcher, 2002)

The practical difficulties of telling donors what will be studied are highlighted in this interview excerpt by identifying an increasing problem that molecular genetics is raising in terms of disease classification. Researchers are discovering new pathways through which disease is caused and this is causing a problem in terms of defining beforehand to patients what areas of their genome will be studied. Informed consent forms that define the focus of research too narrowly run into problems when they discover that the cause a specific disease is in another area of the genome than originally stated. The collection of surgical waste without informed consent provides an increasingly important conduit through which tissue samples are collected and distributed.

The broader interpretation, as well as the decision not to seek informed consent is an important part of the construction of a tissue economy of surgical waste because it moves from a more traditional understanding of a patient as an active participant in research to more of a source who merely contributes at one point in time and is a source of diagnostic samples which can be used for research purposes through an official permit procedure as opposed to consent. The move from collecting donated tissues from patients to collecting samples which can be classified as discarded highlights a central feature of the transformative process associated with the production of biovalue. Since it is unclear as to the applications and uses of the tissues themselves, it is easier for the tissue bank administrators to collect and use the samples without having to define the future uses of the samples in any way as opposed to using a donation scheme that relies on informed consent. The transformation process of biovalue from samples and information to biovalue as scientific knowledge and health to commercial biovalue is so unstable and unpredictable that it makes more sense from a management perspective for the administrators not to define the scope of future use to patients. At the same time, however, they distance the patient further from decision making procedures. The production of biovalue and its transformation from one type to another becomes implicated in the distancing of the sources of the samples with the possible uses and applications of those very same samples.

This trend appears to be the opposite from the position that the UK Biobank has taken, at least in its ethical guidelines and discourse regarding patient participation, and tends to reflect a general trend towards moving away from having the donor as an active participant in the use and decision-making process. Corrigan and Tutton (2004: 101), for example, have noted that in recent years there has been a shift in the language used to describe the people who participate in clinical trials and epidemiological research where the term 'research subject' is being replaced by 'research participant' to emphasize the collaborative nature of the process. They point out that the Human Genetics Commission (HGC) and UK Biobank both prefer to use the term 'participant' in their documents. As Corrigan and Tutton note, however, the degree to which this reflects a change in actual research and participation possibilities remains quite unclear, misleading and inappropriate. The move to broaden the scope of informed consent in this case reflects, on one hand, an attempt to resolve the challenge of what information needs to be articulated to

patient, but on the other, an attempt to develop a system of tissue acquisition, control and operation where the role of the research subject or donor becomes increasingly regarded as a source of information. In relation to the collections of diagnostic samples, however, we are seeing an opposite trend where the patient is being distanced from decision-making related to the collection and use of samples removed from them.

In a recent review of consent practices, Godard *et al.* (2002: 10) emphasize that patients should be given information on 'the purpose of the research, its limitation and outcomes, its risks and benefits, the types of information that could result from genetic research, communication of results, or means of maintaining confidentiality.' Similar perspectives are also supported by the World Health Organization (WHO) (2003), the Council for International Organizations of Medical Sciences (CIOMS) (2002), the Nuffield Council of Bioethics (1995), the Human Genome Organization (HUGO) (1998) and the Council of Europe (1997). This position would seem to indicate a broader view of the information that patients should be given in relation to tissue samples.

In their original acquisition model, the researchers at the Tampere tissue bank made a distinction between clinical research – where it is important to tell the patient what procedures will be done to the patient and what type of medications will be given to them and how it will affect them – and tissue donation connected with diagnosis and treatment of a condition. With tissue donation, such as with blood donation, donors are given general information as to what it will be used for, but not specific information as to who will be using it and how. In this sense, the researchers subscribed to a broad interpretation of informed consent and compared their practices to those of blood donation procedures. Originally, the researchers gave general information – not blanket consent – about what the samples might be used for, such as prostate, breast cancer or brain tumor research. Since the consolidation, however, this model has been discarded in favor of an even more flexible approach where the consent procedure is averted by applying for a permit from the National Authority for Medicolegal Affairs.

The Tampere Research Tissue Bank, therefore, takes this process one step further and is reflected in the choices that have been made as to whether collected diagnostic samples are collected using informed consent or as diagnostic samples that do not need to have informed consent gained from the patients. Classifying the samples as diagnostic samples and not asking for informed consent gives the biobank and researchers more flexibility in the use of the samples. Although well within their rights to do so under current legislation, the decision to move away from the consent practice does nonetheless reflect an attempt to distance and disengage the patient from deciding or having a say in how their samples are used. In the most recent legislative proposal for biobanks in Finland (Hallituksen Esitys, 2008) it is mentioned that patients should be made aware that their samples might be used and that they should have the opportunity to deny this use. Whether being made aware is the same as asking for consent remains unclear from a practical perspective, but it does, however, reflect a move back towards empowering the patient in relation to their samples.

Given the rhetorical significance that innovation policy texts place on the commercialization of research results, one could argue that the role of tissue samples is becoming increasingly important within the production of commercial value. Informed consent would, therefore, have to account for this possible aspect in some way. Yet it seems that the long-term storage and uncertainty of future use is encouraging biobanks to find alternative ways of collecting and storing tissue. The acquisition procedures of surgical waste are becoming less and less a social practice – involving consent procedures – and more and more a technical procedure. Since tissues are no longer donated, they cease to be gifts where researchers and administrators must contend with complicated interpretations of intended use and the preferences of the patient. Instead, they can substitute the gift practice with expert decision-making procedures which interpret the interests of the source of the sample in relation to the interests of scientific research, as well as the needs and interests of private companies. Tissue samples become disentangled from the source of the samples without consent or gifting taking place (cf. Waldby and Mitchell, 2006).

Since its official launch, the Tampere Research Tissue Bank collection has remained quite small (slightly over 3700 samples thus far). The collection, nonetheless, continues to steadily grow and find new customers, both from the public and private research sectors. Although the process of collecting and distributing samples cannot be a commercial undertaking in itself (i.e. they cannot sell samples for a profit) it none-the-less represents the emergence of an important activity within the two hospital departments, where alongside more traditional diagnostic and research activities, the departments take on new roles as distributors of standardized and processed tissue samples. The move from gaining informed consent to collect surgical waste to abandoning it as a model, however, creates variation among the members of the ENRTB since other members still employ the consent model whereby tissues are donated as gifts. At Tampere, however, it has been replaced by the substitution of donation with a system of expert decision-making on whether or not samples can be used for research. Here we see how a singular tissue economy of surgical waste can come about and operate through diverging informed consent practices across transnational networks.

Value in Banking

In trying to understand some of the reasons behind the move to a broader definition of informed consent and subsequently its abandonment alltogether and its function in allowing researchers and private companies access to donated tissue samples, it is important to place the collection and use of diagnostic tissue samples into a broader political context. The researchers using the tissue bank also see their work in broader terms besides reducing the need for animal models and human testing and providing easier access to sample collections themselves. In contextualizing this move, the relationship between the individual, as a donor, and the individual as part of a social system is reflected in the interviews that were conducted. As one researcher at the tissue bank noted in an interview

where we were discussing the significance of the individual and the way it is reflected in international rights documents:

> *"The individual and their wellbeing is significant, but when we are talking about a society, such as our own where there is significant monetary compensation from one group of people to another and we decide on this together, then we should be able to make decisions at the level of the population…that is social policy, family policy or whatever economic policy. When we have a collectively supported healthcare sector, whose development is in the interests of everybody, then there should be opportunities to develop it in such a way that the interests of the whole population could supersede the rights of the individual in a general sense. Of course I don't mean that the individual should lose rights, but rather they should have the right to donate tissue samples for research if they so choose."*
> (Interview with researcher, 2002)

The researcher sees that although the rights of the individual must always be respected, there are broader social issues to which the biomedical use of tissue sample collections are connected to. Research is not just seen in its more strict sense, but rather as an important part of social institutions, especially the healthcare sector. This reflection on the relationship between donation, research and healthcare signifies a form of indebtedness or duty that many researchers see participants to have towards research. The individual is certainly seen to have personal rights, but at the same time is expected to take responsibility and be committed to the social system as a whole as well. Participation is of course voluntary, but the point is that if samples are donated then researchers and society in general also have a responsibility, right and even duty to utilize them to the benefit of the whole society.

It is worth noting that this interview excerpt was taken in relation to the collection of samples using informed consent (the original collection model) and thus samples were being donated. With the replacement of this model with the one in which informed consent was not acquired, the idea that social interests must be taken into account also plays an important role, but this time without the involvement of the patient in the decision-making process as to what is considered important. Therefore, the interests of science and society become increasingly defined and articulated by experts, removing the individual, both from the possibility of making a decision as well as giving a gift to research. The excerpt also has many elements in common with the policy discourse that I discussed in section 4, whereby the interests of individuals become compared and contrasted with the interests of science and society. Here again, we see how the individual and their rights remain closely embedded within the broader social system that they can be located in.

As the original information leaflet given to patients before surgery noted 'by donating tissue you can contribute to medical progress and the development of new treatment

methods for diseases, as well as reduce the need for animal testing' (Helin and Ylikomi, na). With the new model, the sample still continues to contribute, but without the expressed consent of the patient. The opportunity to give the gift is, therefore, removed from the equation. This process alters the social relation that underlined the altruistic donation practice and replaces it with a technical procedure in which the source of the sample is unaware of samples being collected for research purposes and unaware of its future uses. It also makes it difficult for the donor to remove the sample from the research system if they so choose.

Following Waldby (2002) in considering the 'situatedness' of diagnostic samples at the Tampere Research Tissue Bank, the biomedical collection and use of tissues extends the significance of the samples themselves from the day-to-day practices of the biobank that collects the samples to more broader political, social and economic policy issues related to social development and well being. In this sense, tissue collections can be seen as a political vehicle that is being mobilized to realize certain goals, rather than just objects of scientific curiosity and interest. Although the argument used by the biobank administrators can be said to represent very traditional scientific goals of furthering medical knowledge and reducing animal testing, there is also an element of social responsibility which is based on the production of innovations as the basis of this development (see Snell, 2008).

At the same time we can ask, does the collection and use of diagnostic tissue samples represent an exchange system in economic terms or more a regulated supply system through which property is gained without the practice of consent. Although Titmuss (1970) has noted that since the notion of value can be attached to waste and we are talking about an economic good, can such a system be seen to constitute a form of tissue economy in the exchange sense of the word? Without the practice of consent taking place, are we in fact witnessing a breakdown of the notion of exchange and reciprocity and dealing more in terms of acquisition. This acquisition procedure also brings under question the notion of waste itself as a category for the tissue that is collected. Although tissues enter a system of circulation, use and re-use, their form of entrance is outside an exchange paradigm.

The use of 'diagnostic waste' as a classification is very powerful in this context. On the one hand it evokes a sense of optimization where the use of something that would otherwise be discarded can be seen to contribute to social and economic well-being through research and development. On the one hand, it provides an important gateway through which value – scientific, health and commercial – can be added to a substance that is considered at first to be worthless, except for its diagnostic value. In other words, 'diagnostic waste' holds two states of value at the same time: value and non-value. The choice of doing away with informed consent only helps to highlight the way in which the non-value is actually seen to have value, from which the donor is removed from the decision-making process since defining future forms of value which waste can contribute to is becoming increasingly difficult. Therefore, the act of donation is removed from the equation of altruism and reciprocity. The value of the sample comes about through a completely non-personalized means and can still be expressed in other forms of value

such as health, commercial (through new innovations), as well as by reducing the need for animal testing. The problems associated with defining the output of this transformative process associated with biovalue has contributed to the broadening and abandonment of the informed consent procedure altogether with regard to the acquisition of diagnostic samples.

The process of adding value to waste is further signified through the processing of the tissue samples themselves. The processing of tissue samples includes the collection and addition of a multitude of other meta-data that is attached to the sample itself. This data includes the medical history of the patient and possible family history, but also a whole battery of other necessary information that is entered into a database in a standardized format. This format allows the biobank to transfer the data itself in a usable format to those who might be interested in using it. The organization of metadata is a massive undertaking if it is in another format than what one needs it to be in. Therefore the addition of that data in a standardized format is a major factor that adds use value to the tissue samples themselves, not just individually, but as a whole as well.

The case of the Tampere Research Tissue Bank is informative in that it identifies the problems associated with gaining informed consent with the collection of diagnostic tissue samples or what has also been called surgical waste. The case highlights how the difficulties in defining the future uses of the samples, as well as the regulatory allowance for their use in research, has contributed to the up-take of collection practices which do not subscribe to the use of informed consent. Such practices, give rise to a collection system where tissues are no longer donated to research, but instead are considered to be part of the medical record of the patient, and under current law, usable for research by acquiring a permit from the medicolegal council. This can be seen as a way of organizing resource relationships where consent is not sought at all in the collections of tissue samples. At the same time, such practices remove the source of the sample even further from the possibility of making decisions on how samples taken from them are used and can be seen to play a role in restricting the scope of personal autonomy in relation to one's own body samples and personal information.

In the next case, however, I will look at the difficulties of interpretations associated with informed consent in cases which involve large research tissue sample collections or epidemiological sample collections. In this case, we see how interpretations of informed consent are confronted by pressures to re-use existing collections more efficiently to save money and time. This process has brought forth a multitude of discursive approaches to support such practices which I will look at in more detail below with the case of the Finnish Genome Information Centre.

5.2 FINNISH GENOME INFORMATION CENTER – ECONOMIES OF ECONOMIES

> "Practices that are acceptable for the state of the research art at one time may need to be refined in new situations. In human genetic research, the speed with which basic investigations can yield clinically significant findings requires consideration of new ways to achieve the goals of expanding knowledge, and, at the same time, respecting the interests of those who volunteer themselves to be subjects."
> (ASHG, 1996: 471)

Thus far I have examined a case where the collection and use of human tissue samples has remained at a localized level and utilized diagnostic samples. From an epistemic perspective, the Tampere Research Tissue Bank has been limited to rather small-scale collections and research practices. Although this activity represents an important element within the research system in relation to the acquisition of surgical waste and provides a critical perspective on the way samples are collected and the notion of waste, it is important to understand that biomedical research is increasingly becoming 'big science' (although some have argued that it has been that all along) and the infrastructures that are being developed to support this reflect this change (Price, 1963). At the same time, it is increasingly apparent that small tissue sample collections or cohorts are not big enough to study complex or multifactorial diseases. The need for increasingly larger sample collections is leading to a re-organization of resource relations, which in turn has consequences for interpretations of informed consent. Indeed, some studies have shown that people in some countries are willing to provide only general consent when they donate their samples (cf. Kettis-Lindblad *et al.*, 2006).

As researchers in Finland and elsewhere in the world are getting to the point where the genetic causes of simple or monogenetic diseases are becoming known, research interests are moving towards more difficult or complex diseases, such as diabetes and heart disease. As a result, a number of ventures are underway, both in Finland and internationally, where the aim is to build and develop a research infrastructure that will bring together various data gained from sample collections, as well as other healthcare information to produce increasingly large data sets to study these more complex diseases (cf. Keating and Cambrosio, 2003). Invariably, this undertaking will mean that samples taken for one research project can and will be used for another purpose (Holm and Bennet, 2001). In doing so, however, the scope of informed consent becomes subject to re-interpretation and negotiation. In the following I will map out one such venture in Finland that also

serves as a model for global research initiatives and the significance that it has in terms of interpreting the scope of informed consent.

Tissues and International Research Markets

In comparison to the broad range of discussions that have emerged out of the Icelandic government selling exclusive rights for the health sector database to deCode Genetics (see Rose, 2001; Pálsson and Harđardóttir, 2002) and the discussions which have taken place in the UK concerning the setting up of the UK Biobank (Barbour, 2003; Martin, 2001: 168), the discussions in Finland concerning the biomedical use of tissue sample collections has been related more to the economic and commercial aspects of such ventures. The development of the Finnish Genome Information Center[17] was supported by a commissioned study by the Finnish National Technology Agency, Tekes, on the possibility to utilize the extensive sample collections, as well as other population data available in a number of public databases (Technomedicum, 2004a). The setting up of the centre has brought forth a discussion that has been led to a large extent by those who are involved in the development of the Finnish Genome Information Center, namely the researchers themselves and government officials.

In 2003 the Academy of Finland published a proposal entitled *Initiative for the Establishment of a Molecular Medicine Research Center in Finland in Co-operation with the European Molecular Biology Laboratory (EMBL)* (Academy of Finland, 2003c). In the Academy initiative it is noted:

> "Compared to many other countries or regions, one of the Nordic countries' greatest strengths is its extremely wide-ranging and high-quality population-based registers, and patient and sample databases, whose compilation has been extremely well-received by decision-makers, researchers and the general population."
> (Academy of Finland, 2003c: 16)

The policy discourse of the Academy itself reflects the way in which the public trust in the medical research community has been a major contributing factor to the collection of existing sample collections for various studies, but it also reflects the possibility that the positive view on research has for setting up a new genome information center and the re-use of the existing collections in other research projects. In a similar vein, the Finnish National Public Health Institute has noted that 'the genetic homogeneity of the

[17] Although originally called The Finnish Genome Information Center, the project and the center have since taken on the name Finnish Institute for Molecular Medicine (FIMM). On 20.9.2006 The University of Helsinki Council approved the forming of the center, as well as the allocation of funding for setting it up. (See www.fimm.fi)

Finnish population offers an exceptional benefit in studying the genetic background for multifactorial diseases' (National Public Health Institute, 2003).

The initiative sought to strengthen Finland's position in biomedical research with a focus on molecular genetics and epidemiology. The goal of the center was to improve the international profile of Finnish research and improve the effectiveness of the Finnish innovation system as it applied to biomedical research (cf. Science and Technology Policy Council, 2003). The proposal was a response to a demand by the Ministry of Education to explore the possibilities to set up an international molecular genetics research center in Finland, as well as the need to develop a large enough facility (sometimes referred to as Biocenter Finland) to bring together all five Finnish biocenters, as well as other actors in the field (Opetusministeriö, 2005a; 2005b). Although molecular genetics was already a successful field in Finland, with many notable researchers and research groups operating, the new center would specifically be aimed at improving the international standard and visibility of Finnish research.

At the same time that the Academy of Finland was considering the feasibility of the EMBL satellite, another closely related development was underway. In 2003, a feasibility report was published by Tekes on the setting up of a Genome Information Center (GIC) in Finland (Käpyaho *et al.*, 2004). As the report noted, the goal of the project was to 'fully take advantage of the most recent and accumulating genetic information to analyze the interplay between genes, treatment and outcome, disease and environment' (Käpyaho and Holthöfer, 2003: 3). The Tekes report on the utilization of large Finnish study cohorts in genome research focused on nine major population based studies that have been undertaken in Finland during the past ten years and represent a total of 190,000 existing samples with associated healthcare data (Technomedicum, 2004a; 2004b). All of the epidemiological study cohorts have access to 'relevant national registries, the most important being the Death Registry, the National Hospital Discharge Registry, the Cancer Registry, and the National Registry for Reimbursed Medicines' (Technomedicum, 2004a: 6). In addition, the study focused on the applicability to use autopsy samples for research purposes as well. The report suggested the setting up of a research system that would utilize a database federation infrastructure through which different projects could collaborate and combine different information resources (Tupasela, 2007b; Heimbigner and McLeod, 1985).

The feasibility report was a precursor for a larger and more comprehensive study which followed. Both the feasibility report and larger study were funded by Tekes, which was interested to know what types of tissue and data resources were available and had been collected in Finland over the years, as well as what the possibilities were for utilizing these sample collections and related health information within the context of the GIC, as well as commercially. The outcome of the larger study was a comprehensive description of ten major existing study cohorts in Finland, which totaled over 213 000 participants, their samples and carefully collected health and lifestyle information. In addition, the study identified over 1 million samples which were located in pathology collections and which could be used for research, much like those collected at the Tampere tissue bank.

