

ETHICAL REFORMS IN BIOTECHNOLOGY RESEARCH REGULATIONS

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ABSTRACT

Federal regulations for the ethical practice of biotechnology research focus primarily on the health, welfare and safety of the research subject. The regulations rely on the informed consent and voluntary participation of the research subject for ongoing research. One complication to the field has been that federal regulations do not apply to state or privately funded research, and state regulations are inconsistent from state to state.

Furthermore, biotechnology research has greatly evolved since promulgation of the federal regulations. Research subjects are less prevalent, especially for living-cell research. Another complication questions the point at which a researcher's commercial interest in the outcome is a conflict of interest in what will soon be an \$80 billion dollar a year business. Many of the regulations do not define when a financial interest becomes a conflict of interest while the motivation of commercial success has become an important factor in violations of the federal regulations, as recorded in FDA records.

Some research subjects and regulators see the regulations as lacking enough disclosure requirements. This view is supported when the capitalization of research motivates unethical acts. On the other hand, some researchers view disclosure and privacy regulations as already too strict, hampering the ability of research and the business of healthcare to move quickly on new discoveries. In the balance are the donors who want to know in advance how the personal interests of the researcher influence their decision to participate.

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Whether regulators believe researchers are failing to follow ethical guidelines, or donors believe that researchers are unfairly commercializing their bodies, current ethical guidelines are insufficient in the face of the enormous personal interests researchers face. At stake are both the validity of biotechnology research and the commercial interests of all parties.

This article discusses the distinctions in biotechnology research regulations that diminish the usefulness of current ethical doctrines developed for living subject research when applied to living-cell research. Proposals suggest various remedies to decrease incidences of unethical acts in biotechnology research, and recognize that research subjects, researchers, and regulators have common goals—the advance of biotechnology with commercial incentive.

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I. INTRODUCTION

A. *DUE PROCESS LEADS TO THE BELMONT REPORT*

The ethical guidelines and regulations in place today developed from the recognition for the need to balance the due process rights of individuals with society's need for medical information. Setting the balance on the due process side were two very different, but equally important proceedings involving the constitutional rights of people subjected to medical treatment and research.

The first proceeding regarded public vaccination. In 1905, the Supreme Court heard a due process challenge to a State requirement that each person receive a smallpox vaccine or face a fine or incarceration for

noncompliance.¹ With regards to public health, the Court found that the State's police power and interest in preventing disease trumps any due process right.² The Court also justified its decision through a recited history of U.S. and international public vaccinations, including earlier unsuccessful challenges about vaccinations of children attending U.S. public schools.³

The second proceeding regarded medical researchers relying on prisoners for medical research. In the 19th and early 20th centuries, incarcerated prisoners in the U.S. were often involuntary subjects.⁴ Then came the "reported abuses of human subjects in biomedical experiments . . . during the Second World War."⁵ The Nuremberg Trials grimly documented some of the results, which led to the 1947 Nuremberg Code banning research on prisoners of war.⁶ Later reports in the U.S. implicated the federal government in medical and psychological studies on non-consenting subjects from the 1940s and into the 1960s.⁷ In the aftermath of World War II, the World Medical Association adopted the

¹ *Jacobson v. Mass.*, 197 U.S. 11, 26 (1905) (It is "a fundamental principle that 'persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state; of the perfect right of the legislature to do which no question ever was, or upon acknowledged general principles ever can be, made, so far as natural persons are concerned.'").

² *Id.* at 28 ("[T]his court [has] recognized the right of a state to pass sanitary laws, laws for the protection of life, liberty, health, or property within its limits, laws to prevent persons and animals suffering under contagious or infectious diseases, or convicts, from coming within its borders.").

³ *Id.* at 31-32 ("The principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states by statutes making the vaccination of children a condition of their right to enter or remain in public schools.").

⁴ See Richard A. Pizzi, *Salving with Science*, in *THE PHARMACEUTICAL CENTURY*, 34, 43-47 (2000).

⁵ NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RES., *THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH*, (1979) [hereinafter *BELMONT REPORT*], available at <http://ohsr.od.nih.gov/guidelines/belmont.html>.

⁶ See Doug Linder, *The Nuremberg Trials: The Doctors Trial*, <http://www.law.umkc.edu/faculty/projects/ftrials/nuremberg/NurembergDoctorTrial.html> (last visited Nov. 28, 2007).

⁷ See David Resnik, *Research Ethics Timeline* (Oct. 15, 2007) <http://www.niehs.nih.gov/research/resources/bioethics/timeline.cfm>.

Helsinki Declaration to guide physicians in biomedical research involving human subjects.⁸

To advance a goal towards eliminating further unethical practices in medical research, the federal government held a series of meetings to develop U.S. guidelines. From these meetings came the 1979 *Belmont Report* that set guidelines for balancing society's need for medical information.

B. THE BELMONT REPORT LEADS TO FEDERAL GUIDELINES

As a policy document for ethics in medical research, the *Belmont Report* is short—only eleven pages.⁹ Even so, these eleven pages recognize the broad scope necessary for ethical research to set guidelines between the goals of medical research and respect and justice for the research subject. Subsequent federal action led to the development of “modern day” ethical considerations for research as drafted in 1986 and promulgated by the 1991 Federal Policy for the Protection of Human Subjects.¹⁰ The departmental rules under the various Codes of Federal Regulations developed from this policy.¹¹ These rules focus on oversight by an “Institutional Review Board” (IRB) and the volunteerism and informed consent of the subject.¹² Under the regulations, an informed consent document requires a minimum of eight basic statements. These are:

- (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 which are experimental;

⁸ World Health Organization, *Declaration of Helsinki (1964)*, 313 BRIT. MED. J. 1448, 1448-49 (1996).

⁹ BELMONT REPORT, *supra* note 5.

¹⁰ Proposed Model Federal Policy for Protection of Human Subjects, 51 Fed. Reg. 20204 (Jun. 3, 1986) & Federal Policy for the Protection of Human Subjects, 56 Fed. Reg. 28003 (Jun. 18, 1991).

¹¹ See 56 Fed. Reg. 28003 (Jun. 18, 1991). Numerous federal agencies adopted the regulations so there are fourteen copies of the rules in the federal regulations. See, e.g., 45 C.F.R. §§ 46.101-46.409 (2007). The regulations are also defaulted to, or part of, state regulations.

¹² See 56 Fed. Reg. 28003.

- (2) A description of any reasonably foreseeable risks or discomforts to the subject;
- (3) A description of any benefits to the subject 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 subjects' 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.¹³

The informed consent document may have additional statements that address unforeseeable risks, termination of the subject's participation, additional costs to the subject, and the number of subjects in the study.¹⁴ The informed consent rules do not, however, require the researcher to disclose to the human subject a material financial interest in the research.¹⁵

¹³ 45 C.F.R. § 46.116(a) (2007).

¹⁴ 45 C.F.R. §§ 46.116(b)(1)-(b)(6) (2007).

¹⁵ 45 C.F.R. § 46.107(e) (2007) (The regulation only requires that the "IRB may [not] have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.").

