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Biobanks as a Tissue and Information Semicommons: Balancing Interests for Personalized Medicine, Tissue Donors and the Public Health

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BIOBANKS AS A TISSUE AND INFORMATION SEMICOMMONS: BALANCING INTERESTS FOR PERSONALIZED MEDICINE, TISSUE DONORS AND THE PUBLIC HEALTH

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I. INTRODUCTION

The promise of personalized medicine is tantalizing. Match a patient's specific genetic characteristics with a specific therapeutic intervention and patients will be treated more effectively and have fewer side effects.[1] It is the future of medicine, and medical centers, pharmaceutical companies and others are heavily investing in its promise. Patient tissue, including blood and information derived from this tissue is critical to realizing this promise.[2] Tissue information is essential

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1. *See* Ultan McDermott et al., *Genomic Medicine: Genomics and the Continuum of Cancer Care*, 364 NEW ENG. J. MED. 340, 343, 346 (2011) (explaining how personalized medicine improves cancer treatment). Cancer treatment is a strong focus in personalized medicine. For example, Gleevec, one of the first successful targeted therapies, dramatically improved treatment and outcomes for patients with chronic myelogenous leukemia (CML), a cancer of the blood and bone marrow where white blood cells expand uncontrollably. *Id.* at 343. The drug has far fewer bad side effects than previous therapies because it is targeted to a specific abnormal protein on the cancer cells in CML, but not in most other leukemia. *Id.* It targets the abnormal protein that makes the cancer cells grow and divide uncontrollably. *Id.* Non-targeted chemotherapy kills normal and leukemic cells alike (people loose hair, have diarrhea, etc.), but Gleevec preferentially inhibits CML cells resulting in patients having fewer side effects. *Id.* However, the targeted therapy only works if the cancer cells have the specific target, and the only way to know is to test a patient's leukemia cells. Moreover, a patient's cancer cells may be initially treated by a targeted therapy but then develop resistance, which merits another round of molecular testing on the tumor cells to identify the mutation and match new therapy. Research on tumors to develop treatment regimes, including targeted drugs, is only half of the story; the other half is diagnostic testing on tissue once the research is done. *Id.* at 343. The promise of personalized medicine, therefore, relies on human tissue in the research and routine clinical settings.

2. Margaret A. Hamburg & Francis S. Collins, *The Path to Personalized Medicine*, 363 NEW ENG. J. MED. 301, 302 (2010).

for research and for routine clinical care in personalized medicine.[3] The most valuable biobank tissue includes treatment and outcomes information, and it increases in value as it becomes part of a larger collection—benefits increase as collection size increases.[4] Unlike tissue repositories in the past, biobanks are more than just archived remnants of excised human tissue. They are organized, searchable, and data rich entities that, like commercial banks, make lending decisions to qualified researchers or organizations.[5] It is no surprise that many countries, including the United States[6] and the European Union,[7] are investing in and developing biobanking.

There are many different types of biobanks. Some are private not-for-profit; some are owned and operated by pharmaceutical companies; some are funded by national governments; many are university based; and still others are private-public partnerships.[8] Some biobanks have a specific disease in mind, whereas others function as general repositories.[9] Some readily share tissue and information, others are secretive.[10] New joint undertakings between pharmaceutical companies and

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3. *Id.* Margaret Hamburg, the commissioner of the Food and Drug Administration (FDA), and Francis Collins, director of NIH, emphasized the need for testing patient tissue as part of routine clinical care in personalized medicine, writing that the "success of personalized medicine depends on having accurate diagnostic tests that identify patients who can benefit from targeted therapies." *Id.*

4. Alice Park, *Biobanks*, TIME (Mar. 12, 2009), http://www.time.com/time/specials/packages/article/0,28804,1884779_1884782_1884766,00.html. Not only is statistical power greater with larger numbers, but larger and networked tissue biobanks have the additional advantages as explained by previous scholarship exploring the workings of various networks, some of it in the health care setting. *See* Mark A. Hall, *Property, Privacy, and the Pursuit of Interconnected Electronic Medical Records*, 95 IOWA L. REV. 631, 638 (2010) ("[E]ach user receives more benefit as network's size increases."); Mark A. Lemley & David McGowan, *Legal Implications of Network Economic Effects*, 86 CALIF. L. REV. 479, 488 (1998) (stating that generally the value of something increases as the number of users increase).

5. *See* Park, *supra* note 4 (comparing tissue banks to bank accounts).

6. *See American Recovery and Reinvestment Act at NCI*, NAT'L CANCER INST., U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.cancer.gov/aboutnci/recovery/recoveryfunding/cahub (last visited Mar. 25, 2012) (reporting that the American Recovery and Reinvestment Act included $1.3 billion to the NCI, $70 million of which will be devoted to a national cancer biobank); *see also* OFFICE OF BIOREPOSITORIES & BIOSPECIMEN RESEARCH, U.S. DEP'T OF HEALTH & HUMAN SERVS., NCI BEST PRACTICES FOR BIOSPECIMEN RESOURCES 1 (2011) (discussing the NCI's efforts in biospecimen research).

7. *See, e.g., BBMRI During the Transition Phase*, BBMRI, http://www.bbmri.eu/ (last visited Mar. 25, 2012) (describing the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), which was one of the first European Research Infrastructure projects funded by the European Commission (EC)). "BBMRI will form an interface between biological specimens and data (from patients and European populations) and top-level biological and medical research." *Id.*; David Winickoff, *Partnership in U.K. Biobank: A Third Way for Genomic Property?*, 35 J. L. MED. & ETHICS 440, 441 (2007) (stating that many U.K. organizations will spend millions on research into biobanks).

8. *See* Winickoff, *supra* note 7, at 441.

9. *See* Park, *supra* note 4 (stating that biobanks can target specific diseases such as Alzheimer's and diabetes).

10. *See* Winickoff, *supra* note 7, at 447 fig. 1 (providing a chart of the varying property entitlements devised by the U.K. biobank including rights to access, ownership and control).

universities are leveraging the financial resources of drug companies with the tissue and research resources of academia.[11] Many clinical cancer trials today have a tissue collection element to better understand the relationship between treatment and tumor biology, explore pharmacogenetics, or develop lab assays to help targeted therapy.[12] There tends to be an overlap, redundancy and waste, because tissue is often collected for only one purpose and the information gathered is proprietary.

Biobanking has been given a green light, but it is forging ahead with many unsettled ethical and legal issues associated with the collection, maintenance, control and use of tissue and the information derived from tissue.[13] This essay will examine the advantages and shortcomings of the current state of legal rights describing human tissue, and then offer a new way that better recognizes the distinction between, and interdependence of, tissue and tissue information, while balancing important interests and maintaining incentives to realize the potential of personalized medicine. The new way begins by recognizing the unique attributes of human tissue, including how it is related to information derived from it and its

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11. *See, e.g.*, Selina McKee, *Pfizer Hooks Up with Uni of California in Novel Research Pact*, PHARMATIMES ONLINE (Nov. 17, 2010), http://www.pharmatimes.com/Article/10-11-17/Pfizer_hooks_up_with_Uni_of_California_in_novel_research_pact.aspx (announcing that Pfizer partnered with University of California for the purpose of biomedical research).

12. *See* Hamburg & Collins, *supra* note 2, at 301, 304; *see generally* INST. OF MED., A NATIONAL CANCER CLINICAL TRIALS SYSTEM FOR THE 21ST CENTURY (2010) (The IOM report emphasized the importance of annotated Biorepositories and the maintenance of tissue banks for the future of personalized medicine, bemoaned that participation in clinical trials is not the norm today, and reminded readers that it is only through clinical trials that personalized medicine can deliver its promise).

13. *See* Park, *supra* note 4 (explaining that privacy is the biggest challenge facing biobanks and that the accessibility of DNA by the government makes people uncomfortable). Many scholars have concluded that the laws regulating excised tissue ownership remain poorly defined and some have pleaded for new approaches to address the issues presented by large scale biobanking. *See* Stephanie M. Fullerton et al., *Meeting the Governance Challenges of Next-Generation Biorepository Research*, 2 SCI. TRANSLATIONAL MED. 15cm3, 15cm4 (2010) (explaining that new research can help address current and anticipated problems with biobanks); Jennifer Girod & Katherine Drabiak, *A Proposal for Comprehensive Biobank Research Laws to Promote Transnational Medicine in Indiana*, 5 IND. HEALTH L. REV. 217, 218–19 (2008) (describing lawsuits that have developed as a result of the uncertainty surrounding the ownership of biobank tissue); Gail Javitt, *Why Not Take All of Me? Reflections on* The Immortal Life Of Henrietta Lacks *and the Status of Participants in Research Using Human Specimens*, 11 MINN. J. L. SCI. & TECH. 713, 714–15 (2010) (examining the uncertain legal infrastructure surrounding biobanked tissues); Sharon Lewis, *The Tissue Issue: A Wicked Problem*, 48 JURIMETRICS 193, 193–94 (2008) (discussing how advancements in personalized medicine may suffer from tissue availability); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 371 (2007) (depicting the state of confusion and chaos involving ownership and rights over the human bidy). In an article about the electronic medical record, Mark Hall asks whether it matters that the law does not give a clear, complete and consistent answer to the question of who owns medical information. Hall, *supra* note 4, at 642. He notes that the Coase Theorem says it doesn't matter as long as transaction costs are not so expensive as to prohibit reallocation through contracting. *Id.* Hall, however, concludes that property rights must be clear so that parties know their default positions, and that such clarity is absent with medical information property rights. *Id.* at 637, 645.

similarity to clinical health information.[14] The argument continues with the help of Henry Smith's work, and examines and describes biobanks as a semicommons.[15] This essay concludes by outlining a legal infrastructure that would make information derived from tissue in biobanks more accessible to the research community and better able to protect the interests of people who have donated tissue.[16]

In Part II, this essay will examine the current legal landscape governing human tissue, beginning with *Moore v. Regents of the University of California.*[17] *Moore* opened the way for subsequent cases, like *Washington University v. Catalona*[18] and *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,[19] which characterize patient tissue, almost by definition, as gifts to the research institution. The practical approach taken by *Moore* and its progeny, which all involved research universities, as well as the current federal Common Rule governing research, have allowed tissue banking and biobanking to go forward because the legal landscape has given research universities property interests in tissue with little threat of tissue donors successfully claiming property or other legal rights in their tissue, or any legal claim to profits derived from research on the tissue.[20]

Part III will explore a new legal description of excised human tissue derived from understanding its unique attribute, that places it in a space between private property, public property, and intellectual property. Although *Moore* recognized the distinction between tissue and information supplied by the tissue, it failed to explore the nexus between the two. Several attributes of excised tissue make it unique. First, human tissue that is not going to be used for clinical purposes, such as diagnosis, transplantation or transfusion, has no commercial value unless it is transformed into a commodity.[21] Tissue increases in value as it is linked to treatment and outcomes information, because the molecular characteristics of the tissues gain meaning.[22] Only with this linked information can one determine, for example, whether a particular mutation responds to a particular targeted

14. *See infra* Part III.

15. *See infra* Part IV.A.

16. *See infra* Part IV.B.

17. 793 P.2d 479 (Cal. 1990).

18. 490 F.3d 667 (8th Cir. 2007).

19. 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

20. *See infra* Part II.B.

21. *E.g.*, Mark Barnes & Kate Gallin Heffernan, *The 'Future Uses' Dilemma: Secondary Uses of Data and Materials by Researchers and Commercial Research Sponsors*, 3 MED. RES. L. & POL'Y REP. 440, 442–43 (2004).

22. *See, e.g.*, N.J. Sebire & M. Dixon-Woods, *Towards a New Era of Tissue-Based Diagnosis and Research*, 3 CHRONIC ILLNESS 301, 304 (2007) (noting that the value of one person's tissue increases when it is combined with the tissue of others because large numbers of samples are often required to obtain meaningful results from studies).

therapeutic.[23] Secondly, one piece of human tissue generally means little but gains value as it is linked with many others.[24] Thirdly, although human tissue is unique to each individual, research on one person's tissue may benefit others.[25] We have a shared interest in tissue research because it may benefit us, our families, and our communities. Lastly, whereas the tissue itself is rival (others cannot use it if you are), the information from the tissue is non-rival.[26] Understanding these attributes of excised human tissue recognizes the similarities between information derived from tissue and other clinical medical information. It means both types of information may be best defined as a common shared resource to be used for public benefit.

Part IV will describe biobanks as liberal semicommons, and how this characterization will change the look of biobanks. New biobanks, while still holding many sticks in the property bundle, will not hold all of the sticks, because tissue and tissue information will be part of a semicommons. This approach draws on previous property work describing semicommons and liberal commons.[27] Such an approach better recognizes the altruistic intent of tissue donors and the inherent public health aspects of tissue research, while not tearing apart the current regime. The proposed approach recognizes lessons taught by previous biobanks, promotes long term benefits, such as encouraging patient participation in clinical trials, leverages rare disease tissue, and generally promotes the sustainability of biobanking.[28]

Part V identifies areas of concern and identifies some of the implications of treating biobanks as liberal semicommons.

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23. *See* McDermott et al., *supra* note 1, at 343 (stipulating that due to the prevalence of disease mutations, an approach to research using linked information—utilizing tissue samples from a large sample of patients—is necessary to develop targeted drugs).

24. *See supra* note 22 and accompanying text.

25. *See, e.g.*, Moore v. Regents of Univ. of Cal., 793 P.2d 479, 481 n.2 (Cal. 1990) (explaining that tissue from one person can lead to the development of therapies that will benefit others by manufacturing the benefits of the tissue using techniques of recombinant DNA).

26. *See infra* notes 260–66 and accompanying text.

27. *See* Hanoch Dagan & Michael A. Heller, *The Liberal Commons*, 110 YALE L.J. 549, 553 (2001) (defining liberal commons as any type of legal regime that provides a group of people "economic and social benefits from cooperative use of a scare resource"); *see also* Henry E. Smith, *Semicommon Property Rights and Scattering in the Open Fields*, 29 J. L. STUD. 131, 131 (2000) (defining semicommons as a resource that is used by many, but from which individuals have separate ownership rights in the individual property).

28. *See infra* Part IV.B.

II. CURRENT LAW GOVERNING EXCISED TISSUE

A. Moore v. University of California *Introduces the Issues*

Moore v. University of California is a well-known and extensively analyzed case,[29] which comprehensively addressed the legal rights of a patient who did not know that his tissue was being used for commercial development (and for research).[30] Scholars recognized early on that the case was important because it addressed important evolving issues.[31] *Moore* is one reason why informed consent forms for clinical trials routinely include statements that the research subjects have no interests in any commercial benefit derived from research on their tissue.[32] It also established the rationale behind why many research hospitals use broad release forms for research use of tissue removed for clinical purposes.[33] The following,

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29. 793 P.2d 479 (Cal. 1990). A Westlaw search shows *Moore* is cited in more than 1000 articles and thirty-five law review articles have *Moore* in the name of the title. *See* Peter Halewood, *On Commodification and Self-Ownership*, 20 YALE J.L. & HUMAN. 131, 149 (2008) (emphasizing the importance of *Moore* in both law and academia); Russell Korobkin, *"No Compensation" or "Pro Compensation":* Moore v. Regents *and Default Rules for Human Tissue Donations*, 40 J. HEALTH L. 1, 3 (2007) (arguing that *Moore* and its progeny establish a default rule for patients in the research setting assuming unselfish transactions unless the parties note otherwise). *See generally* Lisa Milot, *What Are We—Laborers, Factories, or Spare Parts? The Tax Treatment of Transfers of Human Body Materials*, 67 WASH. & LEE L. REV. 1053, 1086–87 (2010) (summarizing the Moore decision in the following terms: "[h]uman body materials here are potentially the property of a third party, but not the person from whom the material was removed").

30. *Moore*, 793 P.2d at 481–82.

31. *See, e.g.*, Halewood, *supra* note 29, at 149 (describing *Moore* as a seminal case because the court addressed the social meaning and rights of the body). Whereas many scholars have recognized the importance of *Moore,* several have also addressed how *Moore* falls short in the context of biotechnology. *See, e.g.*, Rhonda G. Hartman, *Beyond* Moore*: Issues of Law and Policy Impacting Human Cell and Genetic Research in the Age of Biotechnology*, 14 J. LEGAL MED. 463, 464 (1993) (arguing that there is a need to develop new law to govern biotechnology and new laws should strike a balance between respect for individual autonomy and recognition of the value of biotechnology).

