Biobanks, data sharing, and the drive for a global privacy governance framework.

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Abstract:

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.

Full Text:

I. Introduction

Spurred by a confluence of factors, most notably the decreasing cost of high-throughput technologies and advances in information technologies, a number of population research initiatives have emerged in recent years. These include large-scale, internationally collaborative genomic projects (Table l) (1) and biobanks (Table 2), the latter of which can be defined as an organized collection of human biological material and associated data stored for one or more research purposes. (2) Biobanks are a key emerging research infrastructure, and those established as prospective research resources comprising biospecimens and data from many participants are viewed as particularly promising drivers of biomedical progress. Such biobanks, particularly those publicly funded and set up to promote the public interest, have expanded across the globe in recent years. (3)

Biobanks enable large-scale genomic (and other -omic) analyses as well as the validation of findings through samples of large cohorts, thereby promoting translational science and precision medicine. (4) Biobanks also advance genomic research in various other ways for the betterment of

society, including facilitating continuous collection and linking of data over extended periods of time, which maximizes the value of existing resources and realizes the potential to engage in "deep phenotyping" of various medical conditions. (5) Indeed, numerous studies have demonstrated the public good value of biobanking in contributing to research findings on gene-environment interactions and subpopulation susceptibility to diseases. (6)

Biobanks do not operate in an ethical or regulatory void. Coupled with the emergence of these research infrastructures and consortia are international regulatory or ethical instruments that promote the networking and global sharing of resources and encourage good research practices, including the protection of research participants' personal data (Table 3). These international instruments have developed alongside regional or national instruments that take the form of laws, regulations, policies, best practice exemplars, and guidelines.

The normative, hortatory force of these instruments is demonstrable: a survey from 2011 indicated, for instance, that more than 50% of biobanks in Europe engage in regular international data and sample sharing, (7) reinforcing the Council of Europe's observation of "increasing cross border flow of biological materials of human origin and data." (8) One would expect this percentage to have increased in the years since the survey was conducted. Indeed, no one biobank can answer the entire array of challenging and expanding research questions that have direct impact on healthcare. Only by linking data from various resources can researchers begin to develop meaningful answers. (9) International organizations dedicated to accelerating the sharing of genomic and health-related data, such as the Global Alliance for Genomics and Health, have emerged to assist in fostering and operationalizing these data sharing norms in a technically interoperable manner and in a way that promotes best practice. (10) These are positive developments and an ongoing manifestation of successful international collaboration by researchers, of which many examples already exist in the relatively short history of genomics.

The Human Genome Project (1990-2003), for example, comprised an international consortium of researchers. The collective work revealed more than 99% of the complex structure of the human genome through the successful sequencing and publication of its complete sequence. (11) This allowed for more accurate inferences of gene structure and detection of polymorphisms and mutations across the genome of various species, and critically, led to the dramatic fall in the cost of gene sequencing. (12) It also enabled the emergence of a growing genome-based industry with several hundred firms involved in mapping and sequencing, the development of new technology and the commercialization of genomics products, (13) and the fostering of new research applications in cross-cutting areas such as systems biology and neuropsychiatry. (14)

Similarly, the International Cancer Genome Consortium (ICGC), launched in 2008, has developed one of the world's most comprehensive database and catalogs of genomic abnormalities and tumor datasets (more than 50 different cancer types and subtypes). (15) Receiving commitments from funding organizations in Asia, Australia, Europe, the Middle East, North America, and South America to develop 78 project teams in 17 jurisdictions, ICGC has studied over 25,000 cancer tumor genomes to date. (16) The ICGC database, which comprises both open and controlled access phenotypic, germline, and somatic mutation data, has already advanced research and potential clinical applications. For example, the germline variants identified by the ICGC have allowed for the discovery of genes predisposing to familial malignancies, such as PALB2 and breast and pancreatic cancer; also, its small molecule libraries will have a major role in refining potential therapeutic candidates for further study. (17) Moreover, the ICGC developed an international framework for large, multi-centered genomic studies, (18) which facilitates the transfer of new technologies and enables the integration and sharing of research results among researchers around the globe.

Both the Human Genome Project and ICGC suggest that multiple benefits can accrue from widely sharing genomic and health-related data. Our collective interests lie in improving the health and welfare of individuals, communities, and populations, and improving health and welfare requires access to, and use of, widely dispersed quality data. (19) The multiple benefits of, and reasons for, cross-border sharing are well known by now.

