

**POPULATION BIOBANKS AND SOCIAL JUSTICE:
COMMERCIAL OR COMMUNITARIAN MODELS?**

**A comparative analysis of benefit sharing, ownership and access
arrangements**

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Abstract. The combination of developing genomics and information technology in the form of population biobanks has led to wide ranging discussions of the ethical, legal and social implications of this new resource. This article addresses several aspects of social justice, and includes matters relating to the broad themes of balancing public and private interests, and the individual and the common good. These themes will be addressed here by looking at the specific issues of benefit sharing, ownership and access, in relation to three planned database projects, in Iceland, the UK, and Estonia. These issues are considered in relation to the opposing frameworks of commercialism and community.

Keywords: biobanks, population biobanks, genetic databases, genomic databases, benefit sharing, social justice.

Introduction

The combination of developing genomics and information technology in the form of population biobanks has led to wide ranging discussions of the ethical, legal and social implications of this new resource. Whilst the potential offered by the databases has become one area of enquiry, the questions raised by the reality of the development and management of the databases is a continuing theme. Those questions relate not only to issues of internal ethics to do with the participants in the schemes, such as informed consent and confidentiality, but also to broader issues of social justice. The issues of social justice identified by, for example, the Human Genome Organisation, relate to areas of compensatory, procedural, and distributive justice, and include matters concerning the broad themes of balancing public and private interests, and the individual and the common good. These themes will be addressed here by looking at the specific issues of benefit sharing,

ownership and access, in relation to three planned database projects, in Iceland, the UK, and Estonia. Whilst it is acknowledged that these projects are mainly still in the planning stages, there is sufficient information in the public domain to make a preliminary assessment of these areas. As Casado da Rocha (2002) has said in relation to the Icelandic database, “as a scientific and commercial project...it exists both in legal texts and in social perceptions”. In the Icelandic and Estonian projects, specific legislation relating to the governance of the databases has been enacted prior to the creation of the databases themselves, whereas in the UK there is no specific legislation relating to the UK Biobank. In the UK case, arrangements for the governance of the project has been the responsibility of the project founders and interacts with existing UK legislation and other regulatory frameworks, and an Ethics and Governance Framework document was published for comment in late 2003.

Considerations of the tensions between public and private interests and notions of individual and of common good have frequently formed the framework for discussion of genomics technology. For example, Palsson and Rabinow have categorised the discussion of human genome projects as comprising “an intense tug-of-war between communitarian and commercial perspectives on human genome projects”. In this categorisation they link a communitarian approach with “common property arrangements and open access, the public domain” and commercial perspectives with “private property and the free market” (2001:166). Although this categorization does not hold for all aspects of the issues under consideration here, it is a useful framework within which to set the discussion, not least because notions of community and solidarity are increasingly being applied to discussions of human genomic databases. This ‘community’ response to research is defined by Louis (2003): “at the broadest level, both [researchers and research subjects] see their participation as institutionalized progress to benefit science as a public good, as well as to share the material benefits of scientific discovery in larger society”. Furthermore, discussions of ownership and benefit sharing of the databases are frequently based on the ‘common heritage’ aspect of the human genome, and the apparent ‘common pool’ characteristics of medical records and samples that provide the raw material for the databases. This article examines the ways in which the three chosen databases deal with the identified issues of benefit sharing, ownership and access, and attempts to draw some conclusions from this examination.

2. Benefit sharing

The issue of benefit sharing appears to have developed initially in the field of plant genomics, particularly in response to concerns relating to the exploitation of indigenous resources, amid accusations of ‘biopiracy’. This can be seen in terms of the framework of community vs. commercialisation. Whilst in part this is concerned with the increasing commodification, commercialisation and potential exploitation of natural resources, it is also an acknowledgement that it has been the community,

or common-pool resources, of the indigenous peoples that have been appropriated, and that those peoples should therefore receive some benefit. Linked with this, the increased commercialisation of the results of research, and the profit that may be made, have also led to considerations of benefit sharing, for there seems to be an intuitive response that if money is being made from contributions that were freely given, then those who have participated should also receive something. These concerns have led to “an emerging international consensus that groups participating in research should, at a minimum, receive some benefit” as the Human Genome Organisation (HUGO) have said in their statement on benefit sharing (2000). As HUGO have noted, this leads to the question of what counts as a benefit, and several different types of benefit are identified in the statement, ranging from rather vague suggestions regarding participation in the research design itself, to very specific suggestions regarding percentage of profit made. Although these different issues are discussed in the statement, the two most relevant to the discussion here are the recommendations five and six, that is:

- “5) that at a minimum, all research participants should receive information about general research outcomes and an indication of appreciation.
- 6) that profit-making entities dedicate a percentage (e.g. 1–3%) of their annual net profit to healthcare infrastructure and/or to humanitarian efforts” (HUGO 2000).

