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Bank on We the People: Why and How Public Engagement is Relevant to Biobanking

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BANK ON WE THE PEOPLE: WHY AND HOW PUBLIC ENGAGEMENT IS RELEVANT TO BIOBANKING

*Chao-Tien Chang**

ABSTRACT

Biobanks emerged in the early 2000s, and now facilitate scientific research through the provision of resources for research that requires a large scale of biospecimens and data. Biobank projects have also become intertwined with complicated socio-economic initiatives to boost economic development or to shape community identity. While legislators continue to debate the ethical and regulatory challenges associated with biobanks, the federal regulation over research involving human subjects, the Common Rule, is based on a traditional research model that fails to address the complex challenges unique to biobanking. Through an examination of the proposed revisions to the Common Rule concerning research using biospecimens and ethical controversies regarding informed consent, privacy, ownership and benefit-sharing, this article highlights a participatory aspect of biobanking that calls for public engagement with respect to both ethics and norms. Many biobank projects try to appeal to a sense of civic engagement whereby citizens have rights as well as responsibilities with respect to participation in collaborative scientific projects. Domestic and international guidelines describe incorporating public engagement with biobanking as an essential means of protecting research participants and achieving good governance. International experiences with various approaches of public engagement have also proven that involving the general public is feasible. Moreover, the principle of democratic deliberation, which was proposed by the Presidential Commission for the Studies of Bioethical Issues to be a

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guiding principle for bioethics policy decisions, further underscores the criticality of public engagement in biobanking.

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I. INTRODUCTION: BIOBANKS AND WE THE PEOPLE

After the completion of the Human Genome Project in the early 2000s, numerous biobanks were established globally. A biobank is an organized collection of human biological material, DNA, genetic samples, and associated data. Biobanks, especially large-scale ones, are usually considered to be valuable pieces of infrastructure that can enable research in the fields of medicine and biotechnology, and the consequent scientific developments made therefrom could confer benefits on the entire community. The launch of many large-scale biobanks was also motivated by a sense of nation-building because biobanks can preserve natural resources that can boost a country's bioeconomy¹ or serve as the commons for exploring a nation's identity and serve a nation's health and welfare.² The biobank bubble that inflated over the past 20 years has not yet burst. According to a market survey in 2018, the global market of biobanking was estimated to reach 74.54 billion USD by 2025 at a 4.5% compound annual growth rate³, despite the withdrawal of funding in a few countries.⁴ In light of technological developments with respect to storage and computation and the emergence of new research methods such as genomic and big data, researchers using biobanks have begun to integrate information from other databases as well. These research approaches highlight the value of biobanks: biobanks allow researchers to use accumulations of data and link these banked biospecimens with health data.

While some biobanks gained public support because of their nationalistic aspects, growing international cooperation has diluted the nationalistic aspect of biobanks. However, the success of biobanks depends on public support and investment. Because these biobanks cannot operate without maintaining a broad set of samples and data, they require continuous contribution from the general public; however, people have become more concerned about maintaining autonomy and ownership of their own data and tissues. Additionally, the growing budgets necessary to sustain biobanks have increased the importance of establishing transparency, accountability, and public trust with respect to biobanking. Biobank projects today appeal not only to people's desires to make altruistic contributions to the advance-

1. Robert Mitchell, *National Biobanks: Clinical Labor, Risk Production, and the Creation of Biovalue*, 35 SCI. TECH. HUM. VALUES 330, 333 (2010).

2. See HERBERT GOTTSWEIS & ALAN PETERSEN, *Biobanks and Governance: An Introduction*, in BIOBANKS: GOVERNANCE IN COMPARATIVE PERSPECTIVE 3, 7, 10 (Gottweis & Petersen eds., 2008).

3. *Biobanks Market Size Worth \$74.54 Billion by 2025, CAGR 4.5%*, GRAND VIEW RES. (Sept. 2018), <https://www.grandviewresearch.com/press-release/global-biobanks-industry>.

4. Don Chalmers et al., *Has the Biobank Bubble Burst? Withstanding the Challenges for Sustainable Biobanking in the Digital Era*, 17 BMC MEDICAL ETHICS, 2016, at 1, 2, <https://bmcmethics.biomedcentral.com/track/pdf/10.1186/s12910-016-0124-2>.

ment of medicine and public health but also to their sense of civic responsibility. For instance, the Precision Medicine Initiative (PMI), launched in 2016, aims to understand diseases and develop preventive measures and treatments by accounting for individual biological, behavioral, and environmental differences.⁵ An essential project of the PMI, named *All of Us*, is operated by the National Institute of Health (NIH) and seeks to assemble a cohort of one million persons or more to create a large-scale biobank comprising biospecimens and databases containing various health data collected from the participants.⁶ PMI highlights the concept of “participants as partners,”⁷ which describes how people are empowered to have more active roles rather than simply serving as voluntary subjects in need of protection. The *All of Us* project and PMI’s mission statement suggest that citizens have the right to access these resources and the right to determine how such resources are utilized insofar as they are involved in governance once they opt in; simultaneously, however, citizens also share a moral responsibility to donate their biospecimens and data for the public good. Scholars have proposed similar ideas about the relationship between civic engagement and opting in to such large-scale scientific cohorts, referring to the relationship as “genomic citizenship”⁸ or “data citizenship.”⁹ Scientific citizenship mainly describes how people have rights and responsibilities with respect to participation in sharing projects undertaken for scientific research, and people should thus have the right to participate in the collective decision-making process beyond just exercising individual rights.

Biobanks have presented a novel challenge to regulatory frameworks that have been designed to address the ethical issues with respect to the use of human research subjects; however, using banked biospecimens and data are not necessarily within the scope of human subjects research if the biospecimens and data have been de-identified. Moreover, given that biobanks are designed to facilitate general future research, voluntary participation is usually confirmed through broad consent; however, broad consent is ethically questionable because participants have the ability to exercise very limited real control over biospecimens and data. Interlinking of biobanks and other data may lead to breakthroughs in medicine but may also create the potential for unprecedented endangerment of autonomy and privacy. Despite ef-

5. *About the All of Us Research Program*, NAT’L INST. OF HEALTH, <https://allofus.nih.gov/about/about-all-us-research-program> (last visited Oct. 7, 2018).

6. *Id.*

7. PMI WORKING GROUP, THE PRECISION MEDICINE INITIATIVE COHORT PROGRAM—BUILDING A RESEARCH FOUNDATION FOR 21ST CENTURY MEDICINE 39 (Sept. 17, 2015), <https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf>.

8. Maya Sabatello & Paul S. Appelbaum, *Rising Genomic Citizens: Adolescents and the Return of Secondary Genomic Findings*, 44 J.L. MED. & ETHICS 292, 293-94 (2016).

9. Barbara J. Evans, *Power to the People: Data Citizens in the Age of Precision Medicine*, 19 VAND. J. ENT. & TECH. L. 243, 243 (2016).

forts to establish ethical and legal regimes for biobanks both domestically and internationally, the aforementioned ethical issues remain to be settled. Further, because of the considerable number of participants and financial investment that biobanks require, their creation and maintenance also face issues of democratic legitimacy and accountability.

In response to these challenges, many biobank projects made a participatory turn. Public engagement has become a common practice for biobank operators, and an increasing number of calls have been made for biobanks to engage in a dynamic, continuing relationship with participants through the use of information technologies. The participatory turn resonates with the idea of scientific citizenship, which describes the perspective of many large-scale biobanks today that assume citizens have rights as well as responsibilities with respect to participation in communal efforts to achieve public interests. However, the participatory turn was not addressed in the Belmont Report or the four key bioethical principles.¹⁰ Bioethics emphasizes individual autonomy, but has seldom addressed citizen participation in governance or in community decision-making. In the context of biobanking, “We the People” are not just research subjects but are possessors of genomic sovereignty on the basis of which we define justice, domestic tranquility, general welfare, the blessings of liberty, and obligations to posterity. Public engagement, as an approach to realizing popular sovereignty, is crucial to achieve the ethicalness and legitimacy of any biobank project launched with the task of pursuing the public good.

Biobanks have made a significant participatory turn, but relatively little scholarship regarding the laws and regulations of biobanks exists; thus, this article explores the normative importance of public engagement in biobanking, and various models that can enable public engagement. Following Part I’s introduction, Part II reviews the regulatory and ethical controversies of biobanking. The Common Rule is the most relevant regulation, and its two major mechanisms for protecting biobank participants are de-identification and informed consent. Proposed revisions to the Common Rule considered

10. The four widely recognized bioethical principles—respect for autonomy, nonmaleficence, beneficence, and justice—were proposed by Tom L. Beauchamp and James F. Childress in their book *Principles of Biomedical Ethics*, whose first edition was published in 1977. TOM L. BEAUCHAMP & JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* vii, 13 (7th ed. 2013). The four principles share certain similarities with the Belmont Report’s three general principles relevant to human subjects research—respect for persons, beneficence, and justice, NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, *ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (THE BELMONT REPORT)* Part B (1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf. The most significant difference between the two is the scope of application: while the Belmont Report is a document specifically addressing human subjects research ethics, Beauchamp and Childress’s four principles are designed to apply more broadly to general bioethical issues. See Beauchamp & Childress, *supra*.

bringing the secondary use of de-identified biospecimens into the scope of human subjects research regulations as well as granting research subjects the opportunity to give broad consent to enhance individual autonomy. However, the proposal did not survive and was left out of the final version that became effective in 2018 because of the assumption that seeking consent would impose a significant burden on biobanks and the fact that broad consent presents debatable ethical concerns. This article contends that the Common Rule, which was based on an assumption that specific research is performed on human bodies, did not adequately address the challenges of regulating biobanking. Part III assesses three major areas of ethical controversy relating to biobanking—(1) informed consent, (2) privacy and confidentiality, and (3) ownership and benefit-sharing. The discussions concerning these three areas of controversy reveal a trend whereby participants are empowered to take on more active roles instead of being relegated to the status of passive subjects to be protected. Part IV addresses the relevance of public engagement to biobanking by reviewing ethical reasons as well as normative evidence in support of public engagement. The ethical aspects of the communal features of biobanking have inspired calls for public engagement. Involving the public can help ensure that the operation of biobanks fulfills the common good, can serve as a method for implementing good governance, and can reinforce public trust. Domestic and international guidelines regarding biobanking have also added public engagement as a key element of ethical practices, all normatively confirming the necessity of public engagement. Part V examines international experiences with public engagement and categorizes them into four models. The various strategies to include and empower the public in different countries, despite their advantages and disadvantages, confirm an international consensus that public engagement in biobank governance is both feasible and desirable. This part also responds to critiques of public engagement, which are mostly based on administrative costs and people's participatory competence. Part VI concludes the article and argues that the relevance of public engagement can be also supported by the emerging bioethical principle proposed by the Presidential Commission for the Studies of Bioethical Issues (PCSB)—democratic deliberation. Democratic deliberation highlights the importance of public engagement, which resonates with the participatory turn in biobanking elucidated in this article.

II. REGULATION OF BIOBANKING

Two different paradigms exist for biobank regulation. One relies on current regulations and results in the governance of biobanking by a variety of complicated and even sometimes conflicting rules. The other paradigm articulates a specific regulatory framework for biobanking. The United States' regulatory regime takes the first approach. The most pertinent feder-

al regulation is the Federal Policy for the Protection of Human Subjects Research (known as “the Common Rule”). However, applying the Common Rule to biobanks is problematic because the Common Rule does not address the particular characteristics of biobanking activities. Proposed revisions to the Common Rule once sought to broaden the scope of human subjects research to include the secondary use of de-identified biospecimens and mandate the solicitation of research subjects’ broad consent to protect their autonomy. However, the proposed expansion to the scope of human subjects research to include de-identified biospecimens was ultimately not adopted. The unsuccessful revision of the Common Rule seems to indicate the necessity of seeking alternatives for appropriately regulating the ethical issues of biobanking.

A. Regulation Overview

The Common Rule is a set of regulations adopted independently by different federal agencies, among which the most well-known is the Human and Health Services (HHS) regulation codified as 45 CFR 46, part A.¹¹ The Common Rule regulates research funded by federal agencies or conducted in institutes that agree to assume responsibility for the research in accordance with the Common Rule regardless of the source of funding.¹² The Food and Drug Administration (FDA) also adopted certain provisions of the Common Rule that apply to clinical investigations regulated by the FDA, or clinical investigations that support new product applications or product marketing.¹³ The Common Rule was promulgated in 1991 and had mostly remained unchanged since then.¹⁴ Nevertheless, challenges raised by the new technology brought the necessity for revision in order to provide adequate protection for research subjects. HHS published an Advanced Notice of Proposed Rulemaking (ANPRM) in Federal Registrar in 2011, and later HHS published a Notice of Proposed Rule Making (NPRM) in 2015.¹⁵ After receiving more than 2100 comments,¹⁶ the final rule implementing major

11. 1 NAT’L BIOETHICS ADVISORY COMM’N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, 27 (1999), <https://bioethicsarchive.georgetown.edu/nbac/hbm.pdf> [hereinafter NBAC]; *Federal Policy for the Protection of Human Subjects* (‘Common Rule’), U.S. DEP’T OF HEALTH & HUMAN SERVS., <http://www.hhs.gov/ohrp/humansubjects/commonrule/> (last visited Oct. 8, 2018).

12. NBAC *supra* note 11, at 28; 45 C.F.R. § 46.101 (2018).

13. See NBAC *supra* note 11, at 27-28; 21 C.F.R. § 56.101 (2018).

14. Victoria Berkowitz, Comment, *Common Courtesy: How the New Common Rule Strengthens Human Subject Protection*, 54 Hous. L. Rev. 923, 925 (2017).

15. *Revised Common Rule*, OFF. FOR HUM. RES. PROTS., <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html> (last visited Oct. 8, 2018).

16. Jerry Menikoff et al., *The Common Rule, Updated*, 376 NEW ENG. J. MED. 613, 613 (2017).

revisions to the Common Rule was formally announced in January 2017 and took effect in 2018 (Final Rule).¹⁷

The first challenge of applying the Common Rule to biobanks is that the use of human biological materials does not necessarily fit into the scope of the Common Rule. To start, the Common Rule only applies to research involving *human subjects*, while research activities involving biobanks do not necessarily fall within the scope of human subjects research. Human subjects research is defined as that involving a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.¹⁸ Human subjects research by this definition must undergo review by an institutional review board (IRB) and acquire subjects' informed consent by disclosing required information.¹⁹ Based on this definition, when an investigator interacts with a subject to obtain his or her samples or data, it qualifies as human subjects research.²⁰

However, the problem is the use of banked samples and data. Working with stored samples and data is defined as human subjects research only when those samples and data are *identifiable* private information. The definitive characteristic of "identifiable information" is that "the identity of the subject is or may readily be ascertained by the investigator or associated with the information."²¹ Guidance issued by the Office for Human Research Protection (OHRP) deems information not to be identifiable when the specimens or data cannot be linked to specific individuals by the investigator directly or indirectly through coding systems.²² According to OHRP's interpretation, investigations using specimens or data from a coded repository are not considered human subjects research if there is an assurance based on certain agreements, policies or laws from the key holder not to release the decoding key to investigators.²³ By OHRP's standard, a biobank could serve as an efficient way of sharing as the key holder, as long as the biobank codes specimens and data and takes responsibility for ensuring compliance with regulatory requirements.

Next, even if research activities fall within the scope of human subjects research, they might be exempted from IRB review and other regulatory requirements as long as they are unlinked or not publicly accessible. According to the Common Rule, the exemption applies when the identifiable information is publicly available, or the information "is recorded by the

17. *Revised Common Rule*, *supra* note 15.

18. *See* 45 C.F.R. § 46.102 (e)(1) (2018).

19. 45 C.F.R. § 46.109 (2018).

20. NBAC, *supra* note 11, at 28.

21. 45 C.F.R. § 46.102 (e)(5) (2018).

22. Office for Human Research Prots., CODED PRIVATE INFORMATION OR SPECIMENS USE IN RESEARCH, GUIDANCE (Oct. 16, 2008), <http://www.hhs.gov/ohrp/policy/cdebiol.html>.

23. *Id.*

investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects,”²⁴ or when a broad consent has been authorized by the subjects when agreeing to opt in to the biobank.²⁵ The criteria the investigator cannot acquire identifiable information of the research subjects is what the National Bioethics Advisory Commission (NBAC) report refers to as *unlinked* samples— “samples lack[ing] identifiers or codes that can link a particular sample to an identified specimen or a particular human being.”²⁶ Typically, biobank operators send unlinked samples to investigators.²⁷ Such research is generally exempted from IRB review and other regulations, because it is unlikely that investigators, repository operators, or a third party can identify particular individuals in research conducted on such samples.²⁸

Further, even if non-exempted human subjects research is conducted, it could be eligible for an expedited IRB review or a waiver of the requirement to obtain subjects’ informed consent. The IRB review may be expedited as long as the research involves no more than minimal risk.²⁹ The OHRP is authorized to issue a list of categories of research eligible for expedited review, including many forms of human biological materials, such as blood samples drawn by minimally intrusive methods, or a prospective collection of biological specimens gathered for research by noninvasive means, and data collections resulting from noninvasive procedures routinely employed in clinical practices.³⁰ Research using biospecimens and data that have been collected or will be collected for non-research purposes (such as medical treatments or diagnoses) is also eligible for expedited review.³¹ Moreover, the IRB could waive the informed consent requirement to non-exempt human subjects research if all of the following criteria are met: (1) the research involves no more than minimal risk to the subjects; (2) the research could not practicably be carried out without the waiver or alteration; (3) the waiver or alteration will not adversely affect the rights and welfare of the subjects; (4) research can only be practicably carried out by using identifiable private information or biospecimens; and (5) whenever appropriate, the subjects will be provided with additional pertinent information after participation.³² The most critical criterion for a non-exempt protocol is usually

24. 45 C.F.R. § 46.104 (d) (4) (i), (ii) (2018).

25. *Id.* § 46.104 (d) (8).

26. NBAC, *supra* note 11, at 18.

27. *Id.* at 58.

28. *See id.*

29. 45 C.F.R. § 46.110 (b) (2018).

30. Office for Human Research Prots., OHRP EXPEDITED REVIEW CATEGORIES (1998), <http://www.hhs.gov/ohrp/policy/expedited98.html>.

