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FROM BENEFIT SHARING TO POWER SHARING: PARTNERSHIP GOVERNANCE IN POPULATION GENOMICS RESEARCH

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Abstract

Translating knowledge of the genome into clinical applications will require the construction of large searchable repositories of phenotypic and genotypic information. These collections of DNA and biological information call for the sustained involvement of large numbers of research participants, and raise a host of difficult legal and ethical issues. Historically, the commercial value of medical records, bioinformation, and gene patents emerged after the regulatory structures of bioethics came into place. For some bioethicists and policy-makers, the norm of ‘benefit sharing’ has become a necessary corrective for a system seen to facilitate the appropriation of a valuable resource from research participants.

While benefit sharing should be applauded insofar as it attempts to submit relations of biocapital to new claims of distributive justice, the project is likely to fail both as a normative and practical matter without greater attention to issues of procedural justice: in particular, the constitution of distributive agency over resources for genomic research. Governance mechanisms in human subjects research are often justified as protections of research subjects from potential harms, but they also tacitly order the power to make distributive decisions over valuable collections of informational, genetic, and social capital. Benefit sharing as a discourse tends to settle political questions of distributive agency—the power to make distributive choices—in ways that exclude research participants from governing the resources they help to create.

The notion of ‘partnership governance’ presents a productive avenue for achieving a normative shift from ‘benefit sharing,’ a distributive value, to ‘power sharing,’ a procedural one. If implemented, partnership governance would empower participants to exert a share in distributive decision-making in return for contributing to the economic and social capital of the project. But it would also assign research participants with correlative obligations to other capital partners such as funders and researchers, and duties to uphold the charitable missions of biobanks. Legal principles and forms from within charitable trust law and corporate governance could help achieve ‘partnership governance,’ and address obvious challenges such as agency gaps and collective action problems.

Keywords:

genome, genomics, population, biobank, property, distributive agency, procedural justice, distributive justice, biocapital, partnership, human subjects research

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INTRODUCTION

It is widely agreed that translating knowledge of the genome into clinical applications will require the construction of large searchable repositories of phenotypic information about patients including disease diagnoses, environmental factors, and treatments, together with DNA sequences.¹ These collections of DNA and biological information call for the sustained involvement of large numbers of research participants, and raise a host of difficult legal and ethical issues.²

Whether or not participants in large-scale genomics projects are entitled, as an ethical matter, to enjoy some sort of direct benefits from the research—especially where commercial interests may be involved—remains a debated question.³ Benefit sharing proposals in population genomics have emerged in diverse contexts, from concerns about bioprospecting and the exploitation of indigenous groups, to the claims of disease group advocates, to debates over national genomic programs in Iceland, Estonia, Sweden, and

¹ Isaac S. Kohane and Russ B. Altman, 'Health-Information Altruists—A Potentially Critical Resource,' (2005) 253 *New England Journal of Medicine* 2074.

² See, eg, National Bioethics Advisory Commission, *Research Involving Human Biological Materials: Ethical Issues and Policy Guidance* (1999); Henry T. Greely, 'Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses Of Human Tissue Samples and Health Information' (1999) 34 *Wake Forest Law Review* 737; Mark A. Rothstein, 'Expanding the Ethical Analysis of Biobanks,' (2005) 33 *Journal of Law, Medicine & Ethics* 89.

³ See, eg, Kare Berg, 'The Ethics of Benefit Sharing', (2001) 59 *Clinical Genetics* 240; Anne Cambon-Thomsen, 'The Social and Ethical Issues of Post-Genomic Human Biobanks' (2004) 5 *Nature Reviews Genetics* 866, 872; Lori B. Andrews, 'Harnessing the Benefits of Biobanks,' (2005) 33 *Journal of Law, Medicine and Ethics* 22; Cori Hayden, 'Taking as Giving: Bioscience, Exchange, and the Politics of Benefit sharing,' (2007) 37 *Social Studies of Science* 729.

