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YOU DON'T OWN ME: RECOMMENDATIONS TO PROTECT
HUMAN CONTRIBUTORS OF BIOLOGICAL MATERIAL AFTER
WASHINGTON UNIVERSITY V. CATALONA

LAURA B. ROWE*

INTRODUCTION

The last time you had blood drawn or a biopsy taken, did you think about what would happen to that sample after the laboratory tests had been conducted? The thought likely never crossed your mind—and if it did, you probably guessed that it would somehow be destroyed or disposed of. It probably comes as a surprise, then, that your blood, tissue, or other biological material¹ is likely stored in at least one biobank or biorepository.² In fact, the hospital or laboratory that tested your specimen may have even sold it to a biotechnology³ company, profiting from *your* blood, or *your* tissue.⁴

* J.D., Chicago-Kent College of Law, May 2009. B.A., Psychology, University of Wisconsin-Madison, 2006. I would like to thank Professor Lori Andrews and Gina Bicknell for their invaluable guidance. I would also like to thank my parents, Judy and Ed, and my sister, Susan, for their love and support, as well as Michael Greenspan for his endless encouragement.

1. In this note, the term “biological material” or “human biological material” will include human tissues (e.g., blood, bone, muscle, and skin), cells, DNA, gametes (i.e., sperm and ova), and waste (e.g., hair, urine, and feces). See NAT’L BIOETHICS ADVISORY COMM’N, 1 RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 1–2 (1999), available at http://www.bioethics.gov/reports/past_commissions/nbac_biological1.pdf [hereinafter NBAC REPORT]; see also OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS—SPECIAL REPORT 24 (1987), available at <http://www.fas.org/ota/reports/8719.pdf> [hereinafter OTA SPECIAL REPORT].

2. See Lori Andrews, *The Battle Over the Body*, TRIAL, Oct. 2006, at 22, 26. In this note, the terms “biobank” and “biorepository” will be used interchangeably to refer to “[a]n organization, place, room, or container (a physical entity) where biospecimens are stored.” NAT’L CANCER INST., U.S. DEP’T OF HEALTH & HUMAN SERVS., NATIONAL CANCER INSTITUTE BEST PRACTICES FOR BIOSPECIMEN RESOURCES 30 (2007), available at http://biospecimens.cancer.gov/global/pdfs/NCI_Best_Practices_060507.pdf [hereinafter NCI BEST PRACTICES]; see also Michael J. Malinowski, *Taking Genomics to the BioBank: Access to Human Biological Samples and Medical Information*, 66 LA. L. REV. (SPECIAL ISSUE) 43, 43 (2005) (“Biobanking is the organized collection of DNA and accompanying medical information from human populations.”).

3. Broadly defined, the term “biotechnology” “includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses—including recently developed techniques such as gene cloning and cell fusion.” OTA SPECIAL REPORT, *supra* note 1, at 24.

4. Andrews, *supra* note 2, at 26.

Researchers have been storing human biological materials for well over one hundred years.⁵ As the turn of the twenty-first century approached, researchers hoping to discover the genetic causes of various diseases recognized the increasing need for biological data from large populations; as a result, the practice of storing human biological materials in biobanks and biorepositories became significantly more widespread.⁶ The effect of biobanking has been astounding: in 1999, the National Bioethics Advisory Commission (NBAC)⁷ estimated that biobanks across the United States house at least 282 million specimens—from over 176 million individuals—and over twenty million new samples are added each year.⁸ While many individuals knowingly contribute⁹ their specimens to these biobanks for research purposes, a significant portion of these specimens is procured from individuals who, at the time of extraction, are unaware that researchers intend to use their tissue or fluids for research purposes.¹⁰ In many instances, health care providers obtain a patient's biological material during the course of medical treatment;¹¹ once the health care provider has conducted the appropriate tests necessary for the patient's treatment, he or she may reap economic benefits from the patient's biological material by

5. NBAC REPORT, *supra* note 1, at 1; Sheri Alpert, *Privacy and the Analysis of Stored Tissues*, in 2 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE A-1, A-12 (1999).

6. Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343, 346 (2007).

7. NBAC was established pursuant to Executive Order in 1995; after NBAC expired in 2001, the President's Council on Bioethics was established. The President's Council on Bioethics: Former Bioethics Commissions, http://www.bioethics.gov/reports/past_commissions/index.html (last visited January 8, 2009); The President's Council on Bioethics: Executive Order 13237 (Nov. 28, 2001), <http://www.bioethics.gov/about/executive.html>.

8. NBAC REPORT, *supra* note 1, at 1. A report published by the RAND Corporation in 1999 made a "conservative estimate" that over 307 million tissue samples—from over 178 million people—were stored in the United States. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., Apr. 16, 2006, § 6, at 38, 40, available at <http://home.earthlink.net/~rskloot/TakingTheLeast.pdf>.

9. In this note, the terms "contribute" and "contributor" will be used instead of "donate" and "donor," as the latter terms "may imply a waiver of the contributor's rights in the tissue specimen." Barbara J. Evans & Eric M. Meslin, *Encouraging Translational Research Through Harmonization of FDA and Common Rule Informed Consent Requirements for Research with Banked Specimens*, 27 J. LEGAL MED. 119, 124 n.19 (2006) (discussing the Food and Drug Administration's (FDA) concern over the implied meaning of the term "donation"); see also Ellen Wright Clayton, Karen K. Steinberg, Muin J. Khoury, Elizabeth Thomson, Lori Andrews, Mary Jo Ellis Kahn, Loretta Kopelman & Joan O. Weiss, *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786, 1787 (1995) (arguing that it is inappropriate "to refer to people from whom samples are obtained as 'donors'" because this term "implies an intent to make a gift or to relinquish control that may not apply to any particular individual").

10. Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 189–90 (2000); see also NBAC REPORT, *supra* note 1, at 7 ("Once stored, human biological materials have been available for research, usually without the knowledge or consent of the sources . . .").

11. NBAC REPORT, *supra* note 1, at 2; see Elizabeth E. Appel Blue, *Redefining Stewardship Over Body Parts*, 21 J.L. & HEALTH 75, 79 (2007).

selling the specimen to a biotechnology research firm.¹²

As Professor Donna Gitter explains, this system has resulted in an “unprecedented commercialization of the human body, and both researchers and shareholders in biotech firms routinely profit from this process.”¹³ By some estimates, the human tissue industry generates approximately one billion dollars each year.¹⁴ Yet, as Professor Radhika Rao notes, the current state of the law on biomedical research “permits commodification and commercialization of the body by everyone except the person who provides the ‘raw materials.’”¹⁵ For instance, California law prohibits the compensation of women who supply their eggs for embryonic stem cell research, yet it permits the granting of patents upon the human tissue lines created through such research.¹⁶

Without a doubt, research using stored biological materials has led to significant treatments and cures for some of the most devastating ailments and diseases.¹⁷ But, as science and medicine have rapidly advanced, and as

12. Professor Andrews provided an interesting narrative on this issue:

In October 2001, I spoke to the national meeting of the College of American Pathologists and learned that health care institutions were routinely selling their patients' tissue to biotechnology companies, often without consent of the patients involved. Some pathologists in the audience said that adequate diagnosis was being impeded by these sales. Pathologists would attempt to undertake an autopsy, but find that the bones and other tissue had already been removed for sale, preventing them from correctly assessing the medical condition of the individual.

Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005); see also Mahoney, *supra* note 10, at 189–90.

13. Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 WASH. & LEE L. REV. 257, 300 (2004).

14. E.g., Blue, *supra* note 11, at 77 (noting that the tissue industry “has evolved from approximately a \$20 million dollar industry in the early 1990s to a billion dollar industry in 2003”); Michelle Oberman, *When the Truth Is Not Enough: Tissue Donation, Altruism, and the Market*, 55 DEPAUL L. REV. 903, 911 (2006).

15. Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371, 371 (2007). What this means is that a researcher or institution may sell a contributor's sample to a biobank or biotechnology firm for a profit, without compensating the human source of the sample. See *id.* However, if contributors specifically seek out compensation at the time of contribution, they are free to “play the tissue market as well as any biotech company.” Skloot, *supra* note 8, at 44. As a result, some patient groups have begun to create their own tissue banks, allowing them to control the use and commercialization of their tissues. See Anne Nichols Hill, Note, *One Man's Trash is Another Man's Treasure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material*, 5 HEALTH CARE L. & POL'Y 259, 278 (2002).

16. Rao, *supra* note 15, at 380 n.2. The risks, benefits, ethics, and legality of patenting human genes are all beyond the scope of this note. For an excellent discussion of these issues, see Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2 HOUSTON J. HEALTH L. & POL'Y 65, 89 (2002).

17. See Alpert, *supra* note 5, at A-4 (“Many of the most important advances made in medical science would have been more difficult were it not for the analysis of collected and stored human tissues.”). For instance, after a series of studies on precancerous lesions of the uterine cervix in the 1960s, the Pap smear became a commonly used method of early diagnosis of cervical cancer. Allen Buchanan, *An Ethical Framework for Biological Samples Policy*, in 2 NAT'L BIOETHICS ADVISORY

the market value of the human body and its parts continues to increase,¹⁸ many legal and ethical dilemmas have developed.¹⁹ In the area of human subjects research, legal battles over these difficult issues have waged for nearly two decades, beginning with the landmark case of *Moore v. Regents of the University of California*.²⁰ The *Moore* case arose after doctors and researchers at the University of California convinced leukemia patient John Moore to attend postsurgery follow-up visits, during which they withdrew blood, skin, bone marrow, sperm, and other types of cells from Moore.²¹ Moore's physician told him that these visits were "necessary and required for his health and well-being," but in reality, they were looking to use Moore's T-lymphocytes²² to develop a cell line.²³ After successfully doing so, the researchers and the University applied for, and obtained, a patent on Moore's T-lymphocyte cell line.²⁴ The Supreme Court of California held that Moore had successfully stated causes of action against his physician for lack of informed consent and breach of fiduciary duty.²⁵ However, the majority held that Moore could not sustain his claim for conversion, because he had neither ownership nor possessory rights in his excised cells.²⁶

COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, *supra* note 5, at B-1, B-13. Similarly, research on lung tissue from deceased smokers played a significant role in establishing that smoking has a causal effect on the development of lung cancer. *Id.*

18. See Blue, *supra* note 11, at 77 ("[T]he raw component for this industry is the human body, which continues to increase in market value. On average a cadaver generates between \$30,000 to \$50,000 in value, but a single cadaver can generate over \$200,000.").

19. As Professor Andrews explained, the \$28.5 billion biotechnology industry "is not without controversy." Andrews, *supra* note 12, at 22. In particular, Professor Andrews illustrated the numerous issues raised by the biobanking sector of this industry:

What type of information, if any, should the source of the tissue be given before tissue is entered into a biobank? What cultural and personal values might it violate for [a] person's tissue to be used without his or her informed consent? What should be done with the genetic information gleaned from a biobank? Under what circumstances is commercialization of biobank samples and information appropriate? How should the fruits of biobanking be distributed? How can people protect themselves from unauthorized and unwanted use of, or commercialization of, their tissue samples? What new institutional policies and legal regulations might be necessary to govern the emerging biobank economy?

Id. at 23–24.

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

21. *Id.* at 481.

22. A T-lymphocyte is a type of white blood cell that produces lymphokines—or proteins—that regulate the immune system. See *id.* at 481 n.2; see also NEIL A. CAMPBELL & JANE B. REECE, BIOLOGY 904–06 (6th ed. 2002).

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

24. *Id.* at 481–82. See generally Unique T-Lymphocyte Line and Products Derived Therefrom, U.S. Patent No. 4,438,032 (filed Jan. 6, 1983).

25. *Moore*, 793 P.2d at 480, 483.

26. *Id.* at 480, 488–89. According to the *Moore* court, conversion is "a tort that protects against interference with possessory and ownership interests in personal property," and was "originally used to determine whether the loser or the finder of a horse had the better title." *Id.* at 487–88. Furthermore, the court stated that, "[t]o establish a conversion, [a] plaintiff must establish an actual interference with his

In 2003, individuals who had knowingly contributed tissue and fluids for research on Canavan disease²⁷ sued the physician and hospital that used their biological materials to isolate and patent the gene causing the disease.²⁸ In *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the United States District Court for the Southern District of Florida dismissed the plaintiffs' claim for conversion, stating that the plaintiffs did not have any "cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion" because they had made "donations to research without any contemporaneous expectations of return."²⁹

Whereas *Moore* and *Greenberg* involved patients and contributors objecting to researchers trying to control the *products* made from their biological materials (for example, by patenting their cell lines),³⁰ the most recent controversy—*Washington University v. Catalona*³¹—stems from competing claims over the ownership of biological materials *themselves*.³² This dispute began when Dr. William Catalona, a renowned prostate cancer surgeon and researcher, decided to leave Washington University (WU) for

ownership or right of possession. . . . Where [the] plaintiff neither has title to the property alleged to have been converted, nor possession thereof, he cannot maintain an action for conversion." *Id.* at 488 (citing *Del E. Webb Corp. v. Structural Materials Co.*, 123 Cal. App. 3d 593, 610–11 (Cal. Ct. App. 1981)).

27. Canavan disease is a degenerative genetic disease, most typically affecting Ashkenazi Jewish babies. *STEDMAN'S MEDICAL DICTIONARY, CANAVAN DISEASE* 511 (27th ed., Lippincott Williams & Wilkins 2000).

28. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066–67 (S.D. Fla. 2003). See generally *Aspartoacylase Gene, Protein, and Methods of Screening for Mutations Associated with Canavan Disease*, U.S. Patent No. 5,679,635 (filed Sept. 9, 1994).

29. *Id.* at 1064, 1074, 1076. The court went on to distinguish various cases cited by the plaintiffs in support of their argument, stating that these cases "do not involve voluntary donations to medical research." *Id.* at 1075 ("See, e.g., *Brotherton v. Cleveland*, 923 F.2d 477, 482 (6th Cir. 1991) (aggregate of rights existing in body tissue is similar to property rights); *York v. Jones*, 717 F. Supp. 421, 425 (E.D. Va. 1989) (couple granted property rights in their frozen embryos)."). It should be noted that, while the *Greenberg* court dismissed the plaintiffs' claims for conversion and lack of informed consent, among others, the court *did* find that the plaintiffs had sufficiently stated a cause of action for unjust enrichment. 264 F. Supp. 2d at 1072. Under this claim, the plaintiffs argued that they would not have provided the researchers with a benefit—their genetic material, as well as their time and effort—if they had known that the researchers intended to commercialize their genetic material through patents and restrictive licenses. *Id.* According to the plaintiffs, the researchers' retention of such benefits "violates the fundamental principles of justice, equity, and good conscience." *Id.* For further discussion of an unjust enrichment cause of action in this context, see Debra L. Greenfield, *Greenberg v. Miami Children's Hospital: Unjust Enrichment and the Patenting of Human Genetic Material*, 15 *ANNALS HEALTH L.* 213, 214–25 (2006).