31. *Id.*

32. 45 C.F.R. § 46.116 (f)(3) (2018). It is also worth noting that the Final Rule provides an exception for the IRB waiver. If research subjects had been sought for broad consent for

whether it involves “minimal risk.”³³ According to the NBAC’s opinion, research using coded samples in the biobank is regarded as posing a minor risk to subjects, provided that the biobank and the researcher protect the privacy of subjects and have an appropriate plan on disclosure of research findings.³⁴

B. Proposed Revisions to the Common Rule

Applying the Common Rule to biobanks is not without challenges, however. *Identifiability* is a key factor in this framework. The Common Rule allows for a wider range of use and less-strict regulation on research when the samples and data involved is de-identified. The underlying rationale is that research using de-identified materials hardly hurt subjects. Nevertheless, criticisms of the standard of identifiability arise in terms of both technology and ethics. Reforms towards safeguards based on de-identification could be found in ANPRM and NPRM. Despite that the proposed revisions were not adopted in the Final Rule, it is worth reviewing those proposals when examining how the Common Rule protects research subjects in the context.

The technological challenge is that re-identification will become more likely, as biobanks proliferate, store and share ever larger amounts of information. Re-identification usually requires identified or “reference samples,” and biobanks make these samples more widely available.³⁵ Some research has proven the possibility of identifying an individual from a sample, even when specimens and data are anonymized. A *Science* article in 2013 described how to “google” identities of anonymized samples in genetic studies using little more than Internet sleuthing.³⁶ Perfect de-identification seems hardly achievable when biobanks are designed to build massive collections of networked information.

secondary research use of identifiable private information or identifiable biospecimens but refused to consent, then the IRB could not waive consent. *Id.* § 46.116 (e).

33. See NBAC, *supra* note 11, at 31.

34. *Id.* at v (“Recommendation 10: IRBs should operate on the presumption that research on coded samples is of minimal risk to the human subject if: a) the study adequately protects the confidentiality of personally identifiable information obtained in the course of research, b) the study does not involve the inappropriate release of information to third parties, and c) the study design incorporates an appropriate plan for whether and how to reveal findings to the sources or their physicians should the findings merit such disclosure.”).

35. See Amy L. McGuire & Richard A. Gibbs, *No Longer De-Identified*, 312 SCIENCE 370, 370 (2006).

36. See generally Melissa Gymrek et al., *Identifying Personal Genomes by Surname Inference*, 339 SCIENCE 321, 321-24 (2013) (describing a study finding that the anonymity of genome sequencing could be breached by comparing anonymized data with publicly accessible genetic genealogy databases that could identify surnames of the subjects, and then combining the information of surnames with other metadata such as age or residency of state).

In addition, the ethical challenge is whether the benefits of using anonymized specimens and data outweigh the principle of respect for autonomy. The Common Rule has treated de-identification (and even codification) as a sufficient and acceptable alternative to subjects' informed consent.³⁷ However, the public does not necessarily agree. For instance, in *Beleno v. Lakey*, parents sued the state government, which had collected and stored newborn samples and subsequently made them available for undisclosed research purposes without obtaining parents' consent.³⁸ The plaintiffs alleged that they had suffered a violation of privacy even though specimens had been de-identified, arguing that de-identification did not cure the defect of failing to obtain consent initially.³⁹ This case resulted in an out-of-court settlement that called for the destruction of more than 4 million collected specimens.⁴⁰ De-identification in itself does not provide an adequate ethical foundation for research subjects to surrender their autonomy. Another problem is the lack of oversight in the use of purportedly anonymous material: research indicates that researchers using human tissue samples without consent or IRB approval are more likely to use samples in an identifiable form rather than in the properly anonymized form.⁴¹

The NIH's Genomic Data Sharing Policy (GDS Policy) represents a significant shift towards requiring informed consent for the use of de-identified biospecimens and data.⁴² To encourage data sharing that fosters genomic research, NIH requires all of its funded researchers who conduct genome-wide association studies (GWAS) and other genomic research to submit their de-identified studies to the NIH database, Genotype and Phenotype (dbGap).⁴³ In 2014, the NIH announced the GDS Policy, which applies to all funded researchers who generate large-scale human and nonhuman genomic data and the use of these data for subsequent research and imple-

37. Katherine Drabiak-Syed, *State Codification of Federal Regulatory Ambiguities in Biobanking and Genetic Research*, 30 J. LEGAL MED. 299, 320 (2009).

38. See Complaint at 3-4, *Beleno v. Lakey*, 306 F.Supp.3d 930 (W.D. Tex. 2009) (No. 5:09-cv-00188).

39. See *id.* at 6.

40. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING 49 (2012), https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PrivacyProgress508_1.pdf [hereinafter PCSBI I].

41. Katherine Drabiak-Syed, *Legal Regulation of Biobanking Newborn Blood Spots for Research: How Bearder and Beleno Resolved the Question of Consent*, HOUS. J. HEALTH L. & POL'Y, 2011, at 1, 43 n. 235 (referring to Jon Merz et al.'s research indicating that of 13 studies performed without informed consent and IRB approval, only 3 used nonidentifiable samples).

42. See Donna M. Gitter, *Informed Consent and Privacy of Non-Identified Biospecimens and Estimated Data: Lessons from Iceland and the United States in an Era of Computational Genomics*, 38 CARDOZO L. REV. 1251, 1277-78 (2017); *NIH Genomic Data Sharing*, NAT'L INST. OF HEALTH, <https://osp.od.nih.gov/scientific-sharing/genomic-data-sharing/> (last visited Oct. 8, 2018).

43. See Gitter, *supra* note 41, at 1278.

mented it in 2015.⁴⁴ In light of the development of reidentification technology that can cross-reference information from various sources, the GDS Policy requires researchers to obtain research participants' consent for broad future use and general sharing of data, even if biospecimens and data have been de-identified.⁴⁵ Before the GDS Policy, a study of research participants whose de-identified data were submitted to the dbGap also indicated that most surveyed participants placed a high degree of importance on having their consent sought even for the use of de-identified data, and most of them (90%) had consented to share their data with dbGap.⁴⁶ The GDS Policy reflects a different paradigm from the Common Rule, acknowledging the insufficient protection offered by de-identification and calling for strengthening research participants' autonomy.

The ANPRM and NPRM reflected similar concerns as the GDS Policy. One of the major changes proposed in the ANPRM, followed by the NPRM, was how to treat the secondary use of de-identified biospecimens. The ANPRM asked whether prior consent should be required when investigators use de-identified biospecimens, and if consent was required, whether such consent could be obtained for unspecified future research.⁴⁷ Noting that biospecimens are intrinsically identifiable because of the genetic information they contain, the ANPRM proposed that investigators who use biospecimens not be required to seek informed consent prior to its collection, regardless of whether it is identifiable or not.⁴⁸ In addition, the ANPRM proposed a loosened standard for informed consent under which consent need not be study specific.⁴⁹

The NPRM advanced a similar proposal as the ANPRM and called for expanding the definition of human research subjects. The NPRM proposed that "the obtaining, use, study, or analysis of biospecimens . . . be covered under the Common Rule, regardless of identifiability."⁵⁰ The NPRM also suggested that broad consent be permissible for unspecified future research rather than research using biospecimens be required to solicit consent spe-

44. See NAT'L INSTS. OF HEALTH, NATIONAL INSTITUTES OF HEALTH GENOMIC DATA SHARING POLICY 1-2 (Aug. 2014), https://osp.od.nih.gov/wp-content/uploads/NIH_GDS_Policy.pdf.

45. *Id.* at 5; Gitter, *supra* note 42, at 1278-79.

46. Evette J. Ludman et al., *Glad You Asked: Participants' Opinion of Re-Consent for dbGap Data Submission*, J. EMPIRICAL RES. HUM. RES. ETHICS 2010 September, at 1, 6, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3071850/pdf/nihms279224.pdf>.

47. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512, 44515, 44526-27 (proposed July 26, 2011).

48. *Id.* at 44526-27.

49. *Id.* at 44515, 44526-27.

50. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53933, 53944 (proposed Sept. 8, 2015).

cific to each study.⁵¹ In addition, even if the Common Rule's expansion would not have been so broad as to cover all research using biospecimens, the NPRM also proposed two relatively minor expansions to include certain types of research: Alternative A proposed including Whole Genome Sequencing in human subjects research and Alternative B proposed including research that generates bio-unique information.⁵² Another key proposal of the NPRM was broad consent in light of the broadened scope of human subjects research in research using all biospecimens. By balancing the protection of research subjects and the public interests of research, the NPRM suggested that broad consent be permissible for the storage or maintenance of biospecimens and identifiable information for secondary research; the secondary use of stored biospecimens would also have been permissible with research subjects' broad consent and sufficient privacy safeguards.⁵³ The NPRM also outlined the elements that would have been required to be contained in broad consent.⁵⁴

Nevertheless, the Final Rule only adopted broad consent for identifiable biospecimens and did not expand the scope of human subject research to include de-identified biospecimens because of strong objections to the NPRM contained in public comments received. Commenters expressed concerns that the change would create significant administrative burdens because investigators would have to re-identify existing samples in order to seek consent.⁵⁵ Commentators also argued that the burden of seeking consent would significantly impair investigators' abilities to undertake important research.⁵⁶ Conversely, the benefits of seeking consent seemed to be too minimal to offset the costs and harms. Many commenters opined that broad consent was ethically questionable. Research subjects would have no way to fully consent given the limited information about future research.⁵⁷ Broad consent would not stimulate real dialogues between investigators and research participants but would rather reduce the likelihood of research subjects making fully informed decisions concerning the use of biospecimens.⁵⁸ Nevertheless, the Final Rule permits broad consent for the secondary use of identifiable biospecimens and information.⁵⁹ According to the old Common Rule, most investigators, considering the cost of seeking re-consent when using identifiable materials, would choose de-identification to exempt from

51. *Id.* at 53973.

52. *Id.* at 53945-46.

53. *Id.* at 53973.

54. *Id.* at 53973-74.

55. Berkowitz, *supra* note 14, at 956-57.

56. *Id.*; Menikoff et al., *supra* note 16, at 613.

57. Berkowitz, *supra* note 14, at 957-58.

58. *Id.* at 958.

59. 45 C.F.R. § 46.104 (d)(8) (2018).

regulation or seek waiver from the IRB.⁶⁰ In any event, many still believe that the broad consent codified in the Final Rule still enhances research subjects' autonomy by granting them more opportunities to make choices regarding the use of their data.⁶¹

After the implementation of the Final Rule, the storage and maintenance of biospecimens and data require broad consent if they are identifiable. Investigators using materials from a biobank, however, are not mandated to seek consent either personally or through biobank operators because banked materials are considered to be de-identified from the investigators' view. Although the NPRM's proposed change regarding de-identified biospecimens was not adopted, the NPRM's reasoning is illuminating. Compared with the ANPRM's focus on the potential identifiability of biospecimens, the NPRM appealed to public opinion and public trust. The NPRM contended that the enterprise of publicly funded research is increasingly untenable because of concerns about research using de-identified biospecimens without seeking consent, which the majority disfavors because of the effect on legitimate autonomy.⁶² The NPRM argued that it was necessary for the research community to seek permission from the people providing biospecimens and data to build trust and partnership with the public.⁶³ Further, surveys referred to by the NPRM⁶⁴ and related literature⁶⁵ indicated that people have a growing sense of entitlement to their materials and are willing to actively exercise those rights.

III. ETHICAL CHALLENGES AND THE NEED FOR PUBLIC ENGAGEMENT

Based on abovementioned regulatory challenges, it could be found that biobanks introduce unique ethical concerns that the Common Rule framework for human subjects research cannot completely address. In this Part, I further examine three relevant ethical questions, all of which highlight the challenges that biobanking poses to the current ethical framework. The current ethical framework has not been able to provide satisfying answers to these challenges because it fails to consider the communitarian aspects of, and the complicated socio-economic meanings behind, biobank projects.

60. See Menikoff et al., *supra* note 16, at 615. However, the two options of not seeking research subjects' consent—de-identification or IRB waiver—remain to be available in Final Rule. *Id.*

61. See *id.*

62. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53944.

63. *Id.*

64. *Id.* at 53938.

65. Ludman et al., *supra* note 46, at 6; S.B. Trinidad et al., *Research Practice and Participant Preferences: The Growing Gulf*, 331 SCIENCE 287, 287-88 (2011).

Further, a consensus towards empowerment of participants can be found among discussion of these ethical debates.

A. *Informed Consent*

Biobanking brings ethical challenges to informed consent. Informed consent requires disclosure of detailed information of research; however, it is intrinsically difficult for any biobank designed for general future use to specify all the research it will support in the future.⁶⁶ Although an alternative model, *broad consent*, has been adopted by the Final Rule and other international laws, it remains to be seen whether the broad consent really protects the subjects.⁶⁷ The new challenge to informed consent is a reason to consider whether there are aspects not covered by the existing regulatory framework.

1. Difficulties of Gaining Specific Consent and Alternatives

Specific informed consent is difficult because of biobanks' nature as resources for uncertain future research. The trend of building large-scale databases, with interconnected biospecimens and data for sharing, only serves to make the ultimate uses of materials more uncertain. Moreover, individual scientists may not be able to disclose comprehensive information in an informed consent protocol. Because a wide range of scientific expertise is brought to bear in biobank research, participating scientists may themselves have only a partial understanding of the full scope of research.⁶⁸ Further, seeking specific consent for every research program or project is costly. A strict informed consent standard may also hamper new research if important studies are thwarted by not having biospecimens and data numerous or representative enough.⁶⁹

In response to questions of specific consent, one solution is to loosen the criteria of informed consent. Although there are some who hold that specific consent should be required whenever using identifiable samples and data,⁷⁰ there are at least three alternatives with different degrees of authorization by participants: *presumed consent*, *broad consent*, and *layered con-*

66. JANE KAYE ET AL., GOVERNING BIOBANKS: UNDERSTANDING THE INTERPLAY BETWEEN LAW AND PRACTICE 291 (2012).

67. See *infra* Section III.A.1.

68. KAYE ET AL., *supra* note 65, at 290.

69. See PCSBI I, *supra* note 40, at 91; BERNICE ELGER, *Consent and Use of Samples*, in ETHICAL ISSUES IN GOVERNING BIOBANKS: GLOBAL PERSPECTIVES 57, 59 (Bernice Elger et al. ed., 2008).

70. See ELGER, *supra* note 68, at 58-59 (exemplifying that a report made by the American Society of Human Genetics (ASHG) in 1996 contended that specific consent should always be required, including both prospective and retrospective studies, while the report explicitly stated blanket consent to be inappropriate).

sent.⁷¹ The most general authorization is *presumed consent*. The Icelandic HSD Act adopted this paradigm, which automatically enrolled existing medical/healthcare data into the database and gave participants the choice of opting out.⁷² This approach has attracted controversies for infringing on subjects' autonomy. Nevertheless, it is worth noting that the PCSBI report in 2012 also recommended presumed consent. The PCSBI report prefers the opt-out model over an opt-in model, believing that both respect autonomy, but the default of participation will increase the participation rate, and thus benefit scientific and medical research.⁷³

The most widely accepted format is *broad consent* or *blanket consent*.⁷⁴ Broad consent means that participants are asked to consent to the use of their materials for any future research, provided that the research is approved by an IRB or a research ethics committee.⁷⁵ In the Final Rule, broad consent is permitted only with respect to the storage, maintenance, or secondary research uses of identifiable private information and identifiable biospecimens, in an effort to balance subjects' autonomy with practicability of research.⁷⁶ Broad consent in the Final Rule allows flexibilities on specifying information when seeking consent from research subjects.⁷⁷ Internationally, the Human Genome Organization (HUGO) recognizes that blanket consent should be allowed in some cases.⁷⁸ The model of broad consent has been widely adopted by many large biobanking projects.⁷⁹ Broad consent is more flexible for researchers, but it might be ethically problematic. Participants

71. Besides the three different types of informed consent, the PCSBI also names the fourth category— participant-centric or dynamic consent. PCSBI I, *supra* note 40, at 89.

72. NAT'L INSTS. OF HEALTH, ICELAND'S RESEARCH RESOURCES: THE HEALTH SECTOR DATABASE, GENEALOGY DATABASES, AND BIOBANKS 8 (2004), http://grants.nih.gov/grants/icelandic_research.pdf. However, presumed consent only applies to the databases of health information. Broad consent or limited consent is required in terms of biological samples unless samples are taken from clinical care treatments. *Id.* at 11-12.

73. PCSBI I, *supra* note 40, at 92.

74. Rieke van der Graaf & Johannes J.M. van Delden, *Exploring an Alternative to Informed Consent in Biobank Research*, in HUMAN TISSUE RESEARCH: A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES 15, 17 (Christian Lenk et al. ed., 5th ed., 2011).

75. Sigurdur Kristinsson & Vilhjálmur Árnason, *Informed Consent and Human Genetic Database Research*, in THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES 199, 213 (Matti Hayry et al. eds., 2007).

76. 45 C.F.R. § 46.116 (a) (2018).

77. 45 C.F.R. § 46.116 (d) (2018). Broad consent only requires general descriptions of the type of potential research, the type of information or biospecimens shared, the type of institutions or researchers, the period of time of sharing, etc. The reasonable person standard continues to apply to broad consent. See § 46.116 (a) (4), (d) (2).

78. HUGO Ethics Comm., *Statement on Human Genomic Databases* art. 4(a) (Dec. 2002), http://www.hugo-international.org/Resources/Documents/CELS_Statement-HumanGenomicDatabase_2002.pdf.