the UK.⁴ For instance, in an early and influential statement on benefit sharing, the Human Genome Organization (HUGO) Ethics Committee draws upon commitments to the genome as common heritage of human kind, and to the non-exploitation of actual participants, to recommend returning health benefits to participants and allocating 1-3% of profit streams to public health goods.⁵ A different context animates Jon Merz and his group at the University of Pennsylvania; drawing upon the well-known cases of PXE International,⁶ the Canavan's disease group dispute in Florida,⁷ and the Health Sector Database case in Iceland,⁸ Merz *et al.* declare that there 'has been a market failure with respect to the value added to the research enterprise by patient and subject groups.' Accordingly, they argue that 'ways should be found to recognize and reward their contributions.'⁹

Historically, the commercial value of medical records, bioinformation, and gene patents emerged after the regulatory structures of bioethics came into being.¹⁰ For some bioethicists and policy-makers, benefit sharing becomes a necessary corrective for a

⁴ Rothstein, above n 2, 95-97.

⁵ HUGO Ethics Committee, 'Statement on Benefit Sharing,' (2000) 58 *Clinical Genetics* 364.

⁶ See, eg, Sharon Terry, 'Learning Genetics,' (2003) 22 *Health Affairs* 166.

⁷ See, eg, Lori Andrews, 'Who Owns Your Body? A Patient's Perspective on *Washington University v. Catalona*,' (2006) 34 *Journal of Law, Medicine and Ethics* 398.

⁸ See, eg, Henry T. Greely, 'Iceland's Plan for Genomics Research: Facts and Implications,' (2000) 40 *Jurimetrics* 153; Gísli Pálsson and Paul Rabinow, 'The Icelandic Genome Debate,' (2001) 19 *Trends in Biotechnology* 166; David E. Winickoff, *Genome and Nation: Iceland's Health Sector Database and its Legacy*, (2006) 1 *Innovations* 80; Mike Fortun, *Promising Genomics: Iceland and deCODE Genetics in a World of Speculation* (2008).

⁹ Jon F. Merz et al., 'Protecting Subjects' Interests in Genetics Research,' (2002) 70 *American Journal of Human Genetics* 965.

¹⁰ David E. Winickoff, 'Governing Population Genomics: Law, Bioethics, and Biopolitics in Three Case Studies,' (2003) 43 *Jurimetrics* 187, 188-190.

system that previously ignored important questions of distributive justice.¹¹ But as a norm, benefit sharing has also been framed in relation to a second goal. As Canadian jurist Bartha Knoppers has put it, benefit sharing seeks to avoid both ‘*biopiracy* with no return to benefits to the families or community, and ‘*commodification of the person* through payment for access to DNA.’¹² Benefit sharing, in other words, seeks to address the inequities of an appropriation of resource value from research participants, but without recourse to *quid pro quo* payment. Searching for an elusive middle way on the contested question of bodily property,¹³ benefit sharing attempts to stitch a distributive norm at the seam of the market and gift economies.

This article will argue that while benefit sharing should be applauded insofar as it attempts to submit relations of biocapital to new claims of *distributive* justice, the project is likely to fail without greater attention to issues of *procedural* justice. In particular, we need to pay more attention to the constitution of distributive power over resources for genomic research. This position requires specification and justification through three interrelated arguments. First, benefit sharing as a discourse tends to settle political questions of distributive agency—the power to make distributive choices—in ways that exclude research participants from governing the resources they help to create. This is

¹¹ See, eg, Kadri Simm, ‘Benefit Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Human Genetic Research,’ (2005) 1 *Genomics, Society and Policy* 29.

¹² Bartha M. Knoppers, ‘Population Genetics and Benefit Sharing,’ (2000) 3 *Community Genetics* 212, 212-4.

¹³ For a useful, if opinionated, review of different takes on how to walk this middle path, see Jasper Bovenberg, ‘Whose Tissue is It Anyway?,’ (2005) 23 *Nature Biotechnology* 929. See also Charlotte H. Harrison, ‘Neither Moore Nor the Market: Alternative Models for Compensating Contributors of Human Tissue,’ (2002) 28 *American Journal of Law and Medicine* 77; Donna M. Gitter, ‘Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants’ Property Rights in Their Biological Material,’ (2004) 61 *Washington and Lee Law Review* 257.

problematic from the standpoint of both political legitimacy and empirical findings on the expectations of research participants. Second, the notion of ‘partnership governance’ presents a productive avenue for achieving a normative shift from ‘benefit sharing,’ a distributive value, to ‘power sharing,’ a procedural one. If implemented, partnership governance would empower participants to exert a share in distributive decision-making in return for contributing to the economic and social capital of the project. But it would also assign research participants with correlative obligations to other capital partners such as funders and researchers, and duties to uphold the charitable missions of biobanks. Third, and finally, implementing partnership governance might be easier than it seems: legal architectures already exist within charitable trust law and corporate governance that could help achieve ‘partnership governance,’ and address obvious challenges such as agency gaps and collective action problems.

