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ASSIGNING RIGHTS AND PROTECTING INTERESTS: CONSTRUCTING ETHICAL AND EFFICIENT LEGAL RIGHTS IN HUMAN TISSUE RESEARCH

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I. INTRODUCTION

On March 11, 2009, nine families filed suit against the State of Minnesota, arguing that the state, after collecting blood samples from newborns for routine screening, unlawfully retained the samples indefinitely and shared the samples with private research institutions and hospitals — all without parental knowledge or consent.[1] A day later, parents in Texas filed a lawsuit in the U.S. District Court for the Western District of Texas, alleging similar conduct by Texas officials and arguing that retaining and using newborn blood without parental knowledge or consent violates the U.S. and Texas Constitutions.[2] In both of these cases, families objected to the unconsented-to use of human tissue for unidentified research purposes, including genetic research. Meanwhile, on May 12, 2009, the American Civil Liberties Union filed suit against the U.S. Patent and Trademark Office ("USPTO") and Myriad Genetics, seeking to invalidate patents Myriad holds for two genes responsible for most hereditary breast and ovarian cancers.[3]

These are only a few of the most recent cases to raise claims regarding the appropriate regulation of genetic research and its results.[4] As genetic and other research involving human cells progress, similar cases — especially those addressing the nature of the rights retained by those providing the tissue used in research — are likely to arise.[5] Through genetic analysis, researchers hope to identify disease-related and other genes and to measure the frequency of such genes' occurrence across large populations. This kind of research requires population-wide bio-repositories of samples available for study. Already,

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1. Complaint, Bearder v. Minnesota, No. 27-CV-09-5615 (Hennepin County, Minn., Dist. Ct. Mar. 11, 2009).

2. Complaint, Beleno v. Tex. Dept. of State Health Servs., No. SA09CA0188 (W.D. Tex. Mar. 12, 2009).

3. Complaint, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09CV4515 (S.D.N.Y. May 12, 2009).

4. The USPTO, of course, does not directly regulate research; it issues patents and registers trademarks. U.S. Patent & Trademark Office, Our Business: An Introduction to the USPTO, http://www.uspto.gov/web/menu/intro.html (last visited Dec. 20, 2009). In issuing patents, however, the USPTO has enabled others in some instances to control research and testing. More than a quarter of laboratory directors have reported receiving letters "ordering them to stop carrying out clinical tests designed to spot early warning signs" for a whole host of medical conditions — all based on exclusive licenses made possible by genetic-sequence patenting. Julian Borger, *Rush to Patent Genes Stalls Cures for Disease*, GUARDIAN (London), Dec. 15, 1999, at 1.

5. The last few years have seen several prominent decisions regarding the rights of tissue providers. *See, e.g.*, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008) (recognizing Washington University as the exclusive owner of tissues provided by patients seeing a urological specialist, Dr. Catalona, at the University); Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063 (Ariz. Ct. App. 2008) (reinstating claims by the Havasupai Tribe that the University of Arizona inappropriately used tissue donated by tribal members in unrelated and unconsented-to research).

more than 300 million tissue samples from more than 178 million individuals are stored in the United States, and this number has been growing by more than 20 million samples every year.[6]

Yet, as these and other recent cases suggest, individuals providing tissue for research may hesitate to do so if they fear that their interests will not be respected.[7] Tissue providers may have concerns that their cells and genetic material — materials with which they may strongly self-identify — will be used for research they find morally repugnant or about which they were not informed. Unanticipated disclosure of genetic information may negatively impact the ability of unwitting tissue providers and their close genetic relatives to obtain insurance coverage or appropriate medical treatment.[8] And tissue providers may have strong interests concerning the commercialization of their cells and genetic material, especially if they are not permitted to share in the profits.[9]

Researchers and society at large also have strong interests in how tissue is used in research.[10] Scientific research using human cells can be (and has been) immensely beneficial.[11] Inappropriate or onerous restrictions on human tissue research may negatively impact the progress of science and medicine. This concern has been clearly articulated by several courts that have faced the issue of balancing the interests of tissue providers and the interests of researchers in ongoing research. For instance, the district court in *Washington University v. Catalona*,[12] which recognized Washington University as the exclusive owner of disputed tissues, worried that "[m]edical research can only advance if access to these materials to the scientific community is not thwarted by private agendas."[13] In *Moore v. Regents of the University of California*,[14] the California Supreme Court similarly opined that

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6. ELISA EISEMAN & SUSANNE B. HAGA, HANDBOOK OF HUMAN TISSUE SOURCES, at xvii (1999). The National Bioethics Advisory Commission ("NBAC") similarly reported that "as of 1998, more than 282 million specimens of human biological materials were stored in the United States, accumulating at a rate of more than 20 million cases per year." NAT'L BIOETHICS ADVISORY COMM'N, 1 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 13 (1999).

7. *See infra* Part II.A.

8. *See, e.g.*, Susannah Baruch, *Your Genes Aren't Covered for That*, SCI. PROGRESS, June 29, 2009, http://www.scienceprogress.org/2009/06/gina-challenges/ (identifying gaps in protection persisting even after adoption of the Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881).

9. Where individuals knowingly provide tissue for research, they also presumably have an interest in that research taking place — an interest in the progress of science. *See infra* Part II.A.4.

10. *See infra* Part II.B.

11. For an overview of the importance of human biological materials for medical research, see NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 19–24.

12. 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).

13. *Id.* at 1002.

14. 793 P.2d 479 (Cal. 1990).

recognizing a property right in one's cells would have a chilling effect on socially beneficial medical research.[15] Moreover, permitting tissue providers to commercialize their cells may divert tissue from worthwhile research,[16] diminish the necessary incentives for research funders to invest in research and development,[17] and undermine societal dignitary interests.[18]

The interests of tissue providers, of researchers, and of broader society each demand respect and protection. Failing to mediate tensions between these constituencies "may dissuade patients from participating in medical research studies and slow progress in medical research."[19]

This Article makes three contributions to the existing literature. First, in Part II, it provides a systematic account of the interests that tissue providers may have regarding the use of their tissue in research. Existing literature often speaks to one or some of these interests,[20] and it generally does so in piecemeal fashion. This Article instead establishes a four-part system of provider interests at the outset. This sys-

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15. *Id.* at 493 (emphasizing the need not to threaten "innocent parties who are engaged in socially useful activities" with "disabling civil liability").

16. Thomas P. Dillon, Comment, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 634 (1989) ("If society allows individuals to sell their body parts, this process of shopping around will likely increase delays, force competitive bidding, and result in the inefficient use of resources."); *see also* Brian Su, Comment, *Developing Biobanking Policy with an Oliver Twist: Addressing the Needs of Orphan and Neglected Diseases*, 66 LA. L. REV. 771, 780 (2006) ("[C]ommercial biobanks will, by necessity of both market opportunities and restraints, focus their studies on diseases afflicting relatively large, affluent populations to realize a profit or at least recoup research expenditures.").

17. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698 (1998) (explaining that people may underuse scarce resources because too many owners can block each other, and describing how the proliferation of overlapping rights holders in biomedical research has generated this anticommons scenario). *But see* Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARIZ. L. REV. 45, 61 (2007) (arguing that commercial "tissue donations" will not substantially increase the cost of medical research in ways that inhibit its progress).

18. *Moore*, 793 P.2d at 497–98 (Arabian, J., concurring) (asserting that "recogniz[ing] and enforc[ing] a right to sell one's own body tissue for profit" would cause us "to regard the human vessel — the single most venerated and protected subject in any civilized society — as equal with the basest commercial commodity" and would "commingle the sacred with the profane"). Of course, researchers can, and do, commercialize people's cells and tissues — this is precisely what the researchers in *Moore* did. *See id.* at 481–83 (majority opinion).

19. Ted T. Ashburn, Sharon K. Wilson & Barry I. Eisenstein, *Human Tissue Research in the Genomic Era of Medicine*, 160 ARCHIVES INTERNAL MED. 3377, 3381 (2000).

20. *See, e.g.*, Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22 (2005) (describing provider interests in control and commercialization); Ashburn et al., *supra* note 19 (identifying "confidentiality, consent, and compensation" as three core issues in human tissue research); Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995) (discussing interests in consent and confidentiality generally). I have discussed several of these interests in other work. *See* Natalie Ram, *Tiered Consent and the Tyranny of Choice*, 48 JURIMETRICS J. 253, 256–59 (2008).

tem of interests, alongside a similar explication of researcher interests and interests of society at large, guides the analysis that follows.

Second, in Part III, the Article draws on intellectual property rules to suggest a model of legal rights to frame interactions between tissue providers and researchers: "informational property," a right to one's own genetic information.[21] The Article considers, but finds incomplete and unpersuasive, existing proposals that focus on reforming the federal regulations governing federally-funded human subjects research,[22] strengthening contract rights for tissue providers,[23] or uncovering personal property rights in human tissue.[24] Instead, the Article argues that a system of informational property rights that attach to the most valuable and sought-after "stuff" in human tissue — DNA — will best serve the various interests at stake in human tissue research.

Third, the Article explores in some detail how the informational property model can best be implemented to produce an efficient and equitable system of legal rights for human tissue research. In Part III, it draws on literature engaging both open-source intellectual property and its digital rights management counterpart to suggest a sophisticated system of licenses for human tissue research. In Part IV, the Article develops a multi-model theory about how best to construct future tissue provider-researcher interactions and disputes. It advocates an informational property approach modeled on Creative Commons licensing, reinforced by enhanced privacy protections in tort.

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21. The language of information as property has considerable pedigree. *See* sources cited *infra* note 124.

22. The relevant regulations can be found at 45 C.F.R. § 46 (2007). For literature proposing changes to these regulations, see Ashburn et al., *supra* note 19, at 3381–82, which proposed an infrastructure of tissue trustees; Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737, 738 (1999), which proposed "a framework for regulating unforeseen research uses of human biological materials and health information"; Kevin L.J. Oberdorfer, Note, *The Lessons of* Greenberg*: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365, 386–89 (2004); and Robert F. Weir, *The Ongoing Debate About Stored Tissue Samples, in* 2 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, F-1, F-18 (2000). Some well-known articles even argue that sufficient protection for tissue providers can be found within the existing regulations. *See* Clayton et al., *supra* note 20.

23. *See, e.g.*, Oberdorfer, *supra* note 22, at 389–93. Few articles endorse a contract approach outright, as effective contracting depends on the existence of some type of property right with which to bargain.

24. *See, e.g.*, Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 338–39 (2004); MaryJoy Ballantyne, Note, *One Man's Trash is Another Man's Treasure: Increasing Patient Autonomy Through a Limited Self-Intellectual Property Right*, 3 GEO. J.L. & PUB. POL'Y 567, 583–96 (2005); Laura M. Ivey, Comment, Moore v. Regents of the University of California: *Insufficient Protection of Patients' Rights in the Biotechnological Market*, 25 GA. L. REV. 489, 533 (1991). Although Ballantyne refers to a "limited self-intellectual property right," her discussion contains mostly language in the traditional property framework. *See* Ballantyne, *supra* at 587–88.

II. THE INTERESTS AT STAKE

Judith Resnik has remarked in another context that "[t]heories of remedies require theories of harm — about *who* is injured by *what* set of behaviors, imposed by individuals or entities that ought to be subjected to sanctions or alter practices."[25] In much the same way, only with a clear understanding of whose injuries should matter and what should constitute an injury can we then approach the question of what legal structure best meets our needs. Issues of control and ownership of bodies and their parts are the source of profound modern controversy. For instance, regulations limiting the ability of individuals to direct the use of their transplantable organs, and those forbidding the buying and selling of such organs, have been both attacked as bad policy and potentially even unconstitutional deprivations of liberty[26] and defended as essential bulwarks against commodification that would undermine human dignity and jeopardize human flourishing.[27] Similar issues pervade human tissue research.[28] What's more, tissue providers have additional cause for concern, as issues of genetic self-identification, confidentiality, and personal medical benefit complicate our accounting of relevant interests.[29]

This Part first identifies and discusses the interests of tissue providers in control over the uses to which their tissue is put, the confidentiality of the information contained in their cells, the commercialization or non-commercialization of products derived from their cells, and the ability to benefit personally from tissue re-

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25. Judith Resnik, *The Rights of Remedies: Collective Accountings for and Insuring Against the Harms of Sexual Harassment*, *in* DIRECTIONS IN SEXUAL HARASSMENT LAW 247, 250 (Catherine A. MacKinnon & Reva B. Siegel eds., 2004).

26. *See, e.g.*, Charles A. Erin & John Harris, *An Ethical Market in Human Organs*, 29 J. MED. ETHICS 137 (2003) (attacking the current ban on organ sales and advocating an ethically regulated organ market); Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007) (arguing that laws/regulations prohibiting sale of human organs violate a constitutional right to medical self-defense).

27. *See generally* Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1854–55 & n.23 (1987) (arguing that commodification of things important to personhood undermines human dignity and relationships).

28. *See* Korobkin, *supra* note 17, at 47 (arguing that "purchasing tissues for biomedical research should be both legal and socially acceptable"). *But see* Pilar N. Ossorio, *Property Rights and Human Bodies*, *in* WHO OWNS LIFE? 223, 238–39 (David Magnus, Arthur Caplan & Glenn McGee eds., 2002) (describing a possible, but not necessarily inevitable, slippery slope from applying market values to embryos to applying those values to embryo progenitors and children); Korobkin, *supra* note 17, at 47 (recognizing "nearly unanimous opinion in the medical research and public policy communities that tissue donors should be subject to a no-compensation rule"); *see also* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (Cal. 1990) (Arabian, J., concurring) (asserting that "recogniz[ing] and enforc[ing] a right to sell one's own body tissue for profit" would "commingle the sacred with the profane").

29. *See infra* Parts II.A.1–4.

search using their cells.[30] This Part then offers countervailing accounts of society's broader interests in the progress of science and medicine and researchers' interests in the lucrative commercialization of products and tools derived in conjunction with and resulting from such research. The interests of all of these parties are often mutually reinforcing, such that creating a system in which potential tissue providers feel confident that their interests are respected is likely to encourage such individuals to provide tissue for research purposes.

A. The Interests of Tissue Providers

1. Control

The right to decide whether and how one's body and its parts may be used in research has been described as a "fundamental" right,[31] although courts have yet to recognize such strong protection for providers of human tissue for research. Respect for the interests of tissue providers in controlling the ways in which their tissues, and the information contained in their cells, are used flows in part from respect for human dignity. Human dignity demands that all persons be treated not merely as means to an end, but also as ends in themselves.[32] When individuals are made tissue providers without their knowledge and authorization, they may suffer harm in the sense of being deprived of their autonomous right to be let alone.[33] Alternatively, when individuals are not adequately equipped with information pertinent to their decision about whether or not to participate in a course of action — be it medical treatment, direct participation in research, or the provision of tissue for research — they suffer a dignitary harm by being deprived of their autonomous right to choose.[34]

An interest in controlling the use of one's DNA that is grounded on human dignity need not adopt reductionist views about personhood or the relationship between DNA and identity. Particular uses of one's DNA, in research or otherwise, may be viewed as thwarting the will of moral agents where such uses impede or undermine specific goals held by those agents. For instance, individuals may oppose research on the genetics of certain behavioral or other traits, like intelligence or

30. Portions of Part II.A build on my prior work. *See* Ram, *supra* note 20, at 256–59.

31. Robert M. Sade, *Research on Stored Biological Samples Is Still Research*, 162 ARCHIVES INTERNAL MED. 1439, 1440 (2002).

32. IMMANUEL KANT, GROUNDWORK OF THE METAPHYSICS OF MORALS 38 (Mary Gregor trans., Cambridge Univ. Press 1997) (1785); *see also* Sade, *supra* note 31, at 1440 (arguing that tissue providers should be referred to as "research subjects" rather than as "sources" because the latter term "suggest[s] that [tissue providers] are things rather than willing persons").

33. *See* Ballantyne, *supra* note 24, at 576.

34. *Id.*

sexual orientation.[35] Individuals might additionally believe that DNA, including or especially human DNA, should not be patented.[36] In the absence of control over one's genetic material, however, researchers might well use an individual's DNA to conduct such experiments, or to isolate, copy, and patent an interesting gene.[37] "Even if I do not hold extremely reductionist views of personhood, it might still be possible for me to conceive of the use of my bodily materials in these contexts as some way in which I was forced to contribute to a project that I opposed."[38] This frustration of will, in turn, may be said to be an affront to the dignity of the individual.

Concern for tissue providers' interest in control is not merely academic. Many people invest every use of their body, or pieces of it, with moral and ethical significance. Orthodox Jews, for example, often hold religious beliefs that the body must be buried whole; indeed, "[i]f a person's leg is amputated during his or her life, arrangements are made to store that body part for burial with the individual after death."[39] More broadly, some leaders of the Jewish community have at times advised Jews to avoid participating in genetics research, fearing discrimination against and stigmatization of the Jewish population.[40] Native Americans may also hold strong beliefs about the integrity of the body.[41] Limitations short of absolute refusal to the research use of tissues may arise as well:

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35. *See, e.g.*, DEAN HAMER & PETER COPELAND, THE SCIENCE OF DESIRE: THE SEARCH FOR THE GAY GENE AND THE BIOLOGY OF BEHAVIOR (1994) (research on the genetics of sexual orientation); Marc D. Schwartz et al., *Consent to the Use of Stored DNA for Genetics Research: A Survey of Attitudes in the Jewish Population*, 98 AM. J. MED. GENETICS 336, 341 (2001) (finding "a small, but statistically significant, reduction in willingness to participate in studies involving homosexuality or frugality . . . both of which are potentially stigmatizing").

36. *See, e.g.*, Amy Kapczynski, *The Access to Knowledge Mobilization and the New Politics of Intellectual Property*, 117 YALE L.J. 804, 806 (2008) (referring to advocates of a "free genome"); Madhavi Sunder, *IP*^{3}, 59 STAN. L. REV. 257, 275 (2006) (referring to theorists who "worry especially about the commodification of that which is most personal to us — our very identity").

37. Ossorio, *supra* note 28, at 232.

38. *Id.*

39. Andrews, *supra* note 20, at 25.

40. Karen H. Rothenberg & Amy B. Rutkin, *Toward a Framework of Mutualism: The Jewish Community in Genetic Research*, 1 COMMUNITY GENETICS 148, 149 (1999). On the whole, however, the Jewish community has embraced genetic research, including Tay-Sachs testing before marriage in the Orthodox community. *See* Gideon Bach et al., *Tay-Sachs Screening in the Jewish Ashkenazi Population: DNA Testing Is the Preferred Procedure*, 99 AM. J. MED. GENETICS 70, 71 (2001).

41. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 49; *see also* Larry Rohter, *In the Amazon, Giving Blood but Getting Nothing*, N.Y. TIMES, June 20, 2007, at A1 ("'A soul can only be at rest after the entire body is cremated,' said Davi Yanomami, a leader of the [Yanomami tribe in the Amazon of Brazil]. 'To have the blood of a dead person preserved and separated from the remainder of the body is simply unacceptable to us.'").

