Published in final edited form as:

J Law Med Ethics. 2012 ; 40(3): 612–629. doi:10.1111/j.1748-720X.2012.00694.x.

A Trade Secret Model for Genomic Biobanking

John M. Conley,

University of North Carolina at Chapel Hill, and an investigator in the university's Center for Genomics and Society. He received his A.B. from Harvard University in Cambridge, MA, and J.D. and Ph.D. (Anthropology) from Duke University in Durham, NC.

William Rand Kenan Jr. [Professor of Law],

University of North Carolina at Chapel Hill, and an investigator in the university's Center for Genomics and Society. He received his A.B. from Harvard University in Cambridge, MA, and J.D. and Ph.D. (Anthropology) from Duke University in Durham, NC.

Robert Mitchell [Associate Professor in English],

Director of the Center for Interdisciplinary Studies in Science and Cultural Theory, and Faculty in the Institute for Genome Sciences and Policy at Duke University. He received his PhD from the University of Washington in Seattle, Washington.

R. Jean Cadigan [Research Assistant Professor],

Department of Social Medicine at the University of North Carolina, Chapel Hill. She received her PhD in anthropology from the University of California, Los Angeles.

Arlene M. Davis [Research Associate Professor],

Dept of Social Medicine at the University of North Carolina, Chapel Hill and core faculty in its Center for Bioethics. She received her Juris Doctor from the University of Washington School of Law, Seattle.

Allison W. Dobson [scientist-attorney], and

Virginia Beach, VA. She received a BS in applied biology from the Georgia Institute of Technology in Atlanta, Georgia, a PhD in basic medical sciences from the University of South Alabama College of Medicine in Mobile, Alabama, and a JD from the University of North Carolina School of Law in Chapel Hill, North Carolina.

Ryan Q. Gladden [research assistant and third-year law student]

University of North Carolina, Chapel Hill. He received his B.S. in microbiology from Brigham Young University, Provo, Utah.

Abstract

Genomic biobanks present ethical challenges that are qualitatively unique and quantitatively unprecedented. Many critics have questioned whether the current system of informed consent can be meaningfully applied to genomic biobanking. Proposals for reform have come from many directions, but have tended to involve incremental change in current informed consent practice. This paper reports on our efforts to seek new ideas and approaches from those whom informed consent is designed to protect: research subjects. Our model emerged from semi-structured interviews with healthy volunteers who had been recruited to join either of two biobanks (some joined, some did not), and whom we encouraged to explain their concerns and how they understood the relationship between specimen contributors and biobanks. These subjects spoke about their DNA and the information it contains in ways that were strikingly evocative of the legal concept of the trade secret. They then described the terms and conditions under which they might

let others study their DNA, and there was a compelling analogy to the commonplace practice of trade secret licensing. We propose a novel biobanking model based on this trade secret concept, and argue that it would be a practical, legal, and ethical improvement on the status quo.

The current ethical norms of genomic biobanking—creating and maintaining large repositories of human DNA and/or associated data for biomedical research—have generated criticism from every angle, at both the practical and theoretical levels. The traditional research model has involved investigators seeking biospecimens for specific purposes that they can describe and disclose to prospective subjects, from whom they can then seek informed consent.¹ In the case of many biobanks, however, the institution that collects and maintains the biospecimens may not itself be directly involved in research, instead “banking” the biospecimens and associated data for other researchers. Moreover, the future uses of biospecimens may be unknown, if not unknowable, at the time of collection.² Biobanking may thus stretch the meanings of “inform” and “consent” to their breaking point: if you cannot *inform* subjects about what their biospecimens will be used for (because you do not know), what can they *consent* to? Given that informed consent by individual subjects is the ethical gold standard, the seeming dilution of the concept in the context of biobanking is a profound problem.³

Biobanking also calls into question whether customary assurances about protection of identity through anonymity or confidentiality can be adapted to meet the genetic research needs of today and tomorrow. Greely warned several years ago,⁴ even before major advances in identifying individuals in large DNA samples,⁵ “that patient identity is not, and cannot be, effectively protected in large-scale genomic biobanks.” Consequently, he concluded, “the practice of anonymizing data is not only nearly useless, but is itself unethical.” Moreover, even assuming that subjects’ identities can be protected through confidentiality or anonymity, these same safeguards increasingly conflict with the practical needs of genomic research, which requires broad and deep DNA datasets. Research into the possible genetic bases of diseases demands detailed phenotypic and environmental data—information about the people whose DNA it is—in order to seek correlations and infer causation. Given that the cost and difficulty of analyzing such data seem to go down almost weekly, the more information about a subject that is recorded, stored, and linked together, the more implausible it seems that the subject’s identity will be protectable. It also becomes more likely that researchers will discover clinically actionable information about individual subjects, which raises a further set of moral and ethical quandaries, since biobanks generally do not “return results” to those who contribute biospecimens and data.⁶

Concerns like these led Rothstein,⁷ in a symposium in this journal on “Regulation of Biobanks,” to call for “new ethical paradigms for research involving biobanks,” approaches that respect both “the public interest in protecting the rights of human subjects” and the public’s “substantial interest in facilitating research and eliminating unnecessary impediments to bringing to market new products.” To date, proposals for new paradigms have employed two broad strategies. One seeks to adjust existing notions of informed consent and government regulation to the new realities of genomic biobanking. For example, proposals advanced by Greely⁸ and Caulfield⁹ call for donors to give initial “general permission” or “broad consent” to a range of possible research activities, but they also couple this initial consent with enhanced regulation and the requirement that donors have the ability to learn about prospective research and (if they desire) to remove their information or biospecimens. Greely and Caulfield thus seek to retain some meaningful link between “informed” and “consent,” and in this sense, the hallowed twin protections of informed consent and Institutional Review Board oversight remain essentially unchanged in their proposals. A similar strategy is evident in the U.S. Department of Health and Human

Services’¹⁰ recent advance notice of proposed rule-making (ANPRM) to change its human subjects regulations. This lengthy document acknowledges some of the criticisms of the present regime that we note above. But it responds by reaffirming the primacy of informed consent; it characterizes its proposals as making required disclosures to subjects more accurate and meaningful and strengthening existing data security practices, while at the same time making the compliance process for researchers more rational and efficient.¹¹

Others, by contrast, have responded to the ethical dilemmas of biobanking by proposing novel legal and ethical frameworks. Winickoff and Winickoff¹² have advanced a “charitable trust” model, in which the biobank is understood as a trust with the public as the beneficiary and the managers as trustees, assuming all the legal obligations that that position entails. Fullerton and colleagues¹³ characterize the donor-researcher relationship as one of “stewardship,” with the researcher or institution having a duty of careful and responsible management of the biospecimens that are entrusted to their care. The charitable trust and stewardship models might expand the public accountability of biobank managers and ensure new modes of governance over the collected biospecimens, but it remains unclear whether they would address what we see as a fundamental underlying problem: an imbalance of power between donors and researchers that tilts strongly in favor of the latter.

This paper is an effort to respond to Rothstein’s call for “new ethical paradigms” with a biobanking model that is both old and new. Our proposal is old in the sense that it pursues many of the same ethical objectives as the current informed consent regime, with a particular emphasis on respect for persons and its corollary value of autonomy. However, our proposal is new in that it uses an analogy to trade secret licensing to transform today’s research *subject* into tomorrow’s research *participant*, a competent and autonomous partner in the research enterprise. It is also new in that it has been built from the bottom up rather than the top down. The bioethical literature and the medical research practices that both inform and motivate that literature comprise *expert* discourses. When medical and ethical experts promulgated the Common Rule requiring informed consent and mandated supervision by Institutional Review Boards, they spoke *for* subjects; a review of the current ANPRM proposals suggests that little has changed. The rules, practices, and writings of medical and ethical experts embody and give voice to concerns that they think subjects have or, at least, ought to have. But there is little *a priori* reason to assume that the experts have it right, in the sense of giving accurate voice to their claimed constituency. As the anthropologist Hoeyer¹⁴ writes with mordant understatement, “[t]he discrepancy between donor concerns and the ethics literature is worrisome.”

Our proposal, by contrast, emerges from a *folk* discourse of biobanking. Using qualitative methods derived from anthropology and discourse analysis, we conducted and analyzed interviews with 57 people who were asked to contribute to either of two genomic biobanks (about half of them joined and half declined). We interviewed them not to survey them about existing ideas, but to see if they had any new ones. And they did. In particular, people repeatedly described their DNA in ways that were reminiscent of the legal definition of a trade secret. Many then described in detail the terms and conditions under which they might let researchers use their DNA. We found this analogy to trade secret licensing compelling.

This paper reflects our effort to determine whether the trade secret model that our interview respondents suggested to us has practical potential. We concluded that it does, and provided an outline of the model in an earlier publication.¹⁵ Here, we consider in more detail both the premises of our approach and the specifics of the model. In the five sections that follow we describe the theoretical background for our approach, provide a brief legal and practical overview of trade secret licensing, present and analyze examples of the interview data that gave rise to our ideas, provide several examples of how this model might work in practice,

and compare the ethical, legal, and practical implications of our model to the status quo as well as to some of the proposed new approaches to biobanking ethics.