32. *See, e.g.*, Korobkin, *supra* note 29, at 3. Regardless of whether a written and signed informed consent has aspects of a contract, the effect of the decision in *Moore* has been that in the clinical setting patients have no right to proceeds from their tissue unless separately negotiated. *Id.*

33. *See, e.g.*, Hartman, *supra* note 31, at 463 (noting that the Moore court imposed a duty on physicians of full disclosure as to personal interests to patients as part of the informed consent process). An example of a hospital "consent" is:

> By signing my name below, I confirm the following: I have read (or had read to me) this entire consent document. All of my questions have been answered. The Tissue Bank's purpose, procedures, and risks have been explained to me. I voluntarily agree to participate in the Tissue Bank. At any time, I can ask [Medical College of Wisconsin] to stop collecting my Specimens/health information and ask MCW to delete/destroy all my Specimens/health information, if it is still identified as mine. By signing this form, I forfeit any future compensation related to the use of my Specimens or associated health information and waive all legal rights to my Specimens. By signing this form, I authorized Froedtert Hospital to release my protected health information to MCW for the purpose outlined in this informed consent.

rather lengthy, discussion of *Moore* is warranted because its various opinions laid the foundation for subsequent law, as well as discussions about how our law treats excised human tissue and various interested persons.

The *Moore* facts begin in 1976 when John Moore was diagnosed with hairy cell leukemia.[34] Facing a grim prognosis, he sought out Dr. David Golde, a hematologist and researcher at UCLA, who became Moore's treating physician.[35] Golde recommended that Moore's enlarged spleen be surgically removed, which was then part of the standard treatment for hairy cell leukemia.[36] Golde did not tell Moore that he planned to use his tissue for research that had a potential commercial benefit.[37] After surgeons removed Moore's spleen, Golde and fellow researchers used it in ways unrelated to Moore's medical treatment.[38] They did not inform Moore.[39]

After the splenectomy, Moore, who lived in Seattle, traveled to UCLA for follow-up visits from 1976 to 1983.[40] During these visits Golde obtained additional samples of blood, bone marrow, sperm and skin, which were all used for research and further development.[41]

In 1981 the Regents of the University of California, Golde, and Shirley Quann, another researcher. applied for a patent of a cell line derived from Moore's tissue (the "Mo" cell line), as well as for the various methods of using the cell line to produce chemicals called lymphokines.[42] Shortly after the patent was filed in 1981, Golde asked Moore to sign a form that would grant the University of California "all rights . . . in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained from me."[43] Moore

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Consent to Participate in Research: Informed Consent for the Use of Blood and/or Tissue for Research, FROEDTERT HOSP. & MED. COLL. OF WIS., http://www.mcw.edu/FileLibrary/Groups/Pathology/Tissue-Bank/MCWTissueBankConsentForm.pdf (last revised Nov. 16, 2010).

34. *Moore*, 793 P.2d at 481. Hairy cell leukemia is so named because the leukemic white blood cells look "hairy" under the microscope. *General Information about Hairy Cell Leukemia*, NAT'L CANCER INST., NAT'T INST. OF HEALTH, http://www.cancer.gov/cancertopics/pdq/treatment/hairy-cell-leukemia/Patient/page1 (last modified July 15, 2011).

35. *See* Rebecca Skloot, *Taking the Least of You,* N.Y. TIMES, Apr. 16, 2006, § 6 (Magazine), at 38. Moore knew something was wrong when his gums began to bleed, his belly enlarged and he easily bruised. Moore's spleen, enlarged by billions of leukemic hairy cells, made his belly swell, and his bone marrow, also filled with cells, was no longer able to make enough platelets to keep his gums from bleeding and his skin from bruising. *Id.*

36. *Moore*, 793 P.2d at 481.

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.* When Moore complained about having to travel to Los Angeles and suggested that a physician in Seattle could provide follow-up treatment, Golde offered to pay travel expenses and provided lodging at an expensive hotel in Beverly Hills. Skloot, *supra* note 35.

42. *Moore*, 793 P.2d at 481–82.

43. Skloot, *supra* note 35.

refused.[44] The patent was granted in 1984.[45] Golde and UCLA thereafter entered into lucrative agreements with Sandoz Pharmaceuticals and Genetics Institute to commercially develop the patent product.[46]

i. California Court of Appeals Recognizes Moore's Property Interest in Tissue

In 1984, Moore sued Golde, Quan, UCLA, Sandoz and Genetics, stating thirteen causes of action, including conversion, breach of fiduciary duty, and unjust enrichment.[47] The trial court dismissed the case, but, in 1988, the California Court of Appeals recognized Moore's conversion claim, emphasizing that conversion was a strict liability tort and the key issue was Moore's ownership right in his excised tissue, which Moore characterized as his personal property.[48] Driving its decision was the majority's feeling that, "[a] patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."[49] The decision saw a conflict between medical progress and human privacy and dignity.[50]

The Court of Appeals understood that times were changing; tissue traditionally had little financial value but now was taking on "astonishing aspects of value," a fact that "requires examination of our understanding of the legal rights and relationships in the human body and the human cell."[51] The court's reasoning begins with an expansive definition of property as any right or interest "capable of being enjoyed as such upon which it is practicable to place a money value."[52] But whether the cells had value was precisely the question to answer.[53] Did Moore's spleen, marrow, and blood, as they left Moore's body, have intrinsic financial value, intrinsic ethical value, or were they valueless? The defendants argued that the diseased tissue had no value before their work developed the essentially discarded, tissue into something of value.[54] Their work gave the tissue value, which

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44. *Id.*

45. *Id.* at 482.

46. *Id.*

47. *Moore*, 793 P.2d at 482 & n.4; Skloot, *supra* note 35.

48. Skloot, *supra* note 35; Moore v. Regents of Univ. of Cal., 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1988), *aff'd in part, rev'd in part*, 793 P.2d 479 (Cal. 1990).

49. *Moore*, 249 Cal. Rptr. at 508.

50. *See id.* at 509 (noting ethical concern about the links between academics and industry that allow both sides to profit from biological specimens).

51. *Id.* at 504.

52. *Id.* at 505 (quoting Yuba River Power Co. v. Nev. Irrigation Dist., 279 P. 128, 129 (Cal. 1929)).

53. *Id.* at 504. The court stated that since Mr. Moore's cell-line had already been commercialized by defendants, the only question it would consider was which party should share in the profits. *Id.* However, because of the specter of slavery, the court approached the issue with caution, emphasizing that it was not determining whether use of tissue "ought to be 'gift based' or subject to a 'free market.'" *Id.*

54. *Id.* at 507.

made it property.[55] Moore maintained his tissue had value, perhaps minimal value, but enough, nonetheless, so that it could be converted.[56]

The Court of Appeals responded to the defendants' argument, that Moore's tissue had value only because of the work and intellectual capital invested, by focusing on the difference between the tissue and information or ideas derived from the tissue.[57] First, it noted that the plaintiff's complaint alleged conversion of the cells and not conversion of the "ideas gained from study of the cells."[58] The court then argued that, without the cells, the information would never have been uncovered.[59] Therefore, the cells were of at least some value and there was a nexus between the tissue and information derived from the tissue.[60] The court cited a number of property and privacy cases, as well as health and safety codes to make the point that there was some value in the unimproved removed tissue, so that "it cannot be said that a person has no property right in materials which were once part of his body."[61]

In reaching its decision, the Court of Appeals focused on the body and its tissue.[62] It concluded that Moore could pursue a conversion claim because the law did not say that Moore lacked any property right in his tissue.[63] Strong policy considerations mandated a patient's ability to control what happens to their tissue because to do otherwise would affront human dignity and privacy.[64] More importantly, the court, in holding that the plaintiff had stated a cause of action for conversion, acknowledged a distinction between Moore's tissue and information from his tissue, while also acknowledging a connection between tissue and its information.[65]

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55. *Id.* The idea that work gives property value corresponds with one interpretation of John Locke's view of how a person's labor creates property. *See* JOHN LOCKE, TWO TREATISES OF GOVERNMENT AND A LETTER CONCERNING TOLERATION, 111–12 (Ian Shapiro ed., Yale Univ. Press 2003) (1690) (arguing that a man's labor is what makes those things, which exists naturally, his property).

56. *Moore*, 249 Cal. Rptr. at 499–501.

57. *Id.* at 507.

58. *Id.*

59. *Id.*

60. *Id.*

61. *Id.* at 505–06. *See, e.g.*, CAL. HEALTH & SAFETY CODE § 7100 (West 2007 & Supp. 2012) (vesting control over the disposal of a decedent's remains with the decedent's power of attorney or other statutorily eligible family member); Venner v. State, 354 A.2d. 483, 485, 498–99 (Md. Ct. Spec. App. 1976) (holding a person must exert an affirmative property interest in excreted bodily material, otherwise it will be deemed abandoned).

62. *Moore*, 249 Cal. Rptr. at 506–08 (discussing that link between the limited property interests in one's own body and the centrality of one's cells and genes in forming an individual's unique identity).

63. *Id.* at 511.

64. *See id.* at 508 ("A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress.").

65. *Id.* at 507.

ii. The California Supreme Court Avoids an Information Anticommons but not a Patent Anticommons in Moore

The California Supreme Court reversed the Court of Appeals and rejected all of Moore's claims, except for breach of fiduciary duty and informed consent.[66] The Court rejected Moore's conversion claim, in part, because it felt that its approach provided Moore with too broad of a remedy.[67] While concurring on the ultimate judgment, the decision was split and engendered four opinions.[68]

Justice Broussard, concurring and dissenting, interpreted the majority opinion as holding that "*a patient* retains no ownership interest in a body part once the body part has been removed from his or her body."[69] Broussard argued that the majority could not have meant that ownership, or possession rights, could never lie in excised tissue because a conversion claim would undoubtedly be available if a drug company or university had stolen all of Moore's unimproved cells from the UCLA lab.[70] Broussard agreed that patients retain no property rights in their excised tissue in the usual case wherein a patient consents to an operation and to the use of tissue for general research purposes, without the doctor's prior knowledge of the tissue's scientific or commercial value.[71] Moore's case, however, did not fit into this category because Golde knew that Moore's tissue was especially valuable; in fact, this knowledge created the conflict of interest.[72] For Broussard, this meant that Moore had a property interest, one stick in the big bundle, in his tissue before it was removed.[73] Moore's property right was his right to determine how his tissue was going to be used while it was still a part of him.[74] Golde interfered with Moore's "right to control the use of a body part by wrongfully withholding material information from him before its removal . . . ."[75] Broussard argued that Moore's

66. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (Cal. 1990). The Court held that a physician's duty to obtain informed consent includes disclosure of "personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment." *Id.* at 483. The Court said nothing directly about informed consent for doing research on Moore's tissue, but focused on the informed consent for treatment. *Id.* at 483–85. Admittedly, had Dr. Golde disclosed his research interests Moore would have known that his tissue was going to be used, but the Court does not identify a separate interest in consent to using tissue. *Id.* at 485.

67. *See id.* at 496–97.

68. *See generally id.* Justice Panelli issued the decision of the court while Justices Lucas, Eagleson, Kennard and Arabian concurred. Justice Broussard issued a concurrence and dissent, and Justice Mosk dissented. *Id.*

69. *Id.* at 501 (Broussard, J., concurring and dissenting).

70. *Id.*

71. *Id.* at 498–99. Broussard accuses the majority of failing "to maintain its focus on the specific allegations," and of focusing instead on not wanting to impose liability on "innocent scientists" conducting medical research on existing cell repositories. *Id.*

72. *Id.* at 499.

73. *Id.* at 502.

74. *Id.*

75. *Id.* at 499.

tissue was special; it was unique in its context, not unique because it had a specific DNA sequence or because all human tissue is inherently dignified, as maintained by dissenter Justice Mosk.[76]

Broussard's reliance on context is commendable, but otherwise the decision lends little to routine situations of tissue collection in clinical and research contexts. What qualifies as "wrongfully withholding material information?"[77] Golde's actions likely qualify.[78] But ubiquitous general surgical consent forms, that include boilerplate language about tissue possibly being used for unspecified future research, likely do not.[79]

The *Moore* majority used a two-step analysis to reject the conversion claim.[80] The majority began by examining the network of health and safety statutes and regulations and, unlike the Court of Appeals, concluded that these did not support Moore's conversion claim.[81] It then drove a wedge between Moore's tissue and the information derived from the tissue, while ignoring the space in between.[82] The Court did so by distinguishing between Moore's unimproved tissue and the patented products.[83] Recall that the Court of Appeals saw a nexus between Moore's cells and its information and products, and described the patent as derived from the cells.[84] The California Supreme Court majority, in contrast, saw them as separate

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76. *See id.* at 501. Mosk recognized Moore's conversion cause of action, arguing, in part, that failure to do so would encourage commodification of the human body. *Id.* at 516 (Mosk, J., dissenting). He emphasized that Moore's tissue was a part of Moore's body rather than the informational attributes of Moore's tissue: "our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona." *Id.* at 515. Mosk continued by arguing that the researchers' use of Moore's tissue invoked our prohibition against slavery and indentured servitude: "Yet their specter haunts the laboratories and boardrooms of today's biotechnological research-industrial complex. It arises wherever scientists or industrialists claim, as defendants claim here, the right to appropriate and exploit a patient's tissue for their sole economic benefit . . . ." *Id.* at 515–16. Mosk, however, did not argue that Moore had a property right in the information from his cells as a function of natural rights theory. *See* Catherine M. Valerio Barrad, *Genetic Information and Property Theory*, 87 NW. U. L. REV. 1037, 1062, 1064–67 (1993).

77. *Moore*, 793 P.2d at 499 (Broussard, J., concurring and dissenting).

78. *See id.* at 485 (majority opinion) (finding that Golde breached a duty owed to Moore by failing to disclose his research interest).

79. *See* Lynch v. Brookside Obstetrics & Gynecology Assocs., No. CV990175019S, 2000 WL 1995285, at * 3 (Conn. Super. Ct. Dec. 13, 2000) (holding, in the context of a battery claim, that it was a jury question as to whether the use of forceps was consented to under a general informed consent agreement); *Cf.* Rizzo v. Schiller, 445 S.E. 2d 153, 155–56 (Va. 1994) (noting that generalized consent forms did not establish a prima facie case that informed consent existed in the use of forceps in the process of a delivery).

80. *See Moore*, 793 P.2d at 488 (stating that the court will first determine if there is a cause of action under current law and will next consider if the court should extend tort law to apply to this issue).

81. *Id.* at 489 nn.21–27.

82. *See Moore*, 793 P.2d at 492 (finding the patented cell line "factually and legally distinct" from Moore's tissue).

83. *Id.* at 492–93.

84. *See* Moore v. Regents of Univ. of Cal., 249 Cal. Rptr. 494, 507 (Cal. Ct. App. 1988), *aff'd in part, rev'd in part*, 793 P.2d 479 (Cal. 1990) (noting how the plaintiff's cells and spleen were essential

entities; it emphasized the "patented cell line [as] both factually and legally distinct from the cells taken from Moore's body."[85]

The Court's second step was to consider policy matters in order to determine whether conversion liability should be extended.[86] Two policy considerations were of "overriding importance."[87] First, patients should be protected to allow autonomous decision-making in their *clinical* care.[88] Second, researchers should be protected so they can continue to do research, because it was a socially useful undertaking.[89] The majority felt that its decision outlining informed consent and fiduciary principles adequately protected patients' autonomy.[90] Researchers, however, had to be protected from "disabling civil liability" that would result if the Court recognized conversion, as it was a strict liability tort.[91] No researcher could be sure that their use of any cell sample was compliant with the donor's wishes.[92] Interestingly, the Court described the current state of cell lines as a tissue commons, where cell lines and tissue are shared and the "exchange of scientific materials . . . is relatively free and efficient."[93] On the other hand, granting the conversion claim would have created a tissue anticommons, where research grinds to a standstill because the transaction costs of figuring out who has what rights are too great.[94] Investment would dry up and the great promise of biomedicine would fade.[95]

What did the California Supreme Court leave us? It gave individuals no property interest in tissue removed from their bodies, whether they were patients or research subjects.[96] It did avoid a tissue anticommons, which would have resulted

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to the chain of research that eventually allowed the defendants to develop the commercially valuable knowledge in question).

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

86. *Id.* at 493.

87. *Id.*

88. *Id.*

89. *Id.*

90. *Id.* at 494.

91. *Id.* at 493.

92. *Id.*

93. *Id.* at 495. *See also* Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition From Marx to Markets,* 111 HARV. L. REV. 621, 624 (1997) (defining anticommons as a situation in which "multiple owners are each endowed with the right to exclude others from a scarce resource, and no one has an effective privilege of use").

94. *Moore,* 793 P. 2d at 494–95 (stating that increasing liability through conversion will stifle research efforts). *See also* Heller, *supra* note 93, at 624 (referring to multiple owners all with a vested interest as a tragedy of the anticommons).

