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How to cite:

Cordell, Sean and Widdows, Heather (2010). Constructing effective ethical frameworks for biobanking. *Dilemata*, 4(2) pp. 15–31.

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Version: Version of Record

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<http://www.dilemata.net/revista/index.php/dilemata/article/view/52>

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# Constructing Effective Ethical Frameworks for Biobanking

## En busca de un marco efectivo para los biobancos

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**ABSTRACT:** This paper is about the actual and potential development of an ethics that is appropriate to the practices and institutions of biobanking, the question being how best to develop a framework within which the relevant ethical questions are first identified and then addressed in the right ways. It begins with ways in which a standard approach in bioethics – namely upholding a principle of individual autonomy via the practice of gaining donors' informed consent – is an inadequate ethical framework for biobanking. In donating material to a biobank, the individual donor relinquishes a degree of control and knowledge over the way their material is used in large-scale and typically open ended projects; and the identifying nature of genetic material means that third parties have rights and interests which must be taken into account as well as those of the individual donor. After discussing the problems for informed consent in the biobanking context, the paper then considers three emerging alternative approaches which, broadly speaking, conceptualize the subject of biobanking ethics in communal or co-operative terms: one version sees participants in biobanking research as 'shareholders' whilst the other expands on the notion of participation to include the wider public beneficiaries of biobanking as 'stakeholders'. It concludes by outlining a third view, on which the biobanking institution itself is conceived as an ethical subject whose defining function can do useful normative work in guiding and evaluating its activities.

**KEYWORDS:** biobanking; ethics; autonomy; consent; cooperative; stakeholder.

**RESUMEN:** Este artículo habla del desarrollo actual y potencial de una ética adecuada para las prácticas y las instituciones de los biobancos. Necesitamos de un sistema en que se puedan reconocer las cuestiones éticas más relevantes y en que estas cuestiones se puedan contestar en el modo mejor. La actitud típica de la bioética – fundada sobre el principio de la autonomía personal que se puede respetar con el consentimiento informado – no es una actitud adecuada a los biobancos. Cuando una persona dona sus muestras genéticas a un biobanco, pierde parcialmente control y no siempre sabe cómo las muestras se utilizan en proyectos de investigación largos y abiertos. La identificación de la naturaleza de las muestras genéticas permite que también otras personas – no solamente el donante – tengan intereses y derechos que deben ser considerados. El artículo reflexiona sobre las limitaciones del modelo del consentimiento informado y después discute tres modelos alternativos que están emergiendo en el contexto de los biobancos. Estos modelos conceptualizan el tema de la ética de los biobancos de manera diferente, concentrándose en los aspectos cooperativos y comunitarios. En la primera versión los participantes en la investigación son como accionistas. En la segunda la participación incluye a todos los que obtienen ventajas por medio de los biobancos. Al final, se introduce la tercera versión en que la institución de los biobancos es conceptualizada como un sujeto ético que puede contribuir a direccionar y evaluar sus propias actividades.

**PALABRAS-CLAVE:** biobancos; ética; autonomía; consentimiento; cooperación; accionistas.

### Introduction

'Biobanking' essentially involves the procurement and storage of human genetic materials and their use for research and therapeutic purposes. This paper is about the actual and potential development of an ethics that is adequate and appropriate to the practice and institutions of biobanking, the question being how best to develop a *framework* within which the relevant ethical questions are first identified and then addressed in the right ways. One way to approach this question is to consider the ways in which the usual standard approach in bioethics, that of informed consent, is an inadequate ethical framework for biobanking. In biobanking the individual donor must relinquish a degree of control over the way their material is used in these

ISSN 1989-7022

ILEMATA año 2 (2010), nº 4, 15-31



Received: 17/05/2010  
Accepted: 26/06/2010

typically large-scale and open ended projects. Moreover, the identifying nature of genetic material means that third parties have rights and interests which must be taken into account as well as those of the individual donor. Thus whilst informed consent is used to protect personal autonomy and rights in most areas of bioethics, its efficacy as a single or primary guiding principle in the case of biobanking is challenged.

Accordingly, the paper begins by discussing the bioethical primacy of individual autonomy via its focus on donors' 'informed consent' and the problems with this in the context of biobanking. It then considers three emerging approaches to biobanking ethics which, broadly speaking, conceptualizes the subject of biobanking ethics in communal or cooperative terms: one version sees participants in biobanking research as 'shareholders' whilst the other expands on the notion of participation to include the wider public beneficiaries of biobanking as 'stakeholders'. The paper concludes by outlining a third view, on which the biobanking institution itself is conceived as an ethical subject whose defining function can do useful normative work in guiding and evaluating its activities.

### **1. Individual Autonomy and Informed Consent**

Let us start with the notion of informed consent and the reasons for its employment in the ethics of medical research.