> [S]ome people may wish to limit the use of their samples to noncommercial entities. Others may wish to forbid the use of their samples to investigate certain disorders, particularly if the disorders are stigmatizing for a specific population group, as an alcoholism gene might be. In addition, retaining tissue samples or immortalizing cell lines may violate cultural or religious beliefs.[42]

Thus, informed consent — really, informed choice — plays an essential role in protecting tissue providers' interests in control. Consequently, informed consent is fundamentally an expression of respect for human dignity: "To say that one cannot be bound by a promise that one did not voluntarily and knowingly make is to say that the individual should be the author of her own undertakings, that a genuine respect for her dignity requires a broad deference to her choices."[43]

Moreover, respect for the tissue provider's interest in control emerges not only from considerations of respect for human dignity, but also from more consequentialist considerations about maximizing the amount of tissue available for research. Research on public attitudes regarding consent to the research use of tissue reveals that, while most potential tissue providers are happy to grant broad consent for future use of their tissues, a large majority also believe that their consent should be required before research commences where research uses clinically-derived samples retaining personal identifiers.[44]

Individuals may refuse to provide tissue for research if they fear that their interests in controlling the future uses of their cells and genetic information will not be respected. Trust, in other words, is significant. Studies on informed consent consistently show that African Americans consent to genetic research at rates that are statistically significantly lower than those of whites[45] and that African Americans

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42. Clayton et al., *supra* note 20, at 1788.

43. Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899, 900 (1994); *see also* Allen Buchanan, *An Ethical Framework for Biological Samples Policy*, *in* 2 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, B-1, B-16 (2000).

44. Dave Wendler & Ezekiel Emanuel, *The Debate over Research on Stored Biological Samples*, 162 ARCHIVES INTERNAL MED. 1457, 1459–60 (2002). More than ten percent of respondents also indicated that they believed consent should be required for additional research using research-derived samples that have been stripped of personally identifying information. *Id.* at 1460.

45. *See, e.g.*, Donna T. Chen et al., *Research with Stored Biological Samples*, 165 ARCHIVES INTERNAL MED. 652, 654 (2005) (finding that 88.4% of whites authorized unlimited future research using their tissues, while only 75% of African Americans did so ($P<0.001$)); Beth M. Ford et al., *Factors Associated with Enrollment in Cancer Genetics Research*, 15 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1355, 1357 (2006) (finding that 63.4% of white colorectal cancer patient-participants enrolled in cancer genetics research, while only 45.7% of non-white colorectal cancer patient-participants enrolled

are less trusting of medical researchers than whites.[46] Past abuses in medical interventions and research involving African Americans, such as "the infamous Tuskegee syphilis experiment and the chaotic conditions attending early sickle-cell anemia carrier trait screening,"[47] suggest that their distrust of the research establishment is not entirely without foundation. Women are also less likely than men to consent to the research use of their cells.[48]

Broad research participation should not, however, be compelled by dispensing with consent altogether and generally conscripting tissue left over from other interventions. Indeed, doing so might cause individuals concerned about the future use of their cells to forego routine medical care in order to prevent their cells from being so conscripted.[49] This outcome was recently addressed in a lawsuit over the unauthorized use of tissue samples obtained from the Havasupai, a Native American tribe living in the Grand Canyon.[50] Havasupai tribe members learned that tissue samples they had willingly provided for

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(P=0.019)); Geraldine M. McQuillan, Qiyuan Pan & Kathryn S. Porter, *Consent for Genetic Research in a General Population: An Update on the National Health and Nutrition Examination Survey Experience*, 8 GENETICS MED. 354, 357–58 (2006); Patricia G. Moorman et al., *Racial Differences in Enrollment in a Cancer Genetics Registry*, 13 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1349, 1350 (2004) (finding that enrollment of African American women in a cancer genetics registry was lower, by a statistically significant degree, than enrollment of white women (15% and 36%, respectively (P<0.0001)), and that this difference was not due to socio-economic characteristics or other cancer risk factors).

46. *See, e.g.*, Giselle Corbie-Smith, Stephen B. Thomas & Diane Marie M. St. George, *Distrust, Race, and Research*, 162 ARCHIVES INTERNAL MED. 2458, 2460 (2002) [hereinafter Corbie-Smith et al., *Distrust, Race, and Research*] (finding that, even after controlling for certain socio-economic variables, African American participants remained nearly five times more likely than white participants to give distrustful responses); *see also id.* at 2458 (collecting sources of other studies documenting that distrust may play an important role in refusal to participate in research, and identifying some limitations of these studies). *See generally* Giselle Corbie-Smith et al., *Attitudes and Beliefs of African Americans Toward Participation in Medical Research*, 14 J. GEN. INTERNAL MED. 537, 537 (1999) [hereinafter Corbie-Smith et al., *Attitudes and Beliefs*] (finding that distrust of the medical community is a prominent barrier to African American participation in research).

47. Rayna Rapp, *Refusing Prenatal Diagnosis: The Meanings of Bioscience in a Multicultural World*, 23 SCI. TECH. & HUM. VALUES 45, 49 (1998).

48. *See* Ford et al., *supra* note 45 (finding that 66.8% of male colorectal cancer patient-participants enrolled in cancer genetics research, while only 58.2% of female colorectal cancer patient-participants enrolled (P=0.004)); McQuillan et al., *supra* note 45, at 357. This pattern of lower rates of consent by women, and by African Americans, is distinct and separate from broader patterns of under-enrollment of women and minority individuals in medical research. *See* Rebecca Dresser, *Wanted: Single, White Male for Medical Research*, 22 HASTINGS CENTER REP. 24, 24 (1992) (discussing the underrepresentation of women in medical research generally, and noting as "[m]ost amazing" a research project on "the impact of obesity on breast and uterine cancer conducted — you guessed it — solely on men").

49. *Cf.* I. Glenn Cohen, *The Right Not To Be a Genetic Parent?*, 81 S. CAL. L. REV. 1115, 1157 (2008) ("The argument for [a right to consent] becomes stronger when one factors in the cost of self-protective measures an individual might take if the law did not protect that person's interest in unwanted genetic parenthood without any prior consent.").

50. *See* Havasupai Tribe v. Ariz. Bd. of Regents, 204 P.3d 1063 (Ariz. Ct. App. 2008), *review denied*, No. CV-09-0007-PR (Apr. 20, 2009).

genetic research related to diabetes had also been used for a range of unauthorized studies, including some that directly undermined the tribe's core religious beliefs about their origins. In initiating litigation against the university controlling and dispensing the tissue samples, the Havasupai asserted, "Many of our [members] now fear going to the health clinic, seeking medical attention, or providing blood samples for medical diagnosis or treatment."[51] Some African American women have also, on occasion, refused prenatal diagnosis out of fear that their amniotic tissue may be used for unconsented-to research.[52] Respect for provider control therefore has both a deontological and a utilitarian basis.

In addition to a requirement of informed consent, taking the tissue provider's interest in control seriously also generally requires some kind of right to withdraw — especially where a tissue provider discovers that her cells are being used for purposes beyond the terms of her consent. This right ensures that tissue providers have "exit" in addition to voice as a means for enforcing their choices after tissue has been removed.[53] Current federal guidelines governing federally-funded human subjects research recognize the right to withdraw as integral to protecting subjects' autonomy in research participation.[54] Indeed, the Eighth Circuit's decision in *Catalona* acknowledged a limited right to withdraw from research participation via tissue sample destruction, despite the court's recognition of Washington University as the sole owner of the tissue contained in its bio-repository.[55]

2. Confidentiality

A tissue provider's interest in confidentiality is a privacy interest in protecting the provider from the negative impact of unwanted dis-

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51. *Id.* at 1069.

52. Dorothy Nelkin & Lori B. Andrews, *Introduction: The Body, Economic Power and Social Control*, 75 CHI.-KENT L. REV. 3, 7 (1999); *see also* Chen et al., *supra* note 45, at 654 (reporting an empirical study showing that, given the option to permit all future research use of their tissues, African Americans were less likely than whites to provide this unlimited authorization); Corbie-Smith et al., *Distrust, Race, and Research*, *supra* note 46, at 2459 ("African Americans were more likely [than whites] to believe that someone like them would be used as a guinea pig without his or her consent (79.2% vs 51.9%, P<0.01).").

53. On the importance of both voice and exit in mediating relationships between parties, see ALBERT O. HIRSCHMAN, EXIT, VOICE, AND LOYALTY (1970).

54. The Code of Federal Regulations describes the right as follows:

> [I]n seeking informed consent the following information shall be provided to each subject: . . . A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and *the subject may discontinue participation at any time* without penalty or loss of benefits to which the subject is otherwise entitled.

45 C.F.R. § 46.116 (2005) (emphasis added).

55. Wash. Univ. v. Catalona, 490 F.3d 667, 675 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008).

closure of information about the provider that is discovered through research. This interest is of increasing salience as researchers undertake more work involving genetic analysis. This is so because genetic analysis can yield information about the presence or absence of disease-related genes in a specific individual and, in some instances, in her close blood relatives.[56]

There are at least two distinct senses in which breaches of confidentiality may be detrimental to the interests of a tissue provider. First, if third parties such as insurance providers or employers gain access to this information, they may find ways to refuse, limit, or terminate individuals' insurance, employment, or other opportunities.[57] The Genetic Information Nondiscrimination Act ("GINA") promises to protect individuals from discrimination on the basis of genetic information in employment and health insurance.[58] This is an encouraging sign, although it is unclear how the Act will operate in practice.

Second, unrequested disclosure of information to the tissue provider or her family may cause distress or embarrassment.[59] If a tissue provider learns through genetic research that she carries the gene for Huntington's disease, for example, this knowledge is likely to have a profound impact on her and her family,[60] particularly her children, who have a fifty percent chance of also carrying the detrimental gene.[61] In addition to making it more difficult for the tissue provider

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56. *See, e.g.*, Wylie Burke, *Genetic Testing*, 347 NEW ENG. J. MED. 1867, 1867–68 (2002) (identifying a range of medical conditions (primarily ones that result from single nucleotide polymorphisms) for which genetic tests are currently available and observing that "[a] genetic diagnosis often indicates that other family members are at risk for the same condition").

57. *See* DOROTHY NELKIN & LAURENCE TANCREDI, DANGEROUS DIAGNOSTICS: THE SOCIAL POWER OF BIOLOGICAL INFORMATION 3, 6–7 (1989); Ashburn et al., *supra* note 19, at 3378 (2000).

58. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881.

59. *See* Stewart A. Laidlaw, Leslie J. Raffel & Judith F. Daar, *Genetic Testing and Human Subjects in Research*, 24 WHITTIER L. REV. 429, 460 (2002) ("Emotional or psychological harms from learning one is a carrier of a genetic disease can be devastating. This is particularly true when the onset of the disease is a virtual certainty, such as in the case of Huntington's disease."); *see also* Angela Liang, Note, *The Argument Against a Physician's Duty to Warn for Genetic Diseases: The Conflicts Created by* Safer v. Estate of Pack, 1 J. HEALTH CARE L. & POL'Y 437, 444–45 (1998) (characterizing the chronic stress created by the diagnosis of a genetic disorder as the "shattered self-adequacy syndrome"); Sonia M. Suter, Note, *Whose Genes Are These Anyway?: Familial Conflicts over Access to Genetic Information*, 91 MICH. L. REV. 1854, 1860 (1993) ("Genetic data are also unique in how they may affect self-identity. Empirical evidence shows that the knowledge or assumption that one carries certain disease genes can affect self-perception." (citation omitted)).

60. *See* Laidlaw et al., *supra* note 59, at 460 (describing the problem of "family strife," in which some family members "protest[] the test itself so as not to open an investigation into the family's genetic reality").

61. Huntington's disease ("HD") is a neurodegenerative disorder that is caused by a mutation in a single gene: "an expanded trinucleotide repeat in the gene encoding huntingtin . . . located on chromosome 4p16.3." Nat'l Ctr. for Biotech. Info., OMIM - Huntington Disease; HD, http://www.ncbi.nlm.nih.gov/entrez/dispomim.cgi?id=143100 (last visited

to obtain necessary insurance, disclosure of this information is often emotionally devastating. Alternatively, if genetic analysis in research exposes mismatched paternity, disclosure is likely to be stressful to existing family relationships and potentially embarrassing to all parties involved.[62]

Traditionally, researchers have taken a number of steps to protect the confidentiality of tissue providers. Tissue samples may be coded, meaning that they are assigned a number that corresponds to a secret file containing identifying information.[63] Identifying information for a particular tissue sample can only be obtained with access to a decoding program or database. Alternatively, researchers and institutions may "anonymize" or "de-identify" tissue samples, a process designed to completely and permanently separate the sample from identifying information.[64]

In an age of genetic analysis, however, it is unclear whether true anonymization can ever be achieved.[65] DNA is as individually identi-

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Dec. 20, 2009). The disease is a dominant, autosomal disorder, which means that a single copy of the mutated gene will give rise to the disease. As a result, an individual for whom genetic analysis reveals the presence of the HD mutation is nearly certain to develop Huntington's disease. Moreover, because one copy of an individual's HD gene will have been inherited from each genetic parent and passed on to each genetic child, the presence of an HD mutation in one individual indicates that one of that individual's genetic parents also has the HD mutation and that each of that individual's genetic children has a 50% chance of having inherited the gene as well. *See* HARVEY F. LODISH ET AL., MOLECULAR CELL BIOLOGY 395 (5th ed. 2004) (identifying three common inheritance patterns for human genetic diseases).

62. Susan M. Denbo, *What Your Genes Know Affects Them: Should Patient Confidentiality Prevent Disclosure of Genetic Test Results to a Patient's Biological Relatives?*, 43 AM. BUS. L.J. 561, 598 (2006) ("[T]he revelation of genetic test results to family members may cause a special type of harm, one that some commentators have labeled the 'family secrets' problem.").

63. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 58 (defining "[c]oded samples" as samples "supplied from identified specimens by repositories to investigators," which "do not include identifying information" but instead "are accompanied by codes" so that the repository — but not a later investigator — may still "link the research findings derived from a sample with the individual source using the code").

64. *See* Ashburn et al., *supra* note 19, at 3378 (describing an anonymization process adopted by Pfizer that irrevocably breaks links between samples and patient-identifying information while retaining links to information gathered from samples obtained during clinical trials); *see also* 45 C.F.R. § 164.514(b)(2)(i) (2002) (setting forth eighteen identifiers, the removal of which renders what would otherwise be personal health information "de-identifi[ed]" and outside the scope of the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA)). Under the American Recovery and Reinvestment Act of 2009, the Secretary for Health and Human Services must issue guidance within twelve months of the Act's enactment regarding "how best to implement the requirements for the de-identification of protected health information." 42 U.S.C.S. § 17953 (Lexis 2009).

65. *See* Amy L. McGuire & Richard A. Gibbs, *Genetics: No Longer De-Identified*, 312 SCIENCE 370, 370 (2006) (identifying research showing that "an individual can be uniquely identified with access to just 75 single-nucleotide polymorphisms (SNPs) from that person," while "[g]enomewide association studies routinely use more than 100,000 SNPs to genotype individuals"); *see also* M.B. Kapp, *Ethical and Legal Issues in Research Involving Human Subjects: Do You Want a Piece of Me?*, 59 J. CLINICAL PATHOLOGY 335, 338 (2006) (de-

fying as a fingerprint, and so nearly any individual cell could theoretically be traced back to its source.[66] Moreover, protecting confidentiality through anonymization of tissue, particularly when undertaken without the consent of the tissue provider, may be at odds with the provider's ongoing interest in control of the uses of her tissues. If tissue is truly anonymized, the tissue provider will have no way of knowing what research projects are using her tissue, nor will she be able to exercise her right to withdraw, as identifying her sample for destruction would no longer be possible. Nevertheless, tissue providers have a significant ongoing interest in preserving the confidentiality of information revealed about them through genetic and other research.

More problematic still for current approaches to protecting relevant interests is the fact that genetic material is identifying not only to the person who provides it, but also to her close family members. An individual inherits fifty percent of her genetic material from each genetic parent and is expected to have roughly twenty-five percent of her genes in common with any full sibling.[67] Identical twins, of course, are expected to have identical or nearly identical genetic sequences.[68] These inheritance patterns suggest that not only do consenting tissue providers have a stake in the confidentiality of their genetic information, but so also do their close genetic relatives. In this way, genetic information differs significantly from mere fingerprints, which are identifying only to the person from whom they come.[69] The shared nature of genetic information may necessitate new procedures for obtaining familial consent for the public disclosure of genetic information and techniques for coding and storing tissue samples that better respect both the confidentiality interests of tissue providers and the privacy interests of their family members.[70]

3. Commercialization

Control over the use of one's tissues in research also embraces a range of interests in whether and how those tissues, and products derived from them, are commercialized. The interests that tissue provid-

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scribing current requirements under the HIPAA Privacy Rule for de-identifying tissues — requirements that in fact lead to coded, but not truly de-identified, samples).

66. *See* Andrews, *supra* note 20, at 24.

67. BRUCE R. KORF, HUMAN GENETICS AND GENOMICS 36 (3d ed. 2007) (defining Mendelian patterns of genetic inheritance).

68. *See* DANIEL L. HARTL & ELIZABETH W. JONES, ESSENTIAL GENETICS: A GENOMICS PERSPECTIVE 544 (4th ed. 2006) (noting that identical twins are genetically identical because they arise from the splitting of a single fertilized egg).

69. *See* Natalie Ram, *The Mismatch Between Probable Cause and Partial Matching*, 118 YALE L.J. POCKET PART 182, 183–84 (2009), http://thepocketpart.org/2009/04/13/ram.html.

70. I have discussed one aspect of the familial nature of genetic information in other work. *See id.*

ers advance concerning commercialization tend to follow one of two lines. The first approach contends that the commercialization of body products should be wholly proscribed, focusing on moral, ethical, or religious objections to the commercialization of pieces of the human body.[71] American policy writ large reflects this non-commodification sensibility in significant ways. The sale and importation of human organs is forbidden by law,[72] and the sale of born persons is flatly unconstitutional.[73]

Many individuals have also questioned the ethical consequences of permitting commodification and sale of body parts. For some, the language and values of the market — commensurability, fungibility, and the like — threaten to undermine human dignity and human relationships when applied to human bodies or their parts.[74] Separately, concerns about coercion and exploitation of those with little information, education, or other options for obtaining income must also be seriously considered before embracing remuneration for tissue providers.[75] This concern is particularly salient given the global nature of scientific research and data, as those who bear the burden of producing tissue for research may not be the ones who enjoy the benefits flowing from research.[76]

The second approach to interests in commercialization argues for providing compensation to those who provide tissue for research.[77]

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71. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 49 ("Some individuals may object to the possibility that researchers could sell their samples to companies for profit."); Radin, *supra* note 27, at 1877–87.

72. 42 U.S.C. § 274e (2006).

73. U.S. CONST. amend. XIII § 1.

74. *See, e.g.*, Ossorio, *supra* note 28, at 238–39; Radin, *supra* note 27, at 1877–87; Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 GEO. WASH. L. REV. 737, 746–47 (2004) (arguing that the connection between property and markets "undermines the relationships in which we share [genetic information], pushing them toward arms-length transactions as opposed to relationships of trust").