95. *Moore,* 793 P. 2d at 495–96. Justice Panelli states, "the theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery." *Id.*

96. *Id.* at 488–89 (holding that Moore and future patients do not have a property interest in their excised cells, falling short of meeting the requisite elements of a claim for conversion).

from giving patients a strong property right in their excised tissue, but *Moore* did not avoid a patent anticommons.[97] It recognized the social value and public health benefit of research on human tissue, but did not fully understand tissue as a shared community resource or semicommons.[98] It failed to provide legal recognition of the uniqueness of an individual's tissue once removed from the body, but did recognize the uniqueness of the patented cell line.[99] Lastly, it failed to understand the nexus between tissue and information.

Moore focused on consent to protect patients' interests, and, by doing so, it emphasized autonomy interests.[100] The Court envisioned a future where a patient refused treatment, or at least withheld consent for research, if she disapproved of particular research, but only if specific research is anticipated at the time the tissue is excised.[101] The Court did not discuss whether a patient may direct the kind of research that might be done on her tissue, whether she has a right to find out about what kind of research is being planned, whether she has access to research results, whether she has the right to withdraw consent for use of her tissue or any information already derived from research on her tissue, or whether she can direct the destruction of her tissue and information.[102] The *Moore* decision shares the current federal human subject protection law's emphasis on autonomy and its paradigm of understanding human subjects' interest within the context of clinical trial research.[103]

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97. *See also* Lori B. Andrews, *Genes and Patent Policy: Rethinking Intellectual Property Rights*, 3 NATURE REVS. GENETICS 803, 803–05 (2002) (discussing the negative impact of gene patenting on research, medical treatments, and disease diagnosis); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in BioMedical Research*, 280 SCI. 698, 699 (1998) (arguing that the proliferation of intellectual property rights, especially upstream patent rights, lead to underuse of resources because of increased transaction costs, strategic behavior and cognitive bias).

98. *Moore*, 793 P. 2d at 494–95 (describing the "critical role" of research on human cells, while predicting the adverse effect of applying conversion law to tissue property interest upon the broader scientific community). *See also infra* notes 270–76 and accompanying text.

99. *Moore*, 793 P. 2d at 490 (finding that the cells from Moore's tissue were not unique).

100. *Moore*, 793 P. 2d at 483.

101. *Id.* at 492. Justice Panelli wrote: "A fully informed patient may always withhold consent to treatment by a physician whose research plans the patient does not approve. That right, however, as already discussed, is protected by the fiduciary-duty and informed-consent theories." *Id.* The majority did not address Broussard's distinction between Moore's situation where his treating physician knew about the special value of Moore's tissue and the far more common context where tissue is removed for diagnosis and banked for possible and unknown future research. *See id.* at 498–99 (Broussard, J., concurring and dissenting).

102. *Id.* at 483–84.

103. *Id.* at 484–85. Barbara J. Evans, *Waiving Your Privacy Goodbye: Privacy Waivers and the HITECH Act's Regulated Price for Sale of Health Data to Researchers* 5–6, 9 (Univ. of Hous. Law Ctr. Health Law & Policy Inst., Working Paper No. 2010-A-22, 2010), *available at* http://ssrn.com/abstract=1660582 (pointing out that current law allows IRBs to grant consent waivers for research on human tissue and health data collected as part of clinical care, and maintaining that our current law was created during a time when concerns were to protect subjects from interventional research, rather than protecting subjects from privacy concerns).

B. Catalona *and* Greenberg *are* Moore's *Progeny*

Moore paved the way for future cases like *Washington University v. Catalona*[104] and *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,[105] which characterized patient tissue, almost by definition, as gifts to the research institution, and ensured that the light stayed green for biobanking.[106]

Catalona, decided in 2007, is *Moore's* progeny, although citations to *Moore* are conspicuously absent in the appellate decision. *Moore's* conclusion that patients have insufficient property rights in their excised tissue to support conversion may explain its absence.[107] *Catalona* concluded that patient/subject's excised tissue was a valid inter vivos gift, defined by the court as "a voluntary transfer of property by the owner, without consideration or compensation as an incentive or motive for the transaction."[108] This conclusion required an acknowledgment that patients have some property interest in their tissue.[109] Unlike *Moore,* the issue in *Catalona* was about tissue in a biorepository.[110] Such tissue clearly had value, as evidenced by the existence of the dispute and the large numbers of amicus briefs.[111]

The *Catalona* facts took place in a research setting and subjects had given their informed consent for research on their excised tissue.[112] Still, the *Catalona* court could have followed *Moore* by focusing on the difference between tissue just excised (essentially valueless to the patient/subject, according to *Moore*) and tissue

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104. 490 F.3d 667 (8th Cir. 2007). The case involved a dispute between a powerful research institution and a well-known urologist/researcher who wanted to have his patients' banked tissue transferred from the biorepository at Washington University (WU) to his new place of employment, Northwestern University. *Id.* at 670, 672. Catalona sent a letter and release form to between 50,000 to 60,000 people asking that their tissue and blood samples be released to "Dr. Catalona at Northwestern University upon his request." *Id.* at 672. The release form also stated, "I have entrusted these samples to Dr. Catalona to be used only at his discretion and with his express consent for research projects." *Id.* About 6,000 people signed and returned the forms. *Id.* The appellate court held that the tissue was a valid inter vivos gift from patients to WU so that patients/subjects retained no sufficient ownership interest to direct or authorize transfer of tissue to another institution. *Id.* at 674. As *Moore* prevented an anticommons of each individual tissue donor increasing transaction costs to insurmountable levels, *Catalona* prevented a feudal system of researcher fiefdoms.

105. 264 F. Supp.2d 1064 (S.D. Fla. 2003).

106. *See id.* at 1074 (finding plaintiff's tissue and genetic information to be "donations to research" made to the institution); *see also Catalona*, 490 F.3d at 674 (finding the research participants intended to donate their biological materials to the institution).

107. *See* Moore v. Regents of Univ. of Cal., 793 P.2d 479, 489 (Cal. 1990) (Justice Panelli considering several factors but concluding that Moore's conversion claim fails because "the use of excised human cells in medical research does not amount to a conversion").

108. *Catalona*, 490 F.3d at 674.

109. *See id.* at 671, 673 (describing the right and ability of a research participant to transfer his or her tissue to a physician or medical technician, while holding that the research participant ultimately did not retain property interests in their donate tissue).

110. *Id.* at 670.

111. *Id.* at 667. Amici included John Hopkins, Mayo Clinic, Stanford, University of Rochester, Cornell, The Association of American Medical Colleges and Association of American Universities. *Id.*

112. *Id.* at 671.

in a biorepository.[113] This is so because, the work needed to create and maintain a biorepository gives value to banked tissue and information.[114] A single piece of tissue has negligible or no value, but gathered, organized, and annotated tissue has significant value.[115] It is the combinative information that makes a tissue bank valuable.[116] By describing the excised tissue as a gift, *Catalona*, like *Moore,* avoided a tissue anticommons.[117] Also like *Moore, Catalona* failed to recognize the unique quality of the tissue. Although both understood that tissue was important for biomedical research, neither case understood, or recognized, the tremendous public health value of the information held within the tissue, especially the statistical power of collective information.

Greenberg, decided before *Catalona,* is, as the federal district court described the case, "a tale of a successful research collaboration gone sour."[118] *Greenberg*'s facts are solidly and solely in a research setting,[119] but the opinion ignored its own description of the research being "collaborative." Judge Moreno failed to recognize any of the collaborating plaintiffs' contributions, dismissing five of the six causes of action, including conversion, lack of informed consent, and misappropriation of trade secrets, and only allowed the plaintiff's claim for unjust enrichment to

113. *See supra* notes 96–99 and accompanying text.

114. *See Catalona,* 490 F.3d at 670 (outlining the significant effort and funding required to maintain WU's biorepository).

115. Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005) (describing the monetary value of tissue stored in biobanks and the value to society through medical research of the tissue which could lead to the possibility of discovering new treatments for previously incurable ailments).

116. Park, *supra* note 4 (describing that biobanks have the potential to revolutionize medical treatment options because they contain a variety of tissue samples). The court could have explicitly used a contract analysis, and in fact, the *Catalona* court analyzed the case facts like a contract, looking at the language of the informed consent forms and placing significant value on the language in the genetic research information brochure. *Catalona*, 490 F.3d at 674–76. The court continued, adopting an unstated adverse possession analysis, by looking at Dr. Catalona's actions to determine whether patients retained any ownership interest, finding it "difficult to reconcile the use, consumption, and destruction of biological materials by Dr. Catalona and the events that occurred during the research process with the assertion the [research participants] retained an ownership interest in the donated materials." *Id.* at 676.

117. *Catalona*, 490 F.3d at 675–76. *See supra* notes 97–99 and accompanying text.

118. Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1066 (S.D. Fla. 2003).

119. *Id.* at 1066–68. The facts in *Greenberg* can be summarized as follows: Dan and Debbie Greenberg gave birth to two children diagnosed with Canavan disease, a rare, fatal, inheritable, and incurable genetic disease. *Id.* at 1066. They sought out Dr. Matalon to help research and find better ways to diagnose and treat the disease. *Id.* The family worked with Dr. Matalon to collect tissue and create a Canavan registry, which included information about the Canavan families. *Id.* Matalon successfully isolated the Canavan gene, and along with Miami Children's Hospital (MCH), patented the gene. *Id.* at 1067. MCH proceeded to exercise its patent rights and restricted the ability of various clinical labs to test for the gene, which impaired carrier and prenatal testing. *Id.* This was contrary to the intentions of the Canavan families who wanted their tissue and the registry information to be for the public good. *Id.*

continue.[120] The parties eventually reached a confidential out of court settlement.[121] In *Greenberg*, the tissue donor's property rights were found to "evaporate once the sample is voluntarily given to a third party," and, foreshadowing *Catalona*, the decision observed that the tissues "were donations to research without any contemporaneous expectations of return."[122]

Moore, *Catalona*, *and Greenberg* all minimize tissue donors' interests, reflect significant deference to medical research, and fail to understand and articulate the relationship between tissue and tissue's information.[123] All three cases avoided a tissue anticommons and strengthened the tissue research status quo. *Greenberg* and *Moore* distinguish between the patented product and the excised tissue based on the work done by the researcher to obtain the information, but neither recognized the donor's interest in or the value of the excised tissue.[124] *Catalona*, however, did implicitly recognize value to the excised tissue when it concluded the tissue was a valid gift.[125]

C. The Proposal to Ease the Common Rule's Consent Requirements for Tissue Research

The Common Rule, the federal law governing human subjects research, is applicable to all research institutions that accept federal funding.[126] Current interpretation of the Common Rule is that research on tissue, without personally

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120. *Id.* at 1070–77. Moreno reasoned that an informed consent claim was misplaced because, unlike *Moore*, the *Greenberg* facts were not in a clinical care setting and Florida law did not include a duty for researchers to disclose economic interests and other potential conflicts of interests because such a duty would be "unworkable and chill medical research" as well as "give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses." *Id.* at 1070–71.

121. Joint Press Release, Canavan Found. (Sept. 29, 2003), http://canavanfoundation.org/news/09-03_miami.php.

122. *Greenberg*, 264 F. Supp 2d. at 1074–75. *Greenberg* did not analyze whether the tissue transfer met the elements of an inter vivos gift, but instead stated only its conclusion. *Id.* at 1074.

123. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 673–75 (8th Cir. 2007) (finding that the research participant donated their biological materials as inter vivos gifts for the purpose of medical research); *Greenberg*, 264 F. Supp. 2d at 1070 (refusing to extend the informed consent to economic interests for fear that this will have a chilling effect on medical research); Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 488 (Cal. 1990) (declining to extend the liability theory of conversion because doing so would stifle future medical research).

124. Admittedly, it may be, as Russell Korobkin argues, that *Moore* established no more than a default rule for no compensation for patients and subjects who supply their human tissue, but it is a powerful rule that requires significant effort, cost and organization to circumvent. *See* Korobkin, *supra* note 29, at 3, 5–6. One example of a group successfully negotiating around the *Moore* baseline is a group, PXE International, providing researchers with tissue samples from patients with pseudoxanthoma elasticum in exchange for shared patent rights to the disease-causing gene. *See* Paul Smaglik, *Tissue Donors Use Their Influence in Deal Over Gene Patent Terms*, 407 NATURE 821, 821 (2000).

125. *See Catalona*, 490 F.3d at 674–75.

126. 45 C.F.R. §§ 46.101–.409 (2010). The FDA has a similar, but not identical, set of regulations that govern research under its oversight. Protection of Human Subjects, 21 C.F.R. §§ 50.1–.56 (2010).

identifiable information, is not within the scope of the rule and does not need informed consent.[127] However, obtaining identifiable private information, or identifiable specimens, for research purposes is human subjects research, but may be exempt,[128] or an Institutional Review Board (IRB) may waive informed consent requirements.[129] Some critics of the current regulatory regime argue that certain aspects are overly burdensome while others provide insufficient protections for research subjects.[130] Other critics maintain that confusing regulations impede tissue research.[131] The Office of Management and Budget recently put together a group to work on revising the Common Rule,[132] which has drafted an Advance Notice of Proposed Rulemaking asking for comments about how to clarify the requirements on tissue research and enhance protections.[133] The group proposes to require a simplified consent process for individuals to allow future unspecified research on tissue collected from them as part of clinical care or research.[134] The simplified

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127. *Guidance on Research Involving Coded Private Information or Biological Specimens*, DEP'T OF HEALTH & HUMAN SERVS., (Oct. 16, 2008), http://www.hhs.gov/ohrp/policy/cdebiol.html. *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, 336 (2006). The Office of Human Research Protections, which oversees IRBs and research subjects to the federal Common Rule, declared in 2004 that research on tissue that does not have personally identifiable information does not need to meet the informed consent requirements of the Common Rule, because it does not meet the definition of research on human subjects; however, it may be required under FDA rules and regulations. *Id.* at 336.

128. *See* 45 C.F.R. § 46.101(b)(4) (2010) (exempting "[r]esearch, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or the information is recorded by the investigator in such a manner that the subjects cannot be identified directly or through identifiers linked to the subjects").

129. *See* § 46.116(d)

> An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that: (1) The research involves no more than minimal risk to the subjects; (2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; (3) The research could not practicably be carried out without the waiver or alteration; and (4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Id.

130. *See* Ezekiel Emanuel & Jerry Menikoff, *Reforming the Regulations Governing Research with Human Subjects*, 365 N. ENG. J. MED. 1145, 1145 (2011) (discussing the burdensome bureaucratic procedures regarding research on human subjects); Ezekiel Emanuel et al., *Oversight of Human Participants Research: Identifying Problems to Evaluate Reform Proposals*, 141 ANNALS INTERNAL MED. 282, 282–89 (2004) (describing the inadequacies with the current regulatory regime).

131. Emanuel & Menikoff, *supra* note 130, at 1148.

132. *Id.* at 1145.

133. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44512 (proposed July 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, 164 & 21 C.F.R. pts. 50, 56).

134. *Id.* at 44522–24, 44527 tbl.1. Written consent could be for open ended future research and a standardized form would be made available. *Id.* at 44527 tbl.1. The requirement would only be prospective; current approaches for existing tissue would be acceptable. *Id.*

consent would be required regardless of whether the tissue research is identified or de-identified.[135] The proposal also focuses on data security and confidentiality and seeks to place secondary tissue research studies (tissue already collected or collected for clinical reasons) into a category "excused" from IRB review, provided it meets the strict security and confidentiality requirements.[136] The proposed revisions for tissue research emphasize the protection of the information and simplify, but still require, some informed consent; an approach apparently consistent with public opinion.[137]

Other federal laws, such as HIPAA[138] and GINA,[139] also impact biobanking and tissue research by focusing on information and privacy, and recognizing research exceptions.[140]

Current case law is consistent with patient/subject providers of tissue having no property interest,[141] but biobanks would be wise to understand that the legal

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135. *Id.* at 44525, 44527 tbl.1.

136. *Id.* at 44526.

137. *See generally* Christian Simon et al., *Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models*, 13 GENETICS IN MED. 821 (2011) (concluding, on the basis of public surveys and focus groups, that many individuals may want to make an informed choice before participating in a biobank).

138. 45 C.F.R. §§ 164.502(d)(2), .514(a) (2010). HIPAA's restrictions are also generally inapplicable to health information that is de-identified. *See* 45 C.F.R. § 164.514(a) (2010) ("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 recognizes that the research arena justifies disclosure without patient/subject authorization in some instances. *Id.* § 164.514(e) (stating that limited health information may be disclosed for research purposes if it is a limited data set and is released pursuant to a data use agreement between researcher and covered entity).