Making informed consent as a necessary condition of research reflects a primary concern with the autonomy of persons: the condition under which individuals exercise their will and make choices for themselves (literally 'a law unto oneself'). In the case of research and bioethics there are good reasons why autonomy is ranked so highly as an ethical ideal. A key reason for the development of a research ethics in the first place was the protection of the research subject from research projects that may compromise individual autonomy or, in extreme circumstances, destroy it altogether. We can chart the urgency of this concern at least as far back as the Nuremberg Code of research ethics, developed as a list of principles that specify the conditions under which research could and could not be carried out on humans. As well as stating that '[t]he voluntary consent of the human subject is absolutely essential', the code's first principle also explicitly adds that the subject must have 'made known to him the nature, duration, and purpose of the experiment (1949).

Whilst the insistence on voluntary consent alone rules out the commission of certain acts of bodily harm or violation against the individual

person, thus protecting autonomy to some extent, *informed* consent pursues autonomy in at least two further and important senses. Firstly, by relating to conditions of privacy as well as harm, the information condition recognizes the way in which an individual can be wronged without necessarily being harmed in any physical or even psychological sense. Voluntarily consenting to give parts of oneself to medical science does not itself entail giving away to anyone all (or any) of the personal information that can be derived from those parts. And whilst bodily materials such as DNA or blood samples are, once donated, usually alienated from the subject at least in the sense of being unconnected to their immediate psycho-physical well being,<sup>1</sup> what happens to that material after donation can be construed as an invasion of the donor's privacy that violates their autonomy.<sup>2</sup> Secondly, where a concern for individual privacy can be seen as embodying individual autonomy in terms of protection from potential abuses by others, it also reflects a positive 'freedom to' sense by which the individual donor is positively enabled to make certain choices regarding themselves and their interests. When the future usage of genetic material and information is included as one such interest, informed consent of donors in research can be understood as serving the value of autonomy in both the protective and the enabling senses.

We should be careful to note here that this prioritization of individual autonomy begets a particular 'liberal-individualist' view of the person as a singular and discrete unit of ethical focus. Any approach to ethics takes individuals to be its subject some sense: a thoroughly classical utilitarianism, for example, certainly *counts* the well-being of individuals. It is precisely by adding together these units and observing the resulting sum of harms against welfare that the utilitarian view can warrant the erosion of one or more individual persons' autonomy – to the disquiet of some of its critics. By contrast, the liberal individualist view does not allow, and actively seeks to disallow, this erosion.

One reason, then, that research ethics and bioethics has 'reified the individual and individual autonomy' (Koenig, 2001, 33) can be linked to its focus on what gave rise to the sub-discipline of ethics in the first place: on the relation of individual subjects to the practices and projects of medical research. Consider that a plausible and attractive single principle of non-maleficence – of doing no harm – could certainly be evoked to protect individual research subjects from psycho-physical abuses and harms, and this could be combined with a variety of utilitarianism which sought to maximise future public health, for example. But this could also leave untouched both the wronging of privacy invasion and the possibility of preventing important personal choices which

individual autonomy circumscribe. Accordingly this perceived indispensability of autonomy, or at least its importance, in bioethics<sup>3</sup> can be mapped by a trend towards a 'principlism'<sup>4</sup> of autonomy in bioethics.

Historically, bioethics grew out of a professional ethic in which the primary concern has been the relationship between the medical doctor and the patient. Accordingly a particular concern has been to protect the confidentiality of the patient and maintain trust between doctor and patient (Widdows, 2009). To this original professional ethic additional concerns have been added, such as those of research ethics and public health, however, these professional roots goes some way to explain the importance of patient confidentiality as 'one of the most important principles of medical ethics' (Harris, 1985, 225). Correspondingly, donors' informed consent can be seen as playing much the same role as in research ethics as patient confidentiality has done in medical ethics.

#### *Problems with Autonomy and informed Consent*

A fundamental criticism of the liberal-individual view is that its focus on individual autonomy is founded on an unsatisfactory conception of the person as a responsible and moral being. As formulated variously by communitarian, feminist and virtue ethical views among others; this objection claims that the idea that persons can be individuated, in the way that that liberal-individualism requires, rests on a mistake. What, these theorists ask, does such a discrete individual amount to if they are supposed to be a 'person that exists independently of, and able freely to choose, the ends that give her life meaning and value?' (Mulhall and Swift, 1996, 13).<sup>5</sup> On this account the self – a person with values, decisions, projects and character – is necessarily made up of and inseparable from a social world of other such selves: a world without which the meaning of these features of ourselves would prove elusive. To underline this criticism perhaps, we can ask rhetorically whether one could intelligibly make a 'fully informed' decision about one's own action if it were based only on one's own directives chosen in isolation from those of others. What would such autonomous choices and actions be like? And, granting for the sake of argument that these choices and actions were possible, why would we want persons to be like this? Continuing with this objection, the liberal individualist's normative error, then, is to direct ethical attention to a supposedly isolated individual person that is not really a living ethical subject.

