

Partnership in U.K. Biobank: A Third Way For Genomic Property?

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Although scientific and commercial excitement about genomic biobanks has subsided since the biotech bust in 2000, they continue to fascinate life scientists, bioethicists, and politicians alike. Indeed, these assemblages of personal health information, human DNA, and heterogeneous capital have become and remain important events in the ethics and politics of the life sciences.¹ For starters, they continue to reveal and produce the central scientific, technological, and economic paradigms so ascendant in biology today: genome, infotech, and market. Biobanks also illustrate what might be called the new distributive politics of biomedical research. Within those politics, the commodification of persons – or at the very least, of their informational representations – has challenged the ontological, ethical, and political underpinnings of the social contract between researchers and their human research subjects.² In brief, biobanks are unsettling relations between genes, tissue, medical records, and persons (both individual and collective). But it is also clear that these relations are increasingly being restructured by new rights of control, access, exclusion, and use known as “property,” both material and intellectual.

Bioethics scholarship on biobank governance has comparatively ignored property in favor of focusing on consent, Institutional Review Boards (IRBs), and privacy.³ This is both expected and strange. Expected because bioethics as a field has tended to focus on the claims of individuals rather than collectivities, and it has insufficiently theorized the role of capital in research. And strange for two reasons: first, because in a research domain permeated by markets, property entitlement is so obviously constitutive of the ethical order;⁴ second, because recent disputes around the ownership of medical records, genetic data, and tissue samples demonstrate that the now-famous *Moore v. Regents* case was just the tip of a large iceberg of normative unsettlement in this area.⁵ Yet, perhaps in spite of bioethics, biobanks are reanimating old ethical dilemmas about the marketization of persons. One problem in this area has emerged with particular force: how can societies negotiate the desire to incentivize private capital to construct the mega-experimental apparatus of genomic biobanks in order to help drive knowledge and economy forward, even as they remain deeply concerned about the penetration of markets into the personal domains of genome and body, health, and personhood?

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Practical solutions to this ethical dilemma remain elusive, despite some preliminary models both real and imagined. In my own work comparing property relations and governance in multiple biobanking contexts, I have proposed a new legal-institutional vision for negotiating a middle path for genomic resources between commodification and inalienability: the “Charitable Trust Model.”⁶ But I am far from alone in trying to articulate a potential “third way” for treating the ownership of personal information, tissue, DNA, and intellectual property in genomic biobanking. Many of these ideas call for some form of profit sharing and benefit sharing with research donors – whether by contract, regulation, taxation, of ethical standards – to remedy problems of distributive justice.⁷ Nevertheless, these ideas remain only suggestive until real attempts at negotiating such a “third way” occur.

A promising new attempt to find a “third way” has recently emerged in the United Kingdom in the form of the U.K. Biobank project. Although the scientific and social protocols of U.K. Biobank have been questioned by scientists and civil society groups alike,⁸ an international team of peer reviewers recently called governance at U.K. Biobank “exemplary” and predicted it “would be held up as a gold standard across the world.”⁹ Governance in U.K. Biobank deserves attention and scrutiny, as it is staking out a new imagination of the genomic biobank as a common-pool resource. To bastardize a famous British quotation, U.K. Biobank embodies the worst form of governance, except all those other forms that have been tried from time to time.¹⁰ From a pragmatic perspective, the U.K. Biobank’s governance model reveals both strengths and weaknesses that may be instructive to genome project planners around the world.

Property and Control in U.K. Biobank

U.K. Biobank will be a national database and biobank linking the DNA of 500,000 individuals to medical records and lifestyle details and will spend £64 million (approximately \$122 million) in public and private money. The U.K. Medical Research Council (MRC)¹¹ and the Wellcome Trust¹² will reportedly each contribute £28 million (approximately \$55 million), with the remainder falling to various governmental health agencies in the U.K.¹³ Other important contributors to the project include the group of 500,000 volunteers aged between 40 and 69 from the British public, who will be recruited as donors of personal health information and DNA. Further, a multitude of facilities, contractors, and staff will be involved in

the design of the project, which has a central node in Manchester.

Over the last ten years, biobank controversies in Iceland and elsewhere have illustrated that project sustainability will demand innovative thinking in ethical, legal, and social areas that move beyond simply adapting privacy and consent to new contexts.¹⁴ Responding to the obvious need for new institutional forms to govern such large assemblages, the United Kingdom has enacted many thoughtful design innovations in its national biobanking project. U.K. Biobank’s institu-

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tional structure is significant, for it enacts a thoughtful form of shared governance for this newly imagined kind of common pool resource: both in rhetoric and legal entitlement, British politicians and biomedical elites have constituted a form of “partnership” between funders, biobank donors, and future users – a system of shared property entitlements.

1. *The U.K. Learns from Iceland*

The governance approach implemented in the United Kingdom for its biobank project has its roots in the ethical and political critiques emerging out of an earlier project in Iceland. In December 1998, the Icelandic Parliament passed the Health Sector Database Act, which set out a new regime for the control of citizen health information in a modern democracy.¹⁵ Such information was at once declared a “national resource”¹⁶ to be controlled by the state and exclusively licensed to private industry for inclusion into a commercial genomic database of national scope. The Act immediately took on international significance and has been written about widely in the law, bioethics, and social scientific literatures.¹⁷

At the core of the Health Sector Database Act (HSD Act) was the authorization of the database’s creation and operation in Iceland by a private sector licensee.¹⁸ The Health Sector Database could be granted for a renewable term of no more than 12 years and had to meet the requirements of Iceland’s Data Protection Commission, which had been created by a previously enacted privacy law. DeCODE Genetics, an American corporation with an Icelandic subsidiary, secured the license to create and operate the HSD in 2000,

though its exclusive right was explicitly contemplated from the beginning.¹⁹ DeCODE's plans to link the health data with genetic and genealogical information were widely known, although the Act itself said nothing about biological samples or DNA, and did not mention genealogical records. The Act authorized the licensee to use the data for profit, but it provided for the protection of privacy through new encryption technologies. The HSD Act's most controversial provision authorized the transfer of all medical record data to the licensee for commercial development without the express consent of individuals, thereby invoking a rule of "presumed consent."

The Health Sector Database controversy reanimated classic ethical debates about human bodies and markets, but in the new context of the broad commercialization of biomedical research. An early salvo in the Iceland controversy came in a *New York Times* op-ed by the eminent Harvard population geneticist Richard Lewontin, who provocatively declared that Iceland had just transformed "its entire population into a captive biomedical commodity."²⁰ For its critics within Iceland, the Health Sector Database Act embraced a naïve genetic hype and the corporate appropriation of common cultural and scientific resources. Such positions were met by strong counter-arguments concerning the opportunity to leverage private foreign capital for biomedical knowledge-making and economic growth within Iceland, and the Act passed. However, the transfer of national health records to deCODE Genetics never took place, and the database was never built, due to the legal and ethical controversy over informed consent and the commodification of health information.²¹

The formulation of biobank governance in the United Kingdom needs to be seen as an explicit response to Iceland. As the Iceland project limped along, the United Kingdom began to discuss its own genomic initiative in earnest. A House of Lords Science and Technology Committee Report from 2001 demonstrates the extent to which the British approach to property in genomics was a response to the Icelandic controversy. The Committee solicited expert advice on the design of provisions for the control of tissue samples and information, and these experts registered their disapproval of the consent and withdrawal provisions in Iceland.²² Further, an influential report written for the Wellcome Trust by Paul Martin and Jane Kaye noted that "the heavy involvement of industry in human genetics research...can constrict academic freedom and open access to important research resources such as DNA banks," and that "[t]his has been a major worry for those sections of the Icelandic research community not associated with deCODE."²³