The EMBL satellite and the GIC are related to one another in that they would be housed under the same roof. Therefore, the GIC would serve to collect and combine existing sample collections and the analysis would be done by researchers through the EMBL satellite, which would obviously include Finnish researchers, but also serve to attract top-name international researchers as well. A major challenge for the center would be to convince the custodians of the existing cohorts to participate in joint ventures and allow for their collections to be used since this would allow outside researchers access to their sample collections, as well as data to a certain degree. Another major challenge facing this venture is the legal challenge of being able to re-use samples taken for one research purpose for another purpose and the way in which informed consent could and indeed should be interpreted.

Economies of Economies

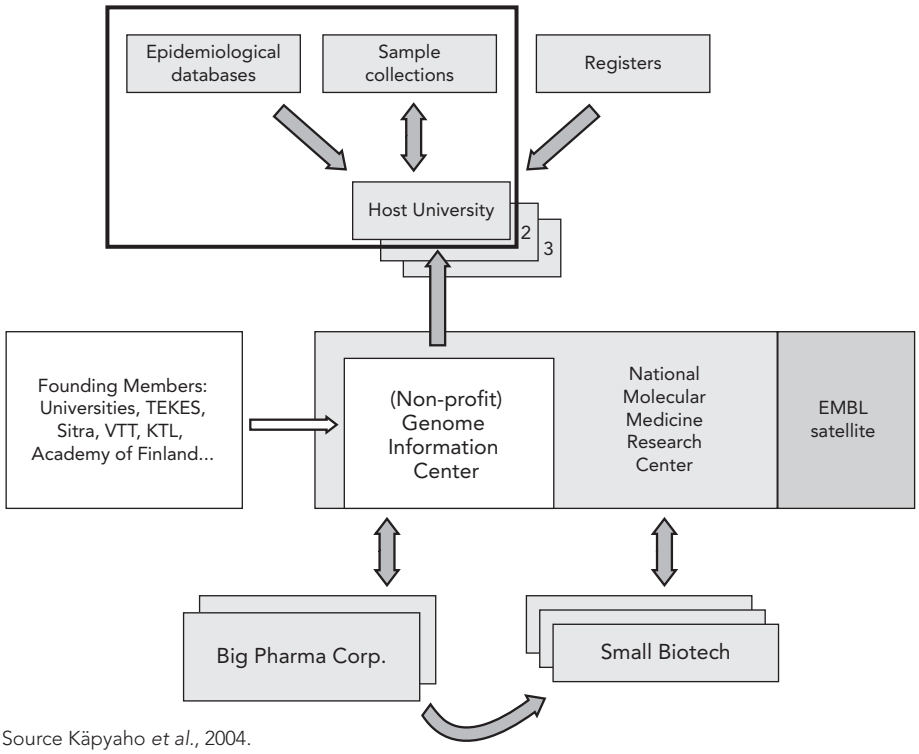
Mäkelä *et al.* (1997: 13) have identified four different legal categorizations for public health service registers in Finland (legally mandated national registers, research registers, patient registers and other registers). In general, biobanks are considered research registers. The Genome Information Center, however, would essentially constitute a fifth type of register, which would be a biobank of biobanks, a meta-register or a virtual biobank. It would not at first maintain any collections itself, but rather serve as a hub that would bring together data from other registers. This would mean that physically, the samples would not be located at the center, but the data from the samples, as well as other data registers would be collected and analyzed through its facilities. This can be viewed as one way of re-organizing existing resource relationships by creating a new infrastructure through which tissue sample collections can be analyzed. Indeed, the goal of many biobanking initiatives, such as CARTaGENE, is to collect samples and data that can be later on combined with data from other biobanks (OECD, 2006).

When we examine the type of tissue economies that exist and are being constructed, it is possible to argue that economies operate on several levels. For example, with pathology samples and surgical waste, it is possible to say that their primary purpose has been for the diagnosis of disease, but that their re-use for research later on represents a secondary purpose. In this sense, economies become extended beyond their original purpose. The extension of tissue economies is an integral part of the production of new forms of bio-value as they relate to tissue sample collections in that it allows for new ways of utilizing existing resources, as well as the possibility of owning new knowledge and products in the form of patents, as well as tacit knowledge. Similarly one can say that collecting gifted and non-gifted surgical waste is one way of extending tissue economies. This follows very closely what Strathern (1999) has argued to be a central development of the past twenty or thirty years of devising new ways of laying claim to objects. In much the same way as waste can be gifted and claimed as an object, so can old tissue collections be 'rejuvenated' and grafted onto new biobank initiatives. If the secondary use of tissues for other purposes than what they were originally intended for is an extension of tissue economies, then the

infrastructure of the Genome Information Center can be said to form, not only a secondary function, but also an economy of tissue economies, or an *economy of economies*.

In Figure 5, the structure of the operation and relation to other actors of the Genome Information Centre is represented as a diagram. A central feature of the center is that it operates based on what is called *database federation* (see Tupasela, 2007b; 2006a: 111). Database federation is the process by which different databases on biomedical information or healthcare information are brought together to form a larger database. Using this technique, individual databases that already exist (and could be called tissue economies in themselves) are brought together to form larger data sets. In the case of the Genome Information Center, this means that universities that are members of the center, gain access to the center's infrastructure. Researchers can, therefore, decide whether to participate, but the benefits of gaining access to the data of others is conditional on one's own participation. Database federation allows for the comparison of different types of databases, including epidemiological databases with disease-based databases, such as developed for cancer research. It also forms an infrastructure on the combining of the larger datasets with the multitude of registers that have been discussed before.

Figure 5. A TISSUE ECONOMY OF THE FINNISH GENOME INFORMATION CENTER – ECONOMIES OF ECONOMIES



Source Käpyaho *et al.*, 2004.

Figure 5 provides a schematic outline of the actors who are involved in the setting-up of the GIC. It is important to note that the center would serve as a hub to all participating universities and the collections that are housed in their facilities and run by their research groups. By far the most important collections are owned by the National Public Health Institute, but due to the fact that several important research professorships are jointly funded by the institute and collaborating universities, the samples could be accessed through university research structures. Another important feature of the center is that the founding members include all the major funding organizations in Finland (Academy of Finland, Tekes and Sitra), as well as the universities themselves.

Such an economy of economies is a significant research infrastructure in relation to the production of scientific knowledge in that it is seen as a major driver and producer of innovations for small biotech companies, as well as large pharmaceutical companies, as the figure indicates. Biovalue as scientific knowledge is seen to translate into commercial biovalue that can be utilized by companies. Here we see how the visual mapping of scientific knowledge production and its subsequent up-take by the private sector is normalized into an official world view (cf. Miettinen, 2002) which is naturalized and self-evident (see also Birch, 2006). Scientific knowledge production and the collections that they utilize are explicitly embedded into this vision of the commercial model of application. Implicitly, this model is seen then as the basis of social relation in terms of the public production and funding of scientific knowledge and its subsequent use by the private sector. In relation to consent, the process of negotiation and re-interpreting consent becomes entangled with issues and concerns related to commercialization.

Where ten or twenty years ago the role of industry was not overtly emphasized in medical research, particularly in Finnish universities, today it has become a central component of why such research infrastructures are developed and funded (see Tupasela, 2000a). Participation in the framework does not just allow for the possibility of university-industry relations, but instead it is now expected that this is the model according to which novel ideas and discoveries are commercialized. Although this is not a new idea in itself, and proponents argue that university-industry links have always existed in the medical sciences, the codification of this relationship in the models themselves and the arguments for them represent an important shift in the significance that biomedical research is seen to have in society. It also ties existing tissue economies to the commercial expectations associated with scientific knowledge production. Here the organization of the resource relationship is, therefore, overtly tied in with commercialization.

The use of the database federation model is based to a large extent on another, already in progress, project where twin cohorts from a number of countries have been combined using the model. The GenomEUtwin project uses data from Danish, Finnish, Italian, Dutch and Swedish twins and the MORGAM population cohorts, which form a combined collection of over 600 000 pairs of twins and 'tens of thousands of DNA samples with informed consents for genetic studies of common diseases' (GenomEUtwin, 2006). The objective of the EU-funded project has been to develop new ways of utilizing existing

collections around the world for the study of complex traits and to develop new molecular and computational methods for genome-wide analyses of population cohorts. In doing so, the project also helped to develop a unique research infrastructure to analyze the data from the various cohorts in one place (Sweden) while maintaining strict security measures to ensure confidentiality of the samples, yet allowing for analysis. This infrastructure has been an important pre-cursor for the development of the Genome Information Center in Finland.

The project points to the possibility and way in which national collections and other register data can be combined at an international level to produce larger data sets. Kere (2007: 864) has argued that current research using genetic association studies is difficult to publish unless several different sample collections have been combined and preferably from different countries. This change in the perceptions concerning the validity of national collections indicates the need for researchers to begin developing networks of research cooperation, which invariably activate national collections into this network. The problem of validity of population samples also highlights the challenge which the scientific disciplines using tissue sample collections are faced with epistemically. The production of valid scientific knowledge from such population samples is not valid under certain conditions unless it is combined with collections and data from other countries as well. This serves as a driver to develop knowledge production machineries which address this issue and it also has a bearing on interpretations of the scope of informed consent since such issues have not necessarily been foreseen when the collections were collected in the first place.

As a result, many small countries, such as Finland, have begun to extend their scientific scope and compete and cooperate with countries with much larger research funding capabilities, as well as tissue collections of their own. The existence of national collections therefore provides opportunities to participate and compete internationally and produce knowledge that will be accepted by international scientific journals and be seen as scientifically valid. At the same time, however, the extension of tissue economies also introduces challenges in interpretations of informed consent.

Economies of Economies and Consent

Consent and biobanking has become an issue of some deliberation in a number of countries in relation to the biomedical use of tissue samples and healthcare records, particularly in relation to large population studies (Deschênes *et al.*, 2001; Berg, 2001). With large population studies, two important issues have emerged in relation to informed consent; what to do with old sample collections that have limited or no informed consent and how much information is sufficient or enough in relation to new informed consent documents in new research projects. These aspects are related to the nature and malleability of tissues as information, but also to the nature and interpretations of the meanings associated with the donation or gift of samples and data in the first place. The consent question is

also related to the notion of waste and re-use of existing collections. These issues have had an important bearing on the interpretations that are given to current regimes of informed consent and are therefore important to examine.

In relation to old sample collections, the status of samples and related information has been classified as tissues being abandoned. This discourse draws on the language of tissues as waste and has become entwined with discourses that highlight the necessity of using existing sample collections efficiently. The notion of abandonment is one which can be applied, however, to any sample collection that is old enough and is used as a strategy to circumvent responsibilities of re-negotiating terms and conditions associated with the re-use of collections. This is one way of making old sample collections available to research and the subsequent commercialization of their research results. This is tantamount to saying that once my personal data becomes old enough it is open to use by third parties without my consent.

What has become increasingly difficult to deal with, however, in relation to genome research and informed consent is the specificity of information that is required to be given to the patient regarding what will be studied. Given that we are seeing the emergence and development of economies of economies, it is becoming increasingly difficult to define beforehand what information should be given to research subjects. This was apparent in the interviews that were conducted with researchers. As one genetic researcher noted in an interview:

> *"I lecture to medical students on multifactorial diseases and I use the term umbrella diagnosis, by which I mean that many of these so-called chronic national diseases (diabetes, heart disease) can be divided into many sub-groups where there is a different disease etiology. The worst case scenario for a geneticist or a researcher is if each individual has their own disease etiology, although it is not like that, but when we talk about type 2 diabetes, then we can see that there are many different paths that lead to the same final phenotype and that is a challenge for research."*
> (Molecular geneticist interview, 2005)

For epidemiological research, the problem of trying to define what causes a specific disease is problematic in terms of informed consent, in that the cause or causes may be very different than what has been generally accepted in science. This means that researchers who collect samples for research should provide information on the focus of their research that is broad enough to allow them to study all the factors that might one day represent a possible cause behind a disease as opposed to defining specific genetic markers that will be studied. This has an important impact on the types of tissue economies that are created, in that the wording of informed consent forms has to be written in a way that will allow for maximum research possibilities in the unforeseen future.

For example, it has recently been shown that infections located in the mouth, such

as gum disease, can play an important role in the onset of heart attacks and other serious health conditions (Lauhio *et al.*, 2007). Due to the systemic nature of many diseases, the causes are difficult to predict beforehand and explain to the research subject, which means that strict interpretations of informed consent become increasingly replaced with more general or broader forms of informed consent. This would seem to be supported by recent findings regarding people's motives for participating and donating tissue samples (see Hoeyer and Lynoe, 2006).

Given that in some instances tissue economies are becoming amalgams of smaller tissue economies, informed consent concerns are becoming superseded more by information management concerns, which changes the nature of the resource relationship in a way where the source of the sample and information has less say in the way their samples are used. In terms of interpreting the scope of informed consent on new studies, recent literature on biobanking appears to support the idea that a move towards a broader definition of informed consent is justifiable. Hansson *et al.* (2006: 266), for example, argue that broad consent and consent for future research are ethically valid provided that personal data are handled safely, donors are granted the right to withdraw consent and new studies are subject to approval by an ethics review board. Deschênes *et al.* (2001) also argue along similar lines. Hansson (2005: 415) has noted that informed consent is an act of trust, but this does not mean that a strict interpretation of informed consent should be adopted, since this may not account for the multiplicity of patient interests which are at stake. Nonetheless, informed consent according to Hansson (2005) represents respect for the moral authority of patients and research subjects.

In relation to the emergence of economies of economies, this is an important shift in interpretation in that it allows for the re-use of existing tissue sample collections for research questions which are different than what the samples and data were originally collected for. This move effectively expands the potential biovalue of tissue sample collections. It represents, therefore, a process of disentanglement from the constraints of consent, which is ironic given that some commentators (cf. Callon, 1998) have noted that it is consent which serves to disentangle tissues from claims of ownership by donors (see also Waldby and Mitchell, 2006).

The most recent legal proposal for biobanking in Finland (Hallituksen Esitys, 2008) suggests that people be allowed to give broad consent, but that they should also have access to information on who is using their samples and for what. They could also withdraw their sample if they so choose. Here we see an important attempt to re-engage research subjects in relation to their samples. Interestingly, however, this move can be seen as a re-entanglement after disentanglement, which raises the question as to the function of informed consent as a process of disentanglement in the first place. It also indicates that issues related to commercialization clearly problematize the use of donated tissue samples for policy-makers and legislators. It would appear, therefore, that practices related to the use of epidemiological sample collections must continually re-negotiate their legitimacy in relation to the source, despite the fact that consent has been given to their use. This

once again can be interpreted as a critique of the idea that consent serves to disentangle gifts from their donor, in that the users of sample are constantly referring back to the source in some situations. This would indicate that commercialization as a practice poses problems in translating some types of donated tissues into commercial biovalue.

Some commentators, however, have gone much further in interpreting the scope of informed consent in relation to donated samples and information. Eriksson and Helgesson (2005b) have argued that

> "Since biobank research does not involve any risk of direct physical harm, and is likely to involve nonphysical harms of different magnitude as compared to research on living human subjects, it is reasonable to treat it as a special kind of research more akin to register research. […] it is by no means clear that guidelines relevant to research on human subjects are also relevant to biobank research. We argue that anonymization should not be an automatically permissible response from researchers and biobank holders to requests of withdrawal. Nor should a request for withdrawal necessarily stop research on identifiable samples. […] those who wish to withdraw their samples from research must present a sufficient argument for doing so, out of consideration of fairness and a duty to contribute to the continuous development of public health resources."
> (Eriksson and Helgesson, 2005b: 1076)

This passage from an article on informed consent reflects some of the issues raised in policy texts that I discussed in section 4. The issue of risk is employed as a measure of what level of autonomy are afforded research patients and their data. Biobank research does not, according to the authors, pose the same types of risk as research on living subjects. This is true and does raise the question of to what degree should re-consent, for example, be sought. What is more surprising, however, is that the authors go even further and argue that limits should be set on the degree to which and conditions under which participants should be able to control information and samples removed from them. Individuals should, according to the authors, 'present sufficient arguments' as to why their data and samples should be removed. This, it is argued, stems from a notion of fairness and a duty to contribute by the donor of the sample.

The passage is indicative of the way in which personal autonomy and control over ones personal information and bodily samples are being encroached upon. Although such practices have not, to my knowledge, been undertaken in any cases (people are still afforded the right to withdraw consent from research), the passage and the position it takes suggests a trend in which research participants are imbued with duties and responsibilities towards society in relation to their personal health information and bodily samples. Such positions go beyond reflecting the technical difficulties associated with what types of information need to be disseminated and introduce normative considerations involving duties and fairness into the acquisition and management process of tissue sample collections.

Much like the policy and legal documents which were analyzed in section 4, such positions contextualize the discussion surrounding personal privacy and rights within a moral and normative discourse. Within these discourses, the interests of science and society supersede the interests and rights of the individual that are laid out within international agreements and documents. Of particular interest is the way in which commercial and private interests have entered as important factors in this discourse. This shift in the interpretation of the scope of informed consent derives also in part from the informational turn in which samples removed from the body are seen as information. Their subsequent study and use in scientific research, however, brings forth the need to further clarify how and when consent and the rights of the research subject can be exerted in relation to samples and information derived from them, as well as further distinctions in the possible harms and risks that are involved in their use. These discussions have failed to discuss, however, the moral rights of individuals to control and have a say in the way information and samples donated or acquired from them are managed and used, which in my view is at the heart of the discussion surrounding autonomy and personal rights.

Broadening the scope of informed consent has important consequences on the forms and types of tissue economies that become possible in the future (indeed some already exist), in that the role of the patient and donor changes from an active participant (cf. Corrigan and Tutton, 2004) to a source of samples and information about health and lifestyle, although the most recent legal proposal in Finland would appear to re-activate the research subject to some degree. At the same time, this process has a tendency of introducing normative and moral arguments to support itself. Such moves also increase the responsibility of institutions and experts in the maintenance of trust and confidence as far as the functioning of those tissue economies is concerned.

Given the application of technical solutions to address the issue of information privacy, as well as the ascent of information as a central object of management in tissue economies, it is, therefore, important to examine the way in which genetic information has come to be viewed in relation to biobanking. Molecular genetics has arguably become an information-driven research field, and there are some important aspects which should be noted concerning the informational turn in this research area in relation to the type of knowledge production that is taking place and some of its most important characteristics.

For this I turn back to the work of Karin Knorr Cetina on epistemic cultures. In her study of high energy physics, Knorr Cetina (1999: 166) has argued that in some research fields, namely big science, the production of scientific knowledge has been taken over by collectives, as opposed to individual researchers producing new knowledge. This she calls the *erasure of the epistemic subject*, in that the individual researcher is no longer seen as the most important unit of production. Knorr Cetina (1999: 168) writes that scientific collectives 'signify that the individual has been turned into an element of a much larger unit that functions as a collective epistemic subject'.

