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## Why Not Take All of Me?<sup>1</sup> Reflections on *The Immortal Life of Henrietta Lacks*<sup>2</sup> and the Status of Participants in Research Using Human Specimens

Gail Javitt\*

### I. INTRODUCTION

It is perhaps a truism that each of us is greater than the sum of our parts. This is particularly apparent when it comes to our tissues, our cells, and their best-known contents, our DNA. In a few cases, such as the case of a woman named Henrietta Lacks, an individual's tissue contains such rare attributes as to result single-handedly in a scientific paradigm shift. More typically, it is the study of vast numbers of tissue samples, in concert, that allows science to move forward. Indeed, recent genetic discoveries<sup>3</sup> made possible by the study of vast repositories of tissue samples known as "biobanks" have

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\* J.D., M.P.H. Counsel, Sidley Austin, Research Scholar, Berman Institute of Bioethics, Johns Hopkins University. The views expressed in this article are those of the author. The author would like to thank Katherine S. Carner for her outstanding research assistance in preparing this article, Joan Scott, Ruth Faden, Joe Ali, and Rebekah Rasooly for their review of and comments on earlier drafts of this article., and Suzanne Javitt for proofreading the manuscript.

1. The phrase is taken from BILLIE HOLIDAY, *All of Me, on LADY DAY: THE COMPLETE BILLIE HOLIDAY ON COLUMBIA (1933-1944)* (Columbia Records, 2001) (1941).

2. REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* (2010).

3. European League Against Rheumatism, *Increased Levels of Certain Cytokines and Chemokines Predict Onset of Rheumatoid Arthritis*, E! SCI. NEWS, June 15, 2009, <http://esciencenews.com/articles/2009/06/15/increased.levels.certain.cytokines.and.chemokines.predict.onset.rheumatoid.arthritis> (reporting on a study that identified factors that can predict the development of rheumatoid arthritis by using blood donated to the Medical Biobank of Northern Sweden).

made clear that, when studied in the aggregate, the biological information contained in each of our individual bodies can yield scientific insights and medical advances impossible through the study of any one individual.

But the use of cells and tissues for research brings with it myriad legal and ethical questions. How should we think about the contributors of these cells and tissues? Are they—increasingly “we” as the number of samples contained in biobanks grows—human subjects of research? And, if so, what consequences should flow from this classification? Should contributors be given the opportunity to specify the type of research that they will permit, or prohibit, with their specimen? Should they be told about potential profits that may accrue to researchers from the use of their tissues and, more to the point, be entitled to a share of such profits? And what about potential health information derived from the research—should they have access to it? Should others? Even more challenging, what rules should govern the voluntary provision of tissues by patient groups to researchers solely for the purpose of identifying the cause of their disease and developing diagnostics and potential cures for their condition? And perhaps most thorny of all: if, as some argue, providing our tissues and cells for research is a moral imperative—part of our collective civic responsibility<sup>4</sup>—does that give rise to a reciprocal moral imperative to ensure that all participants have access to the medical therapies that their cells, among millions of others, helped to produce?<sup>5</sup>

These questions have been percolating for some time in the law and bioethics literature<sup>6</sup>—ever since a man named Mr.

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4. See, e.g., Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research*, 292 JAMA 2500, 2504 (2004).

5. See Ruth R. Faden, Editorial, “Immortal” Cells, *Moral Issues: Case of Henrietta Lacks Shows Need for Ethical Component in Health Care Reform*, BALT. SUN, Feb. 12, 2010, at 21.

6. See, e.g., Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737 (1999); Henry T. Greely, *The Uneasy Ethical and Legal Underpinnings of Large-Scale Genomic Biobanks*, 8 ANN. REV. GENOMICS & HUM. GENETICS 343 (2007); Karen J. Maschke & Thomas H. Murray, *Ethical Issues in Tissue Banking for Research: The Prospects and Pitfalls of Setting International Standards*, 25 THEORETICAL MED. & BIOETHICS 143 (2004); ROBERT F. WEIR & ROBERT S. OLICK, *THE STORED TISSUE ISSUE: BIOMEDICAL RESEARCH, ETHICS, AND LAW IN THE ERA OF GENOMIC MEDICINE* (2004).

Moore had his cancerous spleen removed and parlayed into a lucrative cell line by his physician.<sup>7</sup> Subsequent decades have brought a handful of additional cases whose claimants have included a cancer researcher,<sup>8</sup> a Native American tribe,<sup>9</sup> and family members whose relatives suffered from a rare genetic disease.<sup>10</sup> So far, however, there has not yet emerged a groundswell of “tissue rights” activists pressing for a resolution of these questions or a consensus on how they should be answered. And troublingly, the few courts that have had occasion to address these questions have not applied any coherent legal construct, but, as this article discusses, have retrospectively applied various legal theories in the service of what sometimes appear to be preordained policy goals.<sup>11</sup> At the same time, the number of individuals whose tissue samples are contained in biobanks continues to rise, making it foreseeable that more such disputes will arise in the future.

*The Immortal Life of Henrietta Lacks*, Rebecca Skloot’s moving account of a woman whose cancerous cells revolutionized medical research and facilitated many of today’s lifesaving treatments—vaccines being just one example—thus arrives at a particularly ripe time in scientific and societal history. By focusing on the life and death of one woman, Henrietta Lacks—the mother, literally, of the now-ubiquitous HeLa<sup>12</sup> cell line—and of the consequences that the use of her tissues has had for her descendants, Skloot has put real faces

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

8. See *Wash. Univ. v. Catalona*, 490 F.3d 667 (8th Cir. 2007), aff’g 437 F. Supp. 2d 985 (E.D. Mo. 2006).

9. See *Havasupai Tribe of the Havasupai Reservation v. Ariz. Bd. of Regents*, 204 P.3d 1063 (Ariz. Ct. App. 2008). This case was recently resolved through a settlement agreement in which the Arizona Board of Regents agreed to pay \$700,000 to forty-one of the Havasupai tribe’s members, to return blood samples that were the basis for the suit, and to provide additional assistance to the impoverished tribe. See Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES, Apr. 21, 2010, at A1, available at <http://www.nytimes.com/2010/04/22/us/22dna.html?ref=us>.

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

11. See, e.g., *Moore*, 793 P.2d at 493–96 (holding that there is no property interest in cells and policy concern that holding otherwise could hamper medical research); *Greenberg*, 264 F. Supp. 2d at 1070 (holding that accused doctor had no duty towards the complainant because the doctor was not the treating doctor, and further speculating as to the possible chilling effects of holding otherwise).

12. See text *infra* accompanying notes 20–25.

and voices to abstract legal and policy questions. Although some of the specific circumstances that gave rise to her cells being used in research without her or her family's informed consent would be prohibited today, the story nevertheless has salience to the modern debate. By telling the Lacks family's story in such an engaging, accessible way, Skloot has moved the discussion beyond the narrow confines of courtrooms and academia and into the public domain, where all those with a stake in the answers can participate.

This article briefly describes the story of Henrietta Lacks, as chronicled by Skloot. It then reviews recent findings regarding the the public's attitudes and expectations regarding the use of their cells and tissues in research. It contrasts those public attitudes and expectations with the judicial resolution of legal disputes that have arisen between tissue contributors, researchers, and institutions regarding the use of tissue samples. Finally, it offers some basic principles that should guide the development of policies for the use of human tissue samples in research.

## II. THE STORY OF HENRIETTA LACKS<sup>13</sup>

But for her cancer, Henrietta Lacks's life would have most likely gone little noticed. She was born in 1920, a poor black woman from a family of tobacco farmers in rural Virginia.<sup>14</sup> In the 1940s, she moved with her husband to Baltimore to pursue wartime employment opportunities in the shipyards.<sup>15</sup> In 1951, when she was thirty and had given birth to five children, she developed gynecological bleeding and sought care at Johns Hopkins in Baltimore, Maryland.<sup>16</sup> Hopkins was founded as a charity hospital and was the only major hospital in the area that would treat African-American patients.<sup>17</sup> At Hopkins, her

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13. Unless other sources are cited, the information about Henrietta Lacks's life, the development of HeLa cells, and the views of her family members are all derived from Skloot's account. The author of this paper has no independent knowledge of these issues. Additionally, the excerpts from the book retain the native dialects of the speakers. In the preface to the book, Skloot stated that she made an intentional choice to "capture the language in which each person spoke," in order to best reflect their lives and experiences. See SKLOOT, *supra* note 2, at ix.

14. *See id.* at 18.

15. *Id.* at 26.

16. *Id.* at 13–15.

17. *Id.* at 15.

physician initiated radium treatment, the standard of care at that time.<sup>18</sup> While she was under anesthesia for the procedure that would sew tubes of radium to her cervix, the doctor removed a small piece of her normal cervical tissue and another small piece of her cervical cancer tissue, put them in a test tube, and sent them to George Gey.<sup>19</sup>

George Otto Gey, a physician trained at Hopkins who was at the time in his early 50s,<sup>20</sup> had spent his career, along with his wife and laboratory director Margaret, on a quest to develop methods to grow cells outside the body. Keeping cells alive “in culture” would allow scientists to experiment on the cells in ways not possible in the body and thereby learn more about cell biology. In particular, Gey hoped to develop cultures of cancer cells to enable the study—and eventual cure—of this dread disease.<sup>21</sup> Thus, Gey obtained cancerous tissue samples wherever he could find them<sup>22</sup>—and patients from the major medical institution in which he worked served as a ready source.

Until the day Henrietta Lacks’s cells were brought to his laboratory, Gey’s quest had been unsuccessful. But unlike all his other attempts to grow tissues outside the body, Henrietta’s survived and thrived in culture, becoming the first “immortalized” cell line, meaning cells that will replicate themselves indefinitely as long as maintained under proper conditions.<sup>23</sup> On the day Henrietta died at the age of thirty-one, George Gey went on national television announcing that a breakthrough had occurred in cancer research.<sup>24</sup> Holding up the vial of cells, he introduced the world, for the first time, “HeLa” cells, named for the first two letters of the first and last

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18. *Id.* at 31–32.

19. *Id.* at 33.

20. See Medical Archives of the Johns Hopkins Medical Institutions, The George O. Gey Collection, <http://www.medicalarchives.jhmi.edu/sgml/gey.html> (last visited Apr. 27, 2010).

21. See MICHAEL GOLD, A CONSPIRACY OF CELLS: ONE WOMAN’S IMMORTAL LEGACY AND THE MEDICAL SCANDAL IT CAUSED 16 (1986).

22. See Rebecca Skloot, *Henrietta’s Dance*, JOHNS HOPKINS MAG., Apr. 2000, at 16, available at <http://www.jhu.edu/jhumag/0400web/01.html> [hereinafter Skloot, *Henrietta’s Dance*].

23. See SKLOOT, *supra* note 2, at 30; see generally Wikipedia, Biological Immortality, [http://en.wikipedia.org/wiki/Biological\\_immortality](http://en.wikipedia.org/wiki/Biological_immortality) (last visited Apr. 17, 2010).

24. See Skloot, *Henrietta’s Dance*, *supra* note 22, at 17.

name of their source.<sup>25</sup>

Had the story ended here, the identity and legacy of Henrietta Lacks would forever have remained a mystery. Additionally, when viewed from the vantage point of the 1950s, there would have been nothing particularly troubling about how Gey came to possess her cells. At the time neither Gey—nor pretty much anyone else in medicine—thought it necessary to ask permission to remove tissue samples from a patient.<sup>26</sup> Nor would researchers have thought it necessary for family members to be told about the tissue sample's fate, even if that fate involved a dramatic scientific discovery using their loved one's tissues.