Part I: Theoretical Background

Our bottom-up approach has been motivated, both theoretically and methodologically, by several insights from the social sciences, especially anthropology. These insights concern (i) relationships among gifts, altruism, and medical research; (ii) the status of science as a cultural practice; and (iii) the methods by which ethical approaches are developed and evaluated.

The Gift Relationship

Much current ethical thinking about biospecimen collection has its roots in one of anthropology's oldest concepts: *the gift*, an idea originally advanced by the French anthropologist Mauss in 1924¹⁶ and elaborated by Malinowski¹⁷ and others. Mauss' fundamental insight was that the giving of a gift is neither an isolated event, nor an act of pure altruism, nor the simple transfer of a commodity; rather, it is an act of exchange that establishes or confirms a relationship of reciprocal obligations. As Mauss himself emphasized, the obligations that gift-giving both reflects and prompts may be in part economic, but will likely extend to all realms of human social activity. The contemporary anthropologist Sykes captures this idea eloquently when she writes, "When I receive a gift, it opens more possibilities in my social life than it closes. I puzzle through what to do next."¹⁸

The notion of the gift as the ideal model for tissue contributions was popularized by Titmuss¹⁹ in his famous comparative study of blood donor systems. Titmuss was well aware of (and cited) Mauss's concept of the gift, and appreciated its double-edged quality: even as gift-giving fosters community, it can burden the giver with responsibilities. But Titmuss argued that the anonymity of the UK's blood donation system overcame the burdensome, obligatory aspects of gift-giving. Since Britain's system was premised on gifts to strangers, with neither giver nor recipient having any idea of the other's identity, it filtered out the obligatory element, leaving only the community-building effects. Moreover, he argued that the UK's donation system was more efficient in its use of stored blood and yielded blood that was freer of disease than the U.S. system that allowed individuals to *sell* blood to blood banks.

In setting up the predecessor of the UK Biobank at the start of this century, Britain's Medical Research Council (MRC) drew on Titmuss in its often quoted pronouncement that the gift model of biospecimen contribution is "preferable from a moral and ethical point of view, as it promotes the 'gift relationship' between participants and researchers, and underlines the altruistic motivation for participation in research."²⁰ But the MRC's use of Titmuss's claims about the gift relationship is questionable in several respects. To begin with, to the extent that "altruistic" implies voluntary and "without any expectation of a return,"²¹ Titmuss' underlying argument has been criticized from both empirical and theoretical perspectives. Empirically, doubt has been raised about whether the blood donors Titmuss surveyed were as altruistically motivated as he reported.²² At a theoretical level, critics have long argued that Titmuss' use of the gift concept is not entirely consistent with Mauss' original formulation, that his dismissal of reciprocal obligation is far too facile.²³ The preeminent British social anthropologist Leach wrote that Titmuss' "use of gift theory from anthropology is more token than actual,"²⁴ Tutton concluded that Titmuss' interpretation of "the 'gift relationship' should be read as essentially a political conceptualization of the British donor system, defending the welfare state, and attacking the commercialism represented by the US."²⁵

But even if we assume that Titmuss' analysis of the British blood donor system was sound, there are reasons to doubt the MRC's effort to apply his model of the gift to genomic biobanks. In drawing on Titmuss' claims, the MRC seems to have ignored how closely those claims are tied to a single tissue commodity: *blood*. Donated blood has a relatively short shelf-life, and, as a consequence, when individuals donate blood, they generally understand themselves to be donating to the actual communities to which they currently belong.²⁶ That is, a gift of blood is understood as *for* someone who lives close to the donor and who will use that gift in the near future more or less in the form that it was given. It is the perfect situation for an act of unmitigated altruism.

Donating biospecimens to biobanks for future research is different in many material respects. Regardless of whether the donor conceives of the researcher, the institution, or some future research beneficiary as the recipient, a biospecimen donation lacks the temporal and geographic immediacy of a blood donation. Even if the donor considers future generations as recipients, these future recipients will not receive the gift in (roughly) the same form in which it was given, as in the case of blood; that is, these future recipients will not receive *biospecimens*, but rather therapies or drugs that have been created through the study of biospecimens. Moreover, such treatments will usually have been developed by a corporate enterprise, often acting in partnership with the non-profit research sector. Recipients of these highly mediated gifts are also likely to be found only in the distant future and will have no necessary geographic proximity to donors; as a result, givers and ultimate beneficiaries are likely to have very little felt connection to one another. Consequently, we agree with Tutton that the MRC's drawing of a sharp distinction between gift and market commodity was essentially political,²⁷ true neither to Mauss' original conception of the gift nor even to Titmuss's reformulation. Nonetheless, the Titmuss/MRC formulation has become highly influential, if not dominant. We suggest below that our model develops the idea of contribution-as-gift in a way more that is more faithful to the original.

Science as Cultural Practice

Our approach to the ethics of biobanking has been influenced by another anthropological insight, namely, its emphasis on science--including genetics--as a cultural practice. Anthropology's basic insight is epitomized by Rabinow's²⁸ coinage of "biosociality," intended as an ironic play on sociobiology. Whereas the latter refers to "culture constructed on the basis of a metaphor of nature,"²⁹ biosociality suggests a cultural model of nature. Drawing on Rabinow, Sommer³⁰ has emphasized the historical and discursive aspects of the way that genetics is understood and genetic communities constituted. Analyzing the ancestral genetics business from an anthropological perspective, she concludes that "we are indeed not confronted with genetic determinism, but with an individualized, flexible, open, market- and future-oriented politics of life itself, in which biology--even biohistory--no longer equals destiny, but has become project and commodity."³¹ This implies to us, first, that people outside the community of sanctioned experts may have worthwhile ideas about how the practice of genetics should be carried out; and, second, that those same people may prove to be competent partners in the enterprise. In the words of the anthropologists Lindee, Goodman, and Heath, "those whose bodies are necessary participants in the networks of the new genetics can no longer be construed as invisible or silent."³²

Ethics and Qualitative Data

Our approach was also motivated by a third insight, which is methodological, and which comes from the social sciences more broadly. It is the simple point that ethical analysis and any consequent identification of ethical norms should be informed by the qualitative, open-ended analysis of what the "necessary participants in the networks of the new genetics" have to say. That is, rather than assuming participants' concerns, or asking them to comment on

an a priori menu of issues, the bioethical community should ask them what they think and, as important, listen closely to what they say. Indeed, many researchers have done just that, conducting focus groups, “deliberative democracy” events, or individual interviews with people eligible to join biobanks.³³

Despite these efforts, Hoeyer notes a more general tendency in the expert biobanking literature to ignore differences in studies of participants’ concerns, to try “to make sense of contradictory data by searching for an underlying consensus,”³⁴ often in support of a one-size-fits-all model of informed consent. In his own ethnographic research³⁵ as well as in his review of the empirical work of others, he is struck by “the diversity of perceptions and expectations among different donors.”³⁶ Hoeyer sees this diversity as reflecting such contingencies as biobank type, tissue type, procurement situation, and geographical, social, and historical context. At a deeper level, he sees the diversity of concerns as evidence that ethics is emergent and discursive.³⁷ Ethics is emergent in the sense that moral and ethical views, rather than being prescribed a priori, “emerge in institutional contexts where people relate to each other in particular ways and occupy particular positions.” Thus, rather than dictating practice, ethical norms emerge from that practice. This process of emergence—which includes, importantly, the act of studying ethical positions—is discursive in that “it produces reflections on responsibility; it makes people engage in morally obliging interaction and it produces new discourses on ethics.”³⁸

Hoeyer also identifies a more specific methodological concern: “how the qualitative studies differ from the surveys, in particular in relation to how the consent requirement is viewed.” He attributes this in part “to the way in which surveys conducted without proper qualitative pilot studies tend to get answers that reflect the questions asked rather than the views that respondents hold. . . . When the wrong questions are asked, the main concerns of donors risk remaining unexplored.”³⁹ As a consequence, he concludes, “[a] great part of the biobank literature should probably be read as a story about organizational decision-making rather than ethical reasoning.”⁴⁰

While we think that Hoeyer's critique of researchers using survey methods is too categorical, our own research methods as well as the proposal that we advance have been informed by the concerns he identifies. As described more fully in the next section, the interviewers in our two studies endeavored to encourage respondents to express their own concerns rather than asking them to comment on ours. Moreover, we are persuaded that ethical positions are indeed emergent and discursive, and explicitly acknowledge our role in that process of emergence. Finally, our proposed model, rather than seeking to reconcile diverse participant views, instead adopts that diversity as a fundamental operating premise.

