

Ethical Legal and Social Issues of Biobanking: Past, Present, and Future

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The past 15 years has seen considerable changes in the research environment. These changes include the development of new sophisticated genetic and genomic technologies, a proliferation of databases containing large amount of genotypic and phenotypic data, and wide-spread data sharing among many institutions, nationally and internationally. These changes have raised new questions regarding how best to protect the participants of biobanking research. In response to these questions, best practices for addressing the legal, ethical, and social issues of biobanking have been developed. In addition, new ethical guidelines related to biobanking have been established, as well as new regulations regarding privacy and human subject protections. Finally, changes in the science and the research environment have raised complex ethical issues related to biobanking, such as questions about the most appropriate consent models to use for biobanking research, commercial use and ownership issues, and whether and how to return individual research results to biobank participants. This article reviews some of the developments over the past 15 years related to the ELSI of biobanking with a look toward the future.

Keywords: biobanking, ethical, legal, and social issues, best practices, informed consent, regulations

Introduction

THE PAST 15 YEARS has seen dramatic changes in not only the research environment but also major changes in regulations and policies affecting biobanking. In addition, this period has seen a number of evolving ethical issues and significant shifts in ethical thinking about certain issues over this time. This perspective piece reviews some of the important regulatory and policy developments and evolving ethical issues over this time, with a particular focus on developments in the United States, and provides perspectives on important future issues in these areas. It is not intended to be a comprehensive review of all the ethical issues and regulatory and policy developments during this period.

Since 2002, we have seen major changes in the research environment, from most research being performed in individual researchers' laboratories to multi-institutional projects sometimes with multinational partners and extensive data sharing of often large amounts of data. Funding agencies are not only encouraging widespread data sharing but also in some cases generally requiring such sharing.¹ These changes, coupled with significant advances in powerful genomic and other technologies, have raised new ethical issues, resulting in significant regulatory and policy changes over this period. These include the development of best practices addressing the technical aspects as well as ethical

issues, as well as regulations and policies related to privacy, human subject protections, and genomic data sharing. Over this time period, there has been significant discussion around a number of complex issues related to biobanking, such as how to best obtain consent for future use of specimens, issues related to commercial use and ownership of tissue, and when and how to return individual research results to participants.

From Past to Present

Best practices

Over the past 15 years, the field has made significant strides in the development of best practices for biobanks. The International Society for Biological and Environmental Repositories (ISBER) led the way, with the publication of the first best practices for biobanks, "Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research"² in 2005. The second and third editions of the ISBER Best Practices were published in 2008³ and in 2012, respectively.⁴ These Best Practices are intended as an international document covering the full range of environmental and biological collections. They cover technical as well as ethical best practices for the collection, storage, distribution, and use of specimens in research.

In 2007, the U.S. National Cancer Institute released the NCI Best Practices for Biospecimen Resources (NCI Best Practices), with revised versions published in 2011 and 2016.⁵ This document covers the operational, technical, ethical, legal, and policy best practices for NCI-supported biospecimen resources. Unlike the ISBER Best Practices, however, the scope of the NCI Best Practices is limited to human specimen resource collections.

Other best practices guidelines were also published internationally over this time, including the Organization for Economic Cooperation and Development (OECD) Guidelines for Biological Resource Centers, published in 2007,⁶ and the OECD Guidelines for Human Biobanks and Human Genetic Databases, published in 2009.⁷

Although the ISBER, NCI, and OECD guidelines were developed to cover the full range of technical and ethical issues related to biobanks and cover similar elements, they vary in purpose, scope, and level of detail.⁸

Ethical guidelines

In 2006, to address the emerging ethical issues related to the use of human specimens in research, the Council of Europe adopted the Recommendation of the Committee of Ministers to Member States on Research on Biological Material of Human Origin in 2006 and then updated them in 2016.⁹ Among the provisions of the Recommendation are clear procedures for storing, accessing, using, and transferring specimens and independent oversight of each collection, as well as requirements for consent. Governance, guided by transparency and accountability, is an important theme of the revised recommendation.