Among others, they include: increased statistical power through data aggregation and linkage; reduced costs through reduction in duplicative research; optimal utilization and effective validation, comparison, replication, and refinement; compliance with data sharing requirements by many funding organizations; and transparency obligations imposed in many guidelines and regulations. (20) Understanding genetic risk factors for diseases like cancer and rare diseases requires statistical power of thousands, if not millions, of genomes and associated health-related data markers to separate "the signal from the noise." Validation requires analyses of large numbers of familial cases and controls, ideally from multiple populations. (21) From the perspective of some participant and family needs (particularly the rare disease and autism communities), international collaboration is not merely a wish--it is a requirement. (22) Unduly restricting data sharing across national borders or the matching of biospecimens with medical registries and patient records limits the possibility of validating biological findings in larger cohorts. The results are less powerful scientific results, diminished medical breakthroughs, and lack of tangible improvements in healthcare. (23)

But sharing personally identifiable individual and familial data requires that due thought be given to the ethical and legal interests at stake. To share genomic and health-related data globally, efficiently, and responsibly requires frameworks and tools that facilitate secure sharing, respect the rights and interests of those whose data have been contributed, and support the harmonization of international consortia and biobank projects across national boundaries, as recognized by the bioethical, (24) scientific, (25) and political (26) communities. Most critically, data sharing must occur in an environment whereby the privacy interests of research participants are safeguarded throughout the lifecycle of a biobank initiative, and regardless of the location where the data are processed. (27) Such safeguards can best be instituted where there is a global governance framework that provides substantially universally acceptable assurance that reasonable expectations of privacy will be met, and mutual recognition of the privacy norms in relation to the contemplated uses of data (and biospecimens). (28)

II. Regulating Biobanks and Privacy

While there is a range of overlapping interests at stake, a rich or thick conception of privacy as a foundational value in play can help us to capture the multiple considerations and help us to understand what needs to be addressed. The right to privacy has long been recognized in most societies and is now enshrined in bioethics and international regulatory instruments. (29) Constitutional provisions, laws, regulations, and ethical texts around the world demonstrate the importance of the right to privacy or to respect for private life (30) (and in Europe, for example, an explicit fundamental "right to the protection of personal data"), (31) as well as the duty of confidentiality in certain professional relationships, undertakings, and contracts.

Graeme Laurie and colleagues observe that privacy interests and concerns in biobanking can be placed in four interrelated dimensions: (l) physical privacy (e.g., gathering and storing biospecimens and testing them without consent); (2) informational privacy (e.g., possible misuse of information); (3) decisional privacy (e.g., control or influence over what is done with data and biospecimens); and (4) proprietary privacy (e.g., ownership of biospecimens and the control of identity as it relates to one's genes). (32)

By protecting and promoting privacy in biobanks, risks of privacy breach and data misuse are mitigated. But data misuse and the abuse of privacy (and trust) may still occur. Harms associated with privacy breach can include group discrimination following a scientific publication containing group associations (e.g., cancer and Ashkenazi Jews), (33) individual insurance or employment discrimination, (34) and reusing DNA collected for research for criminal profiling. (35) These are real risks, but with thankfully low incidence, (36) and legal protection has been enacted (or is planned to be enacted) in certain jurisdictions to further lessen the risk and mitigate any harms that may occur from data misuse and abuse of privacy. (37) The fact that the risk remains, though, raises the all-important question: How can we achieve both effective privacy protection and research promotion and scientific advancement in global biobanking? An initial response is that we should assess the extent of the privacy rights

or interests of biobank participants in various jurisdictions--recognizing that privacy is rarely, if ever, in law or ethics an absolute--while also recognizing the (global) public interest in realizing the biomedical benefits arising from these research endeavors. (38) Indeed, most legal systems recognize that privacy must yield in certain circumstances, or that the level of protection might be calibrated relative to other social values and interests. What follows is only a brief assessment of the extent of the privacy rights or interests of biobank participants, focusing on the decisional and informational privacy dimensions.

In biobanks, obligations related to confidentiality and privacy require researchers and healthcare professionals to protect the genomic and health-related data of participants (as well as, it should be mentioned, their biospecimens). This may be accomplished in one of several ways, but often is achieved by data stewards or custodians (39) within a biobank either (l) seeking the explicit (although not necessarily specific) consent of participants to share their data with other researchers, (2) replacing personal identifiers in a dataset with at least one code (also known as reversible de-identification or key-coding), or (3) anonymizing a dataset (i.e., permanently removing direct identifiers, hence the synonymous term irreversible de-identification) before making it available to other researchers. (40) Laurie and colleagues note that "[e]ach [method] has value in the protection of privacy interests but also inherent limitations." (41)

As the literature has discussed for many years, consent, at least as traditionally conceived in its "specific" form, is challenged in the biobanking environment. (42) For those biobanks that are set up as future-oriented research infrastructures, it is not readily possible to disclose to a participant at the initial stage the entire range of researchers and research projects that will make use of the data and biospecimens over the life of the biobank--and potentially beyond, especially if data are moved to another database. Reliance on specific consent in this biobanking context falls into a fallacy of sufficiency: no participant can be sufficiently informed at the initial stage about the range of unknown actors and uncertain events to follow, and therefore to set up specific consent as the requisite criterion for participation means that most biobank initiatives will lack a sufficient ethical or legal basis on which to recruit and operate the resource. (Dynamic consent, an interesting proposal that seeks to continually communicate with participants and allow for individually tailored control, may be possible for some biobanks but is a demanding form of consent heavily reliant on resources and may not be suitable for data that are used for many purposes.) (43)

Further, consent, whether specific or broad, (44) is typically an all-or-nothing affair; it is hardly a locus of privacy control--and wrongly or rightly, many associate privacy with control. Potential participants tend to have two main choices when consenting: they can participate or not--and if they do, they can later withdraw (albeit to a varying extent.) (45) The space for negotiation over the terms of data access and use is virtually non-existent, an important issue for those who view privacy as a necessary dimension of autonomy. Lastly, it bears emphasizing that consent does not fully address privacy concerns, as obtaining participants' consent to share their data does not absolve data stewards (or custodians) and data users from their legal obligations to use data fairly and lawfully.

