

THE JOURNAL OF
LAW, MEDICINE & ETHICS
C O N T E N T S

VOLUME 43:4 • WINTER 2015

Symposium Articles

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INTRODUCTION

*Mark A. Rothstein and
Bartha Maria Knoppers*

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**Biobanks, Data Sharing, and the
Drive for a Global Privacy Governance
Framework**

Edward S. Dove

Biobanks are a key emerging biomedical research infrastructure. They manifest the turn towards greater global sharing of genomic and health-related data, which is considered by many to be an ethical and scientific imperative. Our collective interests lie in improving the health and welfare of individuals, communities, and populations; improving health and welfare requires access to, and use of, widely dispersed quality data. But sharing these individual and familial data requires in turn that due thought be given to the ethical and legal interests at stake. Most critically, data sharing must occur in an environment whereby privacy interests are safeguarded throughout the lifecycle of biobank initiatives, and regardless of the locations where the data are stored, to which they are sent, and where they are ultimately processed. In this article, I outline the complex dimensions of data privacy regulation that challenge data sharing within the biobanking context. I discuss how harmonization may be a remedy for the gaps and marked differences of approach in data privacy regulation. Finally, I encourage the development of foundational responsible data sharing principles set within an overarching governance framework that provides assurance that reasonable expectations of privacy will be met.

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**International Guidelines for Privacy
in Genomic Biobanking (or the
Unexpected Virtue of Pluralism)**

Adrian Thorogood and Ma'n H. Zawati

This article reviews international privacy norms governing human genomic biobanks and databases, and how they address issues related to consent, secondary use, de-identification, access, security, and governance. A range of international instruments were identified, varying in substance — e.g., human rights, data protection, research ethics, biobanks, and genetics — and legal character. Some norms detail processes for broad consent, namely, that even where potential participants cannot consent to specific users and uses, they should be given clear information on access policies, procedures, and governance structures. Some also give guidance about the conditions under which secondary use of data and samples without consent is appropriate, e.g., where consent is impractical.

ble. International norms exhibit a confusing range of terminology relating to de-identification. They also continue to rely heavily on consent and anonymity as the basis for privacy protection, though governance is becoming more prominent. It may not be fatal that such a plurality of norms apply to biobanking; what is essential is that governance be built on shared values, our common interest in the success of genomic research, and practical tools that incentivize responsible, global sharing.

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**Biobanking and Privacy Laws in
Australia**

Don Chalmers

Australian biobanks are largely autonomous and funded by local health care institutions, although some biobanks also receive funding from the National Health and Medical Research Council (NHMRC). There is no formal biobank legislation, but the NHMRC has developed biobanking guidelines. The regulation of biobanks is mainly through privacy laws and human research ethics committees. Australia is moving toward the use of broad consent for biobanking. International data sharing is permitted.

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Biobanking and Privacy Law in Brazil

*Sueli Gandolfi Dallari, Felipe Angel
Bocchi Castellaro, and Iara Coelho Zito
Guerrero*

This article analyzes the current regulatory framework for biobanking, genomic research, and protection of privacy in Brazil. It is divided in four parts. The first describes the biobanking context in Brazil and its evolution in recent years. In the second, the entire regulatory framework on biobanking and genomic research is analyzed. The third part focuses on the critical evaluation of this regulatory framework, specifically on some major ethical dilemmas in biobanking. The fourth part describes the characteristics of the Brazilian biobanking and human research governance system, known as the CEP/CONEP system. Finally, the conclusion summarizes the information in the article and its contribution to the study of the biobanking ethical challenges, especially the protection of privacy. It is highlighted that biobanking regulatory harmonization among countries is necessary, since it increases scientific possibilities that can come from broader cooperation among biobanks and several research centers on the national and international levels.