Martin, a sociologist of science and technology at the University of Nottingham, later submitted a written memorandum outlining the particular challenges of the new commercial involvement in genetics worldwide, stating:

The recent experience of events in Iceland concerning the activities of deCODE genetics and the proposed creation of the Icelandic Health Sector Database highlight the need for transparency in decision making, widespread consultation and public debate, and strong oversight mechanisms. Such an approach to policy in the U.K. could help ensure that genetic databases are well supported, function in an ethical manner and provide genuine benefits.²⁴

In addition to adducing the Iceland project, Martin also noted the emergence of for-profit genomics projects in Framingham, Massachusetts, and elsewhere in the United States as evidence that "public sample collections" were beginning to be "commercially exploited to create human genetics databases."²⁵ Martin noted the many conflict of interest problems associated with commercializing public resources, and in this sense he was prescient: many of these projects, including Framingham Genomics Medicine, subsequently collapsed due to problems of control and access to biological samples.²⁶

2. *The Ideal of Partnership*

Out of these hearings, British politicians began to articulate a vision for genomic property in the United Kingdom that explicitly rejected "ownership," i.e., allocating alienable title in a traditional sense. In 2001, the House of Lords Science and Technology Committee issued a report entitled *Human Genetic Databases: Challenges and Opportunities*. After summarizing testimonies regarding the property aspects of the prospective U.K. Biobank project, the report states that "in common with most of our witnesses, we do not regard ownership of biological samples as a particularly useful concept with respect to human genetic databases." Furthermore, it states that "we prefer the notion of partnership between participants and researchers, for medical advance and the benefit of others, including future generations."²⁷

Parliament's rejection of "ownership" for "partnership" stems from deep public and bioethical concerns about rendering personal health information and human tissue into an alienable commodity. The notion of "ownership" suggests the full and undivided bundle of entitlements associated with property, including rights of possession, use, access, exclusion, and alien-

ation. As property scholar Joseph Singer has usefully stated it, “The core conception is the notion of absolute control; ownership is the ability to do what you like with your own, without having to account to anyone else for your actions.”²⁸ In other words, ownership tends to convey a notion of exclusivity and full mastery. It also conveys the idea of complete alienability and even commodity.

In contrast, the notion of “partnership” works against the notion of exclusive ownership and connotes a form of cooperative human relations with respect to shared conditions and aims. Indeed, from its very beginning as an English word, partner denoted a shared or joint property relation.²⁹ In modern vernacular usage, a partner is “a person with a joint share in or use of something; a person who is party to something.”³⁰ We speak of spouses and intimate relations as “partners,” and in the business context, partners are “individuals with interests and investments in a business or enterprise, among whom expenses, profits, and losses are shared.”³¹ A partnership, then, in English is really a form of joint venture. In business, the Oxford English Dictionary tells us, it is “an association of two or more people as partners for the running of a business, with shared expenses, profit, and loss; the members of such an association collectively; a joint business.”³²

In Anglo-American law, partnership has a specific legal meaning: the “relation which subsists between persons carrying on a business in common with a view of profit”³³ or “an association of two or more persons to carry on as co-owners a business for profit.”³⁴ In both the American and British legal systems, partnership involves joint control of assets and an equity interest in risks and benefits.³⁵ A legal partnership entails mutual duties of loyalty. In his famous 1928 opinion as a New York appellate judge in *Meinhard v. Salmon*,³⁶ Benjamin Cardozo held that Salmon, as a managing partner in a joint venture, owed his investing partner Meinhard a fiduciary duty that required informing him of a new business opportunity. He declared that partners owe each other the highest duty of loyalty – or in his famous phrase, “Not honesty alone, but the punctilio of an honor the most sensitive.”³⁷ Now, the case remains a landmark in the common law of partnership because the latter is a relationship of trust concerning joint assets, risks, and opportunities.

The aspiration of politicians to construct U.K. Biobank as a “partnership” among donors and the research community, lay people and experts, and clinic and country, did not come out of nowhere. For some time in the U.K., leaders within the health system and bioethics community have been noting the erosion of citizen trust towards the health care establishment.³⁸ This “trust problem,” it has been noted, reflects a grow-

ing divide between leaders and experts empowered to make decisions in the biomedical domain and the citizens and patients affected by those decisions. In this context, finding a rhetorical replacement for ownership of tissue, genes, and medical information was an attempt to manage the alienation of these personal effects and parts without further alienating Britain’s wary health consumers. For politicians and planners in the U.K., claims however unfounded of commercial exploitation by national health institutions would further jeopardize the trust of patients and research subjects. The principal of “partnership” was a way to manage these concerns without giving up the potential of collaboration with industry, a key aim of the national program.

3. *Property Entitlements in U.K. Biobank*

U.K. Biobank never became a *legal* partnership between donors, funders, and the nation. Moreover, no one is even talking about partnership these days. Instead, public officials in the United Kingdom and elsewhere are increasingly speaking of the genomic biobank as a collective resource,³⁹ and the language of partnership has shifted to other notions such as stewardship. In 2004, John Newton, the first CEO of U.K. Biobank, said the project would constitute “the world’s biggest resource for the study of nature and nurture in health and disease.”⁴⁰ In a recent Biobank press release, Colin Blakemore, Chief Executive of the Medical Research Council, predicted that “over the coming years the data from this study will grow into a unique resource for future generations.”⁴¹

The system of entitlements for this newly imagined resource institutes an unprecedented set of relations between donors, managers, funders, and the public. Drawing on Elinor Ostrom’s theory of common pool resources,⁴² we can analyze forms of property and governance manifested by U.K. Biobank in order to investigate these relations. Indeed, U.K. Biobank itself, like other genomic biobanks, can be usefully described as a new kind of common pool resource.⁴³ Ostrom’s well-known book demonstrated that common pool resources in the environmental goods context evinced a broad array of formal and informal governance structures that can and do prevent overuse, thus casting doubt on the conclusion that joint ownership necessarily leads to resource depletion. Her schema of common pool resource systems and taxonomy of governance arrangements can help us assess (in the subsequent section) U.K. Biobank as a partnership among donors, managers, and resources.

Extending Ostrom’s work,⁴⁴ we can make a distinction between the “resource system” and the “resource units” of a biobank.⁴⁵ In the case of biobanks, the

resource system consists of the collection of genetic information from human samples; health information drawn directly from participants and their National Health Service medical records; the database's software and hardware architecture; and perhaps even the participants themselves, or certainly their willingness to participate. The resource units consist of data or knowledge derived from the biobank, which may also be the subject of intellectual property that can be licensed or transferred.

Entitlements over these pieces of the common pool resource are determined in the project's founding constitution, mission statement, and terms of donation and use. In order to create U.K. Biobank, the U.K. Medical Research Council and the Wellcome Trust formed U.K. Biobank Limited (Ltd), a charitable company, through a joint venture agreement in order to exercise "management oversight of U.K. Biobank."⁴⁶ U.K. Biobank Ltd's document called the Ethics and Governance Framework (EGF) was developed in 2003 by an Interim Advisory Group, a group charged by U.K. Biobank's major funders "to set standards for the project and make sure that all necessary safeguards are in place to ensure that the data and samples are only used for scientifically and ethically approved research."⁴⁷ Despite statements made in the Parliamentary discussions of biobank ownership, the EGF declares that "U.K. Biobank Limited will be the legal owner of the database and the sample collection" and that "participants will not have property rights in the samples."⁴⁸ Perhaps this is an attempt to deal clearly with a vexed issue. But given the language in the House of Lords report, it is somewhat surprising that the EGF freely invokes and assigns "ownership" in this way.