Part II: Methods: Discourse and Discourse Analysis

We analyzed semi-structured interviews of 57 persons who had been previously asked to join either a federally-funded and government-run biobank (G in the headings of subject quotes) that recruits based on loose geographic residence criteria (29 interviewees) or a foundation-sponsored, community-based biobank (labeled C in the headings of subject quotes) that recruits based on rigid geographic residence criteria (28 interviewees). The vast majority of people recruited for both biobanks are healthy volunteers. The government-run biobank was initially affiliated with a university medical center and thus many recruits have some connection with the university or its medical center. These recruits tend to be well-educated and many have experience working in the healthcare or scientific fields. The government-run biobank pays participants \$20 in cash. The community-based biobank recruits its subjects through a variety of media from a small, economically depressed city and the surrounding suburban and rural area. This group is more diverse in most respects,

and includes people from a wider range of educational, occupational, and economic backgrounds. The community-based biobank gives participants \$10 gift cards from a big-box store. Of the 57 people we interviewed, 30 joined the biobank that recruited them (“joiners”), while 27 declined (“decliners”).

Interviews lasted approximately 60 minutes and followed a topic outline that included questions about how people decided whether to join the biobank, and their perceptions of the benefits and risks of the biobank to themselves, their family, their community, and society. Additionally, respondents were asked about their understanding of certain features of the biobank, such as what types of data and specimens are collected and how long they are stored, the possibility of re-contact by the biobank, the potential for return of individual research results, and the ownership of the specimens. Having raised these general topics, the interviewers encouraged the respondents to go on in whatever specific direction, and at whatever length, they chose. All interviews were transcribed verbatim. The transcripts reproduce all of the words spoken during the interviews, using standard English spellings, but they do not generally capture pauses, non-verbal utterances, stress, and other features of conversation that are often reproduced in linguistic transcripts.

We refer to our method of analysis as discourse analysis. *Discourse* in its basic linguistic sense refers to connected segments of speech or writing, in fact to any chunk of speech or writing larger than a single sentence or utterance.⁴¹ It includes conversations, interviews, stories, question-and-answer sequences, and so forth. But discourse can also refer to more abstract social phenomena. Under the influence of Foucault,⁴² discourse has come to mean not simply talk itself, but the way that something gets talked about--the broad range of discussion that takes place within a society about an issue. Well-known examples from Foucault include the discourse of punishment and the discourse of sexuality. This paper focuses on one aspect of the discourse of DNA. *Discourse analysis* refers to the qualitative, fine-grained, interpretive study of recorded discourse. The method has been applied to almost every conceivable species of discourse, including everyday storytelling,⁴³ legal proceedings,⁴⁴ doctor-patient interactions,⁴⁵ written scientific literature,⁴⁶ and, as here, research interviews.⁴⁷ Since no linguistic production is context-free, no specific context is better or worse for analytic purposes than any other; rather, the key is to be sensitive to the reality that “differences in these interactional contexts can result in differences in the discourse produced.”⁴⁸

Our approach to discourse analysis has its roots in the ethnomethodological perspective inspired by Goffman⁴⁹ and Garfinkel.⁵⁰ Its defining characteristic is a bottom-up approach to the discovery of social structure and meaning. Prescinding from the search for top-down, rigid, or otherwise “real” rules and meanings, a broad range of language scholars (including linguistic anthropologists, sociolinguists, and business discourse analysts) have focused instead on patterns that appear in the course of actual interactions.⁵¹ Rules, structures, and meanings are seen as emergent from the social practice being studied rather than exogenous and pre-ordained.⁵²

The interviews themselves were conducted and recorded by a research group that includes two of the co-authors of this paper. After all of the interviews were completed and transcribed, each member of our team initially read the transcript of the recorded interviews on his or her own. We then met as a group to discuss individual interviews. Proceeding line-by-line, we commented on and discussed whatever issues were noticed by any member of the group. While the interviews themselves followed a topic outline, the analysis sessions were open-ended, with an agenda emerging only as the session proceeded. The whole approach is unapologetically interpretive. It is rigorously empirical, in the sense that every

inference is rooted in specific textual evidence (and can sometimes involve quantification), but it is not positivist and makes no claims to be so.

The fact that a member of a social group analyzes and interprets the world in a particular way does not, of course, permit one to generalize about what other members are thinking or doing. Yet, by the same token, aggregate data about a group as a whole do not allow one to say anything about any particular individual. The special contribution of discourse analysis is to create a set of firm data points grounded in actual members of the group. Unlike aggregate methods, discourse analysis allows researcher to say, “This is what a set of real people actually report about their thoughts and actions.” At a minimum, it can generate “native” hypotheses for subsequent testing by more positivist methods.

Given these strengths and limitations, discourse analysis seemed a perfect fit for our objective, which was not to discover trends or consensus viewpoints but rather to seek new ideas about the regulation of biobanking from those asked to participate in such endeavors. We can make no claim that our 57 interview respondents are representative of any larger population, nor can we claim any statistical mandate for the ideas we report. But we can state that our model emerged from the analysis of statements made by real people--the very people whom biomedical ethics endeavors to protect--when prompted to discuss their hopes and concerns in whatever form they saw fit.

Part III: The Discovery of the Trade Secret Model

We had no idea that we would arrive at a trade secret model of biobanking when we began the analysis of the interviews. Rather, the interviewees suggested the model to us as they responded to questions about other things, such as who they believed “owned” their DNA biospecimens, what they thought about the long-term storage of biospecimens, and the conditions under which they might participate in future research. As we studied their interviews, their thoughts about what DNA is and what their DNA means to them evoked for us the legal definition of a trade secret (explained below). This impression was reinforced as the interviewees talked about the conditions under which they would or would not contribute biospecimens for research purposes, and we saw a clear analogy to the practice of trade secret licensing. We stress that, because we use trade secret licensing as a *model*, trade secret law and practice need not map precisely onto the problem of biobank contributions. Nonetheless, the fit is strikingly good.

The Law of Trade Secrets and Licensing

In contrast to patent law, trade secret law is relatively simple. Under the Uniform Trade Secrets Act (UTSA), a version of which is in effect in most states, a trade secret is defined as “business or technical information . . . that (a) derives independent actual or potential commercial value from not being generally known or readily ascertainable through independent development or reverse engineering . . . and (b) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.”⁵³ The range of things that can constitute a trade secret is unlimited. UTSA defines the category to include, without limitation, “a formula, pattern, program, device, compilation of information, method, technique, or process,” and the courts have gone far beyond this list. Unlike a patentable invention, a trade secret need not meet any particular standard of novelty, inventiveness, or uniqueness as long as it is valuable, not generally known, and not readily discoverable by others. In theory, trade secret protection can last forever as long as secrecy is maintained.

People who possess a trade secret often find that they lack the desire or technical or financial capacity to exploit it themselves, and therefore decide to license it to someone who will exploit it. A license is a contract that allows the licensee to use the licensor's trade secret

under the specified terms and conditions. Common elements of such licenses include: definition and recognition of the trade secret; delineation of the licensee's rights of use; imposition on both parties of a duty to maintain secrecy; provisions to deal with improvements and other future developments; compensation for the licensor; and time limits and other termination provisions. While trade secret licenses may be exclusive, they need not be; like most other forms of intellectual property, a trade secret is a non-rival good that can be used simultaneously by multiple consumers. The Coca-Cola formula, which the Coca-Cola Company has protected since the 1890s and shared with bottlers only under restrictive licensing agreements, is one of the most famous trade secrets.

As with any contract, both parties to a license must give *consideration*--that is, they must exchange something of value. Typically, the licensor gives the right to the trade secret, while the licensee agrees to pay a royalty and to comply with the other terms and conditions. However, consideration need not be financial, and can be any "right, interest, profit or benefit accruing to one party, or some forbearance, detriment, loss, or responsibility, given, suffered, or undertaken by the other."⁵⁴ In our context, valid consideration for the licensing contract could be as simple as the biobank agreeing to use the biospecimen in a way that the participant deems beneficial.

Background Question: Who Owns DNA Biospecimens?

A preliminary point worth noting is that our respondents, like those in the expert community, are divided on the question of who "owns" a contributed biospecimen and the information it contains. A few well-known court cases have addressed this issue, and the fact that they were so bitterly fought indicates the depth of the disagreement, with the possible claimants including contributors, individual researchers, and research institutions.⁵⁵ Despite general agreement among these cases that donors do *not* have a property interest in biospecimens they contribute, and consequently no right to share in patents or financial returns derived from those biospecimens, all the cases to date have been decided under state law, and there is currently no nationally-binding resolution of the ownership issue. Reflecting this confusion, the National Cancer Institute "has chosen to use the term 'custodianship' rather than 'ownership' in the context of human specimens because issues of ownership have yet to be resolved effectively in statute, regulation, or case law."⁵⁶

Our interviewees collectively reflect a similar sense of uncertainty about the question of ownership, as well as the embedded question of whether the physical biospecimen and the information it can yield are a single or multiple pieces of property. Some--and those in this camp tended to use almost identical words--believe that when they gave their biospecimen and received payment, they "sold" their DNA. C105D, a community-based biobank decliner, strongly implied that such "sales" include both the biospecimen and anything the researcher can derive from it. To the question "[w]ho owns the DNA sample like if you had given your blood and your urine?", C105D responded "[t]hey do. . . it's theirs for that ten dollars. They can do whatever they want to with it." Others believe that the contributor retains ownership, at least of the biospecimen itself. For example, C103J, a community-based biobank joiner, responded to the question "[w]ho actually owns the DNA sample that someone gives?" by asserting "I do." Finally, some contributors are--like the NCI--ambivalent about the nature of the transaction. As the following quote from C122D, a community-based biobank decliner, reflects, understandings of the transaction are often emergent, evolving even during the interview, and perhaps influenced here by the interviewer's shift from "DNA sample" to "DNA":

I: . . . Who owns the DNA sample that people that participate in the [biobank] give?