Anonymizing or coding genomic or other personal data in a biobank, ostensibly to protect privacy interests, carries implications for the equally important value of autonomy. Many individuals are deeply concerned about the future research use of their data (not to mention biospecimens), even if they are no longer directly traceable to themselves. (46) Yet anonymization (as distinct from coding) can have a negative impact on both research and participants. Anonymization, which is not completely possible with genomic data, (47) can limit research participants' ability to control (what was once) their data; among other things, it can prevent participants from withdrawing from research projects. It also prevents researchers from linking genomic data with an individual's clinical data or other data sources (e.g., administrative data), and from returning individual results to participants. (48) Thus, beyond the limits to effective data anonymization, especially genomic data, there are clear limits to its benefits as well.

At the same time, it is also critical to note that the exponential growth of open access genomic databases and global sharing of data has been accompanied by the realization that there are significant privacy implications raised by unrestricted or minimally restricted sharing, especially when genomic data are linked with clinical data. (49) Indeed, as the sheer size of genomic databases, either standalone or as part of biobanks, has grown exponentially (it is now common to share "terabytes" of data in datasets that may be "petabytes" in size) (50) and the nature of genomic data is becoming ever-more personally revealing, penetrating technical and socio-ethical questions are raised about security and current conceptions and social norms of privacy. (51) Numerous studies released over the past ten years have shown how sophisticated data re-identification techniques compel ongoing re-assessment of existing privacy standards and information technology (IT) security safeguards. (52) As more data are collected from large cohorts, and as more data are linked and shared across jurisdictions, the risk of re-identification and privacy loss multiplies. It is therefore unsurprising that many people express concerns about privacy protection in the context of biobanks, (53) and that a majority of pharmaceutical companies perceive a higher risk of loss of privacy associated with DNA sampling. (54) Both public and private interests recognize the legitimate privacy concerns of biobanking, just as they recognize the legitimate need to share data to advance research and care.

What these technical studies have shown over the last decade is that de-identification (coding or anonymization) of personal data alone, especially genomic data, does not necessarily offer sufficient means of privacy protection. (55) Adding more sophisticated coding methods may hinder productive research and create a false sense of security if institutional review boards (IRBs) and research ethics committees (RECs), as well as research participants, interpret them to be fail-safe. (56) Once genomic data are shared with other researchers and linked with other datasets, it is virtually impossible to retrieve them or to make them private again. Nor may it be possible, even with signed data sharing agreements and security mechanisms, to know who has access to the data or to what uses they are being put. (57)

Might other technology platforms offer a solution? There is increasing discussion of using cloud computing for genomic research, whereby access to genomic data and the nature of the access can be logged and reviewed to prevent data abuse and privacy breaches. (58) Genomic cloud computing is unquestionably a promising approach to advance science and one that will only gain prominence over time as the local storage capacities of research organizations cannot handle (neither physically nor in a cost-effective manner) the petabytes of data being generated and shared. However, questions remain as to (l) who maintains control and responsibility for what is stored in the cloud(s), (2) in which jurisdiction(s) the data reside, and (3) how researchers can move genomic data to a commercial cloud (or clouds) in a way that satisfies both multi-jurisdictional privacy regulations and legitimate research participant privacy concerns. (59)

In sum, it is a significant challenge to develop and maintain biobanks that promote global sharing of data--and consequent biomedical progress--while sufficiently protecting the privacy of research participants. (60) This realization has led academics, policymakers, research funders, and biobank administrators to develop numerous privacy policies, recommendations, and laws applicable to biobanks, (61) and the intense debate and policymaking flurry continues. Yet, because these initiatives rarely consider the context of international research and database interoperability, all too often the policies are ill-defined, inconsistent, and misaligned, thereby thwarting access and use, creating national data silos, and offering limited privacy protection on the scale needed in the twenty-first century. (62) As discussed further in the next section, it is precisely this lack of policy and regulatory harmonization that unduly impedes the kind of data sharing essential for advancing biomedical research and healthcare.