C. A NEW FRONTIER IN BIOTECHNOLOGY ETHICS

The last thirty years have brought significant change to the field of biotechnology research. Medical research and technology have advanced far beyond what was new at the time of the *Belmont Report*: in vivo testing of natural and basic synthetic compounds, invasive techniques for vascular repair, comparatively low resolution vision assistance, and bulky analyzers. Today, modern research methods test advanced synthetic compounds, implant advanced medical devices, use micrometer scale technology for surgery, and develop gene-based techniques for diagnosis and treatment using living cells instead of living subjects.

The federal regulations that developed from the *Belmont Report* mandate that federally funded medical and biotechnology research have local oversight and follow the federally promulgated ethical regulations. There are problems, however, with these regulations. Disclosure and conflict of interest rules do not mandate the physician's disinterest in the outcome of the research. Furthermore, the informed consent regulations contemplate that the research subject is present to accept or reject further research. A tissue donor often has very little knowledge of the research practiced on the tissue. Nor do the regulations contemplate human living-cell research, since that area of endeavor was in its virtual embryonic state at the time of the *Belmont Report* and the 1991 Federal Policy for the Protection of Human Subjects.

The ethical doctrines based on living subject research are out of focus with collecting cellular material for research, the informed consent of the research subject or tissue donor, and the influence of economic benefits to the researcher and research organization. Just as society and medical research pushed the ethical boundaries of treatment of living subjects years ago, biotechnology is again pushing the ethical boundaries with living-cell research based on outdated ethical practices. Consequently, a new ethical challenge is whether what was good then is good now.

II. BACKGROUND

A. THE REGULATORY DICHOTOMY

1. Regulatory Inconsistency in Research

Although federally funded research is subject to federal regulations, private and state funded medical practice and research are not subject to the same federal regulations. Instead, they are subject to state regulation, but with significant inconsistency. For example, with respect to therapeutic practice, one authority phrased it this way:

In some jurisdictions, a physician's duty to disclose is measured from the patient's point of view. In other jurisdictions, the duty is measured from the physician's point of view. In still other jurisdictions, however, the duty is measured from both points of view: a physician must disclose the facts and risks of a treatment that a reasonably prudent physician would be expected to disclose under like circumstances, and that a reasonable person would want to know or that the particular patient in question would want to know.¹⁶

Consider, for instance, that in Florida, “[m]edical consent law does not apply to medical researchers. [The law] require[s only] that a person's informed consent must be obtained when any genetic analysis is undertaken on . . . his or her tissue.”¹⁷ The impact of this law is that in Florida, state and private medical researchers are not required to provide conflict of interest disclosures, or to get the same degree of informed consent from research subjects and tissue donors as would federal researchers or physicians treating a patient.¹⁸

For examples of other states, Alabama defaults to federal regulations.¹⁹ An Alaska statute provides for civil liability of a health care provider

¹⁶ 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 172 (2002) (citations omitted).

¹⁷ *Greenberg v. Miami Children's Hosp.*, 264 F. Supp. 2d 1064, 1069 (S.D. Fla. 2003) (citing FLA. STAT. § 760.40).

¹⁸ *See id.* at 1069-71.

¹⁹ ALA. CODE § 22-56-4(10) (2006).

failing to obtain informed consent.²⁰ The Alaska Supreme Court, however, found the statute failed to state “the standard by which this disclosure should be measured.”²¹ Consequently, the court interpreted the statute to require a physician “to tell the patient everything that a reasonable person would want to know about the treatment.”²² However, in an age of rapidly advancing medical research and technology, a “reasonable person” requirement inadequately protects the interests of research subjects.

California provides for an “experimental subject’s bill of rights,”²³ which to some degree models the federal standards.²⁴ Unlike Florida, California’s informed consent law also applies to medical experiments.²⁵ And unlike the federal regulations, California expressly requires disclosure “both verbally and within the written consent form, in nontechnical terms,” of “[t]he material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment.”²⁶ The California law defines “material” as “ten thousand dollars (\$10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.”²⁷ As an objective standard, the California law is well ahead of the federal regulations and those of other states. However, like the other states, California defers to federal regulation for federally-funded research within the state.²⁸

One other consideration is disclosure of the source of funding. For instance, medical research publications require authors to disclose their funding source to the publisher and readers.²⁹ The state and federal

²⁰ ALASKA STAT. § 09.55.556(a) (2006).

²¹ *Korman v. Mallin*, 858 P.2d 1145, 1148 (Alaska 1993).

²² *Id.* at 1149.

²³ CAL. HEALTH & SAFETY CODE § 24172 (West 2007).

²⁴ *Compare* §§ 24170-24179.5 with 45 C.F.R. § 46.101 (2007).

²⁵ CAL. HEALTH & SAFETY CODE § 24175 (West 2007).

²⁶ *Id.* § 24173(c).

²⁷ *Id.*

²⁸ *Id.* § 24178(h) (“Research conducted pursuant to this section shall adhere to federal regulations governing informed consent pursuant to Section 46.116 of Title 45 of the Code of Federal Regulations.”).

²⁹ Instructions for Authors, J. AM. MED. ASS’N, <http://jama.ama-assn.org/misc/ifora.dtl> (last visited Feb. 25, 2007) (stating that “JAMA requires *complete* disclosure of all relevant financial relationships and

regulations do not require the same disclosure to research subjects or tissue donors. A reasonably prudent researcher may make the disclosure as part of the information provided for the subject to decide whether and how to participate. Even if source disclosure were required, merely naming the source would be inadequate where the funding is also motivating the researcher's interest in the outcome. Disclosure of an outcome-based financial interest has created so much controversy, as discussed below, that several commentators are calling for disclosure of outcome-based interests.³⁰

2. Regulatory Inconsistency in Tissue Acquisition

As to tissue removal, several states have presumed-consent laws that allow authorized persons to remove tissue of a decedent for research or transplant without the consent of a living person, "if no objection by the decedent's next of kin is known at the time of autopsy and the decedent was not a known member of a religious group with a public position in opposition to tissue removal."³¹ These laws operate on the presumption that the next of kin may be timely located, made aware of the pending autopsy, and can be asked about the tissue removal. Presumed-consent laws also apply to the removal of tissue samples from infants who have died suddenly.³² Neither the decedent's estate nor the decedent's family may deny or require specific use of the tissue for research. This is because common law property rights only provide the right of possession of the body for disposition, but do not provide for rights in removed tissues.³³

potential financial conflicts of interest, regardless of amount or value" and "[a]ll such disclosures must be listed in the Acknowledgment section at the end of the manuscript.") (Emphasis in original).

³⁰ Karine Morin et al., *Managing Conflicts of Interest in the Conduct of Clinical Trials*, 287 J. AM. MED. ASS'N 78, 81-82 (2002) (recommending disclosure of sources of funding and financial incentives to research subjects).

³¹ See, e.g., CONN. GEN. STAT. § 19a-281(a) (2007); see also Radhika Rao, *Property Privacy and the Human Body*, 80 B.U. L. REV. 359, 460 n.76 (2002) ("Fifteen states have enacted presumed consent laws for the removal of pituitary glands or corneas.").

³² CAL. GOV. CODE § 27491.41(g) (West 2007).

