

Postprint

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Consent to biobank research: facing up to the challenge of globalisation

Lipworth W, Kerridge I. (2015)

Abstract

There is broad agreement that open-ended consent to research involving banked specimens and associated data is morally justifiable. Importantly, this approach is justifiable if, and only if, clear mechanisms are in place for 1.ethical and scientific oversight, and 2. ongoing communication with tissue donors. The problem for those in favour of open-ended consent for research is that biobanks have the greatest potential as resources for translational research if they are *networked* - both nationally and internationally. And as networks, by definition, require that custodianship of samples be relinquished at some point, this makes it difficult, if not impossible, to guarantee sound ethical and scientific oversight and to promise ongoing communication with donors. Unless the reality of globalisation is addressed head on, even the most thoughtful ethical proposals, such as that put forward in this article, will soon be obsolete.

There is broad agreement among researchers, biobankers and ethicists that open-ended consent to research involving banked specimens and associated data provides the best means for optimising the enormous potential of biobanks. In a synthesis we conducted in 2011 of empirical sociological studies of biobanking, we found that while most people wanted to be asked, at least initially, about the use of their tissue in research, they generally did not want large amounts of information, and were willing to give open-ended consent (Lipworth, Forsyth, and Kerridge 2011)—a finding consistent with numerous other studies (Lipworth, Ankeny, and Kerridge 2006, Lipworth, Forsyth, and Kerridge 2011, Lipworth et al. 2009, Morrell et al. 2011) and with Grady *et al*, who concluded that that open-ended consent to biobanking research was consistent with community preferences.

Also like Grady et al., we concluded from our synthesis that open-ended consent is morally justifiable if, and only if, clear mechanisms are in place for 1.ethical and scientific oversight, and 2. ongoing communication with tissue donors. Specifically, we found a widespread expectation that general feedback and aggregated results would be provided in exchange for participation, and that all biobanks should have in place formal mechanisms—including institutional review committees and public

consultation—for controlling biobank resources (Lipworth, Forsyth, and Kerridge 2011).

While it is attractive in theory to promise ongoing ethical oversight and communication in exchange for participation and open-ended consent, the reality is that that it might no longer be possible to make such promises. This is because biobanks are increasingly *networked* - both nationally and internationally. This, in turn, makes it difficult, if not impossible, to guarantee sound ethical and scientific oversight of biobanks and to promise ongoing communication with donors. It could be argued that biobanks should simply not be networked so that these ethical conditions can be met, but global biobank networks have become a scientific necessity for certain kinds of research. For example, large numbers of samples are needed for longitudinal analyses of healthy populations (where numerous samples need to be analysed in order to identify relevant genetic variants); for the study of rare diseases; for the study of common but complex, multigenic disorders such as cancer and heart disease; for global multi-centre clinical trials that require testing of fresh tissue; and in cases where it is socio-culturally or practically difficult to obtain tissue—for example the collection of postmortem brain tissue. Pharmaceutical companies also need large networks of biobanks in order to meet the regulatory requirement that they study samples and data from populations of different ethnic origins in the course of their clinical trials. Furthermore, the development of biobank networks is important for economic and practical reasons, because single biobanks, particularly those maintained by single institutions, are rarely sustainable and are inefficient – duplicating the resources and activities of other similar biobanks (Catchpoole et al. 2007).

Given the scientific, economic and practical necessity of biobank networks, and their corresponding rapid growth, it is not sufficient, as Grady and colleagues do, to simply state that further research is needed to “assess the applicability of this proposal to international sample collection”. Instead of a simple caveat at the end of a policy report, what is needed is a systematic program of research and policymaking that addresses head-on the many technical, governance, legal and ethical challenges that arise when research is no longer constrained by institutional, academic, cultural or national boundaries.

Some of the technical, governance and legal challenges posed by the networking of bioabanks that will need to be addressed include: the funding of biobank networks; the technical standardization and quality control of tissue collection, storage and annotation; the institution of policies on intellectual property, and the sharing of specimens and data (Smith 2011). International networks of biobanks also rely upon some degree of regulatory harmonisation because restrictive national regulations prohibiting, or limiting, the import or export of human tissue samples, and lack of regulatory consistency across jurisdictions can be major barriers to the transfer of tissue across borders (Hoeyer 2012).

There are also a number of ethical concerns that will need to be addressed if global biobanking is to succeed. While many of these issues—including consent, commercialisation, privacy, treatment of tissue, return of results, community involvement, benefit sharing, or “ownership”—are also raised by individual

biobanks, each of these issues becomes exponentially more complex when research is globalised and tissues are shared across borders (Hoeyer 2012, Smith 2011).

Ultimately the major challenges that the globalization and networking of biobanks may raise is to community values such as trust, custodianship, benefit sharing, equity, respect for cultural difference and individual or community control over the use of their tissue and information. (Aparicio et al. 2013, Stewart et al. 2014). We know, for example, that trust and control are particular issues for indigenous communities around the world, who have concerns regarding the spiritual and cultural implications of donating human tissue, overstated promises made by researchers, the diversion of attention and resources away from addressing social determinants of health, and exploitation of communities who donate tissue but do not benefit from the results (Jacobs et al. 2010).

Given that scientific and therapeutic advances are increasingly dependent upon biobanks; and that the creation of international networks of biobanks is necessary to optimise their benefits; then it is essential that we:

1. Understand whether and how globalization and networking of biobanks challenge the values and principles upon which biobanks have been developed, and the processes and practices that have been established by successful 'local' biobanks; and
2. Establish new mechanisms to manage the ethical and legal challenges to the networking of biobanks.

Unless we understand and respond directly to the challenges raised by the globalization and networking of biobanks, there is a real possibility that biobank networks will be insufficiently cognizant of community values and fail to gain the trust needed for long-term viability.

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