Benefits, Risks and Trust in Human Biobanks[1]

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Abstract

With the aim to provide a promising future to biomedical research, Biobanks also raises profound ethical and legal questions, such as benefits-sharing, risk and protection to the body sample donors. Concerns about risk and fear from the public are likely to impede the success of human biobanks, and trust is the key to dispelling public fear of risk. To assure the participation and support of the public by gaining public trust and the maintaining trust relationships become crucial to the promoters / researchers of the human biobank projects. Trust in biobanks depends on not only the behaviour of promoters / researchers but also the acceptance from the public and participants to the operation of the biobank projects. A partnership approach that empowers the public to set up, manage, monitor and shape the direction of human biobank projects may be a mechanism to gain public trust.

Introduction

In the era of modern biotechnology, initiating biomedical research such as a large-scale population-based human genetic database, namely the human biobanks, is a new tendency in many countries throughout the world (Sutrop 2006, 243–244). It is anticipated that human biobanks will provide significant contributions to future biomedical research. The benefits include mapping genes for common diseases, gaining a leading position in new scientific development, enhancing health for all humankind as well as treating patients with new types of genetic medicine designed to meet each patient's personal needs.

However, there are concerns that this kind of population-based human genetic database raises profound legal and ethical questions regarding the circumstances under which such banks are established and how the benefits of such banks are harnessed (Andrews 2005, 23). These include social implications for individuals and group autonomy, such as in-

fringing upon privacy and causing certain types of discrimination (Andrews 2005, 23–24; Campbell 2006, 203–204). Human biobanks therefore prompt intensive discussion amongst social scientists and ethicists about the various social and ethical issues arising from the provision of tissue samples and the divulging of personal information for the research purposes of these projects (Tutton 2007, 173).

Given that biobanks are repositories of human biological materials collected for biomedical research, setting up such large-scale population biobanks is a challenge for any researcher. The success of human biobanking projects relies not only on the advancement of scientific knowledge, technology and the endorsement of governance policy, but also on large numbers of 'healthy' individuals being willing to provide body samples and personal information relevant to the research (Tutton 2007, 176). When concerns arise about risks to privacy such as the public showing no support for human biobanks due to distrust regarding their purpose, human biobanks are unlikely to succeed. Gaining support and trust from the public is therefore a crucial task that the promoters / researchers of the human biobank project have to deal with.

This article is structured as follows. Part one highlights the anticipated contributions and benefits of various human biobanks. The second part proceeds to describe and analyze the nature of the risks that may result from the establishment of these biobanks, along with the origin of anticipated public fear with regard to these projects. As the risks and fears of the public are likely to impede the success of human biobanks, part three seeks to suggest that a resolution of the interaction between risk and public trust is the key issue to be grappled with in a move towards promoting the success of a biobank policy.

The anticipated effects of human biobanks

In the post-genomic era, advances in bioinformatics and genetics have made collections of biological specimens and medical information valuable for pharmacogenomic research. As a result, many types of large-scale databanks for genomics have emerged and become established as a new form

of biomedical research (Cambon-Thomsen 2004, 868–870; Deschenes & Sallee 2005, 52). A number of examples of human biobank projects can be observed in Iceland[2], Estonia[3], Latvia[4], Singapore[5], Sweden[6], the UK[7], Quebec (Canada)[8], Japan[9], Scotland[10], and Taiwan[11].

These projects have shown that large sets of tissue, blood samples and health data have profound medical benefits for communities (D. Winickoff & R. Winickoff 2003, 1180). On the one hand, biobanks represent a new paradigm for biomedical research. According to Mark A. Rothstein, with biobanks: (1) the individual or entity obtaining the sample may not be engaged in research, but may be only a broker or intermediary supplying specimens to other researchers; (2) the purpose of a biobank is to develop a repository that can be used for many research protocols, often in numerous scientific areas; (3) a biobank contemplates future research activities, including research by investigators who cannot be specified at the time of sample collection; and (4) research using biobanks seeks to move beyond the one study / one informed consent model to a format of obtaining general (or blanket) consent to participate in the research activities of the biobank (Rothstein 2005, 89). On the other hand, biobanks can support a diverse range of research which is intended to intervene in the biological pathways of disease and medical treatment, improve the prevention, diagnosis and treatment of illness, and develop more effective human health therapies and promote their use throughout society.[12]