139. Genetic Information Nondiscrimination Act of 2008, 42 U.S.C. § 300gg–1 (Supp. III 2009). GINA or the Genetic Information Nondiscrimination Act prohibits discrimination in health coverage and employment based on genetic information. *Id.* § 300gg–53. GINA prohibits employers, health insurers or group insurance plans from requesting that an individual have a genetic test, but it has a "research exception" to allow such a request if it is part of research provided the Federal government is notified, the genetic information is not used for non-research purposes (i.e. underwriting) and the research complies with the Common Rule and applicable state regulations. *Id.* § 300gg–53(d)(4). Many states have laws protecting genetic information. *See, e.g.*, IDAHO CODE ANN. § 39-8303 (2011) (prohibiting employers from access or requesting genetic information to aid in connection with hiring, promotion or retention decisions); MASS. GEN. LAWS ANN. ch. 111, § 70G (West 2003) (prohibiting the testing of genetic material without first obtaining prior written consent); OR. REV. STAT. §192.537 (2011) (protecting an individual's genetic information as private information that must be protected from unauthorized disclosure or misuse).

140. *See* OFFICE FOR HUMAN RESEARCH PROTS., DEP'T. OF HEALTH & HUMAN SERVS., GUIDANCE ON THE GENETIC INFORMATION NONDISCRIMINATION ACT: IMPLICATIONS FOR INVESTIGATORS AND INSTITUTIONAL REVIEW BOARDS 1–3 (2009) (noting that GINA prohibits discrimination but also recognizes research exceptions); *see also* 42 U.S.C.A. § 2000ff–5(b)(2) (West Supp. 2011) (outlining how confidential genetic information should be treated).

141. *See* discussion *supra* Parts II.A.–B.

status of tissue is not codified;[142] new court decisions or changes in governing rules and regulations may significantly alter the legal landscape.

III. SHARED HUMAN TISSUE INFORMATION

This part will explore a new legal description of excised human tissue derived from an understanding of its unique attributes that places it in a space between private property, public property and intellectual property. Others have similarly argued that DNA is best described and treated as a common heritage,[143] or have maintained that tissue is best treated as informational property.[144] This part will also describe biobanking as having attributes of a semicommons and a liberal commons. It will evaluate how informed consent fits into the protection scheme for tissue information.[145] Finally, Part III will conclude that tissue information is best shared for the greater good, but recognizes that we need a legal framework that recognizes the differences and similarities between residual clinical tissue and biobanked tissue to maintain incentives and help make this work.[146]

A. The Context of a Tissue Biobank and Tissue Provider's Control

What legal rights describe a piece of excised human tissue? Not surprisingly, it depends.[147] Similarly, the value attached to a piece of human tissue also depends on how much information is attached to the tissue and whether the tissue is considered singly or as part of a large collective.[148] We can place tissue into a number of categories. First, an unimproved single tissue sample has little research value and will be legally considered an inter vivos gift from the originating person.[149] The second category is improved tissue, or tissue with additional

142. *See* John A. Robertson, *Ethical and Legal Issues in Genetic Biobanking*, *in* POPULATIONS AND GENETICS: LEGAL AND SOCIO-ETHICAL PERSPECTIVES 297, 298 (Bartha Maria Knoppers ed., 2003) (noting that many jurisdictions lack statutes addressing control of tissue and its genetic information).

143. *See* Pilar N. Ossorio, *The Human Genome as Common Heritage: Common Sense or Legal Nonsense?*, 35 J.L. MED. & ETHICS 425, 425 (2007) (analyzing the characterization of the "human genome as part of the common heritage").

144. *See* Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 172 (2009) (arguing that human tissue under an informational property regime would protect against unwanted use of cells).

145. *See infra* Part III.A–B.

146. *See infra* Part III.D.

147. *See* Rao, *supra* note 13, at 371 (noting that different legal rights attach to a person's body depending on whether the individual asserting the rights is an inventor, a scientist, or the owner).

148. *See* Charlotte H. Harrison, *Neither* Moore *nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 83 (2002) (noting that compensation for tissue samples would depend on its usefulness in research and development).

149. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 673–76 (8th Cir. 2007) (noting that where the donor of tissue manifests a present intent to make a gift, the tissue, by itself, is considered an inter vivos gift).

information.[150] This tissue may have clinical information, including perhaps outcome information, genomic information, and protein expression information.[151] The additional information represents a researcher's work and investment, making each piece more valuable, and hainv greater risk for privacy violations of tissue contributors.[152] Owners of this tissue, such as research institutions, have greater legal protections, including conversion.[153] Third is a collection of improved tissue, or a biobank.[154] Whereas each piece of tissue has value, the sum is of greater value than the whole.[155] It is a searchable database.[156] Numbers matter here, because larger numbers will allow greater statistical significance.[157] Similarly the legal protections are also greater and include the near exclusive property rights enjoyed by Washington University in *Catalona*[158] and potential unjust enrichment protections in *Greenberg*. The last category, now far removed from the original

150. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 492–93 & n.35 (Cal. 1990) (stating that the subsequent cell line and products are factually and legally distinct from the original cell material taken from the donor because they have been improved by "human ingenuity"). Although the tissue at issue in *Moore* or *Catalona* may seem to belong in the first category, the tissue better fits category two because it contained diagnostic information. Very little tissue fits in the first category because much of the tissue collected in the United States is tissue that is removed for diagnosis or treatment as part of clinical care and stored in pathology laboratories. This tissue may have tremendous clinical value to the patient because it may provide specific information about what therapeutic regime is best for the patient.

151. *See* Thomas F. Bumol & August M. Watanabe, *Genetic Information, Genomic Technologies, and the Future of Drug Discovery*, 285 JAMA 551, 551–52 (2001) (noting the use of genomic databases and protein identification in developing future drugs); Mildred K. Cho, *Understanding Incidental Findings in the Context of Genetics and Genomics*, 36 J.L. MED. & ETHICS 280 (2008) (stating that human genetic and genomic research produces clinically relevant information).

152. *See* David J. Kaufman et el., *Public Opinion About the Importance of Privacy in Biobank Research*, 85 AM. J. HUM. GENETICS 643, 644 (2009) (highlighting the privacy concerns of tissue donors); Ossorio, *supra* note 143, at 427, 435 (recognizing that treatments derived from research on human tissue is often based on "years of labor and millions of dollars of investment" and that these financial incentives may overcome social and moral interests).

153. *See Moore*, 793 P.2d at 492–93 (finding the cell line developed from Moore's tissue was patentable because of the difficult nature of the "long-term adaptation and growth of human tissues and cells").

154. *See* Silvana Bardelli, *Stem Cell Biobanks*, 3 J. CARDIOVASCULAR TRANSLATIONAL RES. 128, 128 (2010) (defining and explaining the attributes of biobanks).

155. *See* Jennifer E. Sanner & Lorraine Frazier, *Factors that Influence Characteristics of Genetic Biobanks*, 39 J. NURSING SCHOLARSHIP 25, 25–26 (2007) (noting the need to have a large and diverse collection of tissue samples to further information about clinical research).

156. *See, e.g.*, Peter H.J. Riegman et al., *OECI TuBaFrost Tumor Biobank*, 94 TUMORI 160, 160–61 (2008) (describing the OECI TuBaFrost biobank infrastructure which allows users to search the samples).

157. *See* Sanner & Frazier, *supra* note 155, at 25 (stating that research based on larger sample sizes will enable scientists to recognize the genetics responsible for an individual's susceptibility and response to medical treatment).

158. *See* Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 994 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007) (finding that Washington University exerted control over the biological materials); Scott F. Gibson, The Washington University v. Catalona: *Determining Ownership of Genetic Samples*, 48 JURIMETRICS 167, 181 (2008) (noting that WU exhibited "all indicia of ownership" in the biological materials).

excised, tissue but nonetheless still dependent on it, is the patented product, for example the cell line in *Moore*,[159] or the patented gene in *Greenberg*.[160] This category includes patents resulting from work done on biobanked material. The legal rights form a continuum dependent upon how much information and potential utility attaches to the tissue or tissue collections.[161] Legal rights increase and accrue to researchers and organizers of tissue, while tissue contributors remain largely ignored.[162] Current law lacks a coherent framework for describing and explaining this continuum of legal rights.[163]

Commentators have argued that current law fails to adequately protect the diverse interest of biobank tissue providers.[164] One commentator, Natalie Ram, identified four interests of tissue providers: control, confidentiality, commercialization and cure.[165] An interest in controlling the use of one's tissue, including the use of one's DNA, stems from respect for human dignity and autonomy.[166] This interest is currently addressed through informed consent, but questions remain about the adequacy and extent of informed consent.[167] Can people broadly consent for future research, or should future research be specified? When and how should subjects be re-consented? *Catalona* and *Greenberg* show the limits of informed consent's utility to further tissue providers' control.[168] Moreover,

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159. *See* Jasper Bovenberg, *Whose Tissue is it Anyway?*, 23 NATURE BIOTECH., 929, 929 (2005) (describing the court's finding that while the original cells were taken from Moore's body, the subsequent patented cell line was "factually and legal distinct" from the original cells).

160. *Id.* at 930.

161. *See* Roger A. Sedjo, *Property Rights, Genetic Resources, and Biotechnological Change*, 35 J. L. & ECON. 199, 208 (1992) (stating "[t]he increased ability to manipulate genes" would extend property rights associated with that tissue as a way of "protecting improved (rather than wild) genetic resources").

162. *See* Gibson, *supra* note 158, at 181, 185–86 (noting the decisions of *Moore*, *Greenburg* and *Catalona*, which indicate that tissue donors lose their property rights, and citing to subsequent comments from Professor Lori Andrews stating that the decisions "turn patients into treasure-troves rather than partners in research").

163. Current law regarding human tissue creates special categories and treats the tissue accordingly. For example, stem cells are given special status based on their potential for creating human life. *See* Exec. Order No. 13505, 74 Fed. Reg. 10,667 (Mar. 11, 2009) (recognizing the research potential of human stem cells). Transplant tissue is governed by a set of special rules. *See* National Organ Transplantation Act of 1984, 42 U.S.C. § 273 (2006) (limiting the availability of organs for transplantation to qualified nonprofit organ procurement organizations). Tissue stored in pathology labs is governed by CLIA. Clinical Laboratory Improvement Amendments of 1988, 42 U.S.C. § 263a (2006).

164. *See* Leslie E. Wolf, *Advancing Research on Stored Biologic Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J. L. SCI. & TECH. 99, 145–46 (2010) (advocating changing the current regulatory approach to biological materials in order to better protect the risks to and concerns of contributors of human tissue).

165. Ram, *supra* note 144, at 124–25.

166. *Id.* at 125.

167. *Id.* at 127–29.

168. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 673 (8th Cir. 2007) (holding that individuals do not retain an ownership interest in any biological materials that they voluntarily contribute after giving informed consent); Greenberg v Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1069–71 (S.D. Fla. 2003) (finding that Florida medical consent law does not apply to donors of

research may impact family members, or other people who did not consent, but who share genetic traits.[169] For example, inadequately authorized research on Havasupai tribe members' tissue disclosed that aspects of the tribe's origin beliefs were not scientifically verifiable.[170]

Respect for dignity and autonomy also requires that the interest in control include the right to withdraw tissue from current and future research.[171] It is in this setting that control and confidentiality conflict.[172] Anonymizing tissue protects confidentiality, but unidentifiable tissue can no longer be effectively withdrawn.[173] So, anonymizing tissue without the consent of the tissue provider conflicts with the provider's interest in maintaining control.[174] While informed consent in tissue research protects autonomy interests, it may not wholly protect the interests of tissue providers in controlling what happens to anonymized tissue.[175]

One alternative would be to offer tissue providers the option to waive their ability to withdraw their tissue, however the right to withdraw is well entrenched in our current law.[176] The Common Rule[177] and the Declaration of Helsinki[178] mandate that informed consent include the right to withdraw. Many people consider this right inalienable,[179] although the equation may change when the research is on already excised tissue rather than interventional research.

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experimental tissue and extending it would grant research subject control over the progress of medical research).

169. *See* Ram, *supra* note 144, at 129–30 (explaining how disclosing the results of genetic research may cause embarrassment or distress to close blood relatives).

170. *See* Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES, Apr. 22, 2010, at A1 (noting that research suggesting the tribe's ancestors arrived in North America from the Bering Sea clashed with ancient stories that the tribe had originated in the canyon). *See generally* Tilousi v. Ariz. State Univ. Bd. of Regents, No. 04-CV-1290-PCT-FJM, 2005 WL 6199562, at *3 (D. Ariz. 2005) (asserting that defendant used blood sample for research the tribe did not consent to, including "ancient human population migration").

171. *See* Wolf, *supra* note 164, at 154.

172. *See* Ram, *supra* note 144, at 132 (explaining that complete anonymization of tissue samples results in the donor being unaware of any ongoing research involving his tissue and eliminates the donor's right to withdraw).

173. *Id.*

174. *Id*

175. *Id.*

176. *See, e.g.*, Terrance McConnell, *The Inalienable Right to Withdraw From Research*, 38 J.L. MED. & ETHICS 840, 844–45 (2010) (discussing the inalienability of a subject's right to withdraw from medical research). *But see* Monique A. Spillman & Robert M. Sade, *Clinical Trials of Xenotransplantation: Waiver of the Right to Withdraw from a Clinical Trial Should Be Required*, 35 J.L. MED. & ETHICS 265, 268–69 (2007) (arguing that a patient's ability to waive their right to withdraw from continued monitoring after a xenotransplant is fundamental to the continuance of such procedures).

177. 45 C.F.R. § 46.116(a)(8) (2010).

178. WORLD MED. ASS'N DECLARATION OF HELSINKI, ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 3 (2008), *available at* http://www.wma.net/en/30publications/10policies/b3/17c.pdf.

179. *See* McConnell, *supra* note 176, at 845 (arguing for the inalienability of the right and asserting that others' arguments to the contrary are not convincing).

Another problem is that tissue may never be wholly made unidentifiable because of new advanced techniques.[180] Our current regulatory scheme recognizes greater protections for identifiable information in clinical and research settings.[181] HIPAA considers certain information "protected health information" (including genetic information) only if it is "individually identifiable."[182] But effective protections cannot rely on anonymizing tissue if tissue cannot be effectively de-identified.[183] Instead, we would have to rely on the security of information and enforcement of strict penalties for privacy violations.

Tissue providers often have an interest in improving treatment for themselves, their families, and the public.[184] Additionally, tissue research is most effective with attached information, some of which it can be used to identify a person.[185] Because of these two factors, there is an inherent tension between privacy interests and maximizing research efforts. This tension is not only between researchers and tissue providers but the interests of tissue providers may also be internally conflicting.[186] They may wish to maintain their privacy, and also wish to maximize the research benefits.[187]

B. The IOM Report Addresses Consent in Information Based Research

The interaction between an individual's interests in control and privacy, and the public's more general interest in maximizing the benefits of research is the subject of a recent Institute of Medicine (IOM) report, chaired by Lawrence Gostin, Sharyl Nass, and Laura Levit.[188] The report concluded that HIPAA inadequately

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180. *See* Amy L. McGuire & Richard A. Gibbs, *Genetics: No Longer De-Identified*, 312 SCI. 370, 370 (2006) ("[A]n individual can be uniquely identified with access to just 75 single-nucleotide polymorphisms."). *But see* Grigorios Loukides et al., *Anonymization of Electronic Medical Records for Validating Genome-Wide Association Studies*, 107 PROC. NAT'L ACAD. SCI. 7898, 7900, 7902–03 (2010) (reporting an approach to generating data that eliminates the threat of individual reidentification).

181. *See* 45 C.F.R. § 164.502(d)(1)–(2) (2010) (allowing the use of protected health information to be used to create de-identified health information, and once such information is not individually traceable, it can be used freely).

182. *See* 45 C.F.R. §§ 164.502(d)(2), .514(a) (2010) (stating that health information that is not individually identifiable, or is de-identified, is not subject to the protections of individually identifiable health information).

183. *See* McGuire & Gibbs, *supra* note 180, at 370–71 (explaining how protective measures are needed to prevent the compromise of public trust due to rapidly proliferating DNA sequencing methods that would render previously "de-identified" information identifiable).

184. *See* Ram, *supra* note 144, at 135

185. *Id.* at 136.

186. *Id.*

187. *See id.* at 133–34, 136 (arguing that tissue providers' interest in control and cure conflict with their interest in maintaining confidentiality, at least if confidentiality is obtained through de-identifying tissue).

