Towards a Public Human Tissue Trust

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TOWARDS A PUBLIC HUMAN TISSUE TRUST

Currently, major research institutions, graduate medical education programs, and the federal government store over two hundred million human tissue samples available for use in biomedical research.¹ This human tissue archive continues to increase at a rate of approximately twenty million samples per year.² But who “owns” this tissue: the institutions that store it, the researchers who use it, or the research participants who voluntarily provide it? Any adequate response to this question requires striking the best balance between two pressing policy goals: (1) the need to ensure biomedical progress; and (2) the need to protect the right to informed consent. Recent court decisions all vest ownership in research institutions, while legal academics tend to favor vesting ownership in research participants. The door remains open to vest ownership in researchers via the proper contractual arrangements. For reasons stated extensively below, each of these options proves lacking. Instead, this Note aims to show that the creation of a public human tissue trust affords the best option to policymakers.

In Part I, this Note provides an in-depth survey of the relevant case law. Part II discusses the equal importance of the above policy goals and why vesting exclusive ownership in either research institutions, researchers, or research participants fails on policy grounds. Part III explores the nature, mechanics, and scope of the proposed public revocable charitable human tissue trust. Part IV proffers a public

² Id. at 133.
tissue trust as the best policy solution to protect the right to informed consent. In Part V, this Note concludes by briefly addressing the commercialization issues raised in Moore v. Regents of the University of California and Greenberg v. Miami Children's Hospital Research Institute, Inc.

I. CASE LAW

The case law here is quite sparse. Very few courts have addressed the issue of human tissue ownership. Four cases stand out: Moore, Greenberg, and the district court and appellate court decisions in Washington University v. Catalona. This section presents a brief overview of each case. Moore deserves particular attention, as it serves as the source of almost every major policy position in the debate.

A. Moore

In Moore, the Supreme Court of California notably refused to find that a conversion action lay with a patient whose tissue was the source of a valuable cell line. John Moore argued that “defendants’ unauthorized use of his cells constitute[d] a conversion.” While the court recognized a cause of action concerning an alleged violation of Moore’s right to informed consent, the court reversed the court of appeal’s judgment recognizing the validity of Moore’s conversion claim. The majority concluded that Moore simply did not “retain[] an ownership interest” in tissue excised from his body.

In 1976, Moore had developed hairy-cell leukemia and sought treatment at the UCLA Medical Center under Dr. David Golde. Golde advised Moore to undergo a splenectomy to slow down the progress of the disease. Unbeknownst to Moore and prior to his surgery, Golde contacted researcher Shirley Quan about using portions of Moore’s spleen for possibly lucrative medical research. Both Golde and Quan “were aware that certain blood products and blood components were

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3 Karen Gottlieb raises the possibility of a tissue trust in a short, insightful article but provides a précis as opposed to a completed proposal. See Karen Gottlieb, Human Biological Samples and the Laws of Property: The Trust as a Model for Biological Repositories, in STORED TISSUE SAMPLES: ETHICAL, LEGAL, AND PUBLIC POLICY IMPLICATIONS 182 (Robert F. Weir ed., 1998).

4 793 P.2d 479 (Cal. 1990).


7 Moore, 793 P.2d at 487.

8 Id. at 489.

9 Id. at 481.
of great value in a number of commercial and scientific efforts.”

The proposed research activities involving Moore’s tissue were of no therapeutic benefit to Moore, but “neither Golde nor Quan informed Moore of their plans to conduct this research or requested his permission.”

Moore proved to be an “overproducer” of T-lymphokines, a chemical released by white blood cells that aids in the fighting of bacterial infections. Isolating the genetic material that formed the basis for the production of T-lymphokines was heretofore “akin to a search for the proverbial needle in a haystack.” Due to Moore’s overproducer status, however, Golde and Quan were able to create a T-lymphokine producing cell line from Moore’s excised spleen tissue.

Until 1983, Moore made several visits to the UCLA Medical Center from his home in Seattle. During these visits, Golde took additional tissue from Moore, primarily in the form of blood and bone marrow aspirate. Moore consented to these procedures under the assumption that the visits were necessary for his medical well-being. In fact, Golde and Quan, with full knowledge of the Regents, were actively engaged in commercial biomedical research using Moore’s tissue. In 1981, the Regents initiated a patent application for Moore’s cell line and listed Golde and Quan as the inventors. In 1984, the Patent Office granted the application. The Regents then entered into a series of lucrative licensing agreements with various pharmaceutical companies. As of 1990, market analysts calculated the potential value of products developed from the Moore cell line at approximately three billion dollars.

In 1983, Golde requested that Moore sign a consent form granting the University of California “any and all rights [Moore or his heirs] may have in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained from

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10 Id. (internal quotation marks omitted).
11 Id.
12 Id. at 490–91 n.30.
13 See MOSBY MEDICAL ENCYCLOPEDIA 478 (revised ed. 1992) (for the definition of lymphokin).
15 See id.
16 See Moore, 793 P.2d at 481.
17 Id. at 481–82.
18 Id. at 482.
19 See id.
20 WEIR & OLICK, supra note 14, at 157.
Moore refused. Upon Golde's repeated requests that he sign the consent form, Moore contacted an attorney who subsequently discovered the existence of the cell line and patent application. On September 11, 1984, Moore filed suit alleging numerous causes of action. The trial court sustained defendants' demurrers across the board, with special emphasis on the purportedly defective conversion allegations. On the matter of conversion, the court of appeal reversed. On defendants' appeal, the California Supreme Court addressed two issues: (1) Golde's alleged violation of Moore's right to informed consent, and (2) the defendants' alleged conversion of Moore's excised tissue.

In its discussion, the court found for Moore on the first issue. Specifically, the court held that the doctrine of informed consent for medical procedures required Golde to disclose his ongoing research and financial interests to Moore. Such disclosure should have occurred both prior to Moore's splenectomy and during his subsequent visits to the UCLA Medical Center. The court reasoned that "a physician who does have a preexisting research interest [in a patient] might, consciously or unconsciously, take that into consideration in recommending [a] procedure." As such, "the physician's extraneous motivation may affect his judgment and is, thus, material to the patient's consent." Importantly, however, the court found that only Golde, as Moore's treating physician, could engage in the alleged violation of Moore's right to informed consent. The Court thus sustained the trial court's demurrers for the other defendants in this regard.

Moore, famously, did not prevail on the second issue. In denying Moore any ongoing "proprietary interest" in his excised cells, the Court explicitly refused to extend conversion theory into the realm of human tissue ownership. Justice Panelli, writing for the majority, provided three ostensible reasons under existing law for why this was the case: (1) no precedent supported Moore either directly or by analogy; (2) California public health statutes severely constrained the possession of bio-hazardous materials; and (3) Moore could

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21 Id. (second alteration in original) (quoting Patient's Informed Consent—John Moore, in 7 BIOTECHNOLOGY L. REP. 425 (1988)).
22 See Moore, 793 P.2d at 482–83.
23 Id. at 483.
24 Id. at 484.
25 Id.
26 Id. at 486–87.
27 See id. at 493.
28 Id. at 489–91.
29 Id. at 491–92.
assert no proprietary interest in the Regents’ patent and the products thereby derived because Moore contributed nothing more than “naturally occurring raw materials.”

Ultimately, however, the majority opinion turned on policy concerns. While stopping short of a direct prohibition on excised tissue ever counting as property, Justice Panelli argued at length that extending conversion theory in Moore’s favor would undermine “socially important medical research.” The majority feared that granting research participants/patients ongoing proprietary interests in their excised tissue could cripple the biomedical industry: “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.” The majority further noted that rigorous enforcement of the right to informed consent offered the best protection for Moore’s interests. This option avoided interfering with biomedical progress because it assigned no ongoing proprietary interests to Moore. Hence, to safeguard “the socially useful activities of innocent researchers,” the court denied Moore’s attempt to state a cause of action for conversion.

In his concurrence, Justice Arabian eschewed much of the majority’s instrumentalism and relied upon a much more deontological vein of reasoning. He found Moore’s attempt to secure the validity of a conversion action was an affront to the inherent worth and dignity of every human being. To wit, “Plaintiff has asked us to recognize and enforce a right to sell one’s own body tissue for profit. He entreats us to regard the human vessel—the single most venerated and protected subject in any civilized society—as equal with the basest commercial commodity.” On these grounds alone, Justice Arabian argued, the court must deny the validity of Moore’s conversion claim. Justice Arabian, however, was not unmindful of the apparent inequity of allowing the Regents et al. to retain all of the profits ultimately derived from Moore’s excised tissue. Nevertheless,

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30 Id. at 493. This claim is discussed at length below in Part V.
31 Id. at 488.
32 Id. at 495–96.
33 See id. at 494 (“Liability based upon existing disclosure obligations, rather than an unprecedented extension of the conversion theory, protects patients’ rights of privacy and autonomy without unnecessarily hindering research.”).
34 Id. at 497.
35 Id. (Arabian, J., concurring). Here, Kant’s imperative forbidding us from treating any rational person, even ourselves, as “a means only” obviously wields deep influence over Justice Arabian’s opinion. See IMMANUEL KANT, FUNDAMENTAL PRINCIPLES OF THE METAPHYSIC OF MORALS 58 (T. K. Abbott trans., Prometheus Books 1987) (1785).
the legislature, and not the courts, is the “proper deliberative forum” to address such inequity.\(^3\) Justice Arabian concluded by suggesting the need for a legislatively created licensing scheme to compensate all contributors to biomedical progress.\(^3\)

In his concurrence and dissent, Justice Broussard also recognized the validity of Moore’s informed consent action but parted ways with the majority concerning the validity of Moore’s conversion claim. For Justice Broussard, given the facts of the case, a conversion action should have lain with Moore. The key factual allegation turned on temporality: Moore “alleged that defendants interfered with his legal rights before his body part was removed.”\(^3\) Prior to the removal of a “body part,” i.e., tissue, the patient retains the right to control what will become of it once removal occurs.\(^3\) Only in light of adequate informed consent does the right to the disposition and control of human tissue pass to researchers and research institutions.\(^4\) In sum: Moore’s right to control future uses of his excised tissue before its removal, combined with Golde and Quan’s failure to disclose their prior intent to make post-surgical use of said tissue, provided Moore with an adequate cause of action under a common law conversion theory.

Justice Broussard also chastised the majority for failing to see their policy argument through to its logical conclusion. The majority’s policy decision to vest institutions and/or researchers with ownership in human tissue as the best means to insure biomedical progress did not go far enough. Specifically,

\[\text{It is certainly arguable that, as a matter of policy or morality, it would be wiser to prohibit any private individual or entity from profiting from the fortuitous value that adheres in a part of a human body, and instead to require all valuable excised body parts to be deposited in a public repository which would make such materials freely available to all scientists for the betterment of society as a whole.}\]

In other words, Justice Broussard reasoned, equity might well require the creation of a public tissue trust whereby no one individual person

\(^3\) Moore, 793 P.2d at 498 (Arabian, J., concurring).
\(^3\) See id. The scheme would presumably set fixed prices on biomaterial contributions, thereby avoiding the creation of a market therein.
\(^3\) Id. at 499 (Broussard, J., concurring in part and dissenting in part) (emphasis added).
\(^3\) Id.
\(^4\) See id.
\(^3\) Id. at 505.

or entity would profit from the sale or commercial development of human tissue.

