

Editor's Note: Towards Best Practices for Biobanking

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I. INTRODUCTION

Last fall the Stanford Journal of Law, Science, & Policy was privileged to host a distinguished group of scientists, research administrators, and legal scholars for our fall symposium: Biobanking, Bioethics, and the Law.¹ We were fortunate to benefit not only from an exciting day-long symposium but also to be joined by most of the panelists for a workshop the following day in which we discussed proposals for the development of a set of best practices for biobanking.

In particular, we focused on the tension between the Office for Human Research Protections guidelines on what qualifies as research involving human subjects and our own understandings of what the informed consent process is designed to protect.² Although much biobanking research does not currently fall under the protections of the Common Rule,³ we attempted to describe best practices that are consistent with its protections. Participants noted the wide variation in practices across institutions and we discussed potential mechanisms for standardization of practices. What follows in this Note is a summary of the views expressed on a range of issues we discussed that we believe could be used as the basis for forming best practices. While this summary does not fully encapsulate the views of all participants, I do my best to express the consensus views that emerged from our two days of discussion.

¹ For a full agenda from the symposium, see the Symposia section of our website, <http://www.stanford.edu/group/sjlsj/cgi-bin/symposia/index.php> (last visited April 4, 2009).

² For OHRP guidance see Office of Human Research Protections, Policy Guidance, *available at* <http://www.hhs.gov/ohrp/policy/> (last visited Jan. 7, 2008) [hereinafter OHRP Policy Guidance].

³ 45 C.F.R. Pt. 46 (West 2009).

II. SUMMARY OF WORKSHOP FINDINGS AND BEST PRACTICE RECCOMENDATIONS

A. *Informed Consent*

Informed consent is a process that is designed to ensure that participants in research understand both the procedures they will be subjected to during a study and any risks or benefits that participation in the research offers.⁴ As biobanking expands, traditional modes of informed consent are increasingly challenged: at the time researchers collect samples for banking, they will not be able to predict all possible uses of the samples, and therefore cannot ask research participants to consent to them. Further, under OHRP's current definitions, informed consent procedures may not even apply to future research using biobanks.⁵ However, there is growing evidence that public trust is the most important aspect in continuing participation in biobanks, and therefore some sort of participant information and involvement in determining the nature of future research will be essential to the success of biobanks.⁶

To this end, informed consent in the context of biobanks needs to be viewed as an ongoing process rather than a one-time interaction between a researcher and a donor. One of the most popular models to ensure this kind of relationship is a trustee model, where a representative patient group has continued involvement in the management of research conducted with a biobank.⁷ As several articles in this issue reflect, the relationship between donors and biobanks is an evolving one that needs to be increasingly defined.⁸ However, it is clear that we need to adopt an alternative model of donor involvement that protects the freedom of the researcher, remains true to conventional ideas of informed consent, and allows for some level of patient involvement in future research decisions.

B. *Privacy*

Privacy issues are treated with varying levels of concern by different researchers. At one extreme, Church's consent form explicitly states that the privacy of donors is not protected, and the group believes they will still have plenty of donors because 90% of people are altruistic enough that they will still want to donate. However, researchers working with vulnerable populations note that privacy is still a deep concern. As the prevalence of genetic testing in society rises, we believe that privacy will increasingly become a concern of potential biobank donors.

The privacy issue is particularly thorny when applied to biobanks because secondary biobank research, which is not human subjects research, may not be subject to the oversight and protections of an Institutional Review Board (IRB). Workshop

⁴ NATIONAL BIOETHICS ADVISORY COMM'N, ETHICAL AND POLICY ISSUES IN RESEARCH INVOLVING HUMAN PARTICIPANTS iv (2001); Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J.L. MED. & ETHICS 15, 19 (2005).

⁵ See OHRP Policy Guidance, *supra* note 2.

⁶ David E. Winickoff, *Partnership in the U.K. Biobank: A Third Way for Genomic Property*, 35 J. L. MED. & ETHICS 440, 441 (2007).