In examining tissue economies as economies of economies and the need for ever

increasing data sample sizes in relation to interpretations of informed consent, it is by no means hard to imagine that researchers look at data, not from the perspective of consent and personal privacy/autonomy in a strict sense or the individual as a research object, but rather from a data management perspective. The case of the Genome Information Center indicates the way in which researches are increasingly seeking to organize and manage existing tissue sample collections. Issues of informed consent and re-consent become marginalized in light of the task of managing large data sets and increasingly more complex research questions. In this sense I would like to suggest, following Knorr Cetina's thinking, that the emergence and development of economies of economies or systems of database federation, give rise to the erasure of the research subject in one sense. By this I mean that the research participant from whom samples and medical data have been collected is a statistical reference point and the information gained from them is comparable to any other type of information that can be statistically analyzed. This perspective changes the context within which conceptions of rights are interpreted. As one epidemiologist noted in an interview:

> *"When we analyze geno- and phenotypic data we are not interested in the individual per se, but rather in the statistical power that comes from having a large data set. I see that increasingly we will need larger and larger data sets to understand multifactorial diseases and the role of environmental factors in the onset of many diseases. Given the fact that scientific research in this area is premised on the search for unknown or new factors that cause disease and a major factor in this is the combination of a multitude of different risk factors, such as environment, smoking and different genetic factors, it would be unscientific to base informed consent on the traditional way of doing research, where one gene corresponds to one disease."*
> (Epidemiologist interview, 2003)

The interview excerpt provides an example of the way in which data is understood in large studies. The role of the data of one individual is not seen as significant in that it is only one in several thousand. Researchers often also note that epidemiological research cannot be used for diagnostic purposes because there is always the possibility of data corruption with large sample collections and that the methods they use are not standardized, such as in diagnostic laboratories.

The erasure of the individual research subject or research participant is important for several reasons. *First*, this approach has supported more recent attempts to broaden or loosen the scope of informed consent in large population studies, given the fact that the sum of the information is seen to form a more important object than that of the individual (see Aromaa *et al.*, 2002). Such attempts have not been able to make any distinction within the research field between different types of studies (population vs. disease-based studies), nor the fact that in some cases, such as HeLa cells, the samples of the individuals

themselves are of value. The loosening of the interpretation of informed consent would, therefore, also be applicable for the study of hereditary disease, such as in the case of HNPCC, where individuals become important objects of study within families.

Second, understanding the rights of individuals within a collective context has an important bearing on the way legislation is interpreted and written. The new law on biobanking takes into consideration the possibility of allowing people to give broad consent. It also, however, allows them to gain access to information on who is using their samples and for what purpose. This move reflects an attempt to find a balance between communal and personal rights in biobanking. We can see, then, the way in which the necessity of using large epidemiological sample collections and the imperative to use and re-use them in different configurations gives rise to a need to re-interpret the breadth of consent possibilities.

Third, the idea that the research subject or donor is not seen as an individual, but rather as a part of a larger data set raises further theoretical questions relating to the notion of reciprocity as set forth by Mauss (2004). The fact that researchers stress that the individual will get no personal gain from their contribution highlights the way in which tissue economies are in many ways impersonal and do not maintain any system of individual reciprocity *per se*. In one sense then, this could be interpreted as exemplifying the significance of altruism in donation and participation (not for diagnostic samples), since participation would in fact render the individual as part of a broader community of samples that has a general benefit.

Fourth, database federation is also seen as an entry point into international tissue economies. National and local collections become a tool for leverage and access to international partnerships and give researchers both credibility and resources which can be deployed. The collections, therefore, come to have value in terms of bargaining chips on international research markets. Collections help to position national research agendas in relation to international projects and undertakings.

This dilemma in the significance of personal and individual information and its role in knowledge production is yet another example of the different levels at which tissue economies can be seen to operate and the significance that different types of data is seen to have. The development of research infrastructures which utilize database federation and seek to re-use existing tissue sample collections challenges many of the practical practices associated with informed consent. The challenges of defining the scope of possible future research is also a major practical challenge which is changing interpretations of informed consent, alongside the perspective that each data sample represents just one data point among thousands, as opposed to a legal entity which should be afforded individual privacy rights in the strict sense.

To achieve these goals, the research community has been very active in deploying normative and moral narratives to support their cause. In the next section I will look at some of these narratives to show the ways in which certain discourses are deployed in order to support the case set out by many researchers. This analysis is an important

component of the way in which tissue economies and the interpretations of informed consent associated with them are becoming extended in Finland.

Framing the Context of Discussion in Finland

The set-up of the Genome Information Center involves two different, yet inter-related, forms of engagement with non-experts, both of which are a challenge to implement by experts. The first, relates to whether or not researchers are required to re-gain informed consent for samples originally taken for another research project. The second engagement involves the policy aspects related to the organization and utilization of national resources. Both forms of engagement reflect the ways in which the re-use of tissue sample collections activate certain discourses within the language of the research community.

For the first form of engagement, experts have tried, as discussed above, to introduce a more liberal interpretation of informed consent where patients authorize research, but are not necessarily informed of the exact research that the samples will be used in (see Caulfield *et al.*, 2003). As a member of the National Advisory Board on Healthcare Ethics commented on a document (see Aromaa *et al.*, 2002) prepared on the epidemiological use of DNA samples in Finland:

> *"It was a brave and open-minded working group that wanted to provoke discussion about what was really worth protecting and tried to interpret as loosely as possible the existing laws on informed consent. […] We wanted to challenge the existing notions by asking why one couldn't apply for a permit from the National Authority for Medicolegal Affairs for re-using samples originally taken for research, the same way one can do for samples originally taken for diagnostic or treatment purposes. The legislators and the Ministry for Social Affairs and Health have not yet reacted to this … in part due to the international legal obligations we have, which state that every time you develop a new purpose for the samples you should re-gain consent."*
>
> (Member of National Advisory Board on Research Ethics interview, 2004)

Most researchers agree that to re-gain informed consent every time one develops a new purpose for samples is not practical and hinders the progress of research, although a study has shown that gaining re-consent for large population research projects has been shown to be feasible (Stegmayr and Asplund, 2002). At the same time, however, all agree that a regulatory framework through which permits would be gained is necessary to control and regulate research activities.

Within the context of the second form of engagement, a recent workgroup report on biobanks in Finland noted that the main aims of developing a coherent regulatory framework for biobanking is to ensure that the rights of the citizen are *strengthened*, to increase the public's trust and improve informing of the public, to improve the conditions

of medical research, to use more efficiently the already collected and to be collected sample collections and to improve Finland's competitive advantage (Sosiaali- ja terveysministeriö, 2006: 9). According to the working group, in order 'to ensure that this type of information [personal data] is shared fairly and equitably and that society as a whole benefits, the working party has prioritised the importance of balancing the needs, responsibilities, and rights of all those involved.' (Pitkänen and Hassi, 2007: 33)

Jallinoja and Aro (1999) have noted that Finns have a high level of trust in the healthcare system, as well as genetic researchers (see also Tieteen tiedotus, 2004). At the same time, however, they maintain fears concerning research on their own or their children's genes. This would appear to indicate that the trust relationship between researchers and their subjects is not straightforward (see also Eurobarometer, 2002; Kuusi, 2004: 104). The somewhat tenuous trust relationship between experts and the public does not mean that the question of whether or not to set up the Genome Information Center is self evident. Instead, recent writings by researchers reflect a strong imperative to frame the discussion in terms that are favorable to the research community while at the same time allowing the public to have an opinion, but only on certain issues. Given the fact that Finn's are more hesitant about research on themselves and their children's genes, while at the same time having a high level of trust for the researchers themselves, it is important to frame the discussion in terms that do not create suspicion and fear.

The views of Finnish biomedical researchers, however, in general indicate a strong feeling that the public trusts them and researchers can assume broader liberties in, for example, interpreting the scope of informed consent. As one molecular biologist noted:

> *"In short, I would like to see consent to be interpreted rather broadly, and that one would not be required to get re-consent. Getting re-consent for every new gene or new research is based on our very naïve assumption that we know what schizophrenia or hypertension is. […] It's [public trust] definitely a competitive advantage! It indicates that past doctors have done something right because the average Finn, at a European level, regards medical research very positively. […] This is a fantastic competitive advantage and maintaining this level of trust is a great challenge to gene researchers, as well as medical researchers."*
> (Molecular biologist interview, 2003)

Relating the trust that the public has in researchers to the competitive aspects of international scientific research is an important framework into which discussions of science policy are increasingly framed. It also reflects a trajectory in the epidemiological research community that stresses the long-term nature of their research, where investments made today are part of a new infrastructure that will bear fruit in decades to come. In order to maintain the trust of the public, however, visions and expectations need to be deployed in order to create a sense of need and urgency. At the same time researchers emphasize that their actions and decisions are ethically sound, since not following given policies

would result in lost economic and financial opportunities. This forms a type of social reciprocity between researchers and the public, where researchers see that they must deliver particular types of results in order to maintain the trust of the public. National competitiveness, in both scientific and economic performance has become, in this sense, an important aspect of framing scientific justification, which has also been difficult for the public to oppose without being branded as unpatriotic or uncooperative. Expectations and visions, therefore, enter the *lingua franca* of scientists alongside truth claims, experience and expertise. Expectations and visions, however, are impossible to confirm in any way since they have not yet happened.

In addition to the policy and strategy documents I have discussed earlier, a number of important articles appeared in Finnish publications which reflected the aims of the researchers involved in the Genome Information Center project. From these articles and writings, a number of themes arise concerning the arguments for the more efficient exploitation of existing collections in Finland, as well as the arguments for setting up the Genome Information Center. These arguments exemplify the narrative structure and content in which researchers want to frame the Genome Information Center and also reflect the ways in which researchers see their work to influence other areas of society. Two articles, in particular, reflect the framing that researchers would like to introduce to the discussion of the Genome Information Center; the first was published in a Finnish medical journal, *Duodecim* (Palotie and Peltonen-Palotie, 2004) and the second was published in a more general discussion journal on science called *Tieteessä tapahtuu* (Käpyaho *et al.*, 2004).

In both articles, the Finnish case is discussed in comparative terms, where the position of Finland is seen from a competitive perspective. A major argument that is used for the further exploitation of existing collections is that it would give Finnish researchers a leg-up in relation to other countries that have only begun to collect data, such as the UK (UK Biobank), Estonia (Estonian Genome Project) and Canada (CARTaGENE). This opportunity and advantage, however, has to be seized immediately, according to researchers. For example, in the leading article of the medical journal *Duodecim*, two of Finland's top genome researchers, note that Finland has already done what many countries have only begun to do in the collection of samples and that this would provide an excellent opportunity to expand the existing collections. This would also, according to the authors, allow Finland to participate in future international comparative genome studies, since already, it is not clear if national collections are large enough to provide useful epidemiological data on multifactorial causes of many common diseases, such as diabetes (Palotie and Peltonen-Palotie, 2004).

Besides the comparative aspect, justifications for the more efficient utilization of existing collections are always discussed in relation to the impact this will have on the development of the national economy. The relationship between genome research, which for a long time was mainly guided by science policy in Finland, has become increasingly aligned in a much more concrete way with innovation policy, which emphasizes the

commercialization of research results. The commercialization strategy would, according to the authors, prevent the benefits of Finnish national resources from slipping abroad.

> "The information produced from the analysis of the material would most likely have a great impact on the national economy. The achieved results could create the opportunity to utilize funds invested into the Finnish healthcare system to commercializing the new knowledge and even offer the possibility to partially finance the healthcare system of tomorrow."
> (Palotie and Peltonen-Palotie, 2004: 1712) (own translation).

Myers (1991: 64) has noted that in analyzing texts written by scientists, it is apparent that 'articles tell stories that try to enlist readers in a particular view of the present and future of the field.' Currently, Finnish science and technology policy documents are strongly influenced by the need to encourage innovation and economic competitiveness, as is the case in many other European countries, which is also reflected in the way scientists develop their arguments. The framing of the Genome Information Center within this context, as opposed to ethical and legal questions or simply in medical terms, has the advantage of appealing to the public sense of urgency and notion of imperative for economic growth, despite the fact that there is a clear lack of evidence as to the economic impact of genome research on economic development or employment.

In another recent article based on the Tekes report discussed earlier (Käpyaho *et al.*, 2004) on the utilization of existing epidemiological sample collections and other 'national' resources, researchers frame the discussion even more in terms of commercially exploiting existing collections. In responding to criticisms that compare the use of these collections to opening Pandora's box, the researchers ask whether it is justified, from a tax-payer's perspective, not to exploit the huge commercial potential that these collections have developed for Finnish biomedical research?

> "As a counter-question one can ask whether it is justified from the perspective of Finnish taxpayers not to exploit the enormous commercial potential which Finnish biomedical research has produced during the past years?"
> (Käpyaho *et al.*, 2004: 10) (own translation)

The article discusses the ethical and legal question in more detail than the other questions, but despite this discussion, it frames the question in economic terms. The question of whether to use or not to use tissue samples is not a matter that should account for variability in perspectives, but one of necessity and imperative. Indeed, economic incentives in scientific research become a moral imperative. To select 'commercial potential' and use of taxpayer funds as the point on which to make a decision, the authors select and order those arguments which they deem relevant to the discussion. This is, once again, a variation on the waste theme where considerations of productivity are brought to bear

on questions of rights. By making it an imperative, they also close the discussion before it can even begin. Despite emphasizing the role genome information has in developing national markets, the researchers note that, invariably, the use of these collections will entail a commercialization process that is international in nature and that the last link in this chain will most probably be global pharmaceutical and diagnostics companies.

These strategies differ in form and scope from those that can be related to what Collins and Evans (2002) call Studies of Expertise and Experience (SEE), in that there is no experience and expertise that can be applied to the creation and development of expectations and visions. They maintain a different epistemological status all together. Experience and expertise certainly play an important role in the establishment of the credibility of the visions, but visions draw on an altogether different form of experience, namely that of hope and expectations. This is important in relation to the potentiality of the value that might or might not be created from the information that is derived from tissue economies. Biovalue is not tied to an existing form of biovalue such as existing scientific knowledge, a healthcare service or product, or commercial venture, but rather the hope and expectation that is attached to beliefs that information might someday produce such forms of value. These types of expectations and hopes are, however, highly unstable and unpredictable, yet they are employed more and more in the mobilization and organization of resources in tissue economies.

Hospital and research administrators are also one important source for the way discussions are framed within the biomedical research community as it relates to genome research. In relation to setting up closer ties between industry and biomedical researchers, one administrator noted the following:

> *"I think that there is a moral responsibility for the research community to understand that the exploitation of research must show somewhere. One must use all the available potential towards the exploitation of research results. Researchers tend to say that there is a social benefit from their research when new know-how and treatments are developed, but they completely neglect the fact that we could increase the potential ten-fold if we began to commercially exploit the results."*
>
> (Research administrator interview, 2004)

The emphasis on a moral responsibility of researchers to contribute to commercialization underlines the strong normative context into which arguments for setting up the new genome information center are framed. They also point to the way in which economic issues take precedence over social, ethical and legal issues in the way arguments are constructed. It can be argued that what we are seeing is a re-ordering in the social significance attached to different categories related to biomedical research, such as privacy, autonomy and commercial value. The language used to describe the significance of tissue sample collections in commercial terms also helps to constitute the social identities of

the researchers and help to solidify the social relations between them and the sources of those samples.

This rhetorical approach also raises the waste aspect in tissue economies in relation to existing sample collections. Not using collections would be morally un-justified and problematic from a medical perspective given that they might provide the basis for developing cures to many diseases (see Huttunen, 2002: 714). The evocation of the efficient use of public money and connecting it to the development of commercial markets is also a powerful normative stance that helps to reinforce a particular type of world view.

The textual references of recent publications and interviews can be contrasted with those that appeared ten years earlier in a special issue of *Duodecim* that was devoted to genetics research in Finland (cf. Norio, 1994). The imperative of commercialization and relevance of genetic research to economic development is not present in these articles, but rather authors note that research will have application to treating patients.

> "No longer can we lull in the belief that genetics belongs to the theoretical and basic science researchers, because it is in exactly these areas of medicine that research is being applied surprisingly quickly to patient treatment."
> (Kääriäinen *et al*., 1994) (own translation)

An awareness of the willingness of patients and families to take part in research is already strongly present in the texts, but the change in the contextualization of the significance of the research, increasingly to commercial determinants and outcomes has increased significantly over the past decade in Finland, particularly as it applies to such large-scale projects. Here we see how the conceptualization of biovalue has changed from health to commercialization.

The setting up of biobanks around the world has raised a number of critical issues concerning financing and the actual usefulness of the results that they produce. As one researcher in Finland wrote concerning the genome information center initiative: 'in principle the plan is worth supporting, but it is too grandiose and directed too much towards the production of economic profits' (Portin, 2005: 39). In the same article, it is pointed out that one major challenge to the genome information center is the development of a conflict of interest between the rights of individual patients and societal and scientific interests, which are also mentioned in UNESCO's (1997) *International Declaration on Human Genetic Material* (see also UNESCO, 2003; 2001).

In a similar vein, a professor of pathology at the University of Helsinki noted that the attempt to highlight the uniqueness of Finnish collections and accentuating their usefulness is part of the biobank bubble, and that the arguments that are being put forward are more rhetoric than fact (Lehto, 2006: 59). The comparison of the biobank initiative to a bubble is interesting given its connotation to the bursting of the IT bubble. It questions, whether the argument for setting up the center are based more on the creation of expectations and hype around the possible applications and benefits that can be reaped

from the venture. Such critical comments are important in that they provide an important counterpoint to the somewhat one-sided policy rhetoric that has been produced in relation to the Genome Information Center and the commercial expectations associated with biomedical research in general.

Despite criticism within the biomedical community, the project is strongly supported by policy makers and regulators alike and is seen as an important part of internationalizing and developing the Finnish biomedical research and development sector (see Academy of Finland, 2003c; Konsistori, 2006). A recent work group that was set by the Ministry of Social Affairs and Health to consider the possibility of a specific law on biobanking in Finland has noted, however, that the possibility of setting up a tissue bank of tissue banks is not very likely, and that it would be better if some central authority would simply maintain a registry of the tissue sample collections that are available at different universities and institutions (Hallituksen Esitys, 2008).

A significant suggestion that has also been made by the workgroup is to adopt a looser interpretation of informed consent used in clinical research so that tissue samples that have already been taken could be used later on for further research and product development, given that the appropriate ethical permits are acquired. This would, according to the workgroup, ensure that tissue sample collections – those already collected and those that would be collected – would continue to be made available to research and development in the future as well. In this sense we can see that the development of tissue economies does not only have an impact on physical structures developed and organized to manage such resources, but they also extend their scope of influence to legal interpretations of informed consent. The case of the Genome Information Center highlights the way in which researchers and policy makers are seeking to re-organize the existing resource relationships in part by reconsidering the relationship between consent and economic interests, but also by trying to develop new structures for the management of tissue collections.

The significance of the Finnish Genome Information Center and the discussions surrounding it in relation to tissue economies also moves beyond the national context, in that collections and databases are increasingly used in a transnational comparative setting where samples and data from one country or study are connected and compared to those of another collection in another country. National and local collections are in one sense being prepared for use in global tissue economies which invariably requires a re-definition of resource relationships. It is, therefore, important to extend this analysis to the international context as well.

Thus far, I have looked at the way in which interpretations of informed consent have become increasingly broader and looser in relation to two cases (The Tampere Research Tissue Bank and the Genome Information Center). Both cases have provided examples of the way in which collective interests have come to operate in relation to consent. In the next example I will explore the activities of a particular cancer research group in Helsinki to identify the myriad sources of information and tissue samples that are available to researchers in Finland and in many other countries. The case helps to

identify how knowledge and information on an individual's hereditary condition raises the possibility and imperative for prevention in relation to whole families. The idea that tissues also provide information on families serves as an important locus around which problems of consent, privacy and autonomy can be analyzed. Furthermore, the challenges in capitalizing certain types of biovalue serve as an important critique of the possibility of maximizing the production of new forms of value in tissue economies.