A defendant of the liberal individualist view could respond to this criticism by saying that they are not in fact committed to such a metaphysical 'atomist' view of the individual. They can agree that individual moral per-

sonhood is necessarily socially constituted and maintained, and agree that this is a good thing, but at the same time maintain the primary value of autonomy. Whilst it may make no sense to see individual selves and choices as operating within discretely autonomous bubbles, it could yet make all the sense in the world to make individuals, as rights-bearers and beings with interests, the primary focus of our ethical principles. Understanding the human being descriptively as essentially a social or a political animal is perfectly compatible with articulating and defending a normative conception of individual and inalienable human rights, for example. Accordingly some 'relational' accounts of autonomy have urged that certain social relations are at least necessary for persons to make autonomous actions and choices (Christman, 2004; Mackenzie and Stoljar, 2000).<sup>6</sup>

However, although the liberal individualist may be able to defend their normative view, and whilst autonomy may rightly remain a key value in bioethics, the practice of storing and using genetic material and information problematizes informed consent in biobanking and unsettles individual autonomy's status as a guiding principle of ethics in the case of biobanking, as we will see next.

With respect to the privacy and confidentiality conditions circumscribed by informed consent, a basic problem is that the genetic material that an individual donates contains information not only about the donor but also about other people, such that 'disclosure of genetic information by individual DNA donors also exposes information about others with similar genetic profiles' (Mitchell and Happe, 2001, 376). Groups of relevant others can include biological families or whole communities with similar ethnic or social backgrounds (Brock, 2001, 34), and in the context of biobanking projects and overall goals, it is this kind of collective information which biobanks are, typically seeking to make use of, by identifying genetic tendencies and reactions etc. Now recall that, in the present context, the 'informed' in informed consent includes being told about future usage and disclosure about how one's genetic material and information is to be used. If an essential aspect of the autonomy condition is that it is meant to preserve the interests of individuals and to prevent them being harmed, and a piece of genetic material provides information about many individuals' interests and ways in which they may be harmed (for example information about a tendency towards a certain disease), then adhering to the individual donor's informed consent fails with regard to the autonomy of the relevant others.

An obvious concern here is that informing and securing the informed consent of all relevant individual parties is practically problematic or impossible. But there is an important conceptual sense in which the focus on individual autonomy misses the ethical target here as well.

How can one individual (or even a number of individuals less than the total in the relevant group or populace) consent to the usage of something widely and communally shared? The problem is most clearly exemplified in the case of genomic research carried out on the indigenous Haghai tribe of Papua New Guinea in 1994. Here a patent was granted on a cell line containing unmodified Hagahai DNA which had been collected from a small number of individuals. The material was to be used for detecting HTLV-1-related retroviruses, the longer term objective being a diagnostic tool or vaccine for certain types of leukaemia. This patent was 'disclaimed' in 1996 but the Hagahai cell line remains in the public domain at the American Type Culture Collection as ATCC Number: CRL-10528 Organism: Homo Sapiens (human) at a cost of \$290 per sample. (Widdows, 2009, 179) The study, and others like, it was heavily criticized on a number of grounds, not least for the perceived biological imperialism of garnering the DNA of an indigenous community for possibly lucrative Western research projects. For our purposes we can clearly see that in this case, ticking the individual donors' informed consent box neither gained the relevant consent nor gave the relevant information to the persons or community concerned.

The problem here is that by adhering to the informed consent of donors' condition, as if this was doing all the ethical work, individuals ended up unknowingly giving 'permission' to use genetic information about a whole people that had not consented. But the Haghai case and others like it also exemplifies a more general feature of biobanking in relation to individual consent and autonomy. 'Whereas clinical research has specific aims, the aims of biobank research may be vague or non-existent at the time of the participants' donation to the biobank.' (Skolbekken et al., 2005, 336). That is, the nature of biobanking is that its projects are open-ended and possibly as yet undecided, thus at least some of its activities may be unforeseen. Thus a donor to a biobank must in some sense consent to their genetic information being used in such unforeseen ways, and this immediately presents a question as to whether their consent can be informed in the sense thought to preserve their individual autonomy: about which more in the next section.

Hence, where there has been good reason to employ informed consent – in service to the conception of individual autonomy – as the cornerstone of an adequate medical ethics and bioethics, there now appears an inadequacy of that conception in certain cases of genetic research, most conspicuously in biobanking. The defining activities of biobanking and the nature of their projects call into question the extent, if any, to which a principle of personal autonomy can do the right ethical *work* required in governing and guiding biobanking practices. Genetic information given by donors is typically about a number of persons, and the

uses to which it may be put are not specifiable in a way that fits the autonomy respecting aspects of informed consent.