75. *See, e.g.*, Donna Dickenson, Commentary, *Commodification of Human Tissue: Implications for Feminist and Development Ethics*, 2 DEVELOPING WORLD BIOETHICS 55 (2002); Rob Stein, *N.Y. To Pay for Eggs for Stem Cell Research*, WASH. POST, June 26, 2009, at A4 (reporting that critics of New York's policy to pay women to provide eggs for stem cell research "worry that the move could lead to the exploitation of women, especially poor women, who tend not to be in demand for infertility donation").

76. *See* Dickenson, *supra* note 75 (arguing that human eggs required for cloning for biomedical research are likely to come from women in the southern hemisphere and support research in the northern hemisphere and be available only to those in the North); *see also Joint Oversight Hearing on the Implementation of Proposition 71, the Stem Cell Research and Cures Act*, 2005 Leg. (Cal. 2005) (statement of Francine Coeytaux, Pro-Choice Alliance for Responsible Research), *available at* http://www.geneticsandsociety.org/resources/items/20050309_senate_coeytaux.html (noting that so long as financial inducement is available, most human eggs obtained for cloning for biomedical research will come from poor women).

77. *See, e.g.*, Korobkin, *supra* note 17, at 47; William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693, 715–31 (1995) (arguing that recognizing a property right in the body

The status quo results in a system in which researchers and their institutions may profit from the products of research, but those who provide the raw materials of research do not share in the economic benefits of the fruits of that provision.[78] This "double standard" arises because the default rule provides tissue providers with no compensation,[79] while simultaneously permitting researchers, biotechnology companies, and pharmaceutical or medical device makers to reap the commercial rewards of the results of research using human tissue.[80] For individuals whose tissue is uniquely useful, this double standard may appear especially exploitative.

Courts have traditionally been very reluctant to permit individuals to profit from tissue provision. As Bartha Knoppers and Claude Laberge note, "individual agreements to share in profits with the [tissue providers] are often considered morally repugnant."[81] In one recent case, however, a judge permitted plaintiffs to proceed with a claim of unjust enrichment against an appropriating researcher.[82] This suggests that, at least when providers' tissues are unique or uniquely valuable, some right to remuneration may be appropriate. Some scholars have suggested benefit-sharing models that seek to compensate tissue pro-

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will allow the legal system to handle demand for body parts and allow individuals to gain better control over their bodies); Roy Hardiman, Comment, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 213 (1986) (arguing for a limited "commerciality" right in the body).

78. *See, e.g.*, Jasper Bovenberg, Commentary, *Whose Tissue Is It Anyway?*, 23 NATURE BIOTECHNOLOGY 929, 929 (2005); Charlotte H. Harrison, *Neither* Moore *nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 77 (2002).

79. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 489 (Cal. 1990) (precluding Moore from asserting any property right to his cells once removed from his body, while recognizing the propriety of the researchers using his cells to patent and profit from their research results); Harrison, *supra* note 78, at 77 (describing the no-compensation default and noting that the status quo is often criticized as a "double standard"); Korobkin, *supra* note 17, at 45–46 (identifying the no-compensation default for tissue providers).

80. Harrison, *supra* note 78, at 77. As one example, despite cases like *Moore* and *Greenberg v. Miami Children's Hospital Research Institution, Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003), which deny tissue providers any property interest in their excised cells, the USPTO and the Federal Circuit have made the issuance of patents pertaining to genetic sequences from human sources a fairly routine matter. According to one study, nearly twenty percent of human gene sequences are "explicitly claimed" as intellectual property. Kyle Jensen & Fiona Murray, *Intellectual Property Landscape of the Human Genome*, 310 SCIENCE 239, 239 (2005).

81. Bartha Maria Knoppers & Claude M. Laberge, *Research and Stored Tissues: Persons as Sources, Samples as Persons?*, 274 JAMA 1806, 1806 (1995); *see also* ROBERT F. WEIR & ROBERT S. OLICK, THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE 123 (2004) (noting that nearly all ethics and research organizations have adopted some version of a noncommercialization position, with some identifying the removal of human tissue specifically for commercial profit as immoral).

82. *Greenberg*, 264 F. Supp. 2d at 1072–73.

viders for their contributions while minimizing the economic, and potentially exploitative, incentive to provide tissue.[83]

None of the legal systems considered in this Article provide firm guidance on the precise shape that rules governing tissue commercialization should take. As discussed in Part III.B.3, this holds true even for a private property regime.[84] Private property regimes are, of course, often associated with commodification and commercial markets,[85] but not all property is necessarily market-alienable.[86] This Article does not advocate for a specific solution to the commercialization quandary. Instead, it reserves this issue and simply notes where issues of commercialization might enter our analysis of the various frameworks discussed below.

4. Cure

Tissue providers often have a substantial interest in the outcome of research that is distinct from society's general interest in the progress of science. Studies on informed consent show that individuals often want access to health information learned through the research use of their tissues.[87] In the vast majority of cases, tissues stored in American bio-repositories were originally collected in the course of diagnostic or therapeutic interventions.[88] Patients who provide disease-related tissue for research often hope to benefit directly. Information learned about how a particular tumor responds in the lab, for

83. *See* Jon F. Merz et al., *Protecting Subjects' Interests in Genetics Research*, 70 AM. J. HUM. GENETICS 965 (2002); HUMAN GENOME ORG. ETHICAL, LEGAL, AND SOC. ISSUES COMM., STATEMENT ON THE PRINCIPLED CONDUCT OF GENETIC RESEARCH (1996), *available at* http://www.eubios.info/HUGO.htm (prohibiting "undue inducement" to participate in research, but permitting benefit-sharing through "the possible use of a percentage of any royalties for humanitarian purposes"). *But see* Clayton et al., *supra* note 20, at 1789 (noting that some commentators "have expressed concern that offering [tissue providers] a share of profits would be manipulative because the possibility that a profitable product will be developed from any particular research project is so low").

84. *See infra* notes 243–45 and accompanying text.

85. *See, e.g.*, Ossorio, *supra* note 28, at 237 ("[T]he buying and selling in the market is a defining conceptual feature of property."); Suter, *supra* note 74, at 746 ("At heart, the term 'property' connotes control within the marketplace.").

86. *See, e.g.*, Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 510 (Cal. 1990) (Mosk, J., dissenting) ("[S]ome types of personal property may be sold but not given away, while others may be given away but not sold, and still others may neither be given away nor sold." (citations omitted)); *see also* Radin, *supra* note 27, at 1903–36 (advocating that certain interests should be market-inalienable: capable of being given away, but not sold).

87. Wendler & Emanuel, *supra* note 44, at 1459 (reporting that "88.8% of all respondents want to be informed and 82.1% want their physicians informed of research results of uncertain clinical significance"); *see also* Robert F. Weir & Jay R. Horton, *DNA Banking and Informed Consent — Part 2*, IRB, Sept.–Dec. 1995, at 1, 4 (suggesting that many "reasonably prudent persons" would expect to be given information regarding the "future access . . . to the personally relevant information gained through [a genetic] study").

88. NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 14.

example, can inform an individual's cancer treatment.[89] Return of research results is only possible, however, if knowledge gleaned about a particular tissue sample can be traced to an identifiable tissue provider. Thus, like the tissue provider's interest in control, a tissue provider's interest in improved treatment may be in tension with her interest in confidentiality, especially if confidentiality is protected through anonymization of tissues.[90]

Patients as tissue providers may also benefit indirectly as more is learned about the disease from which they suffer. Eventually, research may result in more effective treatments or a cure for their disease. Tissue providers not suffering from a particular disease at the time they provide tissue may also benefit in this way if they or their loved ones develop that disease in the future.

Finally, tissue providers generally have an interest in the progress of science through research.[91] This is a benefit accruing to all knowing tissue providers, independent of their current or future health condition. Healthy individuals providing tissue in the course of routine medical interactions or in specific research collections may advance their interests in promoting research by providing tissue that makes such research possible. Similar to the patient-specific benefits gleaned from research, in many instances the progress of medical research is

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89. *See* Brief of Appellant-Defendants Richard Ward et al. at 40, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (Nos. 06-2286 & 06-2301) ("[T]issue samples provide a record of the state of patients' cancer at the time of their surgery. Comparison of such samples to later tissue biopsies can provide important information about the progress of the disease and response to treatment." (citations omitted)). As this example suggests, the hope for personal benefit from research is not necessarily imagined. Without appropriate information, however, research participants may fall subject to therapeutic misconception — the misunderstanding that the intervention in which they are taking part is therapy, not research. Where potential research participants labor under a therapeutic misconception, they may consent to bear burdens they might not otherwise accept, wrongly believing that researchers have only the participant's health and best interests at heart. *See* David Wendler & Christine Grady, *What Should Research Participants Understand to Understand They Are Participants in Research?*, 22 BIOETHICS 203, 204–07 (2008) (describing therapeutic misconception and identifying three facts that research participants should understand in order to ensure that they properly understand that they are participating in research, not a therapeutic intervention).

90. See Philip R. Reilly, Mark F. Boshar & Steven H. Holtzman, Commentary, *Ethical Issues in Genetic Research: Disclosure and Informed Consent*, 15 NATURE GENETICS 16, 17 (1997) (noting that anonymizing tissue samples "largely eliminates the possibility that a participant in research might gain directly from that activity").

91. *See, e.g.*, Christine Grady, *Payment of Clinical Research Subjects*, 115 J. CLINICAL INVESTIGATION 1681, 1682 (2005) (observing that research participants generally "appear to have a variety of other motives besides those of a financial nature for participation in research, including curiosity, altruism, sensation seeking, and desire for attention provided by physicians"); Margaret L. Russell, Donna G. Moralejo & Ellen D. Burgess, *Paying Research Subjects: Participants' Perspectives*, 26 J. MED. ETHICS 126, 127 (2000) (reporting that research participants identified "benefits to society (for example, 'participate in advancement of knowledge,' 'benefit others'); [and] psychological benefits to the participant (for example, 'contribute . . . to the success of the research')" among their motivations for participation).

best served by maintaining identifiable tissues.[92] Thus, here again, the tissue provider's interest in promoting research crosscuts her interest in protecting the confidentiality of her genetic information.

B. Some Interests of Researchers and Society

Like tissue providers, other constituents in the research enterprise have strong interests in promoting good research using human tissue. Society at large has a profound interest in the progress of science, which manifests itself in several important ways. Chief among these are facilitating researcher access to research materials, incentivizing investment in high quality research, and ensuring that research is conducted in a responsible and ethical fashion. The last of these corresponds most closely with protection of the interests of tissue providers set forth above. The remaining two are reflected in interests asserted by researchers and already recognized by courts: access to research materials and ability to commercialize and profit from gains made through research.[93] Accordingly, these interests require less explication at the outset.

Research involving human tissue is often concerned with tissue as a source of information. While human tissue has always provided information about an individual's health status, today this tissue can provide health and other information with startling specificity. In addition to uncovering the individual and population-wide presence of genes contributing to disease, research may also reveal genetic bases for traits with social, rather than medical, significance.[94] Human tissue is also a valuable source of raw materials for diagnostic tests and cell lines.[95] As Dorothy Nelkin and Lori Andrews note, "[t]he market for skin, blood, placenta, gametes, biopsied tissue and genetic material is expanding, driven in part by commercial incentives fostered by legal developments in the 1980s."[96]

For both researchers and society at large, simple and inexpensive access to the raw materials of research is critical to promoting invest-

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92. Ashburn et al., *supra* note 19, at 3378 ("[M]aintaining a link to the donor's clinical information allows researchers to obtain follow-up information from the donor's clinical records to test, for instance, a putative genetic marker's value as a predictor of disease or to allow follow-up studies.").

93. *See, e.g.*, Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1070, 1076 (S.D. Fla. 2003) (dismissing both a claim of failure to obtain informed consent and a claim of conversion due in part to concerns about "chill[ing]" or "crippl[ing]" medical research); Moore v. Regents of the University of California, 793 P.2d 479, 493 (Cal. 1990) (emphasizing the need not to threaten "innocent parties who are engaged in socially useful activities" with "disabling civil liability").

94. *See, e.g.*, HAMER & COPELAND, *supra* note 35 (sexual orientation); Katrina Kelner & John Benditt, *Genes and Behavior*, 264 SCIENCE 1685 (1994) (behavioral traits); Gail Vines, *Genes in Black and White*, NEW SCIENTIST, July 8, 1995, at 34 (race).

95. Nelkin & Andrews, *supra* note 52, at 5.

96. *Id.*

ment in science and medicine. Researchers and those who fund research have a strong interest in minimizing roadblocks to research. Where there are fewer permissions to obtain, research can proceed more quickly and with less cost. Where property experts once warned about the problems of the commons,[97] modern researchers and scholars are concerned about an anticommons in biomedical research.[98] Some scientists fear that "too many patents related to a single gene may actually impede useful research since it will be difficult (and costly) for a researcher to gain licenses from each patent holder."[99] The addition and protection of more rigorous consent or other requirements designed to facilitate provider control over the use, disclosure, and commercialization of tissue may exacerbate these problems. As such, any policy recommendation must temper protection of tissue providers' interests with an understanding of the interplay of such interests with the overall practice of science.

Researchers — and the institutions in which they work — also have a strong interest in the financial rewards of commercial science and medicine. In the United States, patents are awarded in order to "promote the Progress of Science and the useful Arts."[100] In other words, we award patents in large part to encourage investment in science. Where profits are diluted by burdensome transaction and other costs associated with obtaining access to tissue, investment in research may decrease.[101]

III. A NEW APPROACH

Armed with an understanding of the interests at stake in the relationships between tissue providers, researchers, and broader society,

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97. *See* Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968).

98. *See* Heller & Eisenberg, *supra* note 17, at 698.

99. Nelkin & Andrews, *supra* note 52, at 5 (citing John Murray, Note, *Owning Genes: Disputes Involving DNA Sequence Patents*, 75 CHI.-KENT L. REV. 231, 233–35 (1999)); *see also* Complaint at 2, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09CV4515 (S.D.N.Y. May 12, 2009) ("Ease of access to genomic discoveries is crucial if basic research is to be expeditiously translated in clinical laboratory tests that benefit patients in the emerging era of personalized and predictive medicine. The [BRCA1 & BRCA2] patents make ease of access more restricted.").

100. U.S. CONST. art I, § 8, cl. 8.

101. This profit motive did not always figure so prominently in the practice of science. Before 1980, most inventions made with government funding went unpatented. *See* Joshua A. Newberg & Richard L. Dunn, *Keeping Secrets in the Campus Lab: Law, Values and Rules of Engagement for Industry-University R&D Partnerships*, 39 AM. BUS. L.J. 187, 193 (2002). However, the Bayh-Dole Act, enacted in 1980, permits and encourages government-funded researchers to patent and commercially develop their inventions. 18 U.S.C. §§ 200–212. In the years since Bayh-Dole was enacted, universities, often the recipients of federal research funding, have become avid patentees and may even have come to depend on patents and "tech transfer" as a source of revenue. *See* Rochelle Dreyfuss, *Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?*, 46 ARIZ. L. REV. 457, 463–64 (2004).

this Part offers a new way forward for approaching these relationships and explores how the informational property model works alongside and improves traditional models in tort, contract, and property. Different approaches yield different strengths and weaknesses, of course. Conceptualizing the relationship as one governed by the rules of tort, for instance, may entail significantly different outcomes than a conceptual framework of private property.[102] Nevertheless, the informational property model, if properly formulated, offers significant advantages as a starting point for designing appropriate research governance.

Before introducing potential governance models, it is worth noting the system of public rules and regulations already potentially applicable to such research. At the federal level, research involving human subjects conducted using federal monies must comply with the Common Rule.[103] The Common Rule requires researchers to provide potential research participants with extensive information in the course of obtaining informed consent, including information about the expected risks and benefits of the research and confidentiality procedures to be followed.[104] As noted previously, these regulations also stipulate that human subjects be informed that research participation is optional and consent may be withdrawn at any time.[105] The Common Rule does not specify any rules regarding payment, except to say that participants must be informed about possible compensation to which they may be entitled if research results in injury to them.[106] The Rule also contains a provision relating to the communication of research findings to participants, although such disclosure appears to be conditioned on whether the information "relate[s] to the subject's willingness to continue participation."[107] The FDA imposes similar requirements for all studies submitted for its review.[108] Together, these two federal standards govern the vast majority of human subjects research conducted in the United States. Finally, the Privacy Rule promulgated under the Health Insurance Portability and Accountability Act ("HIPAA") generally requires that a covered entity obtain authorization from an individual for the research use or disclo-

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102. *See* Ossorio, *supra* note 28, at 237 (offering two possible reasons why conceptual framework matters: first, because the framework attached "would likely change the legal landscape with respect to how one's rights were respected and exercised," and second, because "the words we use structure our thinking and our behavior"); *cf. id.* at 241 (concluding that "legal rules governing possession, use, and sale of human bodily materials can and should be promulgated, regardless of whether we affix the label 'property' to these materials").

103. *See* 45 C.F.R. §§ 46.101–.124 (2009).

104. *Id.* § 46.116(a)(2)–(3), (5).

105. *Id.* § 46.116(a)(8).

106. *Id.* § 46.116(a)(6).

107. *Id.* § 46.116(b)(5).

108. *See* 21 C.F.R. §§ 50, 56, 812 (2009).

sure of her protected health information (including individually identifiable genetic information), unless a regulatory permission applies.[109]

To date, however, agencies and courts have been hesitant to impose similar requirements on researchers using human tissue in research, especially where tissue has been "de-identified."[110] In 2004, the federal Office of Human Research Protections issued a guidance document stating that "tissue collection for present or future research purposes is not subject to [Institutional Review Board ("IRB")] review and informed consent provisions of the Common Rule, as long as there is no personally identifiable information attached to the tissue specimens."[111] In 2006, the FDA followed suit.[112] HIPAA's disclosure restrictions are generally inapplicable to health information that has been de-identified, as such information is not included in the Privacy Rule's definition of "protected health information."[113]

Moreover, even if these federal statutes and regulations were applied to human tissue research or genetic information across the board, they would provide relatively little protection for individual tissue providers. Where a violation of the Common Rule is discovered, the funding agency may withdraw federal funds from a researcher or institution.[114] No civil or criminal enforcement action of these rules is mandated. Under HIPAA, the federal government may impose penalties on covered entities and their business associates for violations of the Privacy Rule.[115] Penalties, however, have generally

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109. 45 C.F.R. § 164.512(i) (setting forth regulatory exceptions to the rule of required authorization). GINA clarifies that genetic information is "health information," 42 U.S.C.S. § 1320d-9(a)(1) (Lexis 2009), but HIPAA's disclosure restrictions apply only to health information that is "individually identifiable." *See* 45 C.F.R. § 164.502(d)(2).

110. Again, it is questionable whether DNA can ever be truly de-identified. *See* McGuire & Gibbs, *supra* note 65.

111. Kapp, *supra* note 65, at 336.

112. Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable, 71 Fed. Reg. 1429, 1430 (Jan. 9, 2006) (providing notice that the FDA "intends to exercise enforcement discretion when," *inter alia*, "[t]he study uses leftover specimens"; "[t]he specimens are not individually identifiable"; "[t]he specimens are provided to the investigator(s) without identifiers"; "[t]he individuals caring for the patients are different from, and do not share information with, those conducting the investigation"; and "[t]he study has been reviewed by an IRB.").