³³ *Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1563 (D. Kan. 1995) ("[T]he position universally held by other states . . . recognizes no property right, commercial or material, in the corpse itself but only a right of possession in order to dispose of the corpse appropriately.") (citations omitted).

3. *The Inadequacy of Informed Consent*

Compounding the inconsistency problems of the regulations is the inadequacy of the informed consent forms. From the researcher's viewpoint, the informed consent forms are inadequate because they are too limiting. The fixed set of statements do not allow for open-ended research. On the other hand, from the perspective of the research subject or tissue donor, the informed consent forms do not disclose enough. Ironically, both problems developed from the narrow scope of the informed consent requirements.

Informed consent got its start as a judicial mandate for physicians to inform patients they were going to be treated, and to discuss the treatment with the patient.³⁴ Part of the problem was that physicians took a paternalistic view in perceiving that "patients do not understand the information, that patients don't want to know the information, and that the information can be harmful to patients."³⁵ Later judicial doctrine added informed consent requirements for "risks inherent to a procedure," "all facts relevant to the patient's decision," and, in some jurisdictions, commercial interests affecting treatment.³⁶ Unfortunately, the terms "risks inherent," "facts relevant," and "affecting," are vague and left for the physician or researcher to decide. Even so, the vagueness of these requirements became regulations, but still based on the premise that the person giving consent would be present in some way during the research. Paragraphs (1), (7) and (8) of Section 46.116 of the regulations well-demonstrate this presumption.³⁷

(1) A statement . . . of . . . the expected duration of the subject's participation;

(7) An explanation of whom to contact . . . in the event of a research-related injury to the subject; and

³⁴ Eric Fisher, *Informed Consent in Oklahoma: A Search for Reasonableness and Predictability in the Aftermath of Scott v. Bradford*, 49 OKLA. L. REV. 651 (1996). See also, *Greenberg v. Miami Children's Hosp.*, 264 F. Supp. 2d 1064, 1069 (S.D. Fla. 2003) (stating that patients should have "control over decisions affecting his or her own health.").

³⁵ David Resnik, *Disclosing Conflicts of Interest to Research Subjects: An Ethical and Legal Analysis*, 11 ACCOUNTABILITY IN RES. 141, 147 (2004).

³⁶ See Fisher, *supra* note 34, at 655-56, and *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990) (discussed below).

³⁷ 45. C.F.R. § 46.116(a) (2007).

(8) A statement that . . . the subject may discontinue participation at any time

For instance, paragraph (1) requires that the researcher tell the research subject in writing the estimated end date of the research. This paragraph effectively prevents the researcher from running an open-ended research project. Paragraph (7) advises the research subject that the research might cause her or him injury. This paragraph means that the research subject can plan to be present for the research and likely for the duration of the research, albeit as a somewhat passive member of the research team. While paragraph (8) allows the research subject to opt out of the research, this does not discount that the regulations presume the research subject will, in most cases, be present or available for the duration of the research.

The format of the informed consent document is troublesome for researchers using it for open ended research. A research subject may have “difficult[y] . . . mak[ing] informed and voluntary decisions throughout their involvement in the research.”³⁸ Even limited permission becomes a constraint when a researcher who discovers that a tissue contains valuable research properties must contact the individual donor to get express permission for further research and cannot contact them.

Similarly, the relatively new British Data Protection Act bars disclosure of any personal information (which is broadly interpreted) beyond the express scope of the permission. A British researcher, Peter Furness, recently contrasted two examples of significant discoveries and the effect of the British Data Protection Act.³⁹ First, Furness cited an international study of a rare form of kidney disease that was abandoned because a central review of microscope slides, which contained micrograms of human tissue, required explicit consent from patients in the United States and the United Kingdom.⁴⁰ Second, Furness cited the

³⁸ David E. Winickoff & Richard N. Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 NEW ENG. J. MED. 1180, 1180 (2003) (citing ethical and policy issues in research involving human participants).

³⁹ Peter Furness, Commentary, *Consent to Using Human Tissue: Implied Consent Should Suffice*, 327 BRITISH MED. J. 759 (2003).

⁴⁰ *Id.* (commenting that British data protection laws, as applied to medical research, generally require that the researcher contact the tissue donor before during further research).

example of the discovery of *Helicobacter pylori*, the bacteria noted for causing digestive illnesses, including gastritis and peptic ulcer disease. Researchers had suspected that a microorganism might cause gastritis and were able to prove their suspicion by reviewing microscope sections from 100 gastric biopsies. Furness lamented that “[u]nder current United Kingdom regulations they would now have to complete a 45 page ethical review form [and] [t]he ethics committee would probably require informed consent from all 100 patients—who had presumably gone home and might not have been contactable.”⁴¹ However, while Furness’s premise about the contacting 100 patients may be correct; the more likely scenario is that the discovery would simply have taken longer to find.

Even when a researcher acquires open-ended permission, the regulatory and legal avenues can be problematic. For one, the research subject or tissue donor might exercise paragraph (8) of the informed consent guidelines and demand that any research stop on that person’s tissue. This might occur where the subject has come to believe the research has extended to an area that offends the subject’s beliefs. In other cases, the research subject might feel that he or she was “used” and sue on various grounds to recover damages or a legal interest in the research. Such actions are possible because the informed consent regulations do not require disclosure of outcome-based interests in the research and uninformed subjects are more likely to react disapprovingly.

The exceptions to informed consent are also a problem. For example, paragraph (6) requires an explanation regarding available compensation and medical treatment in the event of an injury, but only “[f]or research involving *more than minimal risk*.”⁴² Consequently, a researcher can perform ‘minimal risk’ research without a research subject’s consent or knowledge. Since the research subject does not even have to be told, the definition of minimal risk may be left to the researcher or IRB without the input of the research subject.

Another exception to disclosure through informed consent exists “for research in which identifying information is obscured or . . . has been

⁴¹ *Id.* at 759 (citing B.J. Marshall & J.R. Warren, *Unidentified Curved Bacilli in the Stomach of Patients with Gastritis and Peptic Ulceration*, 1 LANCET 1311-15 (1984)).

⁴² 45. C.F.R. § 46.116(a) (2007) (emphasis added).

deleted.”⁴³ One commentator added parenthetically that this “protects privacy and minimizes social risks such as stigmatization or discrimination, but does nothing to recognize subjects’ autonomy.”⁴⁴ Thus, the regulations give the researcher and research organization control as to whether there should be disclosure, based on how the researcher and research organization categorize and handle the research.

Although such research is ethical under the regulations, civil and criminal invasions of privacy have caused public demand for privacy protection legislation. One example is the Health Insurance Portability and Accountability Act (HIPAA), discussed below. Informed consent forms now generally include one or more confidentiality disclosure (privacy) statements. Researchers have to balance privacy requirements with their traceability needs for patient health and the integrity of the research. To achieve this balance, most researchers now use coded designations that omit easily traceable information to the research subject.⁴⁵ The Stanford University Sample Consent Forms require the researcher to tell the research subject whether the samples will have code designators (which are traceable, but not by the researcher), or will be unlinked and untraceable.⁴⁶ The confidentiality disclosure, however, also acts as a waiver by allowing disclosure of research records using the patient’s code number for identification.⁴⁷

Researchers and research organizations are still susceptible to regulatory and legal challenges where protocol or training is insufficient. Fortunately, such challenges are generally successful only on a narrow legal theory: where there is researcher malfeasance. Compliance violations, however, are another matter.