In his spirited and oft-cited dissent, Justice Mosk came down squarely on Moore's side. Justice Mosk focused primarily on the abstract notion of property as the familiar "bundle of rights."\(^4\) Classically, a person's retention of all of these "sticks," from exclusive control and possession to right of sale and distribution, conclusively vests ownership of a res or thing in that person. There are many cases, however, where proprietary interests, i.e., "sticks," remain vested in an individual who does not retain the entire bundle.\(^4\) In a series of footnotes, Justice Mosk listed, among other possibilities, the restrictions zoning laws impose on landowners, the sportsman's right to give away captured game but not to sell it, and the right of a person contemplating bankruptcy to sell property for market value but not to give it away.\(^4\) Regardless of whatever property interests Moore lacked in his tissue, "at the time of its excision he at least had the right to do with his own tissue whatever the defendants did with it."\(^4\)

That is, Moore was free to contract with whoever wanted to use his tissue for commercial gain.

In his conclusion, Justice Mosk rejected the majority's policy argument out of hand. Moore, as a victim of "blatant commercial exploitation," clearly deserved more of a remedy than the majority afforded him.\(^4\) Conversion theory provided Moore with the best option. Indeed, fundamental fairness and equity dictated that Moore be entitled to at least some modicum of compensation for his unwitting contribution to the commercial development of his own biological tissues. After all, Justice Mosk reasoned, but for Moore's overproducing T-cells, no commercial development would have been possible.\(^4\)

In sum, Moore identifies the two policy issues at stake: (1) the need to insure unimpeded biomedical progress; and (2) the need to protect patient/research participants' right to informed consent. To balance these goals, the justices proffer a panoply of policy options. The majority does so through vesting research institutions with strong proprietary interests in excised tissue while denying the same to research participants. In his dissent, Justice Mosk does the opposite, and Justice Broussard falls somewhere in between (though closer to

\(^{42}\) Id. at 509 (Mosk, J., dissenting).

\(^{43}\) Id. at 509-10.

\(^{44}\) Id. at 509, n.6, 510 n.9-10.

\(^{45}\) Id. at 510.

\(^{46}\) Id. at 509.

\(^{47}\) Id. at 511-12.
Justice Mosk). As both Greenberg and Catalona reveal, the policy arguments set down in Moore continue to have far-reaching implications.

B. Greenberg

In Greenberg, the plaintiffs were families and non-profit institutions interested in developing a diagnostic test for the fatal genetic disorder Canavan's disease. In 1987, the plaintiffs contacted a researcher who agreed to assist them. The plaintiffs donated money, and, more important, tissue samples from 'Canavan families' around the world. The plaintiffs alleged that the original understanding they had with the defendant researchers and research institutions stipulated that any test developed would enter the public domain.

In 1993, the research team isolated the gene responsible for the disorder. In 1994, and unbeknownst to the families, the Miami Children's Hospital Research Institute ("MCH") applied for a patent that was granted in 1997. MCH proceeded to enter into a number of exclusive licensing and royalty agreements that would sharply limit public access to any clinical diagnostic test developed.

In 2000, the plaintiffs filed suit alleging numerous causes of action, including lack of informed consent, conversion, and unjust enrichment. The U.S. District Court for the Southern District of Florida rejected the plaintiffs' informed consent claim out of hand. First, the court viewed the plaintiffs as non-patient tissue donors, "and thus the voluntary nature of their submissions warrants different treatment" than that of patients who are also tissue donors. The court further found that the standard of informed consent in cases of non-patient tissue donation was much lower than in cases involving patient tissue donation. In the former instance, the policy goal of insuring biomedical progress easily trumped the need to protect informed consent. Indeed, the court reasoned, public policy necessarily precluded the disclosure of commercial interests to both donors and

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49 Id.
50 Id. at 1067.
51 Id.
52 Id.
53 Id.
54 See id.
55 Id. at 1068.
56 Id. at 1071.
57 See id.
research participants who are not patients. Such a requirement would "chill medical research" and would provide "research subjects" with "dead-hand control" over how "medical research progresses."

With regards to the conversion claim, the Greenberg court explicitly followed Moore: "Plaintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion." Plaintiffs fared better, however, on their unjust enrichment claim. By "investing time and significant resources in the race to isolate the Canavan gene," the plaintiffs apparently bestowed a benefit on the defendants that the defendants voluntarily accepted. Inequity would therefore result unless the defendants fairly compensated the plaintiffs for the benefit received. Ultimately, the parties settled on the issue of unjust enrichment. In exchange for defendants permitting outside researchers "free use" of the Canavan disease genetic sequence for non-commercial purposes, the plaintiffs agreed to recognize MCH's exclusive licensing and royalty agreements involving clinical tests for the disease. Importantly, the plaintiffs' victory, such as it was, obviously turned here on equity grounds as opposed to property considerations.

Greenberg is thus notable for three reasons: (1) the court refused to require researchers to disclose the possibility of commercialization to providers of tissue samples who are not patients; (2) the court, following Moore, declined to recognize the validity of a conversion action on the part of research participants involving an alleged misuse of their tissue; and (3) the court did recognize the validity of an unjust enrichment claim in instances where allegedly misused tissue donations resulted in a patented commercial product.

C. Catalona (District Court)

In Catalona, a prominent prostate researcher at Washington University ("WU") decided to leave for Northwestern University and wanted to take several thousand tissue samples with him. The researcher, Dr. William Catalona, sought to have his former patients vested with ongoing proprietary interests in their excised tissue. As

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58 Id. at 1070-71.
59 Id. at 1074.
60 Id. at 1073.
62 WEIR & OLLICK, supra note 14, at 164.
64 Id.
such, he hoped that several thousand of them would agree to withdraw their samples from the WU biorepository and transfer control to him. WU filed for a permanent injunction prohibiting the research participants from doing so, which the U.S. District Court for the Eastern District of Missouri subsequently granted on summary judgment.

Ultimately, the district court denied that the research participants retained any ongoing proprietary interests in their excised tissues and found WU the sole owner thereof. The court’s reasoning rested on three findings: (1) that the research participants made an inter vivos gift of their excised tissue to WU and not to Dr. Catalona, (2) that a research participant’s right to discontinue participation in research involving his or her excised tissue should be narrowly construed; and (3) that granting research participants ongoing proprietary interests in their excised tissue would seriously undermine biomedical progress.

In support of its gift analysis, the court placed heavy emphasis on the following facts. WU had retained complete and exclusive control over the tissue samples since receiving them from the research participants by housing the samples in its biorepository. WU’s intellectual property policy, known to Dr. Catalona, explicitly stated that all “tangible research property” involved in any research funded by an internal or external grant were the property of WU. The WU informed consent forms, emblazoned with the WU logo, never indicated that Dr. Catalona would either own or have exclusive control over the tissue samples. Nowhere did such forms indicate that research participants retained a right to transfer samples held in the WU biorepository to a third party. In light of these facts, the court found that the research participants, at the time they consented, possessed the requisite donative intent to make a gift of their tissue, the delivery of which WU subsequently accepted. Upon acceptance of the tissue, under Missouri law, WU’s “ownership [took] effect immediately and absolutely.” As persuasive precedent, the court cited both Greenberg and Moore.

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65 Id.
66 Id. at 987–88, 1002–03.
67 Id. at 998.
68 Id. at 999–1000.
69 Id. at 1002.
70 Id. at 994.
71 Id. at 989.
72 Id. at 997.
73 Id. at 990.
74 Id. at 997.
The court also rejected the defendants’ argument that the right to withdraw from research “include[d] the right to continue control over the use and location of their excised biological materials.” Instead, the court very narrowly read the right to discontinue participation simply to mean that the research participant has chosen not to make any more inter vivos gifts of his or her tissue to the research institution in question. At their prerogative, research institutions could choose to destroy, store indefinitely, or anonymize (i.e., remove any identifying biological markers) any extant tissue should a research participant request discontinuation.

Lastly, the court, echoing the sentiments of an amicus brief filed by the Association of American Medical Colleges, strenuously objected to the defendants’ claims on public policy grounds. Allowing control of tissue samples to remain in the hands of individual research participants would lead to the “thwart[ing]” of biomedical progress by “private agendas” and “prejudicial influences.” As in Moore and Greenberg, the district court in Catalona found that allowing research participants to retain even the slightest proprietary interests in their excised tissue would “seriously threaten[]” the “integrity and utility of all biorepositories.”

D. Catalona (Appellate Court)

The U.S. Court of Appeals for the Eighth Circuit, while affirming the district court’s ruling, narrowly focused its holding to the exclusion of any policy considerations whatsoever. The appellate court specifically affirmed, “[u]nder the facts of this case,” the district court’s finding that the research participants made an inter vivos gift to WU. The appellate court’s holding is notable for what it does not say. Given the absence of policy analysis, nothing in the appellate court’s ruling would prevent future interested parties from reaching an entirely different outcome via contract. The court’s narrow holding seemingly leaves tremendous room for future researchers and research participants to contract around any obstacles to retaining

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75 Id. at 999.
76 Id. at 1000.
77 Id. at 1002; see also Brief of Amicus Curiae Association of American Medical Colleges Regarding the Legal Status and Use of Donated Biological Materials, Catalona, 437 F. Supp. 2d 985 (No. 4:03CV1065SNL).
78 Catalona, 437 F. Supp. 2d at 1002.
79 Id.
control over excised tissue samples—thus adding a new wrinkle to the debate.

To summarize, the courts side strongly with research institutions retaining exclusive ownership rights over excised tissue samples. Largely on policy grounds, the majority of courts understand the goal of ensuring biomedical progress as requiring the denial of research participants retaining any ongoing proprietary interests in their excised tissue samples. Correspondingly, these courts often discount the need to protect research participants’ right to informed consent through affording such interests. And while the Catalona appellate court leaves open alternative contractual possibilities, the court’s narrow decision by no means undermines the policy-driven common law status quo.

II. POLICY GOALS: STRIKING THE BEST BALANCE

As the majority in Moore discusses, policymakers must take account of two potentially conflicting goals when addressing the ownership of human tissue samples. On the one hand, and in keeping with the Intellectual Property Clause of the Constitution, the purpose of ascribing ownership in human tissue is “[t]o promote the Progress of Science,” specifically, the biomedical sciences. On the other, and given the morally scandalous history of much biomedical research, any ownership regime must also afford deep respect to a research participant’s right to informed consent/refusal. The key then is to identify the ownership regime that strikes the proper balance between these policy goals. The courts, as noted above, tend to give fairly short shrift to the goal of protecting research participant informed consent in order to promote biomedical progress. These twin policy goals, however, are equally important.

A. Promoting Biomedical Progress

As Professor David Korn observes, human tissue samples have been, and will undoubtedly continue to be, perhaps the crucial raw material in the war against disease and disability. For instance, the use of human tissue samples has played an essential role in the study of the etiology, diagnosis, and treatment of the following disorders: cervical cancer, liver cancer, lung cancer, atherosclerotic cardiovascular disease, brain tumors, prion diseases, multiple

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81 U.S. CONST. art. I, § 8, cl. 8.
sclerosis, muscular dystrophy, lymphatic cancer, the genetics of colon
cancer, prostate cancer, and Kaposi’s sarcoma. In conclusion, Professor Korn writes that he could
provide hundreds of additional examples. Human tissue samples are a
“rich and irreplaceable source” constituting a “public treasure.” Indeed, “[t]here is quite literally no comparable research resource to
substitute for it.” Therefore, “public policy must continue to
encourage the accumulation of the human tissue archive and
facilitate its accessibility for medical research.”

B. Protecting Informed Consent

At the same time, however, the history of biomedicine is replete
with ethically egregious behavior on the part of researchers towards
research participants. The horrifying excesses perpetrated at places
like Auschwitz and Dachau continue to cast a moral pallor over
contemporary biomedical research. In the United States, the
eugenics movement of the early twentieth century served as the
inspiration for the “Nazi biomedical vision.” But even the
widespread acceptance of the Nuremberg Code did not prevent
researchers from conducting either the Human Radiation
experiments or the infamous Tuskegee syphilis experiments—both
of which lasted well into the early 1970s. Essentially, and as
discussed at length below, the right to informed consent in research
contexts comprises two basic liberty interests: (1) the freedom to
refuse to participate in research (a first refusal right); and (2) the
freedom to withdraw from any research at any time and for any
reason (a revocability right). Only then is the autonomy and dignity
of research participants given its proper due.