R: I'm assuming [the biobank] once you give it.

I: Okay. So people relinquish the ownership of their DNA once they donate the blood.

R: Well, when you put it that way, that sounds kind of bad.

I: I didn't intend for it to sound bad. I'm sorry.

R: Well, you know it sounds--you know it's like--I mean I never looked at it from that standpoint legally you know.

I: Right. Yeah.

R: So but I would say--I would say [the biobank], and if that is the case, then that might be a big factor why people don't participate.

I: So that might deter people from participating?

R: Sure. Yeah. Sure.

I: To think that someone owns their DNA?

R: Yeah. Sure.

As we will explain, one of the virtues of the trade secret model is that it resolves the contentious ownership issue contractually.

DNA as a Trade Secret?

The idea of the trade secret model initially occurred to us as we heard several respondents describe their DNA as a uniquely valuable source of information about themselves. Their discussions emphasize the fundamental nature of genes and the resulting contrast between genetic information and more conventional personal information. In response to the question of what “you think is the most important thing for [a friend or family member] to understand about being in this [biobank],” G122D, a government-run biobank decliner, responded, “I would tell them that I personally would ask them to think long and hard about surrendering a piece of their essence.” Other interviewees--joiners as well as decliners--made comparable comments, with some emphasizing the immutability that distinguishes DNA from other medical information. G102J, a government-run biobank joiner, noted that whereas an individual might be able to change his or her “cholesterol and blood sugar,” DNA was “different” because “you're not going to be able to change your DNA. It is what it is.” G116J, another government-run biobank joiner, suggested that DNA is “such a personal thing. Like it's your genetics. It's who you are. And, like having that on file is just like . . . more invasive than having your fingerprint on file or having your photo on file or something. I don't know how to explain it better than that. It's like an unsettling feeling I guess.”

We took the point of these and other similar comments to be that DNA is something unique and deeply personal that is capable of revealing a great deal about the individual who is its source. By making a major effort to recruit these subjects to contribute their DNA and the information it contains, the biobank--an institution in the “business” of biomedical research--had identified that information as having value precisely because it was not generally known. The basic elements of the definition of a trade secret thus seem to have been satisfied.

The Licensing Approach

C122D, a community-based biobank decliner, proposed the contractual (or licensing) solution explicitly. Initially, she characterized her DNA as “your medical fingerprint.” She also talked about “partnering” with the biobank. Then she said, in the course of a lengthy

discussion of her concerns about joining: “So I think [the biobank] is just putting themselves up against some legal issues you know there. So I would be more interested in you know a contract being formed between [the biobank] and myself if they literally had my medical fingerprint just right at their disposal.”

Our respondents also discussed the specific terms and conditions that such a contract should include. Their proposals tracked the concept of a trade secret license: I have information that is valuable and not generally known, and I will share it with you only if you agree to certain conditions. In a commercial trade secret license, the conditions typically include compensation, limits on access and use, measures for maintaining secrecy, and provisions for allocating rights in future technological improvements. Our respondents mentioned most of these and added some others, including conditions that evoked the elements of informed consent.

The most commonly discussed term was compensation--a payment that would fit the contractual requirement of consideration but also a long-contested concept in IRB review of consent forms. The discussion of compensation usually emerged in response to questions about reasons for joining or declining. Indeed, in the case of the government-run biobank, which paid twenty dollars in cash, the vast majority of the joiners we interviewed identified easy money as their primary motivation for joining. Conversely, many of those who declined cited the inadequacy of the compensation they were offered. G101J, a government-run biobank joiner, provided a fairly typical response to the question “why did you decide to join the registry?”: “Because, I knew where the [research site] is. And so, it wasn't like a burden to figure out how to get there. And, I thought it would be an easy twenty-five dollars” (the payment was actually twenty).

Among the community-based biobank sample, several of the decliners mentioned the inadequacy of the ten-dollar gift card that was offered as compensation. M105D, for example, interrupted a long monologue about privacy and liability concerns to interject this comment about compensation, ultimately implying a conspiracy between Wal-Mart and the biobank:

No. I don't like that [the biobank accepts no liability for harm], and then another thing too was that you're going to give somebody a ten-dollar Wal-Mart card for coming down to this lab. Why don't you give them ten dollars in cash? I mean that's ridiculous . . . Now they want people to come and do interviews and research with you, and you want to give them a ten dollar Wal-Mart card, but Wal-Mart is so far down the road. You got to drive down there to use the card. . . . That's just like Wal-Mart has some kind of connection with [the biobank]. Okay. “We're going to give you this ten-dollar Wal-Mart card because Wal-Mart's going to let us have it for six dollars if we give them out to you all.” So everybody comes to Wal-Mart because if you come there with a ten dollar card, you're going to spend at least twenty.

Adequate financial compensation thus seemed extremely important to many respondents, just as it would be to a commercial licensor. We see no ethical, legal, or practical reason why this concern should not be recognized and addressed straightforwardly.

Our respondents also stressed other terms and conditions, sometimes in addition to money and sometimes in lieu of it. For example, G102J, the joiner who previously stressed the immutability of DNA (“it is what it is”) emphasized the importance of limiting access. G102J would permit use by legitimate researchers with “good intentions” who follow the proper channels. To the question of “[w]ho can study the DNA in the [biobank],” G102J responded:

I don't know in particular who. But, I imagine they would have to submit some sort of proposal or request to the [biobank]. And, they would make sure that they were legitimate researchers. And, people who I guess have good intentions. And so, it can't be someone pretending to do research or trying to get at genetic information in some roundabout way. So, I think it's strictly for research purposes.

Lack of clarity regarding access was a deal-breaker for G122D, a government-run biobank decliner, who stated that the decision not to join the biobank was “actually pretty easy. Once I thought about it, I was just like ‘No. I'm not interested in putting my information in a repository where I have no understanding of who would have access to it or how long it's going to be [there].’”

Many respondents focused on the terms and conditions of use. Regarding permitted uses, The same respondent (G122D) initially indicated that she would be unwilling to participate in any genetic study (although she has participated in other kinds of studies). In response to the question of whether there would be “certain kinds of genetic studies you could see yourself participating in,” she responded: “I don't think so. . . I'll do viral. I'll do behavioral. But, apparently I won't do genetic. Yeah. Interesting.” However, she later added a “specificity” provision pursuant to which she would permit a genetic study if a family member suffered from some condition:

I think if I had a family member who presented with some disease that they thought had a genetic affiliation. And, asked for a DNA sample in order to rule out something. I would participate. So, again we're back to specificity. If I had a concrete reason that perhaps had a personal revelation in it, I would probably volunteer. It's this anonymous bank[ing of] your blood that just doesn't sit well with me.

Another set of respondent concerns involves the researchers' rights and obligations to re-contact them about individual research results that might be clinically significant or otherwise personally meaningful--currently a hot topic among researchers and ethics commentators. G103J, a government-run biobank joiner, said that failure to contact would be “unconscionable,” a powerful legal concept usually associated with consumer contracts. Although the question was directed at what *will* happen (“If a later study finds a connection between somebody's DNA and a condition or disease, will they give that person this information then?”), G103J responded in terms of an *ought*: “Yeah. I believe so. I mean it would seem unconscionable not to.” C122D, a community-based biobank decliner, made the same point in ethical terms, even distinguishing between possible ethical and legal thresholds for disclosure. In response to the question of whether the biobank would contact an individual should the biobank “fin[d] a connection between someone's DNA and a condition or disease,” C122D responded, “I would certainly hope so from an ethical standpoint. I don't know if they're required to legally, but I would hope so.”

C105D, a community-based biobank decliner, gave an especially detailed and vivid statement of the duty to return clinically significant results. C105D understood the biobank to have “said” that it *would* return clinically significant results, but that it “couldn't [be] held reliable [*sic*; liable?] if they didn't.” This seemed to frustrate the interviewee, who felt that:

if an individual takes their time to come to you for you to do research with them, then you should take your time to go “Okay. You're dying.” Click. It's just that simple. If they taking their time to come down there for that little ten dollars to come to your lab to let you prick and poke them. Maybe two or three times now you could have been there. Now you found something within their DNA. You can't respect them enough after they've given you your stuff to go on with your research because without them you wouldn't have it. . . . So if people are going to do that,

give them--pay them respect. Call them and say . . . “[t]his is [biobank]’s research. You’re dying.” Click. Two seconds you know. . . You know what I’m saying?