Nevertheless, U.K. Biobank Ltd's ownership in the resource *will* be constrained in a number of important ways. The first major restraint lies in its legal obligation as a non-profit entity to act in accordance with its charitable purpose, namely "to build a major resource that can support a diverse range of medical research intended to improve the prevention, diagnosis, and treatment of illness and the promotion of health throughout society."⁴⁹ U.K. Biobank Limited's Board of Directors will have fiduciary duties under U.K. charity law to manage the organization and its property in accordance with its charitable purpose. The EGF clarifies, in fact, that U.K. Biobank's Directors legally act both as charitable trustees under U.K. charity law and as company directors under U.K. corporate law.⁵⁰ Assuming that U.K. Biobank Ltd's property rights in data and tissue samples are enforceable,

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the relation between owner and asset then is not one of a homeowner to an estate, but rather of fiduciaries over a jointly held resource to be managed for public beneficiaries.

This restraint is reinforced by U.K. Biobank Ltd's public pledge to play a role of "steward" over samples and personal health data. Although U.K. Biobank Ltd understands it possesses the full set of core property entitlements in tissue and data, the document explains that

U.K. Biobank does not intend to exercise all of these rights; for example, it will not sell samples. Rather, U.K. Biobank will serve as the steward of the resource, maintaining and building it for the public good in accordance with its purpose. This implies both the judicious protecting and sharing of the resource.⁵¹

In addition to a policy of not selling samples, the EGF pledges that "data and samples will only be used for ethically and scientifically approved research," and that only research uses approved by both U.K. Biobank and a relevant ethics committee will be allowed. Further, the EGF explains that "safeguards will be maintained to ensure the confidentiality of the participants' data and samples."⁵² These will include putting data and samples in reversibly anonymized form, and storing and linking them at "very high standards of security."⁵³

Furthermore, the British taxpaying public enjoys a form of entitlement in the resource, as it is the legal beneficiary of U.K. Biobank *qua* charity. The U.K. public enjoys indirect representation on the Board of Directors, the seven-member body that includes two members from the governmental health bureaucracy, one from the MRC, and the other from the Department of Health. These two institutions, as arms of British government, are in theory accountable to the taxpaying electorate. In practice, however, this power is quite attenuated: the average taxpayer is not likely to care much about U.K. Biobank, and there are few incentives to generate collective action for more direct involvement in governance.

In the U.K. Biobank project, duties to produce public benefit are supplemented by a commitment to accountability. U.K. Biobank Ltd takes a pledge

of transparency, stating that it will “inform participants about uses of the resource...[and] will strive to build a relationship of trust with participants and the wider public, in order to foster acceptance of the ways the resource is developed and used.”⁵⁴ Further, “a detailed Access Policy for use of the resource will be developed, with guidance from the Ethics and Governance Council, which will evolve in response to users, participants and the wider public.”⁵⁵ Participants may not have control over access choices, but at least they will be made aware of guiding policies. U.K. Biobank has also made a major effort to “engage the public” on issues related to biobank governance;⁵⁶ so far, the project has held a number of “public consultations” in the United Kingdom with various segments and stakeholders.⁵⁷

Though declared to give up “ownership” of samples, biobank donors retain certain rights and powers. Research participants must give their affirmative consent according to a process specified in the Ethics and Governance Framework, and donors hold the power to withdraw from the project at any time. Both of these rules confer more powers on donors than did the Icelandic Health Sector Database Act and its notorious time-limited “opt-out” mechanism. Furthermore, the EGF also states that a “participants’ panel” may be set up in the future in order to allow participants to “express views” and submit complaints.⁵⁸

Finally, the constitution of the Ethics and Governance Council (EGC) itself is a significant development in the world of biobank governance, though its relevance to entitlement is a bit unclear. The EGC performs a number of oversight functions for the project.⁵⁹ Its tripartite remit is to do the following: (1) act as an independent guardian of the U.K. Biobank EGF and advise on its revision; (2) monitor and report publicly on the conformity of the U.K. Biobank project with the EGF; and (3) advise more generally on the interests of research participants and the general public in relation to U.K. Biobank. However, it is only within the remit of the EGC to “advise” the Board of Directors, at most a “soft” legal status with little official authority, a source of weakness that has been criticized within public consultations and by biobank commentators.⁶⁰ The group has no veto power on any policy matter, and its real power lies in going public if it is unhappy with U.K. Biobank’s actions. Furthermore, it remains unclear whose interests will be prioritized with respect to EGC constituencies, including the British public, the participants, and U.K. Biobank Ltd itself.

Assessing Governance and Property in U.K. Biobank

By understanding the actual entitlement structure of U.K. Biobank property, one is in a better position to evaluate whether the notion of partnership has been meaningfully realized.⁶¹ Has the U.K. found the elusive “third way” between full alienability and non-commodification of genomic properties? Viewed from a pragmatic perspective, U.K. Biobank indeed holds an intriguing set of property and governance arrangements. In short, the U.K. has likely found a third way. However, the project falls short of its own ideals concerning “partnership,” and in so doing, loses a potential source of strength.

1. Strengths

Politicians and project planners in the U.K. have made a number of choices that make it more likely to succeed where others have failed. First, although U.K. Biobank explicitly appropriates “ownership” of genomic property, its institutional structure achieves an interesting mixture of public and private entitlement. Embracing the need for a trusted intermediary to hold and manage the national genomic resource, the U.K. has adopted a public-private charitable model of institutional governance. It is a useful way of honoring the charitable intent of donors, protecting against liquidation in the event of insolvency, promoting research, and enacting a form of stewardship that respects the dignitary interests of bodies and persons.⁶² For this reason alone, U.K. Biobank’s institutional structure holds important advantages over many other possible property arrangements.⁶³

Second, the firm protection of withdrawal rights for donors is a positive feature that is missing from many other tissue collection projects, and indicates a good faith attempt to endow donors with limited but real rights of control over their tissues. This feature evinces a moral sensibility concerning the relation of individuals to their extracted tissues currently lacking in U.S. common law.⁶⁴

Third, U.K. Biobank’s stance towards public consultation breaks important new ground, for it embraces a soft form of public ownership over this collective technoscientific endeavor. In an effort to learn from diverse stakeholders and shape the protocol into something with broad support, U.K. Biobank Ltd has engaged various British publics and experts in critical ways. Although U.K. Biobank’s “public consultations” have been rightly criticized as too politically tailored by biobank planners,⁶⁵ they nevertheless evince a new type of reflexive relation between science and society. In this new set of relations, publics have an important role in shaping both knowledge and technologi-

cal production, with more “socially robust” knowledge and tools as potential consequences.⁶⁶ Such a shift will be increasingly important for democracies as they grapple with crucial biotechnological choices.

Finally, although this relates less directly to property, U.K. Biobank planners have undertaken their work with proper pacing. They have taken ample time developing the Ethics and Governance Framework before barreling ahead and have learned from pitfalls experienced in similar projects abroad. Although there will always be voices within the research community counseling speed, proper pacing can reap benefits not only in the ethical realm, but in the science as well. In the U.K., voices of reason prevailed, including the voices of civil society critics.⁶⁷

Slowing down the pace has meant that U.K. Biobank’s eventual scientific protocol – though still controversial – will now have the benefit of learning from developments in the field. For instance, in general, population genomics has taken a turn back to the environment as a crucial factor in gene function and health outcomes. As the explanatory power ascribed to genes in isolation of environment has diminished,⁶⁸ the scientific protocol of U.K. Biobank and other genomic cohort initiatives have been reframed to include richer phenotypic and environmental data sets. The “gold standard” population genomics study has begun to look more like a traditional long-term epidemiological study, with genotype included as one of many significant variables used to explain health outcomes. Within the genetics community, we are seeing a new desire to invest in these long-term and continuous relationships with groups of research participants; famous longitudinal studies like the Framingham Heart Study serve as such models.⁶⁹

2. A Weakness

Amidst many strengths one weakness stands out: a critical distance remains between the rhetoric of partnership and actual structure of entitlements within U.K. Biobank with respect to the donors. Parliamentary rhetoric aside, donors possess little control share, and no equity share, in the common pool resource (see Figure 1). The donors do enjoy the right to withdraw of individual donors, and a vague sort of representation by the Ethics and Governance Council. Thus, though donors may be “partners” in a limited sense, they have no role in institutional governance.