30. See *Greenberg*, 264 F. Supp. 2d at 1068; *Moore*, 793 P.2d at 487; Lori Andrews, *Who Owns Your Body? A Patient's Perspective on Washington University v. Catalona*, 34 *J.L. MED. & ETHICS* 398, 400 (2006).

31. 437 F. Supp. 2d 985 (E.D. Mo. 2006), *aff'd*, 490 F.3d 667 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008), and *cert denied sub. nom.* *Ward v. Wash. Univ.*, 128 S. Ct. 1122 (2008).

32. *Id.* at 994; see Andrews, *supra* note 30, at 402.

a new position at Northwestern University (Northwestern) in 2003.³³ For approximately twenty-five years, Dr. Catalona had collected samples of patients' biological materials to use for prostate cancer research, and he was instrumental in establishing the Genitourinary (GU) Biorepository.³⁴ In compliance with the federal research regulations,³⁵ Dr. Catalona and WU required each research participant to complete an informed consent form prior to contributing their biological material.³⁶ In addition to the consent forms, each research participant received and signed a genetic research information brochure.³⁷

When Dr. Catalona accepted the position at Northwestern, he sent letters to his patients and other individuals who had contributed biological materials to the GU Biorepository, informing them of his departure from WU and his intention to continue researching prostate cancer at Northwestern.³⁸ Dr. Catalona also explained that, to succeed in his research goals, he needed continued access to their contributed samples; therefore, he requested that the recipient sign and return a "release form," which authorized the transfer of the contributor's samples to Dr. Catalona at Northwestern.³⁹ After learning of this, WU filed a lawsuit against Dr. Catalona, seeking declaratory judgment that WU was the rightful owner of the biological materials in the GU Biorepository, and a permanent injunction to prevent Dr. Catalona from transferring the samples.⁴⁰ Eight of Dr. Catalona's patients later sought to intervene in the case; while the district court denied that motion, it nevertheless added the patients as defendants, hold-

33. *Catalona*, 437 F. Supp. 2d at 988.

34. *Id.* at 988–89. The GU Biorepository houses biological material, including prostate tissue specimens, blood, and DNA samples, for prostate cancer research. *Id.* at 988. In addition, the GU Biorepository is located in one or more buildings owned by WU, and WU has provided the majority of the funding for its operation and maintenance. *Id.* at 989. As of April 2005, the GU Biorepository contained 100,000 serum samples and 4,400 DNA samples, for example; some of these samples came from Dr. Catalona's patients, some came from other WU physicians' patients, and some came from individuals who were not patients of Dr. Catalona or any other WU physician. *Id.* at 988–89. Dr. Catalona, as well as other WU physicians, had conducted prostate cancer research studies using the material in the GU Biorepository; in some instances, Dr. Catalona was named the study's "Principal Investigator," but the research studies were "collaborative effort[s] involving substantial work by many individuals, all of whom were/are employees of WU." *Id.* at 989–90.

35. See discussion *infra* Part I.

36. *Catalona*, 437 F. Supp. 2d at 990.

37. *Id.*

38. *Id.* at 993.

39. *Id.* The "Medical Consent & Authorization" form read:

I have donated a tissue and/or blood sample for Dr. William J. Catalona's research studies. Please release all of my samples to Dr. Catalona at Northwestern University upon his request. I have entrusted these samples to Dr. Catalona to be used only at his direction and with his express consent for research projects.

Id. Approximately six thousand recipients returned their signed authorization form to Dr. Catalona. *Id.*

40. See *id.* at 987–88.

ing that they were necessary parties to the case.⁴¹

After holding a hearing to determine the ownership of the biological materials—which the district court decided was the dispositive issue in the case⁴²—the court granted summary judgment to WU, holding that the research participants had given the samples to WU as *inter vivos* gifts.⁴³ Accordingly, the court also held that WU owned the biological materials in the GU Biorepository, and that neither Dr. Catalona nor any research participant had any ownership rights or proprietary interest in the samples.⁴⁴

On appeal, the United States Court of Appeals for the Eighth Circuit affirmed the district court's conclusions, holding that research participants “who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research” *do not* “retain an ownership interest” in their materials.⁴⁵ Instead, the Eighth Circuit held that the research participants made valid *inter vivos* gifts under Missouri common law.⁴⁶ The district court expressed grave concern that a contrary ruling would stifle future scientific research.⁴⁷ Ironically, however, the Eighth Circuit's affirmation of that decision, in combination with unclear and insufficient federal research regulations, threatens to do just that.

Part I of this note reviews the doctrine of informed consent and its role in the federal regulations governing research conducted on human subjects. Part II examines the issue of informed consent in *Washington University v. Catalona*; this Part then analyzes the Eighth Circuit's opinion in *Catalona*, ultimately concluding that the court's decision was, first, erroneous under Missouri common law and, second, precluded by the applicable federal regulations. Recognizing the need for reform, Part III proposes amendments to the federal research regulations that will ensure the continued advancement of biomedical research, while also protecting the human contributors of the biological materials that are necessary for future research.

41. Order dated Mar. 14, 2005 at 2, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03CV01065).

42. *Catalona*, 437 F. Supp. 2d at 994.

43. *Id.* at 997.

44. *Id.* at 1002.

45. *Wash. Univ. v. Catalona*, 490 F.3d 667, 673, 677 (8th Cir. 2007), *cert. denied*, 128 S. Ct. 1122 (2008), and *cert. denied sub nom. Ward v. Wash. Univ.*, 128 S. Ct. 1122 (2008).

46. *Id.* at 674, 676.

47. See *Catalona*, 437 F. Supp. 2d at 1002. Interestingly, many of the district court's examples of the tragedies that would result from a contrary decision actually depict the *current* state of biomedical research and biobanking. For instance, the court asserted: “If left unregulated and to the whims of a [contributor], these highly-prized biological materials would become nothing more than chattel going to the highest bidder.” *Id.* However, researchers already frequently sell samples of human biological material to biobanks. See *supra* notes 15 & 18 and accompanying text.

I. THE DOCTRINE OF INFORMED CONSENT AND THE COMMON RULE

Justice Benjamin N. Cardozo established the doctrine of informed consent in the 1914 case *Schloendorff v. Society of New York Hospital*.⁴⁸ Based upon notions of autonomy and bodily integrity,⁴⁹ Justice Cardozo stated that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”⁵⁰ For decades following the *Schloendorff* decision, the United States Congress and various administrative agencies enacted a patchwork of laws, regulations, and guidelines designed to provide increasingly greater protection of human research subjects’ bodily integrity and autonomy.⁵¹ In 1974, the federal agency that was later renamed the Department of Health and Human Services (HHS)⁵² promulgated comprehensive regulations known as the Federal Policy for the Protection of Human Subjects, forming the initial version of 45 C.F.R. part 46, subpart A.⁵³ In response to the *Belmont Report*,⁵⁴ HHS revised the regulations in 1981.⁵⁵ After their adoption by sixteen federal departments and agencies in 1991, the regulations in 45 C.F.R. part 46, subpart A became known as the Common Rule.⁵⁶

48. 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds* by *Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957), *and superseded by statute on other grounds*, N.Y. PUB. HEALTH LAW § 2805-d (McKinney 2007). In *Schloendorff*, a hospital patient consented to a particular examination, but—contrary to the advice of her doctors—refused to undergo an operation. 105 N.E. at 93. While she was unconscious, doctors conducted both the examination *and* the operation. *Id.* The hospital patient alleged that the operation was administered without her consent or knowledge, and sought to charge the hospital with liability for the wrong based on a theory of trespass. *Id.*

49. *See Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 269 (1990) (citing *Schloendorff*, 105 N.E. at 93).

50. *Schloendorff*, 105 N.E. at 93.

51. *See* ERIN D. WILLIAMS, CONG. RESEARCH SERV., FEDERAL PROTECTION FOR HUMAN RESEARCH SUBJECTS: AN ANALYSIS OF THE COMMON RULE AND ITS INTERACTIONS WITH FDA REGULATIONS AND THE HIPAA PRIVACY RULE 12–13 (updated June 2, 2005) *available at* <http://www.fas.org/sgp/crs/misc/RL32909.pdf>.

52. In 1980, the Department of Health, Education and Welfare officially became known as the Department of Health and Human Services (HHS). *Id.* at 5, 14.

53. *Id.* at 5, 14, 63 n.150; *see generally* 45 C.F.R. pt. 46, subpt. A (2007).

54. NAT’L COMM’N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH* (1979), *available at* <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>. The *Belmont Report* outlined three main ethical principles of human subjects research: (1) respect for persons, (2) beneficence, and (3) justice. *Id.* § B.

55. WILLIAMS, *supra* note 51, at 14. This was the first and only time 45 C.F.R. pt. 46 has been amended. *See id.* at 12–16.

56. *See* Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28,003 (June 18, 1991). Today, the Common Rule governs the human research activities conducted or supported by eighteen federal departments and agencies. WILLIAMS, *supra* note 51, at 6. HHS later adopted 45 C.F.R. pt. 46, subpts. B–D, which protect “women and neonates, prisoners, and children, respectively.” *Id.* Since they were adopted later, these subparts are not part of the regulations that are referred to as the Common Rule. *Id.*

One of the most significant sections of the Common Rule codifies the doctrine of informed consent and provides that “no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject’s legally authorized representative.”⁵⁷ One of the essential elements of informed consent under the Common Rule is “[a] statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.”⁵⁸ Finally, 45 C.F.R. § 46.116 states that “[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights”⁵⁹

The Office for Human Research Protections (OHRP)⁶⁰ is charged with interpreting and enforcing the Common Rule.⁶¹ Pursuant to this authority, OHRP is responsible for ensuring that all federally funded institutions, such as WU, comply with the regulations.⁶² Under the Common Rule, all federally funded institutions must provide OHRP with written assurance that it will comply with the requirements set forth in the regulations.⁶³ This assurance obligates the entire institution—including institutional officials and

57. 45 C.F.R. § 46.116.

58. *Id.* § 46.116(a)(8). Section 46.116(b)(5) also provides that, “[w]hen appropriate,” “[a] statement that significant new findings developed during the course of the research which may relate to the subject’s willingness to continue participation will be provided to the subject.” *Id.* § 46.116(b)(5).

59. *Id.* § 46.116 (emphasis added). The entire provision reads as follows:

No informed consent, whether oral or written, may include any exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Id.

60. OHRP is an office of HHS. WILLIAMS, *supra* note 51, at 16. Until 2000, OHRP was known as the Office for Protection from Research Risks (OPRR) and was an office of the National Institutes of Health (NIH). *Id.* at 13, 15–16.

61. *See* Public Health Service Act, 42 U.S.C. § 289 (2006).

62. *See id.* While a great number of research projects in the United States are federally funded and, thus, fall under the guise of the Common Rule, private biobanks are not covered by the Common Rule. Yael Bregman-Eschet, *Genetic Databases and Biobanks: Who Controls Our Genetic Privacy?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 19 (2006). In fact, though private biobanks often obtain their samples from public (federally funded) institutions, private biobanks are generally unregulated in the United States. *Id.* at 1.

63. 45 C.F.R. § 46.103(a). Nearly 10,000 research institutions, including universities and hospitals, have formal agreements (called “assurances”) with OHRP to comply with the federal research regulations. OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP’T OF HEALTH & HUMAN SERVS., OHRP FACT SHEET (2005), available at <http://www.hhs.gov/ohrp/about/ohrpfactsheet.pdf>.

researchers—to comply with the Common Rule.⁶⁴ Under its enforcement power, OHRP may also impose various sanctions on federally funded institutions that are not in full compliance with the regulations.⁶⁵

Although the exculpatory language provision of the Common Rule states that researchers may not ask contributors to waive any of their legal rights,⁶⁶ the Common Rule does not *explicitly* address whether a research participant retains an ownership interest in the biological materials he or she contributes to biomedical research. However, OHRP's "guidance topic" on informed consent provides examples of the exculpatory language prohibited under 45 C.F.R. § 46.116, such as: "[b]y consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research."⁶⁷

Further evidence of the meaning of the Common Rule's exculpatory language provision can be found in an OHRP letter sent to Louisiana State University (LSU) in response to allegations of noncompliance:

HHS regulations at 45 CFR 46.116 prohibit any oral or written exculpatory language in the informed consent process, through which the subject is made to waive, or appear to waive, any legal rights. OHRP finds the following language in the IRB⁶⁸-approved informed consent document

64. See OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP'T OF HEALTH & HUMAN SERVS., OHRP'S COMPLIANCE OVERSIGHT PROCEDURES FOR EVALUATING INSTITUTIONS 1 (2005), available at <http://www.hhs.gov/ohrp/compliance/ohrpcomp.pdf>.

65. See *id.* at 1, 3–7.

66. 45 C.F.R. § 46.116.

67. Office for Prot. from Research Risks [now OHRP], "Exculpatory Language" in Informed Consent (Nov. 15, 1996), <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm> [hereinafter Exculpatory Language Guidance Topic]. The full text of the guidance topic reads as follows:

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence.

Examples of Exculpatory Language: By agreeing to this use, you should understand that you will give up all claim to personal benefit from commercial or other use of these substances; I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items; By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research; I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language: Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur; By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above; This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research; This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

Id. (citation omitted).

68. An IRB is "any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct period review of, biomedical research involving

signed by the subject in the above research to be exculpatory: “By your consent to participation in this research study, you give up your property rights that you may have in your bodily fluids, substances or tissues.”⁶⁹

Additionally, in a letter sent to WU in November 2007—after the Eighth Circuit’s decision—OHRP stated:

[E]xcept in jurisdictions in which it has been conclusively determined that all research subjects have no legal rights in their excised human biological material, OHRP continues to find language that waives any such legal rights on the part of research subjects to be exculpatory. We believe that, to date, no jurisdictions have conclusively determined that all human subjects have no legal rights in their excised biological material that is used for research purposes.⁷⁰

Therefore, based on statements made in its guidance topic and its letters to LSU and WU, OHRP clearly interprets the Common Rule as barring researchers and institutions from asking potential contributors to waive their legal right of ownership in their excised biological material.⁷¹

human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.” 21 C.F.R. § 56.102(g) (2008) (defining the function of an IRB in the similar context of research regulated by the FDA). For the portions of the Common Rule covering IRBs, see 45 C.F.R. §§ 46.107–115.

69. Letter from Carol J. Weil, Div. of Compliance Oversight, Office for Human Research Prots., to John C. McDonald, Chancellor/Dean, La. State Univ. Health Sci. Ctr. Shreveport 2 (Oct. 31, 2005), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR06/jan06a.pdf [hereinafter OHRP Letter to LSU]. Coincidentally, the research project for which LSU used this exculpatory language also involved prostate cancer research. See *id.* at 1. In a similar letter to the University of Michigan, OHRP stated, in pertinent part:

OHRP finds the following language in the IRB-approved informed consent document for the above-referenced research to be exculpatory: “Your DNA samples might be used to develop commercially valuable medical products. By signing this form, you agree not to seek share of any proceeds that might result; that is, you waive any claim to share in the commercialization of products developed from your DNA samples.”