⁴³ R. Alta Charo, *Body of Research—Ownership and Use of Human Tissue*, 355 *NEW ENG. J. MED.* 1517, 1518 (2006).

⁴⁴ *Id.*

⁴⁵ STANFORD UNIVERSITY RESEARCH COMPLIANCE OFFICE – HUMAN SUBJECTS RESEARCH, STANFORD CONSENT FORM TEMPLATE 7 (2007), <http://humansubjects.stanford.edu/consents/SUSampCons.doc> (In a section entitled “Confidentiality,” the forms include the statement: “Your research records may be disclosed outside of Stanford, but in this case, you will be identified only by a unique code number.”).

⁴⁶ *Id.* at 6 (In a section entitled “Procedures,” the consent form requires researchers to disclose whether samples will be linked to participants’ identities.).

⁴⁷ *Id.*

4. *Compliance Violations*

Another regulatory problem is that compliance violations are not abating, despite decades of education, mandatory oversight committees, and Food and Drug Administration (FDA) code enforcement. Table I, in the Appendix, lists selected FDA code violations from 1995 to 2006.⁴⁸ Many of the violations stem from research subjects receiving improper informed consent. Other problems include failures to report side effects or conflicts of interest that have led to the death of several human research subjects.

B. CHALLENGES BY RESEARCH SUBJECTS

There are several factors involved in the lack of compliance to the FDA medical research regulations. As noted above, some physicians maintain a paternalistic view of the patient. Another problem is that there are only approximately 200 FDA investigators to audit the estimated 350,000 medical research testing sites.⁴⁹ Additionally, only the FDA can instigate an action for a regulatory violation. The codes do not allow for a private right of action. Thus, aggrieved research subjects have had to seek redress under the legal principles of property, tort and contract law. As discussed below, these challenges have had limited success.

1. Property Based Challenges – Moore

An interesting anomaly in U.S. law is the absence of law designating ownership of a person's corporal remains or of tissue taken from a person, while alive or deceased. Generally, a family member has very little legal right to the body, tissues, or organs of a deceased relative.⁵⁰

⁴⁸ Interested readers can also find FDA warning letters going back several years on the FDA website. The database is easy to search, and the letters are easily accessible and readable. See FDA's Electronic Reading Room – Warning Letters and Responses, <http://www.accessdata.fda.gov/scripts/wlcfm/indexdate.cfm>.

⁴⁹ Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials*, N.Y. TIMES, Sept. 28, 2007, at A1.

⁵⁰ *Perry v. St. Francis Hosp. & Med. Ctr.*, 886 F. Supp. 1551, 1563 (D. Kan., 1995) (“[T]he position universally held by other states [is one] which recognizes no property right, commercial or material, in the corpse itself but only a right of possession in order to dispose of the corpse appropriately.”) (Citations omitted).

The seminal property-based claim for tissue donation is *Moore v. Regents of the University of California*.⁵¹ In that case, Moore suffered from a cancer that required removal of his spleen as part of the treatment. His doctor realized Moore's blood and tissue contained "competitive, commercial, and scientific advantages."⁵² Moore learned later that the doctor had developed and patented cells from his blood and tissue. He sued for conversion in addition to other causes of action.⁵³ The court stated three reasons why a person does not retain an ownership interest in cells following their removal. As discussed below, each reason is subject to criticism.

The court's first reason was that "no reported judicial decision support[ed] the claim, either directly or by close analogy."⁵⁴ However, as Justice Broussard retorted, "[T]here is no reported judicial decision that rejects such a claim. This is simply a case of first impression."⁵⁵ The court's second reason was that a state statute required disposal of human tissue after scientific use.⁵⁶ As before, Justice Broussard noted the majority was off mark for ignoring the Uniform Anatomical Gift Act and that "section 7054.4 [does not] indicate[] that a doctor or medical facility that removes a patient's organ possesses any greater right than the patient himself to choose the further use to which the removed organ will be put."⁵⁷ In a concurring opinion, Justice Arabian placed the answer where a person might expect it, public policy:

The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared—the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the exposure of researchers to potentially limitless and uncharted tort liability.⁵⁸

⁵¹ *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

⁵² *Id.* at 481.

⁵³ *Id.* at 482.

⁵⁴ *Id.* at 489.

⁵⁵ *Id.* at 502 (Broussard, J., concurring and dissenting).

⁵⁶ *Id.* at 489 (majority opinion) (citing CAL. HEALTH & SAFETY CODE § 7054.4).

⁵⁷ *Id.* at 503 (Broussard, J., concurring and dissenting).

⁵⁸ *Id.* at 498 (Arabian, J., concurring) (citing Mary Taylor Danforth, *Cells, Sales, & Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. &

Thus, the court's concern was not Moore's property interest, but rather the potential for litigation. As discussed below, the court's arguments were unfounded—relying on conjecture and slippery slope arguments.

2. Tort Based Challenges – Duty to Inform – Gelsinger

The distinction between a volunteer subject and an informed subject is a thin line. Without informed consent, the subject has essentially been coerced to volunteer beyond what the subject understood as the scope of the research. Brought to attention by the Nuremberg Code,⁵⁹ the *Belmont Report* has a substantial discussion of the roles of volunteerism and informed consent to medical research.⁶⁰ In *Moore*, the consent form did not disclose that the physician had a commercial interest in the research. Furthermore, Moore's physician had told Moore that the research team was "engaged in strictly academic and purely scientific medical research" and "there was no commercial or financial value to his Blood and Bodily Substances."⁶¹ The *Moore* court held that, "in soliciting the patient's consent, a physician has a fiduciary duty to disclose all information material to the patient's decision."⁶² Thus, even though Moore lost his property rights argument, the court recognized that the duty to disclose information that affects the subject's decision, of whether and how to participate in research, includes the researcher's personal interests related to the subject's health.⁶³

A similar commercial interest case is that of 18-year old Jesse Gelsinger who participated in a study to treat his genetic-based liver disease.⁶⁴ The treatment involved injecting disarmed cold viruses into Jesse to transfer

POL'Y REV. 179, 195 (1988); Thomas P. Dillon, Note, *Source Compensation for Tissues and Cells Used in Biotechnical Research: Why a Source Shouldn't Share in the Profits*, 64 NOTRE DAME L. REV. 628, 634 (1989)).

⁵⁹ 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10 181-82 (U.S. Gov't Printing Office 1949) ("The voluntary consent of the human subject is absolutely essential.").

⁶⁰ BELMONT REPORT *supra* note 5, pt. C (discussing this issue in four of the report's eleven pages).

⁶¹ *Moore*, 793 P.2d at 486.

⁶² *Id.* at 483.

⁶³ *Id.* at 483 ("[A] reasonable patient would want to know whether a physician has an economic interest that might affect the physician's professional judgment.").