79. Kristin Solum Steinsbekk et al., *Broad Consent Versus Dynamic Consent in Biobank Research: Is Passive Participation an Ethical Problem?* 21 EUR. J. HUM. GENETICS 897, 897 (2013).

are not provided with much information before making their decision, so it is questionable whether consent given under such conditions would be valid.⁸⁰ Ethical abuses are likely to happen when participants provide samples to be used without limits because they do not have the capability to foresee risks.⁸¹

Layered consent is a model meant to compensate for the problems of blanket consent. Participants are given multiple options to give or refuse samples to be used for certain purposes or to request re-contact for consent to any research. The NBAC report proposes this model, arguing that consent forms should be developed to provide subjects with a sufficient number of options, such as: (a) refusing future use; (b) permitting only unidentified or unlinked use; (c) permitting identified or coded use for one particular research, but no further contact to ask for permission to do further studies; (d) same with (c) but with further contact permitted to ask for permission to do further studies; (e) permitting identified or coded use for any study relating to the original condition, with further contact allow to seek permission for other studies; or (f) permitting coded use for any kind of future study.⁸² Nevertheless, layered consent is criticized as too costly and too complicated.⁸³ It is also criticized for its potential to hinder large-scale population research by letting individuals opt out from the research.⁸⁴ Layered consent undermines the original purposes of revising traditional informed consent in order to facilitate the use and sharing of information, as it may result in participants' decreased or narrowed scope of collaboration.⁸⁵

Despite the fact that broad consent has been generally adopted, it is ethically debatable whether broad consent can really serve as the mechanism to protect and respect autonomy. The PCSBI finds that the majority of people are willing to share their data and agree with the existence of DNA databases, provided people can choose not to participate in the databases.⁸⁶ Studies also show that most people want to be asked whether their biological materials can be used in research, while at the same time people are willing to donate their materials to support research.⁸⁷ However, the exercise of autonomy is not expected to be too complicated and time-consuming, as surveys also find that most participants prefer to give a one-time general consent.⁸⁸ Alternative models to specific informed consent attempt to find a

80. Kristinsson & Amason, *supra* note 73.

81. ELGER, *supra* note 68, at 59.

82. NBAC, *supra* note 11, at 64-66.

83. ELGER, *supra* note 68, at 79-80.

84. *See id.* at 80-81.

85. *See id.* at 71.

86. PCSBI I, *supra* note 40, at 90.

87. Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 142-43 (2010).

88. *Id.* at 143.

balance between respecting participants' autonomy over their biological donations on the one hand, and facilitating research that involves banked materials on the other. Models of informed consent all tend to focus on the moment when participants agree to join, but biobanks are a long-term program in which participants are in an ongoing relationship with the database, which differs from the typical short-term relationship between investigators and subjects in the setting of traditional human subjects research.

2. After Consent: A Sustained and Continuing Relationship

A critical weakness of informed consent in the context of biobanking is that it simply focuses on consenting to opting-in to biobanks or not. This fails to account for the future-oriented nature of biobanks whereby participants' biospecimens and data are repeatedly used by the biobanks.

One approach to supplementing informed consent relies upon other mechanisms through which research ethics are ensured. Many scholars interpret open consent as having a different effect than specific consent. Open consent does not mean general consent to the use of data and the risks and benefits of research, but only to certain mechanisms of use and sharing of biospecimens and data. Henry T. Greely opined that broad consent should only be considered a grant of permission rather than an expression of real consent and research involving biobanks should be reviewed by an IRB with strict procedures.⁸⁹ Singurdur Kristinsson and Vilhjalmur Arnason also interpreted blanket consent to actually mean that IRBs should make decisions concerning the permissibility of future research activities.⁹⁰ Kaye and Gibbons proposed that consent be given to an agreeable form of governance and oversight of future use of materials; for example, a suitably constituted data-access committee that would oversee future use.⁹¹ These interpretations share a common emphasis on seeking an effective mechanism to protect participants' interest rather than just disclosing sufficient information regarding specific research.

Another approach proposes ongoing contact with participants after receiving the initial informed consent. Informed consent has been criticized because it only provides participants a "take-it-or-leave-it right" whereby they can either agree to or decline to participate.⁹² A study demonstrated that broad consent had the support of a majority; however, people also expressed a preference for opportunities to be informed about the use of their materials. People also expressed a desire to maintain control over, or at least have

89. Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737, 762 (1999).

90. Kristinsson & Arnason, *supra* note 75, at 213-14.

91. KAYE ET AL., *supra* note 65, at 291.

92. Evans, *supra* note 9, at 248.

some input with respect to, their stored materials.⁹³ Jonathan S. Miller proposed a model of “broad consent with recontact” in which broad consent would be obtained from participants as well as permission to recontact them.⁹⁴ Through regular recontact, biobanks could develop a sustained interaction with participants, which would stimulate an ongoing discussion between biobanks and participants.⁹⁵ Participants could ensure that they were making truly autonomous decision about the use of their materials on the basis of updated information.⁹⁶ Sustained interaction could also facilitate research on stigmatized conditions because participants would be more willing to opt into sensitive research initiatives in a context of better understanding and trust.⁹⁷ Models that seek “dynamic consent” attempt to use technologies to facilitate communication with participants and to provide participants with fairly specific options of types of research to support from which they can choose.⁹⁸

These proposed alternatives to informed consent share a goal on shifting the focus from the moment of collection to the ongoing relationship. Ongoing dialogue reinforces transparency and mutual trust. Maintaining public involvement also helps achieve good governance and efficient oversight because both of these require public input and accountability to the public. Ongoing communication is also essential for informing participants. Sophisticated civic-minded participants could contribute to biobank projects not only with their materials but also with their expertise concerning risk management, value judgments, and the pursuit of general welfare.

B. Confidentiality and Privacy

Biobanks are often considered a threat to privacy.⁹⁹ Surveys in European countries with large-scale biobank projects show that the use of personal information in genetic research is a major public concern.¹⁰⁰ While autonomy has been the major principle leading debates regarding confidentiality and privacy,¹⁰¹ discussions on challenges of big data and corresponding new

93. Christian M. Simon et al., *Active Choice But Not Too Active: Public Perspectives on Biobank Consent Models*, 13 GENETICS IN MED. 821, 828 (2011).

94. Jonathan S. Miller, *Can I Call You Back? A Sustained Interaction with Biospecimen Donors to Facilitate Advances in Research*, 22 RICH. J.L. & TECH. 1, 38 (2015).

95. *Id.* at 40.

96. *Id.* at 40-41.

97. *Id.* at 41.

98. Chalmers et al., *supra* note 4, at 10.

99. Salvor Nordal, *Privacy, in THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES*, *supra* note 73, at 181, 181.

100. *Id.*

101. According to the PCSBI’s analysis, respect for person is the most essential principle for analyzing privacy concerns of the whole genome sequencing. PCSBI I, *supra* note 40, at 21, 45-48.

regulatory proposals suggest increasing awareness of the relevance of public engagement.

1. Privacy Law Related to Biobanks

In the research context, the Common Rule stipulates that an informed consent statement shall include a description of the extent to which “the confidentiality of records identifying subjects will be maintained.”¹⁰² The Common Rule provides higher protection to identifiable biospecimens and data than anonymized ones. It allows samples obtained in clinics to be stripped of identifiers and broadly used in research without obtaining further informed consent and IRB review.¹⁰³

In the clinical context, the Health Insurance Portability and Accountability Act of 1996 (HIPAA)¹⁰⁴ is the federal law most relevant to medical privacy. Through the HIPAA, Congress delegates the HHS to enact national data privacy and security standards, by which the HHS issued Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”).¹⁰⁵ The HIPAA and its Privacy Rule apply to “covered entities,” which include (1) a health plan, (2) a healthcare clearinghouse, and (3) a healthcare provider who transmits any health information in electronic form in connection with certain electronic transactions.¹⁰⁶ If the covered entities engage with a business associate to carry out their function to provide healthcare, the HIPAA and the Privacy Rule also applies to the business associate.¹⁰⁷ Covered entities are prohibited from using and disclosing individually identifiable “protected health information” (PHI) without individuals’ authorization, unless some enumerated exceptions exist.¹⁰⁸ PHI is “individually identifiable health information” that is translated by or maintained in electronic media or other forms of media.¹⁰⁹ “Individually identifiable health information” means that the information (1) is created or received by a healthcare provider or other covered entities and (2) relates to the physical and mental health or condition of an individual, the provision of healthcare to individuals, or the payment of provisions to individuals.¹¹⁰ Also, such information is individually identifiable “with respect to which there is a reasonable basis to be-

102. 45 C.F.R. § 46.116 (a)(5) (2018).

103. See *supra* Section II.A.

104. Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

105. *Id.* § 264 (directing the Secretary of the HHS to submit standards of privacy protection); 45 C.F.R. §§160, 164 (2018).

106. 45 C.F.R. §160.103 (2018).

107. *Id.* §§ 160.102–160.103.

108. 45 C.F.R. § 164.502 (2018).

109. See 45 C.F.R. § 160.103 (2018).

110. *Id.*

lieve the information can be used to identify the individual.”¹¹¹ The Health Information Technology for Economic and Clinical Health (HITECH) Act extends privacy protection: it addresses privacy and security concerns associated with the electronic transmission of health information and strengthens civil and criminal enforcement of HIPAA provisions.¹¹² To sum up, the two major mechanisms of privacy protection of HIPAA and the Privacy Rule are de-identification and subjects’ consent.

However, even if the health information is identifiable, the Privacy Rule allows research use of PHI without individual’s authorization. A covered entity is permitted to use and disclose PHI for research purposes without individuals’ authorization, provided that: (1) the covered entity obtains an alteration or waiver of authorization approved either by the IRB or the Privacy Board; or that (2) the use and disclosure of PHI is for activities preparatory to research; or that (3) the use and disclosure of PHI is solely and necessary for research on decedents’ PHI.¹¹³ A covered entity may also use or disclose a “limited set of data” of PHI for research purposes without authorization.¹¹⁴ A “limited set of data” is PHI from which certain specified direct identifiers of individuals and their relatives, household members, and employers have been removed.¹¹⁵ According to the Privacy Rule, banked health information could be used for research without subjects’ consent even if the information is identifiable under the above circumstances. The Privacy Rules’ permission of broad categories of use without consent (including exceptions for research use) has been criticized for its departure from the HIPAA’s origin of protecting patients’ control over PHI.¹¹⁶

Another regulation applies specifically to genetic information. The Genetic Information Nondiscrimination Act (GINA) protects individuals against genetic discrimination in health coverage (Title I) and in employment decisions (Title II).¹¹⁷ Although GINA prohibits misuses of genetic information by health insurers and employers, it is an anti-discrimination law, which does not provide comprehensive data protection.¹¹⁸ GINA authorizes the HHS to revise the Privacy Rule to clarify that genetic information is

111. *Id.* De-identified health information is thus exempted from HIPAA. *Id.* §§160.502(d)(2), 164.514(a)-(b). Information is de-identified either by statistical and scientific standards or removing enumerated identifiers. *Id.* §164.514(b).

112. HITECH Act, Pub. L. No. 111-5, § 13410(d), 123 Stat. 226, 272-73 (2009).

113. 45 C.F.R. § 164.512(i) (2018).

114. 45 C.F.R. § 164.514(e) (2018).

115. *Id.*

116. Deborah C. Peel, *An Implementation Path to Meet Patients’ Expectations and Rights to Privacy and Consent*, in INFORMATION PRIVACY IN THE EVOLVING HEALTHCARE ENVIRONMENT 89, 92-93 (Linda Koontz ed., 2013).

117. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881 (codified as amended in scattered sections of 26, 29 and 42 U.S.C.) [hereinafter GINA].

118. PCSBI I, *supra* note 40, at 66-67.

health information, in order to regulate the use and disclosure of genetic information by insurers for underwriting purposes and employers.¹¹⁹

The right to know and the right not to know are also core issues of fair information practices.¹²⁰ The question in the context of biobanks is whether incidental findings shall be made known to participants. The latest trend in the Clinical Laboratory Improvement Amendments (CLIA)¹²¹ and the Privacy Rule by the HHS moves towards granting individuals greater access to their health information, in order to empower them in healthcare decisions.¹²² The CLIA and accompanying regulations limit disclosure of laboratory test results only when the laboratory complies with the CLIA standards.¹²³ A CLIA laboratory may only disclose laboratory test results to three categories of individuals or entities: authorized persons, persons responsible for using the test results in treatments, and referring laboratories.¹²⁴ An “authorized person” is defined by state laws that authorize individuals to order or receive test results.¹²⁵ This definition means that individuals may not have a right to gain access to their testing results if the state law lacks regulation. The latest amendment in 2014 broadens the scope of disclosure such that a CLIA laboratory may release completed test reports to patients by their request if the result can be identified to that patient.¹²⁶

The privacy laws just discussed do not specifically address issues of confidentiality and privacy related to biobanks. The Common Rule draws the line on identifiability in the sense that no participants are traceable and no rights are violated.¹²⁷ However, besides weaknesses in complete anonymity, another problem is that longitudinal studies cannot be carried out effectively with anonymized data that is static and not updated dynamically.¹²⁸ Most biobanks code biospecimens and data and hold the key from secondary researchers instead of stripping identifiers permanently. Although under OHPR’s guidelines coded biospecimens and data used by researchers with no access to the key are considered de-identified information,¹²⁹ the specimens and data are actually re-identifiable and the protection to privacy re-

119. GINA § 105.

120. Anita L. Allen, *Genetic Privacy: Emerging Concepts and Values*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 31, 45 (Mark A. Rothstein ed., 1997)

121. 42 U.S.C. §263a (2018).

122. The amendment has been in effect since April, 2014. See CLIA Program and HIPAA Privacy Rule: Patients’ Access to Test Reports, 79 Fed. Reg. 7290 (Feb. 6, 2014).

123. PCSBI I, *supra* note 40, at 95-96.

124. 42 C.F.R. § 493.1291(f) (2018).

125. *Id.* § 493.2.

126. 42 C.F.R. § 493.1291(l) (2018).

127. See Bartha Maria Knoppers & Ma’n H. Abdul-Rahman, *Biobanks in the Literature*, in *ETHICAL ISSUES IN GOVERNING BIOBANKS: GLOBAL PERSPECTIVES*, *supra* note 69 at 13, 17.

128. See *id.* at 17.

129. Office for Human Research Prots, *supra* note 22.

lies heavily on security. The HIPAA and HITECH Act only apply to “covered entities” and cooperating business associates, which are mostly health care providers. In this case, clinical sites collecting and storing materials are covered entities. However, given the design of biobanks to share widely, secondary users, who are usually distant from the collecting site, are not covered entities. Nor does HIPAA apply when samples are collected by researchers who are not healthcare providers, such as in population-based research that collects non-diseased samples. GINA as an anti-discrimination law has a narrow scope. It does not address many privacy concerns raised by biobanking, such as autonomy over information and bodies, security, stigmatization, and the psychological impact of research findings on individuals and groups.

2. Regaining Control of Information: Beyond Informed Consent and De-Identification

Many of the characteristics of biobanks make privacy concerns perplexing. First, biobanks’ major collections are sensitive because of the genetic information embedded in biospecimens. Moreover, biobanks are usually interlinked with other databases. The privacy issues of big data are rather complicated and the risk is difficult to evaluate. Technologies that enable re-identification challenge the protection offered by de-identification;¹³⁰ however, informed consent does not provide a particularly satisfying mechanism in response to biobanks’ new paradigm of data collection, processing, and use. The means by which biobanks control banked materials are usually complicated and alien to research participants, and therefore participants cannot meaningfully exercise control over their banked materials. Participants also have little chance to participate in shaping research through giving informed consent, but much research concerns profiling or categorizing participants. The current regulatory framework mainly relies upon the mechanisms of informed consent and de-identification, but neither of these provide satisfying solutions to the challenges posed by biobanking.

To regain control over information, several alternatives to informed consent and de-identifiability have been proposed. One suggestion is to increase transparency.¹³¹ Transparency provides information for participants

130. Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701, 1704 (2010). Re-identification science involves techniques that can unlock identities by discovering uniqueness in the remaining data, even if administrators have removed any important identifiers. Scientists found surprising uniqueness in non-personally identifiable information, such as ZIP codes, birth dates, and sex in US populations. Identification is possible through cross-referencing and analyzing these non-identifiable data points. *Id.* at 1723.

131. See Omer Tene & Jules Polonetsky, *Big Data for All: Privacy and User Control in the Age of Analytics*, 11 NW. J. TECH. & INTELL. PROP. 239, 270-72 (2013); Julie E. Cohen, *Privacy and Technology: What Privacy is For*, 126 HARV. L. REV. 1904, 1932 (2013).

necessary to decide whether to remain in the database. It also strengthens accountability of the database operators and researchers. Omer Tene and Jules Polonetsky underscore the necessity of disclosing the decisional criteria of decision-making, i.e., the factors database operators consider.¹³² They find the analysis of big data is interpretative, and factors decided by operators—such as the definition of the data set, the hypothesis, or the algorithms—affect the results.¹³³ The transparency requirement is argued to have a legal basis on due process—individuals should be informed the basis for decisions affecting their life.¹³⁴ There is also a suggestion to increase accessibility of data. Individuals should have access to the collected data in a useful format and are allowed to let their data analyzed by third-party applications.¹³⁵

Another group of suggestions for regaining control focuses on building trust in regulation. Compared to individual control (through informed consent) or technical protection (through de-identification) of information, this group of suggestions underscores the function of institutions. For instance, Yianni Lagos and Jules Polonetsky propose administrative controls as an additional layer of safeguards to de-identification that could reduce risk of a data breach.¹³⁶ Control over information is realized through public trust in institutions. Onora O’Neill proposes to build trustworthy institutions to supplement the limits of informed consent. Recognizing that individuals cannot be expected to adequately grasp the uses to which their information is put, O’Neill believes that the practical approach is to let individuals consent based on trustworthy backgrounds.¹³⁷ Paul Ohm also argues that while de-identification no longer ensures privacy, regulators should take many human factors into accounts to balance privacy and countervailing values, among which includes trust.¹³⁸ Ohm contends that the loss of trust in technology should be supplemented by trust in people.¹³⁹ The law and regulation of privacy should reflect different degrees of public trust to different institutes.¹⁴⁰

The aforementioned alternatives share a consensus view that promotes both shifting the focus from the initial stage of data collection to the later stages of data storage and use and involving people in an examination of the legitimacy of purposes as well as evaluation of risks and benefits of data

132. Tene & Polonetsky, *supra* note 130, at 271.

133. *Id.*

134. *Id.*; Neil M. Richards & Jonathan H. King, *Three Paradoxes of Big Data*, 66 STAN. L. REV. ONLINE 41, 43 (2013).

135. Tene & Polonetsky, *supra* note 131, at 264.

136. Yianni Lagos & Jules Polonetsky, *Public v. Nonpublic Data: The Benefits of Administrative Controls*, 66 STAN. L. REV. ONLINE 103, 104 (2013).