188. *See generally* INST. OF MED., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 12–13 (Sharyl J. Nass et al. eds., 2009). *See also* Mark Rothstein, *Improve Privacy In Research By Eliminating Informed Consent? IOM Report Misses The Mark*, 37 J.L. MED. & ETHICS 507, 507, 509–10 (2009) (arguing that major flaws in the IOM's proposal

protects privacy, and impedes valuable information based research.[189] It advocates for a clear difference between interventional clinical research and information based research using medical records or stored tissue.[190] The IOM Committee report reasoned that consent requirements are less essential for information based research because consent requirements are "primarily considered a protection against physical harm," and it noted that, historically, "a great deal of information-based health research was conducted using personally identifiable health records without the informed consent of the persons whose records were used."[191] The report proposed that, instead of relying on consent, which, it argues, is poorly suited to protect privacy, the better approach is to directly strengthen and clarify privacy protections and improve security safeguards, including penalizing violators.[192] The report urged the Department of Health and Human Services (HHS) to expand information based research, and "[f]acilitate greater use of data with direct identifiers removed."[193] It foresaw information based research on a large scale, and a need for reliance on technology to protect subjects' interests.[194] The report advises HHS to "develop a mechanism for linking an individual's data from multiple sources such as databases so that more useful datasets can be made available for research in a manner that protects privacy, confidentiality, and security."[195]

According to the IOM report, the need to obtain informed consent hinders the ability to put together a large data network.[196] Informed consent is less important in the context of information based research because current approaches overvalue the ability of informed consent to protect individuals' interests.[197] Instead, we should strengthen effective privacy and security protections. Informed consent for information based research helps "ensure that individuals are able to exercise control over their personal information that is held by third parties, and to give individuals the right to determine whether their personal information can be used in a particular research project."[198] According to the report, participants should be allowed to consent for future information based research so long as an IRB

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to lessen informed consent requirements for human subject research include underestimating the risk to individuals, overvaluing research interests, and inadequate justification to eliminate informed consent for information based research).

189. INST. OF MED., *supra* note 188, at 16.

190. *Id.* at 264.

191. *Id.* at 247, 250.

192. *Id.* at 250, 257.

193. *Id.* at 264–265, 281.

194. *See id.* at 279 (applauding Congressional efforts to create a nationwide health information technology (HIT) system because such a system will facilitate health research, but cautioning Congress that privacy safeguards must also be developed).

195. *Id.* at 49.

196. *Id.* at 35.

197. *Id.* at 250.

198. *Id.* at 33.

approves, and the new study "is not incompatible with the original consent."[199] The creation of the new category of information-based research allows the IOM report to justify its divergence from the Nuremberg Code's specific and fundamental requirement that informed consent is essential in all research.[200] Information based research subjects' interests center on privacy, confidentiality, and control of their tissue.[201] In contrast, interventional research directly affects the subject's body and often impacts treatment choices; autonomy is more directly impacted.[202] Privacy and autonomy have similarities, but information based and interventional research impacts subjects differently, and informed consent is a better fit to protect the latter.[203]

Although Ram and Gostin's IOM Committee both describe a tension between confidentiality/privacy and control/consent in the setting of informational research,[204] they fundamentally differ in how to resolve the conflict. Ram proposes greater control for the tissue providers by granting them informational property rights in their tissue and pursuing a copyright and copyleft approach.[205] The IOM report, conversely, seeks to downplay the importance of individual consent but strengthen security protections to guard against misuse of private information.[206]

In summary, the IOMreport viewed current HIPAA and other applicable regulations as lacking the clarity and uniformity needed to effectively promote human research, especially information-based research, while meaningfully protecting privacy.[207] It emphasized that both privacy and health research are societal goods or public values,[208] and it carved out information-based research (including tissue research) as a category of research that invokes the advantages of scale and requires a protection scheme focused on privacy rather than the physical

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199. *Id.*

200. *See id.* at 124 (outlining the Nuremberg Code). Informed consent requires that a research subject is informed of key facts about the research and any risks or benefits it poses. *Id.* at 126. The IOM's recommendation that research subjects provide "future consent" for research diverges from the Nuremberg Code because subjects will not be informed of what the future research involves. *Id.* at 33.

201. *Id.* at 33.

202. *Id.* The report also finds that "all interventional research" should be subject to "strong security measures," which would include research that directly impacts treatment. *Id.*

203. *See* Louis Henkin, *Privacy and Autonomy*, 74 COLUM. L. REV. 1410, 1419 (1974) (explaining that privacy rights are rooted in the presumptive right to individual autonomy and a reflection of the American system of limited government). *See generally* Stephen Kanter, *The Griswald Diagrams: Toward a Unified Theory of Constitutional Rights*, 28 CARDOZO L. REV. 623 (2006) (providing background on the right to privacy).

204. INST. OF MED, *supra* note 188, at 35 (noting the tension between facilitating research and protecting personally identifiable health information); Ram, *supra* note 144, at 132 (explaining that anonymizing tissue samples to preserve patient privacy compromises the patient's interest in controlling the use of her tissues).

205. Ram, *supra* note 144, at 142, 145–52.

206. INST. OF MED., *supra* note 188, at 35.

207. *Id.* at 31–36.

208. *Id.* at 31, 77.

bodily integrity invoked by interventional research.[209] The researchers argued that these improvements are needed because the current uncertain and non-uniform privacy rules and overly stringent informed consent requirements hinder research and do not fully recognize the public health benefits of informational research.[210]

C. Biobanks and the Problem of a Tissue Anticommons

The IOM report described a tissue anticommons without using that specific term.[211] Tissue donors and IRBs have the potential ability to exclude researchers from using tissue that sits in tissue repositories.[212] This is not only because of uncertain and inconsistent regulations and interpretations of privacy and informed consent rules, but also because federal law gives tissue donors the right to withdraw tissue samples after consent.[213] The result leaves no one with an exclusive privilege to use a scarce resource, because multiple persons have a right to exclude. Although the term "anticommons" is more commonly used to criticize the current state of biotech patents, it appropriately describes biobanks because continued uncertainty about what legal rights govern human tissue in a biobank may limit downstream use.[214] The uncertainty of future consent, of when, whether, and what type of informed consent will be required, along with the variability of de-identified tissue, all combine to hinder tissue research without giving tissue contributors added protections or information.[215]

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209. *See id.* at 264–66 (advising Congress and agencies to develop a new approach to information-based research that focuses on best practices in privacy, including program certification mechanisms, and imposing real consequences for mishandling personally identifiable health information).

210. *Id.* at 16, 35.

211. *See id.* at 214–27 (finding that compliance with the Privacy Rule impeded researchers during an information-based research study because it deterred recruitment and fostered unwillingness to grant authorization waivers). "Anticommons" refers to the underuse of a resource because multiple owners prevent others from having a privilege to use it. Heller & Eisenberg, *supra* note 97, at 698.

212. INST. OF MED., *supra* note 188, at 223 (noting the difficulty at times for researchers to obtain a waiver of authorization).

213. *See id.* at 48 (noting HHS failure to provide clear guidance with regard to HIPAA's applicability to information relating to genetic material has created uncertainty in the research community); *see also* 45 C.F.R. § 46.116(a)(8) (2010) (requiring that research participants be notified of their right to discontinue participation).

214. *See* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1725 (1996) (describing an anticommons problem in biomedical research); Heller & Eisenberg, *supra* note 97, at 698 (warning that privatization of upstream biomedical research through patenting may create an anticommons that impedes subsequent research largely because of high transaction costs); *see also* J.H. Reichman & Paul F. Uhlir, *A Contractually Reconstructed Research Commons for Scientific Data in a Highly Protectionist Intellectual Property Environment*, 66 L. & CONTEMP. PROBS., Winter/Spring 2003, at 315, 319–20 (finding that new laws encouraging privatization and commercialization of scientific data disrupt the traditional custom of sharing data in the public domain).

215. Kapp, *supra* note 127, at 336–37 (noting the difficulty of providing generic consent for future research projects).

Indeed, *Moore* and progeny were concerned about creating a tissue anticommons, although they too did not use the term.[216] The *Moore* majority considered it an "important policy consideration" that they not create an environment where researchers ("innocent parties") were "threaten[ed] with disabling civil liability" that would result from having tissue with "uncertainty about clear title."[217] *Moore* noted that uncertainty about how courts will resolve legal rights in tissue might derail the "infant biotechnology industry" for academic researchers, and that the detrimental impact of uncertainty may extend to product development as well as research.[218]

Admittedly, tissue repositories seem different from Professor Heller's empty Moscow storefronts in his description of the tragic anticommons.[219] Enforcement actions for informed consent or privacy violations in tissue research are exceedingly rare.[220] The Common Rule does not mandate enforcement, and there is little active enforcement of the Common Rule and HIPAA regulations.[221] As seen with *Moore* and progeny, the few tissue donors who have asserted their rights have failed.[222] Therefore, "owners" of biobanks, whether they are academic medical centers, pharmaceutical companies, or some other organization, seem to have an effective privilege of use. Biobanks may seem a far distance from the empty Moscow storefronts, but IRBs, tissue researchers, and others remain confused, and there is significant variability in how and what kind of tissue research goes forward.[223] Moreover, too many patents in biomedical research likely chill and increase the cost of future research.[224]

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216. *See* discussion *supra* Part II.A–B.

217. Moore v. Regents of Univ. of Cal., 793 P.2d 479, 493, 94 (Cal. 1990).

218. *Id.* at 493.

219. *See* Heller, *supra* note 93, at 622–23. Heller defines anticommons as "a property regime in which multiple owners hold effective rights of exclusion in a scarce resource." *Id.* at 668 (emphasis omitted). He explains that multiple rights of exclusion are not necessary for the existence of an anticommons, informal rights may suffice. *Id.* at 669. Heller also points out that anticommons are tragic only when they lead to undesirable underuse, and that not all commons property is an anticommons. *Id.* at 677. *See also* Carol Rose, *The Comedy of the Commons: Custom, Commerce, and Inherently Public Property*, 53 U. CHI. L. REV. 711, 768 (1986) (stating that a "comedy of the commons," which is the reverse of the "tragedy of the commons," may lead to initial underinvestment).

220. *See* Ram, *supra* note 144, at 140–41 (noting that the Common Rule does not mandate civil or criminal enforcement, and the federal government has seldom imposed penalties for HIPAA violations with regard to information in genetic material).

221. *Id.* at 140 (citing Kendra Gray, *The Privacy Rule: Are We Being Deceived?*, 11 DEPAUL J. HEALTH CARE L. 89, 89 (2008)).

222. *Moore*, 793 P.2d at 496–97 (finding Moore did not retain a property interest in his excised cells). *See also* Wash. Univ. v. Catalona, 490 F.3d 667, 676–77 (8th Cir. 2007) (holding that the plaintiffs did not have a right to direct or authorize transfer of biological materials after donation); Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003) (finding that the tissues "were donations to research").

223. *See* Jennifer Girod & Katherine Drabiak, *A Proposal For Comprehensive Biobank Research Laws to Promote Translational Medicine in Indiana*, 5 IND. HEALTH L. REV. 217, 221 (2008) (noting inconsistencies between how the FDA and the Common Rule view IRB ability to waive written

The two recent lawsuits involving Texas and Minnesota's collections of blood spots for newborn screening illustrate the confusion and uncertainty surrounding tissue information based research.[225] Most states recognize an individual and public benefit to newborn screening programs and forego parental consent, opting instead for parental notification.[226] Some states destroy the blood spots after screening, but some store them for future research or quality control for their assays.[227] Texas had the largest blood spot repository in the US, and had given or sold blood spots for various research projects, including those conducted by universities, the

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informed consent); David A. Hyman, *Institutional Review Boards: Is This The Least Worst We Can Do?*, 101 NW. U. L. REV. 749, 772 (2007) (concluding that, even if judged by the standard of "least worst," IRBs "fall well short"); Jerry Menikoff, *The Paradoxical Problem with Multiple-IRB Review*, 363 NEW ENG. J. MED. 1591, 1591 (2010) (noting that the multiple IRB reviews of multi-center studies may decrease the likelihood that studies are following "relevant ethical standards"); Khadija Robin Pierce, *Comparative Architecture of Genetic Privacy*, 19 IND. INT'L & COMP. L. REV. 89, 104–05 (2009) (noting that tissue handling guidelines can be interpreted in inconsistent ways across IRBs); Mark A. Rothstein, *Expanding the Ethical Analysis of Biobanks*, 33 J.L. MED. & ETHICS 89, 93 (2005) (discussing IRB's difficulties with blanket consent for future research on patient/subject's tissue, which although allowed under the Common Rule, should consider patient's objections to particular types of tissue research).

224. Heller & Eisenberg, *supra* note 97, at 698 (arguing that too many owners of previous discoveries can "constitute obstacles to future research"); Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools and Standard Setting*, *in* 1 INNOVATION POLICY AND THE ECONOMY 119, 144 (Adam B. Jaffe et al. eds., 2001) (concluding that infringement actions in several fields creates considerable transaction costs which prevents the creation of new technology).

225. *See* Bearder v. State, 806 N.W.2d 766, 776 (Minn. 2011) (holding that newborn screening is an exception to the Genetic Privacy Act, but only when the Department has express authorization to test for congenital and hereditary conditions and does not provide for the Department to use the tissue samples for any other reason); Settlement Agreement and Release at 3, Beleno v. Lakey, No. SA-09-CA-188-FB (W.D.Tex. 2009) (outlining the settlement terms of a lawsuit between the Texas Department of Health Services and plaintiffs, including the destruction of tissue samples being stored by the Department of Health Services).

226. *See* Kenneth Mandl et al., *Newborn Screening Program Practices in the United States: Notification, Research, and Consent*, 109 PEDIATRICS 269, 272 (2002) (noting that the majority of state newborn screening programs surveyed required parental notification but not consent while some required neither consent nor notification); B.A. Tarini et al., *Not Without My Permission: Parents' Willingness to Permit Use of Newborn Screening Samples for Research*, 13 PUB. HEALTH GENOMICS 1, 3–4 (2009), http://www.cchfreedom.org/pr/tarini_biobanking%20paper_parent%20attitudes.pdf (finding that 76.2% of surveyed parents were "very or somewhat willing" to permit use of newborn screening samples for research if permission was received, 28.2% willing to without permission, and 78% of all respondents were willing to have samples stored); Bradford L. Therrell et al., *Committee Report: Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens After Newborn Screening*, 13 GENETICS MED. 621, 624 (2011) (noting the need for an informed consent process for state newborn screening programs).

227. *See* Mandl et al., *supra* note 226, at 271 (noting that some states retain blood spots after screening); *see also* TEXAS DEP'T OF HEALTH SERVS., *Use and Storage of Newborn Screening Bloodspot Cards*, *available at* www.dshs.state.tx.us/lab/nbsdestructiondirective.pdf (requesting parent or guardian authorization to destroy infant bloodspot cards); News Release, Minn. Dep't of Health, Minnesota Department of Health to Begin Destroying Newborn Blood Spots in Order to Comply with Recent Minnesota Supreme Court Ruling (Jan. 31, 2012) (describing the authorization given to the Minnesota Department of Health to begin destroying the stored blood samples of infants).

Department of Defense, and for-profit companies.[228] A class action suit was filed against the state of Texas, claiming that the State had exceeded its authority and violated both the U.S. and Texas Constitutions.[229] Texas argued that it had fully complied with HIPAA and the Common Rule in its use of the de-identified tissue; thus, had adequately safeguarded privacy interests.[230] Nonetheless, Texas settled the lawsuit and amended the applicable statute by implementing an opt-out or presumed consent provision for blood spots.[231] The statute retained newborn screening as mandatory, excepting religious objections, and provided for retention of the newborn blood spots.[232]

D. The Case for Public Ownership of Tissue Based Information

Using an approach similar to the public health centered IOM report, Marc Rodwin has argued for the public ownership of anonymized or de-identified patient data.[233] He begins by reminding us that patient information, commonly de-identified or anonymized, has poorly defined property interests, but is routinely bought and sold.[234] De-identifying patient data results in privatization, even if it is not clearly acknowledged as property by current law. This is a mistake because it "precludes forming comprehensive databases required for many of its most important public health and safety uses."[235] For Rodwin, the better way is for patient data to be publicly owned.[236] He proposes mandatory federal reporting of de-identified patient data to create aggregate data to promote "public health, patient safety, and research."[237] The data would still be available to private entities, which might analyze and sell results of their analysis.[238]

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228. Sandra J. Carnahan, *Biobanking Newborn Bloodspots for Genetic Research Without Consent*, 14 J. HEALTH CARE L. & POL'Y 299, 305 (2011); *Use of Newborn Screening Blood Spots After Completion of Newborn Screening*, TEX. DEP'T STATE HEALTH SERVS., http://www.dshs.state.tx.us/lab/nbsBloodspotsUse.shtm (last updated Apr. 26, 2011) (disclosing the previous research uses of the newborn screening bloodspot samples).

229. Complaint, Beleno v. Lakey, No. SA-09-CA-188-FB (W.D. Tex. 2009).

230. Order Regarding Defendants' Motion to Dismiss and Defendants' Motion to Dismiss or for Summary Judgment Based on Mootness, Beleno v. Lakey, No. SA-09-CA-188-FB (W.D. Tex. 2009).

231. *See* Settlement Agreement and Release at 3, Beleno v. Lakey, No. SA-09-CA-188-FB (W.D.Tex. 2009). *See also* Carnahan, *supra* note 228, at 308 (stating that the Texas statute was amended); TEX. HEALTH & SAFETY CODE ANN. § 33.011(a)–(c) (West 2010).