SYMPOSIUM

**Harmonizing
Privacy Laws
to Enable
International
Biobank
Research:
Part I**

Guest Edited by
Mark A. Rothstein
and Bartha Maria
Knoppers

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*Letter from
the Editor*

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**Privacy and Biobanking in China:
A Case of Policy in Transition**

*Haidan Chen, Benny Chan, and
Yann Joly*

Disease-based biobanks have operated in hospitals and research institutes in China for decades, and China has recently embarked on a plan to establish further biobank networks with the aim of promoting data sharing among the existing biobanks. Although the Chinese Constitution has only recently begun to recognize individual privacy as a distinct and independent constitutional right, biobanking in China has been loosely regulated under a patchwork of sometimes overlapping laws (such as the Interim Measures for the Administration of Human Genetic Resources) and regulatory instruments, as well as the policies of individual biobanks and networks of biobanks (such as the Shanghai Biobank Network Guidelines). A Draft Ordinance on Human Genetics Resources is currently being developed that will deal in more detail than previous laws with issues such as management measures, legal liability, and punishment for violations. International data sharing will be tightly regulated under this new law, and individual biobanks' policies such as the Shanghai Guidelines may choose to regulate such sharing even more. In contrast with national regulatory instruments, the Shanghai Guidelines also contain detailed de-identification policies, and explicitly endorse broad consent.

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**Genomic Databases and Biobanks in
Denmark**

Mette Hartlev

Biobanking in Denmark is regulated via patients' rights laws, data protection laws, and research ethics reviews. Danish law recognizes tissue samples as personal data for purposes of the data protection laws, meaning research with tissue samples may be subject to research ethics review, data protection laws, and patients' rights requirements depending on the circumstances of collection. However, research on information gained through whole genome sequencing is subject only to data protection laws, despite the similarity in the nature of the information. The regulatory framework treats biobank samples collected from patients differently than samples collected from research participants, particularly with respect to autonomy. Importantly, biobanks established for future unspecified research are not subject to research ethics review. Biobank-based research has gained more prominence on the national level recently, and the potential for a less fragmented and more consistent regulatory approach may emerge from this attention.

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Regulation of Biobanks in France

Emmanuelle Rial-Sebbag and Anna Pigeon

The privacy of biobank research participants in France is protected by a combination of bioethics laws, research laws, and data protection laws. Although the law has attempted to facilitate research by creating an opt-out regime for research with pre-existing samples, other aspects of the law hinder research. The requirement for multiple consents throughout the process of biobank sample collection and use, the lack of acceptance of a broad consent for biobanking, and genetic exceptionalism in the law all complicate biobank research.

With IRB approval, opt-out consent may be used for genetic research using human tissue collected for other purposes, but express consent is still required for research with the associated genetic data. Among the important issues remaining to be addressed are harmonizing and simplifying the various informed consent processes.

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**Genomic Databases and Biobanks in
Israel**

Gil Siegal

Large-scale biobanks represents an important scientific and medical as well as a commercial opportunity. However, realizing these and other prospects requires social, legal, and regulatory conducive climate, as well as a capable scientific community and adequate infrastructure. Israel has been grappling with the appropriate approach to establishing such a repository, and debates over the governance, structure, finance, and mode of operation shed a bright light on the underlying social norms, civic engagement and scientific clout in steering a governmental response to pressing medical needs. The article presents the backdrop of the Israeli scene, and explores the reasons and forces at work behind the current formulation of the Israeli National Biobank, MIDGAM.

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**Biobank/Genomic Research in Nigeria:
Examining Relevant Privacy and
Confidentiality Frameworks**

Obiajulu Nnamuchi

Nigeria's commitment to genomic research and biobanking is beyond dispute. Proof, if there is need for one, is that the country is one of only six nations (others are Canada, China, Japan, the United Kingdom, and the United States) involved in the International HapMap Project. The HapMap Project is an innovative enterprise aimed at developing a haplotype map of the human genome, a tool that is helpful to studying the genetic basis of disease as well as the genetic or hereditary factors that contribute to variation in response to environmental factors, in susceptibility to infection, and in the effectiveness of, and adverse responses to, drugs and vaccines. In addition, the country is home to H3Africa biobank (with 45,358 human samples in storage), affiliated with the Institute of Human Virology of Nigeria (IHVN), and several others. Benefits accruing from genomic research and biobanking are enormous; so also is protection of research subjects. The protection envisaged centers primarily on, inter alia, securing informed consent, safeguarding privacy and maintaining confidentiality of health information — all of which are enshrined in ethicolegal regimes in Nigeria. But whether these frameworks are consistent with international best practices is not at all clear, hence the need for this paper.