137. Onora O’Neill, *Informed Consent and Genetic Information*, 32 STUDS. HIST. & PHIL. BIOL. & BIOMED. SCIS. 689, 701-02 (2001).

138. Ohm, *supra* note 130, at 1765-68.

139. *Id.*

140. *Id.*

use. This shift responds to privacy concerns raised by genomic research and big data research, which are the main research approaches that benefit from biobanks. Both these approaches demonstrate that privacy protection requires a collective view that goes beyond individual decisions. With respect to genomic research, all human beings are part of a big family that shares approximately 99 percent of genomic data. My neighbor sharing her biospecimens containing genetic data could affect me.¹⁴¹ The success of genomic research relies upon human biospecimens, and the benefits of research that unravel the mysteries of human life or promote progress in medicine are usually beneficial to the general welfare; yet, big data analysis also has a similar communal aspect because its privacy issues are complicated and transcend individual concerns. Threats to privacy from big data collection are not just about the collection or use of each person's personal information, but rather about the privacy concerns raised by data aggregation and cross-referencing that can lead to the unexpected identifiability of data or data analysis that results in profiling or social classification that violate the self-identity of data subjects. Results could also possibly be used to categorize people in such a way that the value judgments underlying big data research negatively influence their public or private life.¹⁴² Moreover, genomics and big data usually interlink different sources of biospecimens and data. Any individual could hardly have comprehensive information concerning how their materials have been used at the moment of giving consent and thereafter. Thus, people's decisions to share their personal specimens could possibly affect each other because of the common human genome and the interconnection of data.

Public engagement is highly relevant to privacy protection. Biobanking and the research it supports utilize data in such a way that privacy is interdependent and individuals cannot protect their interests simply through their own autonomous decisions.¹⁴³ Effective privacy protection must turn to empowering data subjects. People should be encouraged to participate in debates and policy discussions regarding the proper use of their information¹⁴⁴ and the value judgments underlying algorithms or results analysis. It has also been argued that if people could access data in a meaningful and engaged manner, they would become a natural check on the inappropriate use of data and encourage compliance with privacy laws.¹⁴⁵ Barbra J. Evans also proposed to examine the collective nature of autonomy and self-governance of data citizens because autonomy entails that people have the power to organ-

141. Evans, *supra* note 9, at 250-51.

142. Cynthia Dwork & Deirdre K. Mulligan, *It's Not Privacy, and It's Not Fair*, 66 STAN. L. REV. ONLINE 35, 40 (2013).

143. Evans, *supra* note 9, at 250-51.

144. Joseph W. Jerome, *Buying and Selling Privacy: Big Data's Different Burdens and Benefits*, 66 STAN. L. REV. ONLINE 47, 52 (2013).

145. Tene & Polonetsky, *supra* note 131, at 269.

ize themselves and defend their rights through collective bargaining.¹⁴⁶ These responses to the privacy challenges of biobanks all entail strengthening public engagement as a possible solution.

C. Ownership and Benefits

An important characteristic of biobanks is that benefits generated by the scientific use of banked materials will not accrue to individual participants. However, the great potential for deriving economic value from human biological materials and increasing commercial involvement challenges the practice that donors of biospecimens and data have no rights over benefits generated from research. Benefit-sharing proposes a new paradigm to answer questions of unfairness, as subjects or donors are not recognized as owners of innovations generated from their biospecimens and data. Nevertheless, benefit-sharing alone does not solve the ethical question of distributive injustice. A just mechanism of benefit-sharing requires deliberation through public engagement.

1. Controversies over Property Rights

The question of who owns our bodies—whether we have property rights over our tissues and genetic and health information—raises many debates in the context of biobanks. Traditionally, the human body and body parts were not treated as property because they were of neither biomedical nor commercial values.¹⁴⁷ It is the modern biomedical applications, such as organ transplantation and human subjects research, that utilize the human body and grant individuals proprietary values in their bodies.¹⁴⁸ Biobanks further complicate the issue because the purpose of biobanks is to share and transmit data, a purpose which conflicts with the exclusivity of property rights.

United States' courts have decided against patients' claim to property rights over human biological materials used in research. In *Moore v. Regents of the University of California*, a patient claimed ownership over cells removed from his body later used in lucrative research; however, the court rejected the ownership argument.¹⁴⁹ The UCLA physician researchers who treated Moore were only liable to the extent that they failed to obtain informed consent by failing to disclose that they were engaged in research.¹⁵⁰

146. Evans, *supra* note 9, at 247.

147. See Remigius N. Nwabueze, *Legal Paradigms of Human Tissues*, in HUMAN TISSUE RESEARCH: A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES, *supra* note 74, at 87-88.

148. *Id.* at 88.

149. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 487 (Cal. 1990).

150. *Id.* at 480.

Later in *Washington University v. Catalona*,¹⁵¹ the court rejected the claim that participants have rights over samples they donate to biobanks. In spite of participants' right to withdraw, the right did not equate to a right to control and use the excised biological materials.¹⁵² The court also recognized that medical research can only advance if access to these materials by the scientific community is not thwarted by private agendas.¹⁵³ *Catalona* sparked debate over patients' rights versus scientific research in terms of property rights—assuming that there is property right over human tissues, whether donation extinguishes the right.¹⁵⁴ Critics of *Catalona* argue for donors' rights, believing *Catalona* is grounded in paternalistic ideas and unfairly bars patients from deciding how to use their own excised tissues.¹⁵⁵ Those who defend patients' property rights believe that, without such rights, patients' voices would not be heard by universities or biotechnology enterprises.¹⁵⁶ Furthermore, patients' loss of control over the downstream uses of their samples, and their skepticism about commercial exploitation of their biological materials, would ruin public trust.¹⁵⁷

The traditional practice favoring scientists and denying participants' contribution is questionable. Robert Mitchell describes participants as contributing "clinical labor" to a biobank.¹⁵⁸ Moreover, denying participants' control over their biospecimens does not necessarily promote free access for scientific innovation. Participants who request to withdraw usually have not done so for proprietary benefits but instead in the interest of saving their biospecimens from commercial exploitation or research viewed to be denigrating to certain racial or ethnic backgrounds.¹⁵⁹ Taken together, these controversies prove that the notion of property rights cannot appropriately address the distributive justice issues raised by biobanks.

2. Benefit-Sharing and Distributive Justice

Benefit-sharing is proposed as a new alternative for distribution between donors and users. This idea dates back to the Rio Convention on Biodiversity (CBD) of 1992, which is an attempt to acknowledge the contributions of local people with a more inclusive and nuanced view to assess their

151. Wash. Univ. v. Catalona, 490 F. 3d 667 (8th Cir. 2007).

152. Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 999 (E.D. Mo. 2006).

153. *Id.* at 1002.

154. DONNA DICKENSON, BODY SHOPPING: THE ECONOMY FUELLED BY FLESH AND BLOOD 124 (2008).

155. *See id.* at 120.

156. *See id.* at 127.

157. *Id.* at 128-29.

158. Mitchell, *supra* note 1, at 333-34.

159. Wolf, *supra* note 87, at 118.

contribution.¹⁶⁰ The CBD addresses the risk of exploitation of biodiversity and traditional knowledge and calls the recognition of contributions of local people; however, the CBD also implicitly assumes that natural resources or traditional knowledge could be subject to ownership rather than commons that is free for taking.¹⁶¹ The application of the CBD to human genome could be problematic because human genome cannot be owned by anyone, as the Human Genome Organization (HUGO) declared that human genome as a common heritage of humanity.¹⁶² Neither could people be considered to make contributions to research simply because they own certain genes.

It could be argued that benefit-sharing both addresses the conflicts of interests and fulfills the demands of redistributive justice as well. To whom the benefits of biobanking should flow and what the benefits are require further examination. The whole community, instead of individuals, is considered to be the appropriate subject to be rewarded in order to prevent controversies regarding the property right and undue inducement.¹⁶³ As for what benefits to share, the HUGO Ethics Committee considered that the benefits are not identical with proprietary profits, but should be determined based on needs, values, priorities and cultural expectations.¹⁶⁴ Benefits could be shared in the other forms besides financial interests, such as access to healthcare or public dissemination of research results.¹⁶⁵ The ideas of sharing with the community and sharing both proprietary and non-proprietary benefits imply that benefit-sharing is based on equity, not on recognition of subjects' proprietary right over their donations.¹⁶⁶

Benefit-sharing seems to provide justification for the biobank mechanism, but it does not constructively deal with the conflict of interest between participants and researchers. An access fee is usually required to be paid by users— researchers of banked materials and data— especially those who seek commercial benefits. However, the question remains as to whether users could be required to pay back more than access fees. An empirical study finds that practitioners around the world, despite agreeing that certain benefit-sharing schemes should exist, have little consensus on how such schemes should operate.¹⁶⁷ Because benefit-sharing provides social compensation and

160. See Kadri Simm, *Benefit-Sharing and Biobanks*, in *THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES* *supra* note 75, at 159, 160 n. 4, 161.

161. See *id.*; Cori Hayden, *Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-Sharing*, 37 *SOC. STUDIES OF SCI.* 729, 735 (2007).

162. See Simm, *supra* note 158, at 161.

163. Hayden, *supra* note 159, at 746.

164. Simm, *supra* note 160, at 166.

165. See *id.* at 166-67.

166. Hayden, *supra* note 160, at 742-43.

167. Agomoni Ganguli-Mitra, *Benefit-Sharing and Remuneration*, in *ETHICAL ISSUES IN GOVERNING BIOBANKS*, *supra* note 69, at 217, 228.

acts as a foundation for public trust to biobank projects,¹⁶⁸ the institution of benefit-sharing should also be formed through a legitimate process. One of the recommendations made by the HUGO's "Statement on Benefit-Sharing" also notices that "there [should] be prior discussion with groups or communities on the issue of benefit-sharing."¹⁶⁹

Cori Hayden maintains that benefit-sharing allows for a new approach of "giving-back" as the legitimacy of science, compared to the "speaking-for" approach taken by social and anthropological studies of science.¹⁷⁰ The speaking-for approach recognizes that scientific knowledge not only depicts the nature, but also represents or "speaks for" different interests in the society.¹⁷¹ Based on the speaking-for approach, legitimate science requires inclusion of people to represent their interests, such as those public participation initiatives in policy-making on bioscience.¹⁷² By contrast, benefit-sharing represents a different model of legitimate science that research is something that can "give back."¹⁷³ However, the issue of inclusion and political representation is as essential for giving-back as speaking-for. Benefit-sharing does not pay interests back to individuals, given its origin from respect of the local community or ethical concerns against undue inducement to research subjects; instead, benefits should return to the community or the collective.¹⁷⁴ Hayden argues that benefit-sharing does not simply address the unequal relations of exchange, but rather it concerns the broader issue of mechanisms of distribution and redistribution.¹⁷⁵ The ethics of benefit-sharing has to deal with the question of the forms of political representation and the mode of resource allocation.¹⁷⁶ Advocates of benefit-sharing by biobank operators and researchers have been paying less attention to the politics of distribution, which may result in benefit-sharing to be skeptically a slogan to facilitate research instead of serving the social compensation duty. A justifiable benefit-sharing mechanism is based upon a speaking-for democracy. Public engagement is necessary for justifiable distribution.

168. Dianne Nicol & Christine Critchley, *What Benefit Sharing Arrangements Do People Want from Biobanks? A Survey of Public Opinion in Australia*, in *PRINCIPLES AND PRACTICE IN BIOBANK GOVERNANCE* 17, 28 (Jane Kaye & Mark Stranger eds., 2009).

169. HUGO Ethics Comm., *Statement on Benefit-Sharing* (Apr. 9, 2000), http://www.hugo-international.org/Resources/Documents/CELS_Statement-BenefitSharing_2000.pdf.

170. Hayden, *supra* note 160, at 732-33.

171. *Id.* (referring to Bruno Latour's notions that "science as itself a 'parliament' or a process of forging a new 'democratic collective,'" and that "scientific knowledge performs a kind of double representational act, bringing the realms of nature and politics together in one fell swoop.").

172. *Id.* at 732-33.

173. *See id.* at 746-747.

174. *Id.* at 734-41.

175. *Id.* at 747-48.

176. *Id.* at 753.

D. Public Engagement as a Solution to Ethical Challenges

The three previously discussed ethical controversies surrounding biobanks demonstrate that biobanks challenge the current ethical framework. Discussions of these three issues suggest that it is necessary to empower participants to have a more active role than their current status permits. Debates over the appropriate models of consent have gradually shifted the focus to establishing long-term relationships with participants and continuing to involve participants after consent is obtained. Debates concerning confidentiality and privacy demonstrate that individuals have minimal control of their materials once they opt in to a biobank project. Privacy is also interdependent in the context of biobanking where participants must empower themselves through participating in collective decision-making rather than exercising discrete individual choices. Debates concerning ownership and benefits also indicate that a fair distribution of benefits requires a scheme formed through public engagement. In fact, the importance of public engagement has been highlighted by ethicists and policymakers; moral and normative calls for public engagement have continued to grow louder.

IV. ETHICAL AND NORMATIVE CALLS FOR PUBLIC ENGAGEMENT

The current ethical framework cannot adequately address the challenges posed by biobanking, but public engagement or participation has come to be seen as a *sine qua non* for biobanking activities.¹⁷⁷ The calls for public engagement have arisen on the basis of various ethical reasons and purposes that are identified and evaluated hereafter. Further, the latest professional and policy guidelines also serve as normative evidence in support of the necessity of public engagement. Such normative evidence further demonstrates that public engagement must be considered in biobanking regulation and governance.

A. Ethical Reasons for Public Engagement

1. The Collective Nature of Biobanks

Arguments in favor of public participation take into account the defining characteristics of biobanking. One reason to favor public engagement is because it relates to the national identity as well as to community benefits. Advocates of biobanks have linked biobanks to the work of nation-building¹⁷⁸ with respect to the role biobanks play in reinforcing or shaping the notions of nation, citizenship, and community. Barbra Prainsack exam-

177. See Knoppers & Abdul-Rahman, *Biobanks in the Literature*, in *ETHICAL ISSUES IN GOVERNING BIOBANKS: GLOBAL PERSPECTIVES*, *supra* note 127, at 13.

178. See GOTTWEIS & PETERSEN, *supra* note 2, at 10.

ined three Israeli biobanks and discovered that they were designed to preserve genetic components of the “collective body” of Israel.¹⁷⁹ The three biobanks attempted to reflect the “homogeneity” of the population, conceiving of the collective body of Israel as Jewish, notwithstanding the fact that 23 percent of the population is non-Jewish.¹⁸⁰ Biobanks are a method for shaping identities of an entire community, and thus require democratic legitimacy, which depends on public engagement.

Other collective features of biobanks also demonstrate the importance of public engagement. The effects achieved and interests promoted by biobanks are beyond the individual. Thus, participants must be involved in a process of shared decision-making. Because risk assessment is difficult, this aspect of biobanking also implies a need for public engagement. Biobanks involve genomic science and data interlinkage, both of which generate uncertain risks. Nevertheless, these uncertainties are not simply scientific and medical issues that could be solved through technology, but rather are issues that combine complex scientific and societal factors. Public engagement can open the process of risk management to different stakeholders beyond scientific and academic professionals.

2. Communitarianism and the Common Good

Another argument in favor of public engagement arises from the communitarian turn aiming to revise the individualistic assumption of bioethics. The impact of research on groups is particularly relevant in the context of biobanks whose mission is to sponsor and enable research to enhance public health. The NBAC report points out the limits of an individualistic interpretation for its failure to address group needs or group harms.¹⁸¹ The NBAC report proposes to involve certain groups when designing research protocols, because the research may have negative impacts on those groups.¹⁸² Yet, paradoxically, biobank projects often use a rhetoric suggesting that their benefits will come from personalized medicine or individually tailored treatments and therapies.¹⁸³ The communitarian turn is not simply based on consideration of group impacts but also on the necessity of revisiting the relationship between individuals and collectives that has been a core issue in public health.¹⁸⁴

179. See Barbra Prainsack, *Research Populations: Biobanks in Israel*, 26 *NEW GENETICS AND SOC.* 85, 85, 97 (2007).

180. See *id.* at 97.

181. See NBAC, *supra* note 11, at 46-47.

182. *Id.* at 50.

183. Ruth Chadwick & Mark Cutter, *The Impacts of Biobanks on Ethical Frameworks*, in *THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES*, *supra* note 75, at 219, 224.

184. *Id.* at 225.

The main idea of the communitarian turn is the common good, which emphasizes public engagement over individual informed consent. A biobank is an institution constituting social assets and communitarian values.¹⁸⁵ The common good perspective holds that a good life is maintained by social conditions that make it possible to form opinions about what kinds of life community members want to live.¹⁸⁶ The common good is the prerequisite for the protection of individual freedom and rights.¹⁸⁷ In light of the common good, individual autonomy has been better respected and protected by participants' discussion of the common good influencing the priorities of research use, rather than by strict criteria of informed consent.¹⁸⁸

Some even believe that there is a moral obligation for each community member to contribute to the communal biobank project based on the common good. Rosamond Rhodes argues that society should institute obligatory participation in medical research at regular intervals for all citizens, considering that human beings are vulnerable to injuries and diseases and contributions of clinical research to the all human beings.¹⁸⁹ John Harris proposes that participation in research is a moral duty resulting from non-maleficence and justice.¹⁹⁰ Lars Oystein Ursin and Berge Solberg also argue for a moral obligation to participate because medical research is usually "politicized" through concepts such as citizenship, community, and patriotism, while the reason to oppose research is also political.¹⁹¹ These arguments for moral obligation in medical research usually describe participation in research out of a sense of community membership or citizenship.¹⁹² Thus participants should be involved in a way similar to their exercise of citizenship, in a way that goes beyond informed consent.

3. Good Governance

The third argument for broader public engagement is based on a belief that participation is the principle of good governance. First, a practical consideration is the influence of participants and stakeholders, as biobanks rely on the support of participants and many other social resources. Kaye et al.'s

185. Erik Christensen, *Biobanks and Our Common Good*, in *THE ETHICS OF RESEARCH BIOBANKING* 101, 103 (Jan Helge Solbakk et al. eds., 2009).

186. *See id.*

187. *See id.*

188. *Id.* at 112.

189. Lars Øystein Ursin & Berge Solberg, *The Health Dugnad: Biobank Participation as the Solidary Pursuit of the Common Good*, in *THE ETHICS OF RESEARCH BIOBANKING*, *supra* note 185 at 219, 220.