5.3 HEREDITARY CANCER RESEARCH – PROBLEMATIC BIOVALUE

Given the significance that has been attributed to the translation of biovalue from knowledge to health and then wealth, it is important to look, within the context of the informational turn (Beaulieu, 2004), at some of the challenges that lie in this translation process. In addition, the study of hereditary disease raises many issues relating to interpretations of personal privacy and autonomy, since questions related to disease are not individual, but relate to relatives as well. Hereditary cancer provides an interesting perspective in biomedical research using tissue samples in that the knowledge that can be produced from it has an impact on our understanding of disease as it applies to whole families and not just the individual (Tupasela, 2006b). The preventive possibilities related to knowledge of hereditary diseases are therefore inherently social. People are not just connected to each other through disease, but also through a genetic relationship. The researchers who produce this knowledge are confronted with the dilemma of the responsibility to safeguard the privacy of their research subjects, while at the same time having a concern of whether or not family members or relatives are made aware of their possible condition. The choice to contact family members and relatives represents a break in the traditional notion of privacy, as it is vested in the individual and re-interprets consent practices within a broader preventive social context.

In developing an understanding of the type of tissue economy and biovalue that is being produced, this is significant because medical practice usually focuses on the individual as the patient or the research subject. With hereditary diseases, however, the knowledge biovalue has an impact on a much broader population (albeit limited given that hereditary diseases are relatively rare). Here we are confronted by the limits of personal privacy and the duty of physicians to help patients in relation to information on cancer and indeed as some commentators have noted, the very notion of the individual as a legal subject is brought under question (Rouvroy, 2008). Some have also argued that genetic risk gives rise to new forms of sociality, where one's genetic conditions help to define one's associations with certain groups (Novas and Rose, 2000). Such changes pose challenges in the way biomedical information can be put to practical use and hence the way in which biovalue can be leveraged and translated. It also implies a strong sense of responsibility

and consent from a communal perspective, in that hereditary diseases necessarily involve family members and relatives.

As discussed earlier, Mäkelä *et al.* (1997: 13) have identified four different legal categorizations for public health service registers in Finland: legally mandated national registers (e.g. national cancer register), research registers (e.g. HNPCC), patient registers (patient health records) and other registers (used for quality control). The HNPCC register was developed as a research register where the Ministry of Social Affairs and Health provided the research permit in 1983 to study the early diagnosis and treatment of hereditary colorectal cancer (Mäkelä *et al.*, 1997: 65).

In what follows, I will examine the way research on Hereditary Non-polyposis Colorectal Cancer (HNPCC) has formed a tissue economy of hereditary disease and the way in which it has produced problematic biovalue in that it challenges existing notions of privacy and autonomy.

Tissue Economies of Hereditary Disease

Although Finland lacks specific legislation on biobanking, such as Estonia or Iceland (see Fletcher, 2004; Rose, 2001), the Finnish medical research community has utilized different types of tissue collections, patient healthcare records and population data for decades with a high degree of specificity and penetrance. This is an important element in the type of tissue economy that is possible, as well as the type of biovalue that can be produced, in that it allows researchers to connect family members to each other in relation to disease. The use of human tissue samples, as well as patient information and other registers, is regulated through a number of legal instruments which I have discussed earlier. All work together to form a regulatory landscape, which governs different aspects of biomedical research and reflects also the complex nature of different information resources that are used.

In evaluating the biovalue emerging from cancer research, it is important to understand the relationship between research on HNPCC, tissue sample collections and the patient register that was developed. As the Icelandic Health Sector Database and the Estonian Genome Project have shown, biobanks are not just repositories of blood or tissue samples, but more importantly, patient health information. HNPCC, however, opens the door to familial relationships as well. HNPCC research is temporally flexible in that it has utilized old samples and records of patients who have already deceased with patients who are alive, and is able to make predictions as to whom should be contacted.

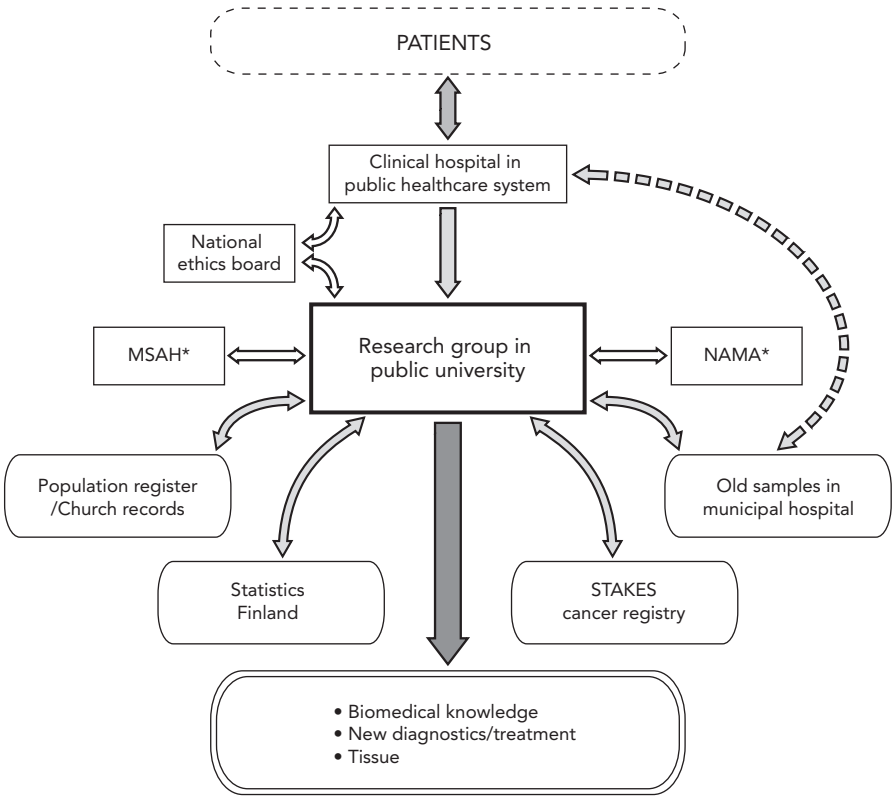
To help represent this process, Figure 6 has been constructed on the basis of interviews with researchers to describe the various stages and information resources that were gathered,

[18] The case presented here focuses on the work done in Finland concerning HNPCC. Research on the disease, however, has been a coordinated international effort that began officially with the founding of The International Collaborative Group on HNPCC (ICG-HNPCC) in 1990 with thirty representatives from eight countries. The international collaborative network, therefore, represents another important element that influences differing notions of value creation in biomedical research that is not examined here.

combined and used to study the HNPCC mutation leading ultimately to its discovery in 1993.[18] The data collection process is important since it is currently used in other hereditary cancer research projects, as well. It therefore, represents a significant biomedical knowledge production process (or epistemic process) and is indicative of the formation of a specific type of tissue economy relating to hereditary cancer. Unlike Iceland, however, these resources have not been monopolized and are available to all research scientists in Finland.

The starting point for research on hereditary cancers is located in the 'index' patient who visits his physician and is diagnosed with colorectal cancer. The clinical hospital setting is an important bridge between the research group and patients, in that diagnosis and treatment take place in the clinical setting. The research group and clinical researchers also form an important relationship in that not only do they apply for the research permit from the Ethics Review Board together, they also form a relationship whereby the clinician provides samples and health information from patients. The clinician is also responsible for the treatment and provision of counseling services to the patients that are involved.

Figure 6. A TISSUE ECONOMY OF HNPCC RESEARCH



* MSAH = Ministry of Social Affairs and Health
NAMA = National Authority for Medicolegal Affairs

The clinician provides samples either directly (solid line) to the research group from living patients or indirectly (dashed line), whereby patients were once operated on to remove tumor areas and a sample was sent to the pathologist for diagnosis. These diagnostic samples are then fixed in a paraffin block for possible later use and stored in the hospital where the operation was performed. The work of the research group in determining the degree to which a cancer is hereditary and what genes play a role in its onset relies in part on comparing samples from the living close relatives of the index patient to each other, as well as gathering information on more distant relatives who might already be deceased. As mentioned earlier, if samples have been taken for the purpose of diagnosis, then it is possible to re-use them for research by obtaining a permit from the National Authority for Medicolegal Affairs.

The construction of family trees is done in part through information gathered from the index patient, but most importantly by collecting data on family members using social security numbers from either the Finnish Population Register or church records. In either case, the research group must apply for a permit from the Ministry of Social Affairs and Health to use social security numbers. This permit also grants researchers access to patient health records in public hospitals, which are an important source of medical histories and previous diagnoses and treatments.

The Finnish Personal Data Law makes an allowance for the use of social security numbers for scientific, historical or statistical research, creating a powerful research tool for researchers. The population register – which develops and controls the registration, maintenance and delivery of population information – is used together with church records since the population register was established only in 1969. These records are used to construct the family trees, as well as to locate health records from across the country. The patient information gathered from these records is then supplemented with mortality information collected from the Statistics Finland Death Certificate Archive that has been maintained since 1936. Together these sources provide researchers an epidemiological map of the medical history in a given family, as well as providing important clues as to whether a particular disease might be hereditary.

If a particular family case history appears to indicate that further research is warranted and more information on other family members needed, the research group is able to run the social security numbers of the family members through the Finnish Cancer Registry. If the search produces 'hits' or cases with a similar diagnosis to the index patient, the researchers can search to see if a tissue sample in a paraffin block is available for analysis from the municipal hospital collection in which the original diagnosis and operation was done. This provides researchers with an additional source of medical information – genetic information – in addition to medical histories.

The old samples, medical histories and related information provide important tools for researchers to construct information on the way in which hereditary cancer is passed on and essentially forms one type of tissue economy where physical samples, family histories and information generated through genetic tests gives rise to the tissue economy. This

economy also helps to erode the boundary between personal privacy and consent in that it encumbers physicians with information on the possible health status of relatives as well. In this sense, economies are not just systems of exchange and circulation, but also give rise to forms of intervention and prevention into personal lives. Next I will look at the significance that this process of scientific knowledge production has in terms of the patient and their families since this is a major axis around which the questions of consent and privacy are framed.

The Preventive Imperative and Consent

Research on HNPCC began in Finland in the early 1980s when a researcher studying patients with Familial Adenomatous Polyposis (FAP) – an inherited condition caused by a mutation in a gene that is inherited in an autosomal dominant way – noticed that there were a number of families in Finland with a similar condition, but which did not form polyps in the lining of the large intestine. Such families had already been discovered in the 1960s to exist in Finland, but very little was known about the non-polyposis forms of the cancer and whether it was hereditary. Researchers then began to search for such families in Finland to try and develop a better picture of the disease and its incidence. At the same time, however, this opened up the question of prevention not just for individuals, but whole families as well.

The research on HNPCC in Finland was complemented by the International Collaborative Group on HNPCC (ICG-HNPCC), which was established in 1989. It held its first official meeting in Amsterdam in 1990, where the criteria for clinical diagnosis of HNPCC based on family history was established. In developing its research protocol the international group argued that:

> "The syndrome's genotypic and phenotypic heterogeneity would require the study of large numbers of families with detailed pedigrees. These studies would involve meticulous clinical histories, molecular genetics, pathology, surveillance, and management concerns, as well as genetic counseling, in order to grasp a better understanding of the disorder and, most importantly, to benefit the high risk patients and families."
> (Lynch *et al.*, 2003: 3)

The collection of tissue samples, as well as detailed patient and family histories on HNPCC, was dictated, therefore, by the criteria that were developed in the ICG-HNPCC. For the Finnish researchers, this meant that their work would require that they not only contact possible patients directly for samples and follow-ups, but also begin a long process of collecting old pathology samples found in hospitals from relatives (now deceased), as well as data on possible cancer candidates from a number of national registers, including the cancer registry. Before the genetic causes of HNPCC were identified, researchers had to

use other diagnostic methods to try and identify possible carriers of the mutations. One characteristic used for preliminary diagnosis was the uncharacteristically young age for cancer patients. In addition, researchers used endoscopy[19] for identifying candidates. Endoscopy, therefore, worked at the same time as an effective preventive technique and allowed for early intervention through surgery, which reduced mortality rates (Järvinen and Mecklin, 1994). In 1993 when a Finnish-American research collaborative identified the gene associated with a DNA mismatch repair system[20] as an important factor in the onset of HNPCC, researchers were able to narrow the list of patients who required regular check-ups based on a genetic test for the mutation.

Those patients that did not want to take part in the research provided a good control group against which the results of regular preventive check-ups could be compared. This was possible by tracking mortality rates of relatives through the Finnish cancer registry. The regular screenings of patients reduced mortality rates by identifying cancers and removing them surgically before they developed further. Here we see how the research contributed to the preventive capacity of the doctors who were treating their patients, and therefore represents a transformation of the scientific biovalue to health biovalue. Along with the endoscopy and the surgical removal of tumors, there developed a collection of tissue samples (biobank), as well as patient medical histories (which also included information on family members), of the cancer itself.

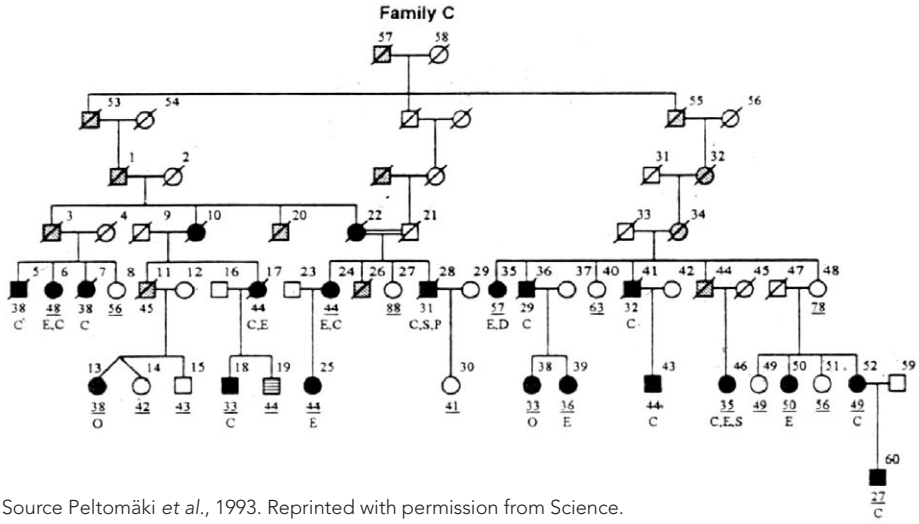
A patient register model was adopted in the mid-1980s from St. Marks hospital (UK). St. Marks had been using such a register since the 1950s to study familial adenomatous polyposis (FAP), a related hereditary condition. As research in Finland progressed, the register became the database of all those patients with the hereditary condition who had consented to taking part in the clinical research on HNPCC. Although the register was a research tool related to the samples and health data being collected from living and deceased relatives, it was also a screening tool.

In Figure 7, we can see an example of a family where researchers have been able to trace the incidence of cancer in that given family. Squares represent men and circles women. The number under each symbol signifies the age of the patient when they were diagnosed with having the condition and a line under it signifies that a sample is available. The number above the symbol is used to identify the patient while the letters under the symbol represent the location of the tumor. A slash through the symbol signifies that the patient has deceased.

[19] Endoscopy is a medical procedure whereby a tube is inserted into the body to provide an image of the interior and allow for a diagnosis. Endoscopy also allows for medical procedures such as biopsies to be taken.

[20] The DNA mismatch repair system is a system by which errors in DNA are repaired by the cells themselves.

Figure 7. PEDIGREE OF FAMILY PREDISPOSED TO COLORECTAL CANCER



Source Peltomäki *et al.*, 1993. Reprinted with permission from Science.

The production of this scientific knowledge comes about as a result of a particular type of epistemic machinery that relies on a certain kind of tissue economy. In this tissue economy, tissue samples do not emerge through the process of being gifted to research, but rather as a result of diagnosis. Issues of property relate more to hospitals maintaining diagnostic sample collections for teaching, research and the maintenance of samples as part of people's medical histories, not with the goal of commercialization or monopolization of resources. Indeed, the researchers have applied for very few patents related to these discoveries. Samples in these collections are not seen as waste if they are not utilized. The operation and impact of this tissue economy is most strongly felt in the way the information that is produced from it impacts on the lives of the individuals and families that are affected and the way in which notions of privacy and autonomy are contrasted and compared with broader interests of prevention.

The cancer register and the discovery of the genetic mutation led to important developments in the opportunity to provide preventive healthcare to those patients and families who are carriers of the mutation and participated in the research. Besides the development of genetic tests for the mutations, results included a significantly reduced mortality rate. As one researcher noted:

> *"When we clinically follow the patients who have the predisposition, mostly using endoscopy, their chances of survival are far greater than those who do not want such clinical follow-ups."*
> (Genetics researcher interview, 2003)

The statement by the researcher is indicative of the preventive imperative which arose through the course of the research. The emergence of a comparative control group indicated to the researchers that it was increasingly important to enroll those that did not want to participate in the screening procedure in order to reduce their mortality rates. The patient register was, therefore, closely linked to the genetic research on the disease, but also opened up the need to ensure that family members were also informed of the possibility of being a carrier of the mutations. This broadened the scope of the original research to family members who had not consented to being included in the research. It necessitated that they be contacted without knowledge that another family member was the source of the information that they might be carriers as well (See Aktan-Collan *et al.*, 2007). This, however, necessitated that informed consent be re-interpreted and the privacy of the individual be re-examined in relation to the duty of the physicians to provide treatment to all family members and relatives as well.

Here we see how the tissue economy of hereditary cancer has given rise to forms of social intervention that were not available before and the ways in which interpretations of privacy and autonomy are re-interpreted in a more broader and social form. The case is a good example of the ways in which different types of tissue collections and research can contribute to preventive healthcare and treatment. It also shows how individual consent practices are inadequate to manage knowledge of familial diseases and highlights the lack of existing mechanisms though which such knowledge is disseminated to other family members.

From Knowledge Production to Treatment – Dealing with Problematic Biovalue

Once the genetic mutations that cause HNPCC were identified and all families mapped, the research had essentially reached its end, and the researchers wanted to deploy the register in the public health service where it could continue to be used as a preventive healthcare tool. After all, it should not be the responsibility of researchers to provide healthcare. In addition to the scientific knowledge biovalue, the biovalue of the research can also be evaluated in relations to the health benefits that it produced for all those who chose to participate in the screening. The value of the research was therefore preventive in nature.

Although research still continued into other forms of hereditary colon cancer and the collected samples and patient data were still available to the researchers, the goals of the HNPCC research had been met. The transformation of the patient register to the healthcare services, however, became problematic when the researchers were asked by the National Research and Development Center for Welfare and Health (STAKES) to up-date their research permits after the 1999 Personal Data Act was amended in Finland. It quickly became evident in this process that the transfer of the research register to a healthcare register was not possible, because the transfer would also change the legal status of the

register, whereby it would become a healthcare register. Legally this meant that the register that had been legal for research was not allowed in the healthcare sector because of the different legal categorizations that were involved for the register (see Mäkelä *et al.*, 1997).

Sections 12 and 14 of the Finnish Personal Data Act (523/1999), which was amended to comply with the Council of Europe (1995) directive on the protection of individuals with regard to the processing of personal data, entails that once the research is completed all registers with *identifiable* personal data must be destroyed or either changed in such a way that individuals can no longer be identified from the register. The anonymization of personal data in research registers after research is completed is to ensure that section 11 of the Act is respected, whereby personal data in registers cannot be maintained if it is based on a health condition, disease, disability etc. (Article 8 of Council of Europe directive). Personal data that classifies people on the basis of health condition, disease, disability, race, ethnicity and sex is not allowed therefore, except for scientific, historical or statistical research purposes.