I. DISTRIBUTIVE AGENCY AND POLITICAL LEGITIMACY

In a recent essay on benefit sharing, anthropologist Cori Hayden has pointed out that by positing norms at the level of ethics rather than formal rights, benefit sharing produces its own kind of political relations among participants, researchers, markets, and variously imagined publics.¹⁴ One thing it does is effectively silence the claims of individual property rights in excised tissue and bioinformation that, if recognized, might perform a much more radical type of redistributive project. In a suggestive turn of phrase, Hayden counsels that we could ‘make benefit sharing a problem about broader

¹⁴ Hayden above n 3, 729-758.

questions of distributive agency, rather than one that is narrowly focused on skewed ledgers of stakeholder interest, badly or better recognized.’¹⁵ This focus on the distributive agency of research institutions is critical in thinking about benefit sharing, for it turns us back to questions of power.

Benefit sharing ought to concern us from the normative perspective of political legitimacy, which tends to posit the importance of accountability and representation within processes of collective resource gathering and distribution. A significant amount of discretionary power sits within the concept of benefit sharing. First, consider the question of what types of benefits are even imagined: compensation in money or health care? Access to research resources? Revenue streams from licensing and intellectual property? Trickle-down streams of the innovation process? Second, consider the question of who exactly should benefit: individual participants? The research group? The political collective? Indeed, the substance and meaning of benefit sharing will depend on who has the ultimate power to answer these questions.

Even within well-governed biobanking projects that explicitly seek to capture value for the ‘public good,’ consider the amount of distributional choice involved. Which public is being imagined, and at what scale of organization—community, nation, or globe? Generating a return to the public is often an explicit goal, but multiple and conflicting visions of how to manage a genomic biobank for the public good coexist, raising important questions. Does public good consist in the generation of a research resource accessible as a commons to a broad set of users? Or does it consist in the ability to spur local economic growth in the form of new biotechnology companies? How will

¹⁵ Ibid 748.

intellectual property be allocated? And when does a definition of public benefit entail giving information and medical benefits back to participants?

This point captures some of my own unease with current discussions and proposals for benefit sharing. The amount of distributive agency entailed in the management of biobank resources raises important questions of who should exert this agency, and how exactly ‘benefit sharing’ and ‘public benefits’ should be constructed. Who sets the rules and policies? Following Elinor Ostrom, the theorist of common resource management, these might be labeled ‘constitutional choices’ in the design of a shared resource, i.e., choices concerning the rules for who has control over policy making.¹⁶ And it is here where I believe current thinking about the governance of genomic capital might be re-imagined.

It seems that even as courts, lawyers, and ethicists decide that individual volunteers and donors cannot exert legal rights of property in their materials once excised for research,¹⁷ it remains up to some ill-defined agency to help ensure that a rather vague principle of benefit sharing is upheld. Benefit sharing as a discourse settles political questions of distributive agency in ways that exclude research participants from sharing in the distributive power over the resources they help to create. Given this range of choices available for distributing ‘public benefit,’ we might be concerned about legitimacy in the organization of distributive agency, and think seriously about how the donor collective will be represented in resource decision-making.

¹⁶ Elinor Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (1990) 50-55.

¹⁷ The canonical case here is *Moore v. Regents of the University of California*, 793 P.2d 479, 493-97 (Cal. 1990). See also *Greenberg v. Miami Children’s Hospital* 264 F. Supp. 2d 1064, 1074-76 (S.D. Fla. 2003); *Washington University v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006).