G121D, a government-run biobank decliner, would condition her potential contribution on the “reward”--which she distinguished from “compensation”--of receiving relevant genetic information in the future. G121D contended that:

[if a person] contributed to a study that was finding out information linking some of their genetic differences to diseases, and, they had one of those genetic differences, I think they would want to know that. Because, they participated in the study. So, they’d want some sort of--not compensation--but, reward I guess for participating. That they’d want to benefit from the study as well as have the knowledge.

This understanding fits well with Mauss’ original conception of the gift, in that the participant’s contribution is seen as creating an ongoing reciprocal relationship. It is also consistent with the legal notion of the contract, where both sides must give consideration, though it need not be financial.

Others suggested two related provisions that are common in trade secret licenses: time limits on the license and the destruction of materials embodying the trade secret when the license ends (as when a trade secret is disclosed on an electronic medium, which must be destroyed along with all copies when the license terminates). G119D, a government-run biobank decliner, responded to an open-ended question at the end of the interview by emphasizing that the deal-breaker had been that the biobank would not document that it was living up to its side of the bargain:

I think one thing for me that might have tipped the scales and convinced me to participate was if there would have been some guarantee that after my blood sample were taken and then analyzed as they needed--that when it was destroyed or gotten rid of somehow, that I could have received some confirmation of that. I mean something even as simple as an e-mail . . . just knowing that in a sense they kept up their end of the bargain by analyzing the sample that I willingly provided. And now, they’ve gotten rid of it. So, that it’s not just floating around out there for anybody to come across.

G119D also noted that he would have been comfortable with the study had the physical samples been destroyed after a relatively short period of time:

. . . for a shorter study if they said “We’re going to analyze your DNA. And then, all the analysis will be done within three years. And then, we’ll destroy the physical material you provided.” Three years or five years. That may have been--I’d have to look at the case by case again of course. But, that may have been more appropriate in my mind. Of course I realize that the actual information--the results of the analysis is probably going to be stored on some computer for decades and decades in the actual database. But, the physical material that I provide. The blood and whatever they do with it. If it were going to be destroyed within a relatively short amount of time, that probably would have been a--that probably would have put my mind more at ease.

Finally, G102J, a government-run biobank joiner, emphasized the importance of a unilateral right to terminate the arrangement--in typical informed consent terms, a right of voluntary withdrawal from the study--in the event of anything that might make one “kind of squirrely.” To the question of what he thought was “the most important thing for someone to understand about being in the [biobank],” G102J responded: “[p]robably the fact that you can withdraw at any time. So, like even if you have any questions about ownership and all

that stuff. Like if you get kind of squirrely about anything then, you just say ‘Look. Okay. I’m calling it quits. Just pull my stuff out. That’s it. I’m done.’”

In summary, we analyzed these interviews seeking new ideas, not to make quantitative claims about how some population thinks. An idea that emerged repeatedly was to structure the contribution of DNA biospecimens on a quid pro quo contractual basis, and in particular along the lines of a trade secret license. Because we use trade secret licensing simply as a model for the transaction, the fit need not be exact. Nonetheless, our respondents’ folk-legal analyses tracked the law and practice of trade secrets with remarkable precision. They saw in their DNA and the information it encodes something of unique value in the “business” of medical research--the traditional definition of a trade secret. They were willing to let others exploit their trade secrets, but only under restrictive conditions. Like other trade secret licensors, they demanded compensation, restrictions on access and use, the opportunity to share in the benefits of future research, a limited term to the license, destruction of the evidence at the end of the term, and a fairly open-ended right of termination.

Part IV: The Practicalities of the Trade Secret Model

The fact that many of our interviewees reasoned about their relationship to a biobank with a logic analogous to that of trade secrets is no guarantee that a trade secret model would prove practical in the world of contemporary research. Yet after considering different ways in which this model might be implemented, we conclude that not only could such a model work, but it could also resolve many of the ethical and practical contradictions that we outlined at the start of this paper.

We stress that the biobank-participant agreement we propose *would be a contract*, explicitly and unequivocally. Present informed consent practice exists in a legal netherworld. The documents look superficially like contracts: the participant agrees to give a biospecimen, and--apparently in return--the researcher or institution typically undertakes at least to use best efforts to protect the participant in various ways. Moreover, money usually changes hands. But researchers have resisted efforts to construe informed consent documents as creating enforceable contractual rights; two courts have agreed with the researchers,⁵⁷ while one has found contractual rights in a much-criticized decision arising from unique facts.⁵⁸ Yet if the informed consent documentation is not evidence of a contract, then what is it? One court⁵⁹ has treated a biospecimen contribution as a gift; if so, then perhaps the informed consent documents amount to a kind of deed. Otherwise, from a legal perspective, the documents seem to be nothing at all: a set of vague consumer disclosures that are mandated by federal regulations but that give injured consumers no privately enforceable rights.

Basing the biospecimen contribution on a contract has the virtue of resolving these ambiguities. The law deems some kinds of contracts unenforceable--you cannot enforce a contract to kill someone, or to buy a child--but a contract to provide a DNA biospecimen between a competent, healthy volunteer and a research institution should be enforceable in all respects. Accordingly, the deal would be whatever the parties defined it to be. Ambiguities like those in the case law would be avoided: participants would have whatever rights--and researchers would have whatever obligations--the contract gave them. Further, as we have reported elsewhere,⁶⁰ donors expect to be able to find written information about the terms and conditions of their research participation in the informed consent forms they signed. It was common for respondents to characterize those forms as “contracts” or legal documents. In our interviews, when respondents could not recall key features of biobank participation, they often noted an expectation that they could find the answers in the form. A simple, explicit, written contract would do a better job of meeting this expectation than the

current generation of informed consent documents, which equivocate on many of the issues most important to our interviewees.

In early presentations of our model, some people from the research community have reacted in a strongly (indeed, viscerally) negative way to the contractual basis of our proposal. One way to interpret the reaction is to see it as self-interested. In the present state of legal ambiguity, subjects have no enforceable rights; the researchers have won that point in most leading cases. Why should they give that up? But there is also a principled side to the objections we have heard: that a contractual approach transforms an idealistic act into a commercial transaction, which is bad, for it will encourage “biobankers and contributors [to] compete against each other to obtain the most favorable economic terms.”⁶¹ This point seems more ideological than empirical. First, contracts need not be commercial. People regularly contract to make charitable contributions, financial or in kind, and our proposal can accommodate consideration other than money.

Moreover, we question the premise that tissue contributions are currently entirely altruistic. Several studies,⁶² including our own, indicate that people have diverse motives for giving biospecimens. Some see it as a purely eleemosynary gesture, whereas others report pursuing various self-interests, including hoped-for medical benefits for themselves or their families, economic benefits to their communities, and--in the case of many of our interviewees--a little easy money. Why should we be squeamish about that? Are such contributions tainted, or somehow unworthy? Biobanks are not turning these people away today, so we see no harm in simply bringing their motives out into the open. Biomedical research *is* a business. Everyone else is being paid--some a great deal--so why not those contributors who would like to be?

This leads to a related objection: that--as the current informed consent regime postulates--it is unethical to view payments to subjects as a direct benefit, and our contractual model would do so. In our view, this objection rests on the linguistic fiction that there is a difference between money as an inducement to participate and money as a gratuity to defray the expense and inconvenience of participation. As noted above, many people we have interviewed already view the small payments they are offered as a direct benefit, and report that adequate compensation can be a strong incentive to participate (whereas inadequate compensation can be an equally strong disincentive). To most people most of the time, money is money. Avoiding calling it a benefit may make the biomedical community feel better about itself, but it seems far removed from everyday reality.

Finally, we acknowledge another obvious criticism of our model: that current research participation, under the Common Rule, may not require subjects to waive their legal rights. But many, if not most current informed consent documents *do* attempt to effect a waiver of legal rights; for example, new draft guidance from the Department of Health and Human Services permits such language as “I give up any property rights I may have in bodily fluids or tissue biospecimens collected during this research” and “[a]lthough future research that uses your biospecimens may lead to the development of new products, you will not receive any payments for these new products.”⁶³ Our model makes legal rights and responsibilities explicit, and thereby urges a fundamental change in how we view participation. The trade secret model would allow researchers and institutions to retain all of the informational aspects of current informed consent practice, while at the same time permitting potential subjects to consider whether or not the offered terms are acceptable to them. Different individuals might participate in the same research study in different ways. The model would let potential subjects gauge the benefit/risk ratio acceptable to *them*, based on *their* perception of the research relationship, not that of some third party. Yet, as we argue in the next section, the greater flexibility of the trade secret model does not necessarily impose

more onerous requirements on biobanks and researchers than the current system, with all its ambiguities.