III. Caution, Confusion, and Complexity: The Need for Privacy Law Harmonization

Concerns about overly cautious and complex data privacy regulation negatively impacting biomedical progress and healthcare are not new, and such concerns have been expressed in regulatory instruments themselves. Indeed, the 1980 OECD Guidelines on the Protection of Privacy and Transborder Flows of Personal Data explicitly warned that disparities in national legislation could hamper the free flow of personal data across borders. (63) However, what is new is that twenty-first century infrastructure science, characterized by--and at times driven by--biobanking, reflects a novel kind of internationally collaborative scientific practice that is insufficiently reflected in data privacy regulation, regardless of whether the regulation is a generation old or new (for instance, as discussed below, the proposed EU General Data Protection Regulation.) (64) To wit, data sharing has been traditionally been envisioned in data privacy regulation as pointto-point "data transfers" from one computer or paper file to another, rather than seamless and real-time "flows" of data to multiple points and through multiple, digital vectors. Moreover, data privacy regulation is fragmented and confounds researchers with a maze of laws, guidelines, and recommendations. (65) The lack of a global privacy governance framework creates numerous risks. As a case in point, Rolf Weber lists several issues created by disparate provisions in national data privacy laws:

Table 1

Selected International Disease and Database Consortia and Projects

Consortium or Project (Jurisdiction)	Year Est.	Objective
Autism Genetics Resource Exchange	1997	• DNA repository and family registry housing database of genotypic and phenotypic information available to autism researchers worldwide • Collection of over 1700 well-characterized pedigreed families (multiplex and simplex)
International HapMap Project	2002	• Identify and catalogue genetic similarities and differences in human beings by developing a haplotype map (by identifying the 250,000 to 500,000 tag SNPs) of the human genome • 270 participants
Type 1 Diabetes Genetics Consortium	2004	• Discover how differences in genes contribute to the risk for development of type 1 diabetes • Over 34,500 participants in study archive
Leiden Open Variation Database	2004	• Freely available tool for gene-centered collection and display of DNA variations • Approximately 3,000,000 variant observations (2,288,050 unique variants) in over 250,000 individuals
Database of Genotypes and Phenotypes (dbGaP)	2006	• Archive of results of studies that have investigated the interaction of genotype and phenotype
International Cancer Genome Consortium	2007	• Obtain a comprehensive description of genomic, transcriptomic and epigenomic changes in 50 different cancer tumor types and/or subtypes • Over 25,000 cancer tumor genomes studied to date
International Serious Adverse Event Consortium	2007	• Identify DNA-variants useful in predicting the risk of drug-related serious adverse events
Psychiatric Genomes Consortium	2007	• Conduct individual-level data meta-studies of genome-wide genetic data for psychiatric disorders • Samples from more than 900,000 individuals currently in analysis
International Human Microbiome Consortium	2008	• Study and understand the role of the human microbiome in the maintenance of health and causation of disease
MalariaGEN	2008	• Explore and identify critical mechanisms of protective immunity against malaria which could lead to successful malaria vaccine development
1000 Genomes Project	2010	• Find most genetic variants that have frequencies of at least 1% in the populations studied • 2,504 participants
UK10K (UK)	2010	• Understand the link between low-frequency and rare genetic changes, and human disease caused by harmful changes within protein-coding areas of DNA • 10,000 participants
International Rare Diseases Research Consortium	2011	• Team of researchers and organizations investing in rare diseases research in order to achieve two main objectives by the year 2020, namely to deliver 200 new therapies for rare diseases and means to diagnose most rare diseases.
100,000 Genomes Project (UK)	2014	• Project will focus on patients with a rare disease and their families, patients with cancer, and those with infectious diseases and antibiotic resistance • Anticipate to sequence 100,000 whole genomes from National Health Service (NHS) patients in England by 2017
Human Longevity Inc. (US)	2014	• Private company that aims to sequence 1 million Americans' genomes by 2020
Precision Medicine Initiative (US)	2015	• Public-private partnership that plans to study links among genes, health, and environment in 1 million Americans by pooling participants in existing cohort studies

* non-compliance with national law;

* unauthorized release of personal data;

* inability to provide individuals with access to their personal data;

* inability to cooperate with national regulators in case of complaints;

* inability of the national regulator to investigate or enforce the law;

* inability to guarantee the protection of personal data in countries with a low protection level;

* conflicts between national and foreign laws;

* possible access to data by foreign governments;

* overseas judicial decisions requiring the disclosure of data;