But the story did not end there. Although the nomenclature used to identify the cell line was standard at the time, because current rules about medical confidentiality had not been established, it meant that the cells' source was identifiable. Although for many years the source of HeLa cells was incorrectly identified in textbooks as "Helen Lane,"<sup>27</sup> it was perhaps inevitable that the identity of the cells' true progenitor would be revealed. And when her family members learned serendipitously about the legacy of their mother's cells two decades after her death, they were understandably confused; how could their mother, whom her younger children did not even remember, still be "alive"? Moreover, they were distressed by the unwanted media attention that the revelation of her identity brought with it and by the fact that her cells were being bought and sold, and angry that no one had asked Henrietta—or them—whether her cells could be removed for research in the first place.<sup>28</sup>

The subsequent action of Hopkins researchers, while undertaken with apparently benign intent, only added to feelings of deception and exploitation by Lacks' children. In a

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25. *See id.*

26. *See id.* at 19 (quoting Ruth Faden, executive director of the Johns Hopkins Berman Institute for Bioethics, as describing the lack of informed consent in Henrietta Lacks's case as, "a sad commentary on how the biomedical research community thought about research in the 1950s. But it was not uncommon for physicians to conduct research on patients without their knowledge or consent. That doesn't make it right. It certainly wasn't right. It was also unfortunately common.").

27. *See id.* at 19; *see also* SKLOOT, *supra* note 2, at 108–09.

28. *See* Skloot, *Henrietta's Dance*, *supra* note 22, at 19; *see also* SKLOOT, *supra* note 2, at 5.

bid to address what had become a serious impediment to using HeLa cells in research, namely, that the cells were contaminating other cell cultures,<sup>29</sup> the Hopkins researchers sought to leverage newly discovered DNA fingerprinting methods to pinpoint whether HeLa cells were in other cells' cultures.<sup>30</sup> To do that, however, they needed samples of DNA similar to that of the HeLa cells. They turned to Henrietta's children, who had received half of their genetic material from her.<sup>31</sup> However, although the researchers thought the family understood the reason they were being asked to donate blood, the family erroneously believed that they were providing blood to determine whether they would develop cancer like their mother.<sup>32</sup> They were understandably worried when they did not receive results from the "tests" they thought researchers had performed.<sup>33</sup>

In addition to satisfying her own longstanding curiosity regarding the history of HeLa cells, part of Skloot's motivation in documenting Henrietta's story appears to have been to help Henrietta's children understand what happened to their mother's cells and gain some measure of closure with regards to the wrong they perceive Hopkins to have perpetrated against the Lacks family. To this end, she movingly recounts an episode in which Hopkins researcher, Christoph Lengauer, invites two of Henrietta's children, Deborah and Zakariyya, to his laboratory and shows them their mother's cells (or, more precisely, descendants of those original cells) under the microscope.<sup>34</sup> In addition to explaining the basics of cell biology in a way that they could understand, Lengauer acknowledged that the cells had come from a person, who was important not only to researchers but to her family members. As recounted by Skloot, the interaction between Lengauer and the family is revealing of the different perceptions held by different parties to the research enterprise and to the complex—and still unresolved—issues at play in the use of human specimens:

"They're *beautiful*," [Deborah] whispered, then went back to staring at the slide in silence. Eventually, without looking away from the

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29. SKLOOT, *supra* note 2, at 153.

30. *Id.* at 216.

31. *Id.* at 185.

32. *Id.*

33. *Id.*

34. *Id.* at 264–66.



cells, she said, “God, I never thought I’d see my mother under a microscope—I never dreamed this day would ever come.”

“Yeah, Hopkins pretty much screwed up, I think,” Christoph said.

Deborah bolted upright and looked at him, stunned to hear a scientist—one at Hopkins, no less—saying such a thing. Then she looked back into the microscope and said, “John Hopkin [sic] is a school for learning, and that’s important. But this *is* my mother. Nobody seem to get that.”

“It’s true.” Christoph said. “Whenever we read books about science, it’s always HeLa *this* and HeLa *that*. Some people know those are the initials of a person, but they don’t know who that person is. That’s important history.”

Deborah looked like she wanted to hug him. “This is amazing,” she said, shaking her head and looking at him like he was a mirage.<sup>35</sup>

The discussion between Lengauer and Deborah also touched on whether the family should have received a share in the monetary profits from HeLa cells.

“Her cells are how it all started,” [Christoph] said. “Once there is a cure for cancer, it’s definitely largely because of your mother’s cells.”

“Amen,” Deborah said. Then, without a hint of anger, she told him, “People always gonna be makin money from them cells, nothing we can do about that. But we not gonna get any of it.”

Christoph said he thought that was wrong. Why not treat valuable cells like oil, he said. When you find oil on somebody’s property, it doesn’t automatically belong to them, but they do get a portion of the profits. “No one knows how to deal with this when it comes to cells today,” he said. “When your mother got sick, doctors just did what they wanted and patients didn’t ask. But nowadays patients want to know what’s going on.”<sup>36</sup>

Those who believe that Hopkins’ actions with respect to the Lacks family were consistent with the standards of the time, and that no admission of wrongdoing is therefore warranted, may find Lengauer’s statements naïve at best, and detrimental to the scientific enterprise, as well as to Johns Hopkins, at worst. It should be noted, however, as Skloot reports, that neither Hopkins nor its researchers ever received direct financial benefit from HeLa cells; the buying and selling of the cells was, and is today, conducted by third parties unaffiliated with the institution.<sup>37</sup> Still, there is no doubt that the discovery was beneficial to the researchers and the institution at which it took place, in terms of intellectual achievement and

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35. *Id.* at 266.

36. *Id.* at 267.

37. *Id.* at 194.

professional prestige.

The duties that Hopkins did or did not owe to Henrietta Lacks or her family members at the time their cells were removed are beyond the scope of this article. Lengauer's words have relevance to the modern debate about the use of human tissue in research in their simple acknowledgment of the human origins of tissue samples used in research, of the emotions and feelings of attachment that contributors of tissue may possess towards their specimens regardless of whether they have formal legal rights to them, and thus the perils of failing to show respect for and of communicating clearly with these contributors. As public opinion research suggests, prospective contributors of human tissue, while they recognize the value of their specimens for research and largely support their use in the interest of findings new treatments for disease, also, as Lengauer phrased it, "want to know what's going on"<sup>38</sup> with their tissue. Moreover, many would-be tissue contributors believe researchers are obliged to inform them before using their tissues in research.<sup>39</sup> As this article discusses, the legal disputes arising from use of tissue samples have involved in some fashion failures to acknowledge the essential human dimensions of the research enterprise involving human tissue.

### III. OUR BODIES, OURSELVES?<sup>40</sup> PUBLIC ATTITUDES ABOUT RESEARCH WITH HUMAN SPECIMENS

#### A. WHAT IS A BIOBANK?

A biobank, also known as a biorepository, is a place that "collects, stores, processes, and distributes biological materials and the data associated with those materials."<sup>41</sup> These "biological materials" are typically human biospecimens, including tissue or blood, and the "data" are the clinical

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38. *Id.* at 267.

39. *Id.* at 315.

40. The phrase is taken from THE BOSTON WOMEN'S HEALTH BOOK COLLECTIVE, OUR BODIES, OURSELVES: A NEW EDITION FOR A NEW ERA ix (2005).

41. See LabAutopedia, Biobank Information and Sites, [http://labautopedia.com/mw/index.php/Biobank\\_information\\_sites#A\\_compliat ion\\_of\\_external\\_resources\\_on\\_biobanks](http://labautopedia.com/mw/index.php/Biobank_information_sites#A_compliat ion_of_external_resources_on_biobanks) (last visited Mar. 25, 2010) (highlighting that a biobank can also include tissues from other animals, cell and bacterial cultures, and even environmental samples).

information pertaining to the donor of that biospecimen.<sup>42</sup> Biobanks allow researchers to conduct genome-wide association (GWAS) studies, which are studies of the entire genome of large numbers of people that seek to identify genetic markers for disease.<sup>43</sup> In recent years, biobanks have been increasingly used to study complex diseases that are believed to have both genetic and environmental causes.<sup>44</sup> By one estimate, in 1999, there were 178 million unique samples contained in biorepositories and the rate of increase would be 20 million samples per year.<sup>45</sup> Assuming this rate of growth is correct, the number in 2010 would be 398 million samples.

There is no mandated centralized registry of biobanks either nationally or internationally; thus the actual number of existing biobanks or number of discrete specimens contained therein is not known.<sup>46</sup> Perhaps the most well-known biobanking effort worldwide is in Iceland. At the beginning of

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42. *Id.*

43. See Stephen J. O'Brien, *Stewardship of Human Biospecimens, DNA, Genotype, and Clinical Data in the GWAS Era*, 10 ANN. REV. GENOMICS & HUM. GENETICS 193, 194 (2009).

44. See Genetics & Pub. Policy Ctr., Issue Brief, *Using Genomic Databases to Study Complex Diseases*, available at <http://www.dnapolicy.org/images/issuebriefpdfs/Genes%20and%20Environment%20Issue%20Brief.pdf> (last visited Mar. 28, 2008). For example, diabetes is known to run in families, and researchers have identified some genetic variants that increase an individual's risk of developing the disease. However, not all individuals who have the variants develop diabetes, and many people with diabetes do not have the variants. This suggests that there may be more variants that affect the risk of developing the disease, but it is also known that diet and exercise play an important role. The collection of large numbers of samples in biobanks could assist researchers in studying both genetic and environmental factors influencing many common diseases, including diabetes, cancer, and heart disease, which could "hold tremendous promise" for understanding how those diseases develop.

45. See ELISA EISEMAN & SUSANNE B. HAGA, RAND MONOGRAPH REPORT, HANDBOOK OF HUMAN TISSUE SOURCES: A NATIONAL RESOURCE OF HUMAN TISSUE SAMPLES xvii (1999).

46. Moreover, consensus does not exist regarding what should be considered a "biobank," i.e., whether it includes all collections of human specimens, regardless of their source, or is limited to only specimens collected under particular circumstances. There are different mechanisms by which samples become available for research, including from patients (leftover samples) and from subjects who are actively recruited. Part of the challenge in crafting legal rules in this context is the heterogeneity, and lack of consensus, about the scope of what constitutes a biobank. See Susan M.C. Gibbons, *Regulating Biobanks: A Twelve-Point Typological Tool*, 17 MED. L. REV. 313 (2009).

2000, deCODE Genetics, Inc., a for-profit genetics company, received a license to establish the Icelandic Health Sector Database (HSD), based on a law passed in the late 1990s.<sup>47</sup> It was expected that “the database containing the healthcare data and in the health records of all Icelanders alive and deceased could be coupled with the genealogy and a genotypic database thus yielding a super-database.”<sup>48</sup> One of the most controversial aspects of the Icelandic law governing the HSD was that it permitted the disclosure of patients’ medical records to deCODE based on the “presumed consent” of the patients rather than express informed consent.<sup>49</sup> Although the biobank has been a “boon for genome-wide association studies,” the company’s efforts to develop drugs from its research findings have not been financially successful; the company was forced to declare bankruptcy in 2009 and, in January 2010, was purchased by Saga Investments LLC, a private consortium.<sup>50</sup>

Other countries have invested significant resources in the development of national biorepositories. For example, the UK Biobank, a not-for-profit charitable company funded by both public and private sources,<sup>51</sup> contains biological samples from more than 340,000 individuals and seeks to eventually collect samples from 500,000 individuals.<sup>52</sup> In Canada, the CARTaGene Project is currently seeking to recruit “a random sample of 20,223 adults aged between 40 and 69 years from

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47. See Sigridur Thorgeirsdottir, *Genes of a Nation: The Promotion of Iceland’s Genetic Information*, 8 TRAMES 178, 178 (2004).