Sample Agreements

In assessing the feasibility of a simple licensing approach, we were influenced by the experience of the University of North Carolina at Chapel Hill with its “Carolina Express Licensing Agreement,” which is intended to streamline the licensing-out of university-owned patents and other intellectual property.⁶⁴ The license itself has a few straightforward terms, including university ownership of intellectual property, a specified annual royalty, and a one-time payment to the university of a percentage of net worth if the licensee company is acquired or goes public.⁶⁵

We think that a similar approach--even simpler in concept, given the absence of financial accounting issues--might work with biospecimen contributions. Although the Carolina Express license is one-size-fits-all, take-it-or-leave it, we see no reason that a biobank contributor license with two or three “menu” options would not be equally feasible. Table 1 presents a working outline of what three such options might look like; actual users would be free to adapt any of these or develop their own. Moreover, our model could function as an innovative supplement to the existing informed consent process or replace it altogether.

There is no legal reason that the actual agreement would have to be expanded significantly beyond these basic points. More particularly, there is no reason to believe that such an agreement would need to be any longer or more complicated than the typical informed consent document; in fact, it could be far shorter and simpler, since its objectives are clear and intended to be forthrightly disclosed. It has been suggested to us that our model would inevitably be harder for subjects to understand than current informed consent documents. While acknowledging that this is an inherently subjective determination, we disagree. Having reviewed many research consent forms, we find they are often long, opaquely worded, and fraught with subtleties (concerning, e.g., the nature of the researcher's obligations). With our model, by contrast, the core concept is very simple--there is an explicit exchange between contributor and biobank--and there is nothing that cannot be conveyed in clear and succinct prose. Our contract need not look like, say, a consumer finance contract, burdened by government-mandated legalese and full of lender-friendly loopholes.

The examples below illustrate the model's capacity to address the modern-day challenges we have discussed (ownership, privacy, access to biospecimens, etc.) in a tailored fashion according to the goals of each biobank and its participants' expectations.

Conclusion

Our research was initially motivated by the widely expressed belief that the traditional informed consent regime is broken, at least when applied to genomic biobanking. This concern about the current system has legal, practical, and ethical elements. The legal problems are manifest in a set of inconclusive cases, binding only in limited jurisdictions, that wrestle with such questions as the nature of the contribution transaction, who owns biospecimens and derived information, whether contributors have a right to share in the fruits of future research and development, and whether researchers have professional obligations to contributors. The practical and ethical components of the critique are closely related. Practically, today's research needs huge biospecimen collections, often linked to phenotypic data. Tomorrow's research needs will be at least as great, but it is difficult to predict just what they will be. At the same time, researcher-hackers continue to demonstrate just how difficult it is to guarantee anonymity and/or confidentiality. The result is a perfect

storm that casts doubt on just how ethical the current regime really is--a doubt that will only grow moving forward.

In search of new ideas, we went to the regime's presumed beneficiaries: people who have been asked to contribute genetic biospecimens to long-term biobanks. As we have noted, we did not survey these people in the formal sense, and we make no claim that their ideas are representative of any larger group. Rather, we listened to them to see if they had ideas for resolving the current quandary. And they did: many of them described a contractual quid pro quo in which they would grant varying degrees of access to their DNA depending on the terms and conditions--including but not limited to compensation--that were offered in exchange. (Many also seemed to believe that they were currently participating in a system with precisely those features, despite the fact that the informed consent documents they received made it clear that they were not.) The analogy to the widespread practice of trade secret licensing struck us as compelling, and we adopted it as a loose model.

Our model, like the current regime and any of the alternatives that have been offered, should be evaluated for its ability to satisfy legal, practical, and ethical criteria. Legally, its key feature is its explicit adoption of the contract as the basis of the exchange. Some who have responded to early versions of our proposal have found the contractual approach both overly legalistic and a regrettable, even dangerous, departure from the ethic of donation that has been understood, at least since Titmuss, as an essential foundation of contemporary biomedical research. Both elements of this view seem to us misguided.

First, the fact that the trade secret model employs an explicit contract renders it *less* complex, legally, than current informed consent documents. In fact, perhaps the most significant benefit of the contractual approach is its legal certainty. Whereas the current regime has produced ambiguity and misunderstanding about the respective rights and obligations of contributors, biobanks, and researchers and their institutions, the very nature of a contract is to define such things in a way that both parties accept.

Moreover, far from hindering the ethic of the gift, the trade secret model in fact returns us to an understanding of the role of gifts in contemporary biomedicine that is closer to Mauss's original, reciprocity-based model. The use of a contract to make explicit the fact of exchange does *not* require that one determine a "price" for human biospecimens, nor does it require that one establish a metric of equivalence between what the two sides are exchanging. Financial compensation can be part of the exchange, but need not be; as our sample menu options illustrate, the exchange can be structured as a sale, an outright gift, or something in the middle in which contributors receive non-financial consideration that they deem significant. Where money is exchanged, our model recognizes it for what it is--compensation, and an inducement to contribute-- and does away with the illusory, if not deceptive, treatment that money gets in current informed consent documents.

These legal benefits also have practical effects. As a logical proposition, it seems incontrovertible that certainty is simpler and more efficient than ambiguity. It is also empirically demonstrable: long, contentious, and expensive disputes like those reported in the best-known cases result in large part from the calculated ambiguity built into the present regime. When the National Cancer Institute⁶⁶ announces that--because of this ambiguity--it will rely on the poorly defined state-law concept of "custodianship," it seems less a solution than an invitation to even greater inefficiency. The same applies to Winickoff and Winickoff's⁶⁷ "charitable trust" analogy and the "stewardship" proposal advanced by Fullerton et al.⁶⁸: because of the legal imprecision of their central concepts and the apparent complexity of adapting them to biobanking, they are, on a practical level, likely to introduce

more problems than they solve. How would they avoid the very sorts of disputes that we have seen under the current regime?

Contracts, by contrast, can be as simple and precise as the parties choose to make them. There is a reason that commercial parties usually insist on written contracts: they do so not out of a desire to be contentious, but to avoid conflict. As our sample outlines indicate, the relevant contracts would not have to be long--indeed, they could and should be shorter than the dense, multi-page informed consent documents used in many biobanking projects. Nor would these contracts have to be difficult to read, since the operative concepts are simple and susceptible of concise, straightforward expression. Here, too, they should fare well in a comparison with the vagueness and opacity of many current informed consent documents.

A final practical question is whether the use of our model would reduce the pool of current volunteers. We see no reason why it should. Those whose motives are purely altruistic could still be given the option to make an outright gift. Those who are interested in compensation--and it is clear that many people are, even under the current system--could get it, without any equivocation. Those with specific concerns would at least have a chance to see them resolved forthrightly. On balance, we see no reason why our proposal should reduce the subject pool, and there are some reasons to believe that it would increase it. From a financial perspective, direct payments to some subjects might increase somewhat, but overall transaction costs (including the cost of preparing documents) would likely decline.

The final question is ultimately the most significant: is our proposal ethical? Looking to the 1976 Belmont principles⁶⁹--respect for persons, beneficence, and justice--as a definition of "ethical," we believe that the answer is clearly yes. The Belmont Report defined respect for persons in terms of "the requirement to acknowledge autonomy" (making an exception for those incapable of self-determination, which is not relevant here since our proposal is directed at healthy adult volunteers). The acknowledgement of autonomy is at the very core of our proposal. It is based on honest disclosure, allowing prospective participants to decide whether and on what terms they will participate, and then requiring the parties to join in a true contract, which is the ultimate expression of autonomy. It thus seems calculated to advance autonomy beyond the current "we know what's good for you, take it or leave it" approach.

Belmont defined beneficence in terms of a dual obligation: "(1) do not harm and (2) maximize possible benefits and minimize possible harms." The presence or absence of beneficence depends largely on the research itself, with the process of recruitment serving to reveal--or sometimes to mask--the possible benefits and harms. By stressing honest disclosure, giving options to participants, and imposing contractual duties on researchers, our proposal should, at a minimum, do nothing to diminish the current level of beneficence. Belmont defined the third principle, justice, "in the sense of 'fairness in distribution' or 'what is deserved.'" By allowing participants a say in defining what is fair and deserved, our proposal seems to satisfy this criterion as well.

In conclusion, we believe that our trade secret model, with its fundamental stress on participant autonomy, offers an opportunity to solve some of the significant problems with the current regime, and in a matter that will survive scrutiny at the legal, practical, and ethical levels. Though the model represents a significant theoretical departure from current practice, its reliance on well-defined legal doctrine means that implementation would not require any complicated new legislation. Nor would it have to be implemented everywhere at once--or even, given the flexibility of the model, in the same way in different places. Since our model emerged from interviews with healthy biobank participants, it would probably make sense to begin testing the model with these populations, though we can

imagine that it might also eventually have application for other groups. And although we have focused on genomic biobanks, the model might also be adaptable to other forms of research transactions.