Table 2
Selected Examples of Large-Scale, International Biobanks

Biobank (Jurisdiction)	Year Est.	Biobank Objective
HUNT/Cohort of Norway (CONOR), Biobank (Norway)	1994	• Investigate the causes of disease • 200,000 participants
Estonian Biobank (Estonia)	2000	• Create a database of health, genealogical, and genome data to look for links between genes, environmental factors, and common diseases • 52,000 participants currently enrolled
UK Biobank (UK)	2002	• Study how the health of 500,000 people from all around the UK, aged 40-69 years at enrollment, is affected by their lifestyle, environment, and genes • 500,000 participants
Marshfield Clinic Personalized Medicine Research Project (US)	2002	• Study which genes cause disease, which genes predict reactions to drugs, and how environment and genes work together to cause disease • 20,000 participants
BioBank Japan (Japan)	2003	• Investigate the pharmacogenetics of common diseases • 300,000 participants
Generation Scotland (UK)	2003	• Create more effective treatments based on gene knowledge to the medical, social and economic benefit of Scotland and its people • 24,000 participants from 7,000 families
Western Australian DNA Bank (Australia)	2006	• Provide scientists with a state-of-the-art facility to store DNA samples needed to undertake critical medical research into common diseases
Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH) (US)	2007	• Discover which genes and environmental factors are linked to specific diseases • 500,000 participants (consenting health plan members) anticipated
CARTaGENE (Canada)	2007	• Biobank that studies the genomic factors on health and disease in population aged 45-69 years at enrollment • 40,000 participants across two phases
LifeGene (Sweden)	2007	• Resource for research in all medical disciplines, enabling new and ground-breaking research on the relationships among heredity, environment, and lifestyle • 500,000 participants anticipated
LifeLines (Netherlands)	2008	• Three-generation longitudinal population-based study initiated to investigate risk factors of multifactorial diseases and its modifiers • 165,000 participants
Taiwan Biobank (Taiwan)	2010	• Conduct large-scale cohort research for a long period of time, using combination of genetic and other medical information, so as to investigate genetic factors behind common chronic diseases in Taiwan, such as cancer, high blood pressure and diabetes, and the interaction of genetic and external risk factors • 200,000 participants anticipated
Qatar Biobank (Qatar)	2012	• Collection of samples and information on health and lifestyle from large numbers of members of the population of Qatar to investigate genetic factors behind common diseases • 60,000 participants anticipated by 2019

* problems with recovery or secure disposal of data; and

* loss of trust/confidence if data are transferred and misused. (66)

The challenge for biobanks lies in ensuring that they can share data along with biospecimens across jurisdictions in as seamless a manner as possible. (67)

Two bottlenecks in global data sharing are worth exploring. First, the misalignment of data privacy laws and ethics review boards and committees (e.g., IRBs, RECs) is an ongoing challenge. Although some data privacy laws around the world emphasize the role of boards and committees as a safeguard, these entities may impose higher standards of privacy protection than privacy laws require, thereby thwarting ethical reflective equilibrium, given the considerable public and private interests that support access and the already-existing safeguards of privacy that laws embody. (68) Moreover, there is an inconsistent level or lack of privacy expertise, training, and oversight of many REC members. (69) RECs are accustomed to reviewing consent in the context of traditional medical research with direct physical intervention on a human body, (70) but biobanks involve specialized areas of knowledge, such as the nature of population and longitudinal studies and the security and changing nature of data collected and linked over time. Such research is conducted on datasets and extracted human tissue, not living human bodies. The considerations in different types of research are also different. Thus, although there are requirements, varying according to institutions, that REC membership include persons with experience in bioethics and in law, there are rarely requirements that specialists in privacy or IT security sit on those committees, and generally that is reflected in practice. Data privacy legislation requires parties who collect, use, or disclose health data to maintain adequate security to prevent unwarranted disclosure. Although regulations can require RECs to consider whether adequate safeguards are in place to protect the privacy and confidentiality of the data in question, to do so requires specialized knowledge regarding information systems and de-identification protocols that REC members may not possess.

The problem, therefore, is twofold: first, that ethics committees may impose higher standards than law (a problem of proportionality), which disrupts ethical reflective equilibrium; and second, that ethics committee members cannot be sure that the protection of relevant privacy norms are adequately, or consistently, dealt with (a problem of expertise). (71) As one commentator notes, "ethics review is hardly an appropriate ... locus of responsibility and authority for resolving the significant privacy issues posed by biobanking, nor for ensuring that our privacy rights and interests are adequately represented and weighed." (72) Consequently, it may be inappropriate for data privacy legislation to delegate the whole range of privacy concerns to local or regional RECs, or to assume that these bodies have the capacity and competence to handle the privacy-related issues affecting biobanks. (73) Such a reliance could overburden already-taxed RECs, as was found in two U.S. Government Accountability Office reports on privacy oversight on research and medical records. (74) Such excessive reliance on RECs also potentially compromises the privacy interests of participants (and related others), and also international collaboration if RECs review biobank projects and data access requests in an overly cautious manner.

Another example of an ongoing data sharing bottleneck due to misalignment of data privacy frameworks is the inconsistent if not incomprehensible terminology describing data privacy techniques. (75) This issue has been raised by commentators for more than a decade; yet despite several attempts at harmonization in different research sectors, (76) many researchers still must deal with numerous disjointed approaches and terms based on local regulatory requirements. How are researchers who receive or access data from multiple databases to know if a "reversibly anonymized" dataset is the equivalent of a "de-identified," "coded," "pseudonymized," or "unlinked" dataset unless there is terminological harmonization, reflected perhaps in an internationally acceptable table of concordance? (77) Not only does this particular issue impede international collaboration, it also will lead to ongoing inconsistent interpretation by regulatory authorities and RECs.