232. TEX. HEALTH & SAFETY CODE ANN. §§ 33.011, .012 (West 2010).

233. Marc A. Rodwin, *Patient Data: Property, Privacy & the Public Interest*, 36 AM. J.L. & MED. 586, 589 (2010). Rodwin notes that public ownership would better protect privacy and that there are many examples of the public health attributes of medical information, including the mandatory reporting laws and Medicare requirements for reporting cost data. *Id.* at 595–96.

234. *Id.* at 587–88.

235. *Id.* at 589.

236. *Id.*

237. *Id.*

238. *Id.*

Rodwin sets forth a two-pronged argument. First, the typical reasons favoring private over public ownership do not apply to patient data, and there is a tradition of state and federal reporting requirements for patient information.[239] Second, treating patient data as public property does not diminish privacy protections.[240] Risks are present whether private or public, and greater security measures are needed in either approach.[241] Current privacy protections for patient information are not based in patients having property rights in their health information, and the inability of patients to control resale of their information leaves them with an impotent either/or choice.[242] Public ownership of data may increase privacy protections because it has the added advantage of increased public oversight to ensure privacy guidelines are followed.[243]

Rodwin emphasizes the "well developed literature" that supports placing scientific information in the public domain.[244] Current norms, federal policies, the phenomenon of large networks, public health concerns, as well as the non-rival attributes of information, support the use of public property approaches in science and patient data.[245] Drawing on the work of Carol Rose and others, Rodwin argues that patient data is a public commons (with privacy safeguards) because aggregate patient data is like Rose's public roads, which are "most valuable when used by indefinite and unlimited numbers of persons—by the public at large."[246] Moreover, the many benefits of private property, such as incentivizing development, are less

239. *Id.* at 589–90.

240. *Id.* at 590. Rodwin emphasizes that he has in mind only de-identified and anonymized patient data, but one wonders how effectively patient data can be de-identified or anonymized while maintaining its value for useful comprehensive data. A. Cambon-Thomsen et al., *Trends in Ethical and Legal Frameworks for the Use of Human Biobanks*, 30 EUR. RESPIRATORY J. 373, 378 (2007) (noting that population databanks without participants' medical data are of little value to researchers and can lead to incorrect conclusions).

241. Rodwin, *supra* 233, at 590.

242. *See* Paul Schwartz, *Property, Privacy and Personal Data*, 117 HARV. L. REV. 2055, 2076–78 (2004) (identifying a market failure in personal information because the individual choice is either to refrain from disclosing any information or selling it with no ability to control whether third parties get access to their personal information). Although not specifically about health information, it is applicable in the health care information setting where such information must be routinely transferred for billing, reimbursement, and medical care purposes. *See* Pamela Samuelson, *Privacy as Intellectual Property?*, 52 STAN. L. REV. 1125, 1127 (2000) (noting that when individuals transfer property interest in data they lose control over its use and confidentiality, and even private data made public is no longer protected by trade secret law).

243. Rodwin, *supra* 233, at 614.

244. *Id.* at 597.

245. *Id.* at 597 & n.57, 598.

246. *Id.* at 599 (quoting Carol Rose to show that there is a longstanding acceptance of public ownership and that conditions exist where public ownership or a commons has advantages over private ownership). Rodwin does not, however, distinguish between the use of patient information itself and use of the resulting analysis. *See generally id.* Patient information would not be directly used by "indefinite and unlimited numbers of persons," but the results of analyzing the data would benefit the public. *Id.* at 599 (quoting Rose, *supra* note 219, at 774).

applicable in the context of patient information because such information is already routinely collected.[247] Privatizing patient information leads to prohibitive transaction costs for downstream inventions, with little benefit.[248]

There are important similarities between patient data and tissue-based information, but they are not interchangeable. Unlike the IOM report, Rodwin does not explicitly include tissue informational research in his analysis, although he mentions "the interest in data resembles, in part, that of research subjects in how their tissue or cells are used."[249] The similarities begin with both patient data (medical information) and tissue data having ill-defined and unclear legal ownership.[250] Secondly, both are fundamentally information.[251] Third, both would be collected regardless of improved, better defined or more private property oriented legal rules because routine patient care requires collection of information and tissue.[252] However, additional worthwhile work would require added incentives, whether the additional work is to aggregate patient clinical information or conduct research on tissue and analyze results.[253] Fourth, both have tremendous public health potential, but the public must maintain its trust and incentives must exist to gather and organize the data.[254] Lessons from Iceland,[255] Myriad[256] and the Framingham Study[257] show the importance of maintaining public trust.[258] Fifth, like

247. Rodwin, *supra* note 233, at 599.

248. *Id.* at 601.

249. *Id.* at 612 n.125.

250. *Id.* at 587 (describing the uncertain property rights associated with patient data). *See also* Ram, *supra* note 144, at 139–40 (noting the law governing tissue information has unclear requirements).

251. Ram, *supra* note 144, at 139–40; Rodwin, *supra* note 233, at 589.

252. Ram, *supra* note 144, at 136 (discussing how individuals provide tissue information in the course of routine patient care); Rodwin, *supra* note 233, at 590.

253. *See* Rodwin, *supra* 233, at 595 (discussing legislation that will offer physicians and medical facilities financial incentives to adopt electronic medical records and ultimately encourage the sharing of patient data).

254. *Id.* at 587, 601; Ram, *supra* note 144, at 137–38.

255. *See* Gísli Pálsson, *The Rise and Fall of a Biobank: The Case of Iceland*, *in* BIOBANKS: GOVERNANCE IN COMPARATIVE PERSPECTIVE 41, 46 (Herbert Gottweis & Alan Petersen eds., 2008) (noting that Iceland's Health Sector Database's opposition focused on potential violations of the patient-physician trust presented by the presumed consent aspect of the project).

256. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329, 1334 (Fed. Cir. 2011) (upholding the Myriad company's patents on two human genes and the validity of gene patents in general); *see also* Andrew Pollack, *Despite Gene Patent Victory, Myriad Genetics Faces Challenges*, N.Y. TIMES, Aug. 25, 2011, at B1 (discussing the challenges that Myriad will face as a business and how the company previously shared information about particular mutations increasing risk of cancer, but recently opted to treat such information as trade secrets).

257. *See* Eric Niiler, *Collapse of Framingham Data Deal Highlights Lack of Cooperative Model*, 19 NATURE BIOTECH. 103, 103 (2001) (noting that attempts to analyze and sell data from the Framingham heart study data was unsuccessful because of privacy and commercialization concerns of participants); *see also* Christopher Heaney et al., *The Perils of Taking Property Too Far*, 1 STAN. J. L. SCI. & POL'Y 46, 55–56 & n.64 (2009).

258. *See* Heaney et al., *supra* note 257, at 55–56 (noting the public relations disaster Myriad faced in the wake of its scandal that was detrimental to the public's trust). Trust is also an important factor in

patient data, granting individual donors' property rights introduces the risk of anticommons and does not offer the typical advantages true for other types of private property.[259]

The most apparent difference between patient and tissue information is that patient information and tissue-derived information are non-rival, but the tissue itself is rival.[260] Tissue can be exhausted. Admittedly there are millions of tissue samples, but tissues from people with less common diseases remain scarce.[261] If a researcher uses all this tissue for a poorly designed project, there may be a social cost. In addition to the potential personal costs of a damaged reputation, there will be significant costs in replacing the scarce tissue so that others can use it. Tissue information, in contrast, is non-rival.[262] Once produced, it can be used by many people with no added cost.[263] There is a continuum between classic private property, such as a chair, and a perfect or inherent public good like Rose's public park. On one end of the spectrum is a rival and wholly excludable good, and on the other is a non-rival and non-excludable good. Tissue information is non-rival and partially non-excludable.[264] Tissue is partially rival (typically there is enough for more than one researcher), but exhaustible, and it is excludable. However, despite clear differences between tissue and tissue information, the two remain inexorably interrelated and each gains value as more information is added.[265]

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explaining the different rates of participation in clinical research between minority and non-minority groups in the U.S., especially African Americans. *See, e.g.*, Patricia G. Moorman et al., *Racial Differences in Enrolment in a Cancer Genetics Registry*, 13 CANCER EPIDEMIOLOGY BIOMARKERS & PREVENTION 1349, 1350 (2004) (finding statistically significant lower enrollment of African American women in a cancer registry compared with enrollment of white women); *see also* Giselle Corbie-Smith et al., *Distrust, Race, and Research*, 162 ARCHIVES INTERNAL MED. 2458, 2460 (2002) (noting that in a national sample African-Americans were less trusting than white Americans in regards to their willingness to participate in research).

259. Ram, *supra* note 144, at 122 & n.17.

260. *See supra* text accompanying note 26 (stating rival means "others cannot use it if you are"); *see also* Yochai Benkler, *An Unhurried View of Private Ordering in Information Transactions*, 53 VAND. L. REV. 2063, 2066 (2000) (noting that information is generally understood to be nonrival); Anne Cambron-Thomsen, *The Social and Ethical Issues of Post-Genomic Human Biobanks*, 5 NATURE 866, 871 (2004) (noting that the storage conditions of tissue samples in biobanks do not allow for multiple use).

261. *See* Andrews, *supra* note 97, at 3 (discussing the extraordinary range of human tissue sources available to researchers); *see also* Cambron-Thomsen, *supra* note 260, at 867 (2004) (noting that in order to deal with the limited supply of certain tissues gathering multiple samples from one individual may be necessary to reach an appropriate sample size for a given study).

262. Benkler, *supra* note 260, at 2066.

263. *See* MaryAnn Labant, *Biobank Diversity Facilitates Drug & Diagnostic Development*, GENETIC ENG'G & BIOTECHNOLOGY NEWS, Jan. 15, 2012, http://www.genengnews.com/gen-articles/biobank-diversity-facilitates-drug-diagnostic-development/3983/ (noting that virtual biobanks provide greater access to tissue samples).

264. Eric M. Meslin & Ibrahim Garba, *Biobanking and Public Health: Is a Human Rights Approach the Tie That Binds?*, 130 HUMAN GENETICS 451, 459 (2011).

265. Cambon-Thomsen et al., *supra* note 240, at 866–67.

IV. BIOBANKS AS A LIBERAL SEMICOMMONS

A. How a Biobank Best Fits the Description of a Liberal Semicommons

Biobanks contain human biospecimens and associated annotative information.[266] They are comprised of tissue and tissue information.[267] The interaction between tissue, information, and large numbers of both brings value.[268] These attributes make biobanks a semicommons, defined by Henry Smith as "exist[ing] where property rights are not only a mix of common and private rights, but both are significant and can interact."[269] Tissue is rival and amendable to being treated as private property, typically, as in *Catalona* and *Greenberg,* owned by the entity administering the tissue repository.[270] Tissue information, in contrast, is non-rival and often shared within a group that can be described as a commons, such as a university or research co-operative.[271] Describing biobanks as a semicommons recognizes the interaction between the tissue and the information derived from the tissue. By accurately describing biobanks as a semicommons, we can improve our understanding of how to best govern them.[272]

A commons is not open access.[273] A successful commons, Ostrom and others have taught, has rules about entry and management.[274] Importantly, Dagan and

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266. *Id.* at 866.

267. *See* Martin Asslaber & Kurt Zatloukal, *Biobanks: Transnational, European and Global Networks*, 6 BRIEFINGS IN FUNCTIONAL GENOMICS & PROTEOMICS 193, 193–95 (2007) (describing different types of biobanks and the various tissues and information stored).

268. *See* Cambon-Thomsen et al., *supra* note 240, at 866–87 (illustrating that as the size of the collection increases so does the scientific value).

269. Smith, *supra* note 27, at 131.

270. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 670 (8th Cir. 2007) (holding that Washington University was the private owner of the genetic materials in question because they satisfied the requirements of Missouri law as the entity owning the facility, indicating that tissue can be treated as private property); Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1074–75 (S.D. Fla. 2003) (discussing the plaintiff's failed conversion claim and how the tissue is owned by the research institution, not the individual, after it is donated).

271. *See* Meslin & Garba, *supra* note 264, at 459 (describing genetic information as non-rival).

272. Recognition of the dual nature biobanks is suggested by Yochai Benkler's description of a continuum between wholly excludable goods and public goods. *See generally* Benkler, *supra* note 260. He wrote: "Every good can be defined on a spectrum between a perfect economic good—which is rival and excludable, and a perfect public good—which is nonrival and nonexcludable. Information is generally understood to be perfectly nonrival and partially nonexcludable." *Id.* at 2066.

273. *See* Carlisle Ford Runge, *Common Property Externalities: Isolation, Assurance, and Resource Depletion in a Traditional Grazing Context*, 63 AM. J. AGRIC. ECON. 595, 596 (1981) (distinguishing a commons from open access property).

274. *See* ELINOR OSTROM, GOVERNING THE COMMONS: THE EVOLUTION OF INSTITUTIONS FOR COLLECTIVE ACTION 90 (1990) (emphasizing the principles of past successful commons to include "[c]learly defined boundaries," "[m]onitoring," and "[m]inimal recognition of rights to organize"). Ostrom and others first described and studied natural resources as they applied to the commons. *Id.* at 2 (referencing the Garret Hardin's theory of the commons based on cattle herders). Many have expanded and adjusted the approach. *See, e.g.*, JAMES M. ACHESON, CAPTURING THE COMMONS: DEVISING INSTITUTIONS TO MANAGE THE MAINE LOBSTER INDUSTRY 8–11 (2003) (describing elements of a

Heller emphasize that we need not choose between the liberty offered by private property approaches and the strict cooperation mandated by a commons.[275] The "liberal commons" is a "participatory commons regime that also allows members the freedom to come and go."[276] Their notion of a liberal commons recognizes the ability of members to enter and withdraw from the commons without jeopardizing the continued successful operation of the commons.[277] Under the model of a liberal commons, patients/subjects may withdraw consent for use of their tissue at any time, which protects subjects' interests, promotes trust, and respects ethical norms.[278] One can, therefore, describe biobanks as having attributes of Henry Smith's semicommons with aspects of Dagan and Heller's liberal commons.[279] No other description accurately accounts for the interaction between tissue and the information derived from the tissue.

B. Governing Biobanks as a Liberal Semicommons

We could treat all excised tissue not as private property but as common property. Under this model, a large pool of researchers would have a right to use excised tissue. This may address the concern that privatization leads to commodification, but it does not change the potential for profit by institutions while individuals who provided the tissue receive no financial benefit, and it does not recognize any tissue provider interests.[280] Some research would improve because of greater access to larger numbers of samples, but excised tissue is a limited natural resource, and researchers would use it up quickly for both well and poorly designed studies because there would be little cost, and significant potential

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commons). Relying on previous work by Ostrom, Gardner, and Walker, Acheson classified Maine's lobster fishery, which is a renewable resource but subject to over-fishing, as a common pool resource. *Id.* at 11. The fisheries are controlled for the benefit of the fishery, as well as the general public, which continues to be able to eat lobster. *Id.*

275. Dagan & Heller, *supra* note 27, at 553.

276. *Id.*

277. *Id.*

278. *See* Lori Andrews, *Who Owns Your Body? A Patient's Perspective on* Washington University v. Catalona, 34 J.L. MED. & ETHICS 398, 402, 404 (2006) (explaining that research subjects in *Catalona* had the right to withdraw their tissues and that current research practices and ethical regulations support patient consent and foster trust between the researcher and the patient). Andrews also discusses why it is important for courts to consider "the right of a patient to make decisions concerning the products of their own bodies for diagnostic treatment and research purposes." *Id.* at 405. *See also* Dagan & Heller, *supra* note 27, at 566–67 (defining characteristics of a liberal commons).

279. *See supra* text accompanying notes 269, 277.

280. *See* 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, 300 (2004) (explaining that human tissue is already commodified, despite the fact that the subject does not receive benefits while researchers and shareholders of biotech firms profit); Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 389 (2004) (noting that it is a misunderstanding to think that by not compensating donors you are avoiding commodification); Rao, *supra* note 13, at 371 (noting that currently everybody but the person who provides the "raw materials" participates in the commercialization and commodification of the body).

benefits.[281] It would be like putting extra cows on the commons. An open tissue commons would introduce the problems described by Garrett Hardin in his famous 1968 article, *Tragedy of the Commons*: "Freedom in the commons brings ruin to all."[282]

For a limited natural resource, the ungoverned commons leads to overuse and under-investment, but the tragedy can be averted.[283] There must be some ability to exclude for the prudent utilization of tissue. One method, championed by Harold Demsetz and others, is for individual privacy rights to internalize the negative externalities present in a commons, thereby avoiding the tragedy.[284] This is the approach suggested in *Catalona,* where the court granted the University strong property rights in the banked tissue.[285] But there are many ways to govern or manage a resource like tissue short of privatization.[286] Elinor Ostrom has helped us understand that those using a common natural resource can govern its use, as long as the commons meets certain design requirements.[287] For Ostrom, the well-functioning commons has a strong limit on alienability (rights to the commons cannot be transferred outside of the commons) along with a system of sanctions,

281. *See* Asslaber & Zatloukal, *supra* note 267, at 194–97 (explaining the research benefits to different types of biobanks and the impact on drug research and development requiring large numbers of samples to be statistically significant). *See, e.g.*, Martin Yuille et al., 11 CELL & TISSUE BANKING 241, 243–44 (2010) (describing the UK DNA Banking Network's method of using "fair access" instead of "open access" to biobanked materials to ensure the long-term availability of samples to the researchers who submit investigation proposals with the best goals, limiting the researchers who would squander the finite natural resources).