By failing to provide for some governance role for the donors, project planners have lost an important potential strength: from the perspective of pragmatism, some mechanism of meaningful representation of the donor collective could greatly enhance both participation rate, participant trust, and by extension,

project sustainability. Viability of U.K. Biobank will require the recruitment of the 500,000 donors, and also the prevention of mass invocation of the right to withdraw once samples and information are received. Both attracting and retaining participants will require that people trust that the project will be managed in ways that are consistent with their core values and expectations. Mounting evidence suggests that there may be a divide between public expectations and those of biobank managers, thereby creating an agency gap with potentially destabilizing effects.

The core values and expectations of many biobank donors are finally coming to light through social scientific inquiry. Results suggest the possibility of problems looming on the horizon. During one public consultation on U.K. Biobank performed by People Science and Policy Limited in 2002, a number of respondents commented positively on U.K. Biobank’s commitment to engage actively with participants, and its relationship to the public trust in U.K. Biobank. However, public participants also expressed a strong concern that companies would focus on “profitable diseases” rather than on major public health issues and whether any real benefits to the public from U.K. Biobank would emerge down the road.⁷⁰

During a public comment period on the initial draft of the Ethics and Governance Framework, there were major concerns regarding decision-making processes around commercial use. One respondent wondered whether the consent process would

include information about new commercial uses or contracts concerning their samples? Only by providing such information will participants genuinely be allowed to exercise a right of conscience, on the *same model as shareholders* who have ethical objections to particular...practices.⁷¹ (Emphasis added.)

Another response indicated that it would be important to present to the public not only with the intention of “augmenting the value of the resource” and aiming for “the greatest benefit” in generalized terms, but also “to show the form of *checks and balances* that will ensure these intentions – and thus specify who will have influence on defining what actually constitutes benefit – for whom.”⁷² (Emphasis added.) Concerns around governance were explicitly cast in terms of who exactly would be making resource allocations, and addressed the lack of channels for meaningful donor input. As the italicized portions indicate above, respondents explicitly invoked shareholder models and the principle of checks and balances, thus indicating a search for a different governance framework than that of a rule of experts.

Figure 1

Property Entitlements in U.K. Biobank

Entitlement	Explanation of Entitlement	Possession of Entitlement
<i>access</i>	right to enter and enjoy non-subtractive rights	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission. May be licensed to third parties if protocols are approved by U.K. Biobank and an ethics committee.
<i>contribution</i>	right to contribute to the content	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission. Extended to selected individuals within the U.K. health system.
<i>extraction</i>	right to obtain resource units or products of a resource system	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission. May be transferred to third parties if protocols are approved by U.K. Biobank managers and an ethics committee.
<i>removal</i>	the right to remove one's contribution from the resource	Donors as individuals, subject to practicalities. Processed data or material cannot be removed.
<i>management</i>	rights to regulate internal use patterns and to transform the resource by making improvements	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission, with advice from the Ethics and Governance Committee. Rules must be reflected in the Ethics and Governance Framework.
<i>exclusion</i>	the right to allocate access, contribution, extraction, and removal rights and how those rights may be transferred	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission.
<i>alienation</i>	right to sell or lease management and exclusion rights	U.K. Biobank Ltd/Board of Directors, subject to its charitable mission. Current policy expresses the intent never to sell.

Terms of ownership and control were also central themes in a 2004 Scottish study of ten focus groups exploring citizen attitudes about Scotland's arm of the U.K. Biobank.⁷³ This work found that people were willing to contribute to "the common good" and "the future of society" in this way,⁷⁴ but that there were important differences in attitudes across different demographics concerning the role of the private sector. For instance, patient groups seemed more comfortable with the fact that commercial entities would have access to the resource, believing this might speed up the production of new therapies, and they described the role of industry as a "necessary evil."⁷⁵ Nevertheless, the majority of respondents in the focus groups thought DNA and information access should be limited to medical personnel, academics, or "research scientists."⁷⁶ Most respondents thought the database should be "publicly owned" and controlled in some way, though different levels of trust were

expressed towards entities like the Scottish Executive, the U.K. National Health Service, universities, and the medical profession. Finally, there was clear discomfort about a loss of control over what was one's "own."⁷⁷ The researchers concluded that the strong support for "public ownership" of genomic property grew out of a deep uneasiness with losing control of their samples and information.

These and other studies suggest that public consultation and the principles of openness will likely be insufficient to establish trust in the governance of genetic databases. After holding a number of focus groups of their own in the U.K., social scientists Mairi Levitt and Sue Weldon have expressed doubt that the "expert agenda of policy-makers and medical ethics" addresses broader concerns expressed by potential participants such as choice, consent, lack of control, and the difficulty of establishing trustworthy governance arrangements.⁷⁸ They conclude that people

perceive potential users to be motivated by success and profit rather than by health care priorities. These researchers suggest that people will need evidence of a relationship with obligations and expectations on both sides.

Public concerns regarding access, public ownership, and control in the U.K. resonate with recent empirical work conducted in other countries. Swedish anthropologist Klaus Hoeyer and colleagues recently sampled public attitudes concerning public biobanking initiatives there. In a survey sent to approximately 1,200 donors, respondents were asked to rank the importance of different issues raised in

In the context of U.K. Biobank, the Board of Directors will have broad discretion as they set the rules for access to the biobank's "resource system" and "resource units." Actual constraints on U.K. Biobank's Board of Directors in setting policies on intellectual property (IP) and access are currently vague.⁸³ Yet, these policies on access and IP will set the balance among the potentially competing goals of assuring scientific openness, incentivizing commercial investment in the life sciences, and promoting public access to future therapies. Value hierarchies have not been made clear. The encouragement of broad access is one of the stated aims of U.K. Biobank, but so is wealth

creation. How specifically does promoting materials-sharing constrain licensing decisions? The more exclusive the terms of access are, the greater the market value of access *ex ante* will tend to be. In Iceland, the immediate exclusive license to a private company was at the core of ethical and political

In the wake of the well-documented failures of the Human Genome Diversity Project, community participation in research governance of population genetics projects emerged as a central concern.

tissue-based research. Surprisingly, only four percent marked "whether the donor is informed about the purpose of research."⁷⁹ The highest-ranking concerns were actually equality of access to and general applicability of research results, corporate skew of the research agenda, and eugenics. Investigating the motivation to contribute in the face of these concerns, the Swedish researchers found that people wanted to help the collective cause, but feared various misuses of science; they were suspicious of corporate interests in general, but seemed to accept the proposed mix of public and private in the Swedish biobanking project.⁸⁰

Strong public opinions regarding the control of samples raise important questions of donor representation in the distributional decisions of biobanks. In the face of the changing political economy of research, the "distributive agency" of biobank managers has dramatically increased.⁸¹ In democracies, distributional choices tend to be allocated to representational bodies, not experts, because they implicate basic values and visions of a good society, not just technical concerns.⁸² For example, allocating resources and structuring the tax system are core functions of a democratically elected government because of concern for the shape of obligations among individuals and between individuals and the collective. Whereas managing the biomedical research regime used to be more of a technical exercise in which experts steered human subjects research towards common mutual goals, the modern conditions of research have presented biomedical elites with new distributive choices.

debate. How is attracting private investment traded off as a goal against non-proprietary knowledge creation, and should "wealth" effects play into the calculus? There will necessarily be winners and losers when goals within the broad categories of "research," "medical advance," and "health" are given specificity, underscoring classic political questions of who decides.