The use of personal data on individuals was only possible because the activities were classified as scientific research. In order for the HNPCC patient register to be transferred to the public healthcare sector and discontinued as a scientific research project, it would necessitate that it be legally mandated as a national register or the register be changed in such a way that individuals could not be identified. Anonymization, however, would render the register useless, since the preventive component would be lost. Although regular healthcare registers, such as patient records databases, contain information about health, such as disability, they are not organized and categorized in such a way that the defining characteristic of the database is to set individuals with a specific condition apart from others. The original purpose of the clause in the Personal Data Act is to prevent discrimination of individuals as a result of a particular condition. The effectiveness of the HNPCC patient register, however, is based on the characteristic that it is used to keep track of individual patients with the hereditary mutation and call them up for regular check-ups.

A legally mandated register of families and patients with a hereditary genetic disorder would, however, be problematic both legally and practically. Such a register would challenge the existing personal data laws, both in Finland and the EU, raise questions as to mandatory inclusion by those who opted not to take part in the research, as well as set a precedent for future registers based on research on other forms of hereditary genetic diseases. Alternatives, however, also raise ethical and legal questions relating to the relationship of new technologies to existing legal and ethical frameworks surrounding biobanking, as well as healthcare, in that by not contacting family members who were at risk, the doctors were allowing very likely harm to come to those family members who were not aware of this condition in their family. Physicians, therefore, decided to go the route whereby they sought direct contact with family members who had not participated in the research and were not aware of the risk that they were in (Aktan-Collan *et al.*, 2007). This approach represents a particular type of engagement with family members and relatives which can be said to challenge existing notions of privacy and autonomy in that the

preventive imperatives of research extend beyond the original research patient.

In occupying the territory between physical samples and information, it might be argued that the study of hereditary disease provides a good example of the way information gleaned from patient samples and families can be converted into health biovalue. The case of HNPCC, however, redirects our attention to problems associated with some types of knowledge and the role of regulatory and social structures in inhibiting the application of information on disease and heredity, as well the limits of personal privacy and autonomy in relation to information about our bodies. This has consequences for the transformation of biovalue from one form to another. Information is generally seen as productive, neutral or positive. Information can also, however, be problematic, risky and even dangerous (cf. Feenberg, 1991; Irwin, 1995).

Although the knowledge itself on hereditary disease is available and valuable in scientific terms, there are legal, as well as social blocks that prevent it from becoming usable in a regular hospital treatment environment (in this case privacy and discrimination laws). This issue would appear to problematize the assumption that tissue economies give rise to the maximization of forms of value. Researchers have a duty to protect the privacy of their research subjects and there are clear limits on the productive power of information, both in terms of the production of health (some patients choose not to participate in the screening program), the application of knowledge (the register cannot be transferred into the healthcare sector), and in the production of commercial value (there are too few patients for it to be commercially viable and the researchers themselves are not interested in commercialization). Researchers and physicians also have a duty to protect individuals when they know that great harm can come to them if they do not act. In the case of HNPCC, doctors decided that the interests of individuals who were not aware of their conditions should outweigh the strict privacy issues of individuals who had participated in the research. The doctors, therefore, chose to contact family members and recommend counseling, as well as a DNA test that could help them determine if they were at risk (Tupasela, 2006b; Aktan-Collan *et al.*, 2007).

This re-interpretation of the limits of privacy and the extension of responsibility by physicians is important in relation to tissue economies in that it asserts a type of moral responsibility and new form of engagement on behalf of researchers to act and intervene on the basis of the scientific knowledge that they produce. Whereas in the case of the Genome Information Center we saw how the individual research participant was seen as insignificant in relation to the whole set of data that was collected, the case of HNPCC brings forth the issue of how important personal genetic information can be in mapping disease in a family and the forms of intervention that it opens up as well. A personal condition has ramifications for the whole family. Here again, we see how tissue economies give rise and connect to forms of moral and normative actions in relation to the scientific knowledge that are produced from them. Tissues as information come to entail a whole host of issues related to family relations and responsibilities and duties on behalf of the patients, as well as the researchers in the way that information is managed

and further used in relation to others.

In relation to the increased pressures of commercialization within the life sciences, it is important to examine cases where the production of biovalue from tissue economies is problematic or contentious. This is significant in relation to tissue economies and their role for several reasons. *First*, given the increased political interest in coupling biomedical knowledge production with capital accumulation, challenges in commercialization provide an important perspective on the challenges to policy making that is associated with this process. It also raises a new specter on understanding the ways in which non-commercializable forms of biovalue that challenge existing notions of privacy and autonomy can also be seen to produce new forms of solidarity and cohesion among actors.

Second, varying interpretations of ways biomedical knowledge can be applied and used in society questions the validity of commercial forms of biovalue in relation to more traditional ones, such as health and prevention, which also have a financial component in them, but are more difficult to directly measure. All knowledge is not equally productive or useful in the classical sense that commercialization would have us understand. This further problematizes recent policy discourses on the knowledge-based economy and knowledge-based bio-economy since it questions the validity in relation to the significance of commercialization.

Third, the case of HNPCC challenges the legal boundaries which exist between the management of information in different contexts. The information that research on HNPCC has produced can in some ways be labeled as contentious knowledge, in that it cannot, within the current legal framework, be actualized in the healthcare system. Instead, researchers must continue to contact family members themselves in order to apply the usefulness of the medical knowledge in practice. One can ask whether the patients and family members would be subject to any more or any less forms of discrimination depending on whether the database were managed in the healthcare system, as opposed to the researchers. Furthermore, it is problematic that researchers, whose research interests will invariably change, are set with the task of operating the healthcare service indefinitely. Certainly, it can be argued that this is a task best suited for the healthcare professionals and not researchers.

Hereditary Non-polyposis Colorectal Cancer research in Finland is interesting for a number of other reasons as well. *First*, it provides a picture of the ways in which researchers utilize a number of publicly maintained population information registers and combine them with tissue samples collected from around the country. This includes samples taken directly from living patients, as well as pathology samples of deceased patients. In relation to tissue economies, this directs our attention towards structural factors that are related to the way value is created in some knowledge production systems, in that the ability to utilize such information and sample resources has required both a legal framework that allows for such scientific practices, as well as the long-term storage of both samples and information.

Second, the choices and interests of the research group also reflect the myriad of

value choices that researchers themselves have in relation to ways in which research that utilizes tissue samples can be utilized. Commercialization represents only one avenue among many other choices that researchers can utilize to make use of their research results. This reflects the range of possibilities that are associated in relation to the creation of biovalue as it relates to the use of tissues in biomedical research. Owen-Smith and Powell (2002: 5) have argued that the traditional distinction in the life sciences between basic and applied research is being eroded and replaced by new fault lines where 'individual faculty choices in response to a shifting academic terrain have created a myriad of positions that are neither old nor new school, but instead combine characteristics of both.' In this sense, a more complex picture emerges in the interests and motives of academic researchers as it relates to ways in which research is translated into other forms of value (see also Stokes, 1997; Brown and Rappert, 2000). The HNPCC research group does in no way condemn commercialization or patenting and licensing, but instead see the value of their work in different terms and choose to transform the significance of the information that they have produced into health through different means.

Third, tissue economies are more than economies of physical samples; they come to encompass and activate a whole host of resources, including administrative services, permit procedures, information infrastructures, healthcare records, research funding and whole families, including those who have deceased. Knowledge, health and commercial biovalue have a different standing in relation to one another. The knowledge value gained from the research is clear. The health value, however, is somewhat contentious since there are limits to the deployment of the screening program in the healthcare system. Commercial value production is clearly problematic due to the small number of patients involved and the inability to apply the screening in the healthcare system. Biovalue should rather come to be understood as a spectrum of values where capital accumulation represents only one dimension on biovalue. In addition, given the broad spectrum of possible biovalue, the term biovalue itself becomes difficult to define, in that its scope becomes too broad. It is perhaps in this sense that the measurement of biovalue in commercial terms has gained so much popularity and attention, because it remains relatively easy to calculate and express in numerical terms.

Fourth, the case of hereditary cancer also helps to extend our understanding of the limits of personal privacy and autonomy in relation to our samples and the information that can be derived from them, in that researchers are also confronted with the need to protect and warn those who are not aware of the possible danger that they are in. In this sense, responsibility towards patients is extended beyond those who are being studied or treated to family members and relatives as well. At the same time, this opens up the terrain in which tissue economies operate, in that tissue sample collections and their related information make visible the hereditary nature of some diseases which can now be mapped, diagnosed and treated. This, as some have noted (Rouvroy, 2008) is seen as a challenge to the western legal dogma underlying the individual as an independent and autonomous legal subject.

The significance of the HNPCC discoveries and the treatment and check-up procedures that have been made available to the Finnish families that are carriers of these mutations has value in a preventive form, as well as as information in-and-of-itself. The knowledge within families and for individuals opens up a new possibility in terms of decision-making, where prevention becomes a possibility. It could be argued that this possibility, if anything, is far more significant as a form of biovalue than any indicators of capital accumulation or patent applications. Therefore, the case of HNPCC brings forth a broader social significance in relation commercialization by highlighting the role of non-commercial innovations and the production of value from biomedical knowledge. At the same time, such economies of information, as they become connected to the physical tissue economies, also set limits to the ways in which the productive capacity of the information that is produced can be maximized.

Although a public healthcare register of HNPCC carriers – or all hereditary disease carriers – might have an inherent value in saving lives and reducing the social costs associated with post-diagnostic treatment, our current personal data laws set limits on what kinds of information can be used in the healthcare sector. In this sense, the limits of informed consent are met in the HNPCC case, in that physician's feel an overriding need and obligation to contact other family members even though this might in some cases bring forth information on who is currently being treated.

In this section I have looked at three case studies (The Tampere Research Tissue Bank, The Genome Information Center and Hereditary Non-polyposis Colorectal Cancer) to explore the ways in which interpretations of informed consent, privacy and autonomy are being re-interpreted in relation to bodily tissues and related health information as they circulate through different types of tissue economies.

With the Tampere Research Tissue Bank we saw how tissue acquisition does not rely on any system of informed consent related to diagnostic tissue samples, even though they are collected for research purposes. Tissues are collected for research purposes without the consent of patients since the samples are categorized as diagnostic samples and are considered to make up one part of the patient's healthcare record. At the same time, however, the samples contain information on health and can be linked through a coding scheme to other health information of the patient. The interests in the production of new innovations using research samples makes the use of diagnostic samples and surgical waste without gaining consent more useful and flexible for the hospital administrators. In this sense, the expectations of commercial forms of biovalue play a role in adopting an interpretation of practices where consent is not sought for the use of samples for research.

The case of the Genome Information Center provides an example of the way in which samples taken for large epidemiological studies are being re-used and how this practice is problematic in terms of both gaining re-consent and describing in too much detail the future uses of the samples and information. In both cases, we are witnessing

how informed consent is being re-interpreted in practice. In addition, the case provides a good example of the discursive practices that are associated with the mobilization of these resources and how these narratives are tied to national competitiveness. We see how the practices associated with the production of biovalue as scientific knowledge and commercial biovalue has helped to contribute to a re-interpretation of informed consent where the individual sample, and thus research subject, is not seen as tantamount in relation to the overall research purpose.

Hereditary Non-polyposis Colorectal Cancer research opens up new problems related to the limits of privacy and responsibilities of researchers in relation to information gained from one patient through research and its significance to family members and relatives. The limits of consent and privacy are reached as doctors and researchers interpret their responsibilities in relation to knowledge of hereditary disease in broader, more communal terms. Measuring biovalue in commercial terms is problematic since hereditary diseases are rare. Instead the biovalue of HNPCC research can be measured more in terms of scientific knowledge and health. The challenges to privacy and problems of commercialization do not, however, challenge notions of solidarity and cohesion, but rather give rise to new forms as a result of the benefits that are gained through the preventive capacity of HNPCC research

Together the three cases bring forth examples of practices in which interpretations of informed consent are being re-evaluated in relation to the types of biovalue that are produced and made available through such practices. All the cases show how these practices are bringing forth diverging interpretations of consent which pose challenges for policy makers, as well as the management of the scope of personal privacy, autonomy and control of one's samples and health information. In the following section, I will look at how these diverging notions of consent relate to biovalue and the four different conceptions of tissue, some broader issues related to the international use of tissue sample collections, the role of moral and normative discourses in the collections and use of tissue sample collections and the way these relate to hopes and expectations associated with tissue sample collections. The normative and moral imperatives which are deployed in conjunction with the biomedical use of tissue sample collections plays an important role in the ways in which resources are mobilized, but more importantly in the way political and scientific expectations bear upon the arguments and conditions set for the use of these collections. This in turn plays an important role in the interpretations that are being afforded individual rights in relation to biomedical research and human tissue sample collections.

6
DISSECTING TISSUE ECONOMIES

In this section, I will first provide a synthesis of the main research questions as they relate to diverging notions of consent in relation to the theoretical/conceptual aspects of tissue samples, policy and legal documents and the three case studies that I have looked at. I will follow this by looking at the increasingly international character of tissue economies. This is a central feature of emerging knowledge-production economies and the machineries that are set up to facilitate such transnational exchanges, and reflects the organization of resource relationships internationally. Next, I extend my analysis of the ways in which trust plays an important role in the development and maintenance of tissue economies. As noted earlier the configurations in which human tissue samples are collected, used, re-used, activated and exchanged can take place in a multitude of ways and all have introduced new pressures to re-interpret informed consent. Such processes are also contributing to the way in which the relationship between the donor, the collector and the user are being re-defined. I will then look at the way in which tissue economies operate through notions of expectations and hope.

Diverging Notions of Consent

I began my exploration of tissue economies and individual rights by looking at the way in which tissue sample collections have become a central research object in the production of scientific knowledge in Finland. The idea of tissue economies was then connected with the notion of epistemic cultures (Knorr Cetina, 1999) or machineries of knowledge production and the way in which the aspiration to produce scientific knowledge is reflected in policy and legal documents. I have then examined the way in which tissue sample collections are collected and used in non-therapeutic biomedical research with a particular interest

in three case studies.

The purpose of this is to connect scientific knowledge production, within the context of tissue economies, to the expectations and hopes that are associated and connected to biomedical research that utilizes tissues. It also identifies the way in which this creates diverging interpretations of consent, privacy and autonomy in relation to economic and social interests. In exploring the social significance of tissue samples in Finland since the 1990s, this is important for a number of reasons. *First*, given the political significance that the idea of a knowledge-based economy has had in Finnish policy making (Häyrinen-Alestalo *et al.*, 2005; Miettinen, 2002), it can be argued that the creation of expectations are an important element of knowledge production. *Second*, the analysis of scientific knowledge production, as an epistemic activity is important in order to understand the dynamics of tissue economies, as well as some of the possible outcomes or consequences of the related activities. *Third*, given the important role that patients and research participants play as sources of samples and data in the acquisition of tissue samples, the engagement of patients in the operation of tissue economies is of central importance. The production of biovalue, therefore, becomes a central feature, not just within the production of scientific knowledge, but also in the discussions which surround the acquisition of tissue samples and other health related information.

If one considers this from the perspective of scientific biovalue, the benefits become divided according to discoveries and subsequent scientific publications. Scientific discoveries play an important role in the work of scientists, and access to large tissue sample collections and associated personal and clinical data has become of crucial importance in producing novel results. In this sense, collections provide a competitive advantage. This is also reflected in the publications and patents that researchers and research groups are able to produce, which become a measure of the productivity of researchers. At the same time, however, the production of credible scientific knowledge requires larger and larger sample sizes. What is clear, however, is that the production of scientific biovalue has become the basis from which other forms of biovalue are produced; it has become a means to an end, rather than an end in itself. This has resulted in other policy domains, such as innovation policy, to enter science policy and begin to influence its operation. This also means that from a tissue economy perspective, the decisions related to the organization of tissue economies and machineries of knowledge production are increasingly acted upon by policy fields other than science, namely technology and innovation policies.

In relation to biovalue as health, the way in which the discoveries will be translated into practice and who will be able to benefit from them are not as clear. European countries have different capacities in their abilities to uptake new drugs and treatments depending on their healthcare infrastructure and economic situation. This means that some countries will be able to reap the benefits from their participation in different tissue economies with different levels of success. Here we can see how the operations and organization of tissue economies can also have far-reaching consequences into the healthcare systems in which they are embedded (if they are embedded at all). From a

health biovalue perspective, it can also be said that increasingly the value and productive power of health is measured in commercial terms. This has had consequences for the ways in which political policies have penetrated the policies of subsidiary organizations, and therefore, also the research practices that take place within their walls. The neo-liberal model of health care has become increasingly powerful in the production and up-take of health care products and services.

From a commercial biovalue perspective, it is even more unclear who will and can stake a claim as to the profits and benefits of biobanking. Although each country has strong political sentiments as to the economic benefits which they may accrue out of this, it remains highly unclear as to how and in what ways the commercial benefits will be divided up. Indeed, this is something that the OECD has also commented on, noting that despite a strong push to develop international infrastructures, there is surprisingly little in these developments in relation to the ways in which intellectual property, commercialization and benefit-sharing will be organized (OECD, 2006: 123). This is particularly important in relation to policy discourses which claim that commercialization is a reciprocating and community building activity from which the whole society benefits. It remains unclear as to the pathways through which this benefit sharing and reciprocity operates and whether it will be seen as legitimate.

The increasing importance of the production of biovalue in tissue economies raises several issues pertaining to the four conceptions of tissues which I discussed at the beginning in relation to consent practices. The tissue samples that are used in biomedical research have traditionally been conceptualized as gifts from donors, yet the research presented here has shown how surgical waste and diagnostic sample collections are increasingly used in research without any consent practices which would entail a process of gifting to take place. In addition, in the case of old tissue sample collections, although samples and health information have been donated once, it is unclear whether such donations have also been meant for other research purposes. Although there is evidence as to the wishes of donors if they were to be re-contacted (Stegmayr and Asplund, 2002), there still remains a margin of people who do not want their samples to be re-used. This means that every time old samples are re-used without consent, there develops a small margin of people who would not want this to be done. Such practices can be seen as somewhat problematic in relation to the development of trust in the activities of researchers. At the same time, however, it can be seen to be legitimate to re-use samples that have already been gifted or donated for research. This, however, would also necessarily mean that the content and scope of research should be interpreted in a broad sense since all samples that are collected could theoretically always be re-used for other purposes. Here we see how the notion of gift and donation plays an important role in the interpretation of the scope of consent in broader terms; since the sample has been donated already, it is assumed that it can be re-used for further research.

Whether a sample has been gifted or collected without the procedure of donation appears to have very little function or role in relation to the type of biovalue that is

produced, however. This indicates that donation and gift-giving are not central social actions in the production of different forms of biovalue, but rather have come to be a romanticized vision of the interplay between the source and the collector of samples. It has become a way of indicating how acquisition ought to operate, rather than a description of the way tissue collection takes place in all cases. Here the role of traditional research (gaining consent) has gained a prominent role in describing how research operates, but as the empirical data shows, the use of diagnostic samples is quite common in research.

The notions of gift giving and donation also play an important role in framing the reciprocation that researchers see their research to provide through the production of different forms of biovalue. Reciprocation for donation tends to play a legitimating role for researchers in that researchers argue that they are giving something back to society in return for the use of samples. This perspective has a tendency to strengthen the social function of science in society, making it more a communitarian rather than an individual activity, which also helps to strengthen the perspective whereby consent practices are interpreted in a looser fashion. This highlights the value of research in terms of scientific and health value as opposed to commercial forms of biovalue. This would seem to indicate that researchers draw on a dichotomized vision of exchange (gift vs. commodity) (Cf. Frow, 1997), yet one where the production of commercial biovalue has become a symbol of common benefit and reciprocation. This would appear to indicate, following Berking (1999), that commercialization has become a rhetorical and strategic tool in policy making in socialization and community building. Concomitantly, these values become diffused within the operation of tissue economies as well.