References

1. Rothstein MA. Expanding the Ethical Analysis of Biobanks. *Journal of Law, Medicine & Ethics*. 33(2005):89–101. We use “biospecimens,” “samples,” and “human tissues” synonymously, and follow Eisman and Haga's capacious definition of “human tissue” as including both fluids, such as blood, and solids, such as muscle biopsies; see Eisman E, Haga SB. *Handbook of Human Tissue Sources: A National Resource of Human Tissue Samples*. 1999Rand CorporationSanta Monica, CA at 7.
2. Shickle D. The Consent Problem Within DNA Biobanks. *Studies in History and Philosophy of Science Part C: Studies in History and Philosophy of Biological and Biomedical Sciences*. 2006; 37(3):503–519.
3. In the U.S., the doctrine of informed consent began to take on its current form following reports in the 1960s and 1970s by Henry Beecher and others, who revealed the unethical treatment of research subjects in the U.S., most infamously in the 40-year Tuskegee Syphilis Study. H. Beecher, “Ethics and Clinical Research,” *New Engl. J. Med.* 274(1966):1354–60. These revelations punctured the illusion that researchers themselves, acting as moral agents, could be trusted as the arbiters of ethical research conduct. In response, the 1976 Belmont Report (<http://ohsr.od.nih.gov/guidelines/belmont.html>) enshrined three ethical principles for human subjects research: respect for persons, beneficence, and justice. Office of Human Subjects Research, National Institutes of Health, *The Belmont Report*, at <<http://ohsr.od.nih.gov/guidelines/belmont.html>>(last visited Nov. 1, 2011). These principles were operationalized in the 1991 Common Rule, which (as implemented by Institutional Review Boards) governs nearly all federally funded research, with informed consent as its core premise. U.S. Department of Health and Human Services, Federal Policy for the Protection of Human Subjects (“Common Rule”), at <<http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html>>(last visited Nov. 1, 2011).
4. Greely HT. The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks. *Annual Review of Human Genetics*. 8(2007):343–364. at 344.
5. Jacobs KB, Yeager M, Wacholder S, Craig D, Kraft P, Hunter DJ, Paschal J, Manolio TA, Tucker M, Hoover RN, Thomas GD, Chanock SJ, Chatterjee N. A New Statistic and Its Power to Infer Membership in a Genome-Wide Association Study Using Genotype Frequencies,” *Nature Genetics*. 2009; 41:1253–1257.
6. Hayden EC. Secrets of the Human Genome Disclosed. *Nature*. 478(2011):17. [PubMed: 21979022]
7. See Rothstein, *supra* note 1, at 99.
8. Greely HT. Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information. *Wake Forest Law Review*. 34(1999):737–66. [PubMed: 12664910] see Greely, *supra* note 4.
9. Caulfield, T.; Upshur, R.; Daar, A. DNA Databanks and Consent: A Suggested Policy Option Involving an Authorization Model. *BioMed Central Medical Ethics* E1, 4. 2003. at <http://www.biomedcentral.com/1472-6939/4/1>Caulfield, T.; Knoppers, BM. Consent, Privacy & Research Biobanks; Policy Directions Brief Number 1, 2009-2010 Series on Genetic Information, Genome Canada. Jan 26. 2010 p. 1-10.at 4-5, at <<http://www.genomecanada.ca/medias/pdf/en/GPS-Policy-Directions-Brief.pdf>>(last visited Nov. 1, 2011)
10. U.S. Department of Health and Human Services. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators. 2011. 76 Fed. Reg. 44512-44531 (Jul. 26,2011), available at <<http://www.gpo.gov/fdsys/pkg/FR-2011-07-26/html/2011-18792.htm>>(last visited Nov. 2, 2011)
11. The ANPRM treats a biospecimen and genotypic information derived from it as one unit and presumes that individuals who provide biospecimens can be identified (U.S. Department of Health and Human Services, *supra* note 10, at 44525). Given this inherent identifiability, the ANPRM proposes that no research on biospecimens--regardless of whether biospecimens were collected for a study or left over from clinical care--proceed without prospective written consent (U.S.

Department of Health and Human Services, *supra* note 10, at 33515, 44519). Yet under the ANPRM, prospective consent may be broad and undefined regarding future uses and studies may be exempted from IRB review if researchers themselves view it as presenting minimal risk (U.S. Department of Health and Human Services, *supra* note 10, at 44515). The ANPRM thus strengthens oversight by expanding regulatory coverage, but simultaneously gives greater discretion to the research community whose original indiscretions led to the creation of the whole regulatory apparatus.

12. Winickoff DE, Winickoff R. Charitable Trust as a Model for Genomic Biobanks. *New Engl. J. Medicine*. 349(2003):1180–1184.
13. Fullerton SM, Anderson NR, Guzauskas G, Freeman D, Fryer-Edwards K. Meeting the Governance Challenges of Next-Generation Biorepository Research. *Science Translational Medicine*. 2010; 2(15) 15cm3.
14. Hoeyer K. The Ethics of Research Biobanking. *Biotechnology and Genetic Engineering Reviews*. 25(2008):429–52. at 440. [PubMed: 21412365]
15. Mitchell R, Conley J, Davis A, Cadigan J, Dobson A, Gladden R. Genomics, Biobanks, and the Trade-Secret Model. *Science*. 332(2011):309–10. [PubMed: 21493846] see also Letters and Response, *Science* 333 (2011): 1574-75
16. Mauss, M.; Halls, WD. *The Gift*. Routledge; London: 1954. orig. 1924)
17. Malinowski, B. *Crime and Custom in Savage Society*. Helix Books; Tonowa, NJ: 1985. orig. 1926): at 24-27
18. Sykes, K. *Arguing with Anthropology: An Introduction to Critical Theories of the Gift*. Routledge; London: 2005. at 1
19. Titmuss, R. *The Gift Relationship: from Human Blood to Social Policy*. Allen & Unwin; London: 1970.
20. Medical Research Council (MRC). *Human Tissue and Biological Samples for Use in Research*. MRC; London: 2001.
21. Tutton R. Gift Relationships in Genetics Research. *Science as Culture*. 11(2002):523–42. at 526. [PubMed: 15971368]
22. Rapport FL, Maggs CJ. Titmuss and the Gift Relationship: Altruism Revisited. *Journal of Advanced Nursing*. 40(2002):495–503. see Tutton, *supra* note 21. [PubMed: 12437598]
23. See, e.g., Leach E. The Heart of the Matter. *New Society*. 17(1971):114–15. Tutton, *supra* note 21; Waldby C, Mitchell R. *Tissue Economies: Blood, Organs, and Cell Lines in Late Capitalism*. 2006Duke University PressDurham, NC
24. See Leach, *supra* note 23, at 114.
25. See Tutton, *supra* note 21, at 528.
26. Starr, DP., editor. *Blood: An Epic History of Medicine and Commerce*. Alfred A. Knopf; New York: 1998. Blood can be fractionated and blood components stored for longer periods and distributed to geographically distant communities.. at 101-21Rabinow, P., editor. *French DNA: Trouble in Purgatory*. University of Chicago Press; Chicago: 1999. However, the national publics that donate blood are often not aware of this fact. The emergence in the 1980s of HIV in the French donated blood supply, for example, revealed that blood components had been imported from the U.S., which caused a huge scandal among a French public that had been led to believe that its stored blood supply was derived entirely from indigenous sources.. at 71-111.
27. See Tutton, *supra* note 21, at 538; Waldby and Mitchell *supra* note 23, at 19.
28. Rabinow, P. *Essays on the Anthropology of Reason*. Princeton University Press; Princeton, NJ: 1996. at 99
29. Rabinow, *supra* note 28, at 99.
30. Sommer M. DNA and Cultures of Remembrance: Anthropological Genetics, Biohistories and Biosocialities. *BioSocieties*. 5(2010):366–90.
31. Sommer, *supra* note 30, at 383.
32. Lindee, MS.; Goodman, AH.; Heath, D. Anthropology in and Age of Genetics: Practice, Discourse, and Critique. In: Goodman, AH.; Heath, D.; Lindee, MS., editors. *Genetic Nature/Culture*. University of California Press; Berkeley, CA: 2003. p. 1-22.at 7