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Regulation of Biobanks in South Africa

Pamela Andanda and Sandra Govender

The availability of biological samples and data is critical for the establishment of biobanks for health research purposes. Such availability should be ensured in accordance with relevant national legislation and ethical principles. In this article, we consider the extent to which the current legal and ethical regulatory frameworks in South Africa are capable of governing the use of stored biological samples in a manner that facil-

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itates health research while at the same time protecting the interests of sample donors. These two attributes are essential for establishing biobanks in the country. Our evaluation of the frameworks is based on desk review of the current literature with a special focus on oversight mechanisms in place that ensure compliance with national legislation and ethical review processes to facilitate future and secondary uses of data, the extent to which informed consent policies foster sharing of research samples, data and protocols as well as mechanisms for safeguarding confidentiality. We established that there is an urgent need to streamline South Africa's legal and ethical frameworks because they are currently ambiguous and disjointed. There is equally a need to bring the frameworks in line with the current developments at the national and international levels.

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Spanish Regulation of Biobanks
Pilar Nicolás

The Spanish legal framework for the processing of samples and data with biomedical research purposes has sought to encourage scientific research, protect the right to freedom of research, and guarantee the interests of donors. The pillars of this legal framework are firstly, the duty to inform the donor in order to ensure that he or she is aware of the importance and the consequences of the donation; secondly, the control by ethics committees (RECs and External Ethics Committees of biobanks); and third, the supplementary application of the general rules on data protection.

There are three different possibilities for processing samples (project, collection, and biobanks) — each one reinforcing specific consent or requiring other added guarantees. This system, which is applied consistently in the entire national territory, is producing very satisfactory results. However, there are some issues that need further policies or legal development, as the specific conditions and procedures for the international transfer of samples and data with research purposes.

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Taiwan Regulation of Biobanks
*Chien-Te Fan, Tzu-Hsun Hung, and
Chan-Kun Yeh*

This paper introduces legal framework and governance structure in relation to the management and development of biobanks in Taiwan. At first, we briefly describe Taiwan's population, political system and health care system. Secondly, this research introduces biobanking framework of Taiwan including 25 biobanks established with the approval of the Ministry of Health and Welfare. In those biobanks, "Taiwan Biobank" is the first and the largest government-supported biobank which comprises population-based cohort study and disease-oriented study. Since the collection of information, data, and biological specimen of biobanks often involve highly sensitive personal information, in the legal framework of Taiwan, there is a specific regulation, "Human Biobank Management Act" (HBMA), which plays an important role in regulating biobanks in Taiwan. HBMA, the Personal Information Act and other regulations constitute a comprehensive legal and regulatory privacy framework of biobanks. Through the introduction and analysis of the current legal framework applicable to biobanks, we found that there are several challenges that need to be solved appropriately that involve duplicate review systems, the obstacles in the international collaboration, and data sharing between biobanks in Taiwan.

Independent Articles

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**Automatic Placement of Genomic
Research Results in Medical Records:
Do Researchers Have a Duty? Should
Participants Have a Choice?**

*Anya E.R. Prince, John M. Conley,
Arlene M. Davis, Gabriel Lázaro-Muñoz,
and R. Jean Cadigan*

In genomics research, it is becoming common practice to return individualized primary and incidental findings to participants and several ongoing major studies have begun to automatically transfer these results to a participant's clinical medical record. This paper explores who should decide whether to place genomic research findings into a clinical medical record. Should participants make this decision, or does a researcher's duty to place this information in a medical record override the participant's autonomy? We argue that there are no clear ethical, legal, professional, or regulatory duties that mandate placement without the consent of the participant. We conclude that informing participants of results, together with a clear explanation, relevant recommendations and referral sources, and the option to consent to placement in the medical records will best discharge researchers' ethical and legal duties towards participants.

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**Conflict Resolution in the Clinical
Setting: A Story Beyond Bioethics
Mediation**

Haavi Morreim

Because ethics consults are often more about conflict than moral puzzlement, the skills of conflict resolution and communication facilitation are now deemed a core competency for ethics consultants. Those skills range beyond the traditional ambit of "bioethics mediation," as illustrated here by a recent mediation regarding a difficult discharge. As conflict permeates healthcare, often spawning downstream ethical issues, conflict resolution services might be deemed a genre of preventive ethics suitably offered by ethics committees. If so, a strong distinction must be made. "Bioethics mediation" as historically defined is a curious amalgam between a consultant who recommends, and a mediator who facilitates consensus among the parties at the table. On closer examination this approach is problematic, particularly in the clinical setting. A mediator who acts as consultant, telling parties what they should do or directly circumscribing the limits of an "acceptable" decision, quickly becomes just another pair of fists in the fight. At that point the odds for reaching genuine agreement, as opposed to a transient acquiescence, diminish markedly. Accordingly, those who undertake conflict resolution in the clinical setting need to distinguish quite sharply between facilitative mediation, versus a consultant's role.