⁶⁴ Resnik, *supra* note 35 at 141-42.

corrective genes to his liver.⁶⁵ Instead of getting better, Gelsinger died from an immune response to the viruses.⁶⁶ His family learned that the “principal investigator, James Wilson, owned stock in . . . [the] company [he had] founded, which contributed \$4 million per year to human gene therapy research at the University . . . where the experiment took place.”⁶⁷ The family alleged that had Gelsinger known about these financial interests, “he would not have [participated] in the research study.”⁶⁸ A federal government investigation revealed that the “patient consent forms did not disclose all possible dangers.”⁶⁹ Adding to the problem were apparent “false statements and claims . . . made to federal regulators about the gene therapy trial, including the misrepresenting of information that would have halted the experiment.”⁷⁰ Thus, it seems that Dr. Wilson withheld more information from the Gelsingers than just his financial interests.

3. Contract Based Challenges – Greenberg

As noted in the FDA complaints in Table I, informed consent contracts for medical research have been problematic for researchers. One difficulty has been the ambiguity of contracts with respect to disclosure. Moore, for instance, filed the contractually related causes of action of “unjust enrichment,” “quasi-contract” and “bad faith breach of the implied covenant of good faith and fair dealing.”⁷¹ The trial court held the pleadings were “too conclusory” and granted the defendants’ demurrers without leave to amend.⁷²

In *Greenberg*, the plaintiffs similarly failed to satisfy the specificity requirement for a claim of fraudulent concealment, but met with success on their unjust enrichment claim against Dr. Matalon, a medical researcher.⁷³ The plaintiffs had pooled their resources to hire and fund Dr. Matalon to detect and find a cure for Canavan disease, a fatal genetic

⁶⁵ Susan FitzGerald & Virginia A. Smith, *Penn to Pay \$517,000 in Gene Therapy Death*, PHILA. INQUIRER, Feb. 10, 2005, at A1.

⁶⁶ *Id.*

⁶⁷ Resnik, *supra* note 35 at 142.

⁶⁸ *Id.*

⁶⁹ FitzGerald, *supra* note 65.

⁷⁰ *Id.*

⁷¹ *Moore*, 793 P.2d at 483.

⁷² *Id.* at 482-83.

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

disorder. The plaintiffs also provided tissue samples, familial pedigree information, and contacts that together proved fruitful when the “research team successfully isolated the gene responsible for Canavan disease.”⁷⁴

Acting covertly from his benefactors, Dr. Matalon applied for and received a patent, which he assigned to his employer—the hospital.⁷⁵ The hospital then sought to exact testing charges by “restricting public accessibility through negotiating exclusive licensing agreements and charging royalty fees” to “the centers that offered Canavan testing.”⁷⁶ In suit over ownership of the patent, the *Greenberg* plaintiffs were as unsuccessful as Moore with their property-based claim.⁷⁷ They did prevail, however, on their unjust enrichment claim. The court found that “[w]hile Defendants claim that they have invested significant amounts of time and money in research, with no guarantee of success and are thus entitled to seek reimbursement, the same can be said of Plaintiffs.”⁷⁸ This helped push a settlement for royalty-free research by institutions and scientists searching for a cure, while allowing certain laboratories to continue royalty-based genetic testing.⁷⁹ Consequently, the *Greenberg* case supports the premise that there is an implied contract for research subjects to enjoy the financial rewards of the research, where the research subject provides some measure of funding for the research.

4. *Informed Consent Limitations – Catalonia*

Moore was successful in that a researcher must disclose a financial interest in the research. The *Greenberg* plaintiffs were successful in that research subjects who fund and provide the means for the research have an interest in the proceeds. The *Greenberg* court did not clarify whether providing the tissue alone was enough to give a research subject this interest. In *Washington University v. Catalonia*, the court answered in the negative.⁸⁰

⁷⁴ *Id.* at 1067.

⁷⁵ U.S. Patent No. 5,679,635 (filed Sept. 9, 1994) (issued Oct. 21, 1997).

⁷⁶ *Greenberg*, 264 F. Supp. 2d at 1067.

⁷⁷ *Id.* at 1075 (“[T]he property right in blood and tissue samples ... evaporates once the sample is voluntarily given to a third party.”).

⁷⁸ *Id.* at 1072.

⁷⁹ Press Release, Canavan Foundation, (Sept. 29, 2003),

http://www.canavanfoundation.org/news2/09-03_miami.php.

⁸⁰ *Wash. Univ. v. Catalonia*, 437 F. Supp. 2d 985 (E.D. Mo. 2006).

The Washington Hospital Biorepository houses thousands of patient tissue samples, some of which were from patients of Dr. Catalona, a highly respected urologist and urologic surgeon who was a well-established medical researcher of prostate cancer.⁸¹ In 2003, Dr. Catalona decided to leave Washington Hospital to continue his research at Northwestern University.⁸² Shortly before leaving, Dr. Catalona sent letters and published a statement in a newsletter to about 60,000 patients and others to inform them that he was leaving.⁸³ The letters and statement included a request that patients sign an authorization for release of their samples in the biorepository to Dr. Catalona.⁸⁴ Although some 6000 persons signed and returned the form to Dr. Catalona, Washington University refused to honor the releases and sued for a declaration of ownership of the samples.

The *Catalona* court found several factors favoring Washington Hospital. On a property-based rationale, Washington Hospital not only had possession and control over the samples, but according to the court, Moore and Greenberg affirmed the principle that the donative nature of the samples favored Washington Hospital.⁸⁵ Furthermore, many of the research subjects were not Dr. Catalona's patients.⁸⁶ The court also noted that the informed consent forms had the hospital's logos, expressed that Washington Hospital had to approve the research, would protect the subjects' privacy, and lacked any suggestion that the patients were only entrusting their samples to Dr. Catalona and not the hospital.⁸⁷ Lastly, the court noted that "[a]ll the experts testified that they knew of no instance wherein a research participant had his/her samples returned to them."⁸⁸ In ruling for Washington Hospital, the court said Dr. Catalona failed to show that "the medical research community . . . considered the relationship between a [research participant] and a medical research institution to be one of bailment."⁸⁹ As such, the *Catalona* court merely affirmed what other courts had already held: a

⁸¹ *Id.* at 988-89.

⁸² *Id.* at 988.

⁸³ *Id.* at 993.

⁸⁴ *Id.* at 993.

⁸⁵ *Id.* at 997.

⁸⁶ *Id.*

⁸⁷ *Id.*

⁸⁸ *Id.* at 1001.

⁸⁹ *Id.*

donee cannot extend the right to informed consent to a right of control over the tissue. More troubling to the ethical issues for medical research, however, were the public policy rationales the court espoused in support of its ruling.