83 David Kom, Contribution of the Human Tissue Archive to the Advancement of Medical
Knowledge and the Public Health, in II RESEARCH INVOLVING BIOLOGICAL MATERIALS:
ETHICAL ISSUES AND POLICY GUIDANCE E-1, E-4 to -21 (National Bioethics Advisory
Commission 2000).
84 Id. at E-22.
85 Id. at E-23.
86 Id.
87 Id.
89 Id. at 22.
90 AURORA PLOMER, THE LAW AND ETHICS OF MEDICAL RESEARCH: INTERNATIONAL
91 See generally JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYphilIS EXPERIMENT
(new & expanded ed. 1993).
92 See, e.g., World Medical Association Declaration of Helsinki: Ethical Principles for
Putting the two together, satisfying the first policy goal requires creating as much unfettered researcher access to tissue samples as possible. Satisfying the second policy goal demands protecting the rights of research participants to refrain from, and to revoke, a transfer of their excised tissues to a biorepository. Further, potential success at the first policy goal trades heavily on achieving the second. As Professor Korn observes, researcher access means little without continued tissue archive growth. As Professor Kom observes, researcher access means little without continued tissue archive growth. Research participant consent is thus essential to the growth of the human tissue archive. Yet several recent studies show that many Americans are extremely suspicious about what will become of their transferred tissues.

To weaken the informed consent doctrine, particularly at the point of revocability as the district courts in Greenberg and Catalona have done, might well prove extremely counterproductive to bolstering biomedical progress. Which human tissue ownership regime best maximizes researcher access while preserving a research participant’s right to informed consent? Four candidates present themselves: (1) research institutions; (2) researchers; (3) research participants; and (4) a public trust. To strike the best balance between these policy goals, the first three possibilities prove less than desirable.

C. Research Institutions

Why not follow the courts and vest research institutions with full ownership rights in their stored tissue samples? Following Greenberg and Catalona, an inter vivos gift is the courts’ favored legal vehicle to account for the transfer of tissue from research participants to research institutions. As a result, these institutions retain exclusive ownership in their tissue samples. The courts then marshal policy arguments to support a gift analysis as the best means to ensure biomedical progress. Undoubtedly, a major motivating factor here is the desire on the part of research institutions to retain lucrative patent rights to commercially viable biomedical innovations that rely on

Medical Research Involving Human Subjects ¶ B(24) (1964, last amended 2008), available at http://www.wma.net/e/policy/pdf/11c.pdf ("The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.").

93 Korn, supra note 83, at E-23.

94 See WEIR & O'LiCK, supra note 14, at 26–31 (discussing several recent studies that focused on potential research participants’ attitudes toward tissue donation).

human tissue as a crucial raw material. Nonetheless, the Intellectual Property Clause is not concerned with ownership per se but rather with identifying that ownership regime that best enhances "the Progress of Science." The clause "embodies a carefully crafted bargain" designed to provide an incentive to create new technologies and forgoes reifying ownership as an end itself.

Providing researchers with the broadest possible access to human tissue samples is the best way to maximize the likelihood of biomedical progress. Vesting exclusive ownership in individual research institutions potentially undermines such access. Currently, offsite researchers can access the tissue held in another research institution's biorepository through the use of Material Transfer Agreements ("MTAs"). The typical MTA requires, among other things, that the requesting researchers provide proof of Institutional Review Board ("IRB") approval, compensate the biorepository for the materials desired, and forswear any warranties of the material provided to avoid liability under the Uniform Commercial Code. More to the point, the typical MTA describes offsite researcher access to the material as "a service to the research community," which the research institution exercises at its prerogative.

Traditionally, research institutions routinely honor MTAs from offsite researchers if the requested material is available, but legally, research institutions need not do so. Imagine if Dr. Catalona had successfully transferred thousands of prostate tissue samples from WU to Northwestern. Nothing would stop WU from refusing to provide any samples in the future to researchers at Northwestern. One could easily imagine a tissue "war" breaking out that would require research institutions to form "tissue pacts." To ensure maximal researcher access to tissue samples, however, the safest ownership regime would seemingly a priori preclude individual research institutions from engaging in such deleterious tit-for-tat behavior.

Further, the gift analysis granting exclusive ownership to research institutions fits badly with informed consent revocability rights.

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96 Catalona, 437 F. Supp. 2d at 1000, 1002.
97 U.S. CONST. art. I, § 8, cl. 8.
99 Korn, supra note 83, at E-23.
Classically, *inter vivos* gifts are unconditional and, hence, irrevocable. While the common law of some states, such as Missouri, allows for “imperfect gifts,” the common law of other states does not. Such an odd legal creature inadequately accounts for the right of research participants to withdraw their tissue from research, i.e., to revoke their consent. The result, as the Catalona district court decision exemplifies, is a substantively gutted revocability right. Such a right typically amounts to nothing more than the right to refuse to give future tissue samples, i.e., a prospective right to first refusal. Thus, vesting exclusive ownership in individual research institutions proves wanting in both policy arenas.

**D. Researchers**

What about vesting researchers with exclusive ownership rights? Researchers could acquire tissue from individual research participants through either gift or purchase. Potentially severe policy problems, however, plague this regime from the outset. First, the tit-for-tat scenario discussed above becomes even more extreme when the tissue owner is an individual researcher as opposed to an individual research institution. The numbers of “tissue owners” would increase exponentially overnight. Such a regime would create a disincentive for individual research institutions to create biorepositories, since researchers could easily remove the contents thereof and take it with them to a new institution. Vesting exclusive ownership in individual researchers would reduce research institutions to little more than bailees, hard-pressed to maintain the integrity of their bailor’s tissue collection. Widespread access to tissue samples could occur only at the prerogative of individual researchers—clearly an unlikely recipe for achieving the first policy goal.

Moreover, research participants’ rights to informed consent would also suffer. As noted, revocability of an *inter vivos* gift is very tricky to engineer—it is almost impossible to do so subsequent to the rendering of valuable consideration in exchange for tissue samples. Lastly, the very fact that researchers themselves are not calling for

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105 Only patients such as John Moore with inherently valuable tissue—the case, as it were, of a biological windfall—would benefit from such a system. The vast majority of research participants would not.
such a regime speaks volumes. Presumably, few researchers wish to saddle themselves with the heavy transaction and administrative costs that such a regime would impose.

E. Research Participants

What about vesting research participants with exclusive ownership rights? Taking their cue from Justice Mosk’s dissent in Moore, this proposal receives substantial support from a host of legal academics. Professor Donna Gitter provides the most detailed analysis.106 For Professor Gitter, individuals such as Ted Slavin and groups such as PXE International provide the paradigm cases.107 In the 1960s and 1970s, Ted Slavin routinely sold his antibody-rich blood to researchers who went on to develop the HBV vaccine for Hepatitis B.108 More recently, a group of patients suffering from the rare genetic disorder pseudoxanthoma elasticum (“PXE”) banded together to form PXE International.109 Afflicted members of the group provided tissues to researchers and PXE International subsequently negotiated a share in the patent rights and licensing royalties for the resulting diagnostic test.110 On this model, patients are free to negotiate and contract with the highest bidder for their tissue. The exchange could also involve a nonmonetary quid pro quo, e.g., tissue samples in exchange for freely available diagnostic tests.

Importantly, Professor Gitter’s proposal vests research participants with the complete “bundle of sticks” in their tissue. Such an approach, she argues, provides research participants with maximal control over their tissues both before and after excision. In a Kantian vein, Professor Gitter touts her proposal as the best way to prevent researchers and research institutions from reducing research participants to a mere means to an end.111 She calls on Congress, acting under its Commerce Clause authority, to create a legislative scheme whereby unfairly treated research participants have a host of


107 Gitter, supra note 106, 316–22. Professor Gitter does not discuss the case of Mr. Slavin per se, but he clearly falls under her desired tissue ownership paradigm.


110 Id.

111 Id. at 301 n.174.
remedies at their disposal, including both conversion and unjust enrichment. Professor Gitter further argues that, far from stifling biomedical progress, her system will simply provide tremendous incentives for researchers and research institutions to treat research participants with the utmost respect.

Such proposals appear strongest when the factual backdrop involves either instances of biological uniqueness such as John Moore and Ted Slavin or orphan diseases such as Canavan’s disease and PXE. If generalized across the board to every instance of tissue transfer, however, Professor Gitter’s approach poses a threat to biomedical progress. First, every act of tissue transfer could easily become a protracted legal negotiation. Professor Gitter never thoroughly considers the impact that such potentially devastating transaction costs would have on biomedical research. Indeed, if researchers paid research participants for every tissue sample, financial costs, along with time and opportunity costs, might well become prohibitive.

Second, allowing patients a full set of property rights in their excised tissue would seemingly turn tissue transfers into a simple bailment. As bailors, research participants would presumably retain the right to remove and transfer their tissues willy-nilly—as the district court in Catalona feared. Again, research institutions would face a major disincentive to undertake the construction and maintenance of biorepositories. Third, allowing research participants to set highly specific research agendas with regard to their tissue samples would require researchers to seek revised or renewed consent on a frequent basis. Again, the threat of fatal transaction costs looms large.

In sum, Moore, Greenberg, and Catalona generate fears amongst potential research participants that any viable system of human tissue ownership must address. Allowing research participants to retain a full range of ongoing proprietary interests in their excised tissue, however, goes beyond what is necessary to protect rights to first refusal and revocability. In doing so, such proposals threaten to

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112 Id. at 338–40.
113 Id. at 340–41.
115 Id.
116 See William Grizzle et al., Recommended Policies for Uses of Human Tissue in Research, Education, and Quality Control, 123 ARCHIVES OF PATHOLOGY AND LABORATORY MED. 296, 299 (1999) (describing the requirement for specific informed consent from donors of tissue to be used for research purposes, and the difficulty inherent in anticipating and obtaining such consent for all possible future research uses of that patient’s tissue).
endanger biomedical progress by burdening the research process with enormous and unending transaction costs.

III. CREATING A PUBLIC TISSUE TRUST

A properly instituted public tissue trust avoids the most serious problems that infect the current and proposed ownership regimes. As shown below, such a trust strikes the best balance between promoting biomedical progress and protecting the right to informed consent. In what follows, this Note addresses the nature and underlying presuppositions of a public tissue trust, the mechanics of such a trust's creation and maintenance, its scope, and the compatibility of a public tissue trust with the Bayh-Dole Act.

A. Nature and Underlying Presuppositions

The following elements constitute any trust: (1) the settlor; (2) the transfer; (3) the property, corpus, or res; (4) the trustee; (5) the purpose; and (6) the beneficiary.\(^{117}\) To create a trust, the settlor must voluntarily provide, i.e., "dedicate," the trust's property or res by transferring the legal title thereof to a trustee. In turn, the trust agreement binds the trustee to exercise ownership for the well-being of a third party, the beneficiary.\(^{118}\) The creation of a fiduciary relationship between a trustee and a beneficiary constitutes the normative essence of any trust. A revocable trust exists if the settlor retains the power to terminate the trust.\(^{119}\) The trust may, however, set limits on the settlors' power to revoke.\(^{120}\) If the settlor retains no powers of revocability then the trust is irrevocable, not unlike a completed inter vivos gift.\(^{121}\) While settlors may create trusts for a variety of purposes, the law of trusts views those created to benefit the public at large as charitable in nature.\(^{122}\)

Here, the research participant, i.e., the original "owner" of the tissue in question, would be the settlor.\(^{123}\) Presumably, research participants (or their proxies) would have to satisfy the competency requirements that the doctrine of informed consent for medical research imposes. At the culmination of the informed consent process,

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\(^{117}\) See Restatement (Third) of Trusts §§ 2–3, 28 (2003).