II. THE QUESTION OF WHO WIELDS DISTRIBUTIONAL AGENCY

One way to handle the large amount of distributive agency entailed in the management of biobanking resources would be to do it through transparent expert committees. Consider the so-called Newfoundland and Labrador Model of benefit sharing that has been endorsed by Gill Haddow, Graeme Laurie, Sarah Cunningham-Burley and Kathryn Hunter—whom I will call the Edinburgh group—as a way of dealing with community concerns about commercialization in genomics research.¹⁸ In this model, developed by Pullman and Latus,¹⁹ an additional expert committee is established to solicit and negotiate collective benefits that will flow from deals between the genomic biobank and commercial companies. Pullman and Latus tell us that this committee would consist of people with appropriate expertise in genetics, medicine, pharmacology, business, law, health policy, and medical ethics, appointed by various governmental and university authorities.²⁰ The Edinburgh Group praises the principles underlying this model: distributive justice, the communal nature of genetic information, and the promotion of health as a public good.²¹ They argue that ethical oversight bodies, such as

¹⁸ Gillian Haddow et al., ‘Tackling Community Concerns About Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal,’ (2007) 64 *Social Science & Medicine* 272.

¹⁹ Daryl Pullman and Andrew Latus, ‘Reconciling Social Justice and Economic Opportunism: Regulating the Newfoundland Genome’ in Bartha M. Knoppers (ed), *Populations and Genetics: Legal and Socio-Ethical Perspectives* (2003) 543.

²⁰ *Ibid.*

²¹ Haddow et al., above n 18, 279.

the Ethics and Governance Council in UK Biobank,²² would be ‘ideally placed to recommend the adoption of benefit sharing arrangements.’²³

The governance model here is far superior to many models elsewhere, where institutional owners of biobank resources, whether corporate or non-profit, make resource allocations tacitly. However, a central problem remains: the Pullman and Latus approach praised by the Edinburgh Group seems so concerned with avoiding individual claims to benefit, that it also deprives donors from having any real control, either as individuals or as a collective group, in the dispensation of the biovalue they have been so instrumental in creating. In other words, what these models seem to ignore is the ability of individuals and collectives of volunteers to have a say in what sorts of charitable uses should be preferred. In a field in which values surely conflict regarding the allocation of collective goods through biobanks, expert decision-making becomes less legitimate. In other words, these approaches fail to protect the control interest of charitable research participants in allocating access and use rights to their biomaterials and biological information. Because managing these resources entails choices between potentially conflicting goals, e.g., between building local economic value and advancing global research access, this control interest becomes more important.

Recent empirical findings about attitudes of research participants toward commercialization underscore the importance of this control interest in bodily property and information. The Edinburgh Group found that research participants care deeply

²² UK Biobank is a project funded by the UK Medical Research Council and the Wellcome Trust that plans to collect medical data and DNA samples from 500,000 research participants. For more on UK Biobank, see project website at <http://www.ukbiobank.ac.uk/> (visited 30 September 2008).

²³ Haddow et al. above n 18, 280.

about maintaining their samples and information for public benefit, but that the issue of control is central to resolving their ambivalence about commercial access.²⁴ In addition to identifying commodification as a concern, Haddow et al. state that ‘the root of public ambivalence [about commercialization] seems to lie in (i) notions of justice and fairness about private profit being made through public exploitation, and (ii) a perceived lack of control in terms of governance.’²⁵ In these responses, the group discerns support for the control of biobank material and information by a public and trusted intermediary, and for the operation of the expert Ethics and Governance Committee within UK Biobank for handling allocation decisions in commercial relations. My own view, which I have expressed in writing elsewhere,²⁶ is that an opportunity is missed for drawing a more radical conclusion from this research: namely, that the volunteer participants within such projects would desire and deserve some sort of role in distributive decision-making. Control is a major concern for research participants, so that addressing control—not just distribution—might be an important pragmatic goal for preserving trust and interest.

Thus, in my view, procedural justice and pragmatism both require the constitution of real rights not of benefit, but of partial control of biobanks as common-pool resources. While this approach has its own challenges and problems, I also believe this approach to benefit sharing is more legitimately generalized across situations and cultures, both in developed and developing countries.

²⁴ Ibid 277.

²⁵ Ibid 278.

²⁶ David E. Winickoff, ‘Partnership in U.K. Biobank: A Third Way for Genomic Property?’, 35 *Journal of Law Medicine & Ethics* 440, 446-49.