C. *THE SLIPPERY AND INCONSISTENTLY APPLIED "PUBLIC GOOD" DOCTRINE*

1. *The Obligation to Defer to Public Betterment*

The *Belmont Report* declares that “respect for persons demands that subjects enter into the research voluntarily and with adequate information.”⁹⁰ Seeking a balance for public betterment, however, the *Belmont Report* also mandates that “members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.”⁹¹ As if reading from the same page, the courts in both *Greenberg* and *Catalona* cited similar public policy justifications. The *Greenberg* court said that “the expansive [property] theory ... would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital.”⁹² The *Catalona* court declared “[m]edical research can only advance if access to these materials to the scientific community is not thwarted by private agendas.”⁹³

One danger of the “public good” doctrine is in the misapplication of the benefit. The courts’ fear of loss of “access to these materials to the scientific community” as “thwarted by private agendas” is off the mark, as the agenda promoted by the courts was that of private research institutions, rather than public institutions, where the public really does have a right to “possess the results.” Furthermore, while citing *Greenberg* for other principles, the *Catalona* court overlooked that the researcher in that case had changed facilities, the plaintiffs followed him, and the researcher subsequently discovered the desired results.⁹⁴ The misapplication (and irony), is that the court may have prevented Dr. Catalona and his participants from achieving the same medical research

⁹⁰ BELMONT REPORT, *supra* note 5, at pt. B1.

⁹¹ BELMONT REPORT, *supra* note 5, at pt. B2.

⁹² *Greenberg*, 264 F. Supp. 2d at 1076.

⁹³ *Catalona*, 437 F. Supp. 2d at 1002.

⁹⁴ *Greenberg*, 264 F. Supp. 2d at 1067.

success as the researcher in *Greenberg*.⁹⁵ Thus, the court failed to consider the public policy benefit that Dr. Catalona should have the samples so that his research might come to fruition.

Another justification the *Catalona* court cited was that Dr. Catalona's successor had "raised substantial funds for the GU Biorepository."⁹⁶ This justification fails for at least two reasons. First, the court did not cite any correlation between fund raising and quality of research, so there is no guarantee that the substitute researcher is as qualified. Second, there was no showing that Dr. Catalona's successor would be successful with Dr. Catalona's research. As such, the public may have lost all benefit that Dr. Catalona could have advanced at Northwestern University using the samples.⁹⁷

2. Unsubstantiated Fears

In voiding the 6000 "Medical Consent & Authorization" forms, the *Catalona* court raised the specter that "[s]elling excised tissue or DNA on E-Bay [*sic*] would become as commonplace as selling your old television on E-Bay [*sic*]."⁹⁸ Similarly, the *Moore* court fretted about "competitive bidding for such materials."⁹⁹ These, however, are misplaced and unsupported slippery slope arguments. The courts apparently ignored that tissue sales are already a staple of the medical industry.¹⁰⁰ Federal law prohibits only the sale of organs for human

⁹⁵ A search of the U.S. P.T.O. did not show Dr. Catalona as the recipient of any patents as of Feb. 11, 2007, although Dr. Catalona is an author of numerous "Other References" for other patents.

⁹⁶ *Wash. Univ.*, 437 F. Supp. 2d at 989. Dr. Catalona's successor's commercial success is apparent. In 2005 he joined the Clinical Advisory Board of Viking Systems. See *Viking Systems, Inc. Names Dr. Gerald Andriole, of Barnes-Jewish Hospital and Washington University in St. Louis, to Clinical Advisory Board*, BUS. WIRE, Oct. 3, 2005.

⁹⁷ However, the studies are still ongoing. See, e.g., *PSA Test plus Digital Exam Best at Spotting Prostate Cancer*, HEALTHDAY NEWS, Mar. 24, 2005, available at <http://news-info.wustl.edu/clip/page/normal/4857.html>.

⁹⁸ *Wash. Univ.*, 437 F. Supp. 2d at 1002.

⁹⁹ *Moore*, 793 P.2d 479, 498.

¹⁰⁰ See, e.g., Brain and Tissue Bank for Developmental Disorders, <http://medschool.umaryland.edu/BTBank/glisoftis.html>.

transplant.¹⁰¹ The scandal is in the *sale* of donated tissue for medical research and treatment, not in the *donation* by a tissue donee.

In 2004, the U.C.L.A. Willed Body Program was shut down for close to two years and its director arrested for selling parts of bodies donated to the UCLA School of Medicine.¹⁰² In 2007, another case cites “hundreds of [people] nationwide . . . are living with the knowledge that they carry bones and tissue taken illegally from cadavers in what has become a bizarre tale of selling body parts for profit.”¹⁰³ In these instances, the tissue was illegally harvested and then sold in the normal course of business for medical research and treatment. These are not isolated instances, with “more than 16,800 families [from 1987 to 2006] represented in lawsuits claiming loved ones’ body parts were stolen for profit.”¹⁰⁴ While all subsets of people (e.g., sellers, lawyers, judges, doctors, and researchers) have a few “bad apples,” there are no facts supporting the court’s premise that sales of tissue by donors would become “commonplace.”¹⁰⁵

The *Moore* court also espoused an argument of exposing “researchers to potentially limitless and uncharted tort liability.”¹⁰⁶ This argument is unfounded, as most industries, such as extreme sports, revise consensual waivers to avert adverse legal consequences for inherent risks.¹⁰⁷ The key to resolving disputes is to prevent them by better informed consent.

¹⁰¹ 42 U.S.C. § 274e(a) (2007) (“It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”).

¹⁰² Stan Wilson, *UCLA Suspends its Willed Body Program*, CNN, Mar. 9, 2004, <http://www.cnn.com/2004/LAW/03/09/ucla.cadaver.suit/index.html>.

¹⁰³ Jan Jarvis, *N. Texan Suing over Transplanted Tissue*, FORT WORTH STAR-TELEGRAM, Sep. 25, 2007.

¹⁰⁴ Stephanie Armour, *Illegal Trade in Bodies Shakes Loved Ones*, USA TODAY, Apr. 26, 2006, at A1.

¹⁰⁵ Apparently the court was not aware that eBay expressly prohibits the sale of “the human body, or any human body parts.” See Human Remains and Body Parts Policy, <http://pages.ebay.com/help/policies/remains.html> (last visited Nov. 24, 2007).

¹⁰⁶ *Moore*, 793 P.2d 479, 498.

¹⁰⁷ See, e.g., VAVi Sport & Social Club, *Contract for Voluntary Participation in VAVi LLC Recreational Sports Assumption of Injury Risks*, <http://www.govavi.com/waiver.shtml> (last visited Nov. 24, 2007).

The *Catalona* court additionally expressed a fear of “prejudicial selectiveness” of a “donor being able to dictate that his/her blood can only be transfused into a person of a certain ethnic background.”¹⁰⁸ The court’s fear is unfounded, as Congress has, through its interstate commerce power, the authority to ban such activity; just as it has banned the sale of organs for human transplant,¹⁰⁹ and prohibited discrimination based on race, color, religion, sex, handicap, familial status, or national origin in the selling, purchasing, renting, financing or occupying of housing.¹¹⁰

3. *Inconsistent Application*

Another problem with the public good doctrine is its inconsistent application by the bench. Moore, for instance, prevailed on his causes of action for breach of fiduciary duty and lack of informed consent from his physician. The court’s rationale was that “Golde’s representation that he had no financial interest in this research became false . . . when he ‘began to investigate and initiate the procedures . . . for [obtaining] a patent.’”¹¹¹ The *Greenberg* plaintiffs, on the other hand, lost their informed consent challenge because they were not in a “therapeutic” relationship with the researcher at the time of contract. The court overlooked, however, that the purpose of the relationship was to discover the cause *and* the cure. Thus, the *Greenberg* plaintiffs expected a therapeutic relationship to eventually develop.