48. *Id.* at 178–79.

49. *See id.*

50. See Jocelyn Kaiser, *Cash-Starved deCODE is Looking for a Rescuer for its Biobank*, 325 SCI. 1054, 1054 (2009). According to a company press release, “deCODE will continue all of its operations and product lines in this field, including its deCODE diagnostics disease risk tests; deCODEme™ personal genome scans; and contract service offerings including genotyping, sequencing and data analysis. Going forward, deCODE will concentrate on translating its science into medically and commercially important products and services.” Press Release, deCode Genetics, *Announcing the New deCode*, Jan. 21, 2010, available at <http://www.decode.com/news/news.php?story=112>.

51. Press Release, UK Biobank, *HRH The Princess Royal Officially Opens UK Biobank Storage Facility, Further Funding of £6 Million Announced* (July 28, 2009), available at <http://www.ukbiobank.ac.uk/docs/HRHVisit.pdf>.

52. See Genetics Perspectives on Policy Seminar, *Genetic Biobanks: Deposits, Withdrawals, and Consumer Protection 4* (Dec. 9, 2008) (transcript of National Press Club panel discussion), <http://www.dnapolicy.org/resources/GenePOPS11transcriptedited.pdf> [hereinafter *Genetics Perspectives Seminar*].

four metropolitan areas of Quebec” and to “create a bank containing data on health and a biobank containing biological material.”<sup>53</sup> Other countries are also establishing biobanks.<sup>54</sup> In the United States, there are several large scale biorepositories under the aegis of large academic institutions: Vanderbilt University Medical Center,<sup>55</sup> the Marshfield Clinic,<sup>56</sup> and Northwestern University.<sup>57</sup> Kaiser Permanente, which is the largest not-for-profit private health care provider in United States,<sup>58</sup> has also established a biobank and is recruiting participants to contribute samples. The biobank contains 40,000 DNA samples from its members as of early 2009 and is expected to contain 500,000 samples by 2010.<sup>59</sup> The Kaiser biobank is notable for the depth of information it will contain,

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53. CARTaGENE, General Objectives, [http://www.cartagene.qc.ca/index.php?option=com\\_content&task=view&id=14&Itemid=22](http://www.cartagene.qc.ca/index.php?option=com_content&task=view&id=14&Itemid=22) (last visited Mar. 25, 2010). The CARTaGENE Project is fully publicly funded and will seek to recruit an additional 30,000 patients in 2011 if its public funding is renewed. See CARTaGENE, CARTaGENE Project FAQ, [http://www.cartagene.qc.ca/index.php?option=com\\_easyfaq&Itemid=52&lang=english](http://www.cartagene.qc.ca/index.php?option=com_easyfaq&Itemid=52&lang=english) (last visited Mar. 25, 2010).

54. See, e.g. Norwegian Inst. of Pub. Health, Welcome to Biohealth Norway, [http://www.fhi.no/eway/default.aspx?pid=238&trg=MainArea\\_5811&MainArea\\_5811=5906:0:15,4627:1:0:0:::0:0](http://www.fhi.no/eway/default.aspx?pid=238&trg=MainArea_5811&MainArea_5811=5906:0:15,4627:1:0:0:::0:0) (last visited May 10, 2010) (Norwegian biobank intended to comprise “biological samples and standardized health and exposure data from 500,000 Norwegian individuals of all ages, corresponding to approximately 1/10 of the Norwegian population.”); LifeGene, About LifeGene, [http://lifegene.ki.se/about/index\\_en.html](http://lifegene.ki.se/about/index_en.html) (last visited May 10, 2010) (Swedish biobank intended to collect biological samples and medical information for 500,000 individuals in Sweden).

55. Dep’t of Biomed. Informatics, Vanderbilt Univ. Med. Ctr., Vanderbilt BioVU: Vanderbilt’s DNA Databank, <http://dbmi.mc.vanderbilt.edu/research/dnadatabank.html> (last visited Mar. 25, 2010). Vanderbilt’s biobank, which is known as “BioVU,” contains two main components: a biobank of DNA samples from more than 50,000 individuals coded by a “Research Unique Identifier (RUI) and the “Synthetic Derivative” database, a collection of deidentified information extracted from Vanderbilt Medical Center’s electronic clinical information systems.

56. See Genetics Perspectives Seminar, *supra* note 52, at 4.

57. See *id.*

58. Kaiser Permanente, Fast Facts About Kaiser Permanente, <http://xnet.kp.org/newscenter/aboutkp/fastfacts.html> (last visited Mar. 25, 2010). According to the company’s website, Kaiser serves more than 8.6 million members.

59. Susan J. Landers, *Kaiser Fills a Biobank with a Wealth of Data*, AM. MED. NEWS, Jan. 13, 2009, <http://www.ama-assn.org/amednews/2009/01/12/hlsc01113.htm>.

combining the participants' DNA samples with "information on their health, the air they breath[e] and their likely exposure to toxins. The bank will also note whether sidewalks or safe parks are near enough to allow the participants to exercise or if nearby stores sell fresh vegetables."<sup>60</sup>

#### B. PUBLIC ATTITUDES TOWARD BIOBANKING

In recent years there have been several efforts to better understand the public's attitudes toward, and willingness to contribute tissue samples to biobanks for research. This article does not provide a comprehensive review of the literature—much of which reports on research conducted in non-U.S. populations.<sup>61</sup> It also recognizes that, to the extent the research discussed was conducted using hypothetical scenarios, asking people what they *would* do under certain conditions may not be an accurate measure of how people actually behave when confronted with real-world circumstances.<sup>62</sup> Nevertheless, this type of research provides some insight regarding the public's views regarding use of their tissues in research. Studies to date appear to support the following with respect to the attitudes of the U.S. population: (1) there is significant public support for the goals of biobank research;<sup>63</sup> (2) a majority of the public

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60. *Id.*

61. See, e.g., Philippe A. Melas et al., *Examining The Public Refusal to Consent to DNA Biobanking: Empirical Data from a Swedish Population-Based Study*, 36 J. MED. ETHICS 93 *passim* (2010); Aaro Tupasela et al., *Attitudes Towards Biomedical Use of Tissue Sample Collections, Consent, and Biobanks Among Finns*, 38 SCANDINAVIAN J. PUB. HEALTH 46 *passim* (2010); Klaus Hoeyer, *Donors Perceptions of Consent to and Feedback from Biobank Research: Time to Acknowledge Diversity?*, PUB. HEALTH GENOMICS, Nov. 26, 2009, <http://content.karger.com/ProdukteDB/produkte.asp?Aktion=ShowFulltext&ArtikelNr=262329&Ausgabe=0&ProduktNr=224224>; Hazel Thornton, *The UK Biobank Project: Trust and Altruism Are Alive and Well: A Model for Achieving Public Support for Research Using Personal Data*, 7 INT'L J. SURGERY 501 *passim* (2009); Shaun Treweek, Alex Doney & David Leiman, *Public Attitudes to the Storage of Blood Left Over from Routine General Practice Tests and its Use in Research*, 14 J. HEALTH SERVICES RES. & POL'Y 13 *passim* (2009).

62. See generally GEORGE F. BISHOP, *THE ILLUSION OF PUBLIC OPINION: FACT AND ARTIFACT IN AMERICAN PUBLIC OPINION POLLS* *passim* (2005).

63. See SHAWNA WILLIAMS ET AL., *GENETICS AND PUB. POLICY CTR., JOHNS HOPKINS UNIV., THE GENETICS TOWN HALL: PUBLIC OPINION ABOUT RESEARCH ON GENES, ENVIRONMENT, AND HEALTH* *passim* (2008), available at [http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Genetics\\_a](http://www.pewtrusts.org/uploadedFiles/wwwpewtrustsorg/Reports/Genetics_a)

would agree, at least under some conditions, to contribute tissue samples for research;<sup>64</sup> (3) there is significant public concern about ensuring the privacy of the information derived from their tissue sample as well as any associated medical information that is included about them as part of the research;<sup>65</sup> and (4) there is significant public interest in receiving information from research conducted with their tissues if it could be relevant to one's health, and in having a choice regarding what information they receive.<sup>66</sup>

A study undertaken by the Genetics and Public Policy Center, at Johns Hopkins University, in 2007 is one example of research that supports the above conclusions.<sup>67</sup> The Center sought to assess attitudes regarding a proposal being considered by the National Institutes of Health (NIH) and other agencies to create a biobank including a nationally representative sample of at least 500,000 people in order to study the roles of genes and environment in health.<sup>68</sup> Through a combination of focus groups, town halls, and an online survey of more than 4,500 U.S. adults, the Center assessed the public's willingness to participate in such research, privacy concerns, views about informed consent and data sharing, and the impact of modest incentives on willingness to participate.<sup>69</sup>

The population-based survey revealed that a majority of respondents supported the general idea of the study and would

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nd\_Public\_Policy/2009PCPTownHalls.pdf; David Kaufman et al., *Veterans' Attitudes Regarding a Database for Genetic Research*, 11 GENETICS MED., May 2009, at *passim* [hereinafter Kaufman et al., *Veterans' Attitudes*].

64. See WILLIAMS ET AL., *supra* note 63, at *passim*; David Kaufman et al., *Public Opinion About the Importance of Privacy in Biobank Research*, 85 AM. J. HUM. GENETICS, Nov. 2009, at *passim* [hereinafter Kaufman et al., *Public Opinion*]; Kaufman et al., *Veterans' Attitudes*, *supra* note 63, at *passim*.

65. WILLIAMS ET AL., *supra* note 63, at 8.

66. *Id.* at 9; Kaufman et al., *Veterans' Attitudes*, *supra* note 63, at 334; Murphy et al., *Public Expectations for Return of Results from Large-Cohort Genetic Research*, AM. J. BIOETHICS, Nov. 2008, at 36–41 [hereinafter Murphy et al., *Public Expectations*].

67. Results from this study were reported in a number of publications: Kaufman et al., *Public Opinion*, *supra* note 64, at *passim*; Juli Murphy et al., *Informed Perspectives on Health: Public Perspectives on Informed Consent for Biobanking*, 99 AM. J. PUB. HEALTH 2128 *passim* (2009) [hereinafter Murphy et al., *Informed Perspectives*]; Murphy et al., *Public Expectations*, *supra* note 66, at 36–41.