Letter from Patrick J. McNeilly, Compliance Oversight Coordinator, Div. of Compliance Oversight, Office for Human Research Prots., to Fawwaz T. Ulaby, Vice President for Research, Univ. of Mich. 2 (June 29, 2004), available at http://www.hhs.gov/ohrp/detrm_lettrs/YR04/jun04c.pdf [hereinafter OHRP Letter to U of M].

70. Letter from Ivor A. Pritchard, Acting Dir., Office for Human Research Prots., to Samuel L. Stanley, Jr., Vice Chancellor for Research, Wash. Univ. Sch. of Med. 5a (Nov. 29, 2007) (on file with The Chicago-Kent Law Review) [hereinafter OHRP Letter to WU]. In this letter, OHRP confirmed that it conducted a compliance oversight investigation of WU in 2000, and that it did not make a finding of noncompliance with regard to a WU informed consent document template that contained the following language: “[N]or can you claim ownership rights to any medical or scientific product that results from research with your tissue. . . . You will receive no monetary payment nor can you claim ownership rights to any medical or scientific product that results from research with your tissue. . . .” *Id.* at 4a–5a. However, OHRP indicated that this finding did not equate to a finding of compliance: “[P]lease note that OHRP’s failure to make a finding of noncompliance regarding this informed consent language is not an indication that OHRP found this language to be in compliance with the HHS protection of human subjects regulations.” *Id.* at 5a. In addition, OHRP stated in this letter that, when it conducts compliance oversight investigations, it will find that an institution’s consent form contains prohibited exculpatory language if the consent form includes any of the example language in OHRP’s guidance document. *Id.* at 4a. Therefore, OHRP asked WU to “ensure that any such language is removed from consent documents currently used at [WU] for human subjects research . . .” *Id.* at 5a.

71. See Reply in Support of Petition for a Writ of Certiorari at 4–5, *Ward v. Wash. Univ.*, 128 S.

II. WASHINGTON UNIVERSITY V. CATALONA

A. The Role of Informed Consent

At first glance, *Moore*, *Greenberg*, and *Catalona* are quite similar: in all three cases, the courts were called upon to address ownership disputes that arose as a result of biomedical research.⁷² In fact, they are the only published decisions that address this specific issue.⁷³ However, unlike the other two cases, *Catalona* also involved the interpretation of both the Common Rule and written consent forms.⁷⁴

In compliance with the Common Rule, Dr. Catalona and WU required each research participant to complete an informed consent form.⁷⁵ While the consent forms used in all the relevant research studies “generally” contained the same language, they “differed slightly” from study to study.⁷⁶ In fact, the district court admitted into evidence fifteen different versions of the consent form, which had been used for six different research studies.⁷⁷ As the district court noted, the consent forms “typically”: (1) stated that the research participant could not “‘claim ownership rights’ to any medical or scientific product that results from research with the sample”; (2) used the term “‘donate’ to characterize the delivery of the sample”; and (3) stated that “‘[y]our participation is voluntary and you may choose not to participate in this research study or withdraw your consent at any time.’”⁷⁸ Notably, most consent forms also stated that, by participating in the study, the research participant “‘agree[s] to waive any claim [he] might have to the body tissue that [he] donate[s].’”⁷⁹

Ct. 1122 (2008) (No. 07-521), 2008 WL 55107.

72. See generally *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006); *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

73. See *Blue*, *supra* note 11, at 108–12 (reviewing only *Moore*, *Greenberg*, and *Catalona* in a discussion of the case law regarding removed human body parts or biological material that is used for research purposes).

74. See *Catalona*, 437 F. Supp. 2d at 998.

75. *Id.* at 990.

76. *Id.*

77. *Wash. Univ. v. Catalona*, 490 F.3d 667, 671 n.3 (8th Cir. 2007).

78. *Catalona*, 437 F. Supp. 2d at 990. Despite OHRP’s disapproval of informed consent language that exculpates a contributor from sharing in the commercialization of any products developed from her tissue, see OHRP Letter to U of M, *supra* note 69, at 2, some of the consent forms in *Catalona* state that the contributor “waives his ‘rights to any interest in products commercialized as a result of this research.’” Post Hearing Brief of Patient/Defendants at 11, *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03 CV-1065 SNL), 2005 WL 3623796.

79. *Catalona*, 490 F.3d at 671. It should be noted that only the Eighth Circuit addressed the fact that this statement typically appeared in the consent forms. While the district court extensively detailed the consent forms’ language, see *Catalona*, 437 F. Supp. 2d at 990, it seemingly saw this particular language as irrelevant.

In addition to the consent forms, the research participants also received and signed the WU Genetic Research Brochure.⁸⁰ One of the most noteworthy statements in the brochure is: ““You will receive no monetary payment for your tissue nor can you claim ownership rights to any *medical or scientific product that results from* research with your tissue.””⁸¹ The brochure also informed the contributors of “their right to have their biological materials *destroyed upon request* should they change their minds about participating in the research study.”⁸²

B. *The Eighth Circuit's Decision*

The Eighth Circuit framed the issue in *Catalona* as follows: “[W]hether individuals who make an informed decision to contribute their biological materials voluntarily to a particular research institution for the purpose of medical research retain an ownership interest allowing the individuals to direct or authorize the transfer of such materials to a third party.”⁸³

In addressing this issue, the court first turned to Missouri common law, “which defines an *inter vivos* gift as ‘a voluntary transfer of property by the owner to another, without any consideration or compensation as an incentive or motive for the transaction.’”⁸⁴ To prove the existence of an *inter vivos* gift, the party claiming the existence of the gift—WU, in this case—must show by clear and convincing evidence⁸⁵ that (1) the donor—the research participants, in this case—had “present intent” to make a gift; (2) the donor delivered the property to the donee; and (3) the donee accepted the gift, and the donee’s ownership took effect “immediately and absolutely.”⁸⁶

Under the first element of the *inter vivos* gift test, the court held that “the circumstances surrounding the [research participants’] decisions to participate in genetic cancer research demonstrate . . . their intent to make gifts of their biological materials to WU’s medical research activities.”⁸⁷ In

80. *Catalona*, 437 F. Supp. 2d at 990.

81. *Catalona*, 490 F.3d at 671 (emphasis added).

82. *Id.* (emphasis added).

83. *Id.* at 673.

84. *Id.* at 674 (citing *Pilkington v. Wheat*, 51 S.W.2d 42, 44 (Mo. 1932)).

85. The district court stated that “[t]he person claiming that the gift exists has the burden of proving it with clear, cogent and convincing evidence.” *Catalona*, 437 F. Supp. 2d at 997 (citing *In re True*, 285 B.R. 405, 414 (Bankr. W.D. Mo. 2002); *In re Estate of Campbell*, 939 S.W.2d 558, 562 (Mo. Ct. App. 1997); *Duvall v. Henke*, 749 S.W.2d 714, 716 (Mo. Ct. App. 1988)).

86. *Wash. Univ. v. Catalona*, 490 F.3d at 674 (citing *Clippard v. Pfefferkorn*, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005)).

87. *Id.*

reaching this conclusion, the court relied on many aspects of the circumstances surrounding the contributors' participation, such as the fact that they signed consent forms that (1) bore WU's logo; (2) characterized their participation as a "donation" and "a free and generous gift"; and (3) emphasized that their participation was voluntary and that they had the right to decline participation in the study or to withdraw consent at any time.⁸⁸

The only mention of the second element in the court's opinion was a brief statement that the court felt an analysis of this element was unwarranted: "The [research participants] unquestionably delivered their biological materials to WU at the time of their donation; thus, we focus our inquiry on the first and third elements."⁸⁹

The court held that WU satisfied the third element of the *inter vivos* gift test because WU had "accepted and retained absolute possession of the biological materials immediately upon donation."⁹⁰ The contributors argued that their ability to withdraw consent to the researchers' use of their samples at any time precluded any *absolute* acceptance of possession.⁹¹ However, the court held that "an *inter vivos* gift nevertheless may be subject to a condition allowing the donor to exercise a particular revocation right in the future. The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid *inter vivos* gift."⁹² Further, after addressing the relevant provisions in the consent forms and brochures, the court held that the contributors "did not retain the right to revoke and physically repossess the donated biological materials."⁹³ The court appeared to have based this conclusion on the fact that the consent forms and brochures did not contain language specifically granting contributors the right to revoke their biological materials, but rather entitled them to request that their biological materials no longer be used and, thus, destroyed upon request.⁹⁴ Finally, the court stated in a footnote that, because the research participants clearly made an *inter vivos* gift, it was "unnecessary to address the effect or validity of the consent forms' waiver language."⁹⁵

88. *Id.* at 674.

89. *Id.*

90. *Id.* at 675.

91. *Id.*

92. *Id.* (citation omitted).

93. *Id.*

94. *Id.*

95. *Id.* at 675 n.7.

C. Critique of the Eighth Circuit's Decision

The Eighth Circuit correctly concluded that human biological material is property, and that it should be governed by property law.⁹⁶ However, many of the other findings by the Eighth Circuit are questionable, beginning with the way it framed the issue in the case.⁹⁷ Like the *Greenberg* court,⁹⁸ the Eighth Circuit classified the research participants as willing donors.⁹⁹ However, as explained below, the contributors did not *willingly donate* their biological material;¹⁰⁰ in fact, the research participants consistently argued that they never intended to give up any ownership rights in their samples.¹⁰¹

In addition, this note argues that the Eighth Circuit erred in two ways: (1) it incorrectly concluded that the research participants made valid *inter vivos* gifts under Missouri common law, because the research participants did not intend to make a gift and deliver their materials to WU, and WU did not accept absolute ownership over the contributors' biological materials; and (2) even if the court was correct that the participants' contributions constituted valid *inter vivos* gifts, such a conclusion was precluded by federal regulations.

1. The Eighth Circuit's conclusions are erroneous under Missouri common law.

a. *The research participants did not "intend to make a gift."*

The court noted that, while the circumstances surrounding the transfer may create an inference of a donor's present intent, "the donor must intend 'to part with his right in and dominion over the property immediately and irrevocably.'"¹⁰² While the contributors may have intended to part with

96. See Leonard Glantz et al., *Rules for Donations to Tissue Banks—What Next?*, 358 NEW ENG. J. MED. 298, 302 (2008) (observing that the court clarified the legal status of the human body by recognizing it as property). In *Moore*, for instance, the Supreme Court of California determined that Moore's biological material was not his property. 793 P.2d 479, 488–89 (Cal. 1990). Likewise, the *Greenberg* court stated that "the property right in blood and tissue samples . . . evaporates once the sample is voluntarily given to a third party." 264 F. Supp. 2d 1064, 1075 (S.D. Fla. 2003).

97. See *Catalona*, 490 F.3d at 673. For the actual language used by the court, see *supra* text accompanying note 83.

98. See Gitter, *supra* note 13, at 335; *id.* at 337 ("[A]lthough the [*Greenberg*] court relied upon the notion of voluntary donation by the plaintiffs, this justification proves to be entirely fictional when one considers that the plaintiffs were unaware of the true use of their tissue, largely because they did not have the benefit of informed consent.").

99. See *Catalona*, 490 F.3d at 673.

100. See discussion *infra* Part II.C.1.a.

101. Rao, *supra* note 15, at 374.

102. *Catalona*, 490 F.3d at 674 (quoting *Ridenour v. Duncan*, 246 S.W.2d 765, 769 (Mo. 1952)).

their samples in a *physical* sense, in that they did not expect to physically repossess their samples, they may not have intended to irrevocably part with the right to retain *ownership and control* over their samples.¹⁰³ Furthermore, the fact that the research participants could withdraw consent—and even *request destruction* of their samples—at any time¹⁰⁴ could have reasonably led them to believe that they were not *irrevocably* giving up their rights in and dominion over their samples.¹⁰⁵

In addition, under Missouri law, the state of mind of an alleged donor is relevant to determining his intent.¹⁰⁶ Richard Ward, one of the eight contributor-defendants, testified at the district court hearing that he had researched his reserved right to withdraw his sample, and that he did not believe he was giving up all his rights to his tissue.¹⁰⁷ Likewise, contributor-defendant Tom McGurk testified that he did not intend for WU to own his tissue, nor did WU ever inform him that they would assert ownership over his sample.¹⁰⁸ In contrast, WU did not present any witnesses who disputed the research participants' clear intentions at the time they provided their tissue.¹⁰⁹

Finally, many of the contributors' samples in the GU Biorepository were initially transferred there from another biobank.¹¹⁰ Thus, these participants also may have reasonably inferred that they retained the right to control WU's future possession of their biological materials, as they did prior to their transfer to WU.¹¹¹ Accordingly, rather than intending to make an irrevocable donation to WU, the participants' intentions may have been more akin to a *conditional grant of use* to WU.¹¹² Therefore, the court mistakenly concluded that WU established by clear and convincing evidence

103. See *infra* notes 122–25 and accompanying text.

104. See *supra* text accompanying notes 78 and 82.

105. See *Catalona*, 490 F.3d at 674 (“The consent form emphasized the voluntariness of the [research participant’s] participation and discussed [their] right to . . . withdraw consent at any time.”); Glantz et al., *supra* note 96, at 302 (explaining that, if the contributors had given WU an unconditional gift, as WU argued, the contributors could not have discontinued their participation at any time). Furthermore, as contributor James Ellis testified, “[y]ou don’t have the right to withdraw if you’ve . . . given a gift, if you’ve donated in that sense” Transcript of Hearing at vol. 1, 168, Wash. Univ. v. *Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03-CV-1065 SNL).

106. See *LeMehaute v. LeMehaute*, 585 S.W.2d 276, 281 (Mo. Ct. App. 1979).

107. Transcript of Hearing, *supra* note 105, vol. 2, at 71.

108. *Id.* vol. 1, at 211.

109. Brief of Appellant-Defendants Richard Ward, et al. at 37, Wash. Univ. v. *Catalona*, 490 F.3d 667 (8th Cir. 2007) (Nos. 06-2286, 06-2301), 2006 WL 2180106 [hereinafter Brief of Appellant-Defendants].

110. Andrews, *supra* note 30, at 402.

111. *Id.*

112. See *id.* at 401, 402 (noting that this conclusion is especially possible in light of the fact that the consent forms repeatedly refer to the contributors' tissue as “your tissue”).

that the participants intended to make an unconditional donation of their biological material to WU.

b. The research participants did not “deliver” their biological materials to Washington University.

Next, the court improperly concluded that the research participants “unquestionably delivered their biological materials to WU at the time of their donation.”¹¹³ In fact, this was the only statement evidencing the court’s treatment of the second element of the *inter vivos* gift test. Perhaps the court assumed that the samples were “unquestionably delivered” to WU because the biological materials were housed in the GU Biorepository,¹¹⁴ which was located in WU’s facilities.¹¹⁵ Nevertheless, whether the research participants delivered their samples to WU was actually one of the unsettled issues before the court, as the contributors alleged that they had delivered their samples to *Dr. Catalona*, not WU.¹¹⁶ Therefore, it was improper for the court to gloss over this contested issue without explaining how WU satisfied this element by clear and convincing evidence.

c. Washington University did not “accept absolute ownership” of the biological materials.