190. *Id.* at 221.

191. *Id.* at 235.

192. Some hold the view that participation in medical research is a civic obligation, similar to paying taxes or military conscription; however the obligation is not legally compulsory. *See* SØREN HOLM ET AL., *Conscription to Biobank Research?* in *THE ETHICS OF RESEARCH BIOBANKING*, *supra* note 185, at 255, 256-57, 261-62.

empirical studies find that many practitioners of biobank research regard stakeholders' concerns as important, despite the fact that these stakeholders currently do not have any direct role in the regulatory framework.¹⁹³ Public engagement is relevant because it helps those who run biobanks understand and respond to public concerns.

Moreover, public engagement helps change the power asymmetry in the current governance framework. Traditionally, research ethics relies heavily on self-governance and lacks transparency. Critics to informed consent argue that this emphasis works to entrench power inequality between researchers and participants.¹⁹⁴ To challenge the current power asymmetry, a new approach to governance needs not only to disclose information, but also needs mechanisms for communication and representation to build partnerships with participants,¹⁹⁵ such as including donor representation in the governing body of a biobank. Biobank operators' and researchers' accountability would be strengthened through mechanisms of empowerment, were participants granted a more equal position from which to evaluate potential risks and benefits of research.

4. Public Trust

The fourth frequently mentioned reason for public engagement is to build public trust, which is particularly relevant for large-scale biobanks run or sponsored by public funds.¹⁹⁶ Besides the intuitive argument that trust is important because biobanks would fail without the support of participants and society, there are also several features that make trust crucial. First, the operation of biobanks involves risks, safety, and security matters that cannot be solved by technical advancement alone, for these are matters of intertwined social and scientific factors. These matters are also connected to the notion of responsibility, such as questions as to whether biobank operators and researchers can show enough trustworthiness to deal with them properly and effectively.¹⁹⁷ Moreover, while there are many purposes publicized to

193. KAYE ET AL., *supra* note 65, at 291. Kaye et al. recognized that it is necessary to consider stakeholders' interests and concerns; however, they believed that granting stakeholders a direct voice in biobank governance may go too far. *Id.*

194. Nadja K. Kanellopoulou, *Reciprocity, Trust, and Public Interest in Research Biobanking: In Search of a Balance*, in HUMAN TISSUE RESEARCH: A EUROPEAN PERSPECTIVE ON THE ETHICAL AND LEGAL CHALLENGES, *supra* note 74, at 45, 47-48.

195. *Id.* at 51-52.

196. According to a survey of four European countries with national biobanking projects, trustworthiness is the main concern among them. Respondents agreed with the importance of bioscientific research but were cautious about privacy issues. MATTI HAYRY & TUJJA TAKALA, *Bioethical Analysis of the Results: How Well Do Laws and Regulations Address People's Concerns?* in THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES, *supra* note 75, at 249, 250.

197. Cornelia Richter, *Biobanking: Trust as Basis for Responsibility*, in TRUST IN BIOBANKING 43, 43 (Peter Dabrock et al. eds., 2012).

promote biobank initiatives and some of them conflict with each other, such as commercialization and public benefits, there seem to be no mechanisms to oversee whether all the purposes are appropriately pursued.

Legislation has been a way to build public trust by forcing biobanks to submit to management in compliance with ethics,¹⁹⁸ yet legislation's focus on informed consent and data protection does not fully address trust.¹⁹⁹ Trust is not necessarily built through informed consent or assured by legal contracts. According to Cornelia Richter, "[t]rust is built through recognition; it may evolve when people think and act similarly or loyally support each other's otherness."²⁰⁰ Richter argues that trust is based on social stability gained from social consensus but not restricted to traditional life,²⁰¹ and it should take into account more than knowledge and consent by considering the sense of uneasiness, fear, and need for security.²⁰² In this sense, public engagement plays a role in building and affirming trust as a necessary process to shape consensus and recognition as well as to form respectful relationships between different stakeholders. Public engagement is especially relevant to assuring biobanks' public health purpose whenever trust is undermined by commercialization. Klaus Hoeyer finds that the health needs pursued by biobanks are co-produced with social definition of and knowledge about health and illness, while commercialization might bias the judgment.²⁰³ Hoeyer thus argues for multiple decision-making regimes to consider broader views and to prevent a homogenization of decision-making according to a market-oriented priority.²⁰⁴ Public engagement could serve as the mechanism for legitimate decision-making as well as providing check and balance to commercial uses.

Paradoxically, critics of trust also originate from the perspective of enhancing public engagement. Critics contend that trust relies upon the authority of experts, making the assumption that experts are the ones competent to know the correct answer and to make the right decisions.²⁰⁵ However, in reality issues regarding biobanks encompass genuinely uncertain and unpredictable factors.²⁰⁶ Critics believe that trust-building is intrinsically in conflict with public engagement. A trusting person is "an intermediary state

198. HAYRY & TAKALA, *supra* note 196, at 253.

199. See Pascal Ducournau & Roger Strand, *Trust, Distrust and Co-Production: The Relationship Between Research Biobanks and Donors*, in THE ETHICS OF RESEARCH BIOBANKING, *supra* note 185, at 115, 117; Klaus Hoeyer, *Trading in Cold Blood? Trustworthiness in Face of Commercialized Biobank Infrastructures*, in TRUST IN BIOBANKING, *supra* note 197 at 21, 35.

200. Richter, *supra* note 197, at 45.

201. *Id.*

202. *Id.* at 42.

203. Hoeyer, *supra* note 199, at 35.

204. *Id.*

205. Ducournau & Strand, *supra* note 199, at 127.

206. *Id.*

between being knowledgeable and ignorant[,]” implying an abstention from exercising critical and autonomous judgment.²⁰⁷ Emphasizing public trust reproduces the asymmetry between experts and laypeople, implying that lay participants are incapable of participating in biobank governance.²⁰⁸ Pascal Ducournau and Roger Strand thus argue that democratic participation is necessary in order to heighten the quality of scientific research as well as to improve the scientific knowledge’s relevance to the general public.²⁰⁹ Vilhjálmur Árnason also proposes an opt-out system with informed trust to re-consent, believing that dynamic interchanges with participants offer better conditions for empowerment.²¹⁰

The aforementioned ethical reasons that suggest the need for public engagement reflect that participation in a biobank project is not simply an individual choice, but also involves a citizen’s choice to participate in public affairs. Features of biobanks indicate that these projects are the concern of the whole community in need of a communal method of governance, (re)distribution, and identity-formation. Given this communal nature, public engagement is necessary, not only to achieve practical goals such as gathering enough samples or gaining enough public investment, but also to achieve normative aims such as democratic legitimacy and accountability. Some rationales for public engagement also contend that citizens have a moral duty to contribute to biobank projects, and in turn contend that citizens should be empowered to share in decision-making. Such rationales link biobanks with citizenship and thereby further strengthen the role of public engagement in biobanking.

B. Normative Evidence for Public Engagement

An emerging consensus with respect to the necessity of public engagement is also evident in policy and ethical guidelines regarding biobanking. Such guidelines also provide normative grounds for public engagement because they usually urge the relevant authorities to formulate laws or policies employing their principles.²¹¹ They also serve as important references for governmental lawmaking and biobank operators’ policymaking.

Public engagement has been highlighted in international documents. The World Medical Association published the Declaration of Taipei on Eth-

207. *Id.* at 118.

208. *Id.* at 125.

209. *Id.* at 129.

210. Vilhjálmur Árnason, *Scientific Citizenship, Benefit, and Protection in Population-Based Research*, in *THE ETHICS OF RESEARCH BIOBANKING*, *supra* note 185, at 131,137.

211. *WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks*, *WORLD MED. ASS’N* para. 24 (Oct. 2016), <https://www.wma.net/policies-post/wma-declaration-of-taipei-on-ethical-considerations-regarding-health-databases-and-biobanks/>; UNESCO Int’l Bioethics Comm., *Report of the IBC on Big Data and Health*, para. 117, U.N. Doc. SHS/YES/IBC-24/17/3 Rev.2 (Sept. 15, 2017).

ical Considerations Regarding Health Databases and Biobanks (Declaration of Taipei) in 2016.²¹² Based on ethical principles governing human subjects research, the Declaration of Taipei noted that large-scale databases collecting biospecimens and data have the potential to promote new research strategies but also create risks for misuse and abuse of those databases.²¹³ The Declaration of Taipei intended to find an ethical standard that would take into account the research participants' willingness and trust in addition to ensuring a high standard of protection of their rights.²¹⁴ In addition to the right to consent, the Declaration also explicitly declared that participants have a right of access to their data as well as the right to correct it.²¹⁵ Moreover, the Declaration requires databases to be responsible to the whole community rather than simply to participants. Principles of good governance espoused in the Declaration exhibit a broad scope that goes beyond database participants: transparency requires that relevant information be available to *the public*; participation and inclusion requires database operators to involve participants as well as *their communities*; and accountability requires responsiveness to *all stakeholders*.²¹⁶ The mandate to be accountable to the general public reflects the communal nature of databases such as biobanks that have purposes and benefits that affect the entire public.

The International Bioethics Committee (IBC) of the United Nations Educational, Scientific and Cultural Organization also underscored the importance of public engagement in its report on big data and health.²¹⁷ The report proposed that biobanks or large databases designed for broad future research adopt "dynamic consent."²¹⁸ Dynamic consent empowers participants to monitor data with the help of information technology.²¹⁹ Participants are involved in an ongoing fashion and they can "vote for" or opt out of research depending on whether they support it—this turns the project into a joint enterprise between participants and researchers and lowers the risk of exploitation.²²⁰ The IBC also deemed citizen involvement or engagement to be an element of good governance that would prevent the exploitation, manipulation, or improper control of data.²²¹ Citizen involvement is not simply a preferable approach for protecting individual rights. The report indicated

212. *Declaration of Taipei*, WORLD MED. ASS'N, <https://www.wma.net/what-we-do/medical-ethics/declaration-of-taipei/> (last visited Oct. 8, 2018).

213. *Id.*

214. *Id.*

215. *WMA Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks*, *supra* note 209, at para. 14.

216. *Id.* para. 20.

217. *See generally* UNESCO Int'l Bioethics Comm., *supra* note 211. The scope of this report includes databases such as biobanks. *See id.* para. 51.

218. *Id.* paras. 51, 55.

219. *Id.* para. 55.

220. *Id.*

221. *Id.* para. 103.

the problem of democratic legitimacy that besets most big data projects. Big data projects or databases promise to deliver public benefits; however, those projects usually lack a democratic mandate from the people in which the notion of public good is defined.²²² In light of the questionable publicity of big data projects or databases, an ethical governance framework must guarantee that a real public good is promoted.²²³ With respect to the elements contributing to good governance, the IBC also mentioned engaging participants through various means such as keeping participants informed²²⁴ or involving them in the design of governance procedures over service providers.²²⁵ The IBC considered public engagement to be not only a safeguard for individual rights but also a mechanism for oversight or a check on the publicity of big data projects or databases.

Public engagement is at the core of the Precision Medicine Initiatives (PMI)'s guidelines, the Privacy and Trust Principles ("PMI Principles"). The PMI Principles were drafted by an interagency working group assembled by the White House, and their task was to consider and finalize an ethical guideline over the activities of the initiatives.²²⁶ Despite sharing certain similar ethical commitments with other guidelines concerning biobanks, the PMI Principles do not address much with respect to the appropriate approach for handling difficult ethical problems. The PMI Principles instead articulate guidance based on the initiatives' spirit—participants as partners.²²⁷ The PMI Principles are based on an appeal to people to engage in the science of medicine as active collaborators and to not only share their biospecimens and data but also to participate in decision-making concerning the use of stored materials.²²⁸ Epitomizing this spirit, the first rule of the PMI Principles stipulates that "[g]overnance should include substantive participant representation at all levels of program oversight, design, implementation, and evaluation."²²⁹ The second principle also stipulates that "[g]overnance should create and maintain active collaborations" among various stakeholders.²³⁰ In addition to citizen participation in governance, two more major approaches for strengthening the partnership with civil society

222. *Id.* para. 104.

223. *Id.*

224. *Id.* para. 109(o).

225. *Id.* para. 109(q).

226. *Precision Medicine Initiative: Privacy and Trust Principles*, NAT'L INST. OF HEALTH, <https://allofus.nih.gov/about/program-overview/precision-medicine-initiative-privacy-and-trust-principles#precision-medicine-initiative-privacy-and-trust-principles-6> (last visited Oct. 8, 2018) [hereinafter PMI Principles].

227. PMI WORKING GROUP, *supra* note 7, at 1.

228. *See id.*

229. *Governance*, NAT'L INST. OF HEALTH, para. 1, <https://allofus.nih.gov/about/program-overview/precision-medicine-initiative-privacy-and-trust-principles#precision-medicine-initiative-privacy-and-trust-principles-1> (last visited Oct. 8, 2018).

230. *Id.* para. 2.

are proposed. One is the empowerment of participants, which aims to improve participants' understanding and to facilitate participants' access to their information in consumer-friendly ways.²³¹ The other is respecting participant preferences—the PMI should involve participants in a dynamic and ongoing dialogue on the use and sharing of data, permitting them to exercise their autonomy in a meaningful way.²³² Compared with other ethical or policy guidelines, the PMI Principles further propose concrete directions for achieving public engagement in a project that operates a large-scale database.

To summarize, guidelines underscoring public engagement are supported by both normative and practical reasons. The importance of public engagement results from the fact that many biobanks or similar large-scale databases appeal to citizen engagement. The PMI and the PMI Principles provide a key example of the connection between the two trends. The PMI seek to leverage a highly engaged population, collect abundant data, and “usher in a new and more effective era of American healthcare.”²³³ The PMI also aim to reflect the diversity of the population in sampling,²³⁴ which sounds quite similar to a governance body that is mandated to represent the political diversity of the people. The PMI and other recent guidelines seem to endorse the approach of people-powered science in which people work together to assemble large-scale resources for research and also enjoy a certain degree of self-governance.²³⁵ Here, self-governing means not only rights but also responsibilities to actively participate. Another reason for participation is that the human genome is the commons, and people share mostly the same genes and are interdependent. Scholars describe the rights as well as responsibilities as *genomic citizenship*—individuals have rights and responsibilities to access genomic information as well as participate in decision-making on matters that affect the community or even the nation.²³⁶ Many biobanks face ethical or financial challenges; citizens who are invested in biobanks help to sustain those databases. The link between citizens and biobank projects demonstrates the relevance of public engagement. Participants as well as stakeholders, based on their citizenship, should have the

231. *Participants Empowerment Through Access to Information*, NAT'L INST. OF HEALTH, para. 3, <https://allofus.nih.gov/about/program-overview/precision-medicine-initiative-privacy-and-trust-principles#precision-medicine-initiative-privacy-and-trust-principles-3> (last visited Oct. 8, 2018).

232. *Respecting Participant Preferences*, NAT'L INST. OF HEALTH, para. 2-3, <https://allofus.nih.gov/about/program-overview/precision-medicine-initiative-privacy-and-trust-principles#precision-medicine-initiative-privacy-and-trust-principles-3> (last visited Oct. 8, 2018).

233. PMI WORKING GROUP, *supra* note 7, at 1.

234. *Id.* at 2.

235. Evans, *supra* note 9, at 262.

236. Sabatello & Appelbaum, *supra* note 8, at 292-93.

right as well as responsibility to join in governance or collective decision-making of biobank projects.

V. MAKING PUBLIC ENGAGEMENT POSSIBLE: VARIOUS APPROACHES

Given the importance of public engagement, the next question is how people may become engaged. In the following section, I will review different models of public engagement. The origins and practices of these models reflect an awareness of the limits of current research ethics and the need for public engagement in the context of biobanks. These models not only propose different approaches of how to involve the public, but also reveal different views of how to incorporate the idea of public engagement into research ethics. A summary of the models reviewed appears in appended *Table 1*.

A. Community Engagement

Models of community engagement can be categorized based on the presence or absence of “teeth” (i.e., having the legally-binding power to enforce compliance) into *group consent* and *community consultation*, respectively. Group consent grants groups veto power and community consultation treats communication with the community as a supplement to regulatory requirements for biomedical research.

1. Group Consent

The notion of group consent can be traced to the Model Ethical Protocol (hereinafter “the Protocol”), which was drafted by the North American Regional Committee (NAAmC) of the Human Genome Diversity Project (HGDP) in response to criticisms raised by advocates of indigenous movements.²³⁷ The Protocol contends that group consent is required in addition to individual consent because of the group-defining nature of HGDP’s population research.²³⁸ The Protocol requires researchers to seek informed consent through the subject community’s “culturally appropriate authorities where such authorities exist” before they begin sampling.²³⁹ Researchers may seek consent from the larger group provided the existence of a “larger identity among the population” and “the existence within the broader group of entities that the population itself recognizes as culturally appropriate authori-

237. JENNY REARDON, RACE TO THE FINISH: IDENTITY AND GOVERNANCE IN AN AGE OF GENOMICS 98-99 (2005).

238. Dr. Kenneth M. Weiss et al., *Proposed Model Ethical Protocol for Collecting DNA Samples*, 33 HOUS. L. REV. 1431, 1443 (1997).

239. *Id.* at 1443-44.

ties.”²⁴⁰ Compared to the Common Rule, which only requires individual consent without granting the group any role, the notion of group consent further extends the notion of informed consent, regarding groups as the subject of consent. However, most believe that group consent does not replace individual consent but serves as an additional layer of safeguard.²⁴¹ Group consent is described to grant a “veto power” to the study population,²⁴² that is, the study population has the power to approve or veto research protocols despite consent obtained from individuals.

Critics of group consent target two major assumptions held by the Protocol. First, the assumption that these groups exist and could serve as an appropriate unit for consent (the Protocol expects scientific researchers to define groups by their sampling criteria²⁴³). Second, the assumption that an authority exists that is capable of consenting on behalf of the whole group.²⁴⁴

As to the first of these, critics point to the complexity of “groupness,” while the Protocol assumes that groups could be defined by researchers’ sampling criteria. Defining groups or communities is never simple or clear-cut but comes with varying criteria. For instance, the Canadian debates regarding the definition of “community” in public health policy include at least three divergent but overlapping perspectives, such as population, culture, and nation.²⁴⁵ The variant delineations of community reveal that the definition of group is neither “natural” nor neutral.²⁴⁶ The subjective ap-

240. For example, the Navajo group is one of the large populations among Native Americans speaking Na Dene. The Navajos consider themselves as an independent group with its people and culture. There is a Navajo tribal government comprising a President and a tribal council. When investigators intend to take samples in a Navajo village, they must seek consent both from the village and the tribe. *Id.* at 1444-45.