The *Greenberg* court claimed that extending informed consent to cover an ownership interest of the researcher in the research would “mandate that researchers constantly evaluate whether a discloseable event has occurred” and “give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses.” Cumulatively, these factors would allegedly “chill medical research.”¹¹² However, the premise of informed consent and the procedure for obtaining a patent do not support this conclusion.

First, informed consent acts to inform the research subject of the scope of the research. The informed consent requirements arose because

¹⁰⁸ *Wash. Univ.*, 437 F.Supp. 2d at 1002.

¹⁰⁹ 42 U.S.C. § 274(e) (2007).

¹¹⁰ 42 U.S.C. §3604 (2007).

¹¹¹ *Moore*, 793 P.2d at 486.

¹¹² *Greenberg*, 264 F. Supp. 2d at 1070-71.

physicians and researchers had the paternalistic attitude that they could use people as research subjects for public benefit both without informing the person and without getting consent from the person.¹¹³ Informed consent procedures establish a boundary by which the research subject and researcher agree on the scope of the research.

Second, the informed consent regulations establish a duty of disclosure from the researcher to the research subject. Researchers must advise research subjects of “appropriate alternative procedures or courses of treatment.”¹¹⁴ While the informed consent regulations do not expressly apply to the researcher’s ownership interest in the research, an ownership interest in the research is clearly a conflict of interest that potentially affects the subject’s health and could affect a subject’s decision to seek “appropriate alternative procedures or courses of treatment.”

Third, researchers are more aware than a research subject of the potential financial gain from the research. Assignment provisions have been a staple of research employment contracts for quite some time, thus the researcher knows at the time of the informed consent whether the researcher has a potential ownership interest in the research. Even if a researcher misses the disclosure at the time of informed consent, the *Moore* court stated that Golde’s “financial interest in this research [arose] at least . . . when he “began to investigate and initiate the procedures . . . for [obtaining] a patent.”¹¹⁵ Thus, the researcher’s best opportunity for disclosure is at the point of obtaining informed consent. Saving the disclosure for the point of applying for a patent is merely an attempt to remedy the error of non-disclosure.

Fourth, the *Greenberg* court implies that evaluating whether a discloseable event has occurred is difficult. However, patent applications are rife with disclosure requirements. As the inventor, Dr. Matalon had to sign the inventor’s oath (declaration) averring to both his inventorship and the truthfulness of the document.¹¹⁶ Additional

¹¹³ Resnik, *supra* note 35, at 147.

¹¹⁴ See 56 Fed. Reg. 28003 (June 18, 1991).

¹¹⁵ *Moore*, 793 P.2d at 486.

¹¹⁶ See U.S. Patent & Trademark Office, *Declaration for Utility or Design Patent Application*, Form PTO/SB/01 (07-06) (“I hereby declare that: I believe the inventor(s) named below to be the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought.”).

disclosure requirements apply to the inventor's knowledge of prior art.¹¹⁷ The inventor may also execute a document to designate a prosecuting attorney. The oath clearly states that, "willful false statements may jeopardize the validity of the application or any patent issued."¹¹⁸ These documents are intended to place an inventor on notice of the legal implications involved. While the oath of patent application does not apply to informed consent disclosures, the court's implication that it is difficult to evaluate whether a discloseable ownership event has occurred is erroneous.

The *Greenberg* court also lamented the potential for a research subject to control medical research by not agreeing to the terms of the ongoing research after a researcher disclosed an ownership interest. The court's argument here also fails. For one, there are often years between a discovery and garnering proceeds. A disputed ownership interest does not necessarily affect the progress of the research, but merely the distribution of the proceeds at a future time. Second, the informed consent regulations already allow a research subject to withdraw.¹¹⁹ Whether this would have the court's lamented effect is conjecture at best. Many other subjects are likely participating to continue the research.

Another inconsistency of the public good doctrine is the extent to which a person must forgo a personal interest before remuneration is due. The *Greenberg* plaintiffs won their case on the unjust enrichment challenge for their financial contributions to the research. Moore, however, lost his unjust enrichment challenge, even though he made special extended trips for biopsies that were not for therapeutic purposes, but rather were for the researcher to collect more specimens.¹²⁰ The *Moore* court apparently did not consider Moore's efforts as worthwhile, and, unlike the *Greenberg* court, the *Moore* court failed to recognize the unjust enrichment cause of action.¹²¹

¹¹⁷ 37 C.F.R. § 1.56 (2007).

¹¹⁸ See U.S. Patent & Trademark Office, *Declaration for Utility or Design Patent Application*, Form PTO/SB/01 (07-06).

¹¹⁹ 45 C.F.R. § 46.116(a) (2007).

¹²⁰ *Moore*, 793 P.2d at 481.

¹²¹ Compare *id.* at 479, with *Greenberg v. Miami Children's Hosp.*, 264 F. Supp. 2d 1064, 1073 (S.D. Fla. 2003) ("Plaintiffs also invest[ed] time and significant resources in the race to isolate the Canavan gene. Therefore, ... the Court finds

Similarly, courts have also been inconsistent in analyzing conflict of interest disclosures. If the researcher fails to disclose an upcoming economic interest, then the researcher has a conflict of interest because of differing goals with the subject. For example, “Gelsinger was told Wilson ... could benefit financially from the experiment [but] he was not told about the ... stock ownership.”¹²² Compounding this failure of disclosure, the medical researcher also “recruited patients who may have been too sick to participate; underreported side effects; and kept FDA regulators and university monitors in the dark about critical changes in the study.”¹²³ Thus, the researcher’s inadequate conflict of interest disclosure to the subject suggests that the researcher likely had differing goals than the subject.

While the *Moore* and *Gelsinger* courts found a cause of action for failure to disclose a conflict of interest, the *Greenberg* plaintiffs lost this challenge. As a researcher-employee of the hospital, Dr. Matalon was aware at the time of the informed consent that a patent might result from his research and that as an employee he would have to assign the patent to the hospital. The inconsistency here is that the *Greenberg* court failed to consider that a researcher has an actual conflict of interest when the researcher’s interest diverts in any way from the tenets of the informed consent regulations.¹²⁴ A researcher has a potential conflict of interest at that time if any facts exist that suggest an actual conflict of interest may arise later. Therefore, the analysis for a conflict of interest should begin before execution of the informed consent document. This applies independent of whether the research subject funds the research or takes on a detriment for the benefit of the research.

The *Greenberg* court’s concern that “dead-hand control” by “research subjects” would chill medical research is outweighed by the public policy that a research subject should not die (as did Gelsinger and others) or suffer injury or loss to benefit a medical researcher’s economic interest in the research.¹²⁵ That none of the *Greenberg* plaintiffs died as a result of the research is immaterial since Caravan disease is a fatal

that Plaintiffs have sufficiently pled the requisite elements of an unjust enrichment claim.”).

¹²² Resnik, *supra* note 35, at 144.

¹²³ FitzGerald, *supra* note 65.

¹²⁴ See 45 C.F.R. § 46.116(a) (2007).