Even if the court’s conclusion that WU successfully satisfied the first two elements of the test was correct, WU still did not show *by clear and convincing evidence* that the participants made valid *inter vivos* gifts, because WU did not accept absolute ownership of their biological materials. In concluding that WU accepted and retained absolute ownership of the samples upon donation, the court made two critical errors—one involving the court’s focus on possession,¹¹⁷ the other regarding the court’s underlying conclusion that WU’s acceptance was absolute.¹¹⁸

First, WU’s *possession* of the contributors’ biological materials does not necessarily lead to the conclusion that WU *owned* the samples.¹¹⁹ Pos-

113. Wash. Univ. v. Catalona, 490 F.3d 667, 674 (8th Cir. 2007).

114. *Id.* at 671–72.

115. *Id.* at 670.

116. See Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 998 (E.D. Mo. 2006). For instance, James Ellis, one of the eight contributor-defendants, testified at the district court hearing that he did not give his tissue to WU. Transcript of Hearing, *supra* note 105, vol. 1, at 158.

117. See Blue, *supra* note 11, at 110–11 (“[T]he court in *Catalona* equated [WU’s] possession and control over the research samples with ownership under state law and concluded that [WU] owned and controlled the removed samples.”).

118. See *Catalona*, 490 F.3d at 675.

119. See *State v. Hughes*, 702 S.W.2d 864, 867 (Mo. Ct. App. 1985) (explaining that, under Missouri law, a person can retain legal or “constructive” possession of property even if another person or

session alone does not require a finding that a gift has been made unless there is “an intention to give”;¹²⁰ and, as already established, the participants did not intend to make a gift to WU.¹²¹ Furthermore, possession is merely one of the many manifestations or incidents in the “bundle of rights” that constitutes property ownership.¹²² As Professor Julia Mahoney notes, “[p]roperty is a flexible concept, not an all-or-nothing one.”¹²³ In fact, under basic property law principles, multiple parties may have an interest in the same piece of property.¹²⁴ Accordingly, it would be possible for WU to have a possessory interest in the contributors’ samples, while the contributors retained their ownership interest in their biological material.¹²⁵ Therefore, WU’s physical possession of the research participants’ samples was not dispositive, and the court improperly focused on possession in concluding that the participants had made an *inter vivos* gift.

Second, the court erred in concluding that WU had accepted absolute ownership of the participants’ biological materials.¹²⁶ The court justified this conclusion, in part, by rejecting the participants’ argument that the attachment of a condition upon the transfer precluded the transfer from being construed as a gift, stating that “an *inter vivos* gift nevertheless may be subject to a condition allowing the donor to exercise a particular revocation right in the future. The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid *inter vivos* gift.”¹²⁷ However, the court apparently disregarded the fact that the condi-

entity has “actual” or “physical” possession of the property).

120. *Michaelson v. Wolf*, 261 S.W.2d 918, 924 (Mo. 1953).

121. See discussion *supra* Part II.C.1.a.

122. See MOE LITMAN & GERALD ROBERTSON, *The Common Law Status of Genetic Material*, in LEGAL RIGHTS AND HUMAN GENETIC MATERIAL 51, 62 (Bartha Maria Knoppers et al. eds., 1996); see also *Brotherton v. Cleveland*, 923 F.2d 477, 481 (6th Cir. 1991) (“The concept of ‘property’ in the law is extremely broad and abstract. The legal definition of ‘property’ most often refers not to a particular physical object, but rather to the legal bundle of rights recognized in that object. Thus, ‘property’ is often conceptualized as a ‘bundle of rights.’”); Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L.J. 16, 21–22 (1913) (describing property as a complex aggregate of rights, privileges, and powers).

123. Mahoney, *supra* note 10, at 202.

124. One example of such a mutual property interest is the concept of “joint tenancy.” See Melanie Baird, Note, *When and Why Does What Belong to Whom? A Proposed Model for the International Protection of Human Donors of Biological Material*, 32 CAN.-U.S. L.J. 331, 346 (2006) (citing Recent Case, *Guomundsdottir v. Iceland*, No. 151/2003 (Nov. 23, 2007) (*Ice.*)), 118 HARV. L. REV. 810, 815–17 (2004)).

125. See *id.*; Mahoney, *supra* note 10, at 202. Elaborating on an analogy used by Professor Andrews, see Andrews, *supra* note 30, at 401, consider what happens when a son borrows his father’s car. Although the son temporarily has a possessory interest in the car, his possession does not also give him an *ownership* interest in the car; rather, the father is still the owner of his car.

126. See *Wash. Univ. v. Catalona*, 490 F.3d 667, 675 (8th Cir. 2007).

127. *Id.* (citations omitted). The court also cited hazardous waste laws to support its conclusion that the research participants made an absolute gift to WU, stating that WU’s acceptance of the materials

tion in this case was one of *control*. Certainly, conditioning a transfer upon the right to retain control over the transferred material—even to the point where the contributor may *request its destruction*—may very well “negate or void an otherwise valid *inter vivos* gift.”¹²⁸ In fact, in no other case has a court determined that a gift has been made, giving absolute ownership to another party, when the alleged donor retained the right to destroy the property in question.

2. The Eighth Circuit’s conclusions are precluded by the Common Rule.

Pursuant to the Supremacy Clause of the United States Constitution, the “Constitution, and the Laws of the United States . . . shall be the supreme Law of the Land.”¹²⁹ The Supreme Court of the United States has stated that “[i]t is a familiar and well-established principle that the Supremacy Clause invalidates state laws that ‘interfere with, or are contrary to,’ federal law.”¹³⁰ Furthermore, federal regulations—like federal statutes—may preempt conflicting state common law rules, as well as state legislation.¹³¹ Therefore, to the extent that Missouri’s *inter vivos* gift law¹³² conflicts or interferes with the Common Rule, the Common Rule takes precedent.¹³³ Accordingly, even if the research participants in *Catalona* made valid *inter vivos* gifts under Missouri common law, the Eighth Circuit’s conclusion that WU is the sole owner of the samples is precluded by

was absolute, in part because hazardous waste laws prohibited the participants from physically repossessing their excised biological material. *Id.* at 676. This is rather weak support for the court’s conclusion, however, because at no time did the research participants request to have their biological materials returned to them, and they never asserted that they retained any such right.

128. *See id.* at 675. Under Missouri common law, an *inter vivos* gift cannot be made “where the donor reserves, either expressly or in the circumstances, the power of revocation or dominion over the subject of the gift.” *Cartall v. St. Louis Union Trust Co.*, 153 S.W.2d 370, 375 (Mo. 1941); *see also* *Donnelly v. Donnelly*, 951 S.W.2d 650, 653 (Mo. Ct. App. 1997) (“[O]nce a gift is made the donor may not revoke the gift upon a change of mind.”).

129. U.S. CONST. art. VI, cl. 2.

130. *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 712 (1985) (citation omitted) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824)); *see Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (explaining that federal law preempts state law when the state law “stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress”).

131. *See Hillsborough County*, 471 U.S. at 713; *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 881 (2000).

132. *See, e.g., Clippard v. Pfefferkorn*, 168 S.W.3d 616, 618 (Mo. Ct. App. 2005).

133. *See Hillsborough County*, 471 U.S. at 712–13. While there is an exception to the Common Rule’s preemption of state law, the exception applies only if the applicable state law imposes “additional protections” to human subjects. 45 C.F.R. § 46.101(f) (2007). In this case, the conflicting state law is Missouri’s *inter vivos* gift law, which does not provide research participants with additional protections. *See, e.g., Clippard*, 168 S.W.3d at 618. Thus, the exception did not apply in this case. *See Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 849 (Md. 2001) (holding that the informed consent provisions of the Common Rule preempted conflicting state law, which did not provide *greater* protection to research participants than did the Common Rule).

the federal regulations' ban on contributors waiving any of their legal rights, such as the right to retain ownership of their biological materials.¹³⁴

In addition, the Supreme Court of the United States stated in a 2007 opinion that "an agency's interpretation of its own regulations is 'controlling' unless 'plainly erroneous or inconsistent with' the regulations being interpreted."¹³⁵ Thus, if the Eighth Circuit found that the regulations were ambiguous, because they do not *explicitly* state that the right of ownership is a legal right that a contributor cannot waive, the court should have resolved the ambiguity by looking to OHRP's interpretations of the Common Rule.¹³⁶

Overall, the Eighth Circuit improperly concluded that WU satisfied its burden of proving all three required elements of the *inter vivos* gift test by clear and convincing evidence. First, there was significant evidence that the research participants did not intend to irrevocably relinquish their ownership and control over their biological materials, and, therefore, that they did not intend to make an absolute gift.¹³⁷ Second, the court did not provide any reasoning to support its conclusion that the research participants delivered their biological material to WU.¹³⁸ Finally, there was significant evidence that WU did not accept absolute ownership of the research participants' biological material, such as the fact that the participants could request the destruction of their samples at any time.¹³⁹ And, in any event, the Supremacy Clause precluded the Eighth Circuit from finding that the research participants had made valid *inter vivos* gifts under Missouri common law, since that state law conflicts with the Common Rule's exculpatory language prohibition.¹⁴⁰

134. See 45 C.F.R. § 46.116; see also *Hillsborough County*, 471 U.S. at 712–13; *Grimes*, 782 A.2d at 849.

135. *Long Island Care at Home, Ltd. v. Coke*, 127 S. Ct. 2339, 2349 (2007) (quoting *Auer v. Robbins*, 519 U.S. 452, 461 (1997)) (holding that, where "an agency's course of action indicates that the interpretation of its own regulation reflects its considered views . . . we have accepted that interpretation as the agency's own, even if the agency set those views forth in a legal brief"); see also *Geier*, 529 U.S. at 883 ("The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements."). The Eighth Circuit itself had previously held that, under principles of administrative law, an agency's interpretation of its own regulation is entitled to substantial deference, and may even be considered "determinative authority." See *Glover v. Standard Fed. Bank*, 283 F.3d 953, 962–63 (8th Cir. 2002).

136. See *Coke*, 127 S. Ct. at 2349. Two of OHRP's interpretations that were available at the time of the Eighth Court's decision included OHRP's guidance topic on exculpatory language, see *Exculpatory Language Guidance Topic*, *supra* note 67, and OHRP's letter to LSU, see *OHRP Letter to LSU*, *supra* note 69, at 1.

137. See *supra* Part II.C.1.a.

138. See *supra* Part II.C.1.b.

139. See *supra* Part II.C.1.c.

140. See *Petition for a Writ of Certiorari at 16–17, Ward v. Wash. Univ.*, 128 S. Ct. 1122 (2008) (No. 07-521), 2007 WL 3071024.

III. REFORMING THE COMMON RULE

According to the Eighth Circuit in *Catalona*, contributors do not “retain the right to direct or authorize the use, transfer, or destination of [their] biological materials” after their contribution.¹⁴¹ Rather, the court held that research participants’ “subsequent rights to their biological materials [are] expressly limited to the option to discontinue participation in the study to avoid answering more questions, donating more biological materials, or allowing their biological materials to be used for further research.”¹⁴² By recognizing only these extremely limited rights, the *Catalona* decision has left human contributors of biological material largely unprotected and vulnerable to the goals of researchers, institutions, and biotechnology firms.¹⁴³

Part III of this note illustrates the need for federal reform by identifying the insufficiencies and consequences of the current regulations governing the protection of research participants. In addition, this Part will propose recommendations for regulatory reform that will both effectively enable the advancement of scientific and medical research, and ensure that the rights and interests of human contributors of biological material are more fully protected.

A. *The Need for Reform*

Although legislation to amend the Common Rule has been introduced in every session of Congress since 1997,¹⁴⁴ the regulations remain exactly

141. Wash. Univ. v. Catalona, 490 F.3d 667, 675 (8th Cir. 2007).

142. *Id.*

143. It is important to note at this point that many, or even most researchers likely have a strong moral character, and are trying to advance science and medicine for the good of society. However, as journalist Rebecca Skloot noted about her interview with biomedical researcher Anna O’Connell, “she wanted to make one thing clear: scientists aren’t out to deceive people about their tissues. ‘We genuinely want to gather as much information as we can to advance research. The problem is, in all that excitement, sometimes scientists don’t think about consequences.’” Skloot, *supra* note 8, at 41 (quoting Anna O’Connell).

144. WILLIAMS, *supra* note 51, at Summary. One notable example of this proposed legislation is the Protection for Participants in Research Act of 2003, which would have, in effect, extended the reach of the Common Rule and other subparts of 45 C.F.R. part 46 to *all* research, whether publicly or privately funded. See H.R. 3594, 108th Cong. § 2 (2003). Additionally, the Act would have required researchers to provide contributors with information on how to contact OHRP to submit questions about their rights or to report concerns about certain research. *Id.* Furthermore, the Act would have required the HHS Secretary to publish a determination in the Federal Register, specifying whether there were “circumstances in which research that studie[d] human tissue or other types of clinical specimens,” or that did not “involve any interaction or intervention with a living human” should have been “considered human subject research.” *Id.* Finally, under the Act, “the HHS Secretary would have been required to establish expanded informed consent criteria that provided for ‘the provision of full and complete information relevant to the research to a prospective human subject.’” WILLIAMS, *supra* note 51, at 24–25 (quoting H.R. 3594 § 2).

as they were after the 1981 revisions.¹⁴⁵ In contrast, the landscape of biomedical research has seen extensive changes.¹⁴⁶

Traditionally, a research study occurred at a single location, such as an academic institution, and was largely federally funded.¹⁴⁷ Additionally, researchers would ask participants to provide a sample for one particular purpose, such as trying to understand the genetic basis of a specific disease.¹⁴⁸ In these situations, researchers could more easily fulfill their legal obligation to inform potential contributors of the risks and benefits of participating in the research.¹⁴⁹

Current practices are vastly different, however. Researchers are usually not aware of the potential research for which they may use collected samples, because much of the future research is dependent on the outcomes of the studies for which the samples are initially requested.¹⁵⁰ As a result, researchers now commonly obtain biological material from contributors using practices known as “blanket consent” or “prospective authorization,”¹⁵¹ enabling them to store vast amounts of tissue for future research, the topic and scope of which are yet to be determined.¹⁵² However, as Professor Hank Greely explains, when researchers use blanket consent, “[p]otential subjects cannot be informed of the specific risks and benefits of the research because the biobanks do not know what those risks and benefits may be; they do not even know what the research topics will be.”¹⁵³

145. See WILLIAMS, *supra* note 51, at 14; Greely, *supra* note 6, at 349 (citations omitted) (“Criticisms and suggestions for reform have continued, but the legal and ethical frameworks have not been reformed.”).

146. See WILLIAMS, *supra* note 51, at 16.

147. *Id.* at 10.

148. Greely, *supra* note 6, at 357.

149. See *id.*

150. See *id.*

151. “Blanket consent” and “prospective authorization” are terms used to describe a type of “informed” consent, whereby researchers provide research participants with general information on foreseeable risks and benefits of their contribution, but provide no information about the particular research that may eventually be conducted on the research participants’ biological materials. *Id.* at 358; see also NBAC REPORT, *supra* note 1, at 49. In situations where researchers request blanket consent, contributors are essentially giving researchers “open-ended permission” to use their biological material for undetermined future research projects. David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 N. ENG. J. MED. 1180, 1180 (2003).