To be clear, the point is not that biobanking necessarily involves and affects large numbers of individuals and aims at wider societal goods and so, therefore, biobanking ethics needs to modify its ethical outlook in order to be practically efficient and achieve its goals, for example. (Such an argument could be resisted by pointing out that one important reason for having a biobanking ethics in the first place is surely to limit the potential risk of ignoring individual rights and autonomy in pursuit of greater goods.) Rather, it is that the collection of large quantities of genetic data and the use to which biobanking puts it necessarily gives rise to an ethical *subject* that comprises more than one individual. Thus whilst individual autonomy remains a key ethical concern, it is found wanting as the overarching ethical framework for biobanking.

## 2. Moving on from Informed Consent

### *Broad Consent*

Summarizing the problems outlined in the last section – genetic material containing information about people other than the donor and the open-endedness of biobank projects – the basic problem is that of what exactly the individual donor is consenting to by participating in a biobank. Donating material to a database of a mass of genetic information that may be used in comparative studies, as well as population or generational ones means that consent becomes harder to inform in the relevant autonomy-respecting sense. One way round this particular problem is to move to a condition of general or ‘broad’ consent where, given the nature of the biobanking projects one is participating in, the donor consents to the ‘multiple purposes of biomedical research and future consent to as yet unspecified biomedical research’ (Hansson et al., 2006, 266). Here it could be argued that, as long as the information about those purposes and that research is properly communicated and understood by the individual donor, the consent given is as fully informed as such a project requires and will allow.

A problem with this broad consent model concerns whether the consent given is in effect permission to do anything the recipient biobank sees fit with genetic material. Whilst it has been suggested that broad consent ‘can be seen as a means of maximising autonomy’ (McHale, 2006, 196) in the biobanking context, it could be taken to be its opposite: a wholesale abrogation of individual autonomy, particularly with



respect to the knowledge of the materials and information's future usage. The worry here is that in giving broad consent, the donor is being informed of little more than the fact that they have relinquished the access to knowledge about its future usage. Actual models of broad consent have sought to assuage this concern; for example the UK Human Tissue Act (2004) maintains the right of the donor to withdraw their sample at any time, and recommends that they be updated with any significant change of the purpose to which material may be put, for example 'if their samples will or could be used for research involving the commercial sector' (2004, para. 80).

With these kinds of caveats in place, the attractiveness of broad consent is that it recognizes both the importance of donors' agreement and understanding – as far as possible – what they are agreeing to, and that it is inappropriate to expect donors to biobanking research to be informed about every possible and future specific use of their genetic materials. But by the same token it highlights the urgency of something already alluded to, namely that the purposes and aims of biobanks and their projects are clear and that they are communicated effectively to donors. Broad or general consent may be appropriate in the biobanking case, but if it is not to be 'blind' or 'carte blanche' consent (Maschke, 2006, 193), then it too has to be well-informed if it is to improve on the previous consent model. Where the specifics of a single clinical research programme are replaced with more generally stated aims, purposes and rationales, the latter need to be formulated to researchers and subjects just as clearly as the former (or perhaps even more clearly, given that they warrant a much wider range of possibilities). 'General', in this context, should not mean vague, protean or unintelligible.

Accordingly, neither informed consent nor broad consent is sufficient to respect the ethically significant features of the public and donors in relation to biobanking. Problems, such as the need to address the ongoing nature of the research and the rights and interests of third parties, have led ethicists to seek new models which attempt to address such concerns. In the rest of the paper we will explore three such models; the first and second are the 'shareholder' model and the 'stakeholder' model which broadly fit under the category of 'trust models' (or possibly conditional gift models) in that they both involve initial broad consent supplemented by additional ethical and governance frameworks; the third is an institutional alternative which begins with the proper function of biobanks and presents the biobank itself as the ethical subject.

*The Shareholder Model*

Empirically, the importance of subjects' faith in biobanking institutions and professionals to adhere to their aims and purposes in the right way has been underlined in a study of a Norwegian focus group of biobank participants which found that 'consenters base their participation on trust in the researchers and the regulation of research in Norwegian society, rather than on specific information on the research in question' (Skolbekken et al., 2005, 335). Key to successful biobanking is the need to establish and maintain trust: in establishing a biobanking ethics, '*process and trust matter*' (Skolbekken et al., 2005, 335). In other words the workings and ethos of the biobank and related projects and institutions need to be visible, reliable and commensurate with the donors' wishes to an extent that justifies their participating and consenting.