In sum, whether viewed as overly paternalistic, anachronistic, or inadequate, the common thread of national data privacy frameworks is characterized by significant gaps and marked differences of approach, impeding privacy safeguards, and collaborative biobank research. (78) Harmonization, which can be defined as a process in which points of legislative, regulatory, or policy convergence are identified and differences made compatible so as to make various national legislation, regulation, and policies substantially equivalent to one another, is a strong and strongly desired remedy for these gaps and marked differences of approach.

The desire for greater harmonization is evident, for example, in the European Commission's Data Protection Regulation, which was first proposed in January 2012. (79) The Regulation aims to remedy the 1995 Data Protection Directive 95/46, which is seen as having injected too much fragmentation and legal uncertainty in the way personal data protection was implemented in the European Union member states. (80) This is not entirely unsurprising, though, as per European Union law, Directives allow each member state some discretion as to how to achieve the result of data protection in a way that accords with national legal traditions. Yet, this had been deemed by regulators and policymakers as problematic enough over the years such that a different regulatory device was needed, namely a Regulation, which in principle allows no room for legal maneuvering by member states and is transposed and directly applicable across the European Union. As the European Commission observed in an explanatory memorandum accompanying the January 2012 proposed regulation, "[h]eavy criticism has been expressed regarding the current fragmentation of personal data protection in the Union, ... [t]he direct applicability of a Regulation ... will reduce legal fragmentation and provide greater legal certainty by introducing a harmonized set of core rules, improving the protection of fundamental rights of individuals...." (81)

No doubt a Regulation will achieve greater data privacy legal harmonization for Europe, if for no other reason than because of the nature and procedure of a Regulation in European Union law: continental-wide rules will be implemented top-down. But Regulations must be crafted carefully, and harmonization as a process must be undertaken with diligence, persistence, and respect both for varying legal traditions and communities affected by data privacy regulation--including patients, research participants, and researchers. Past drafts of the Data Protection Regulation did not achieve this. Numerous commentators from both the legal and research communities criticized the draft texts for their unduly strict and arguably protectionist approach to biomedical research, including requirements for specific consent (i.e., prohibiting the use of broad consent in biobanking) and stringent restrictions on international data transfers. (82) Moreover, and somewhat ironically, several draft texts left EU member states the possibility to adopt exceptions to the strict consent rules in their national laws for research purposes. While arguably beneficial from a research perspective, from a legal perspective this undermines the very purpose of a Regulation, and would fail to harmonize areas of scientific research where genomic and health-related data are being used extensively. The drafting of the Data Protection Regulation thus serves as a case study of the "dark side" of harmonization. Harmonization is in principle a beneficial approach for enabling efficient and responsible data sharing across the globe, but only to the extent that the substantive rules and principles are good law. If the harmonized law(s) or framework in question is poorly drafted, fails to properly account for the arguably unique nature of biobanks and health data-driven research, and allows carve-outs for national law, in many ways harmonization will be no better, and likely worse, than an approach openly amenable to national interpretation and flexibility. While some suggest there is convergence (a kind of "race to the top") towards a European data privacy model, (83) there would be room for skepticism in relation to a data privacy model based on the Data Protection Regulation draft texts. An ostensibly harmonizing Regulation that fails to permit efficient global data flows will merely perpetuate the global misalignment of data privacy frameworks, as few biomedical researchers and participants want to operate in--and few globally-minded regulators likely want to adopt--a data privacy framework that is viewed by many as cautious, confusing, complex, and protectionist. If we want a global privacy governance framework to enable efficient and responsible sharing of data for biobanking, the Data Protection Regulation may not be the primary one on which to build.

Table 3

Selected Examples of International Instruments That Discuss Networking and Sharing of Genomic Resources

International Organization and Instrument	Year	Statement
UNESCO, *Universal Declaration on the Human Genome and Human Rights*	1997	States should make every effort, with due and appropriate regard for the principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity, and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries. (Art. 18).
UNESCO, *International Declaration on Human Genetic Data*	2003	Researchers should…subject to the provisions of Article 14 [Privacy and confidentiality]…encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge… (Art. 18(c)).
UNESCO, *Universal Declaration on Bioethics and Human Rights*	2005	Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. (Art. 15). States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge. (Art. 21).
Council of Europe, *Recommendation on Research on Biological Materials of Human Origin*	2006	Member states should take appropriate measures to facilitate access by researchers to biological materials and associated data stored in population biobanks. (Art. 20(1)).
OECD, *Guidelines on Human Biobanks and Genetic Research Databases*	2009	The operators of the HBGRD should strive to make data and materials rapidly and widely available to researchers so as to advance knowledge and understanding. (Principle I.C).
Global Alliance for Genomics and Health, *Framework for Responsible Sharing of Genomic and Health-Related Data*	2014	The Framework…interprets the right of all people to share in the benefits of scientific progress and its applications as being the duty of data producers and users to engage in responsible scientific inquiry and to access and share genomic and health-related data across the translation continuum, from basic research through practical applications. (Preamble)