The World Medical Association (WMA) also weighed in with guidelines for biobanks in 2016 by issuing the WMA Declaration of Taipei on Ethical Considerations regarding health databases and biobanks.¹⁰ This guideline only applies to identifiable specimens. Among the provisions of the declaration is a very narrow provision for waiver of consent for use of identifiable specimens, that is, only where there is a “clearly identified, serious, and immediate threat where anonymous data will not suffice.” Like the Council of Europe Recommendation, governance is an important theme, with a specific paragraph related to governance mechanisms based on transparency, engagement, and accountability.

Regulations

On the regulatory front, concerns about privacy in health records, as well as other privacy concerns, led to new privacy rules during the past 15 years, both in the United States and in Europe. In 2000, the U.S. Department of Health and Human Services (HHS) published the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, followed by modifications to the HIPAA Privacy Rule in 2002.¹¹ This rule provides privacy protections for the uses and disclosures of individually identifiable health information by health providers, health plans, and healthcare clearinghouses. Although the Privacy Rule does not apply to the use of human specimens *per se*, it may apply to the use and disclosure of private health information associated with the specimens. The Rule generally requires authorization from an individual for the use and disclosure of their individually identifiable health information, although there are

some exceptions if certain conditions have been met. A number of important modifications were made to the Privacy Rule in 2013 to decrease burdens on research.¹² These modifications include clarification that an authorization for future use of individually identifiable health information need not be study specific. Other changes include a general prohibition on the sale of “protected health information” without patient authorization, although reasonable compensation for the costs of processing the information is permissible.

In Europe, the European Union General Data Protection Regulation was adopted in 2016 to provide privacy protections for EU citizens and enable people to better control their personal data, including data used in research. It is also intended to provide more uniform protections across the EU member states.¹³ Although the regulation does not apply to specimens *per se*, it affects researchers’ ability to process data that may be associated with specimens or derived from specimens for scientific research.

In addition to privacy regulations, the past 15 years saw significant changes proposed to the existing U.S. Federal Policy for the Protection of Human Subjects (Common Rule)¹⁴ by the U.S. Department of HHS. These changes were proposed to provide additional protections in response to the dramatic changes in the research environment over this time, as well as to reduce regulatory burden, delay, and ambiguity for investigators.¹⁵ The rule changes were proposed in a series of steps in the regulation-making process prescribed by the Administrative Procedure Act, Pub. L. 79-4-4, 60 Stat. 237. This included the issuance of an Advanced Notice of Proposed Rulemaking (ANPRM) published in 2011¹⁶ followed by a 90-day public comment period. The ANPRM invited comment on a number of questions related to human specimen research, including whether specimens should in themselves be considered identifiable, whether consent should be required for research on all specimens, even those that have been deidentified, and whether a broad consent for future use of specimens should be considered acceptable.

After considering the more than 1100 comments received on the ANPRM, HHS proceeded to the next step of the regulatory process: the issuance of a Notice of Proposed Rulemaking (NPRM)¹⁷ in 2015, followed by a 120-day public comment period. Among the proposed provisions of the NPRM was a general requirement for consent for the use of any human specimen, whether deidentified or not, with a suggested broad consent template to be developed by HHS. In addition, the NPRM included a very narrow provision for an IRB-approved waiver of consent with waivers only expected to be used in rare circumstances. More than 2100 comments were received from the public, with significant opposition to most of the proposals related to human specimen research.¹⁸ In particular, great concern was expressed regarding the impact of the strict consent requirement on the use of archived specimens collected during the course of routine care.¹⁹