Chadwick and Berg have suggested that underlying the concept of benefit sharing is the “ethically strong ideal of equal opportunities”, which results in the “duty of those who are well off to share with the poor” (2001:321). Whilst this concept of distributive justice holds particularly true in the relationship between the developed and developing world, a more general principle of compensatory justice would also seem to underlie concepts of benefit sharing. The HUGO recommendations can be seen as reflecting two aspects of benefit sharing as compensatory justice. Recommendation five relates to individual or community compensation for participation in the research, whereas recommendation six relates to social compensation, in respect of the databases being built from information and collections originally provided and developed largely from public funds.

Before discussing the benefit arrangements themselves a further requirement of the HUGO statement will be considered. In the statement on benefit sharing HUGO has declared “the actual or future benefits discussed should not serve as an inducement to participation”. Such a statement is in line with the commonly held understanding that participation in research should be voluntary and not coerced. The Human Genes Research Act (entered into force January 2001) which regulates the Estonian Genome Project put this most strongly, in stating that: “It is prohibited to influence a person’s decision to become a gene donor, including by threatening the person with negative consequences, promising material benefits or providing subjective information.”

This section of the Act thereby represents in legislation the notion of respect for persons, and explicitly refers to potential coercion of various forms. This may also be read as a positive reinforcement of peoples right not to be coerced into participa-

tion. The Ethics and Governance Framework of the UK Biobank also addresses this issue, but frames the response somewhat differently: “Participants will not be offered any significant financial or material inducement to participate, at enrolment or later, irrespective of whether the use of data or samples might ultimately lead to profit” (2003:14).

This difference in language between the Estonian and the UK databases implies a difference in approach, which may be explained by the different origination of the statements. The Estonian Government Act appears to prioritise the rights of the individual, whereas the UK case, from a primarily research-based organisation, appears to attempt to balance the interests of participants and potential commercial users. The UK statement may be read not as a reinforcement of a person's right not to be coerced, but as an implicit reference to a person *not* having the right to a share in any profit. At the least, the inclusion of such a statement suggests a different emphasis, and a more overtly commercialised approach, which seems somewhat at odds with the ethos of a publicly funded research organisation. With reference to the Icelandic database, specific mention of coercion is not a part of the documentation. As one of the most controversial elements of the Icelandic project has been the overriding of the principle of informed consent in favour of an assumption of consent, a concern with ensuring that benefit sharing arrangements do not coerce participation is not relevant to this discussion of the Icelandic context.

The other benefit sharing arrangements laid down in the respective ethical and legal frameworks also illuminate the different approaches of the projects considered. The UK Biobank Ethics and Governance Framework includes a complete section on benefit sharing, which relates to knowledge generally, and to intellectual property rights, rather than to specific benefits applicable to participants. For example it is stated that

“the purpose of UK Biobank is to learn... in order to disseminate new knowledge to benefit the health of the public in the UK and elsewhere.... Intellectual property and access policies are being developed that will ensure that UK Biobank is accessible to research users but is not exploited improperly or used in a way that inappropriately constrains others’ use” (UK Biobank 2003:27).

The benefit sharing arrangements here reflect a very general concept of benefit sharing, the general benefit being of the “health of the public”, and an increase in knowledge, including disseminating that information to the public: “Regular communication will be important, to inform participants of general findings from research based on the resource” (2003:12). However the point is made that the role of regular communication is also to “encourage continued participation” (2003: 12), suggesting that the concern with benefit sharing is of an instrumental rather than an ethical nature. Such an emphasis on the instrumental nature of benefit sharing arrangements may be prudent, but is not in keeping with the spirit of the ethical principles underlying the HUGO statement. In contrast, the Estonian Genome Project emphasises the benefits to the individual, incorporated in the Act as the rights of gene donors “to access personally their data stored in the Gene Bank”. The positive nature of this right is emphasised, as the Act also includes the

requirement that there will be no charge to gene donors for accessing their data, and, furthermore, in order to make use of the information, it is stated that “Gene donors have the right to genetic counselling upon accessing their data stored in the Gene Bank. Whilst there is scepticism as to whether there is a corresponding duty on the government to provide and finance such counselling, the promise of better health has been very important. As Tiina Tasmuth (2003) has said, “The personal gene card/map is a small but important part of a myth created in order to persuade Estonians that their health is going to be vastly improved, with the help of a gene card they can start queuing up for now”.