As a result, difficulties in understanding or treating many of the most common life-threatening and debilitating diseases such as cancer, heart disease, and diabetes—in addition to many of the rarer conditions, or those with less-defined profiles, such as mental illness, Parkinson's and Alzheimer's diseases may be surmounted.

Of course, commercial interests need to be accounted for in any project like the human biobank. The success of a drug represents great fortune for profit-oriented and profit-dependent drug companies. In this new commercial battlefield, the pharmaceutical industry certainly plays a major role in the exploration of commercial profiles and dominates / drives the development of this kind of research (Malinowski 2005, 56).

The risks of human biobanks

In comparison to the benefits of human biobanks, risks are also an issue that attracts the attention of social scholars and society at large. Some scholars suggest these risks include physical risk as a result of blood-taking, psychological risks such as privacy concerns, and informational risks such as discrimination (Campbell 2006, supra note 3, 204). These risks can be classified as intrinsic harms (physical risk) and consequential harms (privacy, discrimination) (Rothstein 2005, supra note 18, 90). Due to doubts that these classifications cannot reveal the broad spectrum of the risks concerned, I will divide these risks into three categories, namely: scientific risks, social risks, and management risks. This classification helps to indicate the nature and seriousness of the risks, to evaluate whether the benefits of biobanks can be achieved without any undue risk and to determine whether such projects are necessarily worth undertaking.

Scientific risk, which is also known as technology-inherent risk, (Parsley & Siedow 2002, 227) concerns the risks of the direct effects or potential long-term effects of innovative technology on the natural environment and human health (Gillespie & Tindemans 2002, 192–193; Magnus & Caplan 2002, 81–83; Murphy & Levidow 2006, 98–146). In human biobanks, physical risk to body sample donors harmed in the process of blood-taking is the major direct effect of biobanks. However, the consequences of these intrinsic harms are too minor to be taken into consideration, especially when compared to the potential benefits introduced by the biobanks.

In addition, scientific risk can be the result of knowledge limitation. The rapid evolution of new technology provides limited time and scientific knowledge or methods for society to define, observe, evaluate, manage or handle the risks that are introduced by unknown causes of this technology or other natural processes. The highly-debated safety concerns of genetically-modified organisms (GMO) reflect one such instance. Scientific risk of this type in human biobanks can be observed when the biobanks fail to generate promising benefits. It may be true that biobanks have the potential to further modern scientific research. However, the timing and nature of the payoffs from the research are currently unclear. Although there have been some key findings attributable to

biobanks, general optimism must be tempered by noting the premature exuberance for other highly-acclaimed research methods, such as gene therapy, pharmacogenomics and embryonic stem cell research (Rothstein 2005, supra note 18, 90). Accordingly, human biobanks alone cannot guarantee medical improvement for the public, academic success for researchers and commercial success for the pharmaceutical industry.

Social risk, which is also known as technology-transcending risk, refers to a variety of social, ethical, legal, industrial, managerial, economic and political problems. These include the increase in the prosperity gap between the rich and the poor, both internationally and within individual societies, that results from the use of biotechnology. In other words, this risk relates to the use of the technology, not the technology itself (Magnus & Caplan 2002, supra note 24, 231).