¹²⁵ *Greenberg*, 264 F. Supp. 2d at 1071.

illness the research sought to cure, and people have died in other studies with improper informed consent.¹²⁶

Courts have also misinterpreted intellectual property rights as they apply to research subjects. This last policy problem is with the courts rather than with the federal regulations, but it is one that still affects the rights of research subjects. The *Moore* court cited patent law as one justification for rejecting Moore's property rights in the tissue derivatives. The court noted that "the patented cell line is both factually and legally distinct from the cells taken from . . . [the] body. Federal law permits the patenting of organisms that represent the product of 'human ingenuity,' but not naturally occurring organisms."¹²⁷

Inventorship, however, is a separate right from ownership.¹²⁸ The patent laws and rules avoid any legal interpretation regarding any person's ownership share in a patent. Even a requirement for "human ingenuity" would not disclaim a donee's interest in the patent. The *Greenberg* court understood the law and rejected the defendant's argument as a non sequitur: "Defendants' attempt to seek refuge in the endorsement of the U.S. Patent system, which gives an inventor rights to prosecute patents and negotiate licenses for their intellectual property fails, as obtaining a patent does not preclude the Defendants from being unjustly enriched."¹²⁹ While patent cases may present daunting technical challenges to a court, the legal rights of ownership associated with intellectual property laws are not as complex.

Informed consent regulations developed "out of a treating physician's fiduciary duty to disclose to the patient all facts which might affect the patient's decision to allow medical treatment . . . to guard a patient's

¹²⁶ See *infra* Table I.

¹²⁷ *Moore*, 793 P.2d at 479 (citing *Diamond v. Chakrabarty*, 447 U.S. 303, 309-310, (1980)).

¹²⁸ See 35 U.S.C. § 115 (2007), and Applicant for Patent, 37 C.F.R. § 1.41 (2007) ("A patent is applied for in the name or names of the actual inventor or inventors."); see also Assigned Inventions and Patents, 37 C.F.R. § 1.46 (2007) ("[T]he patent may be issued to the assignee or jointly to the inventor and the assignee.").

¹²⁹ *Greenberg*, 264 F. Supp. 2d at 1072 (citing *Chou v. Univ. of Chi.*, 254 F.3d 1347, 1363 (Fed. Cir. 2001) ("recognizing [a] claim for unjust enrichment in [the] context of [a] gene patent dispute.")).

control over decisions affecting his or her own health.”¹³⁰ Each of us has a constitutional right to not “be deprived of life, liberty, or property, without due process of law.”¹³¹ Forcible treatment deprives a person of liberty.¹³² The goal of the informed consent regulations is to block the unconstitutional coercion of a person’s compliance for public benefit and prevent the researcher from obtaining a personal benefit under that guise. Judicial decisions based on public policy are often laden with conflict between “promot[ing] the general Welfare . . . to ourselves and our Posterity,” and infringing individual constitutional rights.¹³³ Courts have the responsibility to diligently seek and uphold that balance.

D. *THE INADEQUACY OF INSTITUTIONAL REVIEW BOARDS*

1. *The Rules Inadequately Define “A Conflicting Interest”*

The federal government requires disclosure to the grant-making authority, such as the IRB, of significant financial interests on federal medical research grant applications.¹³⁴ The rules define a “significant financial interest” as “anything of monetary value” but “does not include an equity interest [that] does not exceed \$10,000 and does not represent more than five percent ownership interest in any single entity.”¹³⁵ Under these rules, a researcher would not have to disclose an ownership interest of more than \$10,000 if their equity interest is less than five percent.

This regulation excludes important aspects of a conflict of interest. As noted above, California law defines a conflict of interest as a “material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment.”¹³⁶ The California law defines “material” as “ten thousand dollars (\$10,000) or

¹³⁰ *Id.* at 1069.

¹³¹ U.S. CONST. amend. V.

¹³² Rao, *supra* note 31, at 396 n.165 (stating that “[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty” but nevertheless upholding the administration of psychotropic medication to prisoner (citing *Wash. v. Harper*, 494 U.S. 210, 229 (1990)).

¹³³ U.S. CONST. pmb1.

¹³⁴ See 42 C.F.R. § 50.605(a) (2007); *see also*, Objectivity in Research, 60 Fed. Reg. 35,810-19 at 11 (July 11, 1995).

¹³⁵ 42 C.F.R. § 50.603 (2007).

¹³⁶ CAL. HEALTH & SAFETY CODE § 24173(c)(11) (2007).

more in securities or other assets *valued at the date of disclosure*, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.”¹³⁷ As stated, the rule applies to both the investigator and the research institution.

Even so, the California rule is inadequate. First, the fund-raising ability of a research institution is a reputation-based activity. As employees of the research institution, the earning power of IRB members is commiserate with the reputation of the research institution. In this role, IRB members have an inherent stake in the reputation and financial health of the research institution. Thus, if the research would enhance the reputation, the fund-raising ability, and financial health of the organization, every IRB member would have a conflict of interest. Yet, recall that the *Catalona* court justified its decision in part on the successor researcher’s fund-raising ability!¹³⁸ A better step would be to use outsiders on the IRB, just as corporations are moving more towards outside directors to avoid conflicts of interests.

Second, financial interests are essentially investments. Investors, and presumably IRB members, are motivated by an investment’s future value rather than just its present value. Even though the future value is speculative, when an IRB member’s financial investment is in the research, they have an actual conflict of interest, which should give rise to a duty to disclose that interest to the research subject. Ten thousand dollars may represent a small part of an overall investment portfolio for some people, while exceeding the net worth of others. Thus, the dollar value of a conflict of interest is not as important to the ethical motivation of the IRB member as is the motivation of the future value of the financial interest in the research at its close. For this reason, the conflict of interest rules are inadequate in the federal regulations and in state regulations that narrowly view a financial-based conflict of interest.

2. *The Rules Do Not Prevent Indirect Unethical Practices*

The federal regulations bar an IRB member with a conflicting interest from “participat[ing] in the IRB’s initial or continuing review.”¹³⁹ The IRB rules do not, however, require anonymous voting, or for the researcher to leave the room after providing the requested information, or

¹³⁷ § 24173(c)(11) (emphasis added).

¹³⁸ See *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 989 (E.D. Mo. 2006).

¹³⁹ 45 C.F.R. § 46.107(e) (2007).

prevent the researcher from outside private discussions, or bar others with a conflict of interest from discussing the merits of a research project with an IRB member.¹⁴⁰ As one commentator noted, a researcher on an IRB “should leave the room and not vote on his own proposal, when the committee considers it. This type of conflict has such a high potential for bias that it should be avoided whenever possible.”¹⁴¹ Another difficulty is that the presence of an interested researcher during voting, non-anonymous votes, or outside influence, facilitates quid pro quo arrangements.

Fortunately, corporate law provides good examples of ethical rules for IRBs and regulators to adopt. The quorum rule has long acted to safeguard against a minority fraction meeting and voting for its own purpose.¹⁴² In most settings, the quorum is at least a simple majority of the voting members. To further distance conflicts of interests, some organizations bar or ignore the votes of interested members, while others require anonymous voting or require that interested members leave the discussion and voting areas. The latter