241. See Richard R. Sharp & Morris W. Foster, *An Analysis of Research Guidelines on the Collection and Use of Human Biological Materials from American Indian and Alaskan Native Communities*, 42 JURIMETRICS J. 165, 177 (2002); Joan L. McGregor, *Population Genomics and Research Ethics with Socially Identifiable Groups*, 35 J. L. MED. & ETHICS 356, 366 (2007).

242. Richard R. Sharp & Morris W. Foster, *Involving Study Populations in the Review of Genetic Research*, 28 J.L. MED. & ETHICS 41, 41, 42 (2000).

243. REARDON, *supra* note 237, at 100.

244. *Id.*

245. See Fern Brunger, *Problematising the Notion of “Community” in Research Ethics*, in POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES 245, 248-53 (Bartha Maria Knoppers ed., 2003). Community as population considers the group identity—including race, gender and social classes—in relation to risks of disease. Community as culture echoes multiculturalism movements and policy, assuming the community shares similar interests and advocates a culturally sensitive approach to health care. Community as nation not only imagines the community as highly homogeneous and cohesive but also grants it clear political authority. This perspective is significant regarding the aboriginal community since the term “research” is usually synonymous with exploitation and group consent is supported by both political empowerment of aboriginal communities as well as the federal multicultural policy of respect for cultures. *Id.*

246. *Id.* at 246.

proach to self-definition is also taken up by aboriginal communities as a political struggle for their power and rights.²⁴⁷ In contrast, the Protocol takes the notion of community as being able to be defined objectively and scientifically by assuming the group exists and could be defined by researchers. This perspective closes off the possibility of open debates about the existence of groups and the appropriate way to define groups. Researchers' authority of definition might even reinforce the colonial notion of race and indigeneity.²⁴⁸ In fact, the North American Regional Committee (NARC) of the HGDP drafted the Protocol in response to indigenous movements, whose primary concern is that the HGDP reinforces a colonial aspect over their identity and threatens their autonomy.²⁴⁹ Yet the Protocol was drafted upon a belief that groups can be demarcated and substantiated by scientific evidence without involving broader societal and moral debates. Group consent thus does not provide a satisfying proposal for respecting group autonomy.

The more essential problem is that group consent might reinforce racial categories from a biological basis. Skeptics to population-based research or research based on race are concerned about the possibility that genetic differences might be used to justify discrimination against minorities. One argument is that health disparities among populations are complicated matters that involve various biomedical and societal factors, of which genetic variation is only one. This view worries about genetic reductionism or genetic determinism that overestimates the power of genetic research to disclose the secrets of human lives and diseases, while neglecting other factors affecting health status.²⁵⁰ Another argument contends that the racial category is not scientifically significant but rather socially constructed. Sandra Soo-Jin Lee et al. point out that the genetic variation within human populations is greater than that between population groups.²⁵¹ Using racial categorization in a research design implies an anticipation of finding differences between populations, but this anticipation is biased and may preclude more nuanced studies.²⁵² This view also argues against genetic reductionism or genetic determinism that understands identities as ascribed by science instead of by self-identification.²⁵³ Some above-mentioned examples of how biobank projects have served as nation-building or as governance to reinforce national

247. See REARDON, *supra* note 237, at 100, 103.

248. *Id.* at 100.

249. *Id.* at 105.

250. Sandra Soo-Jin Lee et al., *The Meaning of "Race" in the New Genomics: Implications for Health Disparities Research*, 1 YALE J. HEALTH POL'Y L. & ETHICS 33, 38-39 (2001); McGregor, *supra* note 241, at 362.

251. Lee et al., *supra* note 248, at 39.

252. *Id.* at 42.

253. *Id.* at 52. As Lee et al. describe, this is a shift of explanatory power into genetic discourse in identity politics. *Id.*

identity could be adduced again as examples of population-based research being used to maintain or reinforce current social categories or identities. Group consent is criticized because it either enforces categorizations by science or reinforces existing categorizations by providing scientific support for them—both of which run contrary to the original purpose of group consent to respect participants' and the community's autonomy.

The second locus of criticisms directed at group consent surrounds who has the authority to speak for group members. The Protocol says that researchers shall seek consent from "culturally appropriate authority" or "institutions that provide a useful focus for community discussions and consensus," such as the tribal government or "informal authorities" like "elders, religious leaders, traditional leading families or clans, or other people recognized within the culture as having authority."²⁵⁴ Conceding to difficulties in seeking candidate cultural authority, the Protocol encourages the IRB to demand explanation from researchers about this.²⁵⁵ However, critics find that it is difficult, practically speaking, to find the cultural authority if the group lacks political structure, especially when the group in question is geographically diffused.²⁵⁶ A theoretical criticism also considers that group consent undermines variations within a group. Minorities or vulnerable members of the group are usually not well represented if they do not have equal standing in the community.²⁵⁷ Group consent assumes homogeneity in the group, yet even within a group of certain homogeneity there are still diverse values regarding what is the common good.

A more fundamental question might be why a group has a moral right to speak for its members. Here I argue that empowerment of participants, rather than respect for communitarian values, is the real justification for group consent. Most of the above-mentioned critics take issue with the communitarian assumption, which regards individuals as self-identified through their group identities and not isolated atoms. In this sense, individual autonomy remains the focus, which is also what group consent really intends to protect. Group consent may still be found to be unsatisfying because individual identities are too complicated to be simply defined as the subject of informed consent. Neither does this communitarian assumption provide solutions to conflicts existing between individuals and groups. Ad-

254. Dr. Kenneth M. Weiss et al., *supra* note 238, at 1146.

255. *Id.*

256. McGregor, *supra* note 241, at 366.

257. See Erica Haimes & Michael Whong-Barr, *Competing Perspectives on Reasons for Participation and Non-Participation in the North Cumbria Community Genetic Project*, in POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES, *supra* note 245, at 199, 212; Henry T. Greely, *Informed Consent and Other Ethical Issues in Human Population Genetics*, 35 ANNUAL REV. GENETICS 785, 794 (2001) (mentioning that the federally recognized tribal or national government is not necessarily representative to minorities within its group).

vocates of group consent mostly agree that individual consent cannot be waived, but they pay little attention to the power structure within the group. Granting the group veto power seems to be paternalistic or even morally hazardous because group consent does not necessarily enhance individual autonomy. Lee et al. propose to return to individual consent because the individual decision itself reflects values of collectives whom the individual is embedded in.²⁵⁸

However, the history of the Protocol as a response to concerns raised by indigenous movements suggests that group consent recognizes the sovereignty of aboriginal groups against exploitation in the name of research. Yet as Jenny Reardon argues, group consent in the Protocol fails to deal with concerns of indigenous movements.²⁵⁹ Group consent only expands informed consent from individuals to groups, without dealing with complicated issues regarding the political and historical realities of colonialism and north-south relations.²⁶⁰ Reardon describes group consent's failure as the limit of the western bioethical framework that is not able to pay attention to fundamental questions of power.²⁶¹ Meanwhile, despite critics concerns about the definition of groups and cultural authority, group consent has been widely accepted in the context of recognized groups, such as aboriginal groups. Hank T. Greely also describes congressional legislation for a national biobank project as a form of group consent; for example the Icelandic biobank obtained group consent through public debates and congressional legislation, the HSD Act.²⁶² Such examples of group consent are less controversial, not only because of their clarification of groupness and authority, but also because these groups are defined by a political process that takes various social and political concerns into consideration instead of relying solely on the scientific perspective. To summarize the pros and cons of group consent, the real purpose of group consent should be to empower participants by involving them, either directly in debate or indirectly by including their representatives in decision-making bodies.

2. Community Consultation

Community consultation has been recommended by many ethical guidelines in the context of human subjects research involving communities with cultural differences or different public health policies.²⁶³ The Council

258. Lee et al., *supra* note 250, at 62.

259. REARDON, *supra* note 237, at 98.

260. *See id.* at 98-99.

261. *Id.* at 124-25.

262. Greely, *supra* note 257, at 787.

263. *E.g.*, PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, MORAL SCIENCE: PROTECTING PARTICIPANTS IN HUMAN SUBJECTS RESEARCH 79 (2011), <https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/Moral%20Science%20June%202012.pdf> [hereinafter PCSBI II]; 1 NAT'L BIOETHICS ADVISORY COMM'N, ETHICAL AND

for International Organizations of Medical Sciences (CIOMS)'s guideline for human subjects research also mentions that community consultation supplementary to individual consent is advisable when "[r]esearch in certain fields, such as epidemiology, genetics or sociology, may present risks to the interests of communities, societies, or racially or ethnically defined groups."²⁶⁴ The UNAIDS/WHO's guidance on biomedical HIV prevention trials also considers it essential to involve the community in every major stage of the research "in an early and sustained manner" through "a transparent and meaningful participatory process."²⁶⁵ Compared to group consent, community consultation has been generally accepted and incorporated into the existing biomedical research ethics framework. According to the NBAC report, there are two situations where federal regulations require community consultation beforehand—when research subjects are enrolled in circumstances of emergency and when research is carried out in American Indian communities.²⁶⁶ Besides federally required consultations,²⁶⁷ community consultation usually does not have a standard procedure. Community consultation could be implemented in the early stage of designing research protocols and developing informed consent; it could also take place in the post-research stage as a continuing dialogical mechanism to disclose risks and benefits, to seek community review of research results prior to release, and to consider participants' voices regarding the use of samples and data.²⁶⁸

There are several purposes that community consultation is designed for. First, community consultation provides researchers with cultural insights and publicity through communication with the community.²⁶⁹ Communication helps researchers develop a culturally sensitive way to go about recruiting and seeking informed consent. Researchers can also better identify risks

POLICY ISSUES IN INTERNATIONAL RESEARCH: CLINICAL TRIALS IN DEVELOPING COUNTRIES IV, 30 (Apr. 2001), http://bioethics.georgetown.edu/pcbe/reports/past_commissions/nbac_international.pdf.

264. COUNCIL FOR INT'L ORG. OF MED. SCIS., INTERNATIONAL ETHICAL GUIDELINES FOR BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS, Commentary to Guideline 8 (2002), <http://cometc.unibuc.ro/reglementari/cioms.pdf>.

265. UNAIDS/WHO, ETHICAL CONSIDERATIONS IN BIOMEDICAL HIV PREVENTION TRIALS 2, 17 (2012) (Guidance Point 2), http://www.unaids.org/sites/default/files/media_asset/jc1399_ethical_considerations_en_0.pdf.

266. NBAC, *supra* note 11, at 8.

267. An example is that according to the FDA regulation, when a research is considered to be emergent, the IRB may require community consultation and waive the investigator's obligation to seek individual subjects' informed consent, *see* 21 C.F.R. § 50.24 (a) (7) (i) (1996).

268. Sharp & Foster, *supra* note 241, at 180-82.

269. Eric T. Juengst, *Community Engagement in Genetic Research: The "Slow Code" of Research Ethics?*, in POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES, *supra* note 245, at 182.

and benefits with more understanding of the community's shared values.²⁷⁰ Second, community consultation increases researcher accountability. By providing an opportunity for community members to understand and debate about the research, community consultation serves as an additional layer of safeguards to participants and the community.²⁷¹

Compared to group consent as a measure to protect group autonomy, the focus of community consultation is to identify the culturally specific risks and potential benefits and preserve the special values and culture of a given population.²⁷² Eric T. Juengst argues that community consultation has a pragmatic function beyond only operating to enhance the population's control over the ways in which its members are studied.²⁷³ The same criticisms directed at group consent regarding the definition of a group and the reinforcement of current categorization are not as strongly made about community consultation, because the "group" or "community" does not have a defined role as a research subject does. Nevertheless, issues remain with regard to deciding how to define the community and who should be included in the dialogue. Increasingly internal diversity and geographical distribution of populations reveal that there are not necessarily shared values nor common risks posed to a particular group.²⁷⁴ Further, consultation has been criticized as a process of researchers teaching community members instead of communicating with them.²⁷⁵ Consultation without teeth also gives the researchers unchecked discretion to decide what kinds of voices should be taken into consideration. Community consultation puts the community member in a passive and weak position, as community members do not have the power to participate in decision-making. That community consultation has been widely adopted in some areas of research. This can be explained in part by the fact that it poses no real challenge to the existing framework of research ethics. It merely adds a mechanism, with no mandatory outcomes, for researchers to take the community's views into account.

B. *Public Consultation*

1. Public Engagement as an "Ethics Plus" Approach: the UK Biobank

Public engagement could be seen as community consultation on a larger scale of community. The following examples of public consultation are mostly in the context of large population-based biobanks.

270. *Id.* at 187.

271. *See* PCSBI II, *supra* note 263, at 30.

272. Juengst, *supra* note 269, at 187.

273. *Id.* at 190.

274. *Id.* at 187; Sharp & Foster, *supra* note 242, 47-48.

275. *See, e.g.*, Juengst, *supra* note 269, at 189.

The UK Biobank is an example that incorporates public engagement into its governance framework. The UK Biobank is a nationwide project collecting information from 500,000 volunteers, aged between 45 and 69 years, as a resource for research into common multifactorial diseases that affect people in later life.²⁷⁶ Major founders are the independent medical research charity Wellcome Trust (WT), the Medical Research Council (MRC), and the Department of Health (DoH).²⁷⁷ Before the project was initiated, there had been a successful tradition in managing large-scale prospective health population studies with little contention over ethical acceptability, yet in the 1990s a public mistrust towards science and medicine arose due to a failure of regulation regarding the mad cow crisis and genetically modified foods.²⁷⁸ In addition to the ethical requirements of the HTA and the Data Protection Act (DPA), the founders of the UK Biobank were aware of the necessity of gaining support from both participants and the population at large.²⁷⁹ In the planning stage in 2003, an Interim Advisory Group (IAG), composed of experts in ethics, philosophy, law, science, and social science as well as consumer representation, was appointed funders to produce the EGF.²⁸⁰ Before that, funders also held a series of workshops and consultations on aspects of the UK Biobank proposals, and the results were sent to the IAG to be discussed and considered in the process.²⁸¹ With the advice of IAG and opinions gained through public consultation, the draft of the EGF was approved in 2006 and set standards to safeguard collected samples and data used only in scientifically and ethically approved research.²⁸² The independent EGC, formed in November 2004, was tasked with overseeing the UK Biobank and to monitor and report publicly on the conformity of the UK Biobank with the EGF.²⁸³ The EGC also intended to include a variety of perspectives, including community and consumer perspectives.²⁸⁴ A series of public meetings was held annually by the EGC between 2005 to 2009, with short presentations, question and answer sessions, and publicity by lo-

276. *About UK Biobank*, UK BIOBANK, <https://www.ukbiobank.ac.uk/about-biobank-uk/> (last updated Feb. 7, 2019).

277. *Id.*

278. Oonagh Corrigan & Alan Petersen, *UK Biobank: Bioethics as a Technology of Governance*, in *BIOBANKS: GOVERNANCE IN COMPARATIVE PERSPECTIVE*, *supra* note 2, at 143, 143-44.

279. *Id.* at 144.

280. *The Ethics and Governance Council*, UK BIOBANK, <https://www.ukbiobank.ac.uk/the-ethics-and-governance-council/> (last visited Mar. 8, 2019).

281. *Id.*

282. *Id.*

283. *Id.*; UK BIOBANK ETHICS AND GOVERNANCE COUNCIL, <http://www.egcukbiobank.org.uk/> (last visited Mar. 8, 2019).

284. *Members*, UK BIOBANK ETHICS AND GOVERNANCE COUNCIL, <https://egcukbiobank.org.uk/members.html> (last visited Oct. 8, 2018).

cal media and the UK Biobank website.²⁸⁵ The EGF contains statements of the project's commitments to actively engage shareholders as well as the society.²⁸⁶

Efforts in public engagement reveal funders' awareness of insufficiency of compliance with regulatory requirements against a background of public mistrust. Graeme Laurie describes the UK Biobank's bylaws as an "ethics plus" approach that goes beyond the standard laid out in UK law and international standards.²⁸⁷ Laurie indicates that the ethics+ approach resolves ethical controversies. For instance, broad consent becomes less problematic because it is turned into an ongoing engagement by being articulated publicly in the EGF and monitored over time by the EGC.²⁸⁸ The ethics+ approach taken by the UK Biobank incorporates public engagement into a part of its governance framework.

Nevertheless, critics question whether public engagement has been used more so as a method to mitigate concerns against the biobank project than it has to take public opinion sincerely into consideration. Public consultation by the UK Biobank has been criticized for its top-down, narrowly-framed design geared toward deflecting public attention away from a set of concerns and steering the public toward a stance of support.²⁸⁹ Fundamental questions such as the necessity of biobanks on a national scale, commercial involvement conflicting with public interests, or mechanisms of regulation and enforcement were not consulted in the early stage. Critics find that the assumption behind much public consultation views the public as composed of reactionaries—those who are ignorant and whose concerns and distrust are a kind of risk to be managed.²⁹⁰ There is also no public scrutiny of how results of public consultation have been seriously examined and what their impacts are.²⁹¹ Moreover, there is no participant representation in UK Biobank's governing bodies, and neither do participants have any legal rights to be involved in governance after donations. The EGC itself has no power

285. See MED. RESEARCH COUNCIL & WELLCOME TRUST, REVIEW OF THE UK BIOBANK ETHICS AND GOVERNANCE COUNCIL 8 (2010), <https://egcukbiobank.org.uk/sites/default/files/meetings/Review%20report.pdf>.

286. UK BIOBANK ETHICS AND GOVERNANCE FRAMEWORK, *supra* note 77, at 3 ("UK Biobank will seek active engagement with participants, research users and society in general throughout the lifetime of the resource.")

287. Graeme Laurie, *The UK Biobank Ethics and Governance Council: How Valuable is an "Ethics+" Approach to Governance?* in NEW CHALLENGES FOR BIOBANKS: ETHICS, LAW AND GOVERNANCE 239, 239-40 (Kris Dierickx & Pascal Borry eds., 2009).