Risks associated with human biobanks mainly fall within the scope of social risks. The nature and degree of risk related to biobank research depends on (1) the identifiability of the sample and any linked health information, and (2) whether the samples have been collected as part of routine medical activities or are to be collected prospectively. Furthermore, just as the benefits of research go beyond the researchers and their affiliated institutions and entities to the public, the risks of biobanks go beyond the individual body sample donors to population groups with which the donor is associated as well as the general public (Rothstein 2005, supra note 18, 90). In biobanks, people are the source of the raw material for the discovery of genes for research, diagnosis and therapy, raising a host of issues about rights and responsibilities, fiduciary duties and societal obligations (Andrews 2005, supra note 2, 22). Linking health information to the identifiable body sample donors raises the issues of risk to privacy and social discrimination. Human biobanks provide researchers with opportunities to access, disclose or use identifiable personal health information. Any unauthorized or undesired access to, disclosure of, or use of personal health information may pose a threat to the privacy of the identified donors. It may also pose a threat by discriminating against individual body sample donors or the population groups to which they belong. Concerns about privacy and discrimination not only attract countless debates over the legitimacy of the initiation of

large-scale biomedical research, but also play a pivotal role in a potential participant's willingness to enrol in a research study (Weir & Olick 2004, 179). These concerns, along with the lack or loss of public trust in government, science and new technology, would make people in some countries hesitate to either support or participate in human biobank research, and can therefore become a major hindrance to recruiting the targeted amount of human genetic samples.

Management risks include risks to governance and industry. The former concerns wrongful decision-making, which might result in over / under-regulation, misallocation of resources etc. The latter indicates the failure of investment in certain kinds of technology. Both types of management risks can emerge in a biobank project, either when the public, according to the concerns of social risks, shows no confidence in participating in the project or when the biobank project in question, according to the nature of scientific risks, fails to achieve its beneficial goals. Driven by the huge commercial interests that human biobanks may offer, the cost of management of risks may be extremely high should it fail. Commercialization raises important ethical issues. Conflicts of interest, for instance, arising at various stages of the biobanking and research process, (Rothstein 2005, supra note 18, 99) may weaken the public's trust in the researchers and hinder the establishment of human biobanks.

Trust-building in human biobanks

It is members of the public as sources of raw materials for biomedical research and commercial exploration who form the very foundation of human biobanks. A sufficient number of voluntary participants in the research is the key to success for such a large-scale population-based human genetic database. However, setting up such biobanks is a major challenge to governments and project initiators. In the case of the Taiwan Biobank project, 200,000 sample donors are required, whereas in the UK Biobank project, 500,000 volunteers are needed to take part in the project. Both biobanks target nearly 1% of each country's respective population and face the problem of recruiting sufficient body sample donors.

Among many factors, trust is especially important for the ethically adequate practice of science. When there is a climate of trust, the results of science are more likely to be accepted, exploited or applied for the benefit of humankind (Malinowski 2005, supra note 20, 56). The trust of all parties involved, especially the public, affects the success of a population research initiative.

Social risks, such as threats to privacy and social discrimination as a result of unwanted or unauthorized access and disclosure of personal health information are considered as the major issues causing the public to lose trust in biobank projects. Researchers involved with human biobanks often face a dilemma. On the one hand, they believe it will be difficult to recruit research subjects without promising them that their samples and medical information will not contain personal information. On the other hand, using anonymous samples and data will severely limit the utility of the samples and data in their research (Rothstein 2005, supra note 18, 94). These findings suggest that researchers should not routinely adopt anonymous research protocols based on the assumption that there would be serious recruitment problems with using identifiable samples or records (Rothstein 2005, supra note 18, 95). However, in both the Taiwan and the UK human biobank projects, the samples need to be identifiable so as to examine the connection between genetic information and lifestyle and disease risk. The challenge for proponents of human biobanks in this regard is not how to avoid using anonymous samples and data or asking a whole population for unquestioning trust. Instead it is that they need to strive towards adopting credible and efficient mechanisms to gain trust from the lay public.