\(^{118}\) Id. § 3 cmt. d.

\(^{119}\) Id. § 63 cmt. c (describing the presumption of revocability where the settlor has retained an interest in the trust).

\(^{120}\) See id. § 63 (stating the power of the settlor to modify the trust to the extent provided by the trust's terms).

\(^{121}\) Id. § 63 cmt. c(1).

\(^{122}\) See id. § 28 (describing the various permissible purposes for a charitable trust).

\(^{123}\) Gottlieb, supra note 3, at 192.
settlor/research participants would dedicate their proprietary interests in their tissue to the trust. To protect their informed consent, settlor/research participants would retain the power to revoke the trust by having their tissue removed from ongoing research and/or destroyed.

Crucially, however, the research participants would only retain a limited right of revocability, i.e., they could demand the withdrawal and destruction of their tissue but not its return for purposes of transfer. In theory, a trust may limit a settlor's power to revoke in a number of ways. For example, many charitable trusts created to benefit religious organizations permit a settlor to revoke his or her monetary dedication only upon a showing of an adverse change in financial circumstances. Here, a settlor's power to revoke by having his or her tissue withdrawn from ongoing research and destroyed would not extend to a right to withdrawal and transfer. As the district court in Catalona reasoned (and as discussed below), affording research participants such broad revocability rights goes beyond what is necessary to protect the right to informed consent and threatens to undermine the institutional integrity of biorepositories. The trust agreement would further have to institute procedures governing the revocability process, e.g., requiring that settlors revoke in writing. The property or res would be the excised tissue itself.

The trustee, as both title holder to the tissue and the ultimate bearer of fiduciary responsibility, would be the federal government. The trust would impose three basic fiduciary responsibilities: (1) the duty to maintain and secure the tissue samples; (2) the duty to ensure and safeguard the informed consent process; and (3) the duty to ensure access to the trust by individuals engaged in bona fide scientific research. In turn, the federal government would charge research institutions with the local administration of the trust. IRBs would thus play a crucial role in executing the second and third fiduciary duties. IRBs evaluate research not only in terms of its ethical impact on research participants but also on the proposed merits of the research.

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124 See Restatement (Third) of Trusts § 63 (2003) (discussing the power of a settlor to revoke or modify a trust).
128 Gottlieb, supra note 3, at 192. What may count as trust property is only limited by the very concept of property itself: "Any Property May Be Trust Property." Restatement (Third) of Trusts § 40 (2003).
The latter point is to avoid the needless waste of valuable scientific resources such as excised tissue samples. While title would vest in the federal government, no threat to commercialization need occur. As this Note addresses extensively below, a public tissue trust is fully compatible with the Bayh-Dole Act of 1980.

This raises an immediate worry: biorepositories are clearly expensive to construct and maintain—otherwise WU would never have initiated legal proceedings against Dr. Catalona. As noted, a trust would require research institutions to function as the local administrators of their own biorepositories. Further, and as anecdotally evidenced by their uniformly relentless fund-raising efforts and tuition increases, major research institutions are perpetually short of cash. The creation of a public tissue trust would thus necessarily involve a significant increase in federal funding for the maintenance and expansion of the tissue collection contained therein. At the very least, the federal government would have to provide matching funds to research institutions willing to take on the responsibility of a biorepository. Research institutions maintaining biorepositories would thus benefit financially from tissue trust creation. In addition, the independent incentives to establish and maintain biorepositories would remain. Presumably, research institutions currently create biorepositories to enhance their prestige and to attract top-flight researchers. Why would research institutions behave any differently under a trust regime? Prestige concerns would remain unchanged, and, not unlike a large library collection, ready access to a well-stocked biorepository would still provide highly sought-after researchers with an incentive to join the faculty.

Charitable purposes, directed at both “the promotion of health” and “the advancement of knowledge or education,” would constitute the tissue trust’s raison d’être. Such charitable purposes would fit well with the nonprofit nature of major research institutions (e.g., universities), government health agencies (e.g., the National Institutes for Health), and health-care providers. Finally, a trust would ensure that biorepositories remain accessible to researchers well past their administrative life spans. In short, a public tissue trust would benefit the research community as a whole by ensuring the availability of tissue to advance research on the world’s major diseases.

129 See TOM L. BEAUCHAMP & JAMES F. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 320 (5th ed. 2001) (discussing the IRB’s role in reviewing the conditions that must be met in order for scientists to engage in research with human subjects). The authors further note that IRBs must ensure there exists “a reasonable prospect that the research will generate the knowledge that is sought.” Id.


131 Policymakers could further buttress this incentive by including a “first dibs” provision in the necessary legislation. That is, a local researcher’s request for a tissue sample would trump that of a foreign researcher’s request for the same sample if not enough of the desired sample existed to provide the requested amount to each.

of Health), and graduate medical education programs (e.g., Harvard Medical School). Lastly, the trust would have two classes of beneficiaries: (1) the public at large (i.e., all those persons who currently, and in the future, would benefit from basic research involving excised human tissue); and (2) research scientists who seek to advance the cause of knowledge per se. Putting all of the above together, we arrive at a public revocable charitable tissue trust.

A serious wrinkle, however, remains. The requirement that settlor-research participants "own" their tissue prior to transfer, and subsequently retain revocability rights therein apparently flies in the face of Moore and its progeny. Trusts necessarily presuppose the transfer of property from settlor to trustee. Contrary to Moore, can research participants "own" their tissue? Yes. Clearly, Congress could simply supersede the courts here and pass legislation declaring human tissue to be property. A more nuanced argument proves essential, however, if only to convince the members of Congress to pass superseding legislation.

A famous passage in Locke's Second Treatise of Civil Government goes to the intuitive heart of the matter: "Though the earth and all inferior creatures be common to all men, yet every man has a "property" in his own "person." This nobody has any right to but himself." Locke's "self-ownership" thesis, as it were, remains deeply woven into the Western psyche, so much so that we might profitably refer to it as the "Lockean Intuition." The almost universal embrace of the Lockean Intuition provides the most important intellectual backdrop to any ensuing discussion concerning excised tissue ownership. Indeed, the majority in Moore's apparent rejection of this intuition led to widespread revulsion and anger amongst both legal academics and informed laypersons.

Clearly, excised tissue, unlike the human beings whence it comes, is subject to ownership claims. Major research institutions, such as the University of California, certainly view themselves as the owners of the tissue samples stored in their biorepositories. Imagine if researchers from Stanford, in a fit of jealous pique, destroyed the University of California biodepository. Presumably, the University of California would mount a conversion action against the researchers.

133 Gottlieb, supra note 3, at 192.
136 The author of this Note was unable to find a single law review article supporting the majority decision in Moore.
Would the court really refuse to recognize the validity of such a claim? Presumably not—and, as such, the court would have to acknowledge the deprivation of the University of California’s ownership interests in its tissue collection and hold the researchers liable accordingly. Further, in the actual world, the typical MTA informs the recipient researcher that the provider institution “owns” the sample: “The PROVIDER retains ownership of the MATERIAL, including any MATERIAL contained or incorporated in MODIFICATIONS.”\(^1^\) Indeed, the right of provider institutions to deny such requests follows directly from their exclusive ownership rights to the tissue samples in their possession. Hence, the law recognizes and vests exclusive ownership of excised tissues samples in research institutions but refuses to do so in the case of research participants.

From a purely metaphysical point of view, the distinction between research institutions and research participants is one without a difference. Logically, the Moore court’s apparent ex nihilo vesting of exclusive ownership rights in the former, but not the latter, makes little sense. The Moore majority thus makes much of California’s public health laws, which prohibit unlicensed individuals from possessing bio-hazardous materials such as excised tissue samples.\(^1^\) Nonetheless, as Justice Broussard hammers home, such laws speak to public safety and not ownership.\(^1^\) At most, public health laws limit the personal possession, but need not limit the ownership, of human biomaterials.

Under a bailment theory, personal ownership exists in such tissues as blood (e.g., in blood banks), sperm (e.g., in sperm banks), and embryos (e.g., in fertility clinics).\(^1^\) Here, the individual bailor, e.g., a couple with fertility problems, deposits their biological tissue, e.g., fertilized preembryos, with a bailee, e.g., a fertility clinic, for safe keeping until the need for the tissue arises. Clearly, the bailor, and not

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138 See Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 491–92 (Cal. 1990). Justice Panelli, writing for the majority, also claims that the Regents’ patent in Moore’s cell line precludes Moore from making any ownership claims to the fruits thereof. Id. at 493. This argument, however, goes directly to the more narrow issue of conversion, as opposed to the possibility of ownership per se. This Note addresses this argument in Part V.

139 Id. at 503 (noting that nothing in the statute suggests patients should be unable to choose among “legally permissible uses” for the excised tissue such as use for research or commercial purposes).

140 See Göttlieb, supra note 3, at 188–90 (describing bailment theory generally and its application to biological samples). For the case of frozen pre-embryos, see York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989). In the case of pre-embryos frozen for in vitro fertilization (“IVF”) purposes, some courts view such tissue as “quasi-property” insofar as it bears the potential for life. Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992).
the bailee, owns the tissue in question even though possession remains at all times with the latter. The clearest mark of such ownership is a bailor’s retention of the right to remove and transfer his or her tissue to another bailee—even though public health laws may preclude the personal possession of such tissues, e.g., storing preembryos in a home freezer.

A gift analysis produces similar results. The Restatement (Third) of Property defines a gift as a voluntary “transfer [of] an ownership interest to the donee without consideration and with donative intent.” Hence, even the district court’s reasoning in Catalona presupposes that research participants, prior to donation, retain an ownership interest, i.e., property, in their tissue. If not, then the proffered gift analysis makes no sense. Prior to donating their tissue to the WU biorepository, the research participants in Catalona of necessity retained exclusive ownership interests therein. Otherwise, no gift would have been possible. Short of a highly implausible abandonment theory (given the detailed consent forms describing the transfer as a “free and generous gift”), WU’s claim to exclusive ownership in its tissue archive would otherwise crumble.

The use of bodily tissues as evidence in criminal trials provides a useful analogy. In Rochin v. California, a convicted drug trafficker argued that the Court should overturn his conviction because the police had a physician forcibly pump his stomach in order to acquire evidence for trial. Justice Frankfurter, writing for the majority, found that such behavior on the part of the police “shocked] the conscience” and amounted to an egregious violation of the petitioner’s due process rights. Specifically, “[i]llegally breaking into the privacy of the petitioner, the struggle to open his mouth and remove what was there, the forcible extraction of his stomach’s contents . . . . are methods too close to the rack and the screw to permit of constitutional differentiation.” Only if the petitioner had consented to the stomach pumping could the extracted remnants of

141 See York, 717 F. Supp. at 425 (describing the existence of a bailment relationship between potential parents and the medical college at which they stored their cryopreserved zygote).
142 See id. at 425–26 (finding a breach of the bailment contract where defendants refused to consent to a transfer of the biological material).
146 See id. at 166.
147 Id. at 172.
148 Id.
the morphine pills that he had swallowed been admitted into evidence against him.\textsuperscript{149} In their concurrences, Justices Black and Douglas argued that the Fifth Amendment guarantee against compelled self-incrimination provided a better constitutional foundation than the majority's due process approach.\textsuperscript{150} Either way, the lack of consent on the part of the petitioner loomed large.