IV. Establishing Privacy Law Harmonization for Biobanking

While the European Union has enacted some form of data privacy harmonization on a regional scale, and is actively seeking to scale it up, globally harmonized data privacy standards do not exist as of yet. Nonetheless, signs of progress are appearing. A good-faith attempt was made with the Madrid Resolution of 2009 to establish global data privacy principles, albeit without a focus on biomedical research. (84) Similarly, the case for harmonization in the biobanking field has been made on numerous occasions. (85) In the past, a number of projects and organizations have been constituted to improve harmonization and interoperability between biobanks, such as P3G, (86) BBMRI-ERIC, (87) BioShaRE, (88) and ISBER. (89)

What has been lacking to date between the two fields of (i) privacy laws and (ii) biomedical practices, however, is robust international and comparative legal analysis of the specific biobanking practices of countries around the world, and of how data privacy laws impact those

biobanking practices. Biobanking and privacy is a hybrid field of inquiry that largely draws from strands of converging expertise in, among other areas, life sciences, law, social science, and policy. Therefore, what is needed is deeper, multidisciplinary research into an apparently intractable issue that will pinpoint the problem areas and areas of convergence. In turn, this can lead to discussion and analysis that may point to policy recommendations that help resolve a major impediment to global biobanking. As Graeme Laurie and colleagues remark, "If we can better understand the types and range of privacy interests that are in play, and the particular legal devices that can be used to protect them, then we will have come a long way to addressing the problems themselves." (90)

Given the challenges of developing robust transnational regulation, research on biobanks and privacy is both an appropriate starting point and also a way to move tentatively forward. A global framework is a complex and long-term task, but is achievable if crafted as principle-based regulation. Principles are compatible with harmonization, providing an embodiment of the core values and interests at stake within a common language and framework for action that clearly and determinedly promotes data sharing and use. While flexibility remains crucial for local context (for some, principles create too much flexibility at the expense of certainty), principles do nevertheless provide a common frame of reference to promote dialogue on action on how they can be operationalized. Indeed, the role of principles is in driving a form of harmonization that is practical, pragmatic, but also necessarily accommodating of diversity.

It is possible and desirable, then, to achieve greater harmonization of the currently disjointed data privacy laws around the world, for doing so will promote more efficient and responsible sharing and use of data, and lead to advances in biomedical research and healthcare. At the same time, one must be cognizant that due to social, historical, technological, and cultural differences, achieving any real breakthrough in data privacy harmonization in the near future will remain a significant challenge. This necessitates a focus less on working towards a common framework of prescriptive data privacy rules and standards, and more on developing foundational responsible data sharing principles in an overarching governance framework. (91) That we should be so bold as to endeavor.

Declaration of Conflicting Interests

The author was previously the Regulatory and Ethics Working Group Coordinator of the Global Alliance for Genomics and Health (2013-2015), and is a member of the International Cancer Genome Consortium's Identifiability and Privacy Subgroup.

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Table 1
Selected International Disease and Database Consortia and Projects

Consortium or Project (Jurisdiction)	Year Est.	Objective
Autism Genetics Resource Exchange	1997	* DNA repository and family registry housing database of genotypic and phenotypic information available to autism researchers worldwide * Collection of over 1700 well-characterized pedigreed families (multiplex and simplex)
International HapMap Project	2002	* Identify and catalogue genetic similarities and differences in human beings by developing a haplotype map (by identifying the 250,000 to 500,000 tag SNPs) of the human genome * 270 participants
Type 1 Diabetes Genetics Consortium	2004	* Discover how differences in genes contribute to the risk for development of type 1 diabetes * Over 34,500 participants in study archive
Leiden Open Variation Database	2004	* Freely available tool for gene-centered collection and display of DNA variations * Approximately 3,000,000 variant observations (2,288,050 unique variants) in over 250,000 individuals
Database of Genotypes	2006	* Archive of results of studies

and Phenotypes (dbGaP)		that have investigated the interaction of geno-type and phenotype
International Cancer Genome Consortium	2007	* Obtain a comprehensive description of genomic, transcriptomic and epigenomic changes in 50 different cancer tumor types and/or subtypes * Over 25,000 cancer tumor genomes studied to date
International Serious Adverse Event Consortium	2007	* Identify DNA-variants useful in predicting the risk of drug-related serious adverse events
Psychiatric Genomes Consortium	2007	* Conduct individual-level data meta-studies of genome-wide genetic data for psychiatric disorders * Samples from more than 900,000 individuals currently in analysis
International Human Microbiome Consortium	2008	* Study and understand the role of the human microbiome in the maintenance of health and causation of disease
MalariaGEN	2008	* Explore and identify critical mechanisms of protective immunity against malaria which could lead to successful malaria vaccine development
1000 Genomes Project	2010	* Find most genetic variants that have frequencies of at least 1% in the populations studied * 2,504 participants
UKI0K (UK)	2010	* Understand the link between low-frequency and rare genetic changes, and human disease caused by harmful changes within protein-coding areas of DNA * 10,000 participants