152. Greely, *supra* note 6, at 357; see also Andrews, *supra* note 12, at 25 (“Changes in the culture of research since the adoption of the federal regulations also prompt concerns that were not envisioned at the time the informed consent exemption in 45 C.F.R. § 46.101(b)(4) was enacted.”).

153. Greely, *supra* note 6, at 357; see also Buchanan, *supra* note 17, at B-18 (“[T]he difference between blanket consent and what is ordinarily understood by informed consent is so great that it is problematic even to use the same term, ‘consent,’ to refer to both.”). Occasionally, researchers ascertain contributors’ preferences regarding the type of research they are comfortable having performed on their samples; however, if and when individuals’ wishes are discovered, “this is done as a courtesy, rather than as a recognition of patients’ rights to prohibit the use of their tissues for purposes of which they disapprove.” R. Alta Charo, *Body of Research—Ownership and Use of Human Tissue*, 355 N. ENG. J.

Supporters of the status quo argue that reforming the law governing human subjects research is unnecessary because contributors are already sufficiently protected.¹⁵⁴ Academic research institutions argue that they are held strictly accountable for ensuring the welfare of contributors through the mandates of the Common Rule, OHRP enforcement, and their own institutional policies.¹⁵⁵ But what these institutions have not recognized is that, even if OHRP's enforcement of the Common Rule were up to par (which it doubtful at this time),¹⁵⁶ the outdated Common Rule still would not fully protect the rights and interests of contributors. In other words, because the Common Rule was drafted "to govern research on living, breathing humans, not their disembodied tissues," as writer Rebecca Skloot observes,¹⁵⁷ it fails to protect contributors of biological material from potentially significant nonphysical or psychosocial harm.¹⁵⁸ For instance, a contributor could feel harmed or wronged by the stigmatization of his racial or ethnic group that results from research using his biological material.¹⁵⁹ Similarly, a contributor may be harmed or wronged when her biological material is used in a manner that violates her moral or religious beliefs.¹⁶⁰

MED. 1517, 1518 (2006).

154. See, e.g., Brief for Amici Curiae Cornell University et al. in Support of Plaintiff-Appellee and Affirmance at 18–25, Wash. Univ. v. Catalona, 490 F.3d 667 (8th Cir. 2007) (Nos. 06-2286, 06-2301), 2006 WL 2703704.

155. *Id.*

156. Despite what appears to be a comprehensive enforcement scheme, Professor Greely asserts that OHRP's enforcement of the Common Rule "is currently of doubtful efficacy." Greely, *supra* note 6, at 353.

157. Skloot, *supra* note 8, at 45.

158. See Greely, *supra* note 6, at 349 ("The Common Rule . . . has done a decent job of protecting research subjects from physical risks, but has largely ignored the fact that research subjects may have other interests they care about."); see also Buchanan, *supra* note 17, at B-16 ("[T]he requirement of informed consent developed as a safeguard against very tangible harms—the sorts of physical harms that the law generally regards as batteries.").

159. See NBAC REPORT, *supra* note 1, at 45–46; Alpert, *supra* note 5, at A-17 to A-18 (quoting Larry Gostin, *Ethical Principles for the Conduct of Human Subject Research: Population-Based Research and Ethics*, 19 L. MED. & HEALTH CARE 191, 197 (1991)) (arguing that, if research results in information that stigmatizes certain groups, it can "cause intangible hurt to groups such as lowering their self-esteem or racial or cultural pride. Derogatory information about a sub-population can stigmatize and wound its people as much as breaches of confidentiality can affect an individual.").

160. See NBAC REPORT, *supra* note 1, at 49 ("For example, for religious or cultural reasons, some may believe that their biological materials should not be used in contraceptive research or in studies that are aimed at identifying individuals who are prone to violence or other socially unacceptable behaviors."). In addition, the brochure given to the research participants in *Catalona* notified them that, "[i]f this information were to become known outside of the research, you (and family members) may be unable to obtain health, life, or disability insurance. You might also be refused employment or be terminated from your current employment." Brief of Appellant-Defendants, *supra* note 109, at 55. For a discussion of other nonphysical harms that may result from biomedical research, such as group harms and familial conflicts, see NBAC REPORT, *supra* note 1, at ch. 4. For a discussion of the issues that biomedical research raises in various religions, see Courtney S. Campbell, *Research on Human Tissue: Religious Perspectives*, in 2 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE, *supra* note 5, at C-1.

Furthermore, Professor Jordan Paradise and Professor Lori Andrews noted that contributors can feel harmed if their biological material is used for research without their consent (as in *Moore*),¹⁶¹ beyond their consent (as in *Catalona*),¹⁶² or for purposes with which they do not approve (as in *Greenberg*, where researchers used contributors' samples for commercial gain).¹⁶³

The recent case involving the Native American Havasupai tribe illustrates the Common Rule's inability to adequately protect contributors from such psychosocial harm. Members of the Havasupai tribe gave hundreds of blood samples to researchers at Arizona State University (ASU) for diabetes research, because members of the Havasupai tribe—like the majority of the Native American population—suffer from an inordinately high incidence rate of type 2 diabetes.¹⁶⁴ Over the next several years, the ASU researchers attempted to find genetic associations with diabetes, consistent with the uses for which the research participants consented.¹⁶⁵ However, in a lawsuit filed against ASU and the individual researchers in 2004, the Havasupai research participants asserted that, without permission, the researchers also used their samples to study schizophrenia, inbreeding, and the history and migration of the Havasupai people to North America.¹⁶⁶

161. Jordan Paradise & Lori Andrews, *Tales from the Crypt: Scientific, Ethical, and Legal Considerations for Biohistorical Analysis of Deceased Historical Figures*, 26 TEMP. J. SCI. TECH. & ENVTL. L. 223, 262 (2007) (citing *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 486 (Cal. 1990)).

162. *Id.* (citing *Wash. Univ. v. Catalona*, 490 F.3d 667, 674 (8th Cir. 2007)).

163. *Id.* (citing *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1066–67 (S.D. Fla. 2003)). In its Institutional Review Board (IRB) Guidebook published in 1993, OPRR—the predecessor of OHRP, *see supra* note 60—recognized the unique concerns raised by biomedical research, as opposed to more “typical” scientific research:

Unlike the risks presented by many biomedical research protocols considered by IRBs, the primary risks involved in . . . genetic research are risks of social and psychological harm, rather than risks of physical injury. Genetic studies that generate information about subjects' personal health risks can provoke anxiety and confusion, damage familial relationships, and compromise the subjects' insurability and employment opportunities. For many genetic research protocols, these psychosocial risks can be significant enough to warrant careful IRB review and discussion. The fact that genetic studies are often limited to the collection of family history information and blood drawing should not, therefore, automatically classify them as “minimal risk” studies

OFFICE FOR PROTECTION FROM RES. RISKS, U.S. DEP'T OF HEALTH & HUMAN SERVS., PROTECTING HUMAN RESEARCH SUBJECTS: INSTITUTIONAL REVIEW BOARD GUIDEBOOK, ch. 5, § H (1993), *available at* http://www.hhs.gov/ohrp/irb/irb_chapter5ii.htm#h12 [hereinafter IRB GUIDEBOOK].

164. Andrews, *supra* note 2, at 27 (“The Havasupai have one of the highest incidences of type 2 diabetes anywhere in the world: Over half the women and more than one-third of the men have it.”).

165. *Id.*

166. *Id.*; Andrews, *supra* note 30, at 405; Greely, *supra* note 6, at 358. *See generally* *Havasupai Tribe v. Ariz. State Univ. Bd. of Regents*, No. S-0300-CV-20040146 (Coconino County Super. Ct. filed Mar. 12, 2004); *Tilousi v. Ariz. State Univ. Bd. of Regents*, No. S-0300-CV-2004-0115 (Coconino County Super. Ct. filed Feb. 26, 2004). For a discussion of the procedural history and current disposition of these cases, see Julie A. Burger, *What is Owed Participants in Biotechnology Research?*, 84 CHI.-KENT L. REV. 55, 73 n.108 (2009).

The tribe alleges that the schizophrenia and inbreeding research has stigmatized them, and that they never would have consented to the migration studies, because they directly conflict with their religious beliefs.¹⁶⁷ According to Professor Greely, the Havasupai case “indicate[s] that, at least in some circumstances, research subjects can be very unhappy about uses of their samples and data they did not know about and did not like.”¹⁶⁸

The Common Rule was designed to protect human research subjects from harm,¹⁶⁹ but it is becoming less able to do so as it becomes increasingly outdated.¹⁷⁰ And, as *Catalona* illustrates, contributors of biological material cannot even turn to the courts to enforce whatever protections the regulations afford them.¹⁷¹ Therefore, because the Common Rule is currently failing to fulfill its purpose, reform is essential.¹⁷²

B. Recommendations for Reform

1. The Common Rule applies to research using human biological material.

The Common Rule currently states that it applies to “all research involving human subjects,”¹⁷³ and it defines a “human subject” as “a living individual about whom an investigator . . . conducting research obtains (1) [d]ata through intervention or interaction with the individual, or (2) [i]dentifiable private information.”¹⁷⁴ Based on the regulations’ definitions

167. Andrews, *supra* note 2, at 27; Andrews, *supra* note 30, at 405.

168. Greely, *supra* note 6, at 358.

169. *See id.* at 356.

170. *See* Andrews, *supra* note 12, at 25.

171. *See* Brief of Amicus Curiae Us TOO, International in Support of Petitioners at 20, *Catalona v. Wash. Univ.*, 128 S. Ct. 1122 (2008) (Nos. 07-521, 07-525), 2007 WL 4132902 [hereinafter Brief of Us TOO, International]. Us TOO, International is a “prostate cancer support organization founded in 1990 by prostate cancer survivors to serve prostate cancer patients and their families,” and is “the only prostate cancer organization whose exclusive mission is to be the voice of patients.” *Id.* at 1.

172. *See* Greely, *supra* note 6, at 349. Also, because societal views toward the ethical implications of biomedical research are constantly evolving, continually reexamining and even amending the federal research regulations is warranted. *See* Clayton et al., *supra* note 9, at 1787.

173. 45 C.F.R. § 46.101 (2007).

174. The Common Rule’s complete definition of a human subject is as follows:

(f) *Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains

(1) Data through intervention or interaction with the individual, or

(2) Identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes. *Interaction* includes communication or interpersonal contact between investigator and subject.

Private information includes information about behavior that occurs in a context in which an

of “intervention” and “interaction,”¹⁷⁵ researchers who collect human biological material from contributors are conducting human subjects research.¹⁷⁶ However, confusion arises when a researcher uses human biological material that was previously collected by another person—for example, when researchers obtain or purchase samples from biobanks.¹⁷⁷ In this situation, the researcher using the biological material has not had any direct contact—and therefore no intervention or interaction—with the human contributor; as a result, this research is only governed by the Common Rule if it involves “identifiable private information.”¹⁷⁸ Since there is essentially no doubt that biological material and its accompanying information about the contributor constitute “private information,” the critical question then becomes: are the samples “identifiable”?¹⁷⁹

In August 2004, OHRP issued a guidance document, purporting to clarify the Common Rule’s applicability to research involving “coded private information or human biological specimens.”¹⁸⁰ Notably, OHRP states that it “does not consider research involving *only* coded private information or specimens to involve human subjects” if the researcher is using previously collected samples or information, *and* if the researcher “cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain.”¹⁸¹ However, as Professor Greely explains, “coded information—and even anonymized¹⁸² information—may still allow the subject’s identity to be ‘readily ascertained by the investigator.’”¹⁸³ Therefore, OHRP’s rather convoluted and confusing interpretation

individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

Id. § 46.102(f).

175. *See id.*

176. *See* Greely, *supra* note 6, at 354.

177. *See id.*

178. *Id.*; *see* 45 C.F.R. § 46.102(f).

179. *See* Greely, *supra* note 6, at 354.

180. OFFICE FOR HUMAN RESEARCH PROTS., U.S. DEP’T OF HEALTH & HUMAN SERVS., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS 1, 1 (2004), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf>.

181. *Id.* at 3. OHRP’s issuance of this guidance document represented a “dramatic shift” in the research community’s position on this issue, as virtually all members of the community had previously agreed that IRBs had to at least *consider* whether it was necessary to obtain informed consent for research using biological materials. Ellen Wright Clayton, *So What Are We Going to Do About Research Using Clinical Information and Samples?*, IRB: ETHICS & HUM. RES., Nov.–Dec. 2004, at 14, 14.

182. *See infra* Part III.B.5 and note 273.

183. Greely, *supra* note 6, at 355 (quoting 45 C.F.R. § 46.102(f)).

by no means precludes all—or even most—research involving human biological material from being covered by the Common Rule.¹⁸⁴ For instance, this interpretation did not apply to the research conducted in *Catalona*, nor does it apply to future uses of the contributors' samples, because the samples in the GU Biorepository contain DNA and, thus, are always going to be identifiable.¹⁸⁵ Accordingly, Professor Greely recommends that biobanks assume that all their research is human subjects research that is governed by the Common Rule.¹⁸⁶ In fact, it appears as though the research community itself believes that research using human biological material falls within the ambit of the Common Rule, as demonstrated by the researchers requesting informed consent from the contributors in *Catalona*, for example.¹⁸⁷

It becomes apparent from these various opinions and interpretations that the most critical amendment is one clarifying that the Common Rule applies to research conducted on human biological material.¹⁸⁸ Absent a clear meaning of the Common Rule's scope, any other regulatory changes that would otherwise protect the rights and interests of contributors would be futile, and contributors of biological material would remain largely unprotected and vulnerable to nonphysical harm.¹⁸⁹ For example, if this type of research is not governed by the Common Rule, researchers will not even need to seek contributors' informed consent¹⁹⁰—the most fundamental requirement for ethical human subjects research.¹⁹¹ Dr. Catalona testified at the district court hearing that, if the contributors' samples were not governed by the Common Rule, the samples “could be licensed to a drug company, they could be licensed to a biotech company, they could be sold to another university, they could be used to study sexual predator behavior,

184. See NBAC REPORT, *supra* note 1, at 17 (“[F]ew research samples are unidentifiable.”).

185. See Andrews, *supra* note 30, at 404 (citing Plaintiff's Post-Trial Brief at 10, Wash. Univ. v. Catalona, 437 F. Supp. 2d 985 (E.D. Mo. 2006) (No. 4:03-CV-1065 SNL), 2005 WL 3623795 (“Currently, the samples are still linked to participants' identities.”)); *infra* notes 280–82 and accompanying text.

186. Greely, *supra* note 6, at 355.

187. See Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 990 (E.D. Mo. 2006). Likewise, WU has conceded that “[t]he Common Rule requires [WU] to obtain informed consent from individuals who donate tissue samples for use in medical research.” Brief for the Respondent in Opposition at 4–5, Catalona v. Wash. Univ., 128 S. Ct. 1122 (2008) (Nos. 07-521, 07-525), 2007 WL 4466856 (citing 45 C.F.R. §§ 46.116–117). More generally, numerous surveys reveal that most patients and research participants believe that if their biological material is used in research, their consent should be required. Clayton, *supra* note 181, at 14–15.