III. PARTNERSHIP GOVERNANCE: INCORPORATING RESEARCH PARTICIPANTS

In the course 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. Bioethicists involved in the project started to articulate the importance of community consultations as a mechanism to protect the collective interests of the researched group.²⁷ The mechanisms for community consultation ultimately failed to satisfy many indigenous groups that had been approached for sampling, and the Human Genome Diversity Project eventually collapsed.²⁸ Community consultation has survived as an important norm in population genetic research projects,²⁹ but the notion still fails to solve important ethical and legal problems of providing legitimate group representation.³⁰

Drawing from my own comparative study of genomics, I have outlined new representational legal forms for the donor collective in biobanking that would carry both social and scientific benefits for research, and that hold promise for negotiating a better path between raw commodification and market inalienability of human tissue

²⁷ North American Regional Community of the Human Genome Diversity Project, 'Proposed Model Ethical Protocol for Collecting DNA Samples,' (1997) 33 *Houston Law Review* 1431.

²⁸ For an important account of the rise and fall of the Human Genome Diversity Project, see Jenny Reardon, *Race to the Finish: Identity and Governance in an Age of Genomics* (2004).

²⁹ See, eg, Morris W. Foster et al., 'The Role of Community Review in Evaluating the Risks of Human Genetic Variation Research,' (1999) 64 *American Journal of Human Genetics* 1719; International HapMap Consortium, 'Integrating Ethics and Science in the International HapMap Project,' (2004) 5 *Nature Review Genetics* 467.

³⁰ See, eg, Eric Juengst, 'What "Community Review" Can and Cannot Do,' (2000) 28 *Journal of Law, Medicine and Ethics* 52.

collections.³¹ Building on this previous work, and the selected work of others, I believe that a notion of ‘partnership governance’ could enhance the value, viability and legitimacy of genomic biobanks. Partnership governance seeks to go further than existing mechanisms of ‘community consultation,’ by implementing control rights at the level of the research participant collective. Its mechanisms would be the aggregation of individual rights of control through private ordering or contract in order to construct a shared governance structure over a collective genomic resource.

Others have theorized some interesting ways to reconstitute the role of participants in biobanks. In a 2003 essay, anthropologist of science Mike Fortun invokes the notion of trade unionism, via Polish solidarity,³² to suggest ways in which the politics of biobanking could be re-imagined from the ground up. There, Fortun argues that a bioethics structured to protect individual autonomy and privacy in biobanking has the unfortunate add-on effect of reproducing the ‘atomization that benefits the status quo alone.’³³ He asks, ‘what are the means by which the participants in these efforts—the people who provide the informative flesh, without which nothing would be possible—

³¹ See, eg, David E. Winickoff and Richard N. Winickoff, ‘The Charitable Trust as a Model for Genomic Biobanks,’ (2003) 349 *New England Journal of Medicine* 1180, 1180-1184; David E. Winickoff and Larissa Neumann, ‘Towards a Social Contract for Genomics: Property and the Public in The “Biotrust” Model,’ (2005) 1 *Genomics, Society and Policy* 8; David E. Winickoff, ‘Health-Information Altruists,’ (2006) Letter, 354 *New England Journal of Medicine* 530.

³² Solidarity was the name of the famous trade union movement that helped overthrow the ruling socialist state in Poland. See, eg, Timothy G. Ash, *The Polish Revolution: Solidarity* (New Haven: Yale University Press, 2002).

³³ Mike Fortun, ‘Towards Genomic Solidarity: Lessons from Iceland and Estonia,’ *OpenDemocracy* (July 10, 2003), at <<http://www.opendemocracy.net/content/articles/PDF/1344.pdf>> (visited 1 October 2008).

will be given a *collective* voice in the future of the enterprise?'³⁴ 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.³⁵

These are powerful goals, and trade unionism is an interesting paradigm for putting them into practice. But why should the analogy necessarily be labor instead of capital?³⁶ 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, and that this 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, informational and biological capital that could be used to demand a share of power. This is one of the insights to be drawn from the PXE International story, where disease group members formed and retained legal control of a biobank in order to help advance the particular research goals of the organization.³⁷

³⁴ Ibid 3. Fortun invokes solidarity in a different way than bioethicists Chadwick and Bere in the UK Biobank context. These bioethicists use solidarity to emphasize the communitarian obligations of individuals towards the collective public health and biomedical research enterprise. See Ruth Chadwick & K. Bere, 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases,' (2001) 2 *Nature Reviews Genetics* 318. Whereas 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 Marxian and Habermasian inflections to assert the need for enhanced class-consciousness and democratic deliberation.