288. See *id.* at 243.

289. Kathryn G. Hunter & Graeme T. Laurie, *Involving Public in Biobank Governance*, in THE GOVERNANCE OF GENETIC INFORMATION: WHO DECIDES? 151, 154 (Heather Widdows & Caroline Mullen eds., 2009).

290. Corrigan & Petersen, *supra* note 278, at 152; Hunter & Laurie, *supra* note 289, at 154.

291. Corrigan & Petersen, *supra* note 278, at 152; Hunter & Laurie, *supra* note 289, at 154-55.

of veto in matters of research use; that decision-making authority is held by the Board of Director (BoD).²⁹² The UK Biobank's public consultation has been roundly criticized for expecting the public to be a "passive public" prepared to be convinced.²⁹³ Consultations with a passive public may serve as a smokescreen for "business as usual," or the introduction of insidious forms of control, or practices favoring the interests of certain groups.²⁹⁴

The development of public consultation is also worth mentioning, with regards to the role of EGC. According to a report evaluating the performance of the EGC made by an expert Review Panel in 2010, the problem of EGC public consultation is that it lacks clear policy to handle evidence or opinions from the public.²⁹⁵ However, both Review Panel report in 2010 and later in 2015 concluded it was not appropriate for the EGC to keep serving the task for external engagement or the advocacy role to the public; EGC should rather focus on its main function on monitoring the ethics of the project.²⁹⁶ The report somehow resonated with critics by objecting to the lack of clear and effective mechanisms to consider public opinion and the tendency toward promotion rather than real consultation. Moreover, the Review Panel reports seemed to consider public consultation as a part of regular operation that executive bodies should be in charge.

2. Public Engagement Through Legislation

Similar to the UK, many other countries have faced the challenges of ethical concerns and public distrust of science and medicine when establishing large-scale population biobanks. Specific legislation has been a common approach to deal with public concerns. Specific legislation is supposed to represent the consensus of the community regarding those ethical controversies. Public engagement has played an important role in the legislative process in some countries.

Legislation could be considered the result of great social consensus after public debates. For instance, the Icelandic HSD Act, passed by the parliament in 1998, authorized the creation of a centralized database that is considered to be the consensus of the people after extensive public debates.²⁹⁷ The HSD Act and the Icelandic biobank were formed against the

292. UK BIOBANK ETHICS AND GOVERNANCE FRAMEWORK, *supra* note 77, at 13.

293. *See* Hunter & Laurie, *supra* note 289, at 155.

294. Corrigan & Petersen, *supra* note 278, at 155.

295. MED. RESEARCH COUNCIL & WELLCOME TRUST, *supra* note 285, at 9.

296. *Id.* at 1-2; MED. RESEARCH COUNCIL & WELLCOME TRUST, REVIEW OF THE UK BIOBANK ETHICS AND GOVERNANCE COUNCIL REPORT OF THE EXPERT REVIEW PANEL 7 (2015).

297. Margret Lilija Gudmundsdóttir & Salvor Nordal, *Iceland*, in THE ETHICS AND GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES, *supra* note 75, at 53, 53; Piia Tamppuu, *Public Discourse on Human Genetic Databases*, in THE ETHICS AND

background of a long history of carefully registered health information, the acknowledged homogeneity of the society, and the supportive attitude of the Icelandic public to the project.²⁹⁸ The Icelandic biobank's ability to win public support was attributed to the initiator's successful adjustment to the local context, and the high reputation and trustworthy image of representative scientists who played an essential role in convincing the public.²⁹⁹ However, the public debate was a top-down process, in which the lay public was convinced by experts. The legislation was the result of persuasion. Some commentators disagree that the HSD Act represented community consent and say it was flawed because great quantitative public support does not equate "qualitative consent."³⁰⁰

Legislation can be the result of bottom-up civic movements. The Taiwanese Human Biobank Management Act (HBMA) is an example of legislation that was born under pressure brought by human rights groups and ethical, legal and social implications (ELSI) scholars on Taiwan's national biobank. The Taiwan Biobank is a large-scale population-based biobank project launched in 2005, which planned to gather more than 200,000 samples from healthy adults to build a database for research into the interaction among genes, life phenomena, disease mechanisms, and environmental factors.³⁰¹ Meanwhile, human rights groups and ELSI scholars had raised ethical concerns over the project since the project's planning stage. Their concerns were fueled by several factors, including an increasing rights consciousness towards information privacy against government surveillance, and the collection and convergence of personal information. Research scandals had occurred in hospitals and in rural and aboriginal villages where researchers collected samples deceptively without obtaining informed consent.³⁰² There was growing mistrust of commercial exploitation of human samples and data.³⁰³ Although an ethical/legal governance framework similar to the EGF of the UK Biobank was drafted in the planning stage,³⁰⁴ the project continued to face strong opposition when it planned to collect blood samples in 2009, as opponents decried the project as unethical and lacking

GOVERNANCE OF HUMAN GENETIC DATABASES: EUROPEAN PERSPECTIVES, *supra* note 73, at 73, 75.

298. Gudmundsdóttir & Nordal, *supra* note 295, at 53.

299. Tammpuu, *supra* note 297, at 74.

300. *Id.* at 75-76.

301. Chien-Te Fan et al., *Taiwan Biobank: A Project Aiming to Aid Taiwan's Transition into a Biomedical Island*, 9 PHARMACOGENOMICS 235, 235-38 (2008).

302. See Hung-En Liu & Terence Hua Tai, *Public Trust, Commercialisation, and Benefit Sharing*, in HUMAN GENETIC BIOBANKS IN ASIA: POLITICS OF TRUST AND SCIENTIFIC ADVANCEMENT 28, 31-33 (Margret Sleeboom-Faulkner ed., 2009).

303. *Id.* at 29.

304. See Fan et al., *supra* note 301, at 237.

in social consensus.³⁰⁵ Being confronted with strong objections on ethical, legal, and democratic fronts, the HBMA was passed in 2010 to address the absence of biobank regulation.³⁰⁶ Compared to a top-down approach to the regulation of life science and technology that favors economic benefits over ethics, something often associated with East Asian countries, the HBMA represents a turn in the direction of forming political consensus as the basis of biotechnology regulation.³⁰⁷

Nevertheless, the HBMA does not completely resolve human rights groups' and ELSI scholars' concerns about the Taiwan Biobank. The passage of the HBMA does not amount to community consent to the Taiwan Biobank in the way that the Icelandic HSD Act did. The HBMA is designed to regulate all biobanks, not to authorize the creation of the Taiwan Biobank. The Taiwan Biobank project was formally licensed in 2012, followed by the establishment of another private large-scale biobank.³⁰⁸ Moreover, the government plans to integrate the Taiwan Biobank with databases of the national healthcare system to establish a "morbid health cloud," which also raises strong privacy concerns.³⁰⁹ The HBMA was born by civic activism, yet it does not ensure the continuity of public engagement. Legislation by itself may not further public engagement, as the HBMA does not include clauses regarding public involvement. The HBMA could even provide a foundation to justify the establishment of large-scale biobanks in the future.

Another noteworthy observation is the gap between human rights groups, ELSI groups, and the general lay public. It has been found that the general public has not been made quite aware of ethical problems surrounding the national biobanks, as surveys usually show a majority support for the Taiwan Biobank.³¹⁰ The gap between advocates and the general public

305. Jingyi Liu & Hongen Liu, 台灣生物資料庫 荒腔走板 [Taiwan's Biological Database is Deserted], CITIZENS' F. TO WATCH TAIWAN BIOBANK: BLOG (MAY 7, 2009), http://biobankforum.blogspot.com/2009/05/blog-post_06.html.

306. Chin-Yi Liu, *The Biobank Act as a Route to Responsible Research: A First Step for Taiwan?* 110 J. FORMOSAN MED. ASS'N 129, 129 (2011).

307. See JOSEPH WONG, BETTING ON BIOTECH: INNOVATION AND THE LIMITS OF ASIA'S DEVELOPMENTAL STATE 152-53 (2011).

308. See Qui Yizhen, 超越隱私權爭議的全國基因資料庫 [National Gene Database Surpassing Privacy Disputes], TAIWAN ASS'N FOR HUM. RTS. (Nov. 7, 2012, 10:13 AM), <https://www.tahr.org.tw/node/1141>.

309. Chin-Yi Liu, 病態健康雲 將監控全民 [Morbid Health Cloud will Overly Surveil the Citizens], APPLE DAILY (Sep. 20, 2013), <http://www.appledaily.com.tw/appledaily/article/headline/20130920/35307667/>.

310. According to a survey by the Academic Sinica, in Taiwan in 2006 (which is the latest quantitative result among the public released surveys), more than 80% of respondents knew little or never heard about biobanks, but around 70-80% of respondents supported large-scale biobank projects; however, when respondents were reminded of the privacy risk, more than 50% hesitated to donate their blood samples to the biobank project. See GENETIC

raises the question of whether this seemingly bottom-up model really amounts to a robust civil society.

3. Public Engagement by Mini-Publics

A team at the W. Maurice Center for Applied Ethics at the University of British Columbia (UBC) has experimented with different ways of public engagement in a Genome Canada and Genome BC³¹¹-sponsored research project.³¹² The UBC team conducted a study of deliberative democracy to assess whether public engagement could go beyond collecting raw public perceptions to involving participants in deliberation based on sufficient information and diverse views.³¹³ The team recruited a small group of demographically stratified participants by randomly contacting households in five health regions in British Columbia.³¹⁴ Twenty-one participants participated fully in the deliberative event known as the “BC Biobank Deliberation” in April and May 2007.³¹⁵ The event was divided into two weekends. Participants received a booklet of introduction on biobanking in advance.³¹⁶ The first weekend was to provide background information and develop the context of communication.³¹⁷ Participants first listened to presentations by experts and stakeholders regarding science practices, ethical issues, and commercial benefits and then began to discuss.³¹⁸ Participants were divided into three small groups to identify their hopes and concerns regarding biobanks

RESEARCH AND PUBLIC OPINION: SURVEY INTERVIEW AND DATABASE IN TAIWAN (III) 8, 26-27 (2006), https://srda.sinica.edu.tw/datasearch_detail.php?id=879.

311. Genome Canada is an organization sponsored by the Canadian government that invests in genomic research and helps commercialization of research results. *See About, GENOMECANADA*, <http://www.genomecanada.ca/en/about/> (last visited Oct. 8, 2018). Genome British Columbia (BC) is a non-profit organization sponsored by the BC Province government and the Canadian government. The main purpose is to develop a platform for genomic research that will bring benefits to the BC community, *Who We Are, GENOME BRITISHCOLUMBIA*, <http://www.genomebc.ca/about/> (last visited Oct. 8, 2018).

312. Michael Burgess et al., *Biobanking in British Columbia: Discussions of the Future of Personalized Medicine through Deliberative Public Engagement*, 5 PERSONALIZED MED. 285, 286 (2008). *See generally* K.C. O’Doherty & M.M. Burgess, *Engaging the Public on Biobanks: Outcomes of the BC Biobank Deliberation*, 12 PUB. HEALTH GENOMICS 203, 203-15 (2009); David M. Secko et al., *Informed Consent in Biobank Research: A Deliberative Approach to the Debate*, 68 SOC. SOCI. & MED. 781, 781-89 (2009); Heather L. Walmsley, *Mad Scientists Bend the Frame of Biobank Governance in British Columbia*, 5 J. PUB. DELIBERATION 1, 7-22 (2009); Heather L. Walmsley, *Stock Options, Tax Credits or Employment Contracts Please! The Value of Deliberative Public Disagreement about Human Tissue Donation*, 73 SOC. SOCI. & MED. 209, 209-15 (2011) for other descriptions of this experiment.

313. Burgess et al., *supra* note 310, at 286.

314. *Id.* at 287.

315. *Id.* at 286.

316. *Id.* at 287.

317. *Id.* at 291.

318. *Id.*

and then presented their discussion results to the large group.³¹⁹ The focus of the second weekend was the design of a BC biobank.³²⁰ Participants engaged in both small- and large-group discussions to identify agreements and persistent disagreements.³²¹ The BC deliberation is what deliberative democrats called a mini-public—a microcosm of citizens recruited to discuss complicated and contentious political issues.³²² Such a deliberative event is designed to catalyze discussion among uninterested citizens by providing them with background knowledge and exposing them to different perspectives. Through this process, citizens are invited to reflect on the issue and change their initial preferences in light of deliberation.

The design of the deliberation was intended to respond to many of the criticisms leveled at the public consultation done by the UK Biobank: chiefly, that it was a method to steer the public toward acceptance rather than to involve the community in honest communication. The BC Biobank Deliberation was conducted by an organization independent of any institution committed to the establishment of or investment in biobanking.³²³ The deliberation preserved the option of “no biobank” for participants and was open to challenging the assumptions set by organizers.³²⁴ Participants defined issues that they believed to be relevant in the first weekend, being free from issues narrowly framed by organizers. Their task was to explore broadly and express their hopes and concerns about a biobank in BC.³²⁵ Organizers also worked carefully to avoid the trap of a “captured voice,” whereby participants are unduly influenced by overexposure to certain perspectives.³²⁶ Strict time limits were observed in presentations of background knowledge by experts and stakeholders on the very first day, and through the remaining days, participants did not directly contact these speakers.³²⁷ The results of deliberation showed that participants’ opinions remained divergent despite certain changes from their initial positions.³²⁸ This gives evidence that participants were not captured.

However, while the mini-publics model has the advantage of staging informed public debates and giving voice to ordinary, varied citizens, the question of its impact on policy remains unclear. The conclusions of the BC Deliberation recognized that their own opinions cannot be truly representa-

319. *Id.* at 290-93.

320. *Id.*

321. *Id.* at 291-92.

322. JOHN S. DRYZEK, FOUNDATIONS AND FRONTIERS OF DELIBERATIVE GOVERNANCE 155 (2010).

323. O’Doherty & Burgess, *supra* note 312, at 204.

324. *Id.*; Walmsley, *Mad Scientists Bend the Frame of Biobank Governance in British Columbia*, *supra* note 312, at 11.

325. O’Doherty & Burgess, *supra* note 312, at 212-13.

326. Burgess et al., *supra* note 312, at 287, 289.

327. *Id.* at 287, 289.

328. *Id.* at 294.

tive of the whole BC population, but their deliberative engagement may contribute to trustworthy governance.³²⁹ The UBC team also said they would help transfer the results of the deliberation into policies, and a final report was sent to several federal agencies.³³⁰ The result of the Deliberation served as a frame of reference for policy-makers without having a binding effect, but it was decided that it should be seriously considered given its legitimacy born of civic deliberation. Observers also find deliberative engagement is supplementary to informed consent, as it helps individual participants consider and reflect on broader interests than just their own.³³¹ Deliberative engagement can also contribute to political legitimacy, as there are decreased concerns about future use and the right to withdraw after deliberation has taken place.³³²

The BC experiment was not a completely new idea, as experiments like mini-publics have been used in other situations. But conducting a mini-public for biobanking may be a somewhat less obvious application of the model, probably because the relationship between participants and a biobank is regarded as a contractual relationship rather than a form of governance or public policy that requires public deliberation. However, the question of whether the relationship of a biobank to participants should be simply defined as contractual irrespective of its political implications is a question that should remain open and be explored.

The BC Deliberation is also unique for its efforts to define limits for and minimize the influence of organizers in order to preserve the authenticity of civic deliberation. Its results reveal the ability of lay citizens to understand and reflect on complex issues, and to participate in forming policies. For instance, participants were found to be very creative, for example generating a sequence of policy alternatives for benefit-sharing and feedback to donors.³³³

C. Representation in Governance: Shareholder and Stakeholder Models

A common problem of public consultation is how its results or conclusions can be translated into formal recommendations and influence decision-making. Being aware of public consultation having “no teeth,” the shareholder model intends to empower participants through engaging their representation in the governing bodies of a biobank.

329. *Id.*

330. *Id.* at 293-94.

331. Secko et al., *supra* note 312, at 788.

332. *Id.* at 789.

333. See Walmsley, *Stock Options, Tax Credits or Employment Contracts Please! The Value of Deliberative Public Disagreement about Human Tissue Donation*, *supra* note 312, at 215.

David E. Winickoff proposes a Charitable Trust Model as a third way to address the controversies over whether genomic resources could be commodified or are inalienable.³³⁴ The UK Biobank was designed with the principle of “partnership” to alleviate public concerns about commercial exploitation, while keeping alive the potential for collaboration with industry.³³⁵ Partnership is embodied by management structures for public fiduciaries, such as the UK Biobank’s commitment to accountability, the public’s indirect representation through governmental representatives on the BoD, public consultation, and the EGC’s function to advise the BoD.³³⁶ However, the UK Biobank’s weakness in realizing partnership governance is that the BoD has broad discretion over the distribution of banked resources, but mechanisms to ensure the fiduciary duties of the BoD are absent.³³⁷

Winickoff’s solution is to let donors be represented in the governance of the biobank. Winickoff refers to non-profit corporate law as a supplement to the charitable trust nature of the UK Biobank, arguing that donors should be viewed as *shareholders* who are represented in corporate decision-making.³³⁸ A concrete proposal to include shareholder representation is to constitute a Participants Association (PA).³³⁹ Potential donors would be informed in the process of informed consent that a PA would be formed, and they could voluntarily sign on to join the PA.³⁴⁰ With a certain number of petitions, the PA will be formed and leaders will be chosen by PA members’ proxy votes.³⁴¹ The PA leaders will fill a number of seats on EGC, the IRB, or even an additional Donor Approval Committee (DAC) to review research protocols.³⁴² Winickoff regards shareholder representation as a commitment to procedural justice that outweighs short-term increased administrative costs.³⁴³

A revised version proposed by Kathryn G. Hunter and Graeme T. Laurie is to involve *stakeholders*, a more inclusive idea than the shareholder model. These proponents of the stakeholder approach criticize the shareholder model from two aspects. First, they argue that the shareholder model leads to donors’ self-interest, which is contrary to the UK Biobank’s aim to

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

335. *Id.* at 443.

336. *Id.* at 444-45.

337. *See id.* at 448.