The broad discretion of biobank managers is less of a problem to the extent that we believe that their actions will align with the preferences of donors. But alignment is unlikely, and the likely gap in values increases the probability of problems with recruiting and retention. An analysis of the membership of U.K. Biobank's Board of Directors suggests there may be a distributive agency gap between the directors and the donor group, especially with regard to the potential involvement of the commercial sector. Board membership evinces a clear logic of representing important Biobank constituencies, i.e., funders and also potential users.⁸⁴ The U.K. government, and especially the Medical Research Council and the Department of Health, are well represented on the board. Likewise, the Wellcome Trust has one board member. The academic research community is represented by two members. Furthermore, as is usual with corporate boards, membership includes those with status and special experience deemed relevant. The accounting partner with privatization experience signifies that the funders were seeking expertise in financial relations at the public-private interface. Alan Langlands, the Chairman of the Board, was the Chief Executive of the National Health Service from 1994-2000.⁸⁵ His con-

current position as the Chair of the Scottish Institute for Enterprise, a governmental organization seeking to promote business development in Scotland, reinforces that this was a major area of expertise sought by the funders.

One thing is clear about board membership: donor representation is conspicuously absent. The extent to which this matters is debatable. It might be argued that donor representation on the board would be mere tokenism to; no body could adequately represent the donor collective of U.K. Biobank, which will be a collection of 500,000 heterogeneous donors, without a clearly shared goal. At least a for-profit company and its large number of shareholders share a common interest in making money. Will not the collective of U.K. Biobank be likely to lack such goals? And in what way can the donor collective be meaningfully considered a political collective?

Representing the donor collective in biobank governance may be easier than it first seems. First, because payment is not allowed in recruitment, research participants will be solely donating out of the desire to contribute to the public good. Just as shareholders in a company are bound together by a common wish to make money, all donors will likely share the desire to maximize health goods for the public. Collective representation could help promote this shared interest and make management more accountable. In fact, such a group might establish an important source of checks and balances in the system.

Second, just because the group of donors will be defined and created by the planners of U.K. Biobank does not mean that it cannot constitute, *ex post facto*, a new and meaningful community that is worthy of representing. To argue otherwise is simply a failure of imagination. They would constitute a meaningful collective, just as the heterogeneous group of small investors in some private enterprise would constitute a collective. The size of the group's membership, and its likely heterogeneity, do not diminish the claims of shareholders. They should not do so here simply because the shared interests are charitable.

Realizing 'Partnership Governance' in Genomic Biobanks

In the wake of the well-documented failures of the Human Genome Diversity Project, community participation in research governance of population genetics projects emerged as a central concern.⁸⁶ Bioethicists have argued that where researched populations share some genetic characteristics or privacy risks, some form of group consent or community consultation should be required.⁸⁷ Drawing from my own comparative study of genomics, I have concluded that develop-

ing representational forms for the donor collective in biobanking would have both social and scientific benefits for the research as a whole, and hold promise for negotiating a path between raw commodification and market inalienability of human tissue collections.⁸⁸ In the U.K. context, this is also likely to be true from a pragmatic perspective. Given current board membership, there is a significant risk that if certain commercial deals are struck or if public access is somehow limited, there may be a real or perceived sense in which managers have reneged on an implied promise to advance the "public good." The adoption of a controversial policy might operate as a triggering event, eliciting withdrawals of donations and a decrease in the value of the resource.

The practical challenges, however, of adapting representational structures within this context, a national-scale project of 500,000, are daunting. Nevertheless, if donors had some form of real representative power, then project goals would be better achieved. Although existing ideas related to "benefit sharing" and labor organizing are useful, project planners and potential research participants ought to consider new forms of "partnership governance" that draw upon the legal logic of corporate governance in order to solve the agency problems involved in the management of collective genomic assets. Such structures could improve U.K. Biobank's ability to realize a true partnership between donors and researchers and find the elusive "third way" for genomic property.

The problem of how to align biobank resource distribution with the values of the donor collective has not escaped attention in the U.K. Haddow and Laurie et al., the Scottish academics previously discussed, draw upon emerging norms and practices of "benefit sharing"⁸⁹ to achieve this realignment. Having discussed public concerns about public return, they highlight the "Provincial Approval Model" of benefit sharing proposed by Daryl Pullman and Andrew Latus for Newfoundland and Labrador as a viable framework for enforcing these expectations.⁹⁰ This Canadian proposal calls for the establishment of a Standing Committee on Human Genetic Research (SCHGR) that would operate in concert with local ethical review, and would also aim to "ensure that research sponsors enter into appropriate benefit-sharing arrangements with the province."⁹¹ The Scottish group signaled the potential utility of the principles articulated under this model – distributive justice, the communal nature of genetic information, and the promotion of health as a public good⁹² – and they argue that ethical oversight bodies such as the Ethics and Governance Council (EGC) in U.K. Biobank would be "ideally placed to recommend the adoption of benefit sharing arrangements."⁹³

A greater concern for benefit sharing, and more attention to the issues of distributive justice within project oversight more generally, are important governance issues for such an oversight body as the EGC. Benefit-sharing proposals such as this, however, do not address the core agency problem underlying this discussion – i.e., the problem of representing donor interests. Although a greater emphasis on benefit sharing may produce more equitable and acceptable arrangements in the eyes of the EGC, this would only help solve the agency gap to the extent that we believed the EGC actually represented adequately the preferences and views of the donors. It might be, for instance, that under certain circumstances the donor collective might favor a completely private sector approach to some scientific problems. But donors would still lack any institutionalized forum to bring these preferences forward to the EGC or Biobank Managers, and also any power to exert these preferences.

Using the analogy of labor for the organization of donors is another creative possibility for addressing this collective action problem. In a 2003 essay, anthropologist of science Mike Fortun invoked the notion of trade unionism, via Polish “Solidarity,”⁹⁴ to suggest ways in which the politics of biobanking could be reimagined from the ground up. There Fortun argues that a bioethics arrangement to protect individual autonomy and privacy in biobanking has the unfortunate additional effect of reproducing the “atomization that benefits the status quo alone.”⁹⁵ He asks, “[W]hat are the means by which the participants in these efforts – the people who provide the informative flesh, without which nothing would be possible – will be given a *collective* voice in the future of the enterprise?”⁹⁶ Stressing the need for a more democratic biopolitical order, Fortun argues that organized labor might be a useful model for producing collective education, deliberation, and decision-making.⁹⁷

Trade unionism is a very interesting idea, but also has its problems. Fortun’s call for “genomic solidarity” recognizes the collective importance of donors and enjoins us to imagine alternative forms of collective action that could redistribute power in biobank governance. Working from the normative intuition that the existing power and ownership relations among research institutions and donors may be unfair, Fortun equates the participants with the group of laborers. But why should the analogy necessarily be labor instead of capital?⁹⁸ After all, the donors are providing the physical and information capital necessary for the collective resource to be built. It is true that the value of biobanks is enhanced if participants are willing to be recontacted and to update their information over time, which could be construed as a form of labor.