While the \textit{Rochin} Court did not address the issue of tissue ownership \textit{per se}, presumably both the majority and concurring opinions presupposed that the contents of the petitioner's stomach belonged to him, and not to the State. Otherwise, the lack of consent would not have been constitutionally problematic. In line with the Lockean Intuition, \textit{Rochin} stands for the proposition that our persons (and their contents) are our property, and, \textit{other things being equal}, the State may only take or intrude upon our property with our consent.

More directly, Professor Karen Gottlieb points to \textit{Venner v. State}.\textsuperscript{151} In \textit{Venner}, the Maryland court found that the defendant drug smuggler had abandoned hashish-filled balloons upon their excretion from his gastrointestinal system. Voluntary relinquishment of ownership constitutes abandonment, and, as first finders, the police could claim title to the balloons.\textsuperscript{152} The court thus denied the defendant's claim that police performed an illegal search on his feces (and the balloons therein) because they did not have a warrant to do so. Nonetheless, as Professor Gottlieb observes, the court, \textit{in dicta}, did view the defendant's feces as his property:

\begin{quote}
It could not be said that a person has no property right in wastes or other materials which were once a part of or contained within his body, but which normally are discarded after their separation from the body. It is not unknown for a person to assert a continuing right of ownership, dominion, or control, for good reason or for no reason, over such things as excrement, fluid waste, secretions, hair, fingernails, toenails, blood, and organs or other parts of the body, whether their separation from the body is intentional, accidental, or merely the result of normal body functions.\textsuperscript{153}
\end{quote}

\begin{footnotes}
\item 149 Id. at 179 (Douglas, J., concurring).
\item 150 Id. at 175 (Black, J., concurring); id. at 178-79 (Douglas, J., concurring).
\item 152 Id. at 498-99.
\item 153 Id. at 498 (footnote omitted).
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Although it occurs within the context of Fourth Amendment jurisprudence, the *Venner* decision is important to the present discussion. It neatly illustrates the power and scope of the Lockean Intuition with regard to the personal ownership of human tissue.

Clearly, the conclusion that research participants own their tissue prior to its removal from their bodies appears inescapable. What about post-removal? Here, policy considerations come to the fore. Any acceptable theory of post-removal ownership of human tissue for research purposes must strike the best balance between the policy goals of promoting biomedical progress and protecting informed consent. That is, we may temper the Lockean Intuition to serve other pressing policy goals.

Other constitutional arenas, particularly Fourth Amendment jurisprudence, again provide some illustrative examples. As noted, *Rochin* and *Venner* stand for the proposition that, *other things being equal*, the criminal justice system must afford the Lockean Intuition great respect. Nonetheless, *all things considered*, the interests of justice may, on occasion, trump the Lockean Intuition.

For instance, in *Schmerber v. California*, the petitioner, convicted for drunk driving, argued that a blood alcohol test drawn without his consent violated, among other things, his right to be free from unreasonable searches and seizures. The Supreme Court, in rejecting the petitioner's claim, reasoned that the "Fourth Amendment's proper function is to constrain, not against all [bodily] intrusions as such, but against intrusions which are not justified in the circumstances, or which are made in an improper manner." Specifically, the Court found that the police officer involved could "reasonably have believed" that without the test vital evidence would have been lost, that the test itself was minimally invasive, that the petitioner did not object on religious grounds, and lastly, that the physician properly performed the test. As such, the State's need to secure vital evidence for trial outweighed the petitioner's interest in being free from a non-consensual, minimally invasive bodily intrusion.

In *United States v. Montoya de Hernandez*, the respondent was caught attempting to smuggle narcotics into the United States via

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155 Id. at 759.
156 Id. at 768.
157 Id. at 770-71.
158 Id. at 772.
balloons in her alimentary canal. Acting under police direction, a physician conducted a rectal exam and discovered a narcotics-filled balloon. The police subsequently detained the respondent for several days until she passed all of the balloons. Prior to the exam, the respondent refused the option of leaving the country on the next available flight to Colombia. The respondent claimed that the rectal search and subsequent detention constituted an unreasonable search and seizure of her person and its contents. The Supreme Court rejected the respondent’s claim and reasoned that “[t]he permissibility of a particular law enforcement practice is judged by ‘balancing its intrusion on the individual’s Fourth Amendment interests against its promotion of legitimate governmental interests.’” Here, the need to gather evidence for trial and to prevent large quantities of narcotics from entering the United States outweighed the respondent’s right to avoid the search of her alimentary canal and detention of her person (particularly since the respondent had the option of leaving prior to the search).

Similarly, in Skinner v. Railway Labor Executives’ Association, the Supreme Court upheld the mandatory blood, urine, and breathalyzer testing of railroad employees involved in accidents and other major safety violations. Following Schmerber, the Court reasoned that such tests did not constitute an undue infringement on the “justifiable expectations of privacy of covered employees.” The need for public safety tempered a railroad employee’s right to be free from such intrusions.

Importantly, none of the above decisions represent a retreat from Rochin: government behavior that “shocks the conscience” remains strictly prohibited. Rather, in these decisions, the Court permits certain nonconsensual bodily invasions (justified by the circumstances and properly administered) to serve other legitimate, narrowly circumscribed governmental interests (e.g., the prevention of narcotics smuggling). In a similar vein, the need to promote biomedical progress may temper the breadth of the Lockean Intuition concerning the ownership of human biomaterials upon their excision.

160 Id. at 532–33.
161 Id. at 535–36.
162 Id. at 534.
163 Id. at 537 (quoting United States v. Villamonte-Marquez, 462 U.S. 579, 588 (1983)).
165 Id. at 628; see also Nat’l Treasury Employees Union v. Von Raab, 489 U.S. 656 (1989) (holding that the Customs Service could require employees eligible for promotion to undergo a drug test because it was necessary to prevent drug users from occupying sensitive official positions).
166 Skinner, 489 U.S. at 615.
and removal from the research participant’s body. The key is to identify an ownership regime that protects the research participant’s right to informed consent without undermining biomedical progress.

Three excised tissue ownership regimes constitute viable candidates: (1) gift; (2) bailment; and (3) trust. As noted extensively above, an inter vivos gift regime seemingly provides research institutions with free rein over their tissue samples. By definition, such gifts are irrevocable. In light of worries over research institutions refusing to share these precious donations with their peers, why not simply extend an inter vivos gift analysis to a national biorepository? Such an institution would presumably work wonders in guaranteeing researchers unfettered access to human tissue samples. Nonetheless, applied to any level—individual researcher, research institution, or a public repository—such a theory of property transfer precludes the research participant from retaining any revocability rights, thereby undermining informed consent.

Bailment operates at the other end of the spectrum. Presumably, by enabling research participants to retain full ownership rights over their excised samples, the protection of informed consent reaches its zenith and the Lockean Intuition reigns supreme. As Professor Gottlieb observes, however, the theory of bailment and human tissues excised for research purposes make an uneasy fit. First, in the vast majority of tissue sample transfers, “the originator of the biological sample does not . . . keep legal title to the samples.” Further, research participants cannot reasonably expect researchers and research institutions to return their samples to them for the simple but conclusive fact that such research normally requires the permanent alteration and routine destruction thereof.

Policy reasons provide the last nail in the coffin. A bailment regime would clearly vest research participants with a host of exclusive ownership rights going beyond what is necessary to protect their informed consent while simultaneously threatening to undermine biomedical progress. As noted in the previous section, a bailment

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167 Irrevocable transfer in exchange for valuable consideration is also a possibility, and nothing in this Note precludes potential research participants from pursuing such options, much like Ted Slavin, outside of a tissue trust network.
169 Gottlieb, supra note 3, at 190.
170 Id.
171 Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 1001 (E.D. Mo. 2006), aff’d, 490 F.3d 667 (8th Cir. 2007), cert. denied, 128 S. Ct. 1122 (2008). Here, tissue stored for research parts ways with tissue stored in blood and sperm banks, and fertility clinics—where a bailment analysis is appropriate.
theory renders any tissue archive inherently unstable.\footnote{Id. at 996–97, 1002.} It permits research participants to withdraw samples and transfer them to another research institution or commercial enterprise at their whim. Post-removal and post-transfer, the Lockean Intuition loses much, but not all, of its bite.

Ultimately, a trust regime vesting settlors/research participants with a limited power of revocation offers the best compromise: it preserves the virtues of both the gift (transfer of title) and bailment (revocability) regimes while surrendering to none of their respective vices (irrevocability and extreme archival instability). A limited revocability trust regime enables research participants to withdraw their tissue from ongoing research, protecting their informed consent. Such a regime, however, would not permit the wholesale removal and transfer/sale of previously dedicated biomaterials, thus providing for a high degree of institutional stability for biorepositories. Clearly, a certain amount of archival instability remains ineliminable. As previously shown, irrevocability offers the only complete cure for instability. Irrevocability, however, comes at too steep a price: the evisceration of informed consent.

A limited revocability public tissue trust both protects informed consent and provides maximum researcher access. To wit, in acknowledging that research participants own their tissue prior to its dedication and subsequently retain limited revocability rights, a trust regime squares neatly with the Lockean Intuition without undermining biomedical progress. A public tissue trust further vests accredited researchers everywhere with a right of access. Future Dr. Catalonas need not fear for loss of access to a tissue archive simply because they change jobs. Going back to Justice Broussard’s dissent in Moore, the creation of a public tissue trust leads to a paradigm shift in the conception of tissue ownership. What was once my tissue or your tissue becomes our tissue: a treasured and respected public resource with great potential to alleviate the biomedical suffering that continues to permeate the human condition.

A residual worry: as discussed extensively below, the creation of a public tissue trust need not pose any threat to research institutions acquiring title to biomedical patents under the Bayh-Dole Act of 1980.
B. Mechanics and Maintenance

The Commerce Clause clearly grants Congress the requisite authority to create a public tissue trust. In *United States v. Lopez*, the Court "identified three broad categories of activity that Congress may regulate under its commerce power": (1) the *channels* of interstate commerce; (2) the *instrumentalities* of interstate commerce; and (3) those activities having a *substantial relation* to interstate commerce. Congress need not invoke the third category if the regulated activity falls within the parameters of either the first or the second categories. Presumably, research activity involving excised human tissue would fall under both the second category involving the instrumentalities of interstate commerce and the third category as having a substantial relation to interstate commerce.

Human tissue samples fall squarely within the "instrumentalities of interstate commerce" category. Researchers and research institutions routinely ship such samples throughout the United States. As the routine use of MTAs shows, the acquisition of such samples often requires money to change hands. Further, research participants and/or patients, the sole sources of such samples, routinely cross state lines prior to the transfer of their tissue to a biorepository.

In *United States v. Morrison*, the Court provided a four-pronged test to govern congressional enactments falling into the "substantial relation" category. To prove airtight, a statute enacted under Congress’s Commerce Clause authority must: (1) regulate economic activity; (2) provide a jurisdictional element connecting the act to interstate commerce; (3) rely on supportive congressional findings; and (4) evidence a link between the regulated activity and interstate commerce that is not too attenuated.

With regard to the first prong, human tissue research clearly involves economic activity. The construction and maintenance of biorepositories and scientific laboratories, the purchase of lab equipment, and the payment of researchers and lab assistants all involve the exchange of money.

The second prong merely requires that Congress insert a formal jurisdictional element tying the "Tissue Trust Act" to interstate commerce. Such an element would expressly limit the reach of the

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174 Id. at 558–59.
175 Id. at 558.
176 Id.
177 529 U.S. 598 (2000).
178 See id. at 609–15.
179 Id.
“Tissue Trust Act” to those tissue samples sufficiently connected to interstate commerce. Congress could also readily generate supportive findings so as to satisfy the third prong.