68. Murphy et al., *Informed Perspectives*, *supra* note 67, at 2129.

69. *Id.*

likely participate if asked.<sup>70</sup> However, significant concern was expressed about whether the privacy of their medical information would be protected.<sup>71</sup> Black non-Hispanics, American Indians, Alaskan Natives, and participants who “self-identified” as multi-racial were all “significantly more likely” than white participants to state that they were concerned about the privacy of their medical information.<sup>72</sup>

The survey also assessed preferences regarding consent. Nearly half of those surveyed expressed a preference that consent be obtained at the outset of all research to be undertaken and not prior to each individual research project.<sup>73</sup> Supporters of this type of “blanket” consent appreciated that by allowing participants to pick and choose the type of research they would consent to, the ability to conduct the research could be compromised, or at least made more complex.<sup>74</sup> However, a sizeable minority expressed a preference for separate consent for each project undertaken with their samples.<sup>75</sup> Findings from the focus groups also shed light on individuals’ preferences regarding the return of research results. Focus group participants were asked their preferences for receiving results from different types of studies. While preferences varied, accuracy of the information was a key predictor of whether participants wanted to receive their results. Actionability of information<sup>76</sup> did not appear to be a strong predictor of desire for return of results. For example, the participants in the focus groups voiced a “strong desire” for the research results, “even if they indicated a heightened risk of an untreatable disease such as Alzheimer.”<sup>77</sup> As one male focus group participant stated, “You have an obligation to tell these people. They expect something back from you. I’m volunteering some of my flesh for you to evaluate me. Tell me what’s wrong with it. Not that you could do something about it necessarily,

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70. *Id.* at 2131; see also Kaufman et al., *Public Opinion*, *supra* note 64, at 645.

71. Murphy et al., *Informed Perspectives*, *supra* note 67, at 2131; Kaufman et al., *Public Opinion*, *supra* note 64, at 645.

72. Kaufman et al., *Public Opinion*, *supra* note 64, at 645.

73. Murphy et al., *Informed Perspectives*, *supra* note 67, at 2131.

74. *Id.*

75. *Id.*

76. Murphy et al., *Public Expectations*, *supra* note 66, at 39.

77. WILLIAMS ET AL., *supra* note 63, at 9.



but at least let me know.”<sup>78</sup>

Some participants, however, believed that subjects should recognize that the purpose of the research is to “generate knowledge for the common good, and should participate out of altruism rather than a desire to obtain results.”<sup>79</sup>

Members in most focus groups expressed the view that study participants should be given choices at the beginning of the study about what research results they would receive and the frequency and mode of communication in which they received them.<sup>80</sup>

The focus groups also yielded interesting, although incomplete, insights into the public’s perception of the participant-researcher relationship. According to the findings, the term “contract” arose spontaneously and repeatedly in discussing study participation.<sup>81</sup> Focus group members “viewed a contract as a binding agreement between participants and researchers and did not view it simply as participants’ agreement to participate.”<sup>82</sup> According to the findings, focus group members “thought that a contract might offer participants greater protection than an institutional review board or study oversight committee and provide participants with some level of recourse if researchers strayed from the agreed-upon terms.”<sup>83</sup> Participants also identified specific terms they believed should be included in the contract between researchers and participants, such as what specific samples would be collected, how they would be used during the study, who would have access to data from the study, what would happen to the samples and data after the study closed, and what would happen if the terms of the contract were breached.<sup>84</sup> While acknowledging that more research on the specific understanding of the term “contract” would be useful, the Center concluded that, “the repeated use of ‘contract’ by focus group participants in each city and the overwhelming desire for a contract demonstrated by the survey data suggested that the public believes that there are or should be

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78. Murphy et al., *Public Expectations*, *supra* note 66, at 40.

79. WILLIAMS ET AL., *supra* note 63, at 9.

80. Murphy et al., *Public Expectations*, *supra* note 66, at 40.

81. Murphy et al., *Informed Perspectives*, *supra* note 67, at 2131.

82. *Id.* at 2132.

83. *Id.*

84. *Id.*

reciprocal obligations between researcher and participant.”<sup>85</sup>

The Center also hypothesized that the desire for a contract may reflect a lack of trust in the research enterprise,<sup>86</sup> but noted that the success of biobanks “depends upon ongoing public support, participation, and trust in the research endeavor.”<sup>87</sup> The importance of trust was similarly observed in a survey conducted by researchers at Duke University, who found that willingness to participate in biobank research is strongly correlated with the degree of trust that respondents have in researchers.<sup>88</sup> As discussed in the next section, the current regulatory framework is not optimized to instill trust and foster participation in biobank research.

#### IV. PERCEPTION V. REALITY: THE CURRENT LEGAL LANDSCAPE

##### A. HISTORICAL ROOTS OF HUMAN SUBJECT PROTECTION

The current framework for human subject protection is rooted in, and is a reaction to, extreme physical and psychological abuse. The Nuremberg Code—the seminal articulation of the rights due participants in medical research—emerged in the aftermath of unspeakable Nazi atrocities in which prisoners were subjected to grueling experiments of no possible benefit to them.<sup>89</sup> The subsequent Belmont Report,<sup>90</sup> which laid the intellectual foundations for

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85. *Id.* at 2133.

86. *Id.*

87. Murphy et al., *Public Expectations*, *supra* note 66, at 41.

88. Laura M. Beskow & Elizabeth Dean, *Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions*, 17 *CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION* 1440, 1440 (2008).

89. *See* 2 *TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10*, at 181–82 (1951) [hereinafter *NUERNBERG CODE*]. Among other principles, the Code states that the “voluntary consent of the human subject is absolutely essential,” and specifies the components of such consent. The Code also specifies the limits of the risks that subjects should be asked to assume as part of research and articulates the duties that researchers owe to research participants: “The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.” *Id.* at 181.

90. Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, 44 *Fed. Reg.* 23,192, 23,192–97 (April 18, 1979), *available at*

legal protections for research subjects in the United States, was written in response to, among other abuses, the decades-long government-funded study in which poor black men with syphilis were denied effective treatment in order to study the natural history of disease.<sup>91</sup>

Thus the current legal framework for human subject protection<sup>92</sup>—now nearing its fourth decade—was developed in response to predominantly physical harms perpetrated on vulnerable populations—including prisoners,<sup>93</sup> children,<sup>94</sup> the disabled,<sup>95</sup> and minorities<sup>96</sup>—who were unwilling or unwitting subjects of research. A key remedial purpose of this framework was to ensure that no human being would be required to take part in physically risky research against his will. To effectuate this purpose, a key component of the framework requires full disclosure of the risks of participation to the individual prior to any agreement to participate in research—what we now know as “informed consent.” To be sure, the rules have been broadened beyond that foundation to encompass certain types of non-interventional research,<sup>97</sup> but they are nevertheless rooted in concerns about preventing physical harm to vulnerable populations.

As discussed below, the use of tissue in research was not contemplated at the time current regulations were put in place. Yet, as discussed previously, the collection and use of stored tissue for research has become commonplace, from our first day of life forward.<sup>98</sup> As discussed below, there are no generally

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<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

91. JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT passim* (1981).

92. Protection of Human Subjects, 45 C.F.R. §§ 46.101–.505 (2009).

93. See ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT pt. 2, ch. 9, at 263–83 (1995), available at <http://www.hss.energy.gov/healthsafety/ohre/roadmap/achre/report.html>.

94. See *id.* at ch. 7, at 196–226.

95. See *id.* at ch. 5, at 139–71.

96. See *id.*

97. For example, the Common Rule covers research in which only information is obtained from subjects if the information obtained “is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, or reputation.” 45 C.F.R. § 46.101(b)(2) (2009).

98. Nearly every newborn in the United States has a small quantity of

applicable rules governing the research use of such tissues. Whether and to what extent federal rules apply depend on (1) whether the research at issue is federally funded,<sup>99</sup> and (2) whether the tissue samples used in the research can be linked back to their source, *i.e.*, if they are “identifiable.”<sup>100</sup> Even where federal regulations do apply, they do not address many of the concerns and preferences—discussed above—of the contributors of such tissue. For non-federally funded research, the applicable requirements vary based on individual state laws, and, as described below, different courts have invoked different legal theories to resolve disputes between researchers,

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blood removed and tested for certain genetic disorders. The blood is collected on “Guthrie cards,” which are named for the individual who developed them. See Jean E. McEwen & Philip R. Reilly, *Stored Guthrie Cards as DNA “Banks”*, 55 AM. J. HUM. GENETICS 196, 196 (1994). The cards are often stored indefinitely, and there are no uniform policies regarding their destruction or use in research. Guthrie cards have the potential to be immensely useful in research because they can be linked with the individual’s medical record, and a researcher can obtain follow-up information to track the individual longitudinally. Guthrie cards are also useful even if they are “anonymized.” Their use in research, however, is controversial because they were obtained for a health-related purpose and are being re-directed for research without the consent of the parents or the child. At least two states, Texas and Minnesota, have recently faced litigation brought by civil rights groups representing parents concerned about potential uses of their children’s blood stored on Guthrie cards. See Adam Doerr, *Newborn Blood Spot Litigation: 70 Days to Destroy 5+ Million Samples*, GENOMICS L. REP. (Feb. 2, 2010), <http://www.genomicslawreport.com/index.php/2010/02/02/newborn-blood-spot-litigation-70-days-to-destroy-5-million-samples/> (last visited Apr. 27, 2010); Katherine Drabiak-Syed, *Newborn Blood Spot Litigation Continues in Minnesota and Texas*, PREDICTER NEWS (Nov. 20, 2009, 10:09 AM), <http://predicter.blogspot.com/2009/11/newborn-blood-spot-litigation-continues.html> (last visited Apr. 27, 2010) (describing the Minnesota and Texas litigation). As a result of a settlement in the Texas litigation, the State of Texas has agreed to destroy blood samples collected from more than 5 million newborn babies over the last five years. See Doerr, *supra*. The judge in the Minnesota litigation dismissed the case in late November 2009, but the plaintiffs plan to appeal the decision and to continue to object to the State’s retention and use of newborn’s blood samples in research. See Katherine Drabiak-Syed, *Minnesota Judge’s Dismissal of Newborn Blood Spot Case Misses the Mark*, PREDICTER NEWS (Dec. 14, 2009, 8:27 AM), <http://predicter.blogspot.com/2009/12/minnesota-judges-dismissal-of-newborn.html> (last visited Apr. 27, 2010).

99. 45 C.F.R. § 46.101(a) (2009).

100. See OFFICE FOR HUMAN RESEARCH PROTS., DEPT OF HEALTH & HUMAN SERVS., GUIDANCE ON RESEARCH INVOLVING CODED PRIVATE INFORMATION OR BIOLOGICAL SPECIMENS 3 (2008), available at <http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf> [hereinafter OHRP GUIDANCE].

participants, and institutions.

#### B. FEDERAL OVERSIGHT OF TISSUE-BASED RESEARCH

The “Common Rule,”<sup>101</sup> as the federal human subject protection regulations are known as, sets forth requirements for the protection of all human subjects of federally funded research. These requirements include that the investigators obtain the “legally effective informed consent of the subject or the subject’s legally authorized representative.”<sup>102</sup>

The Common Rule applies to “all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research.”<sup>103</sup> Although the federal regulations do not

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101. Protection of Human Subjects, 45 C.F.R. §§ 46.101–.505 (2009).

102. *Id.* § 46.116. The basic elements of informed consent include: (1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental; (2) a description of any reasonably foreseeable risks or discomforts to the subject; (3) a description of any benefits to the subjects or to others which may reasonably be expected from the research; (4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) an explanation of whom to contact for answers to pertinent questions about the research and research subject’s rights, and whom to contact in the event of a research-related injury to the subject; and (8) 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.