282. *See* Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243, 1244 (1968). Hardin, a professor of biology, argued that the incentives of a commons are such that each individual will continue to over-use the commons to the determent of others. *Id.* Things held in common, like water and air should be, therefore, regulated to prevent abuse. *Id.* at 1245 (describing how water and air show the tragedy of the commons through pollution and that coercive laws or taxing devices can be used to regulate this type of commons). So, too, Hardin argues, the "freedom to breed" should be limited by educating people about the dangers of the commons. *Id.* at 1244–46, 1248.

283. *See id.* at 1244–45 (highlighting the theory of overuse and under-investment and that education is a means to avoiding the tragedy); Elinor Ostrom et al., *Revisiting the Commons: Local Lessons, Global Challenges*, 284 SCI. 278, 278, 281 (1999) (explaining that over the years people no longer believe the tragedy is inevitable and that theory is being reassessed based on scholarly discussions of the conditions most likely to produce a successful commons).

284. Harold Demsetz, *Toward a Theory of Property Rights*, 57 AM. ECON. REV. 347, 348–56 (1967). *But see* Samuelson, *supra* note 242, at 1127–29 (discussing the benefits and shortcomings of treating personal data as property, particularly in the context of cyberspace).

285. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 670, 673–74, 676 (8th Cir. 2007) (holding that the university is in full ownership of the donated biological materials).

286. *See* Ostrom et al., *supra* note 283, at 279 (listing successful alternatives for governing common pool resources, such as group property rights, individual property rights or governmental property rights); *see also* Gardner M. Brown, *Renewable Natural Resource Management and Use Without Markets*, 38 J. ECON. LITERATURE 875, 890 (2000) (explaining that a private property rights system is the best option "only when it pays to do so").

287. *See* OSTROM, *supra* note 274, at 15, 18, 90.

community participation, and forums for discussions about management.[288] Ostrom and others concentrated on the management of natural resources, but recently scholars have extended Ostrom's approach to information and knowledge-based goods.[289] Together, this prior work gives guidance on how to govern natural resources like excised tissue and information derived from the tissue in order to create a well functioning commons.[290]

A biobank is more than only tissue. It is also information derived from tissue.[291] As mentioned, biobanks inexorably combine non-rival information with rival, potentially excludable tissue, and both ideally gain greater value and usefulness over time.[292] Tissue information can be shared with others for much less than it costs to initially obtain the information, and there is public benefit to making the tissue information widely available.[293] The potential problem is that there may be little concrete economic benefits to create the tissue information if there is no ability to exclude another's use. All one has to do is wait until another researcher does the work and then get a free ride.

Avoiding this free rider problem and providing incentives is one justification for creating intellectual property rights so that the producers of the product can exclude others, make money through licensing, and recoup costs.[294] There are, however, disadvantages with this approach. Enforcing exclusion is expensive,

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288. *Id.* at 90 tbl.3.1. Ostrom did not require shared normative beliefs for members for the common's survival. *Id.* In contrast, Michael Taylor says stable membership requires normative beliefs beyond their collective action. *See* Dagan & Heller, *supra* note 27, at 564 (comparing the view of both Ostrom and Taylor and describing that for Taylor "a community is a more or less stable set of members with some shared beliefs, including normative beliefs and preferences beyond those constituting their collective action problem, who expect to continue interacting with one another . . . and whose relations are direct . . . and multiplex").

289. *See* Michael J. Madison et al., *Constructing Commons in the Cultural Environment*, 95 CORNELL L. REV. 657, 670–71 (2010) (discussing the utility of applying Ostrom's approach to intellectual property).

290. *See id.* at 703–04 (providing guidance regarding governance mechanisms in a constructed commons, emphasizing "formal access to public sanctioning and/or enforcement mechanisms" in achieving effective self-governance); OSTROM, *supra* note 274, at 90 (articulating design principles that are common to robust CPR institutions that can be used as guidance for other similar institutions).

291. Jordi Camí & Jaume Bertranpetit, *The Promising Future of Biobanks: Building a Global Perspective, in* GENOMICS REVOLUTION: RESHAPING VACCINE DEVELOPMENT & DELIVERY 119 (2005) ("Biobanks are large collections of biological specimens (tissue and blood samples) and individual information intended for increasing knowledge and research.").

292. *See supra* text accompanying notes 264–65.

293. *See* Labant, *supra* note 263 (noting the cost-effectiveness and public benefits of biobanks); Andrews, *supra* note 115, at 23 (describing the benefits and uses of biobanks throughout the world).

294. Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1024–25 (1989); Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, L. & CONTEMP. PROBS., Winter/Spring 2003, at 289, 295 ("[W]ithout patents to permit pricing in excess of marginal cost, no one would be motivated to incur R&D expenses that were vulnerable to appropriation by free riders . . . ."). *See also* Sinclair & Carroll Co., Inc. v. Interchemical Corp., 325 U.S. 327, 330–31 (1945) ("The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences.").

which will raise the price of the information, and lead to underuse and suboptimal social benefit.[295] Also, in the context of biobanking, datasets are presumed not to be subject to copyright, although publications analyzing and drawing conclusions from the data are subject to copyright.[296] The challenge is typically not collecting data, but making meaningful use of the data. Moreover, the free rider problem may be minimal in the setting of tissue information. Researchers are driven by personal ambition, peer recognition, promotion, generosity, reciprocity, and other social motivations. Grants and prizes implicitly recognize the public good of tissue information and fund much tissue research.[297] Being "first to market" offers marketing benefits to commercial interests.[298] And on a larger scale, spillovers or externalities enhance social welfare.[299] Easily obtained, cheap information will lead to more information, not less.[300]

A semicommons has its own set of potentially destructive incentives. A biobank semicommons, with its combination of tissue and tissue information, potentially combines the worst of both private property and commons. In a commons lacking governance, the incentives are to overuse and under-invest, with members of the commons enjoying short-term benefit without investment.[301] Researchers may strategically overuse tissue and administrators may strategically

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295. *See* James Grimmelmann, *The Internet Is A Semicommons*, 78 FORDHAM L. REV. 2799, 2811 (2010); Niva Elkin-Koren, *Copyright Policy and the Limits of Freedom of Contract*, 12 BERKELEY TECH. L.J. 93, 99–100 (1997). *See generally* Henry E. Smith, *Intellectual Property as Property: Delineating Entitlements in Information*, 116 YALE L.J. 1742 (2007) (discussing advantages and disadvantages of governance and exclusion for defining intellectual property rights and comparing within this context copyright and patent law).

296. *See* Feist Publ'ns, Inc. v. Rural Tel. Serv. Co., Inc., 499 U.S. 340, 352 (1991) (noting that prior to this decision some federal courts had extended copyright protection to unoriginal data compilations on a "sweat of the brow" theory); *see also* Jane C. Ginsburg, *Creation and Commercial Value: Copyright Protection of Works of Information*, 90 COLUM. L. REV. 1865, 1868–69 n.13–14, 1895–1900 (1990) (citing cases where courts found works copyrightable due to the amount of labor expended by the plaintiff and discussing the history of "sweat work" as the basis for copyrightability); 17 U.S.C. §102(b) (2006) ("In no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery, regardless of the form in which it is described, explained, illustrated, or embodied in such work.").

297. *See, e.g.*, John Giardina, *Federal Grants to Fund Tissue Regeneration Research*, UCONN TODAY BLOG (Feb. 8, 2012), http://today.uconn.edu/blog/2012/02/federal-grants-to-fund-tissue-regeneration-research/ (illustrating that the NIH has provided grants to support tissue research).

298. *Cf.* Marvin B. Lieberman & David B. Montgomery, *First-Mover Advantages*, 9 STRATEGIC MGMT. J. 41, 46 (1988) (demonstrating that in the commercial context, the "first to market" gains advantages with consumers with regard to their preferences and perceptions that often allows them to gain a larger share of the market).

299. Brett M. Frischmann & Mark A. Lemley, *Spillovers*, 107 COLUM. L. REV. 257, 266 (2007) (arguing that spillovers are common as evidenced by how no inventor has ever captured all of the social benefits of his or her invention). Innovation spillovers promote further innovation, as evidenced by the success of the Silicon Valley in contrast to Boston's Route 128. *Id.* at 270.

300. *See id.* (demonstrating how increased information led to greater innovation in Silicon Valley).

301. Ostrom et al., *supra* note 283, at 278.

direct tissue use, while under-investing in tissue and database upkeep.[302] Freely available tissue information may benefit some commercial free riders operating independently of the peer incentives described above; however, a biobank semicommons may be worthwhile because allowing multiple users broad access will increase productivity, and better recognize both the public health and tissue donor interests.[303]

Our current landscape consists of hundreds or thousands of diverse tissue repositories, many in research universities, but some in pharmaceutical companies, government agencies, or commercial tissue banks.[304] Tissue may be collected for one purpose and left unused thereafter.[305] Some university pathology departments have tissue extending back more than 50 years.[306] Small, disorganized tissue repositories have little value and little research potential. At best, we change this hodgepodge into a federation of repositories that together make up a national networked biobank where those who use the tissue must give back the information they have gained from the tissue samples they use, thereby increasing the value and usefulness of the biobank. Such a federation of tissue repositories would create a biobank with a linked, vibrant, and growing database.[307] This approach would extend to tissue research what Gostin's IOM report envisioned for other information-based research, namely linking multiple sources "so that more useful datasets can be made available for research in a manner that protects privacy, confidentiality, and security."[308]

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302. *See id.* (stating that the level of overuse has contributed to "central government control of all common-pool resources").

303. The trick is to achieve the best balance between access and incentives. *See* Glynn S. Lunney, Jr., *Reexamining Copyright's Incentives-Access Paradigm*, 49 VAND. L. REV. 483, 485 (1996) (discussing the access versus incentives compromise at the heart of most policy discussions about patents and about intellectual property); *see also* Elizabeth Weeks Leonard, *The Public's Right to Health: When Patient Rights Threaten the Commons*, 86 WASH. U. L. REV. 1335, 1385 (2009) (identifying a "commons of biomedical research" as part of the public health interest).

304. Andrews, *supra* note 115, at 23.

305. *See* Alayne R. Brisson et al., *Translational Research in Pediatrics: Tissue Sampling and Biobanking*, *PEDIATRICS*, Jan. 2012, at 153, 154 (illustrating how prospective sample collections use tissues for particular research purposes and remaining portions are kept for future research).

306. Matthew A. Smith et al., *Evaluation of Integrity, Regulatory Compliance, and Construction of Searchable Database from Print Reports*, 135 AM. J. CLINICAL PATHOLOGY 753 (2011) (describing how some biospecimen are kept for fifty years).

307. *See* NAT'L CANCER INST., NATIONAL BIOSPECIMEN NETWORK BLUEPRINT 7–9 (Andrew Friede et al. eds., 2003) [hereinafter BLUEPRINT] (envisioning a national biospecimens repository that employs standardized procedures for storage and distribution, streamlines the collection and analysis of biospecimen samples, allows for extensive sharing of specimens, and is accessible to researchers at public and private institutions throughout the country).

308. INST. OF MED., *supra* note 188, at 11. *See* Peter H. J. Riegman & Evert-Ben van Veen, *Biobanking Residual Tissues*, 130 HUM. GENETICS 357, 357 (2011) (noting that the collection of samples and data must be completed in a standardized way and that regulation on the use of tissue recognizes donors' interests).

Under this approach, and compatible with current case law, repository tissue would still be "owned" by the university, pharmaceutical company, or whatever entity is responsible for maintaining the tissue and the database,[309] but they would have only a few small sticks of the proverbial bundle. As a biobanking semicommons, member researchers would have access to all relevant tissue and datasets to enable greatest effectiveness.[310] Membership would span across university, pharmaceutical, and public institutions.[311] This places strong limitations on the tissue "owners" ability to exclude, but would not preclude reasonable use fees.[312] In keeping with Henry's notion that "[t]he solution to a semicommons is usually a governance regime rather than exclusion rules,"[313] evolving rules, regulations, and norms, including those already in place like IRBs, would govern tissue distribution, and ensure privacy interests, although additional privacy safeguards are likely needed.[314] Recent federal initiatives, like the cancer Human Biobank (caHUB), are consistent with this approach, and federal funding acknowledges the public health interests in biobanking.[315] A public-private approach is important to maintain incentives for the upkeep of tissue.[316]

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309. *See* Wash. Univ. v. Catalona, 490 F.3d 667, 673 (8th Cir. 2007) (holding that donors do not retain an ownership interest in biological materials); Greenberg v. Miami Children's Hosp. Research Inst., Inc., 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003) (holding that individuals do not own their tissue samples); Moore v. Regents of Univ. of Cal., 793 P.2d 479, 489 (Cal. 1990) (holding that individuals do not have an ownership interest in their cells after the cells have been removed from their bodies); *see also* Karen J. Maschke, *Biobanks: DNA and Research*, *in* FROM BIRTH TO DEATH AND BENCH TO CLINIC: THE HASTINGS CENTER BIOETHICS BRIEFING BOOK 11, 13 (Mary Crowley ed., 2008) (noting that institutions often own the "biospecimens stored in their repositories").

310. *See* Smith, *supra* note 27, at 131 (defining a semicommons); *see, e.g.*, ELISA EISEMAN ET AL., CASE STUDIES OF EXISTING HUMAN TISSUE REPOSITORIES: "BEST PRACTICES" FOR A BIOSPECIMEN RESOURCE FOR THE GENOMIC AND PROTEOMIC ERA 158 (2003) (providing an example of a current research network composed of over forty academic research centers and twelve private industry partners where all participants have access to the biobank database).

311. *See, e.g.*, EISEMAN ET AL., *supra* note 310, at 22–23 (describing a collaborative relationship between pharmaceutical companies, academic institutions, government and companies in the biotech industry).

312. *See, e.g.*, Henry E. Smith, *Governing the Tele-Semicommons*, 22 YALE J. ON REG. 289, 299 (2005) ("In a semicommons, those with access to the commons cannot easily be excluded from its privately owned attributes."); *see also* EISEMAN ET AL., *supra* note 310, at 117 (noting that the University of Pittsburgh Health Sciences Tissue Bank provides researchers reserves some tissue for pilot projects, but also maintains a fee structure for additional specimens).

313. Smith, *supra* note 312, at 294.

314. *See* EISEMAN ET AL., *supra* note 310, at 128 (noting that, in addition to IRB oversight, all of the repositories in the case study protect the confidentiality of patients through guidelines, policies, and procedures); *see also* INST. OF MED., *supra* note 188, at 98–99 (noting that the Institute of Medicine recommends that all institutions involved in the collection, use, and disclosure of patient-identifying information take measures to safeguard the security of health data, such as appointing a security officer on IRBs and Privacy Boards, using encryption and encoding techniques, and implementing a breach notification requirement).

315. *See* OFFICE OF BIOREPOSITORIES & BIOSPECIMEN RESEARCH, DEP'T OF HEALTH & HUMAN SERVS., NCI BEST PRACTICES FOR BIOSPECIMEN RESOURCES 1, 6 (2011) (identifying guiding principles for biospecimen resources in an effort to promote biospecimen quality and support adherence to ethical

Tissue information, in contrast, would be a pure commons within the biobanking semicommons. De-identified information, inexorably tied to its tissue, would be available to all members of the semicommons, which would include researchers and tissue donors.[317] Confidentiality and privacy would be protected through stringent security measures, and tissue would still be identifiable (coded, at minimum) so that when a tissue donor wants to withdraw their tissue sample, the tissue and its information can be found and destroyed.[318] A record of consent, withdrawal of consent, documentation of tissue destruction, and whether the tissue donor wanted all or only future tissue information destroyed would be maintained.[319]

Public-private biobanks are not new,[320] and previous undertakings provide valuable lessons. For example, Iceland's Parliament granted a license to DeCODE

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and legal obligations); *The Cancer Human Biobank*, NAT'L CANCER INST., http://cahub.cancer.gov/about/ (last visited Apr.18, 2012). The National Cancer Institute developed the Cancer Human Biobank "in response to the critical and growing need for high-quality, well-documented biospecimens for cancer research." *Id.* The caHUB initiative builds on the NCI Best Practices for Biospecimen Resources. *Id.*

316. *See* Winickoff, *supra* note 7, at 445 (noting that the U.K. Bank has adopted a public-private model, which promotes research, honors the intent of the donors, and welcomes a form of public ownership). Public-private joint ventures are increasingly common in biotech. *See, e.g.*, Peter Lee, *Toward a Distributive Commons in Patent Law*, 2009 WIS. L. REV. 917, 974–76 (2009). The 1986 Federal Technology Transfer Act authorized cooperative research and development agreements between NIH and pharmaceutical companies for joint venture research and development. *Id.* at 974. Taxol, an effective anticancer drug that was developed by NIH and Bristol-Myers Squibb, was developed through a NIH-pharmaceutical joint venture. *Id.* at 975. Despite controversy over the pharmaceutical company getting the better end of the Taxol deal, the GAO and others have noted that the drug has benefited many cancer patients and has a tremendous public health benefit. *Id.* at 976.