113. *See* 45 C.F.R. § 164.502(d)(2); § 164.514(a) (2009) ("Health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually identifiable health information."). The Privacy Rule also permits protected health information to be disclosed without authorization in some instances, including for research purposes. 45 C.F.R. § 164.514(e) (specifying that protected health information may be disclosed for, *inter alia*, research purposes, so long as the information released contains only a limited data set and is released pursuant to a data use agreement between researcher and covered entity (but not the individual whose information is at issue)).

114. 45 C.F.R. § 46.123 (2008); *see also id.* § 46.113 (providing for suspension or termination of IRB approval of research where the requirements of the Common Rule are not met).

115. 42 U.S.C.S. § 1320d-5(a) (Lexis 2009).

been few and far between.[116] Recent amendments to HIPAA enacted as part of the American Recovery and Reinvestment Act permit state attorneys general to bring enforcement actions[117] and require the federal government to act in limited instances.[118] It is too soon to tell whether and how effective these statutory changes will be. Meanwhile, courts have generally held that the relevant regulations do not create private rights of action for third-party beneficiaries of government regulations (i.e., research subjects).[119]

State law often provides similarly slim protection. As of January 2008, just more than half of U.S. states required informed consent to disclose genetic information.[120] Only eight required informed consent for the retention of genetic information.[121] And while five states affirmatively recognize genetic information as the personal property of the individual from whom that information derives,[122] at least two of these (Colorado and Georgia) nonetheless permit the research use of genetic information without consent.[123]

This leaves tissue providers facing recourse to private law systems to protect their interests.

A. Informational Property

1. Defining Informational Property

Informational property recognizes a limited right to control how the information contained within one's cells is used.[124] This approach

116. Kendra Gray, *The Privacy Rule: Are We Being Deceived?*, 11 DEPAUL J. HEALTH CARE L. 89, 89 (2007) ("Since the implementation of the Privacy Rule, the U.S. Department of Health and Human Services ('HHS'), Office for Civil Rights ('OCR') has received thousands of complaints, but has not imposed a single civil fine and has prosecuted only two criminal cases.").

117. 42 U.S.C.S. § 1320d-5(e) ("Enforcement by State attorneys general").

118. *Id.* § 1320d-5(c) ("Noncompliance due to willful neglect").

119. *See, e.g.*, Wright v. Fred Hutchinson Cancer Research Ctr., 269 F. Supp. 2d 1286, 1289 (W.D. Wash. 2002) (holding that there is no private right of action under the Common Rule). Case law is also clear that where Congress did not intend to create rights enforceable in private actions, there is no basis for a judicial remedy. *See* Gonzaga Univ. v. Doe, 536 U.S. 273, 286 (2002) ("[W]here the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit.").

120. Nat'l Conference of State Legislatures, Genetic Privacy Laws, Jan. 2008, http://www.ncsl.org/default.aspx?tabid=14287.

121. *Id.* (Alaska, Delaware, Minnesota, Nevada, New Jersey, New Mexico, New York, and Oregon).

122. *Id.* (Alaska, Colorado, Florida, Georgia, and Louisiana).

123. COLO. REV. STAT. § 10-3-1104.7(5) (2009); GA. CODE ANN. § 33-54-6 (2009). In addition, Florida's genetic testing statute has been interpreted as providing little protection in the context of genetic research. Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1069, 1075 (S.D. Fla. 2003) (discussing FLA. STAT. § 760.40 in the context of informed consent and conversion claims).

124. Others have also explored the propertization of information. *See, e.g.*, Jacqueline Lipton, *Information Property: Rights and Responsibilities*, 56 FLA. L. REV. 135, 136–37

adopts the contours of American intellectual property. In particular, a rights regime adapted from copyright appears to capture many of the needs and interests to be protected in research involving human tissue. Unlike tangible property, copyright cannot be lost through unconscious abandonment during its statutory period.[125] Moreover, copyright attaches even to unpublished (i.e., undisclosed) works.[126] Personal genetic information protected by a copyright-like informational property right would thus be unavailable for unauthorized use no matter how or from where it was obtained.

A critical caveat, however, is that close genetic relatives may serve as a source of tissue and genetic information, even if a particular individual will not. In the absence of some form of familial or even community-based agreement, substantial amounts of one's individualizing genetic information may be compiled through the collection of tissue samples from related individuals, notwithstanding one's personal consent. Nonetheless, researchers working within an informational property regime would be unable to access a particular person's genetic information directly in the absence of appropriate permission. Moreover, in instances in which an individual's tissue is valuable because of a unique, non-shared mutation, informational property rights would provide true protection from unauthorized access to the desired gene sequence.

Informational property controls would likewise persist even in downstream creations like digitized genetic sequences, as the information contained in such records would be identical to that of the original cells, even if their forms were different.[127] Cell lines might also be subject to informational property controls where a tissue provider's genetic sequence and the genetic sequence of a cell line are similar in material ways.[128] This assignment of rights and the now-common

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(2004) (listing sources); Pamela Samuelson, *Information as Property: Do* Ruckelshaus *and* Carpenter *Signal a Changing Direction in Intellectual Property Law?*, 38 CATH. U. L. REV. 365 (1989); *cf.* Joseph Blocher, *Reputation as Property in Virtual Economies*, 118 YALE L.J. POCKET PART 120 (2009), http://thepocketpart.org/2009/01/19/blocher.html (describing intangible reputation as the object of property rights).

125. *See* 17 U.S.C. § 302(c) (2006) (guaranteeing copyright protection for works that are published anonymously or under pseudonyms); *see also infra* text accompanying notes 251–55 (describing how traditional property can be abandoned and used without regard to the prior owner's interests).

126. 17 U.S.C. § 104(a) (2006).

127. Rebecca S. Eisenberg, *How Can You Patent Genes?*, AM. J. BIOETHICS, Summer 2002, at 3, 9 (discussing genetic information stored in computer-readable format).

128. Cell lines are a complicated downstream creation to analyze in the informational property framework. The value of a cell line lies in the extent to which it maintains the genome of the original provider. In this sense, informational property controls ought to extend to cell lines as well because they target the same genetic information. But cell lines are often substantially genetically different from the cells of the original human provider. This stems in part from the way in which cell lines are created — by fusing a kind of cancer cell with the provider's cells. The result is that the cells of a cell line may have entire chromosomes from the cancer cell, and they may lose entire chromosomes from the initial pro-

practice of patenting human genes are not necessarily mutually exclusive.[129] Just as downstream inventors must often obtain licenses to make use of upstream patented works, researchers would also need to obtain prior consent from the individuals whose tissues and genetic information form the basis for their research.[130]

Although this model builds on an analogy to American intellectual property, the synonymy of these two constructs is inexact. Individuals invest no creativity in creating their genetic information, while at least a modicum of creativity is generally required in intellectual property.[131] Nonetheless, adopting and adapting the language and rights of intellectual property for personal genetic information has intuitive appeal, as it attaches a property-like right to the most valuable part of tissue samples — the information they contain.[132]

Moreover, both the proposed informational property right in personal genetic information and intellectual property rights arise at least in part for the instrumental reason that they encourage innovation and

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vider. Moreover, the genomes of cell lines often develop numerous mutations over time, including large duplications or deletions of genetic material. *See* Chad A. Cowan et al., *Derivation of Embryonic Stem-Cell Lines from Human Blastocysts*, 350 NEW ENG. J. MED. 1353, 1355 (2004) (noting that after prolonged culture several cell lines displayed trisomy (three copies) of chromosome 12, as well as other changes). For purposes of this Article, a cell line will be considered as falling within the scope of a tissue provider's informational property protections so long as the cell line contains genetic sequences from the provider's cells that are individualizing. This Article will denominate such cell lines as "similar in material ways" or "materially similar." In other words, as stated above, where a tissue provider's genetic sequence and the genetic sequence of a cell line are materially similar, the informational property protections affixed to the former extend to the latter.

129. On the patenting of the human genome, see Jensen & Murray, *supra* note 80, at 239, which reports that twenty percent of the human genome has already been patented, with some genes subject to as many as twenty patents.

130. Although informational property rights would not necessarily be in direct conflict with current patent practices, recognizing informational property rights in genetic information emphasizes the difficulties that arise when patents are available for unmodified gene sequences. Informational property rights might thus provide another reason for doing away with these problematic patents. Gene patents have been subject to criticism by "professional medical organizations, Nobel Prize winners, government officials, religious leaders, and bioethics councils." Eileen M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 TENN. L. REV. 707, 727 (2004); *see also* Complaint, Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, No. 09CV4515 (S.D.N.Y. May 12, 2009); Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS. GENETICS 803, 803–05 (2002) (addressing the negative impact gene patenting may have on research, medical treatments, and disease diagnosis); Symposium, *Probing the Human Genome: Who Owns Genetic Information?*, 4 B.U. J. SCI. & TECH. L. 2 (1998) (transcribing panel presentations discussing the issue of gene patenting and ownership).

131. *See infra* text accompanying notes 248–49.

132. *See* Buchanan, *supra* note 43, at B-6 ("[F]rom the standpoint of many of the interests at stake in the way biological samples are used, what is most import [sic] is the information the sample can yield, not the physical embodiment of the information."); *cf.* Pilar Ossorio, *Legal and Ethical Issues in Biotechnology Patenting*, *in* A COMPANION TO GENETHICS: PHILOSOPHY AND THE GENETICS REVOLUTION 408, 416 (2002) (recognizing that the role of DNA as information carrier comes closest to linking human dignity concerns to objections to genetic research patenting).

investment in research.[133] Patent and copyright reward successful innovation and so encourage would-be inventors to invest their time and resources in hopes of securing certain time-limited exclusive rights with respect to the result. Informational property rights would encourage investment in research in two senses: first, by enabling individuals to provide their tissues for research use with confidence that their interests will be respected ("investment" as resources); and second, by increasing public trust in the ethical conduct of scientific research ("investment" as both public resources and emotional energy).

2. Informational Property as a Personal Right

Generally, intellectual property may be committed to the commons, or rights to it may be assigned to specific individuals or institutions.[134] Given that the vast majority of human genetic data is identical — indeed, the genetic makeup of even non-related individuals differs only by hundredths of a percentage[135] — it may be attractive to conceptualize this information as a commons to which all have equal access and to which none may assert a preferential right of access or control.[136] A total genetics common, however, would also permit indiscriminate use of any DNA for any purpose. Such an ap-

133. Much of American intellectual property law arises by operation of the Constitution's Progress Clause, which grants Congress the power to "*promote the Progress of Science and useful Arts*, by securing for limited Times to Authors and Inventors the exclusive Right to use their respective Writings and Discoveries." U.S. CONST. art I, § 8, cl. 8 (emphasis added).

134. *See* Jasper A. Bovenberg, *Mining the Common Heritage of Our DNA: Lessons Learned from Grotius and Pardo*, 2006 DUKE L. & TECH. REV. 8, ¶¶ 9–12, www.law.duke.edu/journals/dltr/articles/pdf/2006DLTR0008.pdf (delineating the ancient categories of non-private property — *res nullius*, *res communis*, and *res publicae* — and describing whether and under what circumstances such property becomes private). A third type of ownership may also arise: a semicommons, in which "a resource is owned and used in common for one major purpose, but, with respect to some other major purpose, individual economic units — individuals, families, or firms — have property rights to separate pieces of the commons." Henry E. Smith, *Semicommon Property Rights and Scattering in the Open Fields*, 29 J. LEGAL STUD. 131, 131 (2000).

135. Human Genome Project Information, SNP Fact Sheet, http://www.ornl.gov/sci/techresources/Human_Genome/faq/snps.shtml (last visited Dec. 20, 2009) [hereinafter SNP Fact Sheet] ("[M]ore than 99% of human DNA sequences are the same"). What is more, protein-coding DNA comprises barely two percent of the human genome, with vast stretches of non-coding DNA in between. Elizabeth Pennisi, *DNA Study Forces Rethink of What It Means to Be a Gene*, 316 SCIENCE 1556, 1556 (2007).

136. *See, e.g.*, JOHN SULSTON & GEORGINA FERRY, THE COMMON THREAD: A STORY OF SCIENCE, POLITICS, ETHICS, AND THE HUMAN GENOME (2002) (providing an insider's perspective on the Human Genome Project and arguing for keeping the human genome an unpatented commons); HUMAN GENOME ORG. ETHICS COMM., *supra* note 83 (adopting four principles for any recommendations HUGO makes, including "[r]ecognition that the human genome is part of the common heritage of humanity"). This sort of commons might best be classified as a public trust, rather than as common possession. *See* Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425, 437 (2007).

proach is inconsistent with a commitment to tissue provider control over the use of one's genetic information in research — especially genetic information that is personally identifying and identity forming.

Instead, the informational property approach considers genetic information to be the property of the individual from whom it was obtained.[137] Genetic information plays a role in self-identity and may contain indications about one's present and future self — indeed, this is one reason why unauthorized use of one's genetic material is often perceived as offensive to human dignity. Like a right to control the use of one's likeness,[138] a right to control the use of one's genetic material would flow from a personal right that arises without the specific intent or perhaps innovation of the rights holder. Under an informational property rights regime, unwanted uses or disclosures of genetic information may be prevented ex ante, and unauthorized uses or disclosures could be remedied ex post.[139]

3. Operationalizing Informational Property: Copyleft Licensing

Under a system of personal informational property rights, any researcher wishing to gain access to the information contained in an individual's cells would need to obtain a license from that individual. Such a license would fill much the same role that an informed consent document plays in our current system — a license authorizes access to and use of the desired material.[140] A license may be proprietary,

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137. As discussed in more detail below, the shared nature of genetic information calls for different forms of control over genetic information that is shared by all persons as compared with genetic information that is personal and may be identifying to a specific individual. *See infra* text accompanying notes 166–74.

138. *See* Haelan Labs., Inc. v. Topps Chewing Gum, Inc., 202 F.2d 866, 868 (2d Cir. 1953) (coining the term "right of publicity").

139. *See* Ira V. Heffan, Note, *Copyleft: Licensing Collaborative Works in the Digital Age*, 49 STAN. L. REV. 1487, 1509–10 (1997) ("Courts have held that an author can pursue claims of copyright infringement if a licensee makes use of the author's work in a manner that is outside the scope of the license."); *see also* Costello Publ'g Co. v. Rotelle, 670 F.2d 1035, 1045 (D.C. Cir. 1981); Gilliam v. Am. Broad. Cos., 538 F.2d 14, 20–21 (2d Cir. 1976); Microsoft Corp. v. Very Competitive Computer Prods., 671 F. Supp. 1250, 1257 n.4 (N.D. Cal. 1987). Where no license was obtained, forced tissue providers would likewise have a claim similar to copyright infringement.

140. We should, of course, distinguish between the process of facilitating informed consent and the documentation of that consent (here, as a license) when given. Informed consent is meant to be a process that enables individuals to understand the nature of the research in which they are invited to participate and the ways in which that research may or may not advance their own goals and life plans. *See* Ram, *supra* note 20, at 259–62 (describing the ethical demands of informed consent). *See generally* RUTH R. FADEN, TOM L. BEAUCHAMP & NANCY M. P. KING, A HISTORY AND THEORY OF INFORMED CONSENT (1986). It may be appropriate to think about informed consent documents both as memorializing the informed consent process and as a legal document setting forth the terms of a limited license. The point, however, is that constructing informed consent documents to serve also as licenses or other legal documents should not override the primary function of

meaning that the rights holder has "all rights reserved," and that each downstream researcher must obtain permission from the rights holder to use, copy, modify, or distribute the protected material.[141] Alternatively, licenses may be open source and "copyleft" in nature, meaning that the rights holder has "some rights reserved," and that downstream researchers may freely use, copy, modify, and distribute the protected material subject to specific restrictions enumerated in the license.[142] In particular, a copyleft license generally requires "any derivative work made from the copyleft-licensed work be itself licensed under the same copyleft license, preserving all the same rights and responsibilities the original licensee had to downstream licensees."[143] In the context of tissue provision, this kind of "viral licensing" provision would reinforce tissue providers' ability to exercise their interests with respect to derivative works, such as cell lines or commercial products.[144]

Again, researchers may be able to "route around" individual tissue providers by obtaining tissue from genetic relatives, which raises questions about whether and how familial or community consent ought to be required in some instances. For present purposes, protecting informational property rights means, at a minimum, protecting the human dignity of individuals by preventing their individually-identifying genetic information from being used in research to which they object. The use of genetically similar, though non-identical, tissues in research may therefore cause family conflict, but does not constitute an affront to respect for human dignity. Identical siblings, of course, complicate this picture.

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informed consent — enabling individuals to act in an informed manner according to their interests.

141. *See* Brian W. Carver, Note, *Share and Share Alike: Understanding and Enforcing Open Source and Free Software Licenses*, 20 BERKELEY TECH. L.J. 443, 454 (2005) (describing the rights associated with copyright ownership).

142. *Id.* The primary providers of open source, copyleft licenses are Creative Commons and the GNU Project. *See* Creative Commons, http://creativecommons.org (last visited Dec. 20, 2009) (providing open source licenses for many kinds of copyrighted works); GNU Project Licenses, http://www.gnu.org/licenses/ (last visited Dec. 20, 2009) (providing open source licenses for computer software).

143. Carver, *supra* note 141, at 453.

144. Throughout this Article, "derivative works" refers to physically distinct, but informationally similar cellular or other products. Enzymes or hormones produced by a particular tissue sample would constitute a derivative work of this kind, as would cell lines (at least those in which the genetic sequence of the cell line and the tissue provider's genetic sequence are materially similar). So too would digitally rendered genetic sequences. Technically speaking, children could be considered derivative works of their parents — downstream genetic "products" that arose through the combination of chromosomes from each genetic parent. However, this Article will not include genetic relatives, who share many of the same genes, among derivative works. At least with respect to this derivative works component, each individual remains free to consent to the use of or refuse to provide tissue for research purposes, independent of the choices of her relatives.

If proprietary rights were asserted, recognizing informational property rights for tissue providers would be likely in many instances to disserve the broader interests of tissue providers, as well as of researchers and society, in facilitating research. Proprietary informational property rights to one's personal genetic information may exacerbate anticommons problems in biomedical research by adding another rights holder from whom authorization must be obtained and to whom licensing fees may have to be paid before research may commence.[145]

Open-source licensing systems, by contrast, may avoid this significant pitfall by adopting standardized kinds of authorization that can be granted or withheld, and by doing so one time, rather than requiring each potential user of protected material to negotiate independently with a rights holder. Creative Commons licensing, for example, permits combinations of four kinds of conditions limiting the use of protected material by downstream users: attribution ("BY"), noncommercial ("NC"), no derivatives ("ND"), and share alike ("SA").[146] These conditions signal the sorts of interests that matter to individuals engaging in creative activities generally protected by copyright.