In view of this requirement, a view of the biobanking project as a kind of cooperative scheme has been employed as a model of biobanking ethics: the 'trust model' or 'conditional gift' are the two terms most often used in the literature for this type of conception. We can see in this approach the potential for fostering the confidence which is required by donors mentioned in the last paragraph. In the trust models, additional ethics and governance mechanisms are introduced to supplement consent, and to ensure that the samples are used in accord with the expectation of the donor and with the conditions on the original consent. In the trust model "when a person agrees to donate tissue, the recipient has a responsibility to serve as a trustee, or steward, of the tissue in order to ensure protection of the contribution". (Winickoff and Winickoff, 2003, 1182).

One version of the trust model formulated by David E. Winickoff identifies this relationship as a partnership of shareholders. Concerned to reflect the breadth of communities and individuals involved in biobanking projects, Winickoff advocates 'developing representational forms for the donor collective in biobanking' (Winickoff, 2007, 451). For Winickoff, a problem to be addressed here, is an 'agency gap' between the donor collective who give their biological and informational material for research, and those who manage and oversee biobanks (Winickoff, 2007, 450). This gap, he suggests, could be bridged by – among other things – the formation of donors' voluntary associations who would elect representatives who could sit on the board of directors and take places in any relevant Ethical advisory or regulatory bodies. Moreover, Winickoff thinks that this strategy 'may work towards solving the well documented trust problem' and will be required if 'the social project of biobanking is to move forward fairly and sustainably'(Winickoff,

2007, 452).

What this proposal, based on a corporate shareholder model, offers then, is a significant move away from the focus on the individual and their autonomy. Instead, the framework it recommends is concerned with constructing a biobank in a certain kind of way so as to further its stated rationale as a social and cooperative venture. In so doing, the shareholder conception goes some way towards a substantial template that can provide the visibility and reliability conditions crucial to informing donors' general consent. Thus the problem of providing adequate but broad consent might be addressed in the process of solving what Winickoff refers to as the 'trust problem'.

### *The Stakeholder Approach*

Whilst the shareholder strategy encompasses the donor collective and urges their participation in shaping the ethical conduct of the biobank to which they 'belong', objections have been raised to the shareholder model as a way of conceptualizing and applying the cooperative scheme idea. The idea of participants as stakeholders is that their interests are represented and heard among those of, for example medical researchers and managers, and that all participants shape the way biobanking is carried and out and regulated. Hence the framework of biobanking ethics, on this view, becomes the actual ongoing deliberation involving all those involved in the project, or representatives thereof. Among some other criticisms, however, Kathryn Hunter and Graeme Laurie have seen in the shareholder strategy:

*a danger that vocal minorities might come to dominate within the shareholder model, especially if connected to groups that are already well-organised, resourced and mobilised (e.g. patient or advocacy groups) and which have strong preconceived and fixed preferences about the use of the resource and/or the distribution of resources. It might also lead to a presumption that a model of representation is truly representative and that no further engagement is required.*

(Hunter and Laurie, 2009, 158-9).

One way of developing this worry a bit further is to say that the 'gap' between parties involved in biobanking highlighted by Winickoff may actually be reproduced and multiplied by positing more and more agencies in the structure of biobank regulation. Here the problem can be taken as an instance of a more general one about factions and particular interests. Why, to use Winickoff's proposed example, does an association representing donors' interests fill a gap between their perceived interests and those of managers, when it could just as easily isolate and particularize those interests in oppo-

sition to those of other groups within the organization? Put most forcefully '[t]he 'shareholder' analogy envisions not 'partnership' or 'co-operation' but, rather, *self-interest* and *control*' (Hunter and Laurie, 2009, 164).

In light of this worry, and others, about the efficacy of the shareholder model, Hunter and Laurie suggest that a 'stakeholder' model is more appropriate to biobanking ethics and governance. They argue for a far broader inclusion of interested parties that goes beyond participants and which 'would include (among others) participants such as the board of directors, ethics committees; funders and members of the company; researchers; communities; the wider public or society and, most importantly in contrast to the 'stakeholder model', 'future generations whose health the resource is intended to improve' (Hunter and Laurie, 2009, 170).

The main strength of the stakeholder view can perhaps be brought out by considering once again the inadequacy and inappropriateness of subjects' consent as the basis of a biobanking ethics. We have seen that by its defining practices and projects, biobanking transactions between individuals and researchers and institutions involve many more people, groups and communities than an ethics of individual autonomy addresses. Hunter and Laurie's vision of biobanking ethics and governance is of a participatory scheme that encompasses this scope, maintaining and expanding on the insights of the shareholder model whilst improving on its restriction to participants as akin to shareholders in a corporation.

An obvious concern with the stakeholder approach, acknowledged to some extent by its proponents Hunter and Laurie (2009, 171), is that by rightly recognizing the breadth of the cohort of relevant 'stakeholders', it thus concludes that all and any individuals within a society are or could be legitimate stakeholders, and that whilst this conclusion may be conceptually persuasive, the actual problem of how to include all these stakeholders is arguably no more tangible than the problems of how to run a political society. We might add that ongoing biobanking research is certainly not restricted by national boundaries, and that therefore this difficulty of inclusion does not stop at geographical or political borders.