Such claims to general benefit sharing in the form of improved health are commonly part of the positive language of the pro-database approach, but the Icelandic project adds a further element. For example the economic benefits of the databases have been emphasised, in claiming that the process of developing the database would bring benefits to Iceland in the form of jobs and investment. Similar broad claims relating to potential benefits are being made for the Estonian Genome Project, stressing both the contribution to knowledge and the benefits to the country. One of the founders of the Estonian Genome Project has called it a “resource for basic science”, stating that “It’s our turn to put something into this collective pool of knowledge...this is putting Estonia on the map.” (Metspalu in Tzortzis 2003). Returning to discussion of the arrangements of the Icelandic database, in contrast to the UK and Estonian projects, the benefit sharing arrangements of the Icelandic database are both financial and specific. The Operating Licence granted by the Ministry of Health and Social Security requires that the licensee is responsible for costs relating to the set-up and monitoring of the database, and, additionally, “a fixed remuneration to the Icelandic government and a share of the profit from the operation...such share to be used to promote health services, research and development” (Operating licence, MoHass, Jan 2000, article 10.6). The annual royalty payment is reported to be 6% of revenues, capped at 70 million Kronor (US\$1m), and Icelanders are also to be entitled to drug treatments developed as a result of the database, such drug treatments are to be freely available to the entire Icelandic population. It should be noted that there is some scepticism as to whether such arrangements will result in the provision of any benefits at all, or whether in fact the openness of the wording will mean it is easy to avoid this apparent obligation.

This overview of the benefit sharing arrangements relating to the three databases in question shows how different the interpretation of the concept, and indeed of ‘benefit’ itself can be. It could perhaps be argued that with the increasing commercialisation of ownership of the databases, the benefit sharing arrangements become seemingly more specific and more financially or materially oriented. However, the examples shown from the UK Biobank Ethics and Governance framework show that there is no simple correlation between the type of ownership and management of a database and the principles reflected by the administrative and legal framework, in terms of community and commercialisation as outlined in the introduction to this paper. That is, even where a database such as UK Biobank is publicly funded and emphasises the common-pool nature of the resource, fitting well

with the notions of ‘community’, the language of the benefit sharing arrangements is primarily commercial. Whilst the potential benefits from the Icelandic and Estonian databases may be uncertain, the codifying of benefit sharing arrangements within the legislation at least offers some ‘return’ to participants from the commercial endeavours of the respective projects. The UK Biobank, while stipulating general benefit sharing arrangements, has not clearly addressed the issue of arrangements relating to potential profits, and is therefore open to criticism on this matter. It is to be hoped that this area will be addressed before the Ethics and Governance Framework is finalised.

3. Ownership

In order to further explore the similarities and differences between the projects, the following section looks briefly at the ownership arrangements of each database as they are set out in the relevant documentation. Social justice is represented in matters concerning ownership in several ways. In one sense questions of ownership are important in terms of benefit sharing, as it might be assessed that the most just form of ownership is the one that will provide the most benefits. In this case the question becomes largely one of efficiency rather than ethics, with the debate being framed in terms of the relative efficiency of public or private ownership. In terms of ethics, the larger issues relate to questions of property rights, or rights of ownership of genetic materials, and the corresponding matter of the justice of the appropriation of a common-pool resource, or a ‘global public good’ as HUGO have defined human genomic databases. How are these issues reflected in the governance frameworks of the databases? As noted above, the UK Biobank is a publicly funded endeavour, being jointly funded by the Medical Research Council, the Wellcome Trust and the Department of Health. An alternative arrangement is represented by the Estonian Genome Project, which will be a public-private partnership between the Estonian Genome Project Foundation (EGV, a non-profit foundation founded by the Estonian Government) and Egeen. According to the project website, “EGV is the owner of the database and acts as a privacy shelter. Egeen, the exclusive commercial licensee of the database, will finance the project to the benefit of both parties”. Finally, the Icelandic database will be run by the commercial company deCode. The three databases therefore offer three different models of ownership, and the following section examines how this might be reflected in the arrangements relating to some aspects of ownership.

Two of the three databases make a distinction between ownership of the database and ownership of the ‘human material’ from which the database is built, in that the right to use the sample for research purposes does not equate to the right to do as they please with any sample. In the case of the Estonian Genome Project, it is the ‘chief processor’, that is, a non-profit foundation within the Ministry of Social Affairs, which has the right of ownership of the samples, rather than Egeen, the commercial arm of the enterprise, and

“the chief processor’s right of ownership of a tissue sample, description of state of health, other personal data and genealogy is created from the moment the tissue sample or personal data is provided or the moment the state of health or genealogy is prepared”.

A similar arrangement applies in Iceland, where the Act on Biobanks states that “the licensee shall not be counted as the owner of the biological samples, but has rights over them”. Given the different ownership arrangements of the UK Biobank, it is not surprising that the same distinction does not apply to the samples in the UK Biobank, which will “serve as the legal custodian of the data and samples (2003:6)” as “UK Biobank Limited will be the legal owner of the database and the sample collection” (2003:18). Despite this difference, in all three cases the ownership of the ‘human material’ of the databases remains within the public realm.