The interests of tissue providers serve as analogous bases for formulating conditions that might be available in an open-source licensing system for tissue provision.[147] Although the number and types of conditions might expand beyond those recognized by Creative Commons, the range of possible conditions could nonetheless be cabined and standardized by policy or guideline. For example, the provider's interest in control might be achieved through restrictions placed on the types of research for which a tissue sample may be used. Such restrictions might include the possibility that the tissue sample may only be used for the specific project for which it was pro-

145. On the problem of the anticommons in biomedical research, see Heller & Eisenberg, *supra* note 17.

146. Creative Commons Licenses, http://creativecommons.org/about/licenses (last visited Dec. 20, 2009). An "attribution" condition allows others to "copy, distribute, display, and perform your copyrighted work — and derivative works based upon it — but only if they give credit the way you request." *Id.* A "noncommercial" condition allows others to "copy, distribute, display, and perform your work — and derivative works based upon it — but for noncommercial purposes only." *Id.* A "no derivatives" condition allows others to "copy, distribute, display, and perform only verbatim copies of your work, not derivative works based upon it." *Id.* A "share alike" condition allows others to "distribute derivative works only under a license identical to the license that governs your work." *Id.*

147. Creative Commons has already embarked on a related project aimed at spreading the open-source, Creative Commons approach to collaborative research to biomedical research. *See* Science Commons, http://sciencecommons.org/ (last visited Dec. 20, 2009). The Science Commons project, however, seeks to expand Creative Commons licensing among researchers without specific reference to the interests of those providing the raw materials for research. *See* Science Commons Biological Materials Transfer Project, http://sciencecommons.org/projects/licensing/index.html (last visited Dec. 20, 2009).

vided while also requiring that those limitations persist where cells or other products derived from the original sample move among researchers. Interests in confidentiality could give rise to conditions respecting the anonymization of tissue samples and the disclosure of identifying genetic information. These conditions might also include provisions for the retention of linked records to enable therapeutically helpful information to be relayed from researcher to tissue provider. And while the Creative Commons noncommercial condition enables creators only to prohibit commercial uses of their works (and derivative products based on those works), licenses for tissue research might expand the scope of discretion granted to tissue providers. Under this formulation, tissue providers could elect to prohibit commercialization — or at least restrictive patent enforcement — of derivative products outright or, alternatively, elect to require benefit-sharing of the fruits of those products.

The noncommercial condition in Creative Commons licensing has been the source of considerable controversy. This controversy springs primarily from the difficulty of teasing apart "commercial" from "noncommercial" uses in today's "interlocking personal and professional lives."[148] These sorts of line-drawing problems could similarly bedevil a noncommercial designation in the informational property context. For instance, is research "commercial" only when conducted by for-profit companies? Or would non-profit organizations, such as universities, also run afoul of a noncommercial designation through patenting research results? Is patenting the locus of commercialization? And are all sales in connection with human tissue research equally "commercial" in nature?

In a white paper on licensing university technology, leading U.S. research universities, in conjunction with the Association of American Medical Colleges, offered one possible definition of noncommercial research purposes: "Use of PATENT RIGHTS for academic research or other not-for-profit or scholarly purposes which are undertaken at a non-profit or governmental institution that does not use PATENT RIGHTS in the production or manufacture of products for sale or the performance of services for a fee."[149] This definition, of course, presumes the existence and propriety of patent rights. As such, adopting this definition would do little to address the objections of those who

148. Gordon Haff, *Does the Noncommercial Creative Commons License Make Sense?*, CNET NEWS, Nov. 27, 2007, http://news.cnet.com/8301-13556_3-9823336-61.html; *cf.* Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (construing the well-accepted experimental-use exemption in patent law by observing that academic research conducted at Duke University "unmistakably further[s] the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects").

149. CAL. INST. TECH. ET AL., IN THE PUBLIC INTEREST: NINE POINTS TO CONSIDER IN LICENSING UNIVERSITY TECHNOLOGY 10–11 (2007), http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf.

oppose all market alienability of human tissue.[150] These questions indicate the manifold difficulties of navigating the commercialization aspect of genetic and other tissue research. They need not, however, dissuade us from looking to Creative Commons in thinking about how best to structure an informational property licensing system.

The Creative Commons system also provides a baseline from which to analogize an appropriate right to withdraw. The right to withdraw is an important facet of the power to exercise one's ongoing interests in the use of one's cells and genetic information in research. Although Creative Commons licenses are not generally revocable,[151] "[y]ou can stop distributing your work under a Creative Commons license at any time you wish; but this will not withdraw any copies of your work that already exist under a Creative Commons license from circulation . . . ."[152] As Creative Commons licensing is adapted to suit the needs and interests of tissue providers and researchers, the right to prevent future access to the original cell sample might be protected, even as continued use of derivative products within the bounds of the original license might be permitted. This middle ground position seems likely to reassure tissue providers that their interests are sufficiently respected, while also reassuring researchers that their research materials, and especially derived cell lines and cultures, will not be subject to arbitrary revocation.[153]

Limiting and standardizing the types of conditions that rights holders may place on their protected materials would also assist in the movement of materials and derivative products without the enormous transaction costs likely to be incurred where an unlimited number of restrictions may be imposed.[154] Standardized conditions, however, also ensure significantly more control over the future use of one's protected genetic material than a blanket license would provide.[155]

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150. *See supra* notes 71–76 and accompanying text.

151. Creative Commons Baseline Rights, http://creativecommons.org/Baseline_Rights (last visited Dec. 20, 2009) ("Every license . . . is not revocable.").

152. Creative Commons Frequently Asked Questions, http://wiki.creativecommons.org/FAQ#What_if_I_change_my_mind.3F (last visited Dec. 20, 2009).

153. This right to withdraw is, in fact, similar to the right to withdraw that the Eighth Circuit protected in *Catalona*. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 675 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008).

154. The notion that limited forms serve the interests of society through limiting transaction costs is a familiar one in property, where the *numerus clausus* (meaning "the number is closed") principle recognizes the imperative for limited types of land transfer. *See* Thomas W. Merrill & Henry E. Smith, *Optimal Standardization in the Law of Property: The* Numerus Clausus *Principle*, 110 YALE L.J. 1, 3–4 (2000).

155. Most tissue for research is originally collected for clinical use following, at most, blanket consent to the future use of the tissue for research purposes. *See* WEIR & OLICK, *supra* note 81, at 169. In many instances, no consent at all is obtained for research use of excised tissues, and researchers treat the tissues as abandoned by the patient. *See id.* Some scholars advocate continuing to collect only blanket consent. *See, e.g.*, Chen et al., *supra* note 45, at 652 (suggesting that binary consent forms that allow participants to authorize or

Indeed, Creative Commons and other open-source/copyleft mechanisms are suggestive of a tiered informed consent approach. Tiered consent documents present potential tissue providers with a menu of research categories to which they may consent.[156] Potential tissue providers may consent to some, all, or none of the research categories presented, facilitating provider choice while constraining that choice to a manageable set of options. By standardizing the range of research categories to which tissue providers may consent and obtaining this consent upfront, tiered consent assuages many of the concerns identified by courts and regulators declining to impose consent requirements on those obtaining tissue for research purposes.[157]

Tiered consent is most likely to be encountered in cancer research, where the National Cancer Institute has formally recommended use of tiered consent in its best practices.[158] Patients undergoing biopsy or surgery are routinely asked to provide their excised tissues for research purposes.[159] Consent for such provision often takes the form of tiered consent presenting three options:

> 1. My tissue may be kept for use in research to learn about, prevent, or treat cancer. [Yes/No]
> 2. My tissue may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease). [Yes/No]

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refuse all future research "might allow individuals to control use of their samples, simplify consent forms, and allow important research to proceed").

156. *See* Natalie Ram, *Regulating Consent to Human Embryo Research: A Critique of Health Canada's Proposal*, 14 HEALTH L. REV. 19, 22–25 (2005) (describing and comparing blanket, tiered, and project-specific models for obtaining and documenting informed consent for the third-party use of human eggs, and recommending tiered consent as the model that best accommodates the interests of egg providers and the imperatives of research).

157. *See supra* notes 13–15 and accompanying text. *Cf.* Mary Anderlik Majumder, *Cyberbanks and Other Virtual Research Repositories*, 33 J.L. MED. & ETHICS 31, 33 (2005) (discussing a planned database program including "a taxonomy for expressing varying degrees of consent constraining potential use of individual specimens").

158. *See* NAT'L CANCER INST., MODEL CONSENT FORM FOR USE OF TISSUE FOR RESEARCH, http://www.cancerdiagnosis.nci.nih.gov/specimens/model.pdf (last visited Dec. 20, 2009) [hereinafter MODEL CONSENT FORM] (setting forth the model informed consent document for the National Cancer Institute); NAT'L CANCER INST., PATIENT INFORMATION SHEET, http://www.cancerdiagnosis.nci.nih.gov/specimens/patient.pdf (last visited Dec. 20, 2009) [hereinafter PATIENT INFORMATION SHEET] (offering a model consent form distributed to, but not necessarily used by, doctors).

159. *See* Brief for Am. Cancer Soc'y as Amicus Curiae Supporting Plaintiff-Appellee at 8, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (Nos. 06-2286 & 06-2301) ("It is common . . . for cancer patients undergoing biopsy or surgery involving removal of malignant or benign tissue to consent to a small amount of the tissue being stored for later research."); PATIENT INFORMATION SHEET, *supra* note 158.

> 3. Someone from xyz may contact me in the future to ask me to take part in more research. [Yes/No][160]

Like open-source licensing, tiered consent establishes boundaries for permissible downstream use in one consent event rather than repeated interactions. While tiered consent could likely be successfully employed in tort, contract, or property models as well, the informational property model, drawing from intellectual property and the open-source/copyleft approach specifically, appears uniquely well-suited to its implementation. The fact that numerous kinds of intellectual property have already been licensed in this fashion provides further reason to believe that such an approach would be successful.[161]

This is not to say that proprietary rights would not be useful in some instances. The privacy of tissue providers may be well protected through enforcement of a proprietary rights regime governing the linking of specific tissue samples to specific individuals and their medical records. Similar to digital rights management, a system of informational rights management would prevent certain kinds of access or access to certain kinds of information.[162] Access to data linking genetic profiles to identifiable individuals could be prevented by a series of security measures like firewalls, minimizing the risk of unauthorized disclosure of identifying genetic information. Informational rights management systems would therefore be exactly what they sound like: systems for managing access to information for the purpose of protecting tissue providers' informational property rights. It is not now necessary to specify the precise form that such informational rights management systems should take (and indeed it would likely be unwise to do so at this time). It is enough to recognize that a proprietary informational property right to identifying information supported by informational rights management measures would enhance tissue

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160. MODEL CONSENT FORM, *supra* note 158; *see also* Ram, *supra* note 20, at 267.

161. Creative Commons licenses are already in use for text, audio, images, video, and educational works, among others. Creative Commons Frequently Asked Questions:, http://wiki.creativecommons.org/FAQ#Is_Creative_Commons_building_a_database_of_licensed_content.3F (last visited Dec. 20, 2009).

162. Digital rights management (DRM) systems are

> [S]ophisticated software lock-out systems that prevent access to digitized content except on the terms dictated by the owner. Such content management software . . . may govern a wide range of user behaviors, such as the number of times a work may be accessed, the duration of access, the ability to reproduce or transmit the work, and the payment schedule for additional access.

Dan L. Burk, *DNA Rules: Legal and Conceptual Implications of Biological "Lock-Out" Systems*, 92 CAL. L. REV. 1553, 1563 (2004). Burk discusses DRM in the context of discussing biological "locks" embedded in the DNA of genetically engineered seeds, which raises a host of legal, ethical, and social questions quite apart from those discussed in this Article.

providers' ability to control the disclosure of identifying information about them to others.

4. Operationalizing Informational Property: Fair Utilization

Adopting a legal regime analogous to intellectual property for protecting personal genetic information is not without difficulties. For one, copyright's fair use doctrine threatens to undermine the whole project of providing effective protection of the interests of tissue providers in research. As a matter of statutory (and perhaps constitutional) law, fair use permits the use of copyrighted materials without authorization for identified (socially useful) purposes.[163] Indeed, fair use is a complete defense against infringement claims, protecting downstream creators' rights to use another's intellectual property even when such use is offensive to the rights holder.[164] Were the fair use exceptions of copyright applied wholesale in the context of informational property rights, it is likely that some, if not all, human tissue research would be construed as fair use.[165]

Properly formulated, however, a fair use cognate may in fact encourage adoption of an informational property model and provide useful balance between tissue providers' interests and the free flow of research materials. A limited "fair utilization" exception to informational property rights might include research aimed at discovering information about the regions of DNA that all persons have in common. This approach would permit generally unobjectionable research

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163. 17 U.S.C. § 107 (2006) (permitting fair use of copyrighted material for purposes of "criticism, comment, news reporting, teaching (including multiple copies for classroom use), scholarship, or research"). Section 107 specifies that whether fair use exists in a particular case will be determined on the basis of four factors:

> (1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work.

Id. As a matter of constitutional law, "the Supreme Court has never held that fair use is constitutionally required, although some isolated statements in its opinions might arguably be enlisted for such a requirement." Universal City Studios, Inc. v. Corley, 273 F.3d 429, 458 (2d Cir. 2001). On this point, see Campbell v. Acuff-Rose Music, Inc., 510 U.S. 569, 575 (1994) ("From the infancy of copyright protection, some opportunity for fair use of copyrighted materials has been thought necessary to fulfill copyright's very purpose, '[t]o promote the Progress of Science and useful Arts . . . .'" (quoting U.S. CONST. art. I, § 8, cl. 8)). *Corley* itself sidestepped the issue of the constitutional origin of fair use. *Corley*, 273 F.3d at 458–59.

164. *See* White v. Samsung Elecs. Am., Inc., 989 F.2d 1512, 1513–14 (9th Cir. 1993) (Kozinski, J., dissenting) (describing the need for limits on intellectual property rights in the interests of society and the promotion of investment in innovation).

165. Statutory fair use permits unauthorized use of copyrighted works for educational, scholarly, and research purposes. 17 U.S.C. § 107. At the very least, academic research would largely fall within the scope of fair use.

to proceed with fewer hurdles while maintaining adequate protection for the interests of tissue providers where such protection is desirable. None of the genetic information obtained would be unique to a single individual, and therefore confidentiality concerns would be minimized while control concerns would not be significantly undermined. For those who harbor religious or other objections to any use of their tissue in research, the opportunity to opt out of fair utilization might be sufficient and practicable.[166] In any event, since nearly all tissue collected for some research would likely be used in multiple projects, most tissue providers would have the opportunity to make their preferences known through a more complete licensing procedure, such as the tiered consent licensing system described above. These licenses would enable tissue providers to permit the use of their tissues for some, but not all, types of research.

The line between shared and unique regions of human DNA is not, unfortunately, one that is simple to draw.[167] There is a great deal that we do not know about genetics and genomes.[168] Consider, for instance, a recent study examining just one percent of "the human genome." Although only two percent of the genome consists of protein-coding DNA, *eighty* percent of the bases studied "showed signs of being expressed."[169] And while biologists have often assumed that genes are compact, the new research indicates that "genes can be sprawling, with far-flung protein-coding and regulatory regions that overlap with other genes."[170] These findings "suggest that a multidimensional network regulates gene expression" and that researchers need to be more thoughtful in how they think about genes as opposed to non-coding DNA.[171] Additionally, the notion of "the human genome" is a fiction: "The international Human Genome Project constructed a representative sequence of human DNA by piecing together

166. Opting out of fair use is not possible in copyright. The needs of an informational property rights system, however, are not identical to those of a copyright system. For the reasons set forth in Part II.A, *supra*, fair utilization, including an opportunity to opt out of such utilization, represents a better accommodation of the interests present in human tissue research than would be available in a system with an irrevocable fair use exception.

167. Even the distinction between human and nonhuman genes is slippery:

> [M]any genes that occur in human populations also occur in primate, mammalian, and other animal populations. It would be a mistake to think of human genes as genes that occur only in human populations, since many genes that play an important role in nonhuman populations also play an important role in cellular regulation, growth, development, and physiology in human populations.

David B. Resnik, *The Morality of Human Gene Patents*, 7 KENNEDY INST. ETHICS J. 43, 44 (1997) (citations omitted). Resnik advocates categorizing a gene as a human gene "if and only if it contributes to the structures or functions of human beings." *Id.*

168. *See generally* Pennisi, *supra* note 135 (noting questions raised by a DNA study).

169. *Id.* at 1556.

170. *Id.*

171. *Id.* at 1557.

information from many different individuals."[172] The result is that researchers will not always know, ex ante, whether a region of the genome that they wish to study could include an individualizing mutation — theoretically, any region of DNA could include a non-inherited mutation that arose during genetic recombination. In the face of this uncertainty, the best way forward might be to adopt a probabilistic approach that conditions the application of the fair utilization exception on a certain probability that the specific region of the genome under study might be unique. As more DNA and whole genomes are sequenced, our probability calculations will become better informed and more accurate, and the line between shared and unique human genomic domains will be more precise.

If such a line can be drawn with sufficient precision, fair utilization would yield at least three advantages to an informational property approach alone. First, like standardized categories for consent, fair utilization would further limit the transaction costs associated with human tissue research by limiting the circumstances in which more detailed informed consent authorization is required. Researchers exploring regions of DNA shared by all humans would face fewer permission-seeking hurdles in accessing material for research, and fewer hurdles means fewer costs to research.[173] Second, incorporating fair utilization in an informational property system begins to grapple with the tensions that shared genetic identity present for traditional notions of private property. As suggested above, a commons-centered approach to human genetic information may in many ways appear attractive because even non-related individuals differ at the genetic level only by tenths of a percent.[174] Fair utilization would open access to material for purposes of researching those portions of DNA that are shared among all humans — essentially creating a limited genetics common. Finally, fair utilization could bring commons-based and private-property approaches into harmony. By permitting individuals to opt out of fair utilization and to assert greater control where individualizing genetic information may be at stake, the cabined nature of fair utilization provides more rigorous protection where tissue providers have a stronger stake in the research enterprise.

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172. Ossorio, *supra* note 136, at 432.

173. *See* Heller & Eisenberg, *supra* note 17. The prospect of inexpensive, whole genome or large-scale sequencing suggests that the benefits of a fair utilization approach may be short-lived because whole genome sequences will inevitably contain some unique genetic information requiring more demanding tiered consent licensing. *See* Howard Wolinsky, *The Thousand-Dollar Genome*, 8 EMBO REP. 900, 902 (2007) (noting some research benefits of whole genome sequencing as opposed to genotyping on a smaller scale). Perhaps. The research benefits of whole genome sequencing may in fact be so great that they outweigh the relative efficiency benefits of proceeding by way of fair utilization. Alternatively, it may be that the existence of the fair utilization exception will spur additional innovations designed to yield rapid, inexpensive, high-quality genetic sequencing in non-whole-genome fashion.

174. *See* SNP Fact Sheet, *supra* note 135.

Existing rules suggest that a fair utilization exception such as the one suggested here is both possible and generally acceptable. The Common Rule currently permits IRBs to approve research conducted with limited or no consent in circumstances where risk of harm is minimal and obtaining consent is impracticable.[175] Other proposals for regulating consent and human tissue research have also distinguished generally unobjectionable research from research that may be objectionable to a significant minority or lead to group-based harms.[176] These existing or proposed standards suggest that the different consent demanded where a fair utilization exception exists accords with our ethical sensibilities.