The notion of tissues as property remains in unstable territory in relation to biobanking. Although the Moore case in the US clearly declared that Moore did not have property rights in his own tissues, it remains clear from European policies that there are diverging notions as to the status of donated and collected samples. Some policy documents highlight the fact that genomic databases are global public goods (HUGO, 2002) where individuals, families, communities, commercial entities, institutions and governments should foster the public good, while others claim that we can make claims on body samples that are akin to property rights (WHO, 2003: 8). At the same time, national and international policy documents make strong arguments for the role of biobanking in the development of commercial opportunities, and this could be seen in the collection of surgical waste and the Genome Information Center. Interestingly, however, the researchers that were interviewed did not see sample collections as property.

I am not claiming that such perspectives cannot be reconciled with one another. What I would like to point out is that the status of tissues as property remains unclear and unstable across different policy documents and case examples. This instability has consequences for the interpretations of rights that individuals are afforded, particularly in relation to consent. Both the common heritage and commercial perspectives, however, increasingly divest the individual of control rights and lay them squarely within the hands of researchers and institutions. The difference is that with the common heritage discourse,

the control appears to remain with public institutions and organizations, whereas within the commercial discourse, control is something that can be transferred to the private sector as well.

From a consent perspective, what this signifies is the movement of control of tissue and personal information away from the donor and more into the hands of biobank managers and institutions. With the increasing amount of health information that can be gathered through various registers, it should be asked whether some forms of controls should be in place to allow individuals the possibility to control the use of their personal information. The fact that some tissues are also gained without consent means that the status of tissues remains unclear. But even with donated tissues, it is evident from a policy perspective that it remains unclear whether tissues are a common public good or are they private property. Consent practices are seen to disentangle tissues from their source, but recent legislative proposals in Finland, which would allow donors to control (through removal and knowledge of who is using the sample) the use of their samples in biobanks after their donation, appears to indicate that the property paradigm is inadequate to describe the status of samples after their donation. This would indicate that consent only party disentangles samples from their donor, and that researchers remain dependent on the willingness of donors to allow them to continue to use their samples and personal information. This gives rise to a whole new type of tissue economy where responsibility and control and divided between the source of the samples and their users/managers. Here we can see a re-distribution of power relations between the actors.

The notion of surgical residue or tissue as waste plays a powerful role in the transformation of tissues into useful and productive objects. The classification of surgical residue as waste serves to disentangle the samples as objects from their user by laying claim to their status as being useless objects for those from whom they are removed. At the same time, this process masks a far more important practice related to consent and the right of individuals to decide whether or not they want their samples to be used in research. By classifying tissues as waste, the collectors and users of the samples deny those whose samples are being taken for research the opportunity to decide and participate in the decision-making process. Although this has been common practice in the case of using old diagnostic samples, the difference in this situation is that the samples are specifically collected for research purposes. In this case, the collectors know that the samples are not for the purposes of diagnosis alone, but for research as well. The term waste, however, is also misleading since the tissue samples clearly have a function and demand within the research system. Waste is paradoxically valuable already before it is collected, which means that it is not waste at all.

The notion of waste serves a central role in the transformation of tissues into different forms of biovalue. Given that samples are classed as waste, their transformation into productive objects takes place through technical manipulation and processing. After this, their further transformation into different forms of biovalue takes place in the same manner as with other tissue. The notion of waste is also enacted in the case of

old epidemiological sample collections which makes it performative in the attempts to re-define consent in broader and looser terms. The use of the term waste to re-use old sample collections could, therefore, be enacted in the future in the case of all sample collections that have been collected, which would in effect make the acquisition of specific consent meaningless.

The role that the informational turn plays in tissue economies is a central one. The transformation of tissue into information and their concomitant use along with health and lifestyle information has become a central feature of human genome research into common diseases. The transformation of tissues to information, however, complicates their classifications as gifts, waste and property for several reasons. *First*, given that information from tissues is in digital form, it can be replicated and copied an infinite amount of times and transferred across the globe in a matter of seconds. The physicality of tissues, therefore, becomes unimportant in that instance. Of course if a researcher wants to get other information out of the tissues that are not in the data that have been originally produced, the physical samples are of central importance. Very often, researchers have to return to the physical samples time and again. This makes the link between physical samples and the derived information of central importance. *Second*, since information from tissues can be copied, the issue of waste becomes less apparent because replication is not a problem. Here too, however, the link between tissues and the information that can be produced from them is important and one which means that the control of the physical samples remains of utmost importance. *Third*, the notion of property is problematic in relation to information. Although we donate samples, the personal information that they contain within them and the health and lifestyle information that we provide is also protected by personal privacy laws. This means that we maintain some rights to control how that information is used and managed. Although samples may be donated and become disentangled, they continue to maintain a connection to their source in many cases. *Finally*, the notion of tissues as information is also misleading since the majority of information on the human body is not derived from physical samples, but rather from clinical and lifestyle information. This would indicate that tissue economies are perhaps more information economies than anything else.

It is as information that non-therapeutic tissues and other health information become most productive, however. This productive capacity and potential gives rise to both hope and expectations as to the future possibilities which lie within tissue samples and health information. It is this characteristic which also relates to diverging interpretations of consent in different biomedical research practices. With surgical waste, the use of samples and the need for consent is measured in light of the use value of the sample to the source. With large epidemiological collections, the information character of samples and their large quantity result in the need to interpret consent in broader terms. Consent becomes balanced against issues of risk to individuals and the gains that may be accrued through the research. The rights of the individual are no longer absolute, but rather relative. With hereditary cancer research, the ability to intervene becomes a central feature

of the information that is produced. Here we see, however, how the notions of consent, privacy and autonomy become re-interpreted in light of the preventive imperative. Once again, the rights of the individual are assessed in relation to the interests of science and society; a comparative process which according to international laws and ethical statements should not take place in evaluating the legal rights of the individual since these rights are considered absolute and foundational.

The different concepts of tissue (gifts, property, waste and information) play a central role in the ways in which biovalue is created. At the same time these concepts also play a role in the way different notions of consent practices related to tissue acquisition and use come into play in everyday research practices. Since these research practices are increasingly transnational in scope, it is also necessary to look at these developments in relation to tissue economies in the next section.

From National to Transnational Tissue Economies

As the interest in the biomedical use of human tissue sample collections began to gain momentum during the 1990s, due to the increased possibilities offered by biomedical technologies, so did the possibility of comparing nationally (locally) based collections to each other. At the same, time a scientific and political interest began to develop in mapping the resources that were available for research in terms of various tissue collections around the world.

Earlier, I presented an interview excerpt from a researcher who discussed the amount of data that is needed to do credible science. The researcher noted that there was considerable disagreement over whether 10 Kb or 100 Kb of data on single nucleotide polymorphisms (SNP) was enough to study diseases. The researcher argued that one needed as accurate a picture of the genome as possible to do good science. If the amount of data from one sample is one aspect of genome research, then the size of the sample collection itself is has become another aspect that plays an important role in the way tissue economies are developing and the types of biovalue that they are able to produce. The development of database federation techniques that I discussed earlier has important implications for the development of global tissue economies. With multifactorial diseases which also need to account for lifestyle and environmental information, it is becoming increasingly important to have large data sample sizes. Smaller collections do not produce the necessary statistical significance that is necessary to identify genetic, lifestyle and environmental factors that may influence the onset of common diseases. Kere (2007) has noted, for example, that it is becoming increasingly difficult to publish results from linkage studies without comparative data from different countries. In this sense the elevation of the analytical aspects related to biobanks is moving into a much broader arena of operation. It is in this context that separate national collections become useful as objects of interests for researchers at the international scale. It is here that scaling up also has significance as to the ways in which national collections are made available to local researchers and the

possibilities this affords them at the international level.

For example, in an interview with an EU research administrator working on biobanking it was noted that:

> *"When you start to study these common diseases and their genetic components you need large samples, and that's just the idea here [Europe], that we should start to develop a cohort sample size of two and a half million samples, and that would start to have more statistical significance. That is exactly why these European cohorts should be combined so we could increase the sample size."*
> (EU research administrator interview, 2003)

Given the attention that has been given to national biobanking projects, such as UK Biobank or the Iceland's Health Sector Database, the comment of the administrator is interesting for several reasons. *First*, the size of any useful cohort sample is identified to be two and a half million, which is five times the amount of samples that UK Biobank is looking to collect. This raises questions over whether existing national attempts to collect samples are enough and the credibility that can be attached to their use in the production of scientific knowledge on common diseases.

Second, the statement draws attention to a general policy interest in combining samples to produce one large sample collection. This process would involve bringing together samples from different countries. These issues raise a number of concerns over who would manage this conglomeration of samples and data, and to what degree such an effort is really possible given diverse national interests, laws and standards in what type of data has been collected and how. The most significant point, however, is that national sample sizes are, according to the administrator, too small to tackle common diseases and that they will in the long-run need to be conglomerated. It also raises a further questions as to how will benefits from such ventures be shared.

Third, there is an implicit assumption amongst researchers and policy makers that larger sample sizes will yield answers as to the causes of common diseases. This belief in the productive power of biobanks is a significant driver of hopes and expectations that are deployed in relation to them. There is less discussion, however, as to the degree to which these collections can be compared to each other or not. Many have been collected using different standards and encompass different ways of collecting data on lifestyle and environmental factors.

It is not surprising then that international efforts are underway to try and coordinate the interoperability of different biobanks. The Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), for example, is a pan-European network of biobanks that seeks to develop common standards to facilitate the exchange and dissemination of information and tissues from biobanks between each other (BBMRI, 2008; see also COGENE, 2003; ECVAM, 2002). Such ventures are interesting in that they reflect the increasingly transnational character of biobanking and the direction in which national (local) collections

are moving in. Individual samples and health information are increasingly becoming embroiled in an international market for tissue samples and related health information. Tissue collections become entry or access points for researches into international scientific research markets. This, in part, explains the recent popularity to launch and develop national biobanks since it is through such collections that one gains access to research funding and networks of other biobanking initiatives. Here we see how biobanking becomes a strategic tool to access resources and research funding at the international scale. This also gives biobanks political significance and power in that what emerges is a competition to get one's collections into such international networks.

Access to international research networks is of central importance in the operation of tissue economies. Although tissues, as such, cannot give rise to profit, tissue collections can be used to leverage research funding in areas such as epidemiology and molecular biology. Currently both national and international funding organizations are allocating a great deal of funding to these research areas which makes their international organization and coordination all the more important in relation to existing and planned biobanks. It remains uncertain, however, how the profits and benefits from these transnational ventures will be divided amongst actors. Given that national collections play such an important role in the science and technology discourses of national documents, it becomes increasingly timely to discuss how and who will reap the benefits of the research results that will be produced. As of yet there is no clear policy on this. This is a significant point in relation to consent practices, since these issues must, according to legal and ethical documents, be communicated to research participants.

Cambon-Thomsen *et al.* (2007: 373) have noted how there exists a tension between the diversity of ethical positions and the necessity for a common pedestal of principles and procedures to manage the use of human tissue samples and related personal and clinical data. I would argue in relation to biobanks and consent that what we are witnessing are diverging practices in interpretations of consent which are made to fit in relation to international guidelines on the biomedical use of human tissue sample collections. The imperative to produce different forms of biovalue are increasingly beginning to encroach upon traditionally accepted notions of consent, privacy and autonomy. This can be seen in the policy and legal discourse, as well as in the three case studies that I presented. Increasingly the rights and risks of the individual are measured and compared in relation to expected and potential benefits that may arise out of research. These benefits are said to be communal in nature, but in reality also include private benefits through the commercialization of research results.

It would appear that within the transnational context, European policy makers have taken a far more liberal perspective in interpreting individual rights, whereas in the US for example, issues of privacy and autonomy still outweigh the social benefits which are said to emerge from research. This may reflect a trans-Atlantic difference in approaches in relation to the willingness and ability of policy and law makers to begin re-interpreting the rights of individuals. It also reflects a different attitude to the relationship of the individual

in relation to the interests of science and society. Whereas in Europe the imperative to produce commercial benefits from tissue sample collections is seen as a collective good, in countries, such as the US, this is seen to epitomize private interests, which may not encroach upon the rights of the individual.

It is unsurprising then that issues of consent from research subjects have become a major topic of discussion since the management of the resources has become an international affair. Although most of the sample collections that are being collected at a national scale draw on a rhetorical argument of furthering national interests in studying the population, there is also a much more important goal of developing national resources which will allow for cooperation and access to future research projects in which these collections will become combined. Given the increasingly large data sample sizes and the multitude of information resources, such as cancer registries, the methods and techniques that are adopted in the management of these resources play a central role. The ways in which the tension between the diversity of ethical positions and the necessity for a common pedestal of principles and procedures will be resolved remains to a large extent unattended within the international context. This provokes us to ask in what ways and how will individual rights, particularly in relation to consent, be interpreted in relation to transnational tissue economies.

It remains, therefore, highly unclear how the rights of the individual to control their samples and personal information will develop within the next ten years. Already there is evidence that for samples that are over ten years old, donors have very little ability to control or remove them from use in biomedical research. Even this, however, varies greatly from one country to the next, which is a further indication that tissue economies operate within a highly varied field of consent practices. What becomes a challenge, therefore, is reconciling these differences within the international legal and ethical frameworks that have been set up to ensure harmonization and standards across national boundaries. What is interesting, however, is that the legal status of sample collections changes over time, whereby the more time that has passed and the larger the sample collection is, the more willing policy makers and legislators are to re-interpret the scope of consent. This raises further doubts as to the status of current consent forms in the way their scope is interpreted in the future. In practice, if a sample collection is old and large enough there will be a social and scientific interest to re-use such collections without re-gaining consent. This feature in consent forms, however, is not stressed clearly enough so that donors and the sources of samples would be aware of this fact. Consent forms do not, therefore, completely provide the necessary information that they are supposed to to potential research subjects.

The implicit belief that larger sample sizes and more data will yield answers to the causes of most common diseases is a powerful engine that drives biomedical research. It is also a powerful force in mobilizing resources, both nationally and internationally. The production of different forms of biovalue from biomedical calculations remains highly unstable, though. The transformative power of biobanks to produce scientific knowledge,

health and commercial wealth remain unproven within this broader international tissue economy framework. Politically and scientifically, however, biobanks remain important tools for leveraging access into these international markets and cannot be undervalued in this sense.

The three cases that I presented are all different in many respects. Yet they, along with the policy and legal context, all represent important elements within the fabric of tissue and information exchange, not just nationally, but internationally as well. The focus of such exchanges is increasingly taking place at the transnational level, as research funding has come to emphasize the international nature of scientific research. The organization of tissue economies is not therefore just a national or regional issue, but becoming increasingly embedded within international networks. At the same time, the extraction of information from tissues makes the transfer of data across borders increasingly easy, which sets new questions and challenges to the content and form of informed consent regimes.

Trust and Moral Imperatives

Within the context of the biomedical use of tissue samples it is important to discuss the issue of trust, since the existence of tissue economies relies to a great extent on the trust that research participants place in the researchers who are collecting their samples. Some commentators have noted how the submission of an informed consent is also an act of trust by patients or a research subject (Hansson, 2005). At the same time, trust operates within a context where the collection, use and re-use of samples are framed within a moral and normative imperative, where the productive capacity of scientific knowledge is unquestioned and becomes the standard against which everything else is measured. Although I have shown how samples are collected outside the consent framework, trust is nonetheless a prerequisite of such activities; otherwise they would come under public scrutiny and criticism.

Despite recent national and international concern for the public's distrust of institutions and politics, the Finnish public has consistently shown a high degree of trust in universities, science and the scientific community, as well as biobanking initiatives (Tupasela *et al.*, 2007; Sihvo *et al.*, 2007; Tieteen tiedotus, 2004; Eurobarometer, 2002; Jallinoja and Aro, 1999). Even more interesting is that the two most trusted institutions in Finland are the police and the military, followed by VTT (government research institution) and universities. In addition, 57 % of Finns either agreed or agreed strongly that scientific research was significant in terms of social and economic development (Tieteen tiedotus ry., 2004: 37, 40; see also Sihvo *et al.*, 2007). Such trust in government institutions is very different from the levels of trust that are shown for these same institutions in other countries, such as the UK (see also Tupasela, 2007a).

Some researchers have noted that one reason for the public's distrust of medical expertise in other countries, such as the UK, has in part developed in response to cases of medical impropriety (Levitt and Weldon, 2005), environmental issues (Irwin, 1995) or lack of

critical discussion (Wallace, 2005). Trust in experts in the UK, for example, has suffered due to incidents, such as the Alder Hey and Bristol Royal Infirmary incidents, which raised a number of important questions concerning the trust in the medical community, although recent studies have shown that people are still very willing to donate surgical residue for research despite such incidents (Bryant *et al.*, 2008). This has nonetheless been reflected in a heightened ethical and legal concern in the setting up of UK Biobank (see Tutton and Corrigan, 2004). This, however, does not explain the differences that exist between the UK and Finland in terms of trust towards the medical or research community in a more general sense since improprieties have also taken place in Finland (see TEO, 2005; National Public Health Institute, 2005).

Trust in experts, as well as the level of participation that the public is afforded regarding new genetics, is also uneven depending on what research areas are involved. Häyrinen-Alestalo and Snell (2004: 70) note that when the Act on Gene Technology (377/95) in Finland was revised in 2000, a passage concerning the hearing of the public was added to the text. In 2005, an Academy of Finland research program (ESGEMO) announced that it would hold a public discussion concerning field trials for a genetically modified, non-flowering variety of birch tree. Earlier field trials resulted in activists destroying the field trial lot by cutting down the trees, thus preventing the research from continuing.

Despite the fact that there have been a number of incidents where doctors have been found guilty of research improprieties and the level of public activism differs between different areas of biotechnology, Finland has not experienced a drop in trust in the authority of medical experts, as in some other countries. As one molecular biologist noted concerning the willingness of people to participate in large population studies:

> *"The work of the National Public Health Institute is based to a large extent on large-scale longitudinal studies and they are possible as a result of the willingness of people to participate. That willingness disappears if we lose peoples' trust. This might sound flowery, but it's not. As a researcher in Finland one begins to appreciate more and more the high participation rates in relation to other countries."*
> (Molecular biologist interview, 2005)

The interview excerpt reflects the way in which researchers generally feel about the high level of trust that the public places in them. There is an acute sense of both appreciation, as well as responsibility, that trust brings with it in the medical research community. Researchers also reflect upon this trust in a reciprocating manner in that the trust brings with it a great deal of responsibility. Historically, the high level of trust between the medical community and lay people is also in part due to the strong traditions that researchers have had in studying, characterizing and treating rare monogenic diseases that are overrepresented in the Finnish population (see Norio, 2003). This is also apparent in the way researchers speak when asked about trust. In this sense, recent claims of the

possibility of developing new markets and commercial opportunities from biomedical research merely bolster and reinforce what some have called an 'official world view' of the way development can be accomplished on a national scale in Finland (Miettinen, 2002; Kettunen, 2001).

In terms of extending the analysis of tissue economies and biovalue to trust, what can be said of its relationship to bodily fragments? The different forms of collection, use and application play an important role in the ways in which trust is framed. Reciprocation and the imperatives associated with use are interpreted or directed, not to the individual that has donated the sample, but towards something that is communal and in some cases even nationalistic in form and content or what Waldby and Mitchell (2006: 76) relate to imagined communities.