³⁵ Fortun, above n 33, 3.

³⁶ James Boyle makes this point in his useful discussion of John Moore's famous spleen. James Boyle, *Shamans, Software and Spleens: Law and the Construction of the Information Society* (1997) 97-107.

³⁷ Winickoff above n 10, 222-26.

I prefer the notion of ‘partnership governance’ as a promising principle of power sharing, because it would recognize the contributions of participants as capital, not labor, conferring upon the participant group the legal standing to share in distributive decision-making. The notion of ‘partnership’ works against the idea of exclusive ownership, and at its core connotes a form of cooperative human relations with respect to shared conditions and mutual aims. In modern vernacular usage, a partner is ‘a person with a joint share in or use of something.’³⁸ We speak of spouses and intimate relations as ‘partners.’ In the business law context, partners are ‘individuals with interests and investments in a business or enterprise, among whom expenses, profits, and losses are shared.’³⁹ In both the American and British legal systems, partnership involves *joint control of assets*, and an *equity interest in risks and benefits*.⁴⁰ A legal partnership also entails mutual fiduciary duties of loyalty. In one judge’s famous words, what partners owe each other is ‘not honesty alone, but the punctilio of an honor the most sensitive.’⁴¹

But negotiating the politics of genomic capital will require moving beyond rhetoric to construct a legal architecture for partnership governance. In previous work setting out what I have called the Charitable Trust Model, I have tried to show how this could operate through what are called donor-advised trusts.⁴² I won’t review those proposals here, but instead address important criticisms I have received from friends and colleagues about these ideas. While participatory governance might work for culturally

³⁸ *Oxford English Dictionary* (2nd Ed., 1989). ‘Partner, n.(1),’ first definition.

³⁹ *Ibid* fourth definition.

⁴⁰ See, eg, *Uniform Partnership Act* (US) § 18 (a), (e); and *Partnership Act* (Eng.) (2)-(7).

⁴¹ The words are Judge Benjamin Cardozo’s in the case of *Meinhard v. Salmon* 164 N.E. 545 (N.Y. 1928), a foundational case in the law of partnership in the United States.

⁴² See especially David E. Winickoff and R. Winickoff, ‘The Charitable Trust’ and David E. Winickoff and Larissa Neumann, ‘Towards a Social Contract for Genomics,’ above n 31.

and politically cohesive groups, the criticism goes, achieving it in larger projects with many heterogeneous participants would be virtually impossible: such groups are too large to be meaningfully represented, and their interests are too disparate. 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 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 another to see how these examples are either relevant or useful in thinking through mechanisms to close the agency gap in large-scale projects.⁴³ How then to move ‘partnership’ from rhetoric to practice in large projects involving a diverse group with varied interests and purposes?

While administering such partnership governance in a meaningful way would be a complex task, I propose that principles drawn from the law of corporations should help solve some of the most difficult collective action problems. This is less strange than it may seem, for the corporate form is applicable to organizing collective action not only for profit, but also for charitable goals. Could it be that the law of corporations offers us a way to construct ‘the equity’ of biocapital? Here I refer to equity both in the sense of justice, and in the sense of capital ownership. I think so.

Each individual donor’s stake in the management of a genomic resource is too small to warrant care, but the sum total is valuable and donors are likely to have preferences about its charitable distribution. 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 millions of capital contributors, i.e., the shareholders. An

⁴³ See, eg, Bovenberg, above n 13, 931-32.

individual shareholder might not have sufficient time or interest to attend to matters of corporate policy, but the idea that shareholders will be adequately represented in corporate decision-making is one of the pillars of corporate governance.