Less tractable is research that makes use of human tissue as a raw material rather than as a source of information. The use of human cells as a substrate for growing cell lines or the use of human eggs (from which the genetic material has been purposefully removed) for cloning research might be permissible even in the absence of any licensing agreement from the tissue provider because the genetic information in the cells would not be the source of the sample's usefulness.[177] That said, some information contained within a cell is likely to be uncovered in nearly any research project, and as researchers learn more about how cell signaling occurs, they may uncover additional links between cellular information, over which tissue providers ought to have control, and research outcomes.

Thus, the shortcomings of an informational property rights system are surmountable or, at worst, limited in scope. Informational property rights, in granting tissue providers greater control over the most valuable part of their tissue samples (personal genetic information), likewise grant tissue providers stronger means for protecting their interests in whether and how their cells are used in research.

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175. 45 C.F.R. § 46.116(d) (2008).

176. *See* Buchanan, *supra* note 43, at B-20 (proposing a system of general consent enhanced by project-specific consent where IRBs find "special scrutiny" appropriate); David Wendler, *One-Time General Consent for Research on Biological Samples*, 166 ARCHIVES INTERNAL MED. 1449, 1451–52 (2006) (advocating a two-step approach by which individuals could authorize certain future uses of collected biological samples so long as "[t]he use of the [necessary] protected health information poses no more than minimal risk to individuals").

177. Like somatic cells, of course, eggs contain genetic information outside the nucleus in mitochondria. Mitochondrial DNA is not unique to a single individual but is shared by all matrilineal relatives. Nonetheless, it might be possible to attach informational property rights to this kind of DNA, thus requiring compliance with the informational property licensing system even where enucleated eggs are the tissue in question.

B. Integrating Informational Property with Existing Systems

1. Tort

Tort is a system of common law that imposes duties governing how we must treat one another in the absence of or even alongside other formally binding agreements like contracts or licenses.[178] To protect their interests within the law of torts, tissue providers ostensibly look to the common-law doctrines of informed consent, breach of privacy, and, if interference with property rights is involved, conversion.

Informed consent is at the heart of tort's interaction with the practice of science and medicine. Where consent is inadequate or incomplete, patients and research participants have successfully brought tort claims arising under battery and negligence.[179] Medical professionals who perform procedures or engage in touching without authorization from patients/participants may face claims of battery.[180] Likewise, where consent has been coerced in the context of medical treatment, tort doctrine dictates that such consent is invalid and a battery has occurred.[181] In most cases, however, medical professionals who fail to adequately disclose information material to decision making may be subject only to tort liability under negligence.[182] A successful negli-

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178. BLACK'S LAW DICTIONARY 1626 (9th ed. 2009) (defining a tort as "[a] civil wrong, other than breach of contract, for which a remedy may be obtained, usu. in the form of damages; a breach of a duty that the law imposes on persons who stand in a particular relation to one another"). As Keeton once remarked, however, the concept of the "tort" defies simple definition: "[T]ort is a field which pervades the entire law, and is so interlocked at every point with property, contract and other accepted classifications that, as the student of law soon discovers, the categories are quite arbitrary." W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 1, at 2–3 (5th ed. 1984).

179. *See, e.g.*, Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 858 (Md. 2001); Bryson v. Stone, 190 N.W.2d 336, 339 (Mich. Ct. App. 1971); Stover v. Ass'n of Thoracic & Cardiovascular Surgeons, 635 A.2d 1047, 1052–54 (Pa. Super. Ct. 1993).

180. *See, e.g.*, Bang v. Charles T. Miller Hosp., 88 N.W.2d 186, 190 (Minn. 1958) ("[W]here a physician or surgeon can ascertain in advance of an operation alternative situations and no immediate emergency exists, a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation."); Isaac v. Jameson Mem'l Hosp., 932 A.2d 924, 929 (Pa. Super. Ct. 2007) ("A claim of a lack of informed consent sounds in the intentional tort of battery because an operation performed without the patient's consent is deemed to be the equivalent to a technical assault."). The most widely cited formulation of informed consent comes from an early-twentieth century opinion considering a battery claim. In *Schloendorff v. Society of the New York Hospital*, Judge Cardozo stated, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds by* Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957).

181. JAMES F. DRANE, CLINICAL BIOETHICS: THEORY AND PRACTICE IN MEDICAL ETHICAL DECISION-MAKING 127 (1994).

182. *See, e.g.*, Canterbury v. Spence, 464 F.2d 772, 793 n.132 (D.C. Cir. 1972) (finding that "[t]he obligation to disclose is . . . a part of the physician's general duty to exercise

gence claim must make four showings: first, that the researcher owed a duty of reasonable or greater care to the tissue provider; second, that this duty was breached; third, that the tissue provider suffered a cognizable injury; and fourth, that the researcher's failure to act with due care was the proximate cause of the injury.[183]

Present doctrine surrounding these required showings have made tort law largely unhelpful in protecting tissue providers. For instance, while it is well accepted that physicians have a duty of care to their patients that extends even into the research realm,[184] whether researchers interacting with tissue providers in a purely research relationship owe any similar duty of care is less obvious. In *Greenberg*, the district court held that the duty of informed consent could not be extended to require disclosure of a researcher's commercial interests.[185] Indeed, that court expended considerable energy in deciding whether researchers have *any* duty to obtain consent from tissue providers.[186] And the court did, in fact, conclude that no fiduciary relationship necessarily attaches when a researcher accepts human tissue.[187]

Moreover, even where plaintiff tissue providers might make requisite showings regarding duty and breach of duty, their claims may not succeed under current doctrine because their injuries are not generally cognizable in negligence. Negligence doctrine has a long history of employing narrow conceptions of "harm," emphasizing physical injuries over emotional ones.[188] Yet, once tissue is safely

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reasonable care for the benefit of his patient"); Natanson v. Kline, 350 P.2d 1093, 1106–07 (Kan. 1960); FADEN ET AL., *supra* note 140, at 28–30 (describing the negligence theory of liability in informed consent doctrine).

183. Ballantyne, *supra* note 24, at 578.

184. In *Moore*, for instance, the California Supreme Court wrote:

> (1) [A] physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.

Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 483 (Cal. 1990).

185. Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1070–71 (S.D. Fla. 2003); *see also id.* at 1072 ("There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations and the acceptance of trust, the second constitutive element of finding a fiduciary duty, cannot be assumed once a donation is given."). *But see* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 858 (Md. 2001) (holding that "under certain circumstances, [informed consent agreements in nontherapeutic research projects] can, as a matter of law, constitute 'special relationships' giving rise to duties, out of the breach of which negligence actions may arise.").

186. *Greenberg*, 264 F. Supp. 2d at 1068–70. The court concluded that "in certain circumstances a medical researcher does have a duty of informed consent[,]" but it did not identify how one can identify when this duty does or does not attach. *Id.* at 1070.

187. *Id.* at 1072.

188. Leslie Benton Sandor & Carol Berry, *Recovery for Negligent Infliction of Emotional Distress Attendant to Economic Loss: A Reassessment*, 37 ARIZ. L. REV. 1247, 1251–53 (1995). The emphasis on physical injury or other proxies of emotional distress persists.

removed from the tissue provider's body, no *physical* harm befalls the tissue source directly as a result of research, no matter how that tissue is manipulated during research.[189] Likewise, dignitary torts, although recognized in some instances, are not traditionally protected in informed consent doctrine.[190] The scope of harm that negligence presently embraces, therefore, is likely to exclude precisely the kinds of harms sustained by tissue providers whose interests in control, confidentiality, and commercialization are not respected.

Tort need not, however, be this obstructive of the interests of those providing tissue for research. The same reasoning that drives judges to recognize a duty of care between physicians and their patients could recognize a similar duty between researchers and tissue providers. Imposing the requisite duty of care on those obtaining tissues makes intuitive sense, as these researchers or bio-repositories interact directly with tissue providers by means of a relationship similar to the one that exists between physicians and their patients. Moreover, although courts are often hesitant to impose liability for dignitary or non-physical injuries,[191] they have done so for appropriately circumscribed types of injuries, such as those arising from invasion of privacy[192] and defamation.[193] Particularly in cases in which breaches of confidentiality or privacy lead to loss or inability to obtain health or life insurance or employment, damages for non-physical, economic injuries would likely be awarded.[194] Breach of informed

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Nancy Levit, *Ethereal Torts*, 61 GEO. WASH. L. REV. 136, 145–46 (1992). Scholars have sometimes linked the devaluation of emotional torts to gendered judicial decision-making. *See, e.g.*, Martha Chamallas & Linda K. Kerber, *Women, Mothers, and the Law of Fright: A History*, 88 MICH. L. REV. 814, 814–16 (1990); Sandor & Berry, *supra*, at 1258–59.

189. *See* Oberdorfer, *supra* note 22, at 382. Oberdorfer claims that once tissue is safely removed, "no harm can befall the tissue source." *Id.* However, disclosure of damaging or embarrassing information to the tissue provider or third parties may cause significant emotional distress, and the use of tissue samples in unconsented-to projects may inflict a dignitary, though not physical, harm. Thus, this statement would be more correct if it stated that "no [physical] harm can befall the tissue source."

190. *See, e.g.*, Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW MED. & HEALTH CARE 210, 211–14 (1988); Aaron D. Twerski & Neil B. Cohen, *Informed Decision Making and the Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607.

191. With respect to injuries not involving physical harm, the Restatement (Second) of Torts provides:

> [T]here is no liability where the actor's negligent conduct inflicts only emotional distress, without resulting bodily harm or any other invasion of the other's interests. Such emotional distress is important only in so far as its existence involves a risk of bodily harm, and as affecting the damages recoverable if bodily harm is sustained.

RESTATEMENT (SECOND) OF TORTS § 313 cmt. a (1965).

192. *See* JAMES A. HENDERSON, JR., RICHARD N. PEARSON & JOHN A. SILICIANO, THE TORTS PROCESS 741–84 (6th ed. 2003); William L. Prosser, *Privacy*, 48 CAL. L. REV. 383, 389 (1960).

193. *See* HENDERSON ET AL., *supra* note 192, at 695–740.

194. On genetic discrimination and insurance, see, for example, Richard A. Bornstein, Note, *Genetic Discrimination, Insurability and Legislation: A Closing of the Legal Loop-*

consent, including unauthorized use of samples, disclosure of identifying information, and even commercialization of tissue products without permission, could be similarly circumscribed.

Where courts are willing to recognize causes of action by tissue providers against researchers on the basis of dignitary rights, tort is likely to be an important tool for protecting providers' interests. In the first instance, as noted above, the law of torts governs in the absence of, as well as alongside, other formal legal relationships. This means that failure to create a contract or a valid license for tissue use does not preclude suit in tort. As a corollary, except where predicated on a special relationship giving rise to fiduciary obligations only between specific individuals, tort also escapes the strictures of privity, and thus courts may impose punishment directly on an injuring party, even where that party is a downstream researcher.[195]

This is especially noteworthy for claims involving breach of privacy. The right to privacy is a right against the world.[196] Thus, claims for breach of privacy may be brought against any party that impermissibly obtains or reveals private information, for example, information regarding future health status.[197] Moreover, individuals genetically

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holes, 4 J.L. & POL'Y 551, 563–68 (1996). On genetic discrimination and employment, see, for example, DEP'T OF LABOR ET AL., GENETIC INFORMATION AND THE WORKPLACE (1998), http://www.dol.gov/oasam/programs/history/herman/reports/genetics.htm [hereinafter GENETIC INFORMATION AND THE WORKPLACE] (reporting on the need for federal legislation protecting against genetic discrimination in the workplace and relating several incidents in which individuals lost or were denied employment in reaction to results from genetic tests). In at least one instance, an employer used involuntary or unknowing genetic screening:

> [E]mployers used genetic screening in the early 1970s to identify African Americans who carried a gene mutation for sickle cell anemia. Those carrying the gene mutation were denied jobs — even though many of them were healthy and would never develop the disease. In these cases, genetic screening to identify the sickle cell trait often occurred without the consent of the individuals.

GENETIC INFORMATION AND THE WORKPLACE, *supra*. More broadly, a 1989 survey of 400 firms, conducted by Northwestern National Life Insurance, found that fifteen percent of the companies planned, by the year 2000, to screen the genetic status of prospective employees and their dependents before making employment offers. Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109, 116 (1991). GINA is designed to prevent these kinds of discrimination in employment and health insurance. *See* Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881.

195. On the elimination of the requirement of privity in tort, see Stewart F. Hancock, Jr., *Meeting the Needs: Fairness, Morality, Creativity and Common Sense*, 68 ALB. L. REV. 81, 90–91 (2004).

196. *See* Samuel Warren & Louis Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 199 (1890) ("In every such case the individual is entitled to decide whether that which is his shall be given to the public.").

197. *See* Doe v. High-Tech Inst., Inc., 972 P.2d 1060, 1068 (Colo. Ct. App. 1998) ("[A] person has a privacy interest in his or her blood sample and in the medical information that may be obtained from it. We further conclude that an additional, unauthorized test . . . can be sufficient to state a claim for relief for intrusion upon seclusion."). *But see* Doe v. Dyer-Goode, 566 A.2d 889 (Pa. Super. Ct. 1989) (concluding that unauthorized blood tests could

related to tissue providers who are harmed by the release of their relative's genetic information might also have a viable cause of action for breach of privacy — at least insofar as release of such information constitutes an invasion of their privacy as well.[198]

Dignitary torts would be unlikely, however, to protect against downstream researchers making unauthorized use of tissue. Fundamentally, in the absence of an agency relationship, we do not ordinarily enforce tort claims against those who are recipients of the fruits of a tort.[199] In most instances, a downstream researcher will only be able to make impermissible use of human tissue through the fault — the failure to obtain appropriate authorization — of an intermediate actor with whom the tissue provider has a direct relationship, such as the original procuring researcher or a bio-bank collecting, storing, and distributing tissue samples. This intermediate actor would likely be the "cheapest cost avoider,"[200] as this actor could most easily obtain appropriate consent and communicate the limitations of that consent to others working downstream. Courts are therefore likely to find that dignitary injuries other than breach of privacy arising from downstream, indirect use lie beyond "the eye of ordinary vigilance."[201] As such, these injuries would not form a valid basis for suit.

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not be considered a privacy invasion because the plaintiff, by consenting to a premarital blood test, voluntarily relinquished the blood sample and therefore no longer held the sample in private seclusion). As these cases demonstrate, courts have not developed a consistent doctrine in this domain. *See* Mark A. Rothstein, *Genetic Stalking and Voyeurism: A New Challenge to Privacy*, 57 U. KAN. L. REV. 539, 550 (2009).

I leave aside here the separate and complicated issue of whether and when a physician — who is both in privity with a patient and under additional fiduciary obligations — has a *duty to disclose* the results of genetic testing to a patient's immediate family members. *See, e.g.*, Safer v. Estate of Pack, 677 A.2d 1188, 1192–93 (N.J. Super. Ct. App. Div. 1996) (holding that a physician had a duty to warn those known to be at risk of avoidable harm from a genetically transmissible condition). *But see* Pate v. Threlkel, 661 So. 2d 278, 282 (Fla. 1995) (holding that "in any circumstances in which the physician has a duty to warn of a genetically transferable disease, that duty will be satisfied by warning the patient"). Suffice it to say, where disclosure is to persons other than close genetic relatives — for example, researchers, insurers, employers, or the general public (by means of publication) — a duty to disclose the results of genetic testing is unlikely to complicate the privacy analysis.

198. RESTATEMENT (SECOND) OF TORTS § 652I cmt. a (1977) (explaining that although "[t]he right protected by the action for invasion of privacy is a personal right," an action for breach of privacy may be maintained by "other persons such as members of the individual's family" where "*their own privacy is invaded along with his*" (emphasis added)). To my knowledge, no such case has yet been brought.

199. *See* RESTATEMENT (THIRD) OF AGENCY ch. 2, introductory note (2005) (identifying in broad terms the limited domains of law in which one person is held to the legal consequences of another person's action: three bases in agency (actual authority, apparent authority, and respondeat superior), and two doctrines related to agency (estoppel to deny existence of an agency relationship and restitution)).

200. *See* GUIDO CALABRESI, THE COSTS OF ACCIDENTS 135–73 (1970).

201. Palsgraf v. Long Island R.R. Co., 162 N.E. 99, 99 (N.Y. 1928); *see also* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 493 (Cal. 1990) (emphasizing that downstream researchers are "innocent parties who are engaged in socially useful activities" and "have no reason to believe that their use of a particular cell sample is, or may be, against a donor's wishes").

Instead, these injuries, and those arising from indirect claims regarding unauthorized copying and distribution of genetic material, are more amenable to redress where claims of conversion are available. Yet conversion torts must be supported by a property right of some sort.[202] Tort alone is thus insufficient to protect some of the significant interests of tissue providers. Rather, tort must be undergirded by some system for allocating property rights to the physical cells or the information they contain. The informational property model advanced here would provide the necessary property right to which tort claims could attach. Indeed, informational property rights may be uniquely well-suited to this task, as these rights would function like a property-like corollary to or extension of privacy rights in tort. Both guard the human dignity of tissue providers by ensuring that these providers have control over whether and how the information in their cells is obtained, used, or shared. While privacy torts run primarily to the disclosure of genetic and other information, however, informational property rights are broader, reaching not only the disclosure of information but also its use and, potentially, its commercialization.[203] Integrating the informational property approach with traditional tort actions thus yields a richer system of protection.

2. Contract

"A contract is a promise or a set of promises for the breach of which the law gives a remedy, or the performance of which the law in some way recognizes as a duty."[204] Like tort, informed consent is at the very heart of contract. "Consent is the master concept that defines the law of contracts in the United States."[205] Where a contract can be proven, breach of contract — unconsented-to use of tissue, disclosure without permission, unshared profits, anonymization without consent that deprives patient-providers of the possibility of improved treatment flowing from better understanding of their unique conditions — is a cognizable injury that may lead to some, if often imperfect, remedy. Although emotional distress is typically not compensable in con-

202. Conversion is defined as "[t]he wrongful possession or disposition of another's *property* as if it were one's own." BLACK'S LAW DICTIONARY 381 (9th ed. 2009) (emphasis added). In order for there to be conversion, there must first be property to be converted.

203. The scope and appropriateness of protection by way of privacy in this arena has been the subject of considerable debate. *Compare* Suter, *supra* note 74 (arguing that privacy provides broad control over genetic information and a more appropriate approach than a property rights model), *with* Anita A. Allen, *Privacy-as-Data-Control: Conceptual, Practical, and Moral Limits of the Paradigm*, 32 CONN. L. REV. 861 (2000) (arguing that alternatives to the privacy-as-data-control paradigm are needed).

204. RESTATEMENT (SECOND) OF CONTRACTS § 1 (1981).

205. Schuck, *supra* note 43, at 900.

tract remedies,[206] rescission (i.e., withdrawal), money damages, injunctive relief, or specific performance may be available.[207] Therefore, tissue providers knowledgeable and forthright in asserting their interests may be able to bargain for any number of provisions protecting their interests in control, confidentiality, commercialization, or cure prospects.