For surgical waste, the question is framed within the efficient use and collection of material that would otherwise be lost or wasted. Indeed, in their original consent form, the two researchers appealed to this sense of not wasting resources. The language of waste and use play an important role in these discourses. For the Genome Information Center, the issue is framed within the efficient use of resources that have been collected with tax payer money. Once again, waste and efficiency are used to mobilize resources. With HNPCC, the preventive imperative serves as the basis of the biovalue that is extracted. The preventive capacity is extended to whole families and is no longer associated with the individual alone. Interestingly though, very little is said about property in any of these cases. Issues of ownership, despite being central within policy documents, play a very small role in the material that I have come across, except for its role in policy documents. Despite being a goal with the Genome Information Center or the policies of the National Institute of Public Health, the idea of tissue as property was not highlighted. Rather the issues of diagnostic sample collections, epidemiological collection and other registers are discussed through other form of meaning, such as management or custodianship.

This is particularly interesting given the fact that consent is seen as a form of disentanglement. The conceptualization of trust in these cases can, in my view, be seen as a form of re-entanglement of the disentangled, which I discussed in relation to epidemiological sample collections and the new law on biobanking that Finland is drafting. In it, research subjects who have donated samples would be able to find out who have used their samples and for what purposes, as well as limit the use of the samples in some cases. This raises the question of why this is necessary if the sample has already been disentangled. The more efficient use of waste material and existing resources, as well as the preventive imperative, serve to reconfigure or re-entangle the individual within the broader community of social and economic interests.

In light of what Corrigan and Tutton (2004) have argued concerning the way the term 'research subject' is being replaced by 'research participant', this is significant. There appears to be an attempt to emphasize the significance of individuals, on the one hand, while moving towards making a looser definition of informed consent, on the other. Much of this process has come about through the practical difficulties involved in maintaining

and operating large sample collections and related data. Tissue samples, as physical objects, have been located in a legal terrain that has had a higher and more stringent level of regulation applied to it than classical information. But the re-entanglement of individuals through notions of reciprocity and the evocation of notions of community and solidarity is, in my view, an attempt to compensate for the pressure that commercial and productive imperatives are placing upon scientific knowledge production as a whole.

This also has consequences in relation to trust. Following Marxist thought, Waldby and Mitchell (2006: 33) highlight the way economies are essentially forms of social relationships. This becomes particularly apparent in the donation process that is often necessary in tissue acquisition. My research, however, indicates that there is also considerable use of diagnostic samples for research purposes that fall outside of the remit of social exchanges that Waldby (2002) has suggested to form an important part of tissue economies. Within this context, it can be shown how the use of both tissue, as well as a multitude of healthcare information, does not rely on a social relationship, but is instead technical in nature. This de-personalized acquisition is allowed and legitimated through a much broader social interest perspective which is being emphasized amongst researchers and policy documents. At the inter-personal level, reciprocity is stripped away, while at the more general level, researchers frame their work within the discourse of reciprocity through the commercial and preventive paradigm. This process, however, entails a trust relationship between the source of the samples and their user.

This suggests, however, that values are framed increasingly in terms of financial and economic questions, as opposed to other questions that the public might see as important, such as privacy. Väliverronen (2004: 373; 2007: 58) has shown similar evidence in the ways in which the media in Finland have represented and popularized biotechnology and the ways in which there has emerged a national competition in which everybody is expected to contribute in one way or another. The discourses surrounding gifts, waste, property and information management play important roles in this process in that the concepts can be deployed in different situations to legitimate activities and decisions on biobanks and their use. Increasingly, however, these questions are linked to commercial outcomes. This process, however, does not necessarily erode the will and interest that people have in participating in research. As Berking (1999) has noted, neo-liberal practices may indeed open up new avenues through which community may be expressed. The commercial and preventive paradigms and their connection to biomedical research form a strong moral imperative to utilize samples that researchers are using in their arguments towards the re-interpretation of consent practices. It remains, however, too soon to see whether this model will be successful or not.

As I discussed above, questions of interpreting consent are being strongly influenced by various imperatives, whether they be commercial interests or preventive goals. These imperatives, however, have a strong normative component to them. Barry (2001) has argued that national, organizational and individual capacities emerge as the measure of success and power. Tissue economies form, in one sense, a technological zone and are

becoming increasingly the sites of success and power in biomedical research systems in an international context. At the same time, however, tissue economies remain highly localized, in that samples are locally (nationally or regionally) collected and in many cases fiercely protected to give researchers a competitive advantage. These national resources are deployed to create trans-national research partnerships. As a Finnish researcher has commented on the nature of Finnish disease heritage:

> "Although the Finnish Disease Heritage is without a doubt part of our national identity and peculiarity, the concept is useful from a practical perspective for those who suffer from such diseases. Still we should not try to monopolize our diseases. The vast majority of the field of medical genetics in Finland is international by nature. At the same time, fostering the Finnish disease heritage carries international responsibilities."
> (Norio, 1994) (own translation)

The quotation shows how researchers see the Finnish Disease Heritage (FDH)[21], to be clearly national in one sense, but increasingly international by its nature. This flexibility allows for the fostering of a national identity that can be leveraged to promote international research partnerships. Research is international in nature and the collections that are in Finland should increasingly be used to maximize the possibilities of international collaboration.

Similarly, anthropologist Marilyn Strathern (1999) has elaborated how the notion of *capacity* is central in understanding 'property as a way of securing control over potential with reference to both production and future use.' Here again, the organization and construction of tissue economies reflects one facet in the attempt to develop capacities in relation to the biomedical use of human tissue collections, as well as securing their future use and availability. Control over tissue samples represents the possibility of maintaining control over the potential productive capacity of tissue samples. As Knorr Cetina (1982) has pointed out in relation to the expansion and acceleration of knowledge production, we return to a central question that has to do with resource relationships, which in this case not only include the samples themselves, but a whole host of other healthcare information, as well as research infrastructures. It is the information that can be extracted from samples and connected to other information resources that provide the potential for future capacity. It is here that tissue economies also form an important moral economy[22] of action and decision making. No longer are decisions related to use and value associated with scientific

[21] The Finnish Disease Heritage is considered to be a group of rare hereditary diseases that are over-represented in the Finnish population (Norio, 2003; 2000)

[22] I am using the term moral economy here to denote the way certain decisions are represented as natural and necessary using social imperatives as the argumentative base. This perspective differs from other approaches towards the study of moral economies where social pressure or customs coerce actors to perform according to traditional norms and customs (cf. Thompson, 1971). The moral economy that I am referring to reflects the erosion of traditional scientific norms at the expense of the neo-liberal or commercial paradigm.

discovery and medical progress alone, but increasingly with commercial value, economic progress and preventive capacity. As I showed with the policy documents in section 4, capacity and the imperative to use collections is not just a question of medical ethics and informed consent, but rather, the use of tissue sample collections and healthcare information becomes embroiled in a much broader political landscape of social and commercial expectations. The individual or research participant is in one sense expected to accept that tissue samples are used and re-used in a multitude of new research projects and programs since it does not physically affect them and since the results could have a significant impact on the economy as a whole. Personal information becomes de-personalized and de-politicized as the role of information becomes increasingly based on larger and larger sets of data. At the same time, however, the reciprocation of this imperative serves to bolster the trust that people have towards this system of knowledge production.

Although Titmuss (1970) was trying to distinguish the social from the economic, the use of tissue sample collection in Finland indicates that the social entails the economic and that the two are difficult to separate. This places the individual in the center of economic activities as a necessary and crucial actor. Tissue economies are, therefore social, not just in the sense that research participants donate and serve as the source of samples, but also in the sense that they legitimate research activities which use and re-use samples. The use and re-use of samples would not be possible in Finland if people felt that these activities were not in some way justified. This perspective also gives rise to notable differences in the possibilities that become available to different tissue economies in different locations. Tissue economies are not just dependent on the availability of tissue samples and related information, but also the support of the public. The commercial aspirations represented by researchers and policy-makers play into the social fabric and notions of acceptability, creating, as Berking (1999) has argued, new forms of reciprocity. The ways in which commercialization related to tissue sample collections will end up reflecting social interests remains, however, unclear and unstable.

This line of argumentation and development in the politics of biobanking moves along a similar trajectory as suggested by Waldby (2002) and Schepher-Hughes (2001), where bodily fragments are seen to retain values of personhood. The denial of property rights, as Beyleveld and Brownsword (2000) have suggested, form an important basis for the use of these tissue economies in that current policies in Finland indicate that tissue samples that have been already collected can be incorporated time and again within the research system without having to approach patients for re-consent (Hallituksen Esitys, 2008). Despite the denial of property rights to individuals, even the OECD makes a startling statement in one of its policy documents by noting that 'most of the population database initiatives do not have detailed policies with respect to intellectual property, commercialization or benefit-sharing' (OECD, 2006: 123). In my view, this discrepancy reflects the indeterminacy of policies based on commercialization and their relationship to the samples that they use. Property rights are denied to individuals, but there is also an unwillingness to use the language of property in many cases to fully lay claim to the samples since this may

undermine the levels of trust that research has been afforded. The imperative to use tissue sample collections, however, appear to need a buffer between the donors, users and application of sample collections in some cases. Biobanks appear, at least in part, to serve this function.

As I discussed earlier, reciprocity has been argued by some to play an important role in the decision to participate in donation and medical research projects. The act of donating tissue samples has been compared to that of gift giving, which also binds the recipient to reciprocate this act (Titmuss, 1970). I have argued that the acquisition of tissue samples and related healthcare information becomes available through a multitude of various sources, many of which do not in practical or theoretical terms have anything to do with actual donation. The most notable of these examples is the use and re-use of pathology sample collections in biomedical research, which is not based on the practice of donation, but rather diagnosis. Along these lines, Busby (2004: 40) draws a distinction between the 'gift of life', 'gift to strangers' and the act of 'gifting' where the first category represents gifts for organ transplantation, the second blood donation and the last one serves to clarify a number of legal questions concerning ownership due to the transfer of property rights.

Large epidemiological and cohort studies draw in part on the idea that tissues have been gifted and it is the responsibility, indeed, *moral duty* of researchers to utilize these samples to their full potential. The arguments presented in the Finnish Genome Information Center case explicitly show how the duty to use samples is evoked in trying to find an ethically acceptable foundation for using the samples. The arguments are based, however, on narratives of commercial reciprocity. The case of the Tampere Research Tissue Bank falls outside this discussion, since samples are not donated as gifts, whereas the HNPCC case shows how doctors see their duty as informing relatives of a personal risk and the imperative of prevention. Busby argues that this is in part a reflection of the ethical turn in bioethics, where questions pertaining to the distribution of healthcare and public health are regaining ground in bioethics from what has become the domination of the question of individual autonomy (see also Rouvroy, 2008; Dingwall, 2002; O'Neill, 2002). The distribution of healthcare and public health are, however, also being set alongside the distribution of wealth through activities of commercialization using tissue sample collections.

It is important to note, however, that there is considerable variation in the way this policy discourse is accepted and implemented in practice, where each individual researcher and research group make their decisions based on personal choices. At a broader level, however, the acceptance of the policy discourse concerning the biomedical use of tissue sample collections has become pervasive and infiltrated all levels of government and organizational policy discourse. The moral imperative that is used to underline the relationship between the samples themselves, economic development and preventive capacities is a strong argument used to contextualize the discussion and therefore set the groundwork for codifying these activities through legislation, as well as research funding.

Knowledge Production, Expectations and Hope

In this research, I have been exploring the relationship between the organization of resource relationships and how this is reflected in the balance between individual rights and social and scientific interests. This, I have argued, is an important element in the way resources are made available to the machineries of scientific knowledge production. In relation to biomedical research and biobanks, it is clear that the high level of trust that the public has in the research community does not provide an impetus for the emergence of an active public sphere of political activity. At the same time, the emphasis that some researchers are increasingly placing on the commercial significance of their work tends to increasingly embed the discussion in economic terms which are almost impossible to predict or evaluate, yet they serve as the basis for reciprocation. As one researcher noted concerning the expectations in biotechnology:

> *"Of course the biotech sector is a problem. For the past five to ten years people have been saying how it is the next money machine [sampo[23]], but I would argue that those have been pre-mature expectations. Only now are we beginning to be able to connect the wet lab data with the epidemiological data, but this will still take time."*
> (Interview with molecular geneticist, 2003)

Both written and interview material concerning Finnish research environment indicates a change in the rhetorical strategies and linkages used and applied to characterize the emerging fields, including genome research and its sub-disciplines, yet at the same time there is a clear sense of the way in which these research fields have not yet matured (see Academy of Finland, 2003a; 2002). The move from purely 'scientific' and expertise claims concerning genome research to economic and commercial claims reflects, to a certain extent, the role that science and research is seen to have in Finland today in relation to commercial aspirations (cf. Tekes, 2004a; 2004b). The evocation of the economic imperative in texts and discussions highlights the increasingly closer link that is made between the textual content produced by researchers and science and technology policy makers (see Tekes, 2003; 2002b). At the same time, this linkage in the epistemic grounding and goals of researchers and policy-makers alike has a tendency to limit the possibility of public discussion, dissent and disagreement, given the fact that the economic model is seen to be the main solution to current challenges.

It can be argued, therefore, that from an epistemic perspective, innovation and commercialization strategies, at the national level, have come to play a much larger role

[23] The term 'sampo' was used in the interview. It refers to The Kalevala, Finland's traditional mythology, where it was a machine that produced wealth. In this sense people have tried to connect modern biotechnology with the traditional mythology of the nation. The sampo is comparable to the horn of plenty.

in the formation and structural development of knowledge production infrastructures, such as with tissue economies. Recently, some have argued that hope is being built on expectations and visions that play an increasingly prominent role, not just in policy discourse, but also in the way scientists reflect upon the significance of their work (Borup *et al.*, 2006). Such concerns also have a strong influence on the funding decisions that small countries, like Finland, make concerning research and development. It is in this sense that the link between the expert and policy maker becomes even more prominent. Visions and expectations are accepted as natural in a passive manner, but the choices of individuals can be seen as active and operating within the context of hope (see Tupasela, 2006a; Helén, 2004; Brown, 2003; Brown and Michael, 2003).

Hope and expectations have an important bearing on the relationship between policy makers, experts and the public. As I showed in my analysis of policy discourses in section 4, hope and expectations include a stronger relation between the strategies of researchers and policy makers and an increased emphasis on the role of the citizen as a passive/active participant (cf. Snell, 2002). The normative emphasis on dialogue that appears to underlie recent theories of expert-lay interaction tends to obscure some of the more important features of policy making, which in Finland continue to rely on a paternalistic role of the medical profession.

As Barry (2001: 48) notes 'government is possible by making the individual members of the population interested, informed, and responsive. Liberal government relies on the existence of the informed citizen. […] The citizen must be formed morally and technically.' What the case of Finland highlights, however, is that experts can have varying degrees of influence in terms of the way the citizen should be informed and interested in technical and socially relevant matters. In addition, by linking particular science and technology policies to broader political programs, such as the information society, experts are able to introduce technically difficult subjects within a more understandable framework. This strategy, should, by no means be seen as a negative tactic by the medical or the expert community to subvert power from the public, but is merely seen to be an important condition for the efficient organization of research activities in relation to the way informed consent should be interpreted, as well as an important way for the medical community to justify their actions and find an ethical solution to their activities. Although this culture and organization of relations between actors has a tendency to create and reproduce a normative world view of how development should progress, many have argued that it also provides considerable advantages in terms of the development and coordination of scarce resources in research and development. At the same time, however, there is an imminent concern relating to the rights of the individual in relation to informed consent and their rights in deciding how their samples and personal information are used and managed. Here again, we return to the issue of re-entanglement of the disentangled. Despite the great hopes and expectations that are attached to tissue sample collections, there is a continuous need to re-configure the individual back into policy discourses to legitimate such activities.

For Titmuss (1970), the donation of blood represented in part the identity and good

will of the donor (see also Waldby and Mitchell, 2006: 31). Understanding the formation of tissue economies from the perspective of epistemic cultures or scientific knowledge production brings forth the political preoccupation that policy makers have with the role of information in innovations and economic development. Castells (1996) has argued that information and knowledge intervene on themselves to generate productivity. This so-called 'informational mode of development' can be seen as an underlying driving force in, for example, the case of the Finnish Genome Information Center, in that the structures and sources of information that are being organized and developed would not only give rise to new ways of collecting and analyzing data, but also bring forth new possibilities in social intervention, through prevention programs and medicines. In this sense tissue might, in Castells' view, give rise to, not only new forms of intervention, but also understanding. As Mitchell and Thurtle (2004: 11) note:

> "Although the informational mode of development is only a frame for analysis (and should not be reified as an object in itself), its power comes from its ability to illuminate very real historical consequences of changes in the ways that information is processed. […] as we attempt to create new virtual landscapes […], such as the ability to store large amounts of information, […] that establish new configurations of self and environment."

The current international policy discourse on biobanks and their related tissue economies has focused on the generation of productivity, both in terms of health and capital. To this we can attach the rhetorical strategies of creating expectations. At the same time, however, in the organization of information resources to form new analytical tools for research and new ways of understanding the human body and populations, there arises the possibility of developing a new way of understanding and analyzing disease in populations. This possibility forms an important basis for the expectations and hopes which are attached to human tissue samples.

My first example of the Tampere Research Tissue Bank has offered a perspective into this possibility, in that not only does it provide a tangible acquisition and handling facility for research tissue samples, but it also represents a shift away from consent procedures to utilize diagnostic samples as research samples. The case highlights how the difficulties in defining the future uses of the samples, as well as the regulatory allowance for their use in research has contributed to the up-take of collection practices which do not subscribe to the use of informed consent. Such practices, give rise to a collection system where tissues are no longer donated to research, but instead are considered to be part of the medical record of the patient, and under current law usable for research by acquiring a permit from the medicolegal council. In this sense, the tissue bank becomes a virtual test population for both researchers and industry and operates outside the informed consent framework.

With the Genome Information Center and the example of economies of economies, we can see how the re-interpretation of the scope of informed consent arises from practical

issues related to the management of large sample collections which can be used within systems of database federation. The role of the individual and information gained from them is re-configured within the tissue economy to allow for its use and re-use and thus gives rise to further development of the tissue economy and the information that it produces. The rhetorical strategies employed to justify the setting up of the center highlight the way in which expectations and imperatives come to bear upon and factor into decision making. Questions related to efficiency and waste are configured within the expectations of the productive capacity of these collections, whereby issues of consent become re-interpreted to both disentangle and re-entangle individuals with research practices.

In the case of HNPCC we saw how information on hereditary conditions challenges existing interpretations of privacy and informed consent in that physicians are compelled to protect the lives of those family members who are also at risk. The production of scientific knowledge on the occurrence of hereditary cancer in Finnish families represents a form of hope and expectation that the disease can be mapped and managed in such a way as to reduce mortality within those families which are carriers of the disease. Despite issues related to personal privacy and informed consent, the physicians are determined to open the possibility of diagnosis, treatment and counseling to all those that are affected. Whether individuals choose to participate in treatment remains, however, a personal choice.

All cases provide insight into the ways in which consent, personal privacy and autonomy are challenged in relation to the hopes and expectations that are associated with the productive and preventive capacities of these collections. These interpretations are linked to aspirations related to the production of scientific knowledge and involve, therefore, to one extent or another, practices which require the organization of resource relationships between the sources of the samples and their users. The processes of organization of resource relationships have been strongly attached to hopes and expectations, which also perform an important role in activating resources, as well as enrolling support and public trust in these activities. This approach has served as the basis for diverging interpretations of informed consent into the daily practices of researchers within the field of biomedical research.