A Final Rule was recently published,²⁰ in which many of the previously proposed changes to the Common Rule regarding specimen research were not adopted. The Final Rule does not adopt the proposal in the NPRM to require that research involving nonidentified biospecimens be subject to the Rule, and it does not require that consent be obtained to conduct such research. In general, the Rule maintains the

current practice with respect to oversight of these specimens. In addition, the Final Rule does not include the very strict waiver criteria previously proposed under the NPRM. Under the new rule, researchers will now have the option of relying on broad consent for future research use of stored identifiable data or specimens as an alternative to seeking IRB approval to waive the consent requirement if certain conditions are met.²¹ For more information on these changes, please see the U.S. Department of HHS Office of Human Research Protections website.²²

Changes in science and evolving ethical issues

A number of changes in science and certain other events over the past 15 years have led to new ethical issues or have heightened the importance of existing issues related to the use of specimens and associated data in research.²³

The sequencing of the human genome in 2003 and the increasing use and power of genetic and genomic technologies, as well as widespread data sharing have led to increasing concerns during this time period about the identifiability of human specimens and genomic data and how best to protect participants of human specimen and data research.

Developments since that time have raised new concerns about the identifiability of previously deidentified data and specimens. For example, seminal articles were published demonstrating the ability to identify individual's single nucleotide polymorphisms profile in a mixture of DNA from 1000 individuals²⁴ and the ability to identify anonymous DNA donors in a genome project by matching their DNA sequences to publicly available databases.²⁵ These as well as other developments have raised new concerns about the identifiability of deidentified data and specimens. These concerns have led to key policy changes, for example, a change in NIH's data-sharing policy for whole genome association studies,²⁶ and were integral to the proposed changes to the Federal Policy for the Protection of Human Subjects discussed earlier.

In addition, a number of ethical issues related to human specimen research have been highlighted in the media, in both the United States and abroad. These include the Alder Hey organ scandal from 1988 to 1993, which led to the Human Tissue Act of 2004 and the establishment of the Human Tissue Authority in the United Kingdom.^{27,28} In the United States, a best-selling book published in 2010 concerning Henrietta Lacks,²⁹ the daughter of a poor African American tobacco farmer whose specimens were obtained without her knowledge and used to develop commercially available cell lines, brought much attention to issues related to informed consent and commercial use of specimens. Subsequent posting of the genomic sequence of Henrietta Lacks on a publicly available website without consent of the Lacks family led to its withdrawal.^{30,31} The Havasupai case in the United States drew additional attention to ethical issues related to human specimen research. In this case, specimens were obtained from Havasupai tribe members for the purposes of diabetes research. However the specimens were subsequently used for other research that the tribe found objectionable. This led to a lawsuit that was settled with a monetary payment and return of the specimens and associated data to the tribe.^{32,33}

A number of other court cases during this time in the United States focused on ownership of specimens. After the

Moore Case in 1990,³⁴ two additional cases, the Canavan³⁵ and Catalona^{36,37} cases, involved claims of private ownership of human specimens used in research. Like the Moore Case, in neither of these cases did the court rule that the research participants had any ownership rights to their specimens. It should be noted that these are case law and that there is currently no federal law in the United States addressing the ownership of human specimens.

Several other court cases in the United States led to the destruction of newborn bloodspots retained for research because parental consent had not been obtained. For example, in one lawsuit in Texas, ~5 million samples of newborn blood spots retained for research were destroyed because parental consent had not been obtained.³⁸

These cases underscore the importance of informed consent, transparency, and accountability in research as well as the need for governance and oversight mechanisms for future use of specimens. In addition, cultural issues and perspectives must be considered and respected in the collection, storage, distribution, and use of human specimens.