Lastly, and perhaps most importantly, the link between human tissue research and interstate commerce is by no means too attenuated. Via MTAs, excised tissue samples routinely cross state lines and move in interstate commerce. The entire biomedical industry, spanning the entire United States, relies on such samples as one of its essential raw materials. The supplies and materials necessary to construct both the biorepositories where research institutions store tissue samples and the labs where researchers study them move in interstate commerce. Researchers themselves frequently cross state lines, and out-of-state institutions often directly fund their research involving human tissue samples.

For these reasons, legislation creating a public tissue trust would fall squarely under Congress’s Commerce Clause authority.

The maintenance of such a trust would require Congress to set aside adequate funding to preserve and husband the excised human tissue samples falling within its scope. Funding would also go to insure adequate administrative oversight of local IRBs both to enhance researcher access and to protect research participant informed consent.

Presumably, a “Tissue Trust Act” would mandate periodic inspections, set up an enforcement arm to investigate violations such as breaches of informed consent, and affix monetary sanctions (e.g., the loss of federal support funds, the suspension of federal grants, etc.) to violations of the conditions of the trust.

C. Scope

According to a 1999 Rand Report (the most recent available), various types of institutions, from medical schools to private sperm banks to military pathology databanks, archived over 300 million human tissue samples in the United States. In 1999, this collection was expanding at a rate of approximately 20 million samples per annum. Importantly, the public tissue trust advocated here would not comprise all available tissue samples in the United States. Instead, enabling congressional legislation would limit the scope of the trust to tissue collections controlled by the National Institutes of Health (“NIH”), the Centers for Disease Control and Prevention (“CDC”), Graduate Medical Education Teaching Institutions (“GMEs”), and

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180 EISEMAN & HAGA, supra note 1, at 133.
181 Id.
specialty collections maintained by major biomedical research institutions. Examples would respectively include the National Institute of Mental Health’s Brain Bank (controlled by the NIH), the tissue bank at the National Center for Infectious Disease (controlled by the CDC), pathology specimens at the Ohio State University Medical School, and the tissue samples at the Case Western Reserve University Alzheimer’s Center. So constituted, such a trust would initially comprise approximately 170–180 million tissue specimens (in 1999 figures). The primary rationale for restricting the scope of a public tissue trust to the above types of institutions is that the federal government either directly controls them, e.g., the NIH, or the institutions in question are large biomedical research institutions that receive tremendous amounts of federal funding, e.g., Case Western Reserve University.

Notably, a public tissue trust would exclude several large collections. For example, the trust would not include the tens of millions of specimens controlled by the Armed Forces Institute of Pathology or the million plus forensic specimens under the control of criminal justice agencies. Neither research nor therapeutic purposes provided the impetus for the creation of such collections, and thus worries of informed consent come to the foreground. A public tissue trust would also exclude tissue samples held by fertility clinics and sperm banks as well as the million plus samples owned by commercial enterprises such as LifeSpan BioSciences, Inc. Following Gibbons v. Ogden and given the deep connection of human tissue sample research to interstate commerce, Congress could seemingly nationalize, as it were, the privately held tissue collections of such for-profit entities. Nonetheless, given the possibly politically unpalatable consequences of such behavior, Congress should most likely exercise its “wisdom and... discretion” to choose otherwise.

182 *Id.* at 137–39 (providing statistics on various institutions and their respective quantities of tissue samples).

183 See *id.* at 137, 139.

184 Given the terrible history of unethical medical experiments conducted on members of the armed forces and prisoners, expanding the trust at their expense might well prove counter productive. Although perhaps upon completing their enlistment, the government could encourage members of the armed forces to dedicate their tissue to the trust.

185 EISEMAN & HAGA, supra note 1, at 66. LifeSpan BioSciences is a genomics company that works with genes affecting the aging process as well as genes relating to different diseases. *Id.*

186 22 U.S. (9 Wheat.) 1 (1824). As Justice Marshall noted at length concerning Congress’s Commerce Clause power: “[i]t is the power to regulate; that is, to prescribe the rule by which commerce is to be governed. This power, like all others vested in Congress, is complete in itself, may be exercised to its utmost extent, and acknowledges no limitations, other than are prescribed in the constitution.” *Id.* at 196.

187 *Id.* at 197.
Lastly, a host of private, non-profit, non-educational institutions, such as the American Type Culture Collection ("ATCC") or the Hereditary Disease Foundation, control hundreds of thousands of human tissue samples. Such institutions tend to receive large amounts of federal funding but are not connected to a federal agency, a medical school, or a major biomedical research institution. Presumably, Congress could strongly encourage such institutions to join the trust but need not require it initially. Many of these entities have been in existence for decades (e.g., the ATCC dates from 1925), and it might prove politically problematic to force them into the fold. Further, since these private tissue collections only comprise a small percentage of extant tissue samples, their non-inclusion would not undermine the overall practical purpose and value of a public tissue trust.

D. Compatibility with the Bayh-Dole Act

The proposed tissue trust is fully compatible with both the spirit and the substance of the Bayh-Dole Act of 1980. Prior to Bayh-Dole's enactment, some twenty-six different federal agencies took title to inventions arising out of federally funded research. Further, federal patent policy only allowed for the granting of nonexclusive licenses to commercial developers. Absent the monopoly protection of an exclusive license, commercial developers had little incentive to bring products to market. As a result, by 1980 "only 5% of federally-owned patents were being used." The avowed congressional purpose behind the Act was thus "to use the patent system to promote the utilization of inventions arising from federally supported research or development."

The Bayh-Dole Act unified federal patent policy with regard to the patentable fruits of federally-funded research. In a nutshell, the Act permitted small businesses and nonprofit organizations (specifically research institutions) to take title to inventions created by

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188 EISEMAN & HAGA, supra note 1, at 67.
189 id. at 68.
192 id.
194 Steven R. Englund & Susan E. Hendrickson, The Bayh-Dole Act and Other Regulation of Rights to Intellectual Property Developed with Government Involvement, in INTELLECTUAL PROPERTY TECHNOLOGY TRANSFER 1, 9 (Aline C. Flower ed., 2006); see also Schacht, supra note 191, at 64–65.
such organizations through contractually awarded federal funding. Essentially, the Act "establishes a presumption that ownership of all patent rights in government funded research will vest in any contractor who is a nonprofit research institution or a small business." Upon acquiring title, research institutions may enter into exclusive licensing agreements with commercial developers. The former gains potentially lucrative royalty payments (that the contracting institution must share with the inventor(s)), while the latter receives the protection of an exclusive license to engage in commercial development.

Such exclusivity provides commercial developers with the necessary economic incentive to engage in extensive product development, which they lacked prior to Bayh-Dole. The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license to practice" the invention should a practical application arise. Lastly, the federal government also holds "march-in" rights (as of yet never invoked) to seize title if a nonprofit/small business contractor fails to take reasonable steps towards commercialization.

By most estimates, Bayh-Dole has been extremely successful and, on all accounts, amounts to a vast improvement over what existed prior to its passage. As noted in a celebratory Congressional Report marking Bayh-Dole's twenty-fifth anniversary, Congress credits the Act with leading to the commercial development of numerous products originating from federally-funded research, most notably the MRI machine. The Act has also led to the creation of some 4,000 new American companies. Further, the number of patents awarded to universities now runs at approximately 3,800 a year compared to only 250 a year prior to 1980.

Importantly, the creation of a public tissue trust need not in any way undermine Bayh-Dole's success. Independently of Bayh-Dole, federal ownership over the trust's biomaterials would be no different than funding awarded for research—except for the fact that the government would provide raw materials as opposed to money. The government's role here would be the same: to enable researchers to

196 35 U.S.C. § 202(c)(4). Otherwise, the federal government would have to pay twice: first, the funds to develop the invention, and second the funds to use the invention. For further discussion, see Englund & Hendrickson, supra note 194, at 21–22.
197 35 U.S.C. § 203. For further discussion, see Englund & Hendrickson, supra note 194, at 22–25.
conduct scientific investigations into the etiology of disease and disability.

Further, a trust need not conflict with Bayh-Dole's fundamental goal of increased commercialization. Under a trust regime, universities may still retain title to any patentable discovery that their researchers make involving tissue obtained from the trust. Two different scenarios present themselves. The first and unproblematic case would occur when the researcher acquired the tissue used to make the discovery from his or her home institution. For example, a Case Western Reserve scientist makes a patentable discovery involving brain tissue obtained from Case Western Reserve's Alzheimer's Center. Here, as required by Bayh-Dole, Case Western Reserve would, at its option, retain control of the title.

The second and potentially problematic case would happen when the researcher acquired the tissue used to make the discovery from a foreign institution. For example, the same Case Western Reserve scientist makes a patentable discovery but this time he or she has acquired the tissue from the Harvard Brain Tissue Resource Center. What then? With the advent of a trust, the federal government qua trustee owns all of the biomaterial in question but relies on institutions such as Harvard and Case Western Reserve to administer the trust locally. Nonetheless, government ownership need not present any undue difficulties. Congress could pursue two different avenues here. First, the government could vest both parties with joint title and require them to negotiate a good-faith royalties sharing agreement. Second, after careful study, Congress could similarly vest both parties with joint title but could then simply stipulate what would amount to an equitable split between the recipient and provider institutions (e.g., 70 percent–30 percent of any future royalties).

Seen in the pro-commercialization light of Bayh-Dole, such solutions would actually improve upon the current practice as embodied in the Master Agreement Regarding Use of the Uniform Biological Material Transfer Agreement ("UBMTA") which the Office of Technology Transfer currently employs. The UBMTA provides a regulatory model for the MTAs that university biorepositories already uniformly utilize. Keeping with the above example, the UBMTA would require the recipient organization, Case Western Reserve, to negotiate a licensing deal with the provider institutions.

\[\text{Insofar as it would limit overall transaction costs, the second option might prove preferable but Congress would need to gather more data to make a definitive determination.}\]

organization, Harvard, which the latter could then always refuse. Contrary to Bayh-Dole, this possibility of provider refusal presents a stumbling block to potential commercialization. Under a Bayh-Dole compatible trust regime, Congress could require the parties to reach an equitable agreement (or stipulate the contents thereof) and then take reasonable steps towards commercialization. If the parties failed to do so then they would face the possibility of a loss of title via the government’s exercise of its march-in rights. If anything, then a public tissue trust would seemingly advance rather than retard Bayh-Dole’s goal of commercialization.

Before turning to the next section, an important caveat deserves re-emphasizing. Commercial product development involving human tissue samples is a rare occurrence. Scientists employ the vast majority of human tissue samples in basic research that is not commercially viable. Thus, Bayh-Dole concerns aside, any policymaker should view the commercial development of products arising out of federally-funded research involving human tissue as the exception rather than the rule.

IV. A PUBLIC TISSUE TRUST AND THE PROTECTION OF INFORMED CONSENT

Any proposed trust regime must adequately protect the informed consent of research participants. Not only is such protection necessary out of respect for the inherent dignity of research participants, but purely pragmatic concerns loom equally large. An absence of adequate consent leads to widespread distrust amongst potential research participants and a corresponding deep reluctance to dedicate their tissue for biomedical research. Hence, proper informed consent here is necessary to ensure the adequate procurement of the raw materials “essential to the success of modern medicine.”

As noted above, the right to informed consent to biomedical research comprises two basic liberty interests: (1) a right of first refusal, i.e., a right not to participate in biomedical research at all; and (2) a revocability right, i.e., a right to withdrawal from research regardless of prior consent to participate. In what follows, this Note provides a brief historical overview of the right to informed consent, a

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203 Id. §§ II(6)-(7).
204 OFFICE OF TECHNOLOGY ASSESSMENT TASK FORCE, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 13 (1988).
205 See WEIR & O'LIFF, supra note 14, at 26–31 (discussing public opinion on the use of human tissue for biomedical research).
206 Id. at 3.
discussion of the “Common Rule,” and an argument to show the proposed trust’s compatibility with the Common Rule.