Perhaps one insight of the stakeholder model is that it highlights both the necessary breadth of an appropriate biobanking ethical framework and the practical difficulties of constructing an adequate version. However, whilst the stakeholder approach is largely a case for properly accommodating the correct range of public interests in biobanking ethics, Hunter and Laurie do suggest ways in which to take on the prac-

tical problem that reflect this, for example through regular public meetings and publication of their proceedings.<sup>7</sup> These practices at least reflect the stakeholder rationale of consultation and dialogue in the pursuit of properly informed participants and beneficiaries.

### 3. The Biobank as Ethical Subject

A third proposed ethical framework for biobanking differs from both the focus on individual consent and the trust model. The basic idea discussed in this section is that the biobanking institution, like others, can be seen as an ethical *subject* we can judge to be operating in better or worse ways according to how well or badly it fulfils its function: in short, the 'fit for purpose' biobank as the subject of biobanking ethics. In this section we outline the basis of the functional view, then discuss its application to biobanking in particular and end by considering ways in which it could come at some of the specific problems raised in this paper.

#### *The Institutional Ergon*

The notion of an institution such as a biobank functioning as it should is based on an institution being a good or bad instance of its kind, just as we might say of a pen or a knife that a 'good pen' writes well or that a 'good knife' cuts well. This approach sees the function of an institution as its 'characteristic activity' – in Aristotelian terms the *ergon* – of a particular institution that makes it what it is. (Foot, 1978, 135) Two thoughts underlie this functional view. Firstly, a social institution is defined by its function: it consists in a certain collective human activity or clusters of activities, and this activity or these activities account for what it *is*. Consider that it seems impossible to characterize a social institution *without* referring to a collective social activity: a social institution is what it *does*. Secondly, institutions are in the relevant sense artificial in the sense that they are made, by persons, for some purpose.

On this way of thinking, the institutional *ergon* is not only descriptive but also evaluative and normative. That is, consistent with how it figures elsewhere (Aristotle, 2001, 1097b22-118), the conception of *ergon* as applied to an institution relates not merely (or necessarily) to what an institution happens to be doing, but also to what it *should* do. This might be more intuitive than it first appears when we consider the ways in which institutions can fail to be 'good institutions'. Think of 'institutional racism'<sup>8</sup> or, more recently, investment banks' fatally reckless gambling with customers' money. These are cases of institu-

tions themselves subverting the putative practice which they supposedly embody: failing justly to protect and serve a community and having little or nothing to do with good financial practices respectively.

In terms of determining what the *ergon* of an institution is, one immediate problem here is that the purpose of an institution may not be transparent either from an observation of its current or past activities (it may be a poor instance of its kind); or from studying mission statements, constitutions or policies (these may fail to 'track' the proper *ergon* or they may not be being enacted by the institution).<sup>9</sup> In response, thinking about what would be sought and agreed upon by rational people were these institutions not in existence (security in the case of legal institutions, health in medical institutions etc.) might point to the essential features of institutions that transcend such contingent possibilities.

Developing this thought towards an account of the particular substantive qualities of a good institution, the 'hypothetical contract' model just mentioned, together with the consideration that institutions are constructed by humans for a purpose, shows up the crucial connection between any social institution and some *specific human good or goods*. That is, if there are good reasons for rational persons to establish, promote and maintain a socially constructed institution, whatever form it may take at whichever stage in its history, then those reasons are linked to some human good or goods. Accordingly, the current conception of institutional *ergon* can be characterized by a pair of necessary and jointly sufficient conditions. One is that an institution serves its primary, nominal, purpose and the other is that by doing so it substantiates some and distinctive key human good or set of goods. This links the particular human *goods* of education, or law or health, to the *functions* of educational, legal or healthcare institutions. These are the human goods that figure specifically in an explanation of their existence.

#### *The Ergon of the Biobanking Institution*

What then is the *ergon* of a biobank construed in this sense? Most obviously its goods are those of research and the discovery of knowledge in conjunction with human health and disease prevention. But more particular consideration of the way in which the biobank concerns a certain conjunction of goods gives us a more distinctive grip on its characteristic activity – *ergon*. That is, other kinds of institution such as universities do medical research and are essentially concerned with knowledge and research, whilst hospitals and healthcare institutions are linked essentially to health. The biobanks' defining *modus operandi*

is in its combination of these goods oriented in a specific way by its purpose of large scale data collection.

Finally then, how might this conception do ethical work in the sense required by a biobanking ethical framework? Whilst the idea of institutional *ergon* does not require that an institution be a 'collective person', with all the problematic metaphysical baggage that may bring, it does in a sense see the institution as an ethical quasi-agent that operates in certain ways – and can be evaluated and directed accordingly. When we understand the human artificial nature of an institution and thus what 'better or worse' means in terms of its institutional excellences and ethos, we can instructively view institutions as at least analogous to persons with virtues and character.