Good governance structures and mechanisms should be built into biobank projects in advance to ensure that the projects follow through with their promises to participants and that the trust of the population is maintained (Deschenes & Sallee 2005, supra note 6, 40). Accountability, transparency and monitoring are thought to be fundamental components of a good governance strategy. Their balanced inclusion in research strategy constitutes key components of the consent process and will prove to be the cornerstone of a successful long-term research legacy, and can put to rest some of the public's concerns about population genetic research and biobanking activities.[13]

When risk contributes to public fear of biobank research, a mechanism is needed to help the public differentiate between the facts and certain myths surrounding risk. Transparency in decision-making and information disclosure is crucial to ensuring the public understand the nature of biobank research. Consensus conferences and public participation are the most well-known and popular means to facilitate transparency. The aim of these public forums is to provide information to the participants in order to put them at ease about concerns they may have about the research. This information includes the purpose, mechanism and potential of the project, the procedures for and assurance of protecting the confidentiality of the information and non-disclosure of any personal and institutional financial interests of the researchers (Rothstein 2005, supra note 18, 95).

Trust and risk, rather than the beneficial goals of the research, are key factors that directly contribute to the success of biobank projects. According to Margit Sutrop, public trust in science depends on scientists' behaviour as well as on the public understanding of science and acceptance of the applications of new scientific developments. Trust can be destroyed if some scientists do not follow the rules of good scientific practice, act dishonestly or maintain a conflict of interest. Trust also depends on whether people trust scientists to conduct socially responsible science and believe that society will be able to control and maintain risks which new technologies and high-tech medicine possibly introduce. In biomedical research, society accepts risk only if scientific evidence can assure society that the benefits of biomedical advancement can be achieved without undue moral risk. In other words, authentic trust must involve the awareness of possible risk (Sutrop 2006, supra note 1, 254).

Many factors related to human biobanks may cause a lack of public trust. These include improper informed consent (Oberdorfer 2004, 365; Sharp & Yarborough 2006, 460), no mechanism of benefit sharing, ownership (Gitter 2004, 257), conflict of interests (Koski 2003, 403), issues concerning the liability of Institute Review Boards (IRBs) and responsible decision-making (Hoffman & Ber 2005, 365), commercial exploitation, feedback, confidentiality, privacy, misuse of samples and data or research findings, surveillance, and the formation of appropriate ethical and

governance frameworks (Tutton 2007, supra note 4, 173). Transparency itself can only increase public understanding of biobank projects, but it cannot ensure that researchers practice honestly and make an effort to avoid conflicts of interest, or that the operation of the project will not cause undue risk to body sample donors, especially in the climate of commercialization. However, it is also noteworthy that new types of risks, tensions, increasing mistrust and over-regulation may be the result of processes of transparency, such as risk communications, if they fail to deal with possible irrational fears of the public (O'Neill 2002, 7; Sunstein 2005, 14). Public fear or mistrust of human biobanks will cause the public to show distrust and be reluctant to support the biobank projects in question. Establishing a mechanism or legal regime for trust-building is therefore extremely important.

Before proposing any mechanism for trust-building, it is important to note that the concept of trust indicates two types of relationship. One is public trust, i.e. trust among the general public of scientists and government policy. This trust hinges on whether to support the initiation of the human biobank project. Public trust in this context reflects the belief that government and scientists will provide benefits to society and are capable of controlling risks that human biobanks may generate, which is necessary in order for the public to support such projects.

Another issue of trust is the relationship between body sample donors and the operators and researchers in human biobanks with regard to the use of a database for future research and the possible means of benefit-sharing. This trust is crucial to operating human biobanks because it can foster acceptance of the ways in which the human genomic database is developed and used. In the context of human biobanks, public participation that serves to ensure transparency and information disclosure can be used to build public trust.

Mylene Deschenes and Clementine Sallee propose that any possible oversight can be avoided by ensuring participation of all stakeholders (including representatives of the public), transparency, and monitoring of data protection and security mechanisms. This proposal supports the partnership approach, which can be observed in the doctor-patient relationship and is emerging in the fields of clinical trials to promote trust-

building between body sample donors and researchers (Beyleveld 2006, 151, 156; Ezekiel et al. 2004, 932). The rationale of this approach is that in order for public interests to be further taken into consideration and safeguarded, and for the public to feel that their concerns matter, the public should not only be consulted, educated and informed about the project and its advances, but should also be included in the decision-making process, from the outset of the project (design) throughout its life-cycle. One acceptable avenue would be the constitution of a Committee or Advisory Group constituted of carefully selected representatives of the public that would be consulted prior to any decision being made (Deschenes & Sallee 2005, supra note 6, 42–43).