A. Historical Overview

Foundationally, the doctrine of informed consent exists to protect the intrinsic moral worth and inherent dignity of patients and research participants. The doctrine takes seriously the Kantian dictum that each autonomous, rational being is a “member in the kingdom of ends.” In order to make autonomous decisions, research participants need access to accurate and truthful information. As the district court found in In re Cincinnati Radiation Litigation, “when a person is purposefully misled about . . . crucial facts . . . , he can no longer be said to exercise that degree of free will that is essential to the notion of voluntariness.” In the absence of such “crucial facts,” researchers can easily reduce research participants to a means to an end. In doing so, the researcher treats the research participant as a thing or an object as opposed to a person. As Isaiah Berlin eloquently observed, “[t]o manipulate men, to propel them towards goals which you—the social reformer—see, but they may not, is to deny their human essence, to treat them as objects without wills of their own, and therefore to degrade them.” Properly protected, a right to informed consent prevents such degradation from transpiring.

From an ethical perspective, the Nuremberg Code, the Helsinki Declaration, and the Belmont Report all embody the doctrine of informed consent at their core. The first sentence of the Nuremberg Code reads: “The voluntary consent of the human subject is absolutely essential.” The Helsinki Declaration emphasizes that research participation “must be voluntary” and the participant must be “adequately informed.” Further, research participants “must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal.”

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208 KANT, supra note 35, at 64.
210 Id. at 812.
212 ISAIAH BERLIN, FOUR ESSAYS ON LIBERTY 137 (1969).
215 Id. ¶ B(24).
Belmont Report, the authors stress that “the importance of informed consent is unquestioned.”

Succinctly, “[r]espect for persons requires that subjects . . . be given the opportunity to choose what shall or shall not happen to them.”

While lacking the force of law, the Nuremberg Code, the Helsinki Declaration, and the Belmont Report nevertheless constitute the moral compass of modern biomedical research. Whether taken singly or together, these ethical statements enjoin members of the research community to place the voluntary consent of research participants above all else—including scientific progress. Researcher behavior that transgresses either the substance or the spirit of these documents is, in turn, immediately suspect.

From a legal perspective, a long line of court cases reflects these ethical concerns. Most famously, in Schloendorff v. Society of New York Hospital, Judge Cardozo declared that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.” In Canterbury v. Spence, the appellate court predicated its landmark decision on the “patient’s right of self-determination” and the “patient’s right of self-decision.” Explicitly following Schloendorff, the Canterbury court observed that “[t]rue consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.”

As Faden and Beauchamp note, Canterbury stands for the proposition that “self-determination is the sole justification and goal of informed consent.”

Similarly, in Superintendent of Belchertown State School v. Saikewicz, the Supreme Judicial Court of Massachusetts reasoned that the law developed the doctrine of informed consent as a way to protect the “individual interest in preserving ‘the inviolability of his person.’” Respect for personal autonomy is a “concept, fundamental in American jurisprudence.”

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217 Id.
218 211 N.Y. 125 (1914), abrogated by Bing v. Thunig, 143 N.E.2d 3 (N.Y. 1957).
219 Id. at 129.
221 Id. at 784, 786.
222 Id. at 780.
225 Id. at 424 (quoting Pratt v. Davis, 118 Ill. App. 161, 166 (1905), aff’d, 79 N.E. 562 (Ill. 1906)).
226 Canterbury, 464 F.2d at 780.
While the previous cases addressed informed consent within a clinical context, *In re Cincinnati Radiation Litigation* considers informed consent for research purposes. The case involved poorly educated, cancer-stricken (but not terminally ill) African-Americans whom researchers exposed to very high levels of radiation, thereby inducing severe nausea and vomiting. The researchers deceived their subjects into believing that the radiation "treatments" were for therapeutic as opposed to experimental purposes. The district court found that constitutional due process considerations prohibited such egregiously deceptive practices on the part of researchers. Specifically, "[i]f the Constitution protects 'personal autonomy in making certain types of important decisions,' the decision whether to participate in the Human Radiation Experiments was one that each individual Plaintiff was entitled to make freely and with full knowledge of the purpose and attendant circumstances involved."

**B. The Common Rule**

The "Common Rule" refers to Title 45, Part 46 of the Code of Federal Regulations, entitled "Protection of Human Subjects." The Common Rule constitutes perhaps the most important American legal authority concerning the proper treatment of research participants. It governs all research institutions that receive federal funding. The Common Rule requires such institutions to create IRBs charged with overseeing all research involving human subjects. Specifically, IRBs exist "to safeguard the rights and welfare of human research subjects." An IRB must have at least five members, one of whom is a scientist and one of whom is not affiliated with the institution. The Common Rule invests IRBs with wide latitude to approve or disapprove of research protocols involving human subjects.

A core function of IRBs is to ensure adequate informed consent. IRBs do so through "conducting . . . initial and continuing review[s] of research." The Common Rule provides a comprehensive, eight-

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227 874 F. Supp. 796 (S.D. Ohio 1995); see also Stadt v. Univ. of Rochester, 921 F. Supp. 1023, 1027 (W.D.N.Y. 1996) ("[T]his case does not involve the right to refuse medical treatment, but instead, the right to be free from non-consensual experimentation on one's body . . . ").

228 *In re Cincinnati*, 874 F. Supp. at 803.

229 *Id.*

230 *Id.* at 810–12.

231 *Id.* at 812 (citation omitted) (quoting Whalen v. Roe, 429 U.S. 589, 599–600 (1977)).


233 Levine, *supra* note 82, at 211.

234 45 C.F.R. § 46.107(c)–(d) (2008).

235 *Id.* § 46.109(a).

236 *Id.* § 46.103(b)(4)(i); see also *id.* § 46.109(b)–(c), (e). The Common Rule also requires
element test to determine the adequacy of informed consent. These elements comprise the “core disclosures for research.” Specifically, researchers must provide research participants with the following information in writing: (1) the purpose, nature, and expected duration of the research; (2) the likely risks of participation; (3) the likely benefits to the individual or to society at large of participation; (4) a disclosure of any alternatives (in the case of clinical research); (5) the extent to which researchers can maintain participant confidentiality; (6) whether researchers will provide compensation for participant injury (where research involves more than minimal risk); (7) researcher contact information with whom participants may raise any concerns or inquire further as to their rights; and crucially (8) “[a] statement that participation is voluntary, refusal to participate will involve no penalty . . . and the subject may discontinue participation at any time without penalty.”

The Common Rule, however, also allows IRBs to permit a much less rigorous, much more general consent process “which does not include, or which alters, some or all of the elements of informed consent set forth in this section.” To qualify for the weaker consent procedure, the proposed research must meet the following four elements: (1) the research entails “no more than minimal risk”; (2) a weaker consent procedure will not undermine the rights of the research participants; (3) unless the researcher employs the weaker standard, the research is not practically possible; and (4) researchers must provide participants with “additional pertinent information after participation” if appropriate. Under general consent, researchers need not provide research participants with detailed information concerning the research study. Thus, when both minimal risk and extreme impracticality obtain, the Common Rule permits researchers to shift from informed to general or simple consent.

C. Compatibility with a Public Tissue Trust

Although the Department of Health and Human Services drafted the Common Rule to protect research participants qua experimental subjects, its reach clearly extends to research participants qua tissue
Luckily, the proposed public tissue trust is clearly compatible with the Common Rule. Indeed, a revocable trust analysis is far superior to the gift analysis favored by the courts. As noted above, a gift analysis is inconsistent with a genuine right of revocability. Under a trust regime, IRB overview could ensure that no adverse treatment would occur if a patient or research participant refused to provide a tissue sample. Further, the trust could contact research participants in writing on a routine basis (e.g., once per year) to ascertain whether the continued use of a dedicated tissue sample remained permissible. Again, and in line with the Common Rule, research participants could then easily request that the trust destroy their tissue sample (or at least remove it from research consideration). As discussed throughout this Note, the proposed public tissue trust thus squares nicely with the first refusal and revocability rights essential to the doctrine of informed consent.

Further, a trust regime offers a standardized, uniform way to deal with four tricky consent issues involving human tissue research. First, a tissue trust offers Congress the unique opportunity to impose a uniform standard of disclosure on researchers with regard to research involving human tissue. As Weir and Olick observe, the Common Rule does not provide researchers with a standard of disclosure to determine, for example, the materiality of risk to a research participant.242 This task belongs to the state courts. State courts have traditionally recognized two different standards: (1) the professional standard; and (2) the reasonable person standard.243 Some jurists and bioethicists also advocate a third approach, the subjective standard.244 Hamilton v. Bares245 provides a typical take on the professional standard.246 Therein, the court held that the “duty to obtain informed consent is measured by what information would ordinarily be provided to the patient under like circumstances by health care providers engaged in a similar practice in the locality or in similar

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241 See WEIR & OICK, supra note 14, at 48.
242 Id. at 135.
243 BEAUCHAMP & CHILDRESS, supra note 129, at 80–83.
244 Id. Isolated instances of case law also apparently gesture in this direction. See Scott v. Bradford, 606 P.2d 554, 558 (Okla. 1979). The court held that “the scope of a physician’s communications must be measured by his patient’s need to know enough to enable him to make an intelligent choice. . . . There is no bright line separating the material from the immaterial; it is a question of fact. A risk is material if it would be likely to affect patient’s decision.” Id. While seeming to embrace a subjective standard, the Scott court did so in the context of Canterbury, which stands for an objective reasonable patient standard. Further, the Scott court only criticized the professional standard. Hence, the Scott court’s ultimate position remains unclear.
245 678 N.W.2d 74 (Neb. 2004).
246 See id. at 81.
This standard thus looks to the common practice of the relevant professionals to determine what information requires disclosure.

In contrast, the reasonable person standard and the subjective standard look to the patient/research participant. *Canterbury* is the *locus classicus* for the former: "'[a] risk is . . . material when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk . . . in deciding whether or not to forgo the proposed therapy.'" The *Canterbury* court thus relies upon an objective standard to determine whether sufficient disclosure has occurred. Lastly, the subjective standard emphasizes the individual patient/research participant. Here, what really matters is the idiosyncratic values and desires of each particular patient or research participant. Ideally, physicians/researchers should tailor the consent process to the subjective needs of their individual patients/research participants.

Which standard best applies when dealing with research participants who might serve as a source of human tissue? Weir and Olick make a strong case for the employment of the reasonable person standard. This standard's especially distinct advantage is that "it fits equally well as a standard for disclosure in clinical settings, research settings, or in settings that involve a blending of clinical/research roles." Aside from its applicability across contexts, the reasonable person standard exhibits other virtues as well. Contrary to the aim of informed consent, the professional standard puts researchers and physicians in the driver's seat as opposed to research participants and patients. In doing so, this standard may "subvert[] the [patient’s] right of autonomous choice." Further, the standard's emphasis on a local community of professionals can lead to highly relativistic results and permit standards of disclosure to vary widely across institutions and localities. Researchers could essentially create a very weak standard of disclosure whereby all that would matter is consistency with the prevailing disclosure standards in the relevant local research community. In contrast, the reasonable person standard offers the best chance to ensure that "the patient's

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247 Id.
249 BEAUCHAMP & CHILDRESS, supra note 129, at 83. The subjective standard is primarily an academic creation.
250 WEIR & OLiCK, supra note 14, at 241.
251 BEAUCHAMP & CHILDRESS, supra note 129, at 82.
252 WEIR & OLiCK, supra note 14, at 240.
right of self-decision shapes the boundaries of the duty to reveal." Specifically, "[the scope of the physician's [or researcher's] communications to the patient . . . must be measured by the patient's [or research participant's] need, and that need is the information material to the decision."