However, looking at the situation prior to donation and the transfer of entitlement, the group of donors as a collective possesses a crucial form of material and informational material that could be used to demand a share of power. The ability to construe their contributions as capital, rather than labor, and to collectivize prior to research donation has allowed some rare disease groups to use biobanking to achieve their own research goals.⁹⁹ For example, Pseudoxanthoma Elasticum (PXE) International,¹⁰⁰ mentioned by Fortun, is a non-profit foundation devoted to driving research on the rare tissue disorder. PXE International has become a well-known model for the way it has leveraged its control of the biobank *qua* biocapital in order to achieve collective goals.

A bigger problem with trade unionism might be that project planners, who hold most of the power as project initiators, will be unlikely to facilitate the organization of a donor group in the mode of labor, especially if enhancing an ethos of trust and goodwill is the central goal. The labor analogy imagines an interest-based form of relations that may not promote the very trust and goodwill that both sides, researchers and donors, seek. Unionism also tends to move the discourse away from charity and towards an interest in politics that can undermine reciprocity and productive deliberation.¹⁰¹

How then to move “partnership” from rhetoric to practice in this large of a project, involving such a heterogeneous group?

An idea we have developed elsewhere involves constituting a committee of direct representatives of the research participant group that would play a formal role within the governance of the charitable trust.¹⁰² The by-laws of the non-profit corporation or charitable trust would specify that use of the resource would be contingent on review and approval of two bodies, the typical ethics review board and also a “Donor Approval Committee” (DAC). This body would approve research protocols, but would also serve as a conduit between the donor group, the board of trustees, and the researchers in order to address controversial projects or issues as they arise. In the United States, a similar body has actually emerged out of the Framingham Heart Study in Massachusetts.¹⁰³ And with the U.K. Biobank, the DAC would provide an important democratic element to the governance of the trust, but is envisioned also as a flexible mechanism through which communication and learning could take place among the biobank constituents. But such a body would not come into being spontaneously.

Implementing Partnership through “Charitable Shareholding”

Whether and how such an idea might be adapted productively to a national project are difficult questions. It is one thing to see how a group like PXE International or an American Indian tribe with sovereign legal status might possess the necessary level of political organization and cohesion of purpose to produce a biobanking collective that is able to develop mutually acceptable terms of access and control to bodies, DNA, and health information. It is quite another to see how these examples are either relevant or useful in thinking through mechanisms to close the agency gap in large-scale projects such as U.K. Biobank, where the volunteer group is likely to be large, heterogeneous, and disconnected prior to the research. Given the ethical and pragmatic concerns discussed above, how could such projects move beyond public consultation to embrace a participatory model of resource entitlement, given the special challenges of collective action in these situations?

As discussed above, we began to suggest that certain aspects of non-profit corporate law could supplement the elements of charitable trust law, e.g., that these donor representatives could be elected periodically through proxy voting, in a process akin to the election of board members by corporate shareholders.¹⁰⁴ Using the law corporations for rethinking agency in the biobank context is less strange than it may seem at first, especially if one remembers that the corporate form is applicable to organizing collective action not only for profit, but also for charitable goals. U.K. Biobank, after all, is a legal corporation.

Any Anglo-American introductory course in the law of corporations will quickly introduce students to one central problem: when people come together to form an association, how will they ensure that the leaders designated to make important and binding decisions for the collective will act in accordance with the interests of the collective? Most of the law of corporations is aimed at solving the agency problems that can arise between managers of pooled assets and the shareholders. Rules about fiduciary duties of managers, laws against self-dealing, and proxy voting are all aimed at closing the gap between managers and shareholders, a relationship that is fraught with the potential for mistrust and misappropriation.

The charitable trust form can easily and legally accommodate elements of the non-profit corporate form; indeed this hybrid form describes U.K. Biobank's legal status. Each individual donor's stake in the management of the resulting resource is too small to warrant care, but the sum total is valuable and people might have preferences about its charitable distri-

bution. This is a classic collective action problem, and a familiar one in the realm of corporate governance in the for-profit arena, where a single corporation might have thousands of capital contributors, i.e., the shareholders. An individual shareholder might not have sufficient time or interest to attend to matters of corporate policy, but the idea that shareholders will be represented in corporate decision-making is one of the pillars of the corporate concept. Why should the same concept not apply in the realm of biobanks? Hopefully, I have argued successfully that neither a theoretical nor a pragmatic reason exists for not doing so; to the contrary, there is every reason to do so.

U.K. Biobank planners might begin to implement this idea by taking a lesson from the formation of trade unions. During the consent process, potential donors would be informed that a donor association would be formed, and that they may sign on to the association as a voluntary matter if they chose to do so. Signing on would mean that they would be responsible for voting for donor association leadership, including a president. In order to help institute real power sharing within the biobank governance structure, this president could serve on the U.K. Biobank Board of Directors, akin to how a major institutional investor would sit on such a commercial corporate board. Furthermore, the donor association could be responsible for filling a number of seats on the Ethics and Governance Council, or perhaps form a separate donor approval committee. Once a certain threshold number of signatures were obtained, say 10,000 for the projected 500,000 person biobank, U.K. Biobank Ltd could contact this group and notify them that the association had been formed and make a call for nominees for donor association leadership.

Each signatory to the donor association moving forward would have a voting share in the association elections. The votes could be operationalized by a combination of email and regular mail, just as proxy voting occurs within corporate governance. U.K. Biobank would have to provide support in the form of a staff member who would engage exclusively as a participant liaison and relations officer. An interim leadership group would be appointed in this preliminary process, to be replaced or reconfirmed by annual elections in the future.

It would be the task of the donor association leadership to organize at least one public meeting per year, so that attitudes and preferences could be assessed, and policy choices regarding resource distribution be deliberated. For instance, this group could develop guiding criteria for preferable research topics in the biobank and could also feature presentations from representatives from the other major funders to dis-

cuss joint goals and visions. Leadership would be then bound to represent these collective decisions on the Board of Directors and on the Ethics and Governance Council. As both representatives of the donor group, as well as officials of a charitable organization with a particular mission, the donor association would represent the donors while U.K. Biobank would make distributive and ethical decisions with respect to the use of the common pool resource, the biobank itself.

Some might worry that the shared governance arrangement envisioned here might, as in a trade union, take donors out of the altruistic mode and put them into an interest group modality in which they merely advance their self-interests. Would not this talk of “shareholders” and power sharing undermine the very altruism or sense of obligation that motivates people to participate in the first place? It is true that the representatives of the donor association could help enact the collective preferences of the donor group with respect to how resources are allocated. However, the organization is compelled by law to act in accordance with its charitable mission. Neither the donor representatives nor the Board of Director as a whole could act in a way that would benefit themselves or their groups in a direct financial way without seriously jeopardizing the organization’s mission and tax-exempt legal status.

Furthermore, this objection rests on the mistaken notion that the exertion of agency in how charitable contributions are allocated somehow vitiates the purity of altruism or is contrary to the spirit of public-mindedness. The contrary hypothesis, namely that increasing the agency of charitable donors might actually encourage more investment in public-minded projects, actually seems more likely. Large charitable donors, such as Bill and Melinda Gates among others, are motivated to make large charitable contributions in part because they can direct donations to their most pressing charitable priorities. In sum, donor group representation within biobank management would not imply that they could or should advance narrow self-interests; it only means that they have a share in determining how a collective public resource is charitably allocated, a form of empowerment that might actually enhance the spirit of public giving.

A second objection is that the donor association envisioned here, and its process of electing representatives for terms on the Board of Directors and on the Ethics and Governance Council, will only reproduce the same problems of agency and representation. Donors are unlikely to agree in their preferences, and new forms of representation will always be just that, representations. Somebody must speak for somebody else, and it will be specific donors who take these posi-

tions, and they will hold particular views, which could equally be said of any system of political representation. The challenge for those structuring the process by which aggregated attitudes become embodied in a small set of representatives is to find some way – through deliberation, debate, voting, etc. – to come to an acceptable form of representation. The key insights here are merely that (1) solving the agency gap between biobank donors and managers may work towards solving the well-documented trust problem; (2) the donor group requires direct representation if the social project of biobanking is to move forward fairly and sustainably; and (3) the tools of corporate governance may be useful here as they address problems of agency and collective action.