188. See Greely, *supra* note 6, at 356 (“Even if the failure to apply the protections of the Common Rule or similar systems of human subjects protection to genomic biobanks were legal, it would not be ethical”).

189. See *id.*

190. See WILLIAMS, *supra* note 51, at 22; Clayton, *supra* note 181, at 14.

191. See Brief of Us TOO, International, *supra* note 171, at 11.

alcoholism, criminal behavior, other diseases that these patients never intended to have their samples used for.”¹⁹² Therefore, to reduce the likelihood of these potentially harmful scenarios, it is imperative to clarify that the Common Rule applies to research using human biological material.¹⁹³

2. Contributors retain certain rights in their biological material.

Based on the Eighth Circuit’s holding in *Catalona*, researchers may legally ask contributors to give up nearly *all* property rights in their own excised biological material.¹⁹⁴ But when this occurs, researchers are essentially given a free pass to use another person’s biological material however the *researcher* chooses, and to completely disregard the wishes of the sample’s human source. Of course, it is important for researchers to be able to use biological material in ways that will advance their knowledge and discovery.¹⁹⁵ However, if certain uses are unacceptable to the contributor—for any reason—it is unethical to nevertheless use the contributor’s sample in the name of medical progress.¹⁹⁶

According to NBAC, “[i]t stands to reason that a person’s rights and interests are better protected if that person has some form of control over his or her removed biological material.”¹⁹⁷ Clearly, if contributors can decide what can be done with their samples and who can do it, they will be significantly more capable of avoiding harm and protecting their personal dignity.¹⁹⁸ Thus, it is imperative to amend the Common Rule to allow the

192. Transcript of Hearing, *supra* note 105, vol. 1, at 158, 168.

193. See NBAC REPORT, *supra* note 1, at 68.

194. See *Wash. Univ. v. Catalona*, 490 F.3d 667, 675 (8th Cir. 2007); Reply Brief in Support of Certiorari at 1, *Catalona v. Wash. Univ.*, 128 S. Ct. 1122 (2008) (No. 07-525), 2008 WL 65144. While the court acknowledged that the research participants were expressly given the right to discontinue their participation in the research, WU nevertheless overrode contributors’ requests to withdraw. See Skloot, *supra* note 8, at 75; *infra* text accompanying notes 272–74.

195. See *supra* note 17.

196. See Gitter, *supra* note 13, at 303 (quoting *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1988), *aff’d in part, rev’d in part*, 793 P.2d 479 (Cal. 1990) (en banc)).

197. NBAC REPORT, *supra* note 1, at 7; see Madison Powers, *Justice and Genetics: Privacy Protection and the Moral Basis of Public Policy*, in *GENETIC SECRETS: PROTECTING PRIVACY AND CONFIDENTIALITY IN THE GENETIC ERA* 355, 357 (Mark A. Rothstein ed., 1997) (“[T]he individual has less ability to take additional steps to mitigate potential adverse consequences . . . if he or she has . . . no ability to exercise continuing control of the samples.”). For a thorough discussion of relevant, distinct interests that weigh in favor of granting contributors substantial control over their sample, see Buchanan, *supra* note 17, at B-6 to B-12.

198. See Charles M. Jordan, Jr. & Casey J. Price, *First Moore, Then Hecht: Isn’t It Time We Recognize a Property Interest in Tissues, Cells, and Gametes?*, 37 REAL PROP. PROB. & TR. J. 151, 168 (2002) (“[A] patients’ [sic] pecuniary and dignitary interests will be much better protected than they are today if the law extends and recognizes property rights in tissues and cells even after they are removed from the body.”); LITMAN & ROBERTSON, *supra* note 122, at 60 (“Indeed, as a general proposition, the greater the control conferred on individuals in relation to their bodies, the greater the respect that is being accorded to individuals.”).

human sources of biological material to retain meaningful control over their samples.¹⁹⁹

One basic means of accomplishing this goal is by clarifying the exculpatory language prohibition in the Common Rule.²⁰⁰ As with numerous other Common Rule provisions, the meaning of the exculpatory language prohibition has proven to be the basis of considerable uncertainty.²⁰¹ For instance, some of the testimony given at the district court hearing in *Catalona* indicated that “the research community consistently understood 45 C.F.R. § 46.116 to bar exculpatory language involving releases from malpractice or other negligence.”²⁰² Then again, guidance issued by OHRP reveals a completely different interpretation: the examples of prohibited exculpatory language listed in the guidance document make it extremely clear that OHRP believes that contributors retain property rights in their biological materials.²⁰³ Furthermore, OHRP’s letter to WU in November 2007 reveals that the exculpatory language prohibition does not merely bar researchers from asking contributors to waive their right to bring negligence claims; rather, this letter illustrates that OHRP interprets this prohibition as barring the contributors from waiving *any* of their legal rights—including the right to retain ownership over their samples.²⁰⁴

Yet, as *Catalona* demonstrates, it is insufficient to only have agency interpretations on this subject: while they are certainly authoritative, and while the teachings of the Supreme Court of the United States establish that courts are to view them as “controlling,”²⁰⁵ they nevertheless are not binding law.²⁰⁶ Therefore, the Common Rule’s provision prohibiting exculpatory language should be amended to include examples such as those provided in OHRP’s guidance document.²⁰⁷ Ultimately, by clarifying the meaning of

199. See Jordan & Price, *supra* note 198, at 168.

200. 45 C.F.R. § 46.116 (2007) (“No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights . . .”).

201. See NBAC REPORT, *supra* note 1, at ii.

202. Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 998 (E.D. Mo. 2006). It should be noted, however, that one of WU’s own expert witnesses testified that the relevant language in WU’s consent forms was exculpatory within the meaning of 45 C.F.R. § 46.116. See Transcript of Hearing, *supra* note 105, at vol. 2, 169–71.

203. See Exculpatory Language Guidance Topic, *supra* note 67.

204. See Reply in Support of Petition for a Writ of Certiorari, *supra* note 71, at 4–5; OHRP Letter to WU, *supra* note 70, at 4a. Interestingly, OHRP also stated in this letter (which was written *after* the Eighth Circuit’s decision in *Catalona*): “We believe that, to date, no jurisdictions have conclusively determined that all human subjects have no legal rights in their excised biological material that is used for research purposes.” OHRP Letter to WU, *supra* note 70, at 5a.

205. See, e.g., Long Island Care at Home, Ltd. v. Coke, 127 S. Ct. 2339, 2349 (2007).

206. See *Catalona*, 437 F. Supp. 2d at 998.

207. See Exculpatory Language Guidance Topic, *supra* note 67.

the exculpatory language prohibition, the Common Rule will more effectively protect the rights and interests of the people who contribute their biological material.²⁰⁸

In addition, to ensure that the Common Rule fully protects human subjects, as it was designed to do,²⁰⁹ it is essential to grant contributors the right to control the *type* of research that is ultimately conducted on their biological material.²¹⁰ Recognizing this basic form of property right in one's excised bodily material is the most effective means of protecting contributors from nonphysical harm, because contributors will be able to *protect themselves* from incurring such harm.²¹¹ To illustrate, if a *Catalona* contributor did not want his prostate tissue to be used in a future WU research project to create a human clone, because human cloning violates his moral beliefs, he would be able to prevent such a contravention of his beliefs with the right to control his sample.²¹² Under the *Catalona* holding, however, this contributor would essentially be forced to violate his personal beliefs by being forced to participate in a human cloning research project without his consent.²¹³

Those who oppose granting contributors the right to control the fate of their biological material argue that doing so would thwart the progress of biomedical research.²¹⁴ As WU argued, researchers and biobanks "could no longer rely on aggregate collections of biological materials, because 'samples would come and go.'"²¹⁵ Yet, there is no indication that allowing contributors to retain ownership over their biological materials has hindered advancements in research.²¹⁶ For example, the OHRP guidance topic that gives examples of prohibited exculpatory language was developed by a

208. See NBAC REPORT, *supra* note 1, at 7; Gitter, *supra* note 13, at 304; Jordan & Price, *supra* note 198, at 168.

209. See NBAC REPORT, *supra* note 1, at 68.

210. See *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1988) ("A patient must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress."), *aff'd in part, rev'd in part*, 793 P.2d 479 (Cal. 1990) (en banc).

211. See NBAC Report, *supra* note 1, at 7.

212. For a discussion of Professor Greely's thoughtful suggestions on *how* contributors would be able to control the fate of their excised biological material, see *supra* note 6, at 358–59, discussed *infra* Part III.B.4.

213. See Brief of Us TOO, International, *supra* note 171, at 12.

214. See, e.g., Brief for the Respondent in Opposition, *supra* note 187, at 10.

215. *Id.*

216. Conversely, research advancements may be hindered if researchers do not have the necessary samples to conduct their research, as a result of losing the trust of contributors. For instance, Professor Gary Marchant observes that many Native American tribes are unlikely to contribute biological material just "for the sake of not impeding the progress of genetic research" if doing so would render them vulnerable to "incur the risk of social and political harms." Gary E. Marchant, *Property Rights and Benefit-Sharing for DNA Donors?*, 45 JURIMETRICS J. 153, 167 (2005).

National Institutes of Health (NIH) Cooperative Oncology Chairpersons group.²¹⁷ Thus, as Professor Andrews aptly observed, “[t]he fact that oncology researchers have indicated this is how they conduct their research certainly undercuts [WU’s] arguments that it would be harmful to research” to allow contributors to control the use of their samples.²¹⁸

Critics may also argue that giving contributors this right is impracticable,²¹⁹ and that it would stifle biomedical research by imposing onerous record-keeping requirements, for example.²²⁰ At first thought, this seems to be a reasonable argument: would biobank administrators really be able to successfully track the specific wishes of each contributor? But, in fact, individual samples of biological material are often accompanied by vast amounts of clinical and demographic information, such as the contributor’s age, race, and detailed medical history.²²¹ For instance, the computer database that accompanies the biological material in the GU Biorepository contains “very detailed” “medical information for each particular patient that provided samples.”²²² Thus, as Professor Gitter noted, “in light of the ‘meticulous care and planning necessary in serious modern medical research,’” recording an additional item of data for each contributor is actually a relatively minor undertaking.²²³

Overall, implementing this change would greatly enhance the Common Rule’s protection of contributors, without creating insurmountable obstacles for future innovation. Then, if the Common Rule is successfully amended to grant contributors this right, legislators could even consider adding to contributors’ retained rights, such as granting them the right to specify where and by whom research on one’s biological material may be conducted.

217. See Exculpatory Language Guidance Topic, *supra* note 67; see also Andrews, *supra* note 30, at 404.

218. Andrews, *supra* note 30, at 405. Similarly, the renowned Fox Chase Cancer Center in Philadelphia allows contributors to specify the types of studies in which researchers may use their biological material. Skloot, *supra* note 8, at 45. Yet, logic provides that this institution would not maintain such a practice if doing so was detrimental to its research goals.

219. See Blue, *supra* note 11, at 117.

220. See Gitter, *supra* note 13, at 288–89.

221. See NBAC REPORT, *supra* note 1, at 2, 16.

222. Transcript of Hearing, *supra* note 105, at vol. 1, 64; vol. 2, 112–13.

223. Gitter, *supra* note 13, at 289 (quoting Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 508 n.14 (Cal. Ct. App. 1988), *aff’d in part, rev’d in part*, 793 P.2d 479 (Cal. 1990) (en banc)). Arguing against contributors retaining the right to control the fate of their own biological material, Don Clayton, a spokesman for WU, postulates that “if patients are able to ‘reclaim’ or ‘redirect’ their blood and tissues, biobanks will become ‘impossible to manage’ and ‘so burdensome that scientists will be handcuffed.’” Skloot, *supra* note 8, at 79 (quoting Don Clayton). Yet, biobanks already keep track of vast amounts of samples, information, and other data—and they do not appear to have any difficulty doing so. Thus, continuing communication with contributors in order to discern their wishes regarding potential future uses of their samples likely would not present a significant burden.

3. Contributors must give “fully informed” consent.

One of the possible causes of the dispute between WU, Dr. Catalona, and the GU Biorepository contributors could have been the fact that the contributors did not receive adequate information upon which to base their decision to participate.²²⁴ And this case is by no means an exception to what typically occurs.²²⁵ Such a lack of informed consent may be the result of researchers’ or institutions’ deceptive or misleading practices,²²⁶ or simply their failure to recognize the various interests of the human sources of biological material.²²⁷ Regardless of the cause, it is clear that research participants’ bodily integrity and autonomy may not be protected if they consent to contribute without first being informed of *all* the information that would potentially influence their decision to contribute.²²⁸ Accordingly, to help ensure the complete protection of contributors’ rights and interests, it is crucial to perfect the fundamental informed consent process by amending the Common Rule to require researchers to obtain *fully* informed consent.²²⁹

One element that is essential to contributors’ ability to give fully informed consent is knowing whether, by contributing, they retain ownership or control over their biological material. In *Catalona*, for example, the Eighth Circuit attempted to bolster its conclusion that the research participants did not retain any ownership over their samples by stating: “[A]bsent

224. For example, none of the consent forms stated that WU would become the absolute owner of the contributor’s tissue, thereby preventing the research participant from exercising control over the use of his sample. See Post Hearing Brief of Patient/Defendants, *supra* note 78, at 10–11.

225. See NBAC REPORT, *supra* note 1, at 62 (“In [some] cases, for a variety of reasons, individuals may not understand fully or may not have been given the opportunity to consider carefully how their specimens may be used in the future.”).

226. See Winickoff & Winickoff, *supra* note 151, at 1180; see also Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 81 (2002) (noting that, within the current system, information is often “poorly distributed, if not concealed”).

227. See NBAC REPORT, *supra* note 1, at 47 (“A case can be made that current practices concerning human biological materials sometimes fail to treat persons with due respect, because researchers may unintentionally be misleading regarding why materials are being gathered and the uses to which the materials will be put.”).

228. See NCI BEST PRACTICES, *supra* note 2, at 16; see also Blue, *supra* note 11, at 89 (noting that detailed informed consent procedures allow research participants to exercise their “freedom of choice”).

229. See Harrison, *supra* note 226, at 84; NCI BEST PRACTICES, *supra* note 2, at 16. The Common Rule currently requires researchers to obtain “legally effective” informed consent from subjects before involving them in human subjects research. 45 C.F.R. § 46.116 (2008). Furthermore, this section of the Common Rule lists eight “[b]asic elements of informed consent,” *id.* § 16.116(a), as well as six “additional elements of informed consent,” any one or more of which are required “when appropriate,” *id.* § 46.116(b). Although these provisions ensure that certain basic information is provided to potential research participants, the vagueness and incompleteness of the requirements enables researchers to intentionally or unintentionally conceal additional information that may be material to the contributor’s decision to participate.

from the record is any indication the [research participants] ever were informed they had the ability to direct the transfer of their samples to another entity for research purposes.”²³⁰ Irrespective of the fact that this is not strong support for the court’s conclusion, this statement reveals that WU did not advise the contributors of information that very well may have been material to their decision. That is, just as the research participants were not informed of their ability to direct the transfer of their materials, they also were not informed of their *inability* to do so.²³¹ However, knowing that WU would not allow the transfer of their samples was arguably material to the contributors’ decisions to participate, as illustrated by the fact that over six thousand contributors requested to have WU transfer their samples to Dr. Catalona at Northwestern.²³² In addition, WU never explicitly disclosed to the research participants that, by contributing, they would give up all ownership rights in their excised biological material.²³³ Yet, again, this information clearly would have affected some—if not many—research participants’ decisions to contribute.²³⁴ Accordingly, the Common Rule should require researchers to unambiguously disclose this information to potential research participants during the informed consent process.