317. *See* BLUEPRINT, *supra* note 307, at 44 (noting that all users, including government, industry and academia would have access to de-identified information "associated with the biospecimens" in the National Biospecimen Network.

318. *See, e.g.*, EISEMAN ET AL., *supra* note 310, at 128, 185, 187. At least one repository has implemented security measures, such as password protection, encryption, and firewalls, to protect privacy and confidentiality. *Id.* at 128. A case study reflected that all repositories evaluated within the study use an IRB to oversee practices. *Id.* at 185. Some also rely on separate bioethics advisory committees to ensure privacy and confidentiality. *Id.* The best practice in the area of rights to tissue is to allow a donor to withdraw his consent and to have the tissue and computer records removed from the repository, provided the tissue is identifiable. *Id.* at 187. *See* INST. OF MED., *supra* note 188, at 99 (advocating for heightened privacy measures).

319. *See, e.g.*, UNIV. OF OXFORD, OXFORD MUSCULOSKELETAL BIOBANK: STANDARD OPERATING PROCEDURE WITHDRAWAL OF DONOR CONSENT 6, 8 (2011), weblearn.ox.ac.uk/access/content/group/1850f869-33c4-4df1-af6b-d1d1e59c4401/documents/OMB-MSOP%20024%20Withdrawal%20of%20Donor%20Consent%20V2.0.pdf (stating that the donor's withdrawal of consent must be recorded in the donor's medical records and including templates entitled "notification of sample destruction and data deletion" and "notification to researcher of donor withdrawal").

320. *See, e.g.*, Lee, *supra* note 316, at 990 (noting that Iceland got a population-based biobank in 1996); *see* Helen Swede et al., *National Population-Based Biobanks for Genetic Research*, 9 GENETICS MED. 141, 142 (2007) (noting that deCODE Genetics, a private company, partnered with the Icelandic Parliament to create and operate the world's first population-based biobank, Icelandic Health Database).

genetics to construct a Health Sector Database (HSD) that combined genealogies in the public domain, health care data with presumed consent, and blood sample data with informed consent.[321] Although initially popular, 90 percent of Gallup-polled Icelanders supported the HSD, the initiative eventually failed because of concerns about property, control, informed consent, and privacy since a single commercial interest, DeCODE, had privileged access and interest in biobanked material and information.[322] Critics objected to the use of patient's health care data with only presumed consent.[323] Such use interferes with a patient's ownership and control of information that belongs to individuals and the public, but not a private enterprise.[324] Treating biobanks as a liberal tissue semicommons addresses this problem.

Some of the attributes of a tissue bank semicommons exist in the Cancer Genome Atlas (TCGA), which started in 2006 with $50 million dollar investments each from the National Cancer Institute (NCI) and the National Human Genome Research Institute (NHGRI).[325] The project recognized the advantages of a national network of researchers pooling efforts, leveraging scale and infrastructure, and making data freely and openly available.[326] It created a data portal that provides an open platform for researchers to search, download, and analyze data generated by TCGA.[327] The project includes a "Biospecimen Core Resource," which operates as a centralized biobank.[328] It also invested significant resources for software development (freely available), because it recognized that new technologies produce immense amounts of data, and meaningful analysis is critically important.[329] However, the lessons show that semicommons governance should

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321. George J. Annas, *Rules for Research on Human Genetic Variation – Lessons from Iceland*, 342 NEW ENG. J. MED. 1830, 1831 (2000); Jeffrey R. Gulcher & Kari Stefansson, *The Icelandic Healthcare Database and Informed Consent*, 342 NEW ENG. J. MED. 1827, 1827 (2000).

322. Gulcher & Stefansson, *supra* note 321, at 1827; David E. Winickoff, *Genome and Nation: Iceland's Health Sector Database and Its Legacy*, Innovations, Spring 2006, at 80 80–81.

323. *See* Annas, *supra* note 321, at 1830–31 (arguing that the general rule regarding consent does not apply to medical records that cannot be connected to a particular patient); Gulcher & Stefansson, *supra* note 321, at 1827 (noting that "[s]ome argue that presumed consent is inconsistent with the right of individuals to decide for themselves and actually amounts to no consent at all").

324. *See* Kenneth Gundle, *Presumed Consent: An International Comparison and Possibilities for Change in the United States*, 14 CAMBRIDGE Q. HEALTHCARE ETHICS 113, 116 (2005) (noting that one of the objections to presumed consent is that it does away with individual autonomy and deprives people of the right to control their own bodies).

325. *See Program Overview—The Cancer Genome Atlas*, NAT'L CANCER INST., http://cancergenome.nih.gov/abouttcga/overview (last visited Apr. 18, 2012).

326. *Id.*

327. *See The Cancer Genome Atlas—TCGA Data Portal Overview*, NAT'L CANCER INTS., http://tcga-data.nci.nih.gov/tcga/tcgaHome2.jsp (last visited Apr. 18, 2012).

328. *See Biospecimen Core Resources—The Cancer Genome Atlas*, NAT'L CANCER INST., http://cancergenome.nih.gov/abouttcga/overview/howitworks/bcr (last visited Apr. 18, 2012).

329. *See* Press Release, Nat'l Inst. of Health, The Cancer Genome Atlas Funds for Technology Development, (July 2, 2007) (noting that NIH was awarded $3.4 million to fund innovative technologies for understanding the molecular basis of cancer).

include consent by tissue contributors to allow that their excised tissue can be used for research, and that they have the ability to withdraw their tissue and their tissue information.[330] The consent would include an acknowledgment that the tissue is not wholly anonymous and that the tissue, and tissue information could be used for unspecified future research, subject to withdrawal. The consent would also include notification that tissue information already utilized in research analysis could not be withdrawn, although it could likely be retrospectively anonymized. Tissue contributors would be members of the tissue semicommons and have access to secured de-identified data.[331] With this information they could participate in debates about tissue use, and perhaps track how researchers have used their tissue. Such an approach is consistent with the direction proposed by the current working group that is looking at how to reform the Common Rule, which governs most (but not all) research today, and it is also consistent with current approaches to clinical information, which give patients the right to access their medical record.[332]

C. Questions Raised

The liberal semicommons approach raises many questions. For example, how might this new approach impact intellectual property derived from work on biobanked tissue? Gene patents remain controversial, as illustrated by the discussions surrounding the recent *Myriad* case about the patentability of the BRCA gene.[333] Treating tissue and tissue information as a semicommons is

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330. *See* EISEMAN ET AL., *supra* note 310, at 132, 144 (noting that concerning tissue repositories, informed consent, a process that educates and provides information to the participant about the details of the research, is crucial for protecting the interests and rights of research participants, and it is best practice to allow the withdrawal of consent).

331. *Cf.* BLUEPRINT, supra note 307, at 44 (proposing that de-identified tissue information could be made available through a secure web-based platform). Some people may be concerned that tissue contributors may misinterpret data, but most of the data produced would not provide clear answers and recent controversy about direct to consumer DNA information suggests that such fears may be overstated. *See* Cinnamon Bloss et al., *Effect of Direct-to-Consumer Genomewide Profiling to Assess Disease Risk*, 364 N. ENG. J. MED. 524, 532 (2011) (noting that a recent survey of participants in a direct-to-consumer DNA test study suggests that such fears may be overstated).

332. *See supra* text accompanying notes 132–37 (discussing the current working group); *see also supra* text accompanying notes 126–27 (defining the common rule); *see, e.g.*, Paul V. Stearns, *Access to and Cost of Reproduction of Patient Medical Records: A Comparison of State laws*, 21 J. LEGAL MED. 79, 99 (2000) (noting that patients have a right to access their medical records). Generally patients, providers, hospitals and other institutions that provide medical services have access to patient medical information. *Id.* Patients have a right to obtain copies of their medical records and may have their medical records transferred to another physician. *Id.*; *see* Mark A. Hall & Kevin A. Schulman, *Ownership of Medical Information*, 301 JAMA 1282 (2009) (observing that, while patients have the right to access, clinicians are owners of patients' medical records).

333. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (upholding the patentability of the BRCA gene, mutations of which significantly increase the risk of breast and ovarian cancer in persons who have the mutated gene). *But see* Andrew Pollack, *Patent on Test for Cancer is Revoked by Europe*, N.Y. TIMES, May 19, 2004, at C3 (noting that the European

consistent with the Justice Department's[334] tempering approach in *Myriad* and better recognizes the community of tissue donors, patients, researchers, academic institutions and pharmaceutical companies.[335] A recent Supreme Court decision, *Board of Trustees of Leland Stanford Jr. University v Roche Molecular Systems, Inc.*,[336] emphasized that the Bayh-Dole Act does not change the fact that individual inventors, not universities, retain a central and often primary position in patenting.[337] The case reinforced the importance of agreements between universities and their scientists.[338] This may be an opportunity for universities to promote a semicommons approach that would increase the public benefit. Aligning intellectual property law with the tissue semicommons is consistent with the patent system's Constitutional objective to "promote the Progress of Science and the Arts,"[339] because it would minimize the tissue and patent anticommons, promote research and the trust of tissue donors, and benefit the public good.

Perhaps the biggest objection to a liberal semicommons approach to biobanking would fall along privacy concerns.[340] Current privacy protections are insufficient.[341] In addition, the recent Supreme Court decision, *Sorrell v. IMS Health, Inc.*, which extended commercial speech protections to pharmaceutical

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Patent Office revoked a U.S. biotechnology company's patent on a breast cancer genetic test because there was not enough incentive to meet the patent protection qualifications).

334. Brief for the United States as Amicus Curiae in Support of Neither Party at 12, 17–18, Ass'n for Molecular Pathology v. U.S. Patent and Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011) (No. 2010-1406) (arguing that isolated genomic DNA is not patent-eligible). *Cf.* Ed Silverman, *US Tells the WHO to Support a Patent Pool*, PHARMALOT (Jan. 20, 2011, 11:03 AM), http://www.pharmalot.com/2011/01/us-tells-the-who-to-support-a-patent-pool/ (noting that the U.S. is supporting patent pools for HIV drugs in certain settings). *But see* Ed Silverman, *The Patent Pool for AIDS Meds Lacks Drugmakers*, PHARMALOT (Dec. 16, 2010, 8:07 AM), http://www.pharmalot.com/2010/12/the-patent-pool-for-aids-meds-lacks-drugmakers/ (noting that pharmaceutical companies are less than enthusiastic about NIH's licensing of an HIV drug to UNITAID).

335. *See* Heaney et al., *supra* note 257, at 60 (noting that biobanks can ensure that all stakeholders' opinions regarding issues including regulation, benefits and uses of tissue, by including them in consultative practices).

336. 131 S. Ct. 2188 (2011).

337. *Id.* at 2195–97.

338. *Id.* at 2195, 2199.

339. U.S. CONST. art. I, § 8, cl. 8; *see* Sinclair & Carroll Co., Inc., v. Interchemical Corp., 325 U.S. 327, 330–31 (1945) ("The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences."). *Contra* Lab. Corp. of Am. Holdings v. Metabolite Labs, Inc., 548 U.S. 124, 126 (2006) (Breyer, J., dissenting) ("[S]ometimes *too much* patent protection can impede rather than 'promote the Progress of Science and useful Arts.'").

340. *See* Robert Pear, *Tighter Medical Privacy Rules Sought*, N.Y. TIMES, Aug. 23, 2010, at A11 (noting that criticism from groups like the Privacy Rights Clearinghouse, which estimates that over "five million people have been affected by breaches of medical information in the last 18 months," have prompted the Obama administration and Congress to act to strengthen privacy safeguards); *see also* INST. OF MED., *supra* note 188, at 12; Emanuel & Menikoff, *supra* note 130, at 1145.

341. *See* INST. OF MED., *supra* note 188, at 65–66; *see also* Emanuel & Menikoff, *supra* note 130, at 1145.

detailing profiles of physician prescribing information (patient information de-identified), further blurs how to legislate privacy protections.[342] Sorrell shows how information has monetary value, physician prescription information is clearly valuable to pharmaceutical companies, and tissue biobank information also has monetary value.[343]

Much of the rich body of scholarly work about how to protect informational privacy in the internet age applies to biobanks as semicommons. Some information privacy scholars object to using property interests to safeguard private information because property gives the right to freely buy and sell (it is freely alienable), leading to market failures and inadequate privacy protections.[344] Others, like Professor Paul Schwartz, advocate the use of property interests as the best way to protect private information, although they acknowledge the necessity of strict limitations, including limiting alienability and recognizing that privacy is a public good.[345] The property framework offered by a biobank semicommons would strengthen tort law's ability to set a "baseline" for privacy and confidentiality protections.[346] A liberal semicommons approach to biobanked tissue is a tempered property approach that may capitalize on some of the advantages of using property to protect privacy and allow individuals greater control over "their" information, but the details of the additional needed privacy protections need further work.

V. CONCLUSION

Constructing biobanks as a liberal semicommons would shift the theoretical underpinnings of the role of consent and be in line with the direction of the recent

342. *See* Sorrell v. IMS Health, Inc.,131 S. Ct. 2653, 2659 (2011) (striking down a Vermont law that restricts the sale, disclosure and use of records that reveal physicians' prescribing methods, because it was in violation of the First Amendment and hindered the right to free speech in aid of pharmaceutical marketing); *see also* Kevin Outterson, *Higher First Amendment Hurdles for Public Health Regulations*, 365 N ENG. J. MED e13(1), e13(3) (2011) (noting that *Sorrell* extends First Amendment commercial speech protections to public health regulations, although federal privacy statutes like the Health Insurance Portability and Accountability Act are safe from First Amendment challenges).

343. *See Sorrell*, 131 S. Ct. at 2659–60 (observing that to maximize profits, pharmaceutical salespersons promote high-profit drugs to targeted physicians they foresee being interested in prescribing them).

344. *See* Samuelson, *supra* note 242, at 1138 ("Free alienability works very well in the market for automobiles and land, but it is far from clear that it will work well for information privacy."); *see also* Schwartz, *supra* note 242, at 2076 (discussing how existing markets for privacy lead to undesired results and market failures).

345. Schwartz, *supra* note 242, at 2057, 2076–85 ("[A] strong conception of personal data as a commodity is emerging in the United States, and individual Americans are already participating in the commodification of their personal data.").

346. Ram, *supra* note 144, at 174 ("[T]ort 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.").

proposal to revise the Common Rule[347] and recent research efforts that recognize the tremendous importance of bio-informatics.[348] *Moore* and progeny's emphasis on autonomy give little protection to tissue providers' interest in creating the current landscape where tissue donors typically either consent to tissue use or decline.[349] The shift toward stronger confidentiality and privacy protections, as well as greater individual control of personal information, is a more fine-tuned, narrowly-tailored approach. Of course, many questions remain, and the details of how to govern the liberal semicommons biobank requires further thought and work, and will evolve within the complex context of biobanks and public opinion.[350]

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347. *See* Emanuel & Menikoff, *supra* note 130, at 1149 (discussing the working group to revise the Common Rule to provide for improved oversight procedures); *see also supra* text accompanying notes 126–27.

348. *See, e.g.*, Press Release, NIH News, *supra* note 329 (noting that grants were awarded to fund the genomic basis of cancer).

349. *See* discussion *supra* Part II.

350. Smith, *supra* note 295, at 1796.

> Which degrees of exclusion and governance are called for and how best to manage a semicommons are empirical questions. Recitation of the benefits of open access in terms of nonrivalness or the benefits of entitlements in terms of incentives tells us very little about the shape those entitlements should take or the forms of protection they should receive. If we are to have property rights, why are they not very thin sticks to engage in very specific uses? If someone invents a new compound, why would a patent cover all uses instead of pre-identified ones (fuel-additive, lubricant, etc.)? If the public domain is important why don't we specify the public rights stick by stick?

Id.