103. Protection of Human Subjects, 45 C.F.R. § 46.101(a) (2009). “Research” is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” *Id.* § 46.102(d). The term “human subject” is defined as “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.” *Id.* § 46.102(f). “Private information” is defined as “information about behavior that occurs in a context in which an 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

explicitly define research with human tissue specimens as human subject research, if such research involved “identifiable private information,” it would clearly be encompassed within the definition.<sup>104</sup> However, what about tissue specimens from which identifiers have been removed? The regulations specifically exempt from the requirements of Part 46 research that uses *existing* stored tissue specimens if “the information is recorded by the investigator in such a manner that *subjects cannot be identified*, directly or through identifiers linked to the subjects.”<sup>105</sup> In addition, guidance issued by the Office of Human Research Protections, within the NIH, states that research involving “coded,” or non-identifiable, human specimens is not considered human subjects research.<sup>106</sup>

In short, federally funded research involving identifiable human biological specimens generally is considered human subject research for the purposes of the Common Rule, while federally funded research involving samples whose identity has

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individual can reasonably expect will not be made public (for example a medical record).” *Id.* The regulation provides, further: “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.*

104. This is confirmed by the guidance document issued by the Office of Human Research Protections (OHRP) of the NIH, which provides that, for the purpose of the definition of human subject under 45 C.F.R. § 46.102(f), obtaining identifiable private information or identifiable specimens includes: “(1) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that have been provided to investigators from any source; and (2) using, studying, or analyzing for research purposes identifiable private information or identifiable specimens that were already in the possession of the investigator.” OHRP GUIDANCE, *supra* note 100, at 3. The guidance provides that OHRP considers specimens to be “individually identifiable as defined at 45 CFR 46.102(f) when they can be linked to specific individuals by the investigator(s) either directly or indirectly through coding systems.” *Id.*

105. Protection of Human Subjects, 45 C.F.R. § 46.101(b)(4) (2009) (emphasis added).

106. See OHRP GUIDANCE, *supra* note 100, at 3. The OHRP GUIDANCE uses the term “coded” to signify that human specimens contain “identifying information (such as name or social security number) . . . [that] has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); . . . and a key to decipher the code exists, enabling linkage of the identifying information to the . . . specimens.” *Id.* The OHRP GUIDANCE clarifies the circumstances under which OHRP does not consider research involving coded specimens to involve human subjects.

*Id.* at 4.

been removed or has not been recorded generally is not considered human subject research according to the statutory definition.<sup>107</sup> Even where the use of specimens is considered human subject research, however, this does not mean that researchers must address all of the issues that participants in such research might view as important. For example, the federal regulations do not require that participants be told all of the possible uses of their tissue or to provide information about study results.<sup>108</sup> Nor do they clearly require researchers to disclose whether and to what extent the research may have commercial application.<sup>109</sup> Thus even where they apply, the protections provided under the Common Rule may not be consonant with the expectations and preferences of those who contribute their tissue for research.<sup>110</sup> Additionally, the

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107. In contrast, the Food and Drug Administration (FDA) does appear to consider research involving deidentified human specimens to be human subject research, but the agency has stated that it will exercise enforcement discretion and exempt such research from informed consent requirements if certain conditions are met. *See* Food and Drug Admin., Guidance for Sponsors, Institutional Review Bds., Clinical Investigators and FDA Staff: Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That are Not Individually Identifiable (Apr. 25, 2006), *available at* <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071265.pdf> [hereinafter FDA, Guidance on Informed Consent].

108. *See* Protection of Human Subjects, 45 C.F.R. § 46.116 (2009) (listing the requirements for informed consent under the rule).

109. 45 C.F.R. § 46.116(a)(3) does require that informed consent include a “description of any benefits to the subject or to others which may reasonably be expected from the research.” It could be argued that benefits to the researcher from commercialization should be included within this language. However, OHRP guidance on disclosure of financial interests does not mandate any specific disclosure but rather raises points for IRBs, institutions, and researchers to consider in “determining whether specific financial interests in research affect the rights and welfare of human subjects and if so, what actions could be considered to protect those subjects.” Dep’t of Health and Human Services, Final Guidance Document,

Financial Relationships and Interests in Research Involving Human Subjects: Guidance

for Human Subject Protection (2004), *available at* <http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf>.

110. Moreover, under certain circumstances, an IRB may even waive the requirement for informed consent. 45 C.F.R. § 46.116(c) provides:

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

regulations have no applicability to research conducted with private funds.<sup>111</sup>

### C. CASE LAW

Although there have been only a few legal cases involving disputes between the parties to human tissue research, their resolution reveals starkly the gaps in the current oversight framework as well as a lack of shared perceptions by the different parties to the enterprise. Furthermore, the lack of consistency in the opinions, as well as the differences among jurists in the same case, demonstrates the wide divergence of views on the issues and the need

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(1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs; and

(2) The research could not practicably be carried out without the waiver or alteration.

111. However, FDA has created regulations requiring anyone who submits a marketing application for a drug, biological product, or medical device to disclose information about the compensation to, and financial interests of, any clinical investigator conducting clinical studies covered by the rule. *See* 21 C.F.R. §§ 54.1(b), 312.53(c)(4), 314.50(k), 320.36(b), 330.10(f), 601.2(a), 807.31(d)(3), 812.43(c)(5), 814(b)(12), 860.123(a)(10) (2009). Under the regulations, an applicant is required to submit to FDA a list of clinical investigators who conducted covered clinical studies and certify and/or disclose certain financial arrangements as follows:

1. [The applicant must certify] that no financial arrangements with an investigator have been made where study outcome could affect compensation; that the investigator has no proprietary interest in the tested product; that the investigator does not have a significant equity interest in the sponsor of the covered study; and that the investigator has not received significant payments of other sorts; and/or

2. [The applicant must disclose certain] specified financial arrangements and any steps taken to minimize the potential for bias.

DEPT OF HEALTH & HUMAN SERVS., FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY: FINANCIAL DISCLOSURE BY CLINICAL INVESTIGATORS (Mar. 20, 2001), <http://www.fda.gov/RegulatoryInformation/Guidances/ucm126832.htm> [hereinafter FDA GUIDANCE]. FDA's medical device regulations define a "subject" as "a human who participates in an investigation, either as an individual on whom or *on whose specimen* an investigational device is used or as a control." Medical Devices, Investigational Device Exemptions, 21 C.F.R. § 812.3(p) (2009) (emphasis added).



prospectively<sup>112</sup> to establish and apply clear and consistent rules. From a doctrinal perspective, perhaps the most troubling aspect of the current case law is that it fails to distinguish clearly between the goal of informed consent, which, as demonstrated above, is to protect vulnerable research participants from abuses at the hands of researchers, and the quasi-contractual concept of donation, which presumes that the donor is in an equal position relative to the recipient and therefore has the ability to establish the terms of the donation.<sup>113</sup>

The first, and perhaps best known, legal dispute involving the rights and expectations of human tissue contributors was *Moore v. Regents of the University of California*.<sup>114</sup> Mr. Moore suffered from hairy-cell leukemia, and the recommended treatment included removal of his spleen.<sup>115</sup> The surgery was apparently successful, and Mr. Moore recovered from his illness.<sup>116</sup> However, on several occasions his physician asked him to return for follow-up visits and provide additional blood samples, ostensibly to monitor his health.<sup>117</sup>

Without his knowledge, Moore's treating physician, Dr. Golde, along with a researcher he worked with, Dr. Quan, used Moore's cells from his spleen and other tissue samples he had provided to develop a cell line.<sup>118</sup> The University of California Los Angeles (UCLA), which employed Dr. Golde and Dr. Quan, filed a patent for the cell line, which listed Dr. Golde and Dr. Quan as the inventors.<sup>119</sup> UCLA and Dr. Golde then licensed the cell line to two companies, who provided stock options,

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112. This article should not be construed to recommend a categorical prohibition on the use of specimens already contained in biorepositories whose contributors are unknown, and in many cases are deceased. However, the failure prospectively to develop rules to govern the use of specimens has caused significant practical problems for researchers, as well as for manufacturers, who rely on such samples to develop new medical products. See, e.g., FDA, Guidance on Informed Consent, *supra* 107 (discussing the difficulties associated with finding the source of a leftover specimen and obtaining his or her consent, but noting that human subject protection still must be ensured).

113. See *infra* note 157.

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

115. *Id.* at 481.

116. See *id.*

117. *Id.*

118. *Id.* at 481–82.

119. *Id.*

consulting fees, and salary support to Golde in exchange for exclusive access to the materials and research performed, as well as to the products derived from the cell line.<sup>120</sup>

When he discovered what had been done with his cells, Moore sued UCLA, the researchers, and the companies for a share of the profits derived from his cells.<sup>121</sup> He asserted that the unauthorized use of his cells constituted “conversion,” a common law tort involving interference with one’s ownership or right to possession of property.<sup>122</sup> To succeed on a conversion cause of action, a plaintiff must demonstrate ownership or the right to possess the property in question.<sup>123</sup> In denying Moore’s conversion claim, the majority held that he had no ownership interest in his cells.<sup>124</sup> The court’s review of existing laws led to the conclusion that Moore lacked the requisite property interest to sustain a cause of action for conversion and that applying this theory to Moore’s situation would require expanding the scope of the tort.<sup>125</sup> The majority declined to undertake such expansion, citing concerns about hindering the conduct of research by placing unreasonable burdens on researchers.<sup>126</sup> Adopting the theory of liability asserted by Moore “threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery.”<sup>127</sup> Furthermore, “[b]ecause liability for conversion is predicated on a continuing ownership interest, ‘companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about

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

121. *See id.*

122. *Id.* at 487.

123. *Id.* at 488.

124. *See id.* at 492–93. First, the court rejected the argument that a person has an absolute right to the unique products of his or her body on the basis that Moore’s cells were “no more unique to Moore than the number of vertebrae in the spine or the chemical formula for hemoglobin.” *Id.* at 490. Furthermore, the court reviewed California statutes dealing with various types of tissues and concluded that these laws did not treat tissues as property, but rather as “objects sui generis,” and that different types of tissues were subject to different legal requirements based on the policy objective sought to be achieved. *See id.* at 489.

125. *Id.* at 493.

126. *See* Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 493–96 (Cal. 1990).

127. *Id.* at 495–96.

clear title exists.”<sup>128</sup> The court stated that extending property rights to excised tissues was within the proper purview of the legislature, not the courts.<sup>129</sup>

The court also rejected the argument that allowing a cause of action for conversion was necessary to protect a patient’s autonomy and dignity, holding that such interests were adequately protected through informed consent.<sup>130</sup> The court did appear sensitive to the fact that Moore’s physician had failed to tell him how his cells were being used and, moreover, had induced him to provide additional samples following his surgery under false pretenses.<sup>131</sup> However, the court appeared to believe that expanding the physician’s duties of informed consent could provide adequate protection against such deception.<sup>132</sup> Indeed, the court found that Dr. Golde had breached his duty of informed consent by failing to inform Moore of his economic interest in the cells before seeking his consent to perform surgery.<sup>133</sup> The court stated that, just as patients must be told about physical risks of a procedure, they must be informed of economic interests that might cloud the physician’s judgment.<sup>134</sup>

[A] physician who treats a patient in whom he also has a research interest has potentially conflicting loyalties. This is because medical treatment decisions are made on the basis of proportionality—weighing the benefits *to the patient* against the risks *to the patient* . . . . A physician who adds his own research interests to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to the patient.<sup>135</sup>

In holding in favor of Moore on informed consent while ruling against his claim of conversion, the court appears to have been balancing its desire to protect the research enterprise while preventing blatant deception of patients. However, the court’s reasoning with respect to informed consent is flawed. In particular, the court failed to distinguish between Moore as a patient and Moore as a research subject.

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128. *Id.* at 496.

129. *Id.*

130. *Id.* at 496–97.

131. *See id.* at 496 n.41.

132. *See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 496–97 (Cal. 1990).

133. *Id.* at 486, 497.

134. *Id.* at 485.