⁷ See generally *id.*

⁸ See Christopher Haney et al., *The Perils of Taking Property Too Far*, 1 STAN. J.L. SCIENCE & POL'Y 46 (2009); Brenda Simon, *How to Get a Fair Share: IP Policies for Publicly Supported Biobanks*, 1 STAN. J.L. SCIENCE & POL'Y 65 (2009).

participants agreed that there is only so far that any biobank can go to protect privacy and the deeper question is what best practices should look like. To this end, we recommend that all biobanks obtain Certificates of Confidentiality to protect biobank information from discovery in legal proceedings. While a Certificate of Confidentiality from the NIH will not alleviate all aspects of the privacy concern,⁹ it can provide substantial protections from one of the most apparent risks associated with biobank donation.¹⁰

C. *Recontact and Sharing Results with Participants*

Workshop participants found the idea of patient recontact to share results to be particularly troubling. As a threshold matter, defining what a result is may be difficult. While all information that is gathered from the sample is data, is it a “result” if it is not of clinical utility? At the same time, biobank participant populations are increasingly eager to receive results from their participation in research. Therefore, researchers are in an increasingly difficult position. It is thus essential that researchers clearly define what they will consider to be results and properly manage patient expectations.

Further, should researchers give results back, they must determine how results are presented. Giving patients raw genetic data is unlikely to be useful to them, and in some cases may represent an increased harm to the patient if the “results” cause them undue worry even though they are not of clinical significance. To this end, there are a number of key steps that researchers must take. First, they should be explicit with patients that individual results will not be provided. Second, they should work with the group responsible for continuing patient involvement and their IRB to develop procedures to keep *all* participants informed of aggregate study results. Finally, when aggregate study results are released, researchers should have a protocol in place to direct participants to the proper resources to obtain “individual” results— for example, the general results letter may provide an explanation of clinical testing that is available.¹¹

D. *Withdrawal*

In light of the Eighth Circuit’s ruling in *Washington University v. Catalona*, there are now serious questions about what it means for a participant to have the right to withdrawal from participation in a biobanking study.¹² Furthermore, with NIH’s requirements that all data be shared with the larger Genome-Wide Association Study (GWAS), it is becoming the case that true withdrawal is likely to be impossible.¹³ However, this is not likely to be a large concern because in practice as workshop participants found that post-donation withdrawal rates are extremely low. Therefore, it

⁹ National Institutes of Health, Certificates of Confidentiality: Background Information, <http://grants.nih.gov/grants/policy/coc/background.htm> (last visited Apr. 4, 2009).

¹⁰ For a thorough discussion of this issue and larger concerns about biobanks and privacy, see Teneille Brown & Kelly Lowenberg, *Biobanks, Privacy, and the Subpoena Power*, 1 STAN. J.L. SCIENCE & POL’Y 80 (2009).

¹¹ For examples of the problems that may arise when clinical tests become available and are not shared with participants see Haney et al., *supra* note 8, at 50-55.

¹² 490 F.3d 667 (8th Cir. 2007).

¹³ National Institutes of Health, Policy for Sharing Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWS), 72 Fed. Reg. 49290, 49296 (Aug. 28, 2007) (stating that institutions and researchers may request removal of data from GWAS if a participant has withdrawn but removal will not be possible if the data have been distributed for approved research).

seems likely that traditional ideas about withdrawal from research cannot be applied to biobanks. Instead, IRBs must demand that careful explanations about the inability to withdraw be given to patients. Some limited withdrawal, in the form of refusing future linking of new medical records will always be available under HIPAA,¹⁴ and the contours of this right along with the potential risks that cannot be avoided because of the lack of an ability to fully withdraw should be carefully explained to donors.

E. *Data Sharing*

With the NIH's new data sharing policy under GWAS, it is becoming increasingly difficult for researchers to protect their research populations. There are a limited number of exceptions for groups like the Amish,¹⁵ but as biobanking expands, the ability of new groups to obtain these exceptions is unclear. Data sharing obligations therefore have the potential to change the biobanking landscape in a radical way.

As a result, we must consider whether we want to give researchers the right to withhold their data if such withholding is necessary to protect a vulnerable population. Such concerns will only increase as genetic sampling increases and we broaden our definition of biobanking. Elsewhere in this issue Elena Grigorenko and Susan Bouregy explore the issues related to collections of a single lab falling within the definition of a biobank.¹⁶ If these "biobanks" are forced to share their data through GWAS, there may be substantial concerns about the ability of researchers using vulnerable populations to protect their participants.

F. *Vulnerable Populations*

The concerns about vulnerable populations have been identified above. They primarily relate to issues of data sharing and privacy protection. Overall, the workshop participants felt that even vulnerable populations were only put at risk in the case where lawbreakers could be identified through the data contained in a biobank. This concern can be addressed through biobanking practice. If all biobanks obtain Certificates of Confidentiality, as described above, then the biobank that made the original collection will be protected from legal discovery. As long as the biobank only shares de-identified information, the risks to vulnerable populations should be eliminated. However, if a researcher seeks to share identifying information he should work closely with his IRB to ensure that this data sharing does not pose an unacceptable risk to the study participants.