At least one disease advocacy group has demonstrated the success of the contract model for allocating increased control over research more equitably as between tissue providers and researchers. PXE International, a patient advocacy group for individuals suffering from pseudoxanthoma elasticum ("PXE"), a genetic disease, successfully negotiated for co-ownership of any patents that resulted from study of blood samples collected from PXE patients and their families.[208] PXE International succeeded because it withheld access to its unique resources until researchers signed specific contracts ensuring that intellectual property rights would be shared.[209] By doing so, PXE International was able to steer researchers to search for the genetic basis of PXE and to retain sufficient control over access to those research results to protect its members' interests. The success of PXE International stands for the proposition that, wielded by the right hands, contract can work on behalf of tissue providers and researchers alike. Such positive experiences within the contract model are likely to be few and far between, however, as most individuals face tissue provision alone and must contend with sharp disequilibria of information and power in the researcher-tissue provider relationship.[210]

Tissue providers might also look to informed consent documents as contracts establishing the agreement of an individual to participate in research. Contracts taking the form of tiered consent could provide powerful protection for tissue providers. As explained earlier, tiered consent documents present potential tissue providers with a menu of

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206. RESTATEMENT (SECOND) OF CONTRACTS § 353 (1981) ("Recovery for emotional disturbance will be excluded unless the breach also caused bodily harm or the contract or the breach is of such a kind that serious emotional disturbance was a particularly likely result."); *id.* § 353 cmt. a ("Damages for emotional disturbance are not ordinarily allowed.").

207. Specific performance, like an injunction in tort, is an equitable remedy and that concern for ongoing research may make judges unwilling to grant such discretionary relief.

208. *See* Gitter, *supra* note 24, at 262–63; Paul Smaglik, *Tissue Donors Use Their Influence in Deal over Gene Patent Terms*, 407 NATURE 821, 821 (2000). It is possible that, even in an environment hostile to tissue providers profiting from their tissue provision, PXE's contract would be enforceable because it contracted for *rights*, rather than for cash directly.

209. To date, neither the researchers who discovered the gene responsible for PXE, nor the members of PXE International have challenged the legality of their agreement, and therefore its enforceability has not yet been passed on by a court. Gitter, *supra* note 24, at 263.

210. *See* Bovenberg, *supra* note 78, at 931–32 (discussing bargaining disequilibria between researchers and individual tissue providers).

research categories to which they may consent.[211] Despite their frequent similarity in form to contracts, however, informed consent documents, whether tiered or otherwise, are generally not considered to be contractual documents.[212]

We might conclude upfront that the idea of consent as contract is one that should be discouraged. After all, efforts to make informed consent documents look more like contracts often yield consent forms that are twenty or more pages long and written in highly technical language.[213] These features can subvert the purpose of the informed consent process and the accompanying form by turning consent into something so legalistic that the tissue provider does not understand what she is consenting to.[214] Overly technical or legalistic language may also cause tissue providers to believe that consent — and the consent form — is less about their own understanding and decision-making and more about protecting researchers from legal liability.[215]

Even if the paradigm of consent-as-contract is one we wish to pursue, convincing a court to recognize an informed consent document as a contract is likely to be problematic for a number of reasons. In the first instance, courts may find a lack of consideration for tissue providers, rendering tissue provision a gift rather than an exchange in contract.[216] To prove a contract, tissue providers must show that they derived specific benefits from providing tissue for research that are

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211. *See* Ram, *supra* note 156, at 23–24; *see also supra* notes 156–60 and accompanying text.

212. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 674–76 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008) (holding that the signed consent forms demonstrated the donors' intent to make a gift); Richard S. Saver, *At the End of the Clinical Trial: Does Access to Investigational Technology End As Well?*, 31 W. NEW ENG. L. REV. 411, 428 (2009) (observing that some courts have "treat[ed] the informed consent documents as merely notice of the subjects' consent rather than an enforceable contract"); Nat'l Human Genome Research Inst., Informed Consent, http://www.genome.gov/10002332 (last visited Dec. 20, 2009) ("[T]he informed consent document is not a contract."). *But see* Dahl v. HEM Pharm. Corp., 7 F.3d 1399, 1404–05 (9th Cir. 1993) (interpreting participation in a medical trial as a contract); Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 843–44 (Md. 2001) (finding that the consent form created a bilateral contract between parties).

213. *See* Daniel R. Young, Donald T. Hooker & Fred E. Freeberg, *Informed Consent Documents: Increasing Comprehension by Reducing Reading Level*, IRB, May–June 1990, at 1, 1–2 (noting studies that have found many informed consent documents are written at, or above, college reading level); NAT'L CANCER INST., SIMPLIFICATION OF INFORMED CONSENT DOCUMENTS (2009), http://www.cancer.gov/clinicaltrials/understanding/simplification-of-informed-consent-docs/allpages/print ("Many informed consent documents have become too long and complex, and do not provide a sound basis for informed decision-making.").

214. *See, e.g.*, Corbie-Smith et al., *Attitudes and Beliefs*, *supra* note 46, at 540–41 (identifying difficulties in understanding informed consent documents due to their "technical medical and legal terminology"); James Flory & Ezekiel Emanuel, *Interventions to Improve Research Participants' Understanding in Informed Consent for Research*, 292 JAMA 1593, 1593 & 1600 nn.5–11 (2004) (collecting sources documenting failure to understand); Young et al., *supra* note 213, at 1.

215. Corbie-Smith et al., *Attitudes and Beliefs*, *supra* note 46, at 540–41.

216. *See Catalona*, 490 F.3d at 676.

sufficient to constitute consideration. If providers received payments for their tissues, this would constitute clear consideration.[217] But up-front financial exchange has, to date, been unpopular and uncommon.[218] Alternatively, for patient-providers, who may anticipate that research on their tissue will lead to direct as well as indirect medical benefit for themselves, consideration may seem fairly concrete. For instance, in *Catalona*, "[t]he informed consent forms signed by each participant listed the 'benefits' of the research to 'you and/or society,' including 'help in counseling your family members regarding cancer.' The participants testified as to the clinical benefits they expected to receive from research participation."[219] Notwithstanding this evidence, however, the Eighth Circuit concluded that rather than creating a contract, the tissue providers had made an *inter vivos* gift of tissue to Washington University.[220]

For non-patient providers, it is less clear that the intangible benefits of the advance of medical research are sufficient to constitute adequate consideration creating an enforceable contract.

Moreover, the National Human Genome Research Institute ("NHGRI"), an arm of the National Institutes of Health, has suggested that informed consent documents are not contracts precisely because human subjects may "opt out" of participation even after signing such documents.[221] The fact that tissue providers are often termed tissue "donors," and informed consent documents often refer to "donation," further complicates a case in contract.[222]

Even if a court were willing to recognize an informed consent document as some form of a contract, this contract might be unenforceable or invalid. In particular, contracts providing payment for tissues or lucrative products derived from tissues might be held unen-

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217. *Cf. Grimes*, 782 A.2d at 843–44 (recognizing consent forms as creating a contract in part because the plaintiffs agreed to participate "with the expectation that they would be compensated, albeit, more or less, minimally").

218. *See* Korobkin, *supra* note 17, at 45–46 (noting the no-compensation default (and in some cases immutable no-compensation rule) for tissue providers).

219. Brief of Appellant-Defendants Richard Ward et al. at 39–40, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (Nos. 06-2286 & 06-2301) (internal citations omitted).

220. *Catalona*, 490 F.3d at 676.

221. Nat'l Human Genome Research Inst., *supra* note 212 ("Even after signing, the patient may still opt out of the test or study; the informed consent document is not a contract."). The NHGRI's statements suggest that if informed consent is treated as a contract, then any attempt to withdraw tissue from research use would constitute a breach for which the withdrawing tissue provider would be liable. This is not necessarily so, as parties are free to contract for any desired provisions, so long as they are not against public policy. Tissue providers and researchers could include a unilateral right to withdraw in the contract for tissue provision. That this is unlikely to occur, given the imbalance of authority and power in favor of the researcher in any provider-researcher interaction, is an interesting, but not law-changing, observation.

222. *See Catalona*, 490 F.3d at 671, 674 (emphasizing "donation" language).

forceable as against public policy.[223] Courts may also be disinclined to enforce contracts that attempt to sharply limit the use of tissue in research.[224] Society has a significant interest in promoting research, and limitations on tissue use that substantially interfere with ongoing research or impose considerable transaction costs on researchers may be considered as against public policy. In fact, this same interest in the progress of science may expose overzealous contracting for tissue provision as diminishing the tissue provider's own interests. Too many different details to track across thousands or millions of samples will inevitably slow research and may make it prohibitively expensive to conduct and monitor.[225] This last problem may be largely addressed through the use of a tiered consent process, which aims to limit the variety of different details that must be tracked within the consent-contract system. Yet, tiered-consent-as-contract suffers from most of the other shortcomings of consent-as-contract generally. Tiered consent documents fare no better than traditional consent documents, for instance, where problems of consideration, unacceptable commercialization, or overly restrictive contracting exist.

Nor is it clear whether a valid contract (tiered or otherwise) between a tissue provider and a tissue procurer is enforceable against downstream researchers who violate the terms of the informed consent contract. Here, a lack of privity makes suit against a downstream third-party difficult to prove.[226] Tort (especially in instances of breach

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223. Gitter, *supra* note 24, at 263–64 & n.30 (opining that adherence to a market-inalienability model might render a contract like PXE International's void as against public policy).

224. *But cf.* Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003). The Greenberg court permitted plaintiff tissue providers to pursue their claim of unjust enrichment — a quasi-contractual claim — based on an alleged detriment arising from unauthorized use of the disputed tissue. *Id.* This suggests that contractual arrangements restricting the use of tissue or genetic information may be consistent with public policy. The *Greenberg* court, however, also noted that the relationship between plaintiffs and researchers was "more than just a donor-donee relationship." *Id.* If something more than an ordinary "donor-donee relationship" is required, then many tissue providers are likely to be excluded from recovery on this basis.

225. *See* JOHN WILBANKS & JAMES BOYLE, SCIENCE COMMONS, INTRODUCTION TO SCIENCE COMMONS 9 (2006), http://sciencecommons.org/wp-content/uploads/ScienceCommons_Concept_Paper.pdf ("A complex set of interlocking licenses covering dozens of different materials imposes significant transaction costs simply to gain the opportunity to begin research . . . . The end result benefits no one — less research, less innovation, less diffusion of knowledge.").

226. On the relationship between privity, contract, and third-party liability, see Andrew L. Weitz, Note, *Contractor Duty to Third Parties Not in Privity: A Quasi-Tort Solution to the Vexing Problem of Victims of Nonfeasance*, 63 BROOK. L. REV. 593, 602–04 (1997).

> Lack of privity is dispositive when the issue is one of liability in contract to third parties. This is so because there is, by definition, no duty owed to a plaintiff who is neither a party to a contract nor an intended third party beneficiary who is a victim of a contractor's nonfeasance, unless such a duty is specifically undertaken by a defendant.

of privacy) or free-standing property claims of some kind will often better serve the tissue provider in these situations.

Moreover, principles of contract offer little guidance in instances in which tissue is used in research without any explicit authorization from the tissue provider. Such use is not uncommon, given that many tissue samples are obtained during routine medical exams and are appropriated for research purposes without any research consent being obtained.[227] One way to treat these situations would be to hold that no contract exists. Contracts arise only where there is a mutual intent to create them.[228] Under this interpretation, where individuals are made tissue providers without their knowledge, there can be no requisite intent. In these instances, principles of contract provide little in the way of instruction or remedy. Rather, remedy must come through tort, property, or some other regime.

Alternatively, because the use of cell and tissue samples in research without consent is commonplace, such use may be viewed as governed by an implied contract. In this case, individuals accepting medical treatment, and the cell/tissue extraction that may accompany it, would likewise implicitly assent to the use of their cells for research. Without further specificity, such an implied contract would have no limits, except those imposed by statute or general public policy concerns. This outcome is distressing, since it could impinge on individuals' willingness to seek medical care out of concerns relating to the control, confidentiality, and commercialization of their genetic material.[229]

Thus, where a court will recognize and enforce a contract, tissue providers may hold significant power in the researcher-provider relationship to exercise their interests, particularly against those who procured their original consent. However, the presence of an enforceable contract is not clear even when explicit informed consent or other documents are in use. Nor are principles of contract sufficient to address the harms perpetrated by unconsented-to acquisition and use of tissue in research. Contract thus provides insufficient protection for key interests of tissue providers, while also opening the possibility of damage to both tissue providers' and society's interest in supporting ongoing research.

Id. at 603. Weitz observes that, at least in New York, where a contract exists between two parties, tort liability to third parties is determined by contract liability such that privity reenters the tort equation. *Id.* at 603–04.

227. WEIR & OLICK, *supra* note 81, at 169.

228. RESTATEMENT (SECOND) OF CONTRACTS § 17 & cmt. c (1981) (identifying "mutual assent" or "agreement" as a core element of contract formation). The Restatement recognizes a number of exceptions to this rule, in which contracts can be formed in the absence of a bargain. *Id.* §§ 17(2), 82–94.

229. *See* Nelkin & Andrews, *supra* note 52, at 7; Rapp, *supra* note 47, at 49 (noting a female patient who refused an amniocentesis during her pregnancy after her husband reviewed the consent form).

3. Property

Assignment of property rights to tissue can be critical in resolving conflicts between tissue providers and researchers. Where tissue providers retain a property interest in tissue samples, these providers generally have the right to exclude unwanted acquisition or use of their tissues. However, if tissue providers do not have a property interest in cells once they are removed from the body, then tissue providers may be powerless to prevent the use of their tissue in any way. In contrast to the informational property model discussed in Part III.A, however, the property model considered here extends only to interests protected and incentives shaped by the assignment of a right to the physical cells obtained through tissue extraction.

Property is often described as a "bundle of rights" that may be exercised with respect to a particular object.[230] These rights generally include "the rights to possess the property, to use the property, to exclude others from the property, and to dispose of the property by sale or by gift."[231] The Supreme Court has recognized that the right to exclude is "one of the most essential sticks in the bundle of rights that are commonly characterized as property."[232] Thus, if courts recognize tissue providers as the holders of such a bundle of rights in their tissue samples, then any unauthorized use, disclosure, or commercialization of tissue would be actionable as a violation of property rights. Courts adjudicating disputes between tissue providers and researchers might require defendant-researchers to compensate plaintiff-tissue-providers whose interests were injured or to refrain from making further use of the tissue sample in question, no matter what cost or burden this might place on researchers.[233] Indeed, even in the absence of compensatory damages, punitive damage awards designed to punish defendants and

230. *E.g.*, Kaiser Aetna v. United States, 444 U.S. 164, 176 (1979) (describing "property" as comprising a "bundle of rights"); BLACK'S LAW DICTIONARY 1335 (9th ed. 2009) (recognizing that "property" is "[a]lso termed *bundle of rights*"). Furthering the analogy, rights associated with property are often termed "sticks," such that the Court may make statements like "[t]he State may not put so potent a Hobbesian stick into the Lockean bundle." Palazzolo v. Rhode Island, 533 U.S. 606, 627 (2001); *see also Kaiser Aetna*, 444 U.S. at 176.

231. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 509 (Cal. 1990) (Mosk, J., dissenting).

232. *Kaiser Aetna*, 444 U.S. at 176.

233. Real property (i.e., land) is often protected by the strongest forms of property right protection, even when the costs of such protection greatly exceed the individualized benefits derived from such protection. *See* Pile v. Pedrick, 31 A. 646 (Pa. 1895) (requiring Pedrick to remove a wall built in good faith entirely on his own property, the foundation of which accidentally extended one and a half inches onto Pile's property). Although it is by no means clear that we should desire that human tissue be treated in ways similar to real property, these kinds of cases indicate the strong protection that property law can offer.

compensate plaintiffs for non-physical injury to their interests may be imposed.[234]

Private property rights to the physical cells used in research may also give rise to a right to withdraw tissue from research use, so long as that right is bargained for in the original transfer of property. Much as in contract, tort, and informational property, informed consent can play an important role in protecting the interests of the tissue provider — in property, we might think of informed consent documents as memorializing a bailment[235] or establishing a deed governing transfer of property. A right to withdraw could be accomplished by the creation of an arrangement analogous to a fee simple determinable.[236] Under this kind of property transfer, the recipient of property — in this case, the researcher — holds a property right to the cells so long as they are used in accordance with any specific purposes and restrictions laid out in the informed consent documents. If any material provision is violated, the property right reverts to the original titleholder — in this case, the tissue provider — who could then demand that the tissue be destroyed.[237]

The power to establish and enforce such an arrangement, however, is likely to be limited by the doctrine disfavoring restraints on alienation.[238] Indeed, even if courts are willing to recognize that tissue providers have a property right in their tissue samples, tissue providers may be prohibited from imposing more than minimal restrictions on researchers. Among the most important reasons for disfavoring restraints on alienation is that such restraints diminish incentives to

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234. *See* Jacque v. Steenberg Homes, Inc., 563 N.W. 2d 154, 163 (Wis. 1997) (affirming punitive damages of $100,000 where defendant intentionally trespassed on plaintiff's land after being repeatedly refused access and where only nominal damages of one dollar were otherwise available). At least one property textbook has similarly linked the theoretical strands of *Jacque* and property in the body. *See* JESSE DUKEMINIER & JAMES E. KRIER, PROPERTY 99–101 (5th ed. 2002) (excerpting *Jacque* in the notes following the *Moore* case).

235. *But see* Wash. Univ. v. Catalona, 490 F.3d 667, 676 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008) (holding that consent documents do not necessarily create a bailment).

236. RESTATEMENT (FIRST) OF PROP. § 44 (1936) (defining a fee simple determinable as an estate "created by any limitation which, in an otherwise effective conveyance of land, (a) creates an estate in fee simple; and (b) provides that the estate shall automatically expire upon the occurrence of a stated event").

237. The Eighth Circuit, during oral arguments in the appeal of the *Catalona* case, questioned both appellants and respondents about precisely this kind of property right. Audio File of Oral Argument, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (No. 06-2286), http://www.ca8.uscourts.gov/oralargs/oa_Bycs.html (search "06-2286"; then click "play" to listen) (last visited Dec. 20, 2009). Alternatively, tissue providers might create a fee simple subject to executory interest, in which the original recipient's breach of a material provision of the fee simple would trigger the automatic transfer of the fee to a third party, presumably another researcher or institution.