A similar situation occurs in a further example, where in two out of three of the databases these rights are limited to the context of the database itself. So, in Estonia, “Tissue samples and uncoded information in the ownership of the chief processor and written consent of gene donors are not transferable”. Similarly, in Iceland, “The licensee may thus not pass the biological samples on to another party, nor use them as collateral for financial liabilities, and they are not subject to attachment for debt”. In contrast, in the UK, “Such ownership conveys certain rights... [including] the right “UK Biobank does not intend to exercise all of these rights; for example it will not sell or destroy samples”(2003:18). Whilst it is emphasised that it will not sell samples” (2003:18), the Ethics and Governance framework also includes a section which deals with “the possibility of partial or full transfer or sale of the resource, whether elective or as a result of insolvent liquidation” (2003:29). As with the previous example, in all three cases full rights to the ‘human materials’ are held by public organisations.

So it can be seen that even where ownership of the databases is partly or fully in the hands of a private company, the ownership of the ‘human material’ that makes up the databases remains in public hands, with the private company acting as a licensee. This would seem to demonstrate recognition of the importance of ‘community’ ownership of common-pool resources, and an implicit acknowledgement of the importance of keeping such material under public ownership, alongside an attempt to balance this with the commercial aspects of the databases. Again, it is interesting that the publicly owned UK Biobank emphasises the ownership and property rights of the research institution above that of the individual participants more strongly than the other two databases considered here.

4. Access

Access to the databases by outside authorities is the final area to be considered here. The issues relating to access to the databases and social justice are similar in part to those noted in the above section. So, for example, restricting research access to the information contained on the databases might delay or prevent the

development of beneficial treatments. As Marks and Steinberg have suggested, “The debate, then, can be understood as primarily involving different conceptions of how to best foster the research endeavour in genetics” (2002:4). Broader ethical concerns relate to the potential for discrimination in insurance or employment. The following account includes only a few examples of access arrangements that are considered particularly pertinent to this discussion. As previously noted, and uniquely amongst the three databases, the Human Genes Research Act gives participants in the Estonian Genome Project full rights of access to their genetic data. Whilst Egeen has exclusive license to use the database, the Act restricts the types of research that may be carried out. Furthermore, the Act explicitly prohibits the use of the Gene Bank “to collect evidence for criminal or civil proceedings or for surveillance”. The legislation relating to the Icelandic database also places restrictions on the type of research that may be carried out, but has little to say in relation to more general questions of access. For example, the Act on a Health Sector Database refers only to access by the Ministry of Health, stating that access for statistical information shall always be allowed, and that such access be provided freely. Whilst being in line with the other databases in requiring that all research pass appropriate review procedures, the UK Biobank does not close off any avenue of research, stating that “UK Biobank will not proscribe any research uses at the outset” (2003:19). In further contrast, the Biobank does not automatically prohibit access for purposes of law enforcement, stating that “Access to the resource by the police or other law enforcement agencies will be acceded to only under court order, and, where appropriate, UK Biobank may make representations to resist such access” (2003:19).

As with the ownership arrangements, the examples given of access arrangements demonstrate an acknowledgement of the importance of community control and access in all three cases. Furthermore, in giving participants the right of access to their own data, the Estonian Genome Project could be read as recognising the continuing common-pool aspects of the project. It would appear from the examples given that the commercially funded projects have more stringent rules relating to access. The different responses to access by law enforcement agencies is a particular case in point, and might be said to represent a negative aspect of public funding.

Using examples from three database projects, the above discussion has illustrated some of the ways in which the perspectives of community and commercialisation are balanced in the respective administrative frameworks. Setting the concrete, practical arrangements within the conceptual frameworks of community and commercialisation demonstrates that the tensions between public and private interests, and community and commerce, are not simple oppositional categories. As the discussion has shown, the publicly funded UK Biobank does not represent a wholeheartedly ‘community’ or non-commercial perspective. Similarly, the more commercially funded databases of Iceland and Estonia exhibit some characteristics more commonly associated with a community approach than a commercial one. This somewhat contradictory finding confirms that it may not be helpful to continue

to think in terms of binary oppositions, and suggests that developing a way of linking the two approaches might be an appropriate way forward. A more comprehensive approach could then feed back into discussions of compensatory and distributive social justice and in this way move towards resolving the tensions that currently exist. In terms of practicalities, it would appear that where specific legislation relating to governance of the databases has been enacted then matters of ethical concern are at least identified and an organisational response stated. This approach acknowledges the importance of the relevant ethical questions, and recognises the relevance of these matters to the communities involved. Such an approach is perhaps preferable to the organisational framework as illustrated by the UK Biobank, which, in this comparative analysis, appears to be less ethically grounded, and less able to respond to questions of social justice.

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