33. See Luque JS, Quinn GP, Montel-Ishino FA, Arevalo M, Bynum SA, Noel-Thomas S, Wells KJ, Gwede CK, Meade CD, Tampa Bay Community Cancer Network Partners. Formative Research on Perceptions of Biobanking: What Community Members Think. *Journal of Cancer Education*. Sept.:2011. published online. Streicher SA, Sanderson SC, Wang Jabs E, Diefenbach M, Smirnoff M, Peter I, Horowitz CR, Brenner B, Richardson LD. Reasons for Participating and Genetic Information Needs among Racially and Ethnically Diverse Biobank Participants: A Focus Group Study. *Journal of Community Genetics*. 2(3)(2011):153–163. [PubMed: 22109822] Simon CM, L'Heureux J, Murray JC, Winokur P, Weiner G, Newbury E, Shinkunas L, Zimmerman B. Active Choice But Not Too Active: Public Perspectives on Biobank Consent Models. *Genetics in Medicine*. 13(2011):821–831. [PubMed: 21555942] Some of this work, guided by the principles of “deliberative democracy,” has focused on the BC Biobank Deliberation, a four-day “public engagement event” held in British Columbia in 2007. See Walmsley H. Stock Options, Tax Credits or Employment Contracts Please! The Value of Deliberative Public Disagreement About Human Tissue Donation. *Social Science and Medicine*. 73(2011):209–216. [PubMed: 21683492] Secko D, Preto N, Miemeyer S, Burgess M. Informed Consent in Biobank Research: A Deliberative Approach to the Debate. *Social Science and Medicine*. 68(2009):781–789. [PubMed: 19095337]
34. Hoeyer K. Donors Perceptions of Consent to and Feedback from Biobank Research: Time to Acknowledge Diversity? *Public Health Genomics*. 13(2010):345–52. at 349. [PubMed: 19940458]
35. Hoeyer K. The Power of Ethics: A Case Study from Sweden on the Social Life of Moral Concerns in Policy Processes. *Sociology of Health and Illness*. 8(2006):785–801. [PubMed: 17184418]
36. See Hoeyer, *supra* note 34, at 345
37. See Hoeyer, *supra* note 35, at 797.
38. See Hoeyer, *supra* note 35, at 797.
39. See Hoeyer, *supra* note 14, at 440-1.
40. See Hoeyer, *supra* note 14, at 442.
41. Johnstone, B. Discourse Analysis and Narrative. In: Schiffrin, D.; Tannen, D.; Hamilton, HE., editors. *The Handbook of Discourse Analysis*. Blackwell Publishing; Malden, MA: 2001. p. 635-49. Conley, J.; O'Barr, W. *Just Words: Law, Language, and Power*. University of Chicago Press; Chicago: 1998.
42. Foucault, M. *Discipline and Punish: The Birth of the Prison*. Allen Lane; London: 1977. Foucault, M. *The History of Sexuality*. Random House; New York: 1978.
43. See, e.g., Goodwin C, *Conversational Organization. Interaction between Speakers and Hearers*. 1982 Academic Press New York
44. Shuy, R. Discourse Analysis in the Legal Context. Schiffrin, Tannen, and Hamilton. *supra* note 41, at 437-52
45. Ainsworth-Vaughn, N. The Discourse of Medical Encounters. Schiffrin, Tannen, and Hamilton. *supra* note 41, at 453-69
46. Fleischman, S. Language and Medicine. Schiffrin, Tannen, and Hamilton. *supra* note 41, at 470-502
47. Hamilton, HE. Discourse and Aging. Schiffrin, Tannen, and Hamilton. *supra* note 41, at 568-89
48. Hamilton, *supra* note 47, at 573.
49. Goffman, E. *The Presentation of Self in Everyday Life*. Doubleday; Garden City, NY: 1959.
50. Garfinkel, H. *Studies in Ethnomethodology*. Prentice-Hall; Englewood Cliffs, NJ: 1967.
51. Atkinson, JM.; Drew, P. *Order in Court: The Organisation of Verbal Interaction in Judicial Settings*. Humanities Press; Atlantic Highlands, NJ: 1979. at 18-22
52. See Hoyer, *supra* note 35, at 795-98 for an application of this approach to medical ethics.
53. National Conference of Commissioners on Uniform State Laws, Uniform Trade Secrets Act, at <http://www.nccusl.org/Act.aspx?title=Trade%20Secrets%20Act> (last visited Nov. 2, 2011).
54. Black's Law Dictionary, Abridged Sixth Edition. West Publishing; St. Paul, MN: 1991. p. 211
55. *In Washington University v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008), the United States Court of Appeals for the Eighth Circuit held that neither a former Washington University researcher nor the donors of

biospecimens he had collected had any property rights in the biospecimen and therefore could not compel transfer of the biospecimens to the researcher in his new position. Applying Missouri state law, the court found that the biospecimens had been a gift to Washington University. In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, 264 F. Supp. 2d 1064 (S.D. Fl. 2003), a federal trial court in Miami held under Florida law that donors had no property right in biospecimens they had contributed. The *Greenberg* court cited *Moore v Regents of University of California*, 51 Cal. 3d 120; 271 Cal. Rptr. 146; 793 P.2d 479 (1990), in which the California Supreme Court reached a similar result under California law.

56. National Cancer Institute, Office of Biorepositories and Biospecimen Research. Custodianship and Ownership Issues in Biospecimen Research, Symposium--Workshop; 2008. at: <http://biospecimens.cancer.gov/resources/publications/workshop/cow.asp> (last visited Nov. 2, 2011)
57. See *Catalona* and *Greenberg*, supra note 55.
58. *Grimes v. Kennedy Krieger Institute*, 366 Md. 29, 782 A. 2d 807 (2001).
59. See *Catalona*, supra note 55.
60. See Conley J, Cadigan J, Davis A, Dobson A, Edwards E, Fortson R, Mitchell R, Heffer C, Rock F, Conley J. The Discourse of DNA: Giving Informed Consent to Genetic research. Lay-Legal Communication: Textual Travel in the Legal Process. Oxford University PressOxford, UKforthcoming
61. Dove ES, Joly Y, Knoppers BM. Trade-Secret Model: Legal Limitations. *Science*. 333(2011): 1575. at 1575. [PubMed: 21921179]
62. See Hoeyer, supra note 34, and Hoeyer, supra note 35.
63. U.S. Department of Health and Human Services. Draft Guidance on Exculpatory Language in Informed Consent. Sep. 2011 at <<http://www.hhs.gov/ohrp/newsroom/rfc/exculpatorydraft2011.html>>(last visited Nov. 1, 2011)
64. Kauffman Foundation. Facilitating the Commercialization of University Innovation: The Carolina Express License Agreement. Apr. 2010 at <http://www.kauffman.org/uploadedFiles/UNCagreements_4-19-10.pdf>(last visited Nov. 1, 2011)
65. Office of Technology Development, University of North Carolina at Chapel Hill. Carolina Express User Guide. at 2, at <<http://otd.unc.edu/documents/CarolinaExpressLicenseUserGuide.pdf>>(last visited Nov. 1, 2011)
66. See National Cancer Institute, supra note 56.
67. See Winickoff and Winickoff, supra note 12.
68. See Fullerton, supra note 13.
69. See Office of Human Subjects Research, National Institutes of Health, supra note 3.

OPTIONS	OUTRIGHT SALE	GIFT	LICENSE
Payment	\$75 payment	No payment	\$25 payment
Ownership	Contributor sells the biospecimen to Biobank. Biobank acquires sole ownership of and all rights in the biospecimen, any information derived from the biospecimen, and any technology derived from the biospecimen (for example, a gene patent).	Contributor makes a gift of the biospecimen to the Biobank. Biobank acquires sole ownership of and all rights in the biospecimen, any information derived from the biospecimen, and any technology derived from the biospecimen, for as long as it complies with its promise below.	Contributor retains ownership of the physical biospecimen and of any information derived from the biospecimen, but has no right to recover the actual biospecimen. Biobank acquires ownership of any technology derived from the biospecimen; however, in recognition of the fact that it may earn money from such technology, the biobank promises to use (all or a specified percentage) of its future net income to further its research purposes, and to impose a similar condition on its sublicensees.
Terms of Use	Biobank can use the biospecimen and any information derived from the biospecimen for any purpose now or in the future.	Biobank can use the biospecimen and any information derived from the biospecimen for any purpose now or in the future.	Biobank receives a paid-up, royalty-free, worldwide license to use the biospecimen and any information derived from the biospecimen for any research purposes, and to allow others (sublicensees) to do the same, unless and until the license terminates.
Confidentiality	Biobank promises to make reasonable efforts to maintain the anonymity and/or confidentiality of contributor, but offers no guarantees.	Biobank promises to make reasonable efforts to maintain the anonymity and/or confidentiality of contributor, but offers no guarantees.	Biobank promises to make reasonable efforts to maintain the anonymity and/or confidentiality of the contributor, but offers no guarantees.
Future Contact	Biobank has no obligation to contact the contributor for any reason, but may do so concerning participation in future research projects.	Biobank has no obligation to contact the contributor for any reason, but may do so concerning participation in future research projects.	Biobank will make reasonable efforts to contact the contributor in the event that it becomes aware of research findings that it believes would be significant to the health of the contributor, but has no obligation to seek such findings. Contributor waives any legal claims for negligent failure to discover and/or report such findings. The biobank otherwise has no obligation to contact the contributor in the future, but may do so concerning participation in future research projects.
Termination	[Nothing to terminate]	[Nothing to terminate]	Contributor (or contributor's heirs) can terminate the license at any time (withdraw), at which point the biobank will destroy the biospecimen and make no further use of any information derived from the biospecimen. At time of termination any research projects currently using the biospecimen and any information derived from the biospecimen will be allowed to continue to conclusion. Absent termination by the contributor, the agreement will continue in effect indefinitely.