Another essential element of fully informed consent is knowing that researchers or other entities may profit from products developed from research on a contributor’s biological material.²³⁵ Many potential contribu-

230. Wash. Univ. v. Catalona, 490 F.3d 667, 676 (8th Cir. 2007).

231. The consent forms’ silence on this issue may have been especially misleading to the research participants whose samples were initially transferred to the GU Biorepository from another biobank. See *supra* notes 110–11 and accompanying text.

232. See Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 993 (E.D. Mo. 2006).

233. The consent forms *did* state that, “[b]y agreeing to participate in this study, you agree to waive any claim you might have to the body tissues that you donate.” *Catalona*, 490 F.3d at 675–76 n.7. Despite the fact that WU technically was not allowed to include this statement in the consent forms, see Exculpatory Language Guidance Topic, *supra* note 67, this language nevertheless did not *unambiguously* inform the research participants that WU would become the sole owner of their excised tissue, as evidenced by the testimony of some of the contributors, for example, see *supra* text accompanying notes 107–08.

234. The anger on the part of some contributor-defendants easily leads one to believe that, had they known at the time of contribution what they know now, they would not have made the decision to contribute their biological material. See Skloot, *supra* note 8, at 75 (“‘I just wanted to help Dr. Catalona cure prostate cancer’ . . . ‘Now who knows what’s going on with that stuff?’”) (quoting contributor-defendant Tom McGurk); *id.* (“‘Washington University is saying they own part of our bodies’ . . . ‘They’re trying to preserve their financial interest over our lives and our kids’ lives . . . just thinking about that makes me crazy.’”) (quoting contributor-defendant Richard Ward).

235. See AM. MED. ASS’N, PRINCIPLES OF MEDICAL ETHICS, § E-2.08(2)–(3) (2000), available at <http://www.ama-assn.org/ad-com/polfind/Hlth-Ethics.pdf> (advising physicians to inform patients of researchers’ potential commercial gains from the patients’ tissue, and prohibiting human tissue and its products from being used for commercial purposes without the informed consent of the contributing human source); Clayton et al., *supra* note 9, at 1789. Although the policy issues surrounding the idea of contributors’ entitlement to a portion of the profits is beyond the scope of this note, if researchers do not intend to share their commercial gains with contributors, they should at least inform potential contribu-

tors are uneasy about the thought of others profiting from *their* biological material,²³⁶ especially if this would violate the contributor's religious or moral beliefs. Likewise, some individuals may feel that it is unjust for them to be expected to contribute gratuitously when researchers and institutions stand to make enormous commercial gains from these contributions.²³⁷ In fact, John Moore filed his lawsuit upon learning that researchers were earning millions of dollars from the cell line they created using his biological material.²³⁸ Therefore, because the prospect of commercialization may be significant to potential contributors' decisions, the Common Rule should be amended to require its disclosure as part of the informed consent process.²³⁹

Similarly, contributors should be told that, while research using their biological material may lead to diagnoses, treatments, or even cures, their access to these treatments may be restricted—for example, if the treatment is patented.²⁴⁰ The *Greenberg* case illustrates just how devastating this can be if contributors are not informed of this possibility beforehand.²⁴¹ The plaintiffs in *Greenberg* argued that they never would have agreed to contribute their biological materials, and those of their children, if they knew that the research could result in limited access to and affordability of Canavan disease screening tests.²⁴² To avoid future instances of contributors feeling

tors of this. See NBAC REPORT, *supra* note 1, at 51; Clayton et al., *supra* note 9, at 1791.

236. Ellen Wright Clayton, *Informed Consent and Biobanks*, 33 J.L. MED. & ETHICS 15, 19 (2005); Linda B. Daniels, Comment, *Commercialization of Human Tissues: Has Biotechnology Created the Need for an Expanded Scope of Informed Consent?*, 27 CAL. W. L. REV. 209, 227 (1990); see NBAC REPORT, *supra* note 1, at 49.

237. See Gitter, *supra* note 13, at 281, 300; Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 389 (2004) ("Very few would knowingly and willingly participate in a scheme that uses their unique resources for others' private gain without any compensation or charitable relief."); Marchant, *supra* note 216, at 165 ("[F]rom a fairness perspective, the contributions of tissue donors should not be singled out as necessarily altruistic when every other party involved in the research may profit financially from their contributions."); see also Blue, *supra* note 11, at 89.

238. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482 (Cal. 1990); Goodwin, *supra* note 237, at 389 n.416.

239. Kevin L. J. Oberdorfer, Note, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365, 386 (2004) (arguing that the Common Rule should require researchers to disclose reasonably foreseeable commercial interests to potential contributors when obtaining informed consent, in order to increase contributors' trust in researchers).

240. See Andrews, *supra* note 12, at 27–28 ("People whose tissue samples are solicited or used should be given adequate information upon which to base their decision, including whether the use of their present or past tissue samples will lead to patents—and, if so, it should be disclosed that such patents can lead to higher cost diagnostics and treatments."); see also Gitter, *supra* note 13, at 313 (explaining that some of the commercial products developed from contributors' tissue "may be priced beyond the reach of most consumers").

241. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1068 (S.D. Fla. 2003).

242. See Oberdorfer, *supra* note 239, at 387.

betrayed and deceived like this, the Common Rule should be amended to require full disclosure of this type of information.²⁴³

Of course, there are criticisms of increasing the requirements of informed consent. For instance, David Korn, the senior vice president of the Association of American Medical Colleges (AAMC), recognizes that “consent feels nice,” but argues that it “diminishes the value of tissue.”²⁴⁴ But even if there is some truth to this argument, concealing information from research participants in ways that sometimes approach fraud²⁴⁵ cannot be the answer; the desire to advance knowledge, even for the benefit of society, cannot trump the integrity and deeply held personal beliefs of the individuals who contribute to this research.²⁴⁶ Moreover, in an article commissioned by NBAC, Sheri Alpert argued that full disclosure

is one of the best ways that researchers can demonstrate their respect for the subject—even if fully disclosing all this information costs the researcher some subjects. It is better for the integrity of the overall scientific research establishment to lose subjects by providing full information than it is to lose subjects because they lack trust in that research establishment.²⁴⁷

Therefore, it is in the best interest of both potential contributors *and* the biological research community to amend the Common Rule to require researchers to disclose *all* information that may be material to an individual’s decision to contribute.²⁴⁸

4. Blanket consent is prohibited.

Possibly one of the most important elements of fully informed consent is a complete understanding of the *type* of research for which the contribu-

243. *See id.* at 388. It can even be argued that disclosing as much information as possible to potential research participants also serves the interests of *researchers* by reducing the risk that contributors will initiate legal actions when they realize their expectations about the research were not met. Clayton et al., *supra* note 9, at 1787.

244. *See Skloot, supra* note 8, at 45 (quoting David Korn).

245. *See Buchanan, supra* note 17, at B-10 (“A strong case can be made that current practices concerning biological samples often fail to treat persons with due respect because they systematically mislead regarding why samples are being taken and their uses.”).

246. *See* NCI BEST PRACTICES, *supra* note 2, at 17 (“Respect for individuals who have provided data or biospecimens for research is of paramount concern.”); Blue, *supra* note 11, at 104 (emphasis added) (“Ultimately, there appears to be a deep-seated feeling by many medical professionals in Western democracies that decisions about the body must be made by the individual or his or her next of kin *and not society*.”). Blue also argues that, under the current system, “[p]eople are treated as means, not ends, thereby violating many different religious and philosophical systems of respect for human dignity.” *Id.* at 97.

247. Alpert, *supra* note 5, at A-14; *see also* Clayton et al., *supra* note 9, at 1787.

248. *See* Alpert, *supra* note 5, at A-13 (“[T]he more specific the information in the consent documents, . . . the more informed the consent will be.”); NCI BEST PRACTICES, *supra* note 2, at 16; Harrison, *supra* note 226, at 84.

tor's biological material may be used.²⁴⁹ However, the Common Rule does not explicitly require researchers to inform potential contributors of the fate of their biological material once it has been removed.²⁵⁰ Accordingly, researchers and institutions frequently utilize blanket consent in hopes of saving time and money.²⁵¹ But, even if this gap in the Common Rule *legally* allows researchers to request blanket consent, doing so is still highly unethical:²⁵² by failing to inform contributors of the potential uses of their biological materials, researchers are essentially guaranteed to violate the personal, moral, and religious beliefs of some individuals.²⁵³ This is especially true considering that a poll commissioned by the Institute of Medicine (IOM) in 2007 found that thirty-eight percent of research participants would want to be able to give their specific consent for each research use of their personal information.²⁵⁴ Therefore, the Common Rule should be amended to clarify that researchers may not ask contributors to consent to all future uses of their biological material,²⁵⁵ and that researchers must put forth a good faith effort to be as explicit as possible about the likely uses of contributors' samples.²⁵⁶

Certainly, this is not to say that researchers may only request use of a sample for one specific study. Doing so would surely place insurmountable obstacles in the path of future biomedical research, since researchers often do not know what future research may be warranted at the time of contribu-

249. See NCI BEST PRACTICES, *supra* note 2, at 19 ("If appropriate . . . , human subjects may be allowed to specify the *types of research* for which the contributed biospecimens will be used").

250. Jordan & Price, *supra* note 198, at 167 n.92. Although requesting blanket consent is not explicitly denounced in the Common Rule, it arguably violates the regulations' informed consent requirements, since research participants are not first told about the risks and benefits of the specific research for which their tissue is ultimately used. See 45 C.F.R. § 46.116(a)(2)-(3) (2008); Clayton, *supra* note 236, at 19-20 (noting that many people "oppose allowing individuals to give blanket consent for future research, arguing, for example, that it is impossible in that situation to make an informed choice").

251. See Buchanan, *supra* note 17, at B-17.

252. Greely, *supra* note 6, at 344, 358; see COMM. ON HUMAN GENOME DIVERSITY, NAT'L RESEARCH COUNCIL, EVALUATING HUMAN GENETIC DIVERSITY 65 (1997) ("It is not ethically or legally acceptable to ask research participants to 'consent' to future but yet-unknown uses of their identifiable DNA samples."). For a discussion of the concept of blanket consent, see *supra* note 151.

253. See Andrews, *supra* note 2, at 27.

254. ALAN F. WESTIN, HOW THE PUBLIC VIEWS PRIVACY AND HEALTH RESEARCH 20 (2007) www.iom.edu/File.aspx?ID=48528.

255. See Andrews, *supra* note 12, at 27 ("A general blanket consent to all future research should not be considered sufficient to meet the standards of informed consent."); see also Ad Hoc Committee on DNA Technology, American Society of Human Genetics, *DNA Banking and DNA Analysis: Points to Consider*, 32 AM. J. HUM. GENETICS 781, 782 (1988).

256. See NCI BEST PRACTICES, *supra* note 2, at 16 ("Obtaining informed consent for the collection and storage of biospecimens and for their use in future research is challenging since the specifics of the future research often are not known at the time of biospecimen collection. Despite this challenge, the informed consent information describing the nature and purposes of the research should be as specific as possible.").

tion.²⁵⁷ With this in mind, Professor Greely has advocated a two-pronged strategy to eliminate the use of blanket consent that would ensure the continued advancement of biomedical research, while also respecting the wishes of the human sources who make this important research possible.²⁵⁸

The first prong involves continuing communication with research participants.²⁵⁹ Researchers could accomplish this by creating a regularly updated webpage, or by frequently sending out a newsletter to all contributors, informing them of plans for new research.²⁶⁰ Contributors could also be advised to contact the institution or biobank for further information about any research that may raise special concerns, allowing them to determine if they want to opt out of a particular study.²⁶¹ Dr. Catalona actually utilized this method, sending out a quarterly newsletter to contributors whose samples were stored in the GU Biorepository, and notifying them of the studies' status.²⁶²

The second prong involves recontacting contributors before using their biological materials for a new study.²⁶³ Ideally, this would be done before using a contributor's biological material in any study that the contributor did not originally consent to.²⁶⁴ If this proved to be absolutely impossible, at least *some* potential harm to contributors would be avoided if they were recontacted if an IRB²⁶⁵ "concluded that there was reasonable likelihood that a significant number of the research subjects might object to participating in that research."²⁶⁶ In either case, the responsible IRB could require that the researchers obtain new, fully informed consent from each source before proceeding to use his or her biological material in a particular study.²⁶⁷

257. See Greely, *supra* note 6, at 357.

258. It should be noted that these proposals would only help prevent the current problems with regard to *future* collections of human biological material. Amending the Common Rule to adequately resolve informed consent problems with regard to *existing* collections of samples "present[s] a special challenge," and is beyond the scope of this note. See NBAC REPORT, *supra* note 1, at 48.

259. See Greely, *supra* note 6, at 358.

260. *Id.*

261. *Id.* Similarly, Winickoff & Winickoff suggest using a website to keep contributors informed about research projects and to allow them to opt out of future studies. *Supra* note 151, at 1183.

262. See Skloot, *supra* note 8, at 75; see also Wash. Univ. v. Catalona, 437 F. Supp. 2d 985, 993 (E.D. Mo. 2006) (stating that a quarterly newsletter was published by the Urological Research Foundation, of which Dr. Catalona was the Medical Director).

263. See Greely, *supra* note 6, at 358.

264. See *id.*

265. See *supra* note 68.

266. Greely, *supra* note 6, at 358. Alternatively, Professor Greely suggests that a committee of research subjects—independently or in conjunction with the IRB—could be assembled to identify potentially sensitive research topics. *Id.* at 358–59.

267. *Id.* at 358.

In its report of recommended “best practices” issued in 2007, the National Cancer Institute (NCI) stated that researchers and biobanks “should ensure that the research uses of [biological material] are consistent with the informed consent of the research participant.”²⁶⁸ Researchers will be able to successfully achieve this goal by maintaining communication with contributors—whether through a website, newsletter, or some other means—and ensuring that *each future use* of a contributor’s sample is compatible with his or her personal preferences.²⁶⁹

5. Researchers cannot anonymize a sample after its contributor has requested withdrawal.

According to the Common Rule, one of the basic elements of informed consent is “[a] statement that . . . the subject may discontinue participation at any time”²⁷⁰ Furthermore, the NCI has asserted that, “if a human subject discontinues participation, the investigator is required to withdraw that subject from the research study.”²⁷¹ Nevertheless, after WU refused to transfer several of the contributors’ samples to Dr. Catalona, the contributors attempted to exercise the right given to them in their consent forms²⁷² by requesting that their tissues be removed from the GU Biorepository; again, WU refused, reading the relevant provision of the consent form to mean that they could “anonymize”²⁷³ a withdrawing contributor’s sample and continue to use it as they chose.²⁷⁴ The district court agreed with WU’s interpretation of the consent form language.²⁷⁵ The Eighth Circuit did not address the anonymization issue; rather, it merely stated that one of the contributors’ limited rights to their excised biological material

268. NCI BEST PRACTICES, *supra* note 2, at 17.

269. *See Greely, supra* note 6, at 358–59.