Having such a donors association and process in place could prove exceedingly useful as U.K. Biobank faces policy choices that will inevitably require legitimation. In addition to the terms of commercial access to the resource and its derivative intellectual property, other controversial policy decisions are sure to arise around the terms of recontact of donors, the terms of any benefit share and subsequent charitable use of revenue, and unforeseen types of research at the ethical frontier. Such a system is likely to provide institutional flexibility and political legitimacy at a fast evolving edge of science and commerce.

Conclusion

In this paper, we have been mostly analyzing U.K. Biobank, but there is great danger in trying to generalize from the U.K. example to all other large-scale biobanking projects, especially given divergent political cultures. These cultures carry different conceptions of the obligations flowing between individuals and the collective. And the existing social contract around health care within societies, as well as the current status and distribution of public health, should have a direct bearing on any analysis of the rights and duties flowing from public biobanking projects. Nevertheless, insights developed here may be usefully adapted in a variety of contexts in which tissue donors or other groups of research subjects require increased recognition as collective entities.

As a general rule, biobanking projects across the U.S.A., Japan, and elsewhere lack meaningful forms of collective representation for donors. The U.K. Biobank’s articulation of a partnership ideal, and its thoughtful use of the charitable trust in its innovative form of governance, provide the seeds of a genuinely new approach to the problems of genomic property. And by taking cues from the law of agency and corporate accountability to shareholders, aspiration could become reality. True “partnership” would necessarily

go beyond the idea of consultation to embrace forms of direct representation. This sort of joint venture for science and society could help constitute a just biopolitics for our age.

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35. See, e.g., *id.* at § 18 (a), (e); and *Partnership Act* (Eng.), *supra* note 33, at (2)-(7).
36. *Meinhard v. Salmon*, 164 N.E. 545 (N.Y. 1928).
37. Thanks to Prof. Jon Hanson for making this case and its remarkable language such a central theme (and a bizarre form of entertainment) in his Law of Corporations class at Harvard Law School.
38. O. O'Neill, *Autonomy and Trust in Bioethics* (Cambridge: Cambridge University Press, 2002).
39. See A. Petersen, "Securing Our Genetic Health: Engendering Trust in U.K. Biobank," *Sociology of Health and Illness* 27, no. 2 (2005): 271-292 (stating at 279 that "above all, U.K. Biobank is promoted as a significant resource for research.") See also, X. Bosch, "Beset by Practical Hurdles, U.K. Biobank Moves at Sluggish Pace," *Nature Medicine* 11, no. 7 (2005): at 696 (quoting Yusuke Nakamura, the director of the \$180 Japan Biobank initiative, as saying that "we can accelerate drug development if public universities and industry realize the value of the resource.")
40. See Newton, *supra* note 13.
41. See U.K. Biobank, *supra* note 9.
42. E. Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (Cambridge: Cambridge University Press, 1990).
43. A common-pool resource, often called a common property resource, is a type of good consisting of a resource system, whose characteristics make it difficult, but not impossible to prevent users from obtaining benefits from its use. Unlike pure "public goods," common pool resources are subject to overuse, the so-called "tragedy of the commons" because they are subtractable, but are capable of yielding benefits in a sustainable flow. *Id.*
44. Common pool resource theory is currently being extended beyond the treatment of common pool natural resources, such as fisheries and water. Recently, scholars have been applying Ostrom's theory to informational, jointly managed intellectual property, and other kinds of resources. See, e.g., C. Hess and E. Ostrom, "Ideas, Artifacts, and Facilities: Information as a Common-Pool Resource," *Law and Contemporary Problems* 66, Supplement (2003): 111-146.
45. Resource system refers to things capable in favorable conditions of producing a sustainable flow of resources without harm to the resource system, e.g., fishing grounds, grazing areas, or bridges. In contrast, resource units refer to what may be appropriated or harvested by individuals from the resource system. See Ostrom, *supra* note 42, at 30.
46. U.K. Biobank, *Ethics and Governance Framework*, Version 2, 2006, at 3, *available at* <www.ukbiobank.ac.uk/docs/EGF_Version2_July%2006%20most%20uptodate.pdf> (last visited June 20, 2007) [hereinafter cited as *EGF*].
47. U.K. Biobank, "Setting Standards: The U.K. Biobank Ethics and Governance Framework," in *EGF* Summary document, September 24, 2003 (on file with author). The *EGF* was developed with the advice of a ten-member Interim Advisory Group (IAG), composed of experts in research ethics, philosophy, law, science and social science, and consumer representation. The funders charged the IAG to advise them on "best ethical practice" in order to "provide a sound basis for fostering public trust and confidence in the project." The IAG was established in February 2003, and the first public draft of the *EGF* was published for comment on September 24, 2003. The IAG's deliberations were informed by "public consultations" carried out at several stages during the development of the project to identify concerns and priorities. However, the *EGF* was officially "prepared by the U.K. Biobank Funders and is their document." See U.K. Biobank Ltd's public memo on the IAG (on file with author).
48. See *EGF*, *supra* note 46, at 6.
49. *Id.*, at 3.
50. *Id.*
51. *Id.*, at 14.
52. *Id.*, at 3.
53. *Id.*, at 12.
54. *Id.*, at 14.
55. *Id.*
56. *Id.*, at 9 (stating that "regular communication will be important to inform participants of general findings from research based on the resource and to encourage continued participation" and that "...a variety of media, such as websites, helplines, newsletters, and public meetings will be used to inform participants about the development and use of the resource, and of ways to contact U.K. Biobank").
57. Reports of consultations *available at* <<http://www.ukbiobank.ac.uk/ethics/consult.php>> (last visited June 20, 2007).
58. See *EGF*, *supra* note 46, at I.B.4 (stating that "U.K. Biobank may also establish a participants' panel with a clear remit that it is as representative as possible of the U.K. Biobank population and able to express views typical of the participants generally. U.K. Biobank will also maintain procedures for responding in a timely fashion to any inquiries or complaints"). A Participants' Panel existed at one point, but was disbanded sometime in 2005.