238. *See* DUKEMINIER & KRIER, *supra* note 234, at 227–28 (describing reasons for disfavoring restraints on alienation of property and the Restatement of Property's treatment of such restraints).

improve the property.[239] In the context of human tissue research, the "dead hand" problem would manifest as a disincentive to invest effort in research from which vital tissue samples may be withdrawn or from which profit may be restricted. As with cases involving real property, the movement and use of human tissue in research is considered a public good,[240] and courts might therefore be inclined to invalidate significant restraints on such tissue (restraints on use, disclosure, commercial gain, or forced identifiability for cure) as against public policy.[241] Courts faced with suits regarding human tissue research have appealed to precisely this logic. The court in *Greenberg*, for example, declined to extend the duty of informed consent to cover economic interests because imposing such a duty "would give rise to a type of dead-hand control."[242]

Public policy may also enter into the property calculus by removing certain rights from the bundle attached to a particular type of private property. The fact that an individual has a private property right in her cells does not mean that she may make any use of her body (or its parts) that she wishes.[243] As Justice Mosk, dissenting in *Moore*, pointed out:

> For a variety of policy reasons, the law limits or even forbids the exercise of certain rights over certain forms of property. For example, both law and contract may limit the right of an owner of real property to use his parcel as he sees fit. Owners of various forms of personal property may likewise be subject to restrictions on the time, place, and manner of their use. Limitations on the disposition of real property, while less common, may also be imposed. Finally, some types of personal property may be sold but not given away, while others may be given away but not sold, and still others may neither be given away nor sold.[244]

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239. *Id.* at 227.

240. *See* NAT'L BIOETHICS ADVISORY COMM'N, *supra* note 6, at 9 (identifying that "research use of human biological materials is essential to the advancement of science and human health" as a "basic premise" underlying its analysis).

241. More often, courts simply refuse to recognize tissue providers' property interest in their tissue, and so need not consider whether restraints placed on tissue use in research are valid.

242. Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1071 (S.D. Fla. 2003); *see also id.* at 1070, 1076 (dismissing both a claim of failure to obtain informed consent and a claim of conversion due in part to concerns about "chill[ing]" or "crippl[ing]" medical research).

243. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990) (Mosk, J., dissenting); Radin, *supra* note 27.

244. *Moore*, 793 P.2d at 509–10 (Mosk, J., dissenting) (citations omitted).

Most often, in the context of human tissue, public policy will place restraints on how and by whom tissue may be used for commercial gain, thus giving rise to property that is market-inalienable or inalienable in its entirety.[245] In addition, public policy concerns may dictate that certain uses of tissue are not permitted, as when an individual wishes her tissue to be used for unethical or illegal ends.

Yet, even if private property rights were to extend to human tissue samples with all the trappings of the full bundle of rights, rules of property would be insufficient to protect the interests of tissue providers in a number of critical aspects. For instance, a private property right would not likely extend to products derived from tissue samples. Common law principles of private property have sometimes recognized independent title in derivative or downstream products. For example, crops that have been harvested on rented land are considered the personal property of the tenant farmer, rather than the landlord, even though the crops drew on the natural resources of the rented land in growing.[246] Likewise, cell lines are considered sufficiently new products into which independent effort and intellect have been invested and to which independent title may be asserted.[247] The *Moore* court, for example, rejected John Moore's claim to a property right in the cell line derived from his tissue because the cell line represented a "product of 'human ingenuity.'"[248] This "*inventive effort*" rendered the cell line distinct from the original cells, which merely constituted "naturally occurring organisms."[249] Unlike the operation of natural cell division, which does not include a sufficient independent and creative effort to give rise to independent title, the cultivation of a cell line requires a purposeful human intervention and produces a fundamental change in the physical nature of the cells at issue. The genetic information available in a mass of tissue and a subsequent cell line may be similar in material ways, but their physical identities — the

245. *See* Radin, *supra* note 27.

246. *See, e.g.*, Haldeman v. Wyo. Farm Loan Bd., 32 F.3d 469, 471 (10th Cir. 1994) ("Once severed from the land, crops become personal property."). Note that immature crops still growing at the time a leasehold expires are considered the property of the lessor. *Id.* ("A common law rule of real property is that unmatured crops which continue to draw sustenance from the soil pass with title to the land unless specifically reserved."); *cf.* Taylor v. Newcomb, 82 N.W. 519 (Mich. 1900) (describing ownership rules for manure produced on tenanted farm lands that conclude that the product of the leased land belongs to the lessee).

247. *See, e.g.*, Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1076 (S.D. Fla. 2003) ("Plaintiffs claim that the *fruits* of the research, namely the patented material, was commercialized. This is an important distinction and another step in the chain of attenuation that renders conversion liability inapplicable to the facts as alleged."); *Moore*, 793 P.2d at 492 ("[T]he subject matter of the Regents' patent — the patented cell line and the products derived from it — cannot be Moore's property. This is because the patented cell line is both factually and legally distinct from the cells taken from Moore's body.").

248. *Moore*, 793 P.2d at 492.

249. *Id.* at 492–93.

matter to which private property rights attach — are significantly and sufficiently different.

This approach makes some sense, as much research depends on the creation and patenting of products derived from the original cells. For courts and other bodies desiring to encourage socially useful activity, such as human tissue research and the development of cell lines and other derivative products, granting independent title in downstream products may appear to provide the right incentives for invention. Independent title recognizes that the resulting product constitutes a new and distinct item of property. Independent title, however, may also sever a resulting cell line from any limitations on the use of the original tissue sample. This disjunction between valuable information and physical continuity also arises where a genetic sequence is derived from a physical cell and then stored digitally.[250] These arrangements thus provide a strong incentive for researchers to create derivative products, such as cell lines or DNA databases, from tissue samples. These products ensure not only that the information in particular cells will endure, but also that this information will be available for research use independent of any limitations a tissue provider may have placed on the original cells.

Property principles also provide little recourse for those whom courts construe as having abandoned their property. When property is abandoned, the former title-holder surrenders any right to the object in question, and title is assigned to the first person who takes possession — the rule of finders keepers.[251] To put a finer point on it, cells that are considered abandoned property may be used without permission for any purpose — including privacy-invading ones.[252] Hair and dead skin cells that are lost from the body in daily life are abandoned property, and there is good reason to believe that this logic extends to tissue removed from the body during routine medical treatment. As Lori Andrews observes, "the principle most commonly applied seems to be that of 'finders keepers' where pathologists, physicians, and researchers who have access to patient tissue feel no qualms about keeping it for their own use, beyond the purposes for which the tissue was

250. Eisenberg, *supra* note 127, at 8. In arguing for the non-patentability of genetic information stored in computer-readable format, Eisenberg acknowledges that "[t]he distinction between computer-readable and molecular versions of DNA sequence is particularly difficult to maintain in the context of DNA array technology." *Id.* at 9. This statement admits that the physical form of genetic-sequence information is largely irrelevant to its value or usefulness. As a matter of property law, however, that distinction makes all the difference.

251. DUKEMINIER & KRIER, *supra* note 234, at 120.

252. Police officers have taken advantage of abandoned DNA to obtain genetic profiles of criminal suspects, free of the strictures of ordinary criminal procedure rules. *See* Elizabeth E. Joh, *Reclaiming "Abandoned" DNA: The Fourth Amendment and Genetic Privacy*, 100 NW. U. L. REV. 857, 859 (2006).

collected."[253] Cell samples obtained during routine interactions with medical or research personnel are classified as waste material once their clinical purpose is complete,[254] and waste material is sure to be considered abandoned property. Indeed, the fact that excised cells must be classified as waste material when not being used for treatment and research has been a primary reason why courts have traditionally refused to recognize that tissue providers have any enduring property interest in their cell samples.[255]

In contrast to these shortcomings, an informational property regime goes further to protect against unwanted use of cells that have been abandoned or transformed. Informational property rights, like the intellectual property rights on which they are modeled, are durable. Although a copyright holder may freely give her creation to the public domain, she cannot lose her copyright through unconscious abandonment during the statutory period.[256] Under an informational property model, personal, unique genetic information would therefore be unavailable for use in research without a license, no matter how or from where it was obtained. Moreover, informational property rights would persist even in derivative products like DNA databases — in which no physical cell remains — because the genetic information being stored is identical (or nearly so) to that of the original cells.[257] Informational property could therefore succeed where traditional property claims have thus far failed.

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253. Andrews, *supra* note 20, at 23.

254. *See* 29 C.F.R. § 1910.1030 (2008) (defining "Regulated Waste" as including "[a]ny unfixed tissue or organ (other than intact skin) from a human (living or dead)"); International Center for Alternatives in Research and Education, Human Tissue Banks, http://www.icare-worldwide.org/research/index.html (last visited Dec. 20, 2009) (noting that surgery tissue surplus is currently disposed of as sanitary waste). A number of states have promulgated provisions designating human tissue as waste. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 7054.4 (Deering Supp. 2009) ("Notwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department [of health services] to protect the public health and safety.").

255. As the *Catalona* court observed:

> Noticeably absent from the record is any mention the [research participants] ever were informed they could physically withdraw or request the return of their biological samples. Indeed, in no event *could* the samples physically be returned to their donors. Federal and state regulations prohibit such a result by defining excised body tissue and blood as hazardous substances or infectious waste, and by articulating the proper disposal method.

Wash. Univ. v. Catalona, 490 F.3d 667, 676 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008); *see also* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 491–92 (Cal. 1990) (discussing how Moore's claim of a continuing property interest in his excised cells is undermined by California health and safety codes regulating the disposal of human tissue).

256. *See* 17 U.S.C. § 302 (2006).

257. As discussed *supra* note 128, informational property, unlike the private property model discussed in this Part, would also extend to cell lines materially similar to the tissue provider's cells from which they were derived.

IV. ASSIGNING RIGHTS TO PROTECT INTERESTS

An informational property model provides a more complete approach for protecting the interests of tissue providers and satisfying the needs of researchers than tort, contract, or traditional property alone. The informational property model assigns an enduring property-like right to the stuff in cells that is most likely to be used in ways that raise issues about control, confidentiality, commercialization, and even cure. Significantly, informational property rights bind both downstream and direct users of the tissue in ways that contract and private property models cannot. Except in the context of privacy rights, even tort is limited in its ability to reach downstream users absent a special duty of care. Formulated as an open source, copyleft, tiered consent licensing system limited by a fair utilization exception, informational property rights also ensure that research is able to proceed without over-burdensome transaction costs. In particular, a tiered consent system modeled on Creative Commons licensing minimizes transaction costs because research categories can be somewhat standardized and therefore efficiently tracked without any need to refer to external identifiers.

Informational property rights alone, however, are likely to yield an incomplete governance regime. Tort supplies most of the remaining portion.[258] Tort-imposed duties of care are needed to give form and substance to what is required in obtaining informed consent and appropriate licensing.[259] In so doing, tort should recognize researchers as fiduciaries to their tissue providers.[260] Ethical informed consent is a process demanding not only disclosure, but also understanding. Tort is the system of law that can best set standards that will require such a process rather than simply a signature on a piece of paper. In addition to recognizing the fiduciary duty of informed consent required of re-

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258. As previously explained, a contract is insufficiently protective in most instances because, among other things, it effectively puts the burden of initiating negotiation on the tissue providers, who will almost always be the less-informed and less-powerful bargaining partner. Recognizing private property rights in human tissue is no more helpful, as property rights will inadequately protect individuals from the unconsented-to use of cells sloughed off during everyday life.

259. Tort already performs this role in the context of informed consent for medical treatment, where existing tort doctrine establishes what constitutes sufficient substance and process to yield legally valid consent. *See supra* notes 179–181 and accompanying text. Where an informational property system establishes a duty that researchers obtain informed consent licenses from tissue providers, tort may play a crucial role in defining what that duty entails — what constitutes the exercise of reasonable care or what qualifies as sufficiently informed consent. *See generally* RESTATEMENT (SECOND) OF TORTS § 4 (1965) (explaining that the word "duty" denotes that one is "required to conduct himself in a particular manner at the risk that if he does not do so he becomes subject to liability to another to whom the duty is owed for any injury sustained by such other, of that which the actor's conduct is a legal cause").

260. *Cf.* notes 184–185 and accompanying text.

searchers, tort should likewise impose a fiduciary duty on bio-repositories as these establishments become more central to the process of collecting, maintaining, and distributing tissue for research. Together, informational property rights supported by tort-enforced duties of care act as penalty defaults against researchers and bio-repositories who would otherwise seek unrestricted access to tissues by providing minimal or no information during the consent process.[261]

Tort is also needed to play an ongoing, critical role in protecting individuals from collection of tissue samples without consent where tissue is to be used as a raw material for research, rather than as a source of genetic information. Neither informational nor traditional property rights provide sufficient protection in these instances, and the law of contracts offers no protection where no contract has been created.

Although future scientific findings may provide a basis for extending informational property rights to non-genetic cellular research, an informational property system would at present yield little protection for this kind of research. Informed consent and control nonetheless remain critical, as, for example, women who do not want their enucleated eggs to be used in cloning research likely have a strong interest in preventing such use. In these instances, reliance on explicit contracts (where possible) and general torts requiring informed consent for tissue collection may be needed to fill this gap.

Finally, tort is required for setting the baseline for what privacy and confidentiality controls must protect. Tort identifies what reasonable expectations of privacy should be and imposes liability on those researchers or other actors who fall short of these expectations. Moreover, tort liability can attach even if the tortfeasor is not in privity with the injured party, as when a downstream researcher breaches tissue providers' privacy or when any researcher breaches the privacy of a tissue provider's close genetic relatives.[262] Yet tort doctrines will not unnecessarily define precisely what methods must be used to protect tissue provider confidentiality. This is as it should be — technological innovations in coding samples can and should provide the means for protecting privacy, while tort defends the end goal of sufficient confidentiality. Indeed, an interactive system of tort obligations and informational property rights (and, in particular, appropriate methods of informational rights management) protects interests not only in control and confidentiality, but also in the health benefits of human tissue research. Where confidentiality is guarded by tort-enforced baselines and protected by technological advances in coding,

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261. *See* Ian Ayres & Robert Gertner, *Filling Gaps in Incomplete Contracts: An Economic Theory of Default Rules*, 99 YALE L.J. 87, 91 (1989) (proposing penalty default rules in contract as information-forcing mechanisms).

262. *See supra* notes 195–97 and accompanying text.

tissue providers can reap the benefits of research that can, if necessary, be linked back to identifiable individuals without fearing that such identification will be routine, intrusive, or damaging. In drawing on the strengths of more than one set of legal rules, we can construct a regime that both protects and encourages.

The strengths of any particular system are less clear when considering interests in commercialization. None of the models discussed in this Article is well suited to identifying a specific set of rules for protecting the commercialization interests of tissue providers, especially considering that all may be limited by public policy demands. Each model can be applied to any type of human tissue research, meaning that no model provides a bright line for distinguishing when tissue providers should be permitted to share in the profits of human tissue research using their cells and when financial remuneration should be prohibited. Owing to the lack of clear guidance on the issue of commercialization, this Article declines to advocate for a specific policy on this point. Instead, the crucial issue of ethical financial inducements and rewards in human tissue research is reserved for further exploration elsewhere.

One final inquiry remains: feasibility. Convincing courts to adopt a *sui generis* set of informational property rights would be extremely difficult, and vested interests in unencumbered access to research materials might suggest that legislative and regulatory efforts are unlikely to succeed.[263] Yet, it may well be that *sui generis* rights are unnecessary. The current legal regime does not formally recognize the sort of informational property rights that are integral to creating an effective and ethical research enterprise — but the seeds of such protection do exist.

For instance, under the Uniform Anatomical Gift Act ("UAGA"), which has been adopted in some form by all fifty states, individuals may stipulate that their organs be directed to a particular recipient.[264] This suggests that policy makers in all fifty states are aware of the important relationships that exist between persons, bodies, and body parts. Moreover, the Common Rule provides that informed consent

263. *See* Eisenberg, *supra* note 127, at 10 (suggesting that the biotechnology industry operates on well-entrenched and precedent-based expectations); Ossorio, *supra* note 136, at 427 (contrasting "the well-focused and clearly articulated financial interests of the biotechnology industry" with "the diffuse and difficult-to-articulate social and moral interests of the world's majority").

264. *See* UNIF. ANATOMICAL GIFT ACT § 11(a)(2) (amended 2006), 8A U.L.A. 84 (Supp. 2009). The UAGA was first promulgated in 1968. By 1973, all fifty states and the District of Columbia had adopted it in some form. Tanya K. Hernández, *The Property of Death*, 60 U. PITT. L. REV. 971, 1022 (1999). The UAGA was revised in 1986 and again in 2006. For a recent list of states that have adopted or proposed the Revised UAGA (2006), see Uniform Law Commissioners, A Few Facts About The Revised Uniform Anatomical Gift Act (2006), http://www.nccusl.org/update/uniformact_factsheets/uniformacts-fs-uaga.asp (last visited Dec. 20, 2009).

may not include exculpatory language waiving, or appearing to waive, a research participant's legal rights.[265] Official guidance interpreting this provision identifies impermissible exculpatory language, including clauses waiving "any property rights I may have in bodily fluids or tissue samples obtained in the course of the research."[266] These provisions establish that regulatory rules already exist by which some provider rights could be protected.

Finally, the recent enactment of the Genetic Information Nondiscrimination Act ("GINA")[267] demonstrates Congress's understanding of the importance of genetic information. GINA may serve as a first step in a larger legislative, regulatory, and judicial project that embraces the recognition of informational property rights in genetic information. Thus, although instituting informational property rights demands creative thinking about the nature of the rights inherent in genetic information and human tissue, the foundation for such rights is well laid.

V. CONCLUSION

Respect for and protection of the interests of tissue providers, researchers, and society at large is necessary if human tissue research is to proceed in an ethical and effective manner. If the interests of tissue providers are given short shrift in an attempt to facilitate research, a significant number of potential tissue providers will simply refuse to participate. Some may even avoid necessary health care out of concern about the subsequent research use of their tissue.[268] Research may suffer for lack of truly population-wide sampling and perhaps even an overall dearth of available samples. On the other hand, if onerous transaction costs are imposed on researchers working with human tissue samples or if the commercial gains of such research are too far diminished by tissue providers' claims on profits, then investment in research may fall and, with it, the benefits flowing from such research.

In exploring possible legal models for resolving disputes between tissue providers and researchers, several things have become clear. The nature of human tissue research demands a legal regime that will bind both downstream and direct users of tissue samples. Of the four models considered, informational property rights offer the most robust

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265. 45 C.F.R. § 46.116 (2008).

266. Office for Prot. from Research Risks, "Exculpatory Language" in Informed Consent (Nov. 15, 1996), http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm (providing guidance about what constitutes exculpatory language prohibited by the Common Rule regulations).

267. Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, 122 Stat. 881.

268. *See* Nelkin & Andrews, *supra* note 52, at 7; Rapp, *supra* note 47, at 49.

and enduring protection of tissue providers' control interests. This occurs only when these rights are formulated appropriately (as open source, copyleft, tiered consent licensing, possibly limited by a fair utilization exception) and are supported by tort-enforced duties of care giving substance to the meaning of consent.

Moreover, tort is uniquely well suited to punish direct as well as downstream users for unauthorized breaches of confidentiality. While informational property rights, information rights management, and technologies for coding and databasing samples provide tools for protecting identifiable information linking specific samples to specific individuals, tort is needed to fix the baseline for what constitutes adequate protection of tissue provider privacy. Thus, protecting the interests of tissue providers and researchers in human tissue research demands a mixed legal regime, drawing not only on tort (as the current legal regime suggests), but also on informational property rights (the seeds for which already exist, but which the current legal regime does not formally recognize). A great deal is at stake in governing human tissue research, and creating the right mix of legal rights and obligations is a critical step in that governance.