270. 45 C.F.R. § 46.116(a)(8) (2008).

271. NCI BEST PRACTICES, *supra* note 2, at 19.

272. The consent forms signed by the GU Biorepository contributors stated that they may “withdraw [their] consent at any time.” *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 990 (E.D. Mo. 2006).

273. *Id.* at 992 n.10. “Anonymization” is a term used to describe one method of purportedly protecting contributors’ personal information. *See Greely, supra* note 6, at 349. When researchers attempt to anonymize a sample of biological material, they do so by removing all personal identifiers on or linked to the sample. *Id.* at 351. Theoretically, anonymizing a sample would make it impossible for even biobank administrators to discover the identity of the sample’s human source. *Id.*

274. Skloot, *supra* note 8, at 75. Contrary to WU’s argument, 45 C.F.R. § 46.101(b)(4) *does not* give WU the right to anonymize contributors’ samples. Andrews, *supra* note 30, at 404. That provision, which exempts certain research from the Common Rule, does not apply to samples that were collected for research purposes, as they were in this case. *Id.*; *see* 45 C.F.R. § 46.101(b)(4). Likewise, that provision does not apply to identifiable samples, such as the contributors’ samples in *Catalona*. *See* 45 C.F.R. § 46.101(b)(4); Andrews, *supra* note 30, at 404.

275. The district court found that “the right to discontinue participation in a research project means nothing more than [the] [research participant] has chosen not to provide any more biological materials.” *Catalona*, 437 F. Supp. 2d at 1000.

was the right to discontinue participation in the research.²⁷⁶

WU's belief that it could engage in this practice may have resulted from the Common Rule's failure to explain what is required of researchers when a contributor asks to withdraw.²⁷⁷ Nevertheless, two problems with anonymization make it necessary to prohibit its use: (1) according to NBAC, "true anonymity does not ultimately exist";²⁷⁸ and (2) it is unethical not to follow the express wishes of the human source who has requested withdrawal of his or her biological material.²⁷⁹

First, stripping codes or other identifying information from biological material does not truly render a sample anonymous, largely because of current technologies.²⁸⁰ Although a researcher using an anonymized sample may not know the identity of the biological material's source and may not even have access to personal or medical information regarding the source,²⁸¹ NBAC has noted that, because human cells contain the complete genetic code of their human source, "any cell from any part of the body could be subjected to genetic analysis (with the potential for providing vast amounts of information)."²⁸²

Second, it is unethical to attempt to override a contributor's express wishes that his or her sample be withdrawn by unlinking the contributor's sample with his or her personal information or using any other anonymization technique, and then continuing to use the sample.²⁸³ Doing so violates the contributor's inalienable right not to be researched upon without voluntary and informed consent—a right given to the contributor by the Common Rule.²⁸⁴ In addition, this practice assumes that contributors cannot be harmed by research conducted on their anonymized biological material; however, such an assumption fails to account for the less tangible interests a contributor may have in his or her biological material.²⁸⁵ Since contribu-

276. *Wash. Univ. v. Catalona*, 490 F.3d 667, 675 (8th Cir. 2007).

277. See *Catalona*, 437 F. Supp. 2d at 992; IRB GUIDEBOOK, *supra* note 163, at ch. 5, § H (citation omitted) ("The federal regulations clearly require that subjects be free to withdraw from participation without penalty or loss of benefits to which they are otherwise entitled. What the regulations do not address, however, is how to treat data or tissue samples obtained from subjects who subsequently withdraw from the study.").

278. NBAC REPORT, *supra* note 1, at 41.

279. See Greely, *supra* note 6, at 352–53.

280. See Brief of Us TOO, International, *supra* note 171, at 12; NBAC REPORT, *supra* note 1, at 41; Greely, *supra* note 6, at 351 ("With a rich set of data, [anonymization] will not work—some, and potentially all, of the donors could be re-identified.").

281. See NBAC REPORT, *supra* note 1, at 16–17.

282. *Id.* at 41; see also Buchanan, *supra* note 17, at B-3.

283. See Greely, *supra* note 6, at 352.

284. Brief of Us TOO, International, *supra* note 171, at 5, 11.

285. NBAC sets forth a rather compelling argument that this assumption is misguided:

[I]t is incorrect to assume that because the sources cannot be identified they cannot be harmed

tors may place an intrinsic value in their own biological material, *regardless of whether it is linked to them*,²⁸⁶ using a sample for certain research purposes after its withdrawal or destruction has been requested may still violate the personal preferences, morals, or religious beliefs of its human source.²⁸⁷ Thus, whether a contributor requests to withdraw for moral or religious reasons, or even for no specific reason at all, researchers must abide by the contributor's wishes.²⁸⁸

Because anonymization is neither possible nor ethical, the Common Rule must be amended to reflect this. The regulations should, at the very least, specify that researchers may not continue to use a sample if its source has objected to its use,²⁸⁹ and that a contributor's sample must be destroyed and disposed of if the contributor has asked to discontinue participation in or withdraw from a study.²⁹⁰ Further, if the other recommendations presented in this note are implemented, the regulations could provide more specific instructions explaining what is required when a contributor makes such a request.²⁹¹

C. *Reforming the Common Rule Will Facilitate the Goals of Biomedical Research*

As NBAC observed, “[p]roperly interpreted and modestly modified,

or wronged. Some interests of the sample sources may be harmed even if they are not completely identifiable, and interests of others may also be at risk. For example, there may be group or family interests that could be revealed or placed at risk because of research that is conducted on a class of similar, albeit individually unidentifiable, samples. Individuals have an interest in avoiding uses of their tissues that they regard as morally impermissible or objectionable. Thus, were their materials to be used in research that they would consider objectionable, it is possible that some individuals could be wronged, if not harmed.

NBAC REPORT, *supra* note 1, at 60–61; *see also* Buchanan, *supra* note 17, at B-22; Greely, *supra* note 6, at 356.

286. Philip L. Bereano, Viewpoint, *The National Bioethics Advisory Commission Report on the Use of Human Biological Materials and Research: Ethical Issues and Policy Guidelines*, 18 BIOTECH. L. REP. 322, 325 (1999).

287. *See* Brief of Us TOO, International, *supra* note 171, at 5; Andrews, *supra* note 12, at 24.

288. In a similar context, California recently enacted regulations governing the funding of research involving regenerative medicine; these regulations “require researchers to honor the limits set by donors of embryos or gametes on the kinds of work that can be done even with donated tissue that has been ‘anonymized’—a rule consistent with a theory of property rights in tissue.” Charo, *supra* note 153, at 1518.

289. *See supra* text accompanying note 271.

290. *See* NCI BEST PRACTICES, *supra* note 2, at 19–20. Two possible actions researchers or bio-banks could take if a contributor requests to discontinue participation include: (1) cease using the contributor's sample in the study; or (2) destroy the contributor's sample and accompanying private information. *See id.*

291. For instance, if the regulations are amended to clarify that contributors retain control over the fate of their biological materials, they could also specify that if a contributor requests to withdraw from a particular study, he or she may give the researcher consent to transfer the sample to another researcher at the contributor's request.

present federal regulations can protect subjects' rights and interests and at the same time permit well-designed research to go forward"²⁹² This is possible because human contributors and researchers do, in fact, share the common goal of continuing biomedical advancement.²⁹³ The problem is, they have conflicting viewpoints on how to best achieve this objective.

On the one hand, the fact that researchers in this area depend on access to vast amounts of human biological material²⁹⁴ appears to cause many of them to feel *entitled* to this material—and *entitled* to use it in any way they see fit. To illustrate, David Korn, the senior vice president of the AAMC, believes that “people are morally obligated to allow their bits and pieces to be used to advance knowledge to help others,” and argues that, “[s]ince everybody benefits, everybody can accept the small risks of having their tissue scraps used in research.”²⁹⁵ Yet, many contributors see the situation differently. Statements like Korn's lead contributors to feel like they are not being shown the respect they deserve—like they are being treated as a commodity, not a human being.²⁹⁶ According to Dr. Ellen Wright Clayton, the fundamental problem stems from “the notion that the people these tissues come from don't matter.”²⁹⁷ It has become clear that current practices have, or threaten to alienate contributors of biological material by severing their trust in researchers and research institutions.²⁹⁸ And, because contributors' trust is vital to their willingness to contribute,²⁹⁹ losing it could potentially lead to insurmountable obstacles for

292. NBAC REPORT, *supra* note 1, at ii; see Clayton et al., *supra* note 9, at 1787 (explaining that the federal regulations “are the embodiment of an attempt to strike a balance between the desire to increase knowledge and the protection of individual interests”).

293. See Oberdorfer, *supra* note 239, at 388; see also NBAC REPORT, *supra* note 1, at 4 (noting that biomedical research “is supported vigorously by the American public”).

294. NBAC REPORT, *supra* note 1, at 19 (“Biomedical research routinely relies on the availability of stored human biological materials as well as the willingness of individuals to participate in research protocols by donating blood, tissue, or DNA samples to research. Research in cancer, infectious diseases, and mental disorders is advanced by access to such materials.”).

295. Skloot, *supra* note 8, at 45 (quoting David Korn). While ideas like Korn's are important to consider, there are many problems with his arguments. First, it is undoubtedly critical to retain the value of biological materials to enable them to be most effectively used; however, it is unacceptable to do so at the expense of the *human sources'* diminished sense of value. In addition, people are not morally obligated to allow pieces of themselves to be used in biomedical research, especially if doing so goes against their moral or religious beliefs. And, it simply is not true that everyone benefits from this research: for instance, if a contributor's biological material is used to discover a particular treatment, which is subsequently patented, that contributor may not benefit at all if he or she is unable to afford the cost of the treatment. See Andrews, *supra* note 12, at 28.

296. See Skloot, *supra* note 8, at 75 (quoting Richard Ward, one of the eight contributor-defendants in *Catalona*) (“[WU] is saying they own part of our bodies They're trying to preserve their financial interest over our lives and our kids' lives . . . just thinking about that makes me crazy.”).

297. *Id.* at 45 (quoting Dr. Ellen Wright Clayton).

298. See Clayton, *supra* note 181, at 15; see also NBAC REPORT, *supra* note 1, at 42.

299. See NBAC REPORT, *supra* note 1, at 42.

biomedical research.³⁰⁰

To better illustrate how each of the above recommendations will facilitate the goals of biomedical research, it is necessary to understand how they fit into the entire process. First, if contributors are protected by the Common Rule, if they retain the right to control the specific type of research that is conducted using their biological materials, and if they are aware of all the information that would likely influence their decision to contribute, they will undoubtedly be more willing to give up a piece of themselves for the sake of advancing science.³⁰¹ Contributors will also be less likely to withdraw their samples from research if they *remain* fully informed about the uses of their biological material, and if they are able to consent to its future uses.³⁰² In turn, researchers will not be tempted to override the withdrawing contributors' wishes by trying to anonymize their samples.³⁰³ This will ultimately allow researchers to conduct more thorough studies, since having more information about the source is strongly preferred, if not necessary.³⁰⁴ In the end, contributors' rights and interests will be more fully protected, and researchers will have access to vast amounts of human biological material and its accompanying information—equipped to continue their remarkable innovation and discovery.³⁰⁵

CONCLUSION

As it stands now, the Common Rule's failure to adequately protect

300. *See id.* In her testimony at the district court hearing, Dr. Ellen Wright Clayton stated: "I think that if patients . . . understand that when or if it becomes the law that when you provide samples for research that you in fact lose all control, that you have no right to withdraw at all, then in fact it will radically undermine . . . the research enterprise." Transcript of Hearing, *supra* note 105, at vol. 1, 122.

301. *See* Clayton et al., *supra* note 9, at 1789 ("Patients and their families will often be willing to cooperate when apprised of the investigator's desires."); Skloot, *supra* note 8, at 75 (noting that, in Dr. Catalana's opinion, "[i]f you're honest with patients, and they understand what you're doing, they'll let you use their tissues—they want to advance science as much as we do").

302. *See* Post Hearing Brief of Patient/Defendants, *supra* note 78, at 23 ("Only if patients have the right to participate fully and knowingly, coupled with a meaningful right to withdraw, will they be willing to participate in new and increasingly risky research projects.")

303. *See* NBAC REPORT, *supra* note 1, at 71.

304. *See id.* at 2 ("Sometimes, however, it is necessary to identify the source of the research sample, because the research value of the material depends upon linking findings regarding the biology of the sample with updated information from medical or other records pertaining to its source."); Greely, *supra* note 6, at 352 ("The more the data is removed or obscured, the more scientific value is lost.")

305. *See* NBAC REPORT, *supra* note 1, at 42 ("[V]irtually all parties to the discussion acknowledge both the value of biomedical research and the need to minimize harms and wrongs to subjects. Indeed, the challenge is not to trade off the potential health benefits from research against the protection of sources and others, but rather to find ways in which to maximize the opportunities for developing new knowledge and new treatments while, at the same time, ensuring appropriate protections from harms and wrongs. Only then will the public have the degree of trust in researchers and confidence in scientific research that is needed to facilitate important scientific breakthroughs.")

human subjects threatens to alienate existing and future contributors of biological material across the United States. And the Eighth Circuit's misguided decision in *Catalona* may only exacerbate the situation, as researchers and biorepository administrators will likely interpret it as the court placing their stamp of approval on many unethical and deceptive practices. It is clear, then, that regulatory reform is imperative. Although they are by no means exhaustive, the recommendations set forth in this note will enable the continued advancement of biomedical research, without compromising the rights and interests of the individuals who fuel researchers' discovery and innovation.

But, until there is meaningful change to the regulations, the debate over these issues will carry on, and the American public will continue to learn the truth about human biological materials research—that what they assumed or thought they knew is not what is really taking place. Consequently, more and more potential contributors may think twice before signing on the dotted line, and many of them may even be deterred from contributing altogether. In pursuit of short-term research gains and even administrative convenience, researchers and institutions are risking the long-term goals of biomedical research by ignoring or discounting the rights, wishes, and interests of human subjects.

Alternatively, if researchers show more respect to the human sources of biological material by fully disclosing all pertinent information, most potential contributors will assuredly agree to assist researchers in their quest to discover the causes, treatments, and cures for serious medical conditions. But no matter how pressing the need to advance biomedical science, it cannot usurp the need to respect the dignity and deeply held personal beliefs of individual people. This is especially true when considering the fact that innovation and discovery can continue just as well—if not better—by respecting and earning the trust of the human sources who make this research possible.