135. *Id.* at 484 (emphasis in original).

Although there was evidence presented to the district court that Golde was aware of the potentially lucrative nature of Moore's cells before he removed his spleen, and therefore had a *potentially* conflicting interest,<sup>136</sup> there was no evidence that this actually motivated his decision to perform the surgery or, moreover, that the surgery was not the appropriate treatment for Moore's underlying medical condition. Disclosing his financial interest might have led Moore to seek a different doctor, but presumably that doctor also would have concluded that the surgery was necessary to treat his leukemia. Thus, at least in this instance, there is no evidence that disclosure of Golde's financial interest in his cells would have made Moore-the-patient, better off, and might have needlessly led him to reject a competent physician.<sup>137</sup> Moreover, even recognizing that there are circumstances where a patient's well-being may be compromised by his or her treating physician's conflict of interest, financial or otherwise, and that financial disclosure therefore may be an important element of informed consent to *treatment*, the court's reasoning nevertheless was insufficient in its failure to consider Moore-the-research-subject separately from Moore-the-patient. When Golde took Moore's cells for use in research without telling him, he committed a wrong to Moore-the-research-subject independently of whatever duties he owed Moore as a patient. The court failed to acknowledge Moore's transition from patient to research subject, and therefore failed to consider the duties owed to Moore in that capacity. Had Golde not been his treating physician, or if he had had no inkling of the cells' potential research value at the

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136. According to the California Supreme Court, Moore alleged in his complaint that before Dr. Golde recommended to Moore that his spleen be removed, Golde was "aware that 'certain blood products and blood components were of great value in a number of commercial and scientific efforts' and that access to a patient whose blood contained these substances would provide 'competitive, commercial, and scientific advantages.'" *Id.* at 481.

137. The majority did acknowledge that requiring disclosure could undermine a patient's judgment, but nevertheless viewed such disclosure as necessary. *See id.* at 484–85 ("To require disclosure of research and economic interests may corrupt the patient's own judgment by distracting him from the requirements of his health. But California law does not grant physicians unlimited discretion to decide what to disclose. Instead, it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie. Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision.") (internal quotation marks, citations and footnote omitted).

time of the surgery, he would have been under no obligation, by the court's reasoning, to inform Moore of the value of his cells. Nor, by the court's reasoning, did Dr. Quan or UCLA have any duty to obtain Moore's consent to use his cells. The court's limited holding therefore does little to protect the interests of the growing number of contributors of tissue samples who are not patients, as becomes apparent in *Greenberg v. Miami Children's Hospital Research Institute*,<sup>138</sup> discussed below.

In *Moore*, Justice Broussard, concurring and dissenting, disagreed with the majority's conclusion that the tort of conversion was inapposite.<sup>139</sup> He framed the issue not as about the right to tissue once it was removed, but rather as about the right of an individual to determine the disposition of his or her excised tissue before it is removed.<sup>140</sup> Justice Mosk, who also disagreed with the majority's conclusion regarding the tort of conversion, rejected the majority's focus solely on the needs of the research enterprise, stating that its "single policy consideration . . . is outweighed by . . . policies that are promoted by recognizing that every individual has a legally protectible [sic] property interest in his own body and its products," as well as by considerations of equity, which would preclude the "unjust enrichment of any member at the expense of another."<sup>141</sup> Giving eloquent voice to the views expressed by Dr. Lengauer—the researcher who felt the Lacks family had been wronged—Justice Mosk noted that:

There is . . . a third party to the biotechnology enterprise—the patient who is the source of the blood or tissue from which all these profits are derived. While he may be a silent partner, his contribution to the venture is absolutely crucial . . . but for the cells of Moore's body taken by defendants there would have been no Mo cell line at all. Yet defendants deny that Moore is entitled to any share whatever in the proceeds of this cell line. This is both inequitable and immoral.<sup>142</sup>

Cases that have arisen since *Moore* have similarly failed to properly consider the status of the third parties to biotechnology, and have consistently resolved disputes in favor of the institutions at which the research took place, albeit

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

139. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 499 (Cal. 1990) (Broussard, J., concurring and dissenting).

140. *Id.* at 501.

141. *Id.* at 515–16 (Mosk, J., dissenting).

142. *Id.* at 516 (footnote omitted).

based on different legal theories. In *Greenberg*, family members with children suffering from Canavan disease, a rare genetic disorder, along with non-profit organizations with an interest in the disease, sought help from defendant Dr. Matalon in identifying the genetic mutation causing the illness and in developing a test to detect the mutation.<sup>143</sup> Plaintiffs provided support to Dr. Matalon by contributing tissue, developing a patient registry, and raising money.<sup>144</sup> Dr. Matalon identified the gene and developed the test, but his research institution, Miami Children's Hospital, patented the gene, listed him as an inventor, and sought to enforce the patent and collect royalties for the test's performance.<sup>145</sup> The plaintiffs, who were not told that the gene would be patented and had expected the test to be freely available, sued the researcher and institution alleging lack of informed consent, breach of fiduciary duty, unjust enrichment, fraudulent concealment, conversion, and misappropriation of trade secrets.<sup>146</sup> With the exception of unjust enrichment,<sup>147</sup> the court dismissed all of plaintiffs'

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143. *Greenberg*, 264 F. Supp. 2d at 1066–67.

144. *Id.* at 1067.

145. *Id.*

146. *Id.* at 1068.

147. The plaintiffs had alleged that Miami Children's Hospital was being unjustly enriched by collecting license fees under the patent. *Id.* at 1072. "Under Florida law, the elements of a claim for unjust enrichment are (1) the plaintiff conferred a benefit on the defendant, who had knowledge of the benefit; (2) the defendant voluntarily accepted and retained the benefit; and (3) under the circumstances it would be inequitable for the defendant to retain the benefit without paying for it." *Id.* The parties agreed that the plaintiffs conferred a benefit on the defendants, but the defendants contended that the plaintiffs had not suffered any detriment, nor had any plaintiff been denied access to testing for Canavan disease. *Id.* The court held that the complaint alleged "more than just a donor-donee relationship," in that the "facts paint a picture of a continuing research collaboration that involved Plaintiffs also investing significant resources in the race to isolate the Canavan gene." *Id.* at 1072–73. Under those facts as alleged, the court concluded that the plaintiffs had "sufficiently pled the requisite elements of an unjust enrichment claim" and denied the defendants' motion to dismiss that claim. *Id.* at 1073. The parties ultimately settled the suit. See Joint Press Release, Canavan Foundation (Sept. 29, 2003), [http://www.canavanfoundation.org/news/09-03\\_miami.php](http://www.canavanfoundation.org/news/09-03_miami.php) (last visited Apr. 27, 2010). Although the terms of the settlement are confidential, the Canavan Foundation reported that the agreement "provides for continued royalty-based genetic testing by certain licensed laboratories and royalty-free research by institutions, doctors, and scientists searching for a cure." *Id.*

claims.<sup>148</sup> In particular, the *Greenberg* court held that Dr. Matalon did not have a duty of informed consent with respect to the plaintiffs because, unlike Dr. Golde in *Moore*, he was not their treating physician.<sup>149</sup> The court then questioned whether the duty of informed consent was applicable, under state law, to medical research (while acknowledging that the duty did apply under federal law, which was not at issue in the case).<sup>150</sup> Even if the duty did apply, moreover, the court held that it did not include a duty to disclose the researcher's financial interests in research, because the plaintiffs were tissue donors, and not "objects of human experimentation."<sup>151</sup>

Like the majority in *Moore*, the *Greenberg* court appeared to preference the medical research needs over the concerns of research participants.<sup>152</sup> Also like the *Moore* decision, the *Greenberg* court's reasoning is flawed. Just as the *Moore* court conflated the contexts of medical treatment and human subject research in a manner that discounted Moore's interest as a research subject, the *Greenberg* court confused the differing premises underlying informed consent and donation<sup>153</sup>—again to the plaintiffs' disadvantage. The plaintiffs in *Greenberg* were required by the research institution to sign an informed consent document.<sup>154</sup> The context of such signature was clearly

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148. *Greenberg*, 264 F. Supp. 2d at 1077–78.

149. *See id.* at 1070.

150. *Id.* at 1070–71.

151. *Id.* at 1071.

152. *See id.* at 1070.

153. Because donations are considered gifts and are given without consideration, an agreement to donate is considered an imperfect contract that is void for want of consideration under common law legal systems, although such agreements are considered valid contracts in civil law legal systems. Compare 4 RICHARD A. LORD, WILLISTON ON CONTRACTS § 7:11 (4th ed. 2008) (discussing a lack of consideration in a common law system) with Bürgerliches Gesetzbuch [BGB] [Civil Code] Aug. 18, 1896, Reichsgesetzblatt [RGBL] 195, as amended, § 311 (listing the requirements of contract formation under German law, a civil law legal system). The doctrine of promissory estoppel, which applies where enforcement of promises unsupported by consideration is necessary to avoid injustice, has been used to enforce promises based on donations or gifts. See WILLISTON ON CONTRACTS § 8:8 (discussing the use of the doctrine of promissory estoppel to enforce "purely donative gratuitous promises"). Although an agreement to donate is not enforceable, when a donation is made it acquires the legal status as a transfer of property. RESTATEMENT (THIRD) OF PROP.: WILLS & OTHER DONATIVE TRANSFERS § 6.1 cmt. a (2003).

154. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F.

a research context—the whole point of providing their tissue was in order to have research performed with their tissues. Thus at the time the tissue was provided by the plaintiffs, they had been assigned the role of human subject by the institution, a role by its nature placed the researcher in a fiduciary relationship with the human subjects of research and that therefore required researchers to ensure that that their participation was freely agreed to and that they were given all the information necessary to make a decision.<sup>155</sup> In rejecting plaintiffs' breach of fiduciary duty claim, the court held that plaintiffs had failed to allege sufficiently that defendants had accepted the trust placed in them by plaintiffs, a prerequisite for a finding of breach of fiduciary relationship under common law. "There is no automatic fiduciary relationship that attaches when a researcher accepts medical donations, and the acceptance of trust . . . cannot be assumed once a donation is given."<sup>156</sup> However, the court failed to consider that *simply designating plaintiffs as human subjects*, they stood in a trust relationship with them and were not free to reject plaintiffs' trust after the fact.<sup>157</sup>

The court's after-the-fact designation of the plaintiffs as "donors" similarly seems to misapprehend the significance of the context in which such "donation" took place. According to the court, plaintiffs "are more accurately portrayed as donors rather than objects of human experimentation, and thus the voluntary nature of their submissions warrants different treatment."<sup>158</sup> However, plaintiffs signed a consent document indicating that the purpose of their participation was for a

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Supp. 2d 1064, 1068 (S.D. Fla. 2003).

155. See NUERNBERG CODE, *supra* note 89 ("The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment.").

156. *Greenberg*, 264 F. Supp. 2d at 1072.

157. For reasons not explained by the court, the decision was based on state law, not federal, and the court found that Florida law was unclear on whether there was a duty of informed consent for research subjects, although defendants conceded that a duty "does attach at some point in the relationship" *Id.* at 1070. Moreover, the court appears to have misunderstood the purpose, goals, and duties attendant to human subject research generally, and informed consent specifically, under federal law. Oddly, the court fails to cite the Common Rule, 45 C.F.R. Part 46, and cites FDA regulations despite the fact that the research does not appear to have involved FDA-regulated products. *Id.* at 1069.

158. *Id.* at 1071.