But what about the important issue of control, and the potential gap between the donor group and their representatives? Much of the law of corporations is devoted to solving problems of agency 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. Why shouldn't we bring the same governance arsenal to bear in the realm of charitable biobanking? Hopefully, I have argued successfully that there is neither a theoretical nor a pragmatic reason against doing so—to the contrary, there is every reason to do so.

Such an approach would necessarily have to be adapted to local circumstances, but let's play out the idea in the context of UK Biobank, a project planned to include half a million people.⁴⁴ UK Biobank is already set up as a non-profit corporation, UK Biobank Ltd, with a Board of Directors that makes major institutional decisions and sets project policy. UK Biobank managers might begin to implement partnership governance by taking a lesson from the formation of a trade union. During the consent process, potential donors would be informed that a Participants 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 Participant Association leadership, including a President. In order to help institute real power sharing within the biobank governance structure, this President would serve on the UK

⁴⁴ See above n 22.

Biobank Board of Directors, akin to how a major institutional investor would sit on such a commercial corporate board. Furthermore, the Participant Association would be responsible for filling a number of seats on the Ethics and Governance Council and the Institutional Review Board, or perhaps form a separate Approval Committee. Once a certain threshold number of signatures were obtained, say 10,000 for the projected 500,000 person biobank, UK Biobank Ltd would contact this group and notify them that the Association had been formed, and make a call for nominees for Participant Association leadership.

Each signatory to the Participant Association moving forward would have a voting share in the association elections. Voting could be facilitated by a combination of email and regular mail, just as proxy voting occurs within corporate governance. UK 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 Participant Association leadership to organize at least one public meeting per year, so that attitudes and preferences of donors could be assessed, and policy choices regarding resource distribution deliberated. For instance, this group could develop guiding criteria for preferable research topics in the biobank, and could also organize presentations from representatives from the other major funders to discuss joint goals and vision. The technical aspects of biobank decision making pose significant challenges to generating meaningful discussions among a lay group of participants. However, models for deliberative public engagement on biobanks have

already emerged,⁴⁵ and these would be a useful resource for designing productive and legitimate meetings, whose outcomes would help guide the Participant Association leadership.

Leadership would be then bound to represent these collective decisions on the Board of Directors and on the Ethics and Governance Council. Acting as both representatives of the donor group, and as officials of a charitable organization with a particular mission, their own charge would be to represent the donor collective as UK Biobank makes distributive and ethical decisions with respect to the use of the common pool resource, the biobank.

IV. ADDRESSING OBVIOUS OBJECTIONS

There are obvious objections to this proposal. First, there this is the concern that a ‘shareholding’ discourse will bring volunteers out of the altruistic mode and put them into an interest group model in which they merely advance their self-interests. Wouldn’t 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 Participants Association could help enact the collective preferences of the donor group with respect to how resources are allocated.

⁴⁵ See, eg, Michael Burgess, Kieran O’Doherty & David Secko ‘Biobanking in British Columbia: Discussions of the Future of Personalized Medicine through Deliberative Public Engagement,’ (2008) 5 *Personalized Medicine* 285. See also Gillian Haddow et al., ‘Generation Scotland: Consulting Publics and Specialists at an Early Stage in a Genetic Database’s Development’ (2008) 18 *Critical Public Health* 139.

However, this only underscores the importance of using the law of charitable organizations as a legal structure for the biobank. The major funders of UK Biobank, for one, decided to use this structure. The law requires charitable corporations and trusts to be managed in accordance with their charitable missions. Neither the donor representatives nor the Board of Directors as a whole could act in a way that would benefit themselves or their groups in a direct financial way without jeopardizing the organization's public mission and tax-exempt legal status. Instead, managers of the resource share legal obligations to manage in accordance with the purposes of the organization, which puts a check on self-dealing.

More importantly, this objection rests on the mistaken notion that the exertion of agency in how charitable contributions are allocated somehow vitiates 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 and others, are motivated to make large charitable contributions in part by the fact that they can direct donations to what they see as the most pressing charitable priorities. Research participant 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.

The second major objection to this proposal is that there are significant efficiency costs involved in implementing partnership governance: inviting research participant

representatives to the management table would be difficult to achieve organizationally, and would make consensus more difficult.