A partnership approach provides the public with an opportunity to have an influential role in setting up, managing, monitoring and shaping the direction of the research as well as the future use of research results and benefit-sharing. This kind of 'active citizenship' has been promoted by various government-led efforts over the past two decades to encourage community involvement in local decisions about local government and health (Tutton 2007, supra note 4, 177). However, in a recent study, it was suggested that certain strategies for patient participation in decision-making can hardly be regarded as effective because they do not ensure patients' structural influence on decision-making (Caron-Flinterman et al. 2007, 361). In addition, if the inclusion of the public in all steps of the design and approval process is now a recognized requirement, it remains a challenge to efficiently and meaningfully make them true partners in the decision-making process (Deschenes & Sallee 2005, supra note 6, 42–43). Some issues need to be dealt with before making the partnership approach a moral or legal obligation for the biomedical researchers to utilize. In order for success to be achieved, a new form of agreement among medical institutions, researchers, donors and the community, along with elaborate evaluation of and debates on the adequacy and feasibility of the research, not only among the policy-makers and scientists but also among social scholars and the lay public, are all necessary.

Conclusion

Building a relationship of trust is considered the foundation for success in the emergence of many large-scale databanks for genomics. To ensure that researchers and the lay public collaborate successfully as partners results in a win-win situation. Researchers must understand costs, benefits and risks associated with biobank projects, along with the concerns of potential participants. Researchers need to avoid unnecessary resistance from the public. Building a relationship of trust can assure the participation and support of the public if it can be proven that participants will not be exposed to unnecessary risks. Empowering the public to set up, manage, monitor and shape the direction of human biobank projects will gain public trust. Trust is the key to dispelling public fear of risk, and society can enjoy the benefits that human biobank research promises.

However, the partnership approach to research remains immature and needs further development. Being an introductory note, this paper aims to draw attention to debates on this topic so as to invite effective and efficient trust-building models upon which human biobank research can be founded.

Notes

1 This paper is part of the research result of the NSC project (NSC-96-3112-H-007-004).

2 Icelandic Health Sector Database, www.ministryofhealth.is/laws-and-regulations/nr/31, last visited 2007/11/30.

3 Gene Bank, www.opendemocracy.net/theme_9-genes/article_1250.jsp, last visited 2006/06/01.

4 National Project—Genome Database of the Latvian Population, http://bmc.biomed.lu.lv/gene/, last visited 2007/11/30.

5 The Singapore Tissue Network, http://www.stn.org.sg/, last visited 2007/11/30.

6 UK BioBank, www.ukbiobank.ac.uk/, last visited 2007/11/30.

7 KI Biobank, www.meb.ki.se/biobank/about.php, last visited 2007/11/30.

8 CARTaGENE, www.cartagene.qc.ca/accueil/index.asp, last visited 2007/ 11/30.

9 DNA Data Bank of Japan, www.ddbj.nig.ac.jp/, last visited 2007/11/30.

10 Generation Scotland, http://129.215.140.49/gs/gscience.html, last visited 2007/ 11/30.

11 Taiwan Biobank, www.twbiobank.org.tw/nsc/index.html, last visited 2007/ 11/30.

12 www.ukbiobank.ac.uk/docs/Furtherinfoleaflet0108.pdf.

13 Mylene Deschenes and Clementine Sallee (2005, 40, 51). The authors suggest that there are three critical areas in which accountability, transparency, and proper monitoring are critical: (1) project and protocol assessment process; (2) management of the overall research platform (including the database and biobank); and (3) data privacy protection.

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