*research purpose*, namely, “to identify mutations in the Canavan gene which may lead to carrier detection in my family.”<sup>159</sup> Nothing in the consent process could reasonably have alerted plaintiffs to the fact that they were engaging in a legal transaction with the defendants, one in which the institution had no obligation to act in their best interest. Had they been so alerted, they might have made more efforts to make an independent assessment of their own best interests before agreeing to donate their tissues, for example, by requesting the inclusion of specific terms as a condition of their donation.

As a consequence, plaintiffs failed to receive the protective benefits of informed consent that should have been afforded by their status as research subjects, and also were not given the requisite access to information and ability to negotiate on equal terms that one would expect to accompany the status of donor.

This status confusion is echoed in the court’s decision in *Washington University v. Catalona*.<sup>160</sup> There the dispute was between a researcher, Dr. Catalona, and the institution that had employed him, but the legal status of the disputed tissue samples’ contributors was the key determining factor in the court’s ruling. In that case, Dr. Catalona had established a biorepository containing an extensive collection of tissue samples from patients with prostate cancer, many of whom he had treated personally.<sup>161</sup> The biorepository was housed at the university and funded by the institution.<sup>162</sup> Patients were invited to participate in genetic research by providing their tissue samples to the biorepository and were required to sign a consent form.<sup>163</sup> The forms typically used the word “donate” to characterize the delivery of the sample, and the participants were informed that their samples might be used by different entities, that they had a right to withdraw from the research and have their samples destroyed, and that they did not have any claim to the donated tissues or materials or processes

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159. Complaint at 12, *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1068 (S.D. Fla. 2003) (No. 00C-6779), available at [http://graphics8.nytimes.com/packages/pdf/business/20070128\\_FRAMING.pdf](http://graphics8.nytimes.com/packages/pdf/business/20070128_FRAMING.pdf).

160. *Wash. Univ. v. Catalona (Catalona II)*, 490 F.3d 667 (8th Cir. 2007), aff’g 437 F. Supp. 2d 985 (E.D. Mo. 2006).

161. *Id.* at 670.

162. *Id.*

163. *Id.* at 671.

derived from them.<sup>164</sup>

When he left Washington University, Dr. Catalona sought to take the collection with him to his new institution.<sup>165</sup> To that end, he obtained release forms from the research participants indicating that they sought transfer of their samples to him.<sup>166</sup> Washington University then sought a declaration that it owned the biorepository and the tissue samples, while Dr. Catalona sought a declaration that participants could directly transfer their materials to him.<sup>167</sup>

The district court held that Washington University owned the samples, a decision that was upheld on appeal.<sup>168</sup> The appellate court framed the question as follows: “[Do] 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?”<sup>169</sup>

The court held that they do not, finding that the samples were “inter vivos” gifts from the patients to the institution.<sup>170</sup> The court found that the patients had donative intent, had delivered their property to the donee (the institution), and that the gift had been accepted by the donee.<sup>171</sup> Further, the court held that the fact that the consent form included a right to revoke or destroy the samples did not negate their gift status.<sup>172</sup>

Like *Greenberg*, the court’s decision in *Catalona* is problematic because it confuses informed consent with donation. The two documents that the court evaluates to assess the tissue contributors’ intent were the consent document and the genetics research information brochure.<sup>173</sup> These documents were signed by the contributors in the context of a

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164. *Id.*

165. *Catalona II*, 490 F.3d 667, 672 (8th Cir. 2007).

166. *Id.*

167. *Id.*

168. *See id.* at 673, 677.

169. *Id.* at 673.

170. *Id.* at 673–74.

171. *See Catalona II*, 490 F.3d 667, 674–75 (8th Cir. 2007).

172. *Id.* at 675 (“The attachment of a condition to a charitable donation of property does not negate or void an otherwise valid inter vivos gift.”).

173. *Id.* at 671.

research study in which they were being invited to participate.<sup>174</sup> Although the term “donation” does appear in these documents, it is highly unlikely that participants appreciated—nor should they have been expected to appreciate—that they were signing away legal rights by agreeing to participate in research. Construing the term “donation” after the fact as a legal concept under which participants retained no rights to control the use of their tissues therefore seems to take advantage of their good faith belief that they were human subjects participating in research, who may have reasonably presumed that the institution was obliged to look out for their best interests—expectations they would not reasonably have obtained were they donors engaged in an arms length negotiation.

The court also failed to address the troubling issue of “waiver.” The consent form signed by the contributors included an agreement to waive any claim to “donated” body tissues and “the right to any new material or process developed through research involving [his] tissues.”<sup>175</sup> Such waiver language appears to violate federal regulations, against the inclusion of exculpatory language in consent documents. These regulations state 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.”<sup>176</sup> The language quoted by the court is, at least arguably, “exculpatory” within the meaning of the regulations. Yet, by framing the transaction as a donation, the court avoided the question of the consent documents’ validity:

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174. *Id.* at 674.

175. *Id.* at 671 (alterations in original).

176. 45 C.F.R. § 46.116 (2009). OHRP has issued a guidance document distinguishing between unacceptable exculpatory language and acceptable language, which demonstrates the fine line separating the two. *See* OFFICE FOR HUMAN RESEARCH PROTS., DEPT OF HEALTH & HUMAN SERVS., “EXCULPATORY LANGUAGE” IN INFORMED CONSENT (Nov. 15, 1996), <http://www.hhs.gov/ohrp/humansubjects/guidance/exculp.htm> [hereinafter OHRP INFORMED CONSENT]. For example, according to the guidance, it is impermissible to use the following language: “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.” *Id.* However, it is permissible to include the following statement in an informed consent document: “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.” *Id.*

Because the specific language contained in the consent forms and brochures, as well as the circumstances surrounding the [contributors'] voluntary decision to donate their biological materials, convinces us [they] intended to make inter vivos gifts of their materials, we find it unnecessary to address the effect or validity of the consent forms' waiver language . . . .<sup>177</sup>

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177. *Catalona II*, 490 F.3d 667, 675 n.7 (8th Cir. 2007). The court also gave short shrift to another central tenet of the Common Rule, which is that participants may “discontinue participation at any time.” See 45 C.F.R. § 46.116(a)(8) (2009). The consent form signed by participants stated that their participation was voluntary and that they could withdraw their consent “at any time.” Wash. Univ. v. Catalona (*Catalona I*), 437 F. Supp. 2d 985, 990 (E.D. Mo. 2006). Some of the consent forms indicated that participants “could request destruction of their biological materials if they changed their minds about participating in the study” while others did not. *Catalona II*, 490 F.3d at 671. Washington University took the position that it could satisfy participants’ request to withdraw by anonymizing the samples while continuing to use them for research. *Catalona I*, 437 F. Supp. 2d at 992. The district court appears to have accepted as valid Washington University’s assertion and the issue was not reviewed on appeal. However, there is certainly room for question whether after-the-fact anonymization satisfies the letter or spirit of the federal human subjects regulations. Nevertheless, accepting Washington University’s interpretation was consonant with the court’s conclusion that the participants did not retain proprietary interests in their tissues.

## V. ANALYSIS

## A. IGNORING THE “THIRD PARTY” TO RESEARCH: THE MORAL AND PRACTICAL DANGERS

While one must be careful about making broad generalizations from small numbers, the few cases that have been decided have confused the legal status of contributors of human tissue and have not adequately considered the preferences and expectations of human tissue donors. While there are important policy objectives that may underlie the court decisions—specifically, researchers’ need for unimpeded access to samples in order to make discoveries with the potential for broad societal benefits—there is danger in an enterprise that reflexively preferences the needs of research over those of tissue contributors. First, there is moral danger, specifically, the risk that in focusing solely on the research need for tissue samples we will devalue the human dignity of the contributors of those tissues. The *Catalona* court’s willingness to ignore the question of whether the consent documents were valid shows how easy it is to overlook individual protections in pursuit of objectives with potential to benefit many. Justice Mosk, in his dissent in *Moore*, recognized the dangers of such devaluation:

[O]ur society acknowledges a profound ethical imperative to respect the human body as the physical and temporal expression of the unique human persona. One manifestation of that respect is our prohibition against direct abuse of the body by torture or other forms of cruel or unusual punishment. Another is our prohibition against indirect abuse of the body by its economic exploitation for the sole benefit of another person. The most abhorrent form of such exploitation, of course, was the institution of slavery. Lesser forms, such as indentured servitude or even debtor’s prison, have also disappeared. Yet their specter haunts the laboratories and boardrooms of today’s biotechnological research-industrial complex. It arises whenever scientists or industrialists claim, as defendants claim here, the right to appropriate and exploit a patient’s tissue for their sole economic benefit—the right, in other words, to freely mine or harvest valuable physical properties of the patient’s body: “Research with human cells that results in significant economic gain for the researcher and no gain for the patient offends the traditional mores of our society in a manner impossible to quantify. Such research tends to treat the human body as a commodity—a means to a profitable end. The dignity and sanctity with which we regard the human whole, body as well as mind and soul, are absent when we allow researchers

to further their own interests without the patient's participation by using a patient's cells as the basis for a marketable product.<sup>178</sup>

Second, there is practical danger. Public participation is essential to successful biobank research. Likewise, public trust of the research enterprise is essential to such participation.<sup>179</sup> If prospective contributors of tissue samples perceive that the process is unfair, that information important to them is being withheld, or simply that their contribution is not appreciated, they may begin to object to the use of their samples in research—declining participation when given the opportunity or even taking legal action when tissue is taken without their request.<sup>180</sup> Although their chances of success in such disputes would be low if current precedent is any guide, such actions could nevertheless pose an unnecessary and costly disruption to researchers and institutions, and undermine potentially useful collaborations between the public and scientists.

#### B. ALTERNATIVE APPROACHES

What, then, is the alternative? Must researchers and their institutions open their coffers and shell out millions of dollars for what is essentially medical waste, when the “manufacturers” of the specimens expended no effort to acquire them, may have needed to have them removed for their own medical benefit, and, on their own, could not use them to make discoveries for the benefit of society?<sup>181</sup> For the researchers who put in the time and effort to extract from these specimens novel and important research findings, and for the institutions that support them, demands by tissue contributors for compensation or even simply for information may seem like the ultimate presumption. Such feelings may perhaps best be expressed by

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178. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 515–16 (Cal. 1990) (Mosk, J., dissenting) (citation omitted).

179. See Beskow & Dean, *supra* note 88, at 1447.

180. *Moore*, 793 F.2d at 516 (Mosk, J., dissenting) (citing Thomas H. Murray, *Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes*, IRB, Jan.–Feb. 1986, at 1, 5) (“As Dr. Thomas H. Murray, a respected professor of ethics and public policy, testified before Congress[:] “[i]f biotechnologists fail to make provision for a just sharing of profits with the person whose gift made it possible, the public’s sense of justice will be offended and no one will be the winner.””).

181. See David Korn, *Dangerous Intersections: New Proposals to Protect Genetic Privacy May Collide with the Public Interest in Fostering Medical Research*, ISSUES SCI. & TECH., Fall 1996, at 55, 59.

reference to the old joke about a milliner, who when questioned by a customer about why his hats cost so much, when they are made of “just a few bits of ribbon,” replies “Madam, the ribbon is free.”

Why, then, should the ribbon (tissue) not be free to a researcher seeking to use it to advance science and make discoveries for the benefit of human health? After all, its research value lies only in the information or products that may be derived from it through the input of scientists’ time and expertise. Moreover, only in rare instances does a single sample prove uniquely valuable, as did Henrietta Lacks’ cells, and that value typically is not apparent before the fact.