338. *Id.* at 451; David E. Winickoff, *From Benefit Sharing to Power Sharing: Partnership Governance in Population Genomics Research*, in PRINCIPLES AND PRACTICE IN BIOBANK GOVERNANCE, *supra* note 168, at 53, 60.

339. Winickoff, *supra* note 336, at 61.

340. *Id.*

341. *Id.*

342. *Id.*; *See* Winickoff, *supra* note 334, at 450.

343. Winickoff, *supra* note 338, at 62-63.

benefit the whole community or the society.³⁴⁴ Second, they argue that the shareholder model does not necessarily enhance public deliberation. Representation could help provide reflections on a wide range of interests for deliberation, but in the shareholder model representation speaks on behalf of its own interests.³⁴⁵ Nor does the shareholder approach provide robust, inclusive, and transparent processes to facilitate deliberation.³⁴⁶ Donors' representation may also cause the problem of vocal minority—that is, the replacement of one vested interest by another more recent and influential group, while the voice of the general public remains unheard.³⁴⁷ On the contrary, a stakeholder approach would better fulfill the public-interest goal with its broader inclusion of stakeholders, such as potential participants, beneficiaries, and future generations.³⁴⁸

A pragmatic issue with the stakeholder approach is how to involve stakeholders. Laurie and Hunter examine the stakeholder participation strategy, which attempts to involve stakeholders through granting them an active role in governance bodies.³⁴⁹ Yet this strategy is different from the shareholder model in that the representation is drawn from a wider constituency and is recruited rather than self-selected.³⁵⁰ Laurie and Hunter find the strategy of self-selection unsatisfying because there is no realistic mechanism to assure adequacy of representation.³⁵¹ They instead endorse a stakeholder involvement strategy, which envisions partnership between management and stakeholders by organizational commitments to direct and ongoing dialogues with multiple stakeholders as well as to respond and adapt their concerns.³⁵² Laurie and Hunter consider the EGC and the EGF's commitments to active engagement and public interests to be the basis of this ongoing dialogue, and they further underscore transparent procedures and the justification of decisions with reasons to be criteria of this dialogue.³⁵³ To sum up, the stakeholder approach not only seeks greater constituencies but also a better quality of discussion to fulfill the criteria of deliberation. It may be imagined that identifying stakeholders and their representatives could be practically difficult and controversial, but Laurie and Hunter do not provide a concrete mechanism for identification. Their implicit solution by appealing to reason-giving resonates with what many deliberative democrats be-

344. Hunter & Laurie, *supra* note 289, at 164.

345. *See id.* at 165-66.

346. *Id.* at 158-59.

347. *Id.*

348. *Id.* at 176.

349. *Id.* at 172.

350. *Id.* at 172-73.

351. *Id.* at 173 (quoting Norman Daniels and James Sabin, *The Ethics of Accountability in Managed Care Reform*, HEALTH AFFAIRS Sept.-Oct. 1998, at 50, 61).

352. *Id.* at 174, 176.

353. *Id.* at 175.

lieve: decision-making with justifiable reasons could complement the question of representativeness of the decision-making body.

Both the shareholder and the stakeholder approaches have what consultation lacks—involving participants or the general public in governing bodies through representation. This perspective originates from the assumption of control over samples and data by recognizing that participants have certain proprietary interests. However, a transformation from proprietary interests to citizenship can be seen. Winickoff in his proposal of the shareholder approach indicates that his approach aims toward power-sharing, which is the premise of fair benefit-sharing.³⁵⁴ The stakeholder approach with a broadened constituency and deliberative procedural requirements further proves that the relationship between participants and biobanks is better addressed within a framework of citizenship and governance than cast in terms of proprietary interest and contracts.

D. Patient-Centered Initiatives (PCIs)

The PCI is an initiative to empower patients/participants by establishing patient-centered biobanks. The most significant example is the PXE International, which is a patient-run biobank established by a group of people affected with pseudoxanthoma elasticum to drive research for their treatment.³⁵⁵ Another well-known example of PCI is Genetic Alliance BioBank, an initiative that creates a patient-centered research network where biobanks are encouraged to operate by the principle of community governance—i.e., participants control their samples and data by making decisions on the use of research rather than passively consenting to opt in to a database.³⁵⁶

There are also other programs adopting the patient-generated model of database. A program called “That’s My Data!” helps patients contribute their genomic data to researchers in exchange for open access to research results using these data.³⁵⁷ This program is part of the citizen scientist movements, which challenges the traditional approach of scientific research as a professionals’ domain by encouraging citizens to participate in doing science.³⁵⁸ There is also a mechanism implemented by “Consent to Research” in which participants can attach consent to their donated data and researchers who are willing to accommodate the consent can use the data.³⁵⁹

354. Winickoff, *supra* note 334, at 54-59.

355. Greg Biggers & Leonard D’Avolio, Address from the May 17 Meeting of the Presidential Comm’n for the Study of Bioethical Issues, Session 7 (May 17, 2012) (transcript available at <http://bioethics.gov/cms/meeting-9>).

356. *Id.*

357. Amy Dockser Marus, *Citizen Scientists Take on the Health Establishment*, WALL ST. J. (Dec. 3, 2011), <http://online.wsj.com/news/articles/SB10001424052970204621904577014330551132036>.

358. *Id.*

359. PCSBI I, *supra* note 40, at 90.

A similar mechanism can be found in the proposal of a “walking biobank,” that is, a biobank serves a network connecting participants, while participants are deemed as storage units of their own genomic materials.³⁶⁰ Researchers, when proposing a research in need of biospecimens and data, invite participants to “walk in” to donate their materials for specific research.³⁶¹ The rise of PCIs can be attributed to the growth of information technology: PCIs usually avail themselves of web portal accounts and social media to place participants in a position of interaction.³⁶² The development of information technology makes it possible for participants to express their preferences that shape research in effective and economic ways.

The PCI approach has advantages in addressing legal and ethical concerns regarding biobanks and biomedical research. The PCI approach strengthens and sustains public trust through participants’ involvement with an understanding of biobanks and research.³⁶³ Ethical concerns are likely to be reduced because of transparency and oversight by direct participation.³⁶⁴ There would also be less need of anonymity because participants can be directly approached to seek consent for new research.³⁶⁵ Recruitment would be more efficient and participants would tend to remain in the program.³⁶⁶ Advocates of PCIs seemingly believe that control by participants would mitigate ethical controversies and build trust in scientific research. They also tend to recognize that involving lay perspectives produces better science by bringing professional authority in contact with social values.

However, there are challenges to PCIs. A major question is the quality of data collected by the PCI approach. Patients usually collect and contribute data when they feel motivated to and when they feel it right, but the collected data may not be large enough to yield statistically reliable results or be representative of the whole population; plus, the opt-out option may hinder research.³⁶⁷ A more fundamental issue is whether untrained citizens can participate in doing science, as patients’ interests and their choice of what data to contribute may not coincide with what scientists consider relevant.³⁶⁸ However, the clash does not prove that amateurs cannot contribute to science. Instead, it reveals that patients would present priorities different from

360. Chalmers et al., *supra* note 4, at 10.

361. *Id.*

362. Jane Kaye et al., *From Patients to Partners: Participant-Centric Initiatives in Biomedical Research*, 13 NATURE REVIEWS GENETICS 371, 371 (2012).

363. *See id.* at 371.

364. *Id.* at 373.

365. *Id.*

366. *Id.*

367. Marus, *supra* note 357. However, advocates believe that patient-controlled data is of better quality because it would involve less error information. *See* Kaye et al., *supra* note 362, at 375.

368. Marus, *supra* note 355.

those of scientific professionals, prioritizing what may have been ranked low in the hierarchies of scientists, their institutions, and their funders.

The PCI approach provides a different perspective to describe the relationship between participants and researchers. The Genetic Alliance calls patients *the people*, as they consider the patient's role to move from participant to collaborator.³⁶⁹ PCIs have been advocated for in the context of scientific citizenship rather on the grounds of property rights, notwithstanding that the PCIs tend to result in a small-scale database for specific groups of interest rather than a large-scale population database for wide public benefit. The PCI approach addresses what the existing research ethical framework has hardly dealt with—the power asymmetry between lay participants and scientists. The PCI approach challenges scientists' authority in the realm of scientific research by requiring power-sharing in both knowledge production and the distribution of resources.

E. *Summaries and Responses to Critiques*

Two points are worth noting with respect to the overview of various models of public engagement. First, the focus shifts from consent to participation in governance. In the traditional ethical framework for protecting research subjects or participants, consent is the main protective mechanism and governance is the concern of researchers. Many approaches to public engagement have sought to bolster broad consent by supplementing further consent such as group consent by the community or dynamic consent. However, consent cannot really be voluntary without sufficient information and discussion. Further, given the communal nature of biobanks, participants are interdependent, which requires them to join in collective decision-making. Public engagement in governance grants participants opportunities to be involved in deliberation with other stakeholders and to influence collective decisions through which participants can realize their autonomy. By participating in governance, the general public is also more effectively empowered. Participating in governance enhances a citizen's understanding and capacity to make decisions. Citizens are also likely to gain stronger bargaining power through unionizing peers or stakeholders in any governing body compared with when they give consent individually.

Second, the scope of public engagement seems to extend beyond a biobank to stakeholders or citizens in the community or the nation at large. Earlier approaches to public engagement such as group consent or community consultation have faced the problem of determining who should be involved. Despite the complexity of representation, an emerging consensus suggests that public engagement should not be limited to biobank partici-

369. The transcription of the Presidential Commission for the Study of Bioethical Issues Meeting on May 17, 2012, in Washington, at 2-5, <https://bioethicsarchive.georgetown.edu/pcsbj/sites/default/files/Meeting%209%20Session%207.pdf>.

pants but should include other stakeholders. Even if a citizen does not opt in to a biobank project, her rights may nevertheless be affected as long as her personal information could possibly be used or identified through data-mining, the interlinking of databases, or the shared human genome. Further, many large-scale biobank projects appeal to the public good, use public resources, or financially rely on public investments. Citizens, as voters or taxpayers, should be considered stakeholders with the right to be involved in the governance of biobanks.

Common critiques of public engagement are also worth mentioning. One critique is to question whether citizens are competent enough to participate in deliberation, especially when research involving biobanks is usually related to complicated scientific facts. Another concern is that engagement would increase costs and become an obstacle to research. Still another critique is that public engagement would undermine the accountability of biobank operators or researchers. Analyzing the experience of public engagement in biobanking helps to respond to these criticisms.

Actual experiences with public engagement around the world have proven the competency of citizens. The BC Biobank Deliberation demonstrated that lay citizens were competent to form guidelines for the design of a biobank, and were even capable of proposing new mechanisms of benefit-sharing that had not been implemented by any biobank. A carefully designed deliberative event for presenting various views and keeping topics open could prevent participants from being “captured” by the organizers or others. The biobanking legislation prompted by a civic movement in Taiwan demonstrated a bottom-up model of participation in forming ethical guidelines. PCIs also hold a positive attitude towards citizen participation in the process of producing scientific knowledge.

Another critique argues that public engagement would impose burdens on biobank operators or researchers that would hinder research. Difficulties associated with seeking re-consent would impede research, which is a main reason that the Final Rule did not adopt the NPRM’s proposal to extend the scope of human subjects research to research using nonidentified biospecimens.³⁷⁰ However, similar concerns are not as strong for biobanks. Biobanks today are institutional databases with professional staffs that could help contact participants or stakeholders, if necessary. Even if obtaining re-consent is necessary, it is the biobank operator, not individual researchers, who shall assume this duty.³⁷¹ Approaches like PCIs that take advantage of information technology also demonstrate the practicability of engaging individual participants in continuing interaction with a biobank. Public engagement does take time and money. Nevertheless, the cost should be deemed a necessity given its potential benefits attendant to public trust and potential

370. Berkowitz, *supra* note 14, at 956-57; Menikoff & Kaneshiro, *supra* note 16, at 613.

371. Miller, *supra* note 94, at 66.

costs resulting from ethical and political queries. In addition, public engagement is essential in terms of risk management; it helps risk evaluation and risk communication with the public, particularly with respect to the uncertain and complicated risks of biobanking.

Public engagement does not undermine stewardship. By contrast, it strengthens oversight by requiring biobank operators and researchers to be accountable to the general public. For example, the EGC's duty of publicity, including reporting to the public and advising generally on the interests of participants and the general public,³⁷² demonstrated how public engagement by an oversight body strengthened the UK Biobank's stewardship. The Taiwanese story also exemplified how public engagement strengthened oversight because the HBMA was born out of the pressure of a civic movement demanding the establishment of a legal framework to regulate an area that had previously been self-regulated by scientific professionals.

VI. CONCLUSION

In the book *Banking on the Body*, the author Kara W. Swanson examined the metaphor of a body "bank," which generated controversy over whether body products should be considered commodities or gifts.³⁷³ Body banks that were created by physicians for improving medical care originated on the basis of the "civic property" view that contended that even if body products were private property, they would be stored in banks in order to efficiently support medical treatments.³⁷⁴ The metaphor of banks later adopted the "market property" view whereby body products were considered commodities that could and should be tradable in a free market.³⁷⁵ The title of Swanson's book expressed the great potential for body products to benefit medicine and public welfare; such potential could be further bolstered through efficient exchanges facilitated by body banks. Similar to body banks, biobanking provides a mechanism for maximizing the utility of biospecimens and data. However, considering that the success of biobanks depends on public support and that its legitimacy is based on its contribution to public good, this article argues for *banking on the people* in the context of biobanking. Any sustainable biobank requires the involvement of the people, not simply as donors, as active stakeholders participating in collective decision-making.

This article examined why and how public engagement is relevant in biobanking. Biobanks are not just a type of new scientific practice for ac-

372. Laurie, *supra* note 283, at 239-41.

373. KARA W. SWANSON, *BANKING ON THE BODY: THE MARKET IN BLOOD, MILK, AND SPERM IN MODERN AMERICA* 5-8 (2014).

374. *Id.* at 13.

375. *Id.* at 13-14.

cumulating and consolidating resources for biomedical research: they have too many major and complicated socio-economic implications. Biobanking often contends that its objective is to promote the common good such as public health or economic development. Biobanks are expected to generate considerable economic benefits by serving as a platform for bringing bio-specimens and data into commercial use. Biobanks could also serve as a strategy to create or reinforce community identities. Many biobank projects such as the PMI and its subproject, *All of Us*, appeal to genomic citizenship; that is, people have rights as well as responsibilities with respect to participating in scientific collaboration that could benefit the whole community. Given that the current bioethical framework focuses on the protection of individual rights, it is not up to the task of addressing the many complicated issues involved in biobanks.

As this article has demonstrated, biobanking challenges the current regulatory and ethical framework, specifically in terms of informed-consent, privacy and confidentiality, and property and benefit-sharing. It is not coincidental that public engagement is frequently proposed when discussing new solutions to these challenges. A participatory turn is evident in biobanking, both ethically and normatively, and calls for public engagement have been made on the basis of ethical considerations associated with the communal features of biobanks. Normative developments, as expressed in the latest domestic and international guidelines, have also included mechanisms for engaging the public in the governance of biobanks. Public engagement initiatives have been introduced to formulate ethics as well as to involve the public in governance. These practices demonstrate that public engagement is not only feasible but also gradually becoming prevalent in the context of biobanking.

The ethical and legal challenges, as well as the participatory turn in biobanking, also reveal the increasing relevance of citizen participation in bioethics. In its first report, the PCSBI listed democratic deliberation as an emerging principle when considering the social implications of emerging technologies.³⁷⁶ The principle of democratic deliberation “reflects an approach to collaborative decision making that embraces respectful **debate** of opposing views and active participation by citizens.”³⁷⁷ Later in the final report, PCSBI concludes that democratic deliberation should be used to guide bioethical policy decisions.³⁷⁸ The PCSBI recommended that policymakers

376. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 4 (2010), <http://bioethics.gov/cms/synthetic-biology-report>.

377. *Id.* at 5.

378. PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, BIOETHICS FOR EVERY GENERATION: DELIBERATION AND EDUCATION IN HEALTH, SCIENCE, AND TECHNOLOGY 4-5 (2016), https://bioethicsarchive.georgetown.edu/pcsbi/sites/default/files/PCSBI_Bioethics-Deliberation_0.pdf.

and regulators at all levels should be guided by the principle of democratic deliberation when considering difficult bioethical issues and that stakeholders should be involved in discussions that aim to promote mutual understanding and respect.³⁷⁹ The emerging bioethical principle proposed by the PCSBI echoes the participatory turn in biobanking described in this article. Democratic deliberation as a guiding principle for addressing bioethical challenges as well as the regulatory and ethical debates concerning biobanking, the wide variety of public engagement examples, and the rhetoric of many bank projects that has appealed to citizens all illustrate the importance of public engagement in biobanking.

379. *Id.*

TABLE 1: MODELS OF PUBLIC ENGAGEMENT IN BIOBANKS

Model	Community engagement	Community consultation	Public engagement	Representation in governance	PCI
	Group consent				
Method	Obtain consent from the subject group in addition to consent from individual participants	Communicate with the subject community to understand and account for its culture and opinions	Involve the public in establishing an ethical framework and governance structure	Include stakeholders or shareholders' representatives in governing bodies	Patients have control over what research their samples and data are used in and how their samples and data are used
Examples	HGDP Protocol	CIOMS Guideline NIH Guideline	UK Biobank: public consultation to form EGF and by EGC Taiwan: civic movements led to legislation BC Deliberation: small public sessions held to discuss the design of a biobank	Shareholder model (the charitable trust model): participants' representation Stakeholder model: greater constituency and ongoing dialogues with procedural transparency and reason giving	PXE International Genetic Alliance BioBank "That's My Data!" "Consent to Research" "Walking biobank"
Strength and weakness	Respect for group autonomy Controversies regarding defining "group" and "group authority" by researchers Suspicious of racism	Provide cultural insight to researchers for protocol design and risk-benefit assessment Additional safeguards Disagreements among the community itself Process of teaching instead of communicating	Forming ethical guidelines with public input Achieve democratic legitimacy and establish public trust Uncertain whether should be top-down to steer the public or bottom-up to respond to certain active voices Without teeth (UK, BC) and unclear policy impacts	Representation with teeth Shareholder model: speak for participants' interests Stakeholder model: difficulties of defining and involving stakeholders Vocal minority	Participants' active role in doing science Databases of poor quality: small scale and less representative samples and data