The changes in regulations and policies already discussed as well as publications in the literature^{39,40} suggest that the use of broad consent models may be acceptable in certain jurisdictions and under certain circumstances. This is likely because of the recognition of the importance of the secondary use of specimens, the limitations of specific consent models, and the logistical difficulties of tracking tiered consents and making decisions about what types of research fall within the scope of such consents.⁴⁰ More recently, dynamic consent models have been proposed that use technology to allow participants to decide whether they want to consent to broad consent or consent on a study-by-study basis.⁴¹⁻⁴³ These models show promise, and may be most useful for longitudinal studies and studies in which serial samples are needed or linked specimen types are obtained from patients at different time points.⁴⁴ In addition, they provide greater choice for research participants and a vehicle for ongoing communication, including access of participants to results from the research.⁴⁵ However, dynamic consent models may have certain limitations as has been noted by others,⁴⁶ such as limiting participation from some populations who may not have access to the necessary information technology or choose not to adopt it. In addition, they may be costly to implement. Additional data are needed regarding the feasibility and costs of using these novel consent approaches, particularly for certain types of studies. Further studies may be needed to determine whether participants will be sufficiently vested to maintain ongoing engagement for certain types of studies, and whether these models affect the representativeness of the study population and/or introduce any bias into individual studies.

Over the past 15 years, return of individual research results from biobanks has emerged as a topic of considerable discussion and debate. Although return of individual research results had been hotly debated in the literature for many years, return of such results from biobanks had received little attention until recently. In 2013, Wolf and her colleagues published a framework for the return of research results from biobanks that included a detailed discussion and 10 recommendations regarding the return of results from biobanks.⁴⁷ However, the practical implementation issues and costs of routinely returning research results from users of biobanks were subsequently noted.^{48,49} Various other

research and advisory groups have developed guidance and recommendations related to return of individual research results to biobank participants.^{50–52} Additional data are needed regarding the costs, feasibility, and challenges of returning individual research results to participants in various scenarios,⁵³ as well as participant responses. Obtaining such data will be possible now that some biobanks are beginning to gain practical experience with the return of individual research results to participants. This experience should help inform the development of additional, evidenced-based guidelines and best practices in this very complex area.

Looking to the Future

Looking to the future, additional dialogue and debate regarding unresolved ethical issues may become even more important. For example, we may need to rethink current concepts of identifiability as new and more sophisticated technologies continue to be developed and with the continued proliferation of databases containing genomic and other data unique to an individual. Indeed, in recognition of this, the Final Rule discussed earlier includes a provision that federal departments and agencies that implement the Final Rule re-examine the definition of “identifiable” within a year and then every 4 years thereafter in light of new scientific developments and technologies.²⁰

Clarifying what rights individuals have in their specimens may also be important. In a recent movement that some have termed the “biorights” movement, some patients and patient advocates are raising questions about their rights regarding their specimens. For example, some are calling for some form of direct benefit in exchange for their specimens, such as some form of financial compensation, demanding the return of individual research results, or more control over how their specimens are used in research.^{54,55} This “biorights” movement raises a number of questions including the following:

- What rights do/should individuals who provide their specimens for research have over their specimens, how they are used in research, and any profits from research discoveries made possible from them?
- How much control should/can individuals have regarding how their biological specimens will be used in research?
- What are the practical considerations and limitations regarding any such “biorights”?
- How should autonomy rights be best balanced with societal benefits that derive from the use of human specimens in research?

Moving forward, with more reliance on broad consent for future use of specimens, governance systems for biobanks that include mechanisms for ensuring that specimens and associated data are used appropriately will become increasingly important.

Finally, especially with the development of large cohorts like the Precision Medicine Initiative,⁵⁶ participant engagement and public education about biobanking will be critical. This includes what a biobank is and how they operate, why specimens are essential for research and development and for advances in medical care and how the interests of research participants are protected. Participant and public education around complex issues such as the commercial use of specimens, benefit sharing, and return of individual research results will also be important.

Moving forward, the ISBER,⁵⁷ through its Science Policy Committee,⁵⁸ will continue to follow regulatory and policy developments related to biobanking and provide input as appropriate to shape regulations and policies in a way that facilitates research while at the same time protecting research participants. In recognition of the importance of public education about biobanking, ISBER will be launching some initiatives on this topic as part of its newly released Strategic Plan.⁵⁹ The Society welcomes input and involvement from the biobanking community in these activities.

Author’s Disclaimer

The content and viewpoints expressed herein are solely those of the author and do not represent official legal interpretation or policy advice.

Author Disclosure Statement

No conflicting financial interests exist.

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