59. Ethics and Governance Council Web site, available at <<http://www.egcukbiobank.org.uk/index.html>> (last visited June 5, 2007).
60. U.K. Biobank, *Ethics and Governance Framework: Summary of Comments on Version 1.0*, May 2004, at 35, available at <www.wellcome.ac.uk/assets/WTD003285.pdf> (last visited June 19, 2007) ("Whilst there was a view that the Ethics and Governance Council was acceptable, a number of respondents commented that its powers might not be sufficient in relation to individual uses of the resource, investigation of compliance, and procedures for addressing concerns.") See also, R. Tutton, J. Kaye, and K. Hoeyer, "Governing U.K. Biobank: The Importance of Ensuring Public Trust," *Trends in Biotechnology* 22, no. 6 (2004): 284-5.
61. Offering ethical and political critique across cultures is deeply problematic. Immediately one must interrogate the standards against which one is measuring an arrangement in the world; this is where Winston Churchill's quotation to reference note 10 becomes especially pertinent. Those critics measuring worldly efforts against abstract ideals do have recourse to the comparative mode, which can ground one's analysis and make it more responsive to the pragmatic.
62. See Winickoff and Winickoff, *supra* note 6.
63. For instance, in the United States, it has not been uncommon for Academic Medical Centers to broker tissue and health information of patients to profit-making genomic biobanks in exchange for equity. Here I refer in particular to the arrangements between Beth Israel Hospital, Maine Medical, Chicago and Duke with Arda's Corporation. See Winickoff, *supra* note 15.
64. See *supra* note 5 on the *Greenberg* and *Catalona* cases that have come out against enforcing such rights of tissue donors.
65. See Wallace, *supra* note 8, at 328.
66. H. Nowotny, P. Scott, and M. Gibbons, *Re-thinking Science: Knowledge and the Public in an Age of Uncertainty* (Cambridge, U.K.: Polity Press, 2001).
67. See generally the excellent work of Helen Wallace at GeneWatch U.K., e.g., H. Wallace, "U.K. Biobank: Good for Public Health?" *OpenDemocracy*, July 24, 2003, available at <http://www.opendemocracy.net/theme_9-genes/article_1381.jsp> (last visited June 5, 2007).
68. See, e.g., Collins, *supra* note 8.
69. This study, and other important long-term epidemiological studies around the world, have closely tracked cohorts over multiple generations and have re-emerged as important models for conducting a genomic cohort study. For an insider's history of this study, see D. Levy and S. Brink, *A Change of Heart: How the People of Framingham, Massachusetts, Helped Unravel the Mysteries of Cardiovascular Disease* (New York: Knopf, 2005).
70. People Science and Policy Ltd, *BioBank U.K.: A Question of Trust: A Consultation Exploring and Addressing Questions of Public Trust*, March 2002, available at <<http://www.ukbiobank.ac.uk/ethics/consult.php>> (last visited, June 20, 2007).
71. U.K. Biobank, *Ethics and Governance Framework: Summary of Comments on Version 1.0*, *supra* note 60, at 28.
72. *Id.*, at 26.
73. This study involved ten focus groups chosen to reflect a range of demographics (gender, ethnicity, and age), interests (patient, voluntary, and civic groups), and localities (rural, semi-rural or urban). G. Haddow, G. Laurie, S. Cunningham-Burley, and K. Hunter, "Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal," *Social Science and Medicine* 64, no. 2 (2007): 272-282.
74. *Id.*, at 275.
75. *Id.*, at 276.
76. *Id.*
77. *Id.*, at 277.
78. M. Levitt and S. Weldon, "A Well Placed Trust? Public Perceptions of the Governance of Genetic Databases," *Critical Public Health* 15, no. 4 (2005): 311-321, at 311.
79. K. Hoeyer et al., "The Ethics of Research Using Biobanks: Is Informed Consent Donors' Main Interest?" *Archives of Internal Medicine* 165, no. 1 (2005): 97-100.
80. K. Hoeyer and N. Lynøe, "Motivating Donors in Genetic Research? Anthropological Reasons to Rethink the Role of Informed Consent," *Medicine, Health Care, and Philosophy* 9, no. 17 (2006): 13-23; see also K. Hoeyer, "Studying Ethics as Policy: The Naming and Framing of Moral Problems in Genetic Research," *Current Anthropology* 4 (2005): S71-S90.
81. See Hayden, *supra* note 7.
82. See R. A. Dahl, *On Democracy* (New Haven: Yale University Press, 1998): 35-61.
83. See U.K. Biobank, *Policy on Intellectual Property and Access*, Draft, January 11, 2005 (on file with author) (stating that it "will encourage and provide access to the Resource and the results that flow from it as widely and openly as possible in order to maximize its use and value for research. This will include access for researchers from the academic, commercial, charity and public sectors, both in the U.K. and overseas.") *Nota bene*, a new draft of the policy is due soon, likely by the end of 2007.
84. Board members include the Principal and Vice Chancellor of the University of Dundee, Chair of the Scottish Institute for Enterprise (Chair); a professor of clinical medicine at Oxford who built up the "largest biomedical research department in the U.K."; a partner in a large accountancy firm, and a consultant to various large corporations and government, who played a "role in the privatisation of British Telecom in 1984"; Head of Department for Pathogens, Immunology and Population Studies at The Wellcome Trust; the Director of Corporate Affairs at the U.K. Medical Research Council; a professor of General Practice and Community Health Sciences in the University of Nottingham; and the Head of Research Policy in the R&D Directorate of the Department of Health. For more detail on the biographies of the individuals serving on the seven-member board, see <<http://www.ukbiobank.ac.uk/about/team/directors.php>> (last visited June 20, 2007).
85. See the public biography of Sir Alan Langlands, available at <<http://www.ukbiobank.ac.uk/about/team/directors.php#langlands>> (last visited June 20, 2007).
86. J. Reardon, *Race to the Finish* (Princeton: Princeton University Press, 2004).
87. Such groups might include disease families or ethnic-cultural groups. How exactly this principle should be implemented has remained deeply contested. See H. T. Greely, "The Control of Genetic Research: Involving the Groups Between," *Houston Law Review* 33, no. 5 (1998): 1397-1430. But see also E. Juengst, "Groups as Gatekeepers to Genomic Research: Conceptually Confusing, Morally Hazardous, and Practically Useless," *Kennedy Institute of Ethics Journal* 8, no. 2 (1998): 183-200.
88. See, e.g., D. E. Winickoff, "Health-Information Altruists," *Letter, New England Journal of Medicine* 354, no. 5 (2006): 530-31; see Winickoff and Neumann, *supra* note 2.
89. See, e.g., HUGO, *supra* note 7; Merz et al., *supra* note 3.
90. D. Pullman and A. Latus, "Benefit Sharing in Smaller Markets: The Case of Newfoundland and Labrador," *Community Genetics* 6, no. 3 (2003): 178-181.
91. *Id.*
92. See Haddow et al., *supra* note 73, at 279.
93. *Id.*, at 280.
94. Solidarity was the name of the famous trade union movement that helped overthrow the ruling socialist state in Poland. See, e.g., T. G. Ash, *The Polish Revolution: Solidarity* (New Haven: Yale University Press, 2002).
95. M. Fortun, "Towards Genomic Solidarity: Lessons from Iceland and Estonia," *OpenDemocracy*, July 10, 2003, available at <<http://www.opendemocracy.net/content/articles/PDF/1344.pdf>> (last visited June 5, 2007).
96. *Id.*, at 3. Fortun invokes solidarity in a decidedly different way than bioethicists Chadwick and Bere in the U.K. Biobank context. These bioethicists use solidarity to emphasize the communitarian obligations of individuals towards the collective public

health and biomedical research enterprise to argue against the need for burdensome procedures of going back to individuals everytime a new research protocol was proposed for studying the biobank material; R. Chadwick and K. Bere, "Solidarity and Equity: New Ethical Frameworks for Genetic Databases," *Nature Reviews Genetics* 2, no. 4 (2001): 318-321. Chadwick and Bere use solidarity to make a communitarian defense of open-ended consent so that biobank research can proceed with less hindrance; Fortun uses it with neo-Marxian and Habermasian inflections.

97. *Id.*, at 3.

98. James Boyle makes this point in his useful discussion of John Moore's famous spleen. J. Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (Cambridge: Harvard University Press, 1997).

99. S. F. Terry, "Learning Genetics," *Health Affairs* 22, no. 5 (2003): 166-71.

100. PXE International's homepage can be found at <<http://www.pxe.org/>> (last visited June 5, 2007).

101. See A. Gutmann and D. Thompson, *Democracy and Disagreement* (Cambridge: Harvard University Press, 1996): 1-53 (presenting a useful account of the necessary conditions for a meaningful deliberative political process).

102. See Winickoff and Neumann, *supra* note 2.

103. Personal communication with D. Levy, Director of the Framingham Heart Study (June, 2005). See also *supra* note 63.

104. See Winickoff and Neumann, *supra* note 2.