International Rare Diseases Research Consortium	2011	* Team of researchers and organizations investing in rare diseases research in order to achieve two main objectives by the year 2020, namely to deliver 200 new therapies for rare diseases and means to diagnose most rare diseases.
100,000 Genomes Project (UK)	2014	* Project will focus on patients with a rare disease and their families, patients with cancer, and those with infectious diseases and antibiotic resistance * Anticipate to sequence 100,000 whole genomes from National Health Service (NHS) patients in England by 2017
Human Longevity Inc. (US)	2014	* Private company that aims to sequence 1 million Americans' genomes by 2020
Precision Medicine Initiative (US)	2015	* Public-private partnership that plans to study links among genes, health, and environment in 1 million Americans by pooling participants in existing cohort studies

Table 2
Selected Examples of Large-Scale, International Biobanks

Biobank (Jurisdiction)	Year Est.	Biobank Objective
HUNT/Cohort of Norway (CONOR), Biobank (Norway)	1994	* Investigate the causes of disease * 200,000 participants
Estonian Biobank (Estonia)	2000	* Create a database of health, genealogical, and genome data to look for links between genes, environmental factors, and common diseases * 52,000 participants currently

		enrolled
UK Biobank (UK)	2002	* Study how the health of 500,000 people from all around the UK, aged 40-69 years at enrollment, is affected by their lifestyle, environment, and genes * 500,000 participants
Marshfield Clinic Personalized Medicine Research Project (US)	2002	* Study which genes cause disease, which genes predict reactions to drugs, and how environment and genes work together to cause disease * 20,000 participants
BioBank Japan (Japan)	2003	* Investigate the pharmacogenetics of common diseases * 300,000 participants
Generation Scotland (UK)	2003	* Create more effective treatments based on gene knowledge to the medical, social and economic benefit of Scotland and its people * 24,000 participants from 7,000 families
Western Australian DNA Bank (Australia)	2006	* Provide scientists with a state-of-the-art facility to store DNA samples needed to undertake critical medical research into common diseases
Kaiser Permanente Research Program on Genes, Environment and Health (RPGEH) (US)	2007	* Discover which genes and environmental factors are linked to specific diseases * 500,000 participants (consenting health plan members) anticipated
CARTaGENE (Canada)	2007	* Biobank that studies the genomic factors on health and disease in population aged 45-69 years at enrollment * 40,000 participants across two phases

LifeGene (Sweden)	2007	* Resource for research in all medical disciplines, enabling new and ground-breaking research on the relationships among heredity, environment, and lifestyle * 500,000 participants anticipated
LifeLines (Netherlands)	2008	* Three-generation longitudinal population-based study initiated to investigate risk factors of multifactorial diseases and its modifiers * 165,000 participants
Taiwan Biobank (Taiwan)	2010	* Conduct large-scale cohort research for a long period of time, using combination of genetic and other medical information, so as to investigate genetic factors behind common chronic diseases in Taiwan, such as cancer, high blood pressure and diabetes, and the interaction of genetic and external risk factors * 200,000 participants anticipated
Qatar Biobank (Qatar)	2012	* Collection of samples and information on health and lifestyle from large numbers of members of the population of Qatar to investigate genetic factors behind common diseases * 60,000 participants anticipated by 2019

Table 3
Selected Examples of International Instruments That Discuss Networking and Sharing of Genomic Resources

International Organization and Instrument	Year	Statement
UNESCO, Universal Declaration on the Human Genome and Human Rights	1997	States should make every effort, with due and appropriate regard for the

		principles set out in this Declaration, to continue fostering the international dissemination of scientific knowledge concerning the human genome, human diversity, and genetic research and, in that regard, to foster scientific and cultural co-operation, particularly between industrialized and developing countries. (Art. 18).
UNESCO, International Declaration on Human Genetic Data	2003	Researchers should ... subject to the provisions of Article 14 [Privacy and confidentiality] ... encourage the free circulation of human genetic data and human proteomic data in order to foster the sharing of scientific knowledge ... (Art. 18(c)).
UNESCO, Universal Declaration on Bioethics and Human Rights	2005	Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. (Art. 15). States should foster international dissemination of scientific information and encourage the free flow and sharing of scientific and technological knowledge. (Art. 21).
Council of Europe, Recommendation on Research on Biological Materials of Human	2006	Member states should take appropriate measures to facilitate access by

Origin		researchers to biological materials and associated data stored in population biobanks. (Art. 20(1)).
OECD, Guidelines on Human Biobanks and Genetic Research Databases	2009	The operators of the HBGRD should strive to make data and materials rapidly and widely available to researchers so as to advance knowledge and understanding. (Principle I.C).
Global Alliance for Genomics and Health, Framework for Responsible Sharing of Genomic and Health-Related Data	2014	The Framework ... interprets the right of all people to share in the benefits of scientific progress and its applications as being the duty of data producers and users to engage in responsible scientific inquiry and to access and share genomic and health-related data across the translation continuum, from basic research through practical applications. (Preamble)

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