More specifically for our purposes, can such a conception address the particular issues for biobanking raised in this paper? As to policy formulation and ethical regulation, the human goods conception of *ergon* could plug a gap between contingent facts about the biobank as it happens to be; and the nominal or primary purpose of biobank research which may be interpreted in a number of ways. This is particularly important when we consider that biobanking ethics as a sub-discipline of ethics is as yet ongoing and being defined. For here is the possibility of something to refer to which goes beyond appeal to extant or previous practices and can transcend the perspectives of private interests. For example in debating the question of whether to allow a particular commercial venture to make use of the biobank, which may or may not be disallowed outright by a particular code of practice and about which explicit mission statements may be vague, the conception of *ergon* could be evoked as criteria to decide whether such a project fits with the *ergon* understood properly in the human goods sense. The claim here is not that this conception will alone answer decisively either way in every case, but that it can provide some objective ethical leverage in ethical debates over such procedures. Similarly regarding the 'agency gap', the hope here is that a richer understanding of purpose and aims of a biobank with which all participants are properly acquainted, could at least justify certain expectations of biobanking as reasonable and challenge others as not in keeping with its *ergon*. Accordingly, then, it could offer to provide or supplement the kind of information about purposes that is required to be understood and communicated to donors as meaningfully broad consent.

#### 4. Conclusion

To summarize, we have surveyed and assessed some actual and possible developments in biobanking ethics. Whilst the principle of autonomy and the informed consent condition embody and stem historically from a proper ethical concern for individual donors in their relation to research projects, and whilst a quite general bioethical principle or set of principles that strongly prioritizes individual personal autonomy may be apt for and may rightly constrain certain research activities, it is ill suited in these respects to biobanking projects designed to build databases of information about the genetic tendencies of whole populations and future generations. In light of the failure of informed consent, we then discussed some alternatives, firstly one way in which the consent condition has been modified, and then an expansion of biobanking ethics away from the focus on individual autonomy and towards a conception of the biobank as a cooperative scheme or trust. A further suggestion was made regarding the role of biobanking function as ethical criterion, and of the biobank as an ethical subject by itself.

In conclusion; the adherence to informed consent on the liberal-individual model is unsatisfactory as the basis of biobanking ethics, though this is not to obviate donor consent as an important ethical concern which is dealt with more adequately by broad consent. However, even properly informed broad consent is alone insufficient to cover all the relevant ethical ground in biobanking: donor consent is one ethical issue, and the donor is one ethical subject, among many others. This is highlighted by the more communally based approaches of Winickoff and Hunter and Laurie, and we hope to have offered a further institutional direction with the function – *ergon* – model. It is hoped that by doing so, this paper has suggested at least an appropriate kind of ethical framework for biobanking and some ways in which it could best be developed.

## **Bibliography**

- Aristotle, (2002), *Nicomachean Ethics*, Broadie, Sarah and Rowe, Christopher (trans. & ed.), Oxford, Oxford University Press.
- Beauchamp, T. L and Childress, J. F., (2008): *Principles of Biomedical Ethics* (Sixth Edition) New York, Oxford University Press.
- Bradley, F.H., (1927): "My Station and its Duties" in *Ethical Studies*, Oxford, Oxford University Press.
- Brock, Dan W., (2001): "Genetics and Confidentiality", *The American Journal of Bioethics* 1, 34-35.
- Christman, John. (2004): "Relational autonomy, liberal individualism, and the social constitution of selves", *Philosophical Studies* 117, 143-164.