However, the true value of the tissue cannot be presumed; its assessment requires consultation with the person who provided it. In the joke about the ribbon, the milliner has made the choice to charge the customer only for his labor and not for the materials. Yet presumably the ribbon maker did not donate these materials to the milliner. Whether the ribbon maker expended any effort to make the ribbon or obtained it for free is not the milliner’s concern; he needed the ribbon and was required to engage in a conversation with the supplier of the ribbon maker about the terms under which the ribbon would be supplied. While a single tissue sample may have little monetary value, its true value—which includes all of the considerations that the public expresses when asked about the use of their tissues in research—cannot properly be assessed without consulting with those contributors.

But, it may be argued, there is no consensus about whether human tissue, once removed from the body, is even property. If it is not property, on what basis do we restrict access to it by others? Some might argue that that would be like asking the milliner to track down and reimburse the ribbon manufacturer who left scraps of ribbon in the milliner’s shop. While it is true that there is no legal consensus on the status of human tissue—although the issue has been the subject of scholarly discussion<sup>182</sup>—resolution of the property status is unnecessary in order to impose an obligation on researchers with respect to

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182. See R. Alta Charo, *Body of Research — Ownership and Use of Human Tissue*, 355 NEW ENG. J. MED. 1517 *passim* (2006); Radhika Rao, *Genes and Spleens: Property, Contract, or Privacy Rights in the Human Body?*, 35 J.L. MED. & ETHICS 371 *passim* (2007).

prospective contributors of human tissue. As both Rebecca Skloot's book and public opinion research reveal, many people do harbor strong possessive, or at least protective, feelings towards their tissue. Such feelings may find their source in religious views on the body—as is the case with Henrietta's daughter, who believed that her mother's soul, in some sense, resides in her cells.<sup>183</sup> Alternatively, they may reside in notions of bodily integrity, i.e., the conviction that, as a matter of autonomy, individuals should retain the power to control the use of their body parts by virtue of the fact that those parts originated in, and once were a part of, their body. Even individuals who do not care about the fate of their excised tissues may well care about whether the information derived from that tissue could help, or harm, them in the future. Thus, there are numerous non-property based reasons rooted in religion, autonomy, or privacy—including individual,<sup>184</sup> family,<sup>185</sup> and group<sup>186</sup> privacy—why tissue contributors may

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183. SKLOOT, *supra* note 2, at 266; *see also* Harmon, *supra* note 9 (stating that to the Havasupai tribe, "blood has deep spiritual meaning").

184. Genetic biobank research raises particular privacy concerns because it can reveal personal health information and because of the potential for misuse of that information by third parties. *See, e.g.*, GENETICS & PUB. POLICY CTR., U.S. PUBLIC OPINION ON USES OF GENETIC INFORMATION AND GENETIC DISCRIMINATION 2 (2007), available at [http://www.dnapolicy.org/resources/GINAPublic\\_Opinion\\_Genetic\\_Information\\_Discrimination.pdf](http://www.dnapolicy.org/resources/GINAPublic_Opinion_Genetic_Information_Discrimination.pdf) (presenting the results of a 2007 survey of 1,119 American adults, which found that 92 percent were concerned that "that results of a genetic test that tells a patient whether he or she is at increased risk for a disease like cancer could be used in ways that are harmful to the person"). The Genetic Information Nondiscrimination Act of 2008, Pub. L. No. 110-233, prohibits health insurers and employers from discriminating against individuals based on their genetic information, but the statute does not remedy all of the potential issues that could arise from the disclosure of genetic test results. *See* Susannah Baruch, *Your Genes Aren't Covered for That: One Year Later, Gaps in Genetic Discrimination Legislation Reveal the Challenges Ahead*, SCI. PROGRESS BLOG, (June 29, 2009), <http://www.scienceprogress.org/2009/06/gina-challenges/> (last visited May 11, 2010).

185. Genetic research has implications not only for the research subject, but also for his or her family members. *See, e.g.*, Lainie Friedman Ross, *When Do Family Members Have a Right to Know Genetic Information About a Patient?*, 337 J. MED. ETHICS 390 *passim* (2007); *see also* Béatrice Godard et al., *Guidelines for Disclosing Genetic Information to Family Members: From Development to Use*, 5 FAMILIAL CANCER 103 *passim* (2006) (discussing the issues that arise when an individual's genetic test results indicate that his or her family members may be at an increased risk for a particular disease).

186. Genetic research enabled by biobanks also has potential implications



care, and therefore should be consulted about, the use of their tissues in research.

Respect for these interests requires that would-be contributors be asked if they are willing to have their tissue used for research, and a meaningful opportunity to decline to have it used.<sup>187</sup> This choice should be provided whether or not the tissue is “deidentified.” Deidentification does not change the fact that the tissue was derived from an individual who therefore has an interest in being consulted as to its disposition, although it may alleviate privacy concerns. While some individuals may elect not to contribute their tissues, thereby reducing the number of samples available for research, providing such choice is a requirement of respectful engagement with the contributors. As a practical matter it is likely that most people, when treated with such respect, will choose to contribute;<sup>188</sup> but such choice should not be presumed. Also as a practical matter, in most cases it is likely that any one individual’s tissue will be individually valuable enough to afford significant bargaining power, but if prospective contributors do possess such ability to bargain, either individually or collectively, then researchers will need to weigh the importance of the research against their willingness and ability to meet the terms.<sup>189</sup>

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for group identity. See Dena S. Davis, *Groups, Communities and Contested Identities in Genetic Research*, 30 HASTINGS CENTER REP., Nov.–Dec. 2000, at *passim*; Morris W. Foster & Richard R. Sharp, *Genetic Research And Culturally Specific Risks: One Size Does Not Fit All*, 16 TRENDS IN GENETICS 93 *passim* (2000). For example, research conducted on samples from the Havasupai tribe suggested that tribe’s ancestors had crossed the frozen Bering Sea to arrive in North America, which “flew in the face of the tribe’s traditional stories that it had originated in the [Havasupai Canyon] and was assigned to be its guardian.” See Harmon, *supra* note 9. The tribe was further concerned that this information could potentially threaten the tribe’s rights to its land; according to Edmond Tilousi, the tribe’s vice chairman, their origin from the canyon was “the basis of [their] sovereign rights.” *Id.*

187. See, e.g., E. Vermeulen et al., *A Trial of Consent Procedures for Future Research with Clinically Derived Biological Samples*, 101 BRIT. J. CANCER 1505, 1505 (2009); see also B. Saunders, *Normative Consent and Opt-Out Organ Donation*, 36 J. MED. ETHICS 84, 84 (2010).

188. See *supra* Part III.B.

189. See Sharon F. Terry, *Learning Genetics*, 22 HEALTH AFF. 166 *passim* (2003) (describing the experience of the mother of two children with a genetic disorder, pseudoxanthoma elasticum (PXE), who founded an advocacy organization through which she was able to identify and patent the gene with the causative mutation and thereby control access to samples in a blood and

Because of the problem of status confusion discussed above, there needs to be clear separation between the researcher-subject interaction and the donor-recipient interaction. When tissue contributors sign a consent document, they are being informed of the risks and potential benefits of research participation to them. In contrast, when individuals are asked to contribute their tissues, they are being invited to engage in a legal transaction under which they make a gift of themselves to the researcher and institution, and the terms of that gift should be clearly delineated.

To be sure, there will be overlap between the domains of information needed by subjects and donors. For example, both would-be subjects and prospective donors need to be told if research results will be returned to them, since such results could be considered a benefit of research participation and also could be a factor that a donor considers in deciding whether to make a donation. Similarly, both would-be subjects and prospective donors need to know about the researcher and institution's financial interests in the research. However, the status of research subject does not carry with it the ability to negotiate terms of participation, whereas the status of donor does. Additionally, the informed consent process presumes a fiduciary duty by the researcher and institution to the subject, and, because of this duty, prohibits the inclusion of exculpatory language in the informed consent document under which the subject waives legal rights. In contrast, a donation agreement presumes equal bargaining power and the ability to negotiate terms of the donation. For these reasons, the consent document should not be used as the vehicle for the legal transfer of tissue from the individual to the researcher.

The separation of contributor-as-subject and contributor-as-donor could be accomplished by, for example, first providing a consent form that outlines the purpose of the research and the risks and benefits of participation, and then providing a separate "donation agreement" that makes clear the terms of the legal transaction and the parties to that transaction.<sup>190</sup>

Although requiring separation of consent to research and agreement to donate may seem like a proposal for adding yet

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tissue bank containing specimens from individuals with PXE).

190. For research not covered by the Common Rule or other federal human subject regulations, researchers or institutions should nevertheless be required to provide a donation agreement to prospective contributors of tissue.

another piece of paper to an arguably already cumbersome process, the small piece of paper is performing a huge ethical and legal task; simultaneously protecting the ethical principles embodied in the requirement for informed consent while ensuring that the proper legal framework is applied to human tissue donations.

## VI. CONCLUSION

The events that took place with respect to Henrietta Lacks's cells are long past. However, by casting our gaze backwards at these events, while reviewing what is currently known about public attitudes toward the use of tissue samples in research and the legal disputes that have arisen from such use, allows the identification of limitations in the current legal approach to the use of such tissues. Moreover, the exercise enables the development of new legal and ethical framework to govern interactions between prospective donors of tissue and the researchers and institutions who receive them.

As Justice Mosk recognized in 1990, there is a "third party" to human tissue research: the contributor of the human tissue. Rebecca Skloot's account of one of these contributors, Henrietta Lacks, shows the harms that can result—in the form of feelings of betrayal and distrust—when the interests of these third parties are not considered fully and their legal status not prospectively defined. Subsequent case law has continued to devalue the interests, and to misconstrue the status, of these third parties. Recent public opinion research demonstrates that these third parties have definite, although not uniform, preferences and expectations with respect to the use of their tissues. The human subject framework is an inappropriate, and inadequate, vehicle for mediating the legal interests of these third parties.

Thus what is needed is a legal approach, perhaps best accomplished through new federal legislation that establishes prospectively clear, uniform terms of engagement between the three parties to the tissue research enterprise and that acknowledges prospectively the two distinct roles being played by contributors of tissues, those of research subject and of tissue donor. The law need not dictate precise terms, for example, whether researchers must return results, or whether or not tissue contributors should share in any benefits deriving from the research; rather, the law need only create a

framework that ensures that contributors of tissue understand the dual roles they are being asked to play and are provided information and context appropriate to each of those roles. In particular, the framework should ensure that all parties to the enterprise have equal access to relevant information, so that one party does not disadvantage the other through inadequate information disclosure and that contributors are not disadvantaged after the fact by judicial role confusion. Mandating that roles be properly defined at the outset, and that information appropriate to each of these roles be provided, will ensure fairness to the parties, protect the principles underlying the human subject protection framework, and, perhaps most importantly, help “maintain the trust and goodwill” of human-tissue contributors, which is “pivotal to the success of the research enterprise.”<sup>191</sup> At the heart of the wrong perceived by the Lacks family is that Henrietta “didn’t donate nothing.”<sup>192</sup> Instead, researchers “took [the cells] and didn’t ask.”<sup>193</sup> How fitting it would be if the development of a new, transparency-based framework for tissue donation, one that is premised on the simple notion that tissue contributors should be asked—within a context that allows a meaningful answer—was Henrietta Lacks’s true legacy.

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191. See Beskow & Dean, *supra* note 88, at 1447.

192. SKLOOT, *supra* note 2, at 169.

193. *Id.*