Partnership governance certainly embodies a commitment to procedural justice, and this value can at times conflict with the important goal of administrative efficiency. However, there may actually be efficiency gains from partnership governance, especially in the longer term. The commitment to procedural justice in the biobanking context is based in part on the contention that the solution to difficult and even unanticipated problems in the governance of this fast moving technological field will require a robust, flexible, and appropriate constitution of power. For the oversight of a complex common-pool resource like a genomic biobank, building an architecture *ex ante* for the legitimate representation of research participants, before challenges are encountered, is likely to be a good investment.

In other words, focusing on a constitutional powers approach, rather than fixed *ex ante* benefit share, to address the issue of participant interests is a way to preserve efficient and smooth operation in face of an evolving social compact.⁴⁶ The sudden emergence of personal genomics companies and also the falling price of whole genome scans exemplify this field's fast-moving nature. With the rise of personal genomics companies like Navigenics and 23andMe,⁴⁷ it may be necessary to renegotiate the terms of information provision back to biobank participants in non-profit contexts.

Furthermore, the falling costs of whole-genome scans and their potential integration into

⁴⁶ See generally, Winickoff and Neumann, above n 31.

⁴⁷ Thomas Goetz, '23AndMe Will Decode Your DNA for \$1,000. Welcome to the Age of Genomics' (2007) 15 *Wired Magazine* (17 November) <http://www.wired.com/medtech/genetics/magazine/15-12/ff_genomics>. (visited 1 October 2008).

research models has complicated the analysis of consent, privacy, and benefit sharing in biobanking governance.⁴⁸ As biobank managers begin to weigh whether and how to allocate biobank resources to information return, and make new decisions on privacy policies in face of new technological capabilities, representatives of the donor group would already be sitting at the management table. Circumstances will change and course will have to be altered. Partnership governance may provide an efficient mechanism to handle controversial choices as the managers of genomic capital have to change course in response to new scientific and economic conditions. A commitment to fair decision-making would enhance collective trust in the face of tough policy decisions, a crucial end in itself for research with human participants.⁴⁹ But this speaks to the efficiency objection as well. A behavioral economist might tell you that increasing the agency of charitable donors might actually encourage more investment in public-minded projects.

V. CONCLUSION

To date, the governance of genomic biobanking as well as of human subjects research has tended to ignore the collective interests of research participants, instead focusing on individual consent and privacy issues. Norms of ‘benefit sharing’ and ‘community consultation’ have emerged to help fill a policy lacuna that keeps widening as biomedical research becomes more and more integrated into commercial markets. But the concerns of ‘distributive agency’ articulated by Cori Hayden in her critique of benefit

⁴⁸ Timothy Caulfield, et al., ‘Research Ethics Recommendations for Whole-Genome Research: Consensus Statement,’ (2008) 6 *PLoS Biology* e73.

⁴⁹ Onora O’Neill, *Autonomy and Trust in Bioethics* (2002).

sharing become only more important in an era in which public-private collaborations have become the norm. Governance mechanisms in human subjects research not only protect individuals from potential harms, but also tacitly order the power to make distributive decisions over valuable collections of informational, genetic, and social capital. While justice has been a traditional concern within bioethics, current conditions within the research environment call for its specification as not just a distributive, but also a procedural norm.

What I am arguing for is a different constitution for biobanking, one that moves to the procedural axis of justice by building rules for ‘power sharing’ rather than mere ‘benefit sharing.’ Principles and legal forms derived from charitable trust law and corporate governance, such as trusteeship, fiduciary duties and shareholding, could be useful for solving problems of collective action, representation and agency involved in that shift. Partnership governance could establish appropriate power conditions for negotiated solutions to distributional dilemmas, without recourse to pure market solutions in which individuals are forced to negotiate for benefits against large rent-seeking institutions. Such an approach would be democracy enhancing, and might construct a useful architecture for the new understandings of biological citizenship⁵⁰ that are emerging along with genomic sciences. Without upsetting the public mission of research, power sharing through partnership governance would begin to flesh out process rights to biological citizenship and provide avenues to reorder the relations between individuals and their medical authorities.

⁵⁰ For a review on the emerging literature on ‘biological citizenship,’ see Nikolas Rose, *The Politics of Life Itself: Biomedicine, Power, and Subjectivity in the Twenty-First Century* (2008) 6.