Symposium articles are solicited by the guest editor for the purposes of creating a comprehensive and definitive collection of articles on a topic relevant to the study of law, medicine and ethics. Each article is peer reviewed.

Independent articles are essays unrelated to the symposium topic, and can cover a wide variety of subjects within the larger medical and legal ethics fields. These articles are peer reviewed.

Columns are written or edited by leaders in their fields and appear in each issue of *JLME*.

Next Issue:

Harmonizing Privacy Laws to Enable International Biobank Research: Part II

A Symposium Guest Edited by Mark A. Rothstein and Bartha Maria Knoppers

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An Ethical and Legal Framework for Physicians as Surrogate Decision-Makers for Their Patients

Philip M. Rosoff and Kelly M. Leong

In Western industrialized countries, it is well established that legally competent individuals may choose a surrogate health-care decision-maker to represent their interests should they lose the capacity to do so themselves. There are few limitations on who they may select to fulfill this function. However, many jurisdictions place restrictions on or prohibit the patient's attending physician or other provider involved with an individual's care to serve in this role. Several authors have previously suggested that respect for the autonomy of patients requires that there be few (if any) constraints on whomever they may appoint as a proxy. In this essay we revisit this topic by first providing a survey of current state laws governing this activity. We then analyze the clinical and ethical circumstances in which potential difficulties could arise. We take a more nuanced and circumspect view of prior suggestions that patients should have virtually unfettered liberty to choose their healthcare proxies. We suggest a strategy to balance the freedom of patients' right to choose their surrogates with fiduciary duty of the state as regulator of medical practice. We identify six domains of possible concern with such relationships and suggest straightforward methods of mitigating their potential negative effects that could be plausibly be incorporated into physician practice.

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Regulating Tobacco Product Advertising and Promotions in the Retail Environment: A Roadmap for States and Localities

Tamara Lange, Michael Hoefges, and Kurt M. Ribisl

Recent amendments to federal law and a burgeoning body of research have intensified public health officials' interest in reducing youth initiation of tobacco use, including by regulating the time, place, or manner of tobacco product advertising at the point of sale. This article analyzes legal obstacles to various strategies for reducing youth initiation.

Columns

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CURRENTS IN CONTEMPORARY BIOETHICS

Citizen Science on Your Smartphone: An ELSI Research Agenda

Mark A. Rothstein, John T. Wilbanks, and Kyle B. Brothers

The prospect of newly-emerging, technology-enabled, unregulated citizen science health research poses a substantial challenge for traditional research ethics. Unquestionably, a significant amount of research ethics study is needed to prepare for the inevitable, widespread introduction of citizen science health research. Using the case study of mobile health (mHealth) research, this article provides an ethical, legal, and social implications (ELSI) research agenda for citizen science health research conducted outside conventional research institutions. The issues for detailed analysis include the role of IRBs, recruitment, inclusion and exclusion criteria, informed consent, confidentiality and security, vulnerable participants, incidental findings, and publication and data sharing.

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**PUBLIC HEALTH AND THE LAW
Legal Innovations to Advance a Culture of Health**

James G. Hodge, Jr., Kim Weidenaar, Andy Baker-White, Leila Barraza, Brittney Crock Bauerly, Alicia Corbett, Corey Davis, Leslie T. Frey, Megan M. Griest, Colleen Healy, Jill Krueger, Kerri McGowan Lowrey, and William Tilburg

As conceptualized by the Robert Wood Johnson Foundation and its partners, a culture of health centers on a society in which health flourishes across all populations and sectors. Law, among other tools, is critical to advancing a culture of health across multiple arenas. In this manuscript, Network for Public Health Law colleagues illustrate how legal innovations at all levels of government contribute to societal health. Examples include modern laws that promote healthy and safe low-income housing, telemedicine reimbursement, paid sick and safe time, healthy food and beverages, reduced smoking rates, child vaccinations, universal pre-k, adolescents' healthy sleep, overdose prevention, and medical-legal partnerships.

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Calendar