7
CONCLUSION

The acquisition of human tissue samples and related health information touches upon fundamental aspects of the relationship between the doctor and the research subject in that body samples, and information derived from them, represent two of the most intimate aspects of ourselves. From a legal and ethical perspective, therefore, we have a very strong claim to control these elements and their uses (World Medical Association, 2002). At the same time, tissue samples and the information that can be derived from them are central to the production of biomedical knowledge and have become the object of scientific interest and political attention (Gottweis, 1998). Recent literature on informed consent and the biomedical use of tissue collections has brought under questions, however, the validity of existing informed consent practices and set forth suggestions to develop new ways of interpreting informed consent in an attempt to re-conceptualize the ways in which resource relations are organized and managed in the acquisition and management of these collections (Cambon-Thomsen *et al.*, 2007; Manson and O'Neil, 2007; Hansson, 2005; Eriksson and Helgesson, 2005a; Helgesson *et al.*, 2005). These discussions can be set amidst the policy narratives which emphasize increased efficiency in the use of tissue collections, the organization of scientific practices (cf. Knorr Cetina, 1999), as well as the economic, commercial and preventive expectations associated with the productive capacity of the collections. Sociologically, the narratives and the research practices associated with the use of tissue sample collections reflect an increasing tension between the protection of the rights of the individual in relation to social, scientific and economic interests; in other words, the tension between collective interests and individual rights.

The research presented here has sought to explore the changing interpretations of informed consent through an analysis of policy discourse and three case studies that relate to the acquisition, use and management of human tissue sample collections. The policies and case studies are all bound to the processes and concerns which are related to the production of scientific knowledge derived from tissue sample collections and have

been framed within the conceptual framework of tissue economies (Waldby, 2002; 2000; Waldby and Mitchell, 2006), which locates the exchange and acquisition processes involved in the production of scientific knowledge within attempts to produce different forms of biovalue. Since the questions related to the changes in interpretations of informed consent have consequences in terms of our understanding of tissue economies, I will recapitulate the main points raised by the analysis in relation to policies and the cases and consider the implications each one has for policy making and the regulation of human tissue sample collections.

In *Policy, Laws and Tissue Collections,* the re-interpretation of informed consent was considered in relation to the emergence of new policy discourses on the knowledge-based economy and knowledge-based bio-economy. Although ethical and legal texts on biomedical research juxtapose the interests and rights of the individual against those of science and society, it is evident from policy documents that it is precisely the interests of science and society, in relation to tissue sample collections and the potential that they have in producing new knowledge and wealth, that is contributing to the re-interpretation of consent, privacy and autonomy. The individual, as a legally defined autonomous actor with a set of predefined rights, is always reconnected and re-constituted to the broader social, political and economic setting in which they, and their samples, are located in. The consideration of collective interests, the writing of regulations and inevitably the organization of tissue economies does not, therefore, take place within a narrow context of individual autonomy and rights alone, but is always reflected within a much broader social context that relates to issues of waste, management and efficiency, both from a scientific and administrative perspective, and increasingly a commercial one as well.

The analysis of the political underpinnings surrounding tissue economies leads, therefore, to the conclusion that legal and ethical documents contain misleading ambiguities in relation to the nature and inalienability of personal rights in relation to information and tissue samples removed from ones body. The policy discourse surrounding biobanking is saturated with the interconnections and assumptions between individual and communal values which are seen as the basis of social solidarity. This solidarity is, from the policy perspective, increasingly based on the maximization of the potential productive capacity of these collections. The policy discourse helps to highlight how the development of tissue economies, as a broader policy goal, also attempts to intertwine and re-define personal rights and interests with communal ones. This can be seen to create a tension between the individual, as a supposedly autonomous and independent actor within western legal thought, and the politico-economic interests associated with the use of tissue sample collections.

For policy making, the challenge remains the means through which the interests of society are reflected in the reasoning behind specific policy measures. Recent studies on the attitudes of people towards biobanking in Finland indicate that benefit to coming generations and medical progress were the main reasons for contributing and participating in medical research, not the commercial benefits that companies will accrue from it (Sihvo

et al., 2007; Tupasela *et al.*, 2007). Yet as the analysis of policy making has shown, commercial and economic interests are rated as one of the most important factors on which decisions and solidarity is based. This discrepancy would seem to indicate that policy making is not sensitive enough to the interests of society and needs to develop ways of integrating social and political interests in a more meaningful way.

In evaluating the relevance of tissue economies and biovalue as conceptual analytical tools, it should be noted that in developing the concept of tissue economies, more attention should be directed towards the analysis of the political strategies and interconnections which are created between knowledge production policies and the assumptions that they entail for the ways in which tissue sample collections are organized and made available to the research community. Recent studies have shown how tissue economies and biovalue operate at the personal level in terms of gifts and donation (Waldby and Mitchell, 2006), but more evidence is needed on how such practices relate to science, technology and innovation policies. The linking of the policy discourses to legal formulations and research practices in this research have helped to identify the strong interconnections that exist between the normative basis of interpretations of informed consent and the organization of tissues as resources. At the same time, this analysis has identified the increased emphasis that is based on the production of commercial forms of biovalue and the assumptions that this is seen to have, at the policy level, as the basis for social solidarity.

In the section *Building Tissue Economies*, the three case studies that were examined serve as concrete examples of the ways in which tissue economies are built and operate through different ways of collecting, using and managing tissue samples and related health information. The ways in which various supply systems for tissue and information operate within different scientific knowledge production systems invariably create conditions and the possibility to re-define and re-consider the ways in which informed consent is interpreted. These processes relate to the organization of resource relationships (Knorr Cetina, 1982), as well as to the forms of engagement that are made possible or circumvented through different practices. Increasingly, scientific knowledge production is being modeled on industrial input/output models which remain highly mechanistic and tend to represent tissue resources and their availability more as a technical, as opposed to a social process. It remains unclear in terms of the operation of tissue economies to what extent such industrial models will be successful in the translation of scientific knowledge to commercially viable products.

The collection of surgical waste at the Tampere Research Tissue Bank highlights how the classical understanding of tissues as gifts, suggested by Titmuss (1970), is problematic and limited. It also identifies the way in which the current understanding of tissue economies is limited by its emphasis on the social aspects of tissue exchange. Gift giving is based on the implicit assumption that the donor is aware that he or she is asked to donate a tissue sample. The cornerstone of this donation process has traditionally been structured within the legal and ethical framework of informed consent. I have shown, however, how the collection and use of surgical waste and diagnostic samples operates

within a different supply system that works outside of the donation and informed consent framework. This raises an important question as to the status of the tissue sample; was it ever really waste in the first place? Although classified as surgical waste, the fact that it is being collected with the intended purpose of being used for research gives the samples a dual nature. This practice can also be said to touch on a basic tenet of medical research, which is to protect the autonomy of the patient (World Medical Association, 2002). However, if the patient is not even allowed the possibility of making a choice of whether or not to donate, and indeed is not aware that the sample is being stored for future research, we can see how the whole donation and gift cycle paradigm is undermined, as well as how autonomy itself is brought under question.

From a legal perspective, the case highlights the problematic distinction that is made between diagnostic and research samples. The evidence provided on the recent use of diagnostic samples for research purposes is an indicator of how diagnostic samples serve an important role within the biomedical research community. Although diagnostic samples can be said to be legally located within a different context of acquisition, it is nonetheless, significant to note that their collection for the purpose of research (in addition to diagnosis) constitutes a practice which should also entail a greater consideration for the possibility of engagement with the patient from whom the sample is collected from. Gaining consent for it to be used in research would constitute such a form of engagement. Within the newest legislative proposal for biobanking in Finland, medical practitioners would be required to make patients aware of the collection of surgical waste for research purposes which would appear, at least in part, to reflect some level of engagement. For existing samples, presumed consent is adopted as the mode through which diagnostic samples (surgical waste) are made available to researchers (Hallituksen Esitys, 2008). In light of the policy discourse on engagement, the emphasis that is placed on the rights of the individual and the degree to which samples are used in research, the proposal to inform patients of the collections and use of samples and the adoption of presumed consent within the context of using existing diagnostic samples in research constitutes a type of middle ground of informed consent practices within biomedical research. The acquisition of informed consent before surgery does not, however, in my view constitute an undue burden on the medical community, but would rather help in the disentanglement of samples and their use from their source and increase the legitimacy of the activities (cf. Waldby and Mitchell, 2006). It is suggested, therefore, that the responsibilities of hospitals in collecting surgical waste be clarified in terms of their need to gain informed consent, as opposed to notification.

Recently, literature on informed consent has suggested that donors be allowed to give 'broad consent', particularly in large international biobank studies, where the future uses of the samples and related information are still unclear (Hansson *et al.*, 2006). Such studies indicate a re-interpretation of the content and form of informed consent as it relates to biomedical research using tissue sample collections (see also Berg, 2001). The case of the Finnish Genome Information Center provides a concrete example of the challenges

associated with the management of collections that comprise thousands of samples and the problem of defining in advance the scope of future research. The very nature of the indeterminacy of future research brings under question the possibility of providing specific information of the uses of samples in research. Furthermore, research practices related to database federation allow researchers to bring together a multitude of different types of sample collections, many of which can be decades old. Here again, we can see how the extension of the analysis of tissue economies in relation to epidemiological sample collections raises new issues related to the future management of existing collections. From a scientific research practice perspective, it is not practical to approach the sources of those samples to re-gain consent for every new research project or research question decades after their collection. Tissues, once acquired, enter into a realm of productivity which is averse towards re-establishing consent, and research practices are increasingly based on implicit assumptions as to the will of the research participant. Here again, the interpretations of consent come under question as practical means of disentangling samples from their source, since the time scale of possible future analysis is extended indefinitely.

Although less contentious than the use of diagnostic samples, the discourse surrounding the development of the center indicates a strong expert-led policy agenda within this research model and indicates strong linkages with the policy discourse. The goals of scientific knowledge production at the research level are becoming increasingly intertwined with the knowledge economy policies associated with biomedical research that I discussed. As Häyrinen-Alestalo (2007; 2006) has noted, this represents an increased penetration of political expectations into theoretical explanations associated with scientific knowledge production. Here we see how expectations of the production of commercial biovalue are intertwined within the tissue economy of epidemiological samples, as well as the belief that larger sample sizes will inevitably produce expected results. The indeterminacy of future uses of tissue samples and its concomitant reflection in the broadening of the scope of informed consent reflects the indeterminacy of the type of biovalue that such collections may or may not be able to produce in the future.

The erasure of the research subject is in part an outcome of the informational turn. Research subjects, their related tissue samples and health and life style data become statistical objects, which under personal data laws have a different legal status when used for research. At the same time, the management of the information becomes a technical, not a social issue. Therefore, tissue economies become more responsive to the requirements of scientific markets in that such collections become tools which allow for increased cooperation and exchange among international research groups as well. Biobanks and the information that they contain operate as national scientific capital which opens the possibility of international scientific knowledge production and cooperation. National tissue sample collections become embedded within international tissue economies and markets, where larger and larger data sets are created from smaller units of data. This trend, once again, raises the issue of what type of information is it possible and necessary to impart to research participants, what are the conditions under which such exchange of information

can take place and who decides on whether or not samples are made available to such projects? One can also ask what, if any, role do individuals whose samples are contained within such collections play in this management process? The most recent legal proposal for biobanking in Finland has suggested that people be allowed access to see who and for what types of research their samples and data are being used for. This move represents and respects, in my view, the spirit of autonomy and control that international documents have set forth in protecting the rights of individuals, but it also highlights the way in which disentangled tissues become re-entangled within legal documents. This raises the issue that tissue sample collections retain values of personhood, which regulation must increasingly account for.

It is here that our current understanding of tissue economies is the weakest, in that the conditions under which tissues circulate and become available are highly dependant on the policy and legal environments that are constructed for them, and are subject to radical changes in short periods of time and space. Old sample collections, in particular, help to highlight the political imperative which is imposed on the necessity of re-using exiting collections by allowing for their continued use in research. The classification of tissues as waste if they are not re-circulated and made available is important in that once they have been collected and processed, they also become a form of property that can be controlled. Yet the use of this property is also limited, in that it contains sensitive personal information and it cannot be bought and sold. Indeed, as the OECD (2006) has noted, the status of ownership of many of these collections remains in many cases undetermined. The samples themselves can be used to leverage biovalue (i.e. to produce scientific knowledge which can be commercialized), but they cannot be bought and sold in the traditional sense of economic exchange. The transformation of waste to property and the re-circulation of old and existing epidemiological sample collections, albeit limited in many ways, reflects Strathern's (1999) argument of how Euro-Americans are devising new ways of laying claim to new objects. At the same time, these attempts are also restricted by existing regulatory frameworks that place limits on what they can be used for. Here, then, we begin to see that there are limits to the maximization of biovalue as well. This, in my view, is another limitation of our current understanding of tissue economies and biovalue, in that the emphasis on the maximization of forms of value that can be produced from tissue economies is a contentious assumption and reflects perhaps more the political aspirations associated with tissue economies than what is actually possible. Social, regulatory and ethical issues set limits on many of the conditions under which biovalue can be produced, thus questioning the adequacy of the potential for the maximization of value that can be derived from tissue sample collections.

Stratherns (1999) suggestion that we are laying claim to new objects is also central in my discussion of the relationship between physical tissue samples and the knowledge that can be gained as it relates to the informational turn (Beaulieu, 2004). The increased acquisition of information from physical tissue samples have had important consequences in how the legal status of the physical samples themselves is interpreted (Aromaa *et al.*,

2002). The re-interpretation of informed consent in relation to the legal status of tissue samples reflects the degree to which laws that are applied to information are also applied to the physical samples themselves. Here we see how tissues themselves are in one sense legally interpreted as information. The stretching of one legal framework to apply to another context represents a crucial element on how tissue economies extend beyond the physical realm.

The issues raised in *Hereditary Cancer Research* opens up new problems related to the limits of informed consent, privacy and the responsibilities of researchers in relation to information gained from one patient through research and its significance to family members and relatives. The limitations of consent and privacy are reached as doctors and researchers re-interpret their responsibilities in relation to knowledge of hereditary disease in broader, more communal terms. Some commentators (Rouvroy, 2008) have suggested that what is at stake here is nothing less than a challenge to the liberal unit of the individual that has traditionally been considered as a unitary, stable and embodied entity within western legal thought. The case highlights how the imperative of modern genetics to produce scientific knowledge is confronted by the limits of the same legal framework that made it possible to produce such knowledge in the first place. The legal distinction made between knowledge of hereditary disease in the research and treatment contexts highlight the limitations that exist in the application or transformation of scientific knowledge to maximize its potential. Here again we are met with a limitation of the applicability of the idea that tissue economies allow for the maximization of biovalue. The management and analysis of knowledge of hereditary knowledge in the research context is seen as discriminatory and problematic in the healthcare setting. This transformative limitation highlights how the same knowledge can have a vastly asymmetrical interpretation within different legal categories even if in practice there would be very little difference on how the data would be managed and operated.

The case also raises important aspects as to the forms and possibilities of engagement that become possible and are sometimes circumvented as a result of the imperative to warn family members and relatives of possible risks. The imperative to warn and provide counseling and treatment to family members represents a bifurcation in terms of engagement and consent. On the one hand, the privacy and consent concerns of the individual are over-ridden in relation to the preventive goals of the researchers and doctors. On the other hand, new forms of engagement and intervention are adopted and become available as physicians seek out family members (cf. Aktan-Collan *et al.*, 2007). Here we see how the limits of consent are re-interpreted within the context of the scientific knowledge that has been produced.

The transformation of biovalue from scientific knowledge to commercial forms is also problematic, since hereditary diseases are rare. Not all types of scientific knowledge produced from the genome are equally productive in commercial terms, but rather there are some scientific and political interests which still guide the choices of what types of knowledge should be and are worthwhile in producing. A similar problem is also faced

with common diseases in that the state has a strong interest to intervene and set prices of new products that are relevant to national health policies (Tupasela, 2006c). Instead, the biovalue of HNPCC research can be measured more in terms of scientific knowledge and preventive capacity which it makes available to healthcare professionals.

The objective of this research has been to examine the ways in which interpretations of informed consent are diverging and identify what elements and processes have contributed to this. The overall objective of the biomedical use of human tissues and related health information is the production of scientific knowledge. As I have discussed, however, this production process has become increasingly influenced by commercial aspirations, political programs and preventive imperatives. My presentation of knowledge production in tissue economies through the use of input/output models reflects how knowledge production is increasingly seen in terms of industrial production models (Tupasela, 2006a) where there is a political and scientific imperative to produce new knowledge for economic development and the improved understanding of health. The production and transformation of biovalue from one form to another features heavily within the conceptualization of tissue economies (Waldby and Mitchell, 2006).

Yet the productive capacity of tissue economies and the translation of one form of biovalue, such as knowledge, into another, such as health or wealth, are not straightforward, and remain in many cases highly speculative. The processes that can be attributed to these transformations are highly varied and dependent on numerous different variables, such as the type of tissue in question, its form of collections or acquisition, its use in research and the potential for its application. The notion that tissue economies are systems for the maximization of productivity, while useful, also obfuscates the limitations that collections come with and the potential that they have in producing different forms of biovalue. These limitations derive from legal, social, ethical and economic limitations that different types of samples and collections have attached to them. In this sense one can question whether the maximization of biovalue serves more as a normative assumption or an empirical finding within the theoretical framework of tissue economies. Indeed, politically it has become fashionable to highlight the commercial potential that the human genome holds within it, yet is applications remain limited. It is worthwhile to ask to what extent is it useful to base legal and normative decisions on the use of sample collections on these assumptions and speculations?

In an effort to contextualize the operation of the supply systems of tissue sample collections, scholars in the field of sociology of expectations (see Borup *et al.*, 2006) have developed different approaches to examine the ways in which resources and actors are mobilized. My analysis of knowledge production in tissue economies indicates that the commercial paradigm has become a central feature of policies guiding the collection, use and management of human tissue. The use of tissue sample collections for commercial gain is framed within the context of general social development, where it is indeed

the moral responsibility of researcher and policy makers to make the most of existing sample collections, whether they are used commercially or not. This positive connection between the use of sample collections, their subsequent commercialization and its assumed social benefits would seem to support Berking's (1999) assertion that, rather than receding the boundaries of community and social relations, commercialization may also expand and create new avenues through which trust and mutual recognition are created and re-enforced. This moral economy reflects a new direction and approach that is used by experts to mobilize tissues and other resources. It also provides new openings within the sociology of expectations to link scientific knowledge production to moral expectations and responsibility. It remains, however, far too early to say whether such attempts to reconfigure commercialization as a reciprocating activity to donation will have the intended consequences or whether the pursuit of private profit will have unintended consequences on the willingness of people to participate in public research projects and the levels of trust that they have in the research system as a whole.

At the same time the visions and expectations created by researchers (see Käpyaho *et al.*, 2004), as to the significance of the knowledge that they produce is also virtual, in that such statements are forward-looking and unproven (cf. Helén, 2004). Despite being virtual, such discourses mobilize resources and influence opinions and can be directly linked to the policy discourse surrounding the biomedical use of tissue sample collections. Such linkages also indicate the development of strong ideological dependencies between policy makers and the scientific knowledge producers themselves as they relate to biobanks. Such dependencies have also given rise to diverging interpretations of some of the basic rights which are afforded individuals in biomedical research as they relate to the collection, use and application of human tissue samples and related health information. This can be said to fundamentally challenge the western notion that the rights of the individual are absolute and inalienable within biomedical legislation. ■

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