At the other extreme, the subjective standard seemingly requires too much of researchers and fits poorly within the research context. The vast majority of researchers do not have intimate relationships with research participants. Thus, the subjective standard would require researchers to expend tremendous time and energy to acquaint themselves with research participants' values and desires—a decidedly counterproductive result. Indeed, in many cases such a relationship would not even prove possible as researchers often have no contact with research participants who donated tissue long ago.

In the present context, the reasonable person standard provides the best option. On the one hand, with its focus on objectivity, the reasonable person standard fits well with the often quite tenuous interpersonal link between researcher and research participant. On the other, with its focus on the research participant, the reasonable person standard offers research participants a level of protection not found in the professional standard. Given these benefits, as part of legislation enacting a tissue trust, Congress could insert a provision requiring a reasonable person standard of disclosure. Only under the auspices of a national tissue trust could such a uniform standard arise. Otherwise, research participants are left to the vicissitudes of state disclosure laws, many of which rely solely on the professional standard regardless of the clinical or research context.

Second, a public tissue trust would allow for a uniform approach to protecting the "identity status" of research participants. Currently, a debate rages over the extent to which researchers and others ought to have access to the identity of tissue donors. Depending upon the policy of the local institution, researchers may currently employ "identified" samples (the sample container features the name of the donor), "coded" samples (the sample container features a numerical code that links to the name of the donor stored in a computer database), "anonymous" samples (samples collected

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253 Canterbury, 464 F.2d at 786.
254 Id. (footnote omitted).
255 WEIR & OICK, supra note 14, at 242.
256 Id. at 48.
257 Id. at 140–43.
without any identifiers), and "anonymized" samples (samples from which researchers stripped the original identifiers). Any of these options poses risks to research participants. Inadequate protection of identity status through the use of only identified samples may lead to an increased risk of breaches of confidentiality and genetic discrimination. The use of anonymized samples means that researchers will lack the ability to contact research participants about personal health risks discovered during research or about the use of their tissue to develop commercial products. As part of any consent process, researchers need to explain these risks thoroughly to research participants. Whatever approach policymakers adopt to address the identity status problem, a public tissue trust would at least insure a uniform policy that would cover well over 170 million stored tissue samples. For instance, the trust could require researchers to "code" all collected samples unless research participants decided otherwise.

Third, a public tissue trust would also provide policymakers with a uniform way to handle retrospective studies involving human tissue research. Briefly, scientists may currently conduct research involving human tissue either prospectively or retrospectively. In prospective studies, the researchers designed their protocol prior to acquiring the tissue sample. In retrospective studies, researchers employ archived tissue originally collected for some other therapeutic or research purpose.

Properly conducted, prospective studies easily pass the Common Rule's eight-element consent test while retrospective studies clearly do not. In the latter instance, neither patients, research participants, nor the original researchers themselves, knew of the future research that would eventually employ the collected samples. As such, the

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258 Id. at 48.
259 But see id. at 34 (stating that "genetic discrimination is a rare occurrence" and fears of its imminence are "greatly exaggerated").
260 See id. at 144.
262 This figure is derived from tallying the collections of all of the biorepositories listed by Eiseman and Haga which would fall under the scope of the proposed trust. See EISEMAN & HAGA, supra note 1, at 137–39.
263 Unless samples are at least coded, research participants lose the ability to withdraw the use of their tissue from research for the simple reason that researchers can no longer link research participants' samples to them.
264 See WEIR & OLICK, supra note 14, at 47–48.
265 Post-diagnostic tissue research, i.e., samples collected for therapeutic purposes and subsequently used in research, pose a particularly thorny problem in the case of retrospective studies. Id. at 49.
tissue donors failed to give their informed consent to the use of their samples in such research.

Many researchers and ethicists argue that a doctrine of general or "simple consent" should control here. Given the minimal risk to research participants and the practical difficulties of re-consenting, these scholars claim that the Common Rule clearly permits the loosening of informed consent in this context. Other scholars vehemently disagree and demand that researchers seek new, informed consent each time they employ tissue samples in retrospective studies. Definitive solutions prove elusive. Again, a public tissue trust nevertheless offers a consistent approach to the difficulty, whichever option policymakers ultimately endorse. And, under a limited revocability trust regime, research participants would still retain their first refusal and revocability rights, regardless of whether researchers employed informed or general/simple consent.

Fourth, many research participants want to choose the type of research done with their tissue. For instance, a cancer sufferer might choose to provide tissue for research but only if researchers promise to employ the sample in cancer studies. Some professional research societies, such as the College of American Pathologists, reject this option out of hand. The fear is that allowing research participants to make such choices will enable them to exert too much control over research. Researchers, and not research participants, the argument runs, are in much better position to determine the best of tissue samples in research. So empowering research participants thus apparently threatens to undermine biomedical progress.

The advent of a public tissue trust might well allay some of these fears and provide research participants with more control over the future use of their samples, thereby enhancing the informed consent process. Succinctly, several biorepositories specialize in the tissue samples they store, e.g., prostate tissue, brain tissue, tumors, etc. Research participants who were adamant that researchers only use their tissue "to find a cure for cancer" need not have their desires stymied. A researcher could still collect a sample for the appropriate biorepository. Since every researcher who engaged in bona fide research would have a right of access to the trust, research participant

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266 Grizzle et al., supra note 116, at 299.
267 WEIR & O LiCK, supra note 14, at 57–59.
269 Grizzle et al., supra note 116, at 298–99.
270 Id.
271 EISEMAN & HAGA, supra note 1, at 46–77.
selectivity need not undermine biomedical progress. Administrators of the trust might still have to set limits, however, should too many research participants choose to “specialize.”

In sum, the proposed public tissue trust need not in any way conflict with the Common Rule. A limited revocability trust would clearly allow research participants to exercise their rights to first refusal and revocability, provide a uniform approach to the informed consent process, and grant research participants more control over the final disposition of their dedicated tissue.

V. COMMERCIALIZATION

What legal rights, if any, do research participants retain if researchers develop a commercially viable biomedical product from their tissue? Sketching an answer to this question requires a brief foray into biomedical commercialization. Presumably, researchers should disclose the possibility of commercialization to potential research participants as part of the consent process. As both Moore and Greenberg aptly illustrate, lucrative commercialization ventures involving human tissue, though rare, occasionally obtain. Basic fairness seemingly demands that those who originally provided the raw biomaterial for such ventures receive some sort of compensation. Indeed, while many research participants would continue to dedicate tissue regardless of potential recompense, many might not. Further, if spectacular commercial successes were to occur, but research participants were left out in the cold, a subsequent chilling effect on tissue dedication might well occur. Two types of concerns require resolution: (1) Moore worries; and (2) Greenberg worries. In what follows, this Note succinctly attempts to allay both types of fears.

Moore worries: In Moore, the majority denied the plaintiff’s conversion action against researchers who, without the plaintiff’s consent, employed his tissue to develop several commercial products with an estimated market value of three billion dollars. An important underlying issue in the case is what one might term the “non-fungibility” of Moore’s tissue. Specifically, Moore was an over-producer of T-lymphokines. Moore (as well as Ted Slavin) was the biological equivalent of a “needle in a haystack.” At the time, his over-producer status rendered him unique. His cells (infected with

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272 Researchers also need to inform research participants that if they consent to anonymization of their samples at the outset, it will prove impossible to contact them should successful commercialization involving their tissue occur.

273 Moore v. Regents of Univ. of Cal., 793 P.2d 479, 482 (Cal. 1990).

274 Id. at 482 n.2.
a virus that caused the anomaly) were not fungible with the cells of his biological peers, i.e., the rest of us, relative to their virally enhanced ability to over produce T-lymphokines. Moore was essentially biologically irreplaceable. He was clearly the *sui generis* “but-for” cause of all of the products developed from his patented cell line (ironically named after him even though he retained absolutely no claim to it). Not unlike a supermodel or an amazing athlete, Mother Nature endowed Moore with a unique natural gift. Thus, the decision to deny him any compensation for his deceptively obtained contribution of unique raw material strikes many laypeople and professionals as decidedly unfair.

Further, the difficulties the majority raised in *Moore* are not metaphysical conundrums of the sort a court confronts in a wrongful life action. The deep worry for the *Moore* court is judicial overreaching. The majority readily admits that the legislature could easily pass a law superseding their decision and statutorily expand the concept of conversion to accommodate Moore. Should it choose to create a public tissue trust, Congress ought to include a detailed commercialization provision. The provision should require patent holders to provide some amount of compensation to those research participants whose biologically unique tissue constitutes the raw material of a profitable biomedical product.

Basic fairness seemingly provides an intuitive justification for an equitable compensation scheme. After all, why should researchers, universities, and biotech firms reap profits while biologically unique research participants get nothing? The average person and potential research participant may well choose not to dedicate tissue to a trust which provides everyone but them with the possibility of financial benefit. Sufficiently widespread, such disillusionment amongst potential research participants would bode ill for biomedical progress—regardless of the overall rarity of such cases as *Moore*. Importantly, Congress could follow Justice Arabian’s concluding dicta and devise a compensation scheme that would award an equitable percentage of the profits/lump sum payment to the John Moores and Ted Slavins amongst the trust’s settlors.

*Greenberg* worries: In *Greenberg*, the court refused to dismiss a claim of unjust enrichment against the defendant researchers and research institutions. The defendants misled plaintiffs by employing

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275 Id. at 511 (Mosk, J., dissenting).
276 WEIR & OLICK, supra note 14, at 162–65.
277 Moore, 793 P.2d at 498 (Arabian, J., concurring).
278 Id. at 488 (majority opinion).
279 Id. at 498 (Arabian, J., concurring).
their tissue samples and other resources to derive a diagnostic test for an "orphan" genetic disorder, Canavan's disease. Here, unlike Moore, the tissue involved in developing a marketable commercial product was fungible (at least relative to the universe of persons bearing the Canavan's gene). In other words, tissue from any Canavan's carrier would have been sufficient. One can easily bring more expansive "fungibility" scenarios to mind. Imagine that the tissue sample utilized to develop a cure for prostate cancer could have come from any prostate. In this hypothetical, full fungibility across all prostate tissue would obtain.

Here, the claim for personal compensation for research participants appears much weaker than in Moore. The lack of biological uniqueness makes it impossible for such research participants to claim "without me, no commercial product would exist." Nonetheless, Congress could find a form of indirect compensation to be in order. That is, the trust could require the developers of commercially successful, biomedical products from fungible tissue samples to put a percentage of their profits back into the trust. Such a provision could then assuage any fears that the trust existed to benefit a few technologically savvy elites, as opposed to the public at large.

CONCLUSION

In sum, a national tissue trust offers the best available solution to the ethical, legal, and policy challenges posed by human tissue ownership. Such a trust would uniquely serve the interests of two overriding yet potentially conflicting policy goals: ensuring biomedical progress and protecting informed consent. A limited revocability trust offers a way to provide the requisite archival stability essential to biomedical progress while simultaneously affording research participants the right to revoke their consent to continued use of their dedicated tissue in research. Clearly, a trust theory cannot completely resolve the tension between these two goals. But this apparently less than optimal result is a cause for relief and not worry. By focusing exclusively on one policy goal at the expense of the other, both the gift and the bailment theories prove decidedly unsatisfactory. A gift analysis eviscerates meaningful informed consent while a bailment theory induces radical archival instability. Instead, a trust theory both forges a suitable compromise between its erstwhile rivals and also invites a new way of conceptualizing human tissue ownership. With the advent of a tissue trust, what was once yours or mine becomes ours: a shared national
treasure to make our lives, and the lives of future generations, better off.

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