G. *International Populations*

As Christina DeHayes explains, biobanks are increasingly seeking international collections to control for heterogeneity within their samples.¹⁷ However, international populations do not always have the same institutional protections associated with collection that are applied to research participants in the United States. To ensure

¹⁴ See 45 C.F.R. § 164.508 (West 2009) (establishing that under the HIPAA privacy rule, consent is required each time medical records are to be transmitted).

¹⁵ National Institutes of Health, Genome-Wide Association Studies: Frequently Asked Questions, No. B.7, http://grants.nih.gov/grants/gwas/GWAS_faq.htm#b7 (last visited Apr. 4, 2009).

¹⁶ See generally Elena L. Grigorenko & Susan Bouregy, *Biobanking on a Small Scale: Practical Considerations of Establishing a Single-Researcher Biobank*, 1 STAN. J.L. SCIENCE & POL'Y 32 (2009).

¹⁷ Christina DeHayes, *Managing Global Biospecimen and Data Collection & Placement Programs*, 1 STAN. J.L. SCIENCE & POL'Y 19, 19-20 (2009).

continued trust in biobanking, international donors should be accorded the same protections as domestic ones. While this is already covered in collection protocols run out of American Universities, to whom the Common Rule applies, should researchers increasingly rely upon samples that have already been collected elsewhere, they should assume a duty of due diligence to ensure that samples were collected under procedures that are substantially similar and employ informed consent procedures and privacy protections that are equivalent to those required for human subjects research in the United States.

III. CONCLUSION: EXPLORING SPECIFIC ISSUES RELATED TO BIOBANKING

The remainder of this issue contains articles on specific topics that were developed by conference participants in light of our discussions in the fall. Overall, these articles demonstrate the need for coherent national policy on biobanking,¹⁸ improved researcher evaluation of whether their personal collections are biobanks,¹⁹ ongoing relationships between donors and biobanks,²⁰ the need for sensitive management of intellectual property rights generated from biobank studies,²¹ and protection of donor privacy.²² Each of these articles explores specific contexts of biobanking, but the concerns they raise are broadly applicable.

Susan Stayn addresses the need for a national policy to address the biobanking of blastocysts.²³ Her Article explores how variations in state law create confusion as to the ability of donors to make interstate donations.²⁴ Also exploring the problems of variation in state law and expanding this discussion to an international scale, Christina DeHayes explores the challenges associated with global-scale collection programs.²⁵

Elena Grigorenko and Susan Bouregy address the fact that many individual research collections are now likely to be considered biobanks.²⁶ They explore the technical issues associated with establishing and managing a small biobank and provide suggestions for individual researchers who are collecting genetic samples.²⁷

Christopher Haney and coauthors and Brenda Simon address intellectual property aspects of biobanking and their potentially significant impacts on the relationships between biobanks and their donors. In *The Perils of Taking Property Too Far*, Haney and his coauthors draw upon case studies related to the development of genetic tests for Canavan's disease and BRCA to distill lessons on biobank operation and managing relationships with donors.²⁸ In *How to Get a Fair Share*, Brenda Simon explores how

¹⁸ See generally *id.*; Susan Stayn, *Biobanking of Blastocysts for Research to Improve Human Health: The Need for Coherent National Policy*, 1 STAN. J.L. SCIENCE & POL'Y 7 (2009).

¹⁹ See generally Grigorenko & Bouregy, *supra* note 16.

²⁰ See generally Haney et al., *supra* note 8; Simon, *supra* note 8.

²¹ *Id.*

²² See generally Brown & Lowenberg, *supra* note 10.

²³ See generally Stayn, *supra* note 18.

²⁴ *Id.*

²⁵ See generally DeHayes, *supra* note 17.

²⁶ See generally Grigorenko & Bouregy, *supra* note 16.

²⁷ See generally Grigorenko & Bouregy, *supra* note 16.

²⁸ See generally Haney et al., *supra* note 8.

intellectual property principles should be employed to both encourage innovation and protect the rights of donors.²⁹

Finally Teneille Brown and Kelly Lowenberg provide a thorough explanation of the application of the subpoena power to biobanks. In their Article, they provide a useful discussion of the potential limitations of the protections of Certificates of Confidentiality.³⁰

We hope that you find this issue to be a useful resource in thinking about many of the complex issues that surround the growth of biobanking in scientific research.

Margaret E. Peloso
Editor in Chief

²⁹ See generally Simon, *supra* note 8.

³⁰ See generally Brown & Lowenberg, *supra* note 10.