- Foot, Phillipa, (1978): *Virtues and Vices*, London, Blackwell.
- Harris, J., (1985); *The Value of Life: an introduction to medical ethics*, London: Routledge & Kegan Paul.
- Hansson, Mats G., Dillner, Joakim, Bartram, Claus R., Carlson, Joyce A., Helgesson, Gert, (2006): "Should donors be allowed to give broad consent to future biobank research?", *Lancet Oncology* 7, 266-69
- Hunter, Kathryn G. and Laurie, Graham, (2009): 'Involving Publics in Biobank Governance: Moving Beyond Existing Approaches', in Widdows, H. and Mullen C. (eds), *The Governance of Genetic Information: Who Decides?*, Cambridge, Cambridge University Press.
- Holroyd, Jules, (2009): "Relational Autonomy and Paternalistic Interventions", *Res Publica* 15, 321-336.
- Jonathan Yearworth & ors v Bristol NHS Trust (2009) EWCA Civ 37 (04 February 2009).
- Knoppers, Bartha Maria and Chadwick, Ruth (2005): "Human Genetic Research: Emerging Trends in Ethics", *Nature* 6, 75-79.
- Koenig, B.A. (2001): 'Why Not Grant Privacy to the Family?', *American Journal of Bioethics* 1, 33-4.
- Mackenzie, Catriona, and Stoljar, Natalie, eds., (2000) *Relational Autonomy: Feminist perspectives on autonomy, agency, and the self*, Oxford, Oxford University Press.
- MacPherson, Lord William of Cluny, (1991): 'The Stephen Laurence Inquiry', <http://www.archive.official-documents.co.uk/document/cm42/4262/4262.htm> Accessed on 8th May 2010.
- Maschke, K.J., (2006): "Alternative consent approaches for biobank research", *The Lancet Oncology*, 7, 193-194.
- Moore v. Regents of University of California, 793 P.2d 479 (Cal. 1990).
- Nuremberg Code: Directives for Human Experimentation (1949) <http://ohsr.od.nih.gov/guidelines/nuremberg.html> Accessed 28<sup>th</sup> April 2010.
- Oakley, Justin, and Cocking, Dean, (2001): *Virtue Ethics and Professional Roles*, New York, Cambridge University Press.
- Oshana, Marina, (2006): *Personal autonomy in society*, Alershot, Ashgate Press.
- Skolbekken, John-Arne Ursin, Lars Øystein, Solberg, Berge, Christensen, Erik and Ytterhus, Borgunn, (2005): "Not Worth the Paper it's Written on? Informed Consent and Biobank Research in a Norwegian context", *Critical Public Health*, 15, 335 -347.
- Widdows, Heather, (2007a): "Conceptualising the Self in the Genetic Era", *Health Care Analysis* 15, 5-12.
- Widdows, Heather, (2007b), "Reconceptualising Genetics: Challenges to Traditional Medical Ethics" in *Ethics and Law of Intellectual Property: Current Problems in Politics, Science and Technology*, Lenk, Christian, Hoppe, Nils and Andorno, Roberto (eds.), 159-173.
- Widdows Heather (2009), 'Between the individual and the community: The impact of genetics on ethical models', *New Genetics and Society* 28, 173-188.
- Winickoff D.E., and Winickoff R.N., (2003): "The Charitable Trust as a Model for Genomic Biobanks", *The New England Journal of Medicine* 349, 1180 -1184.

### Notes

1. This disconnection between donated material and bodily harm may not be obvious in the case of certain bodily materials and the reasons for their storage. As exemplified by the case in which six men had their sperm stored for future use whilst they underwent treatment for cancer (Yearworth and ors., 2009) and the NHS trust responsible for storing inadvertently destroyed the sperm. Arguably the men were harmed by the omission of the NHS to do what they should, as a physical capability – for procreation – which depended on the correct conditions for storage being maintained was destroyed by their negligence.
2. In a famous case, for example, Leukaemia patient John Moore's cancer was developed into a lucrative cell-line using bodily materials taken from Moore in the course of treatment. Though the part of Moore's lawsuit which claimed that a property conversion had taken place – and thus that he was entitled to a share of subsequent economic benefits accrued from the patenting – failed, appeal judges concurred that Moore nevertheless had 'a cause of action for breach of fiduciary duty or lack of informed consent' (1990).
3. For a different argument against the priority of autonomy in medical ethics see Oakley and Cocking *Virtue Ethics and Professional Roles*.
4. See Beauchamps and Childress (1979) and Widdows (2007b).
5. For a classic defence of this view see Bradley (1927, p.166 ff.) See also Widdows (2007a.).
6. For the view that such relations are not necessary for autonomous *persons* see Holroyd (2009).
7. Hunter and Laurie suggest that their approach is already embryonic, and could be developed, in actual biobanking contexts. An example they cite is the EGC (Ethics and Governance Council) of UK Biobank, which 'has produced documentation that explores and explains its approach to "advising in the public interest" ' as well as holding regular public meetings at which lists of 'Frequently Asked Questions' are drawn up and made available on its website (Hunter and Laurie 2009, p.175).
8. The term 'institutional racism' came to the fore in the MacPherson inquiry into the Metropolitan Police Force's investigation and handling of case of the murder of black teenager Stephen Lawrence in 1993.
9. Another objection that might be raised concerns whether evil institutions can have an *ergon* – such that they could be functioning well but doing bad things: examples include criminal gangs or organs of violently oppressive regimes. This conception of *ergon* can readily accept this without having to claim that such institutions should be functioning at all. Moreover, in some cases the *ergon* conception can also do some work in determining which institutions we have reason to change or dismantle, and if so why. When wading through the populist bluster of a political party, pressure group, or newspaper in order to establish what it is *really* about, for example, its deep seated racism or sexism will often be rooted in its concern for the narrowly understood goods of one group of persons at the cost of another. So, to find out what makes some institution function 'properly', as a thing of its kind, can be to find out that it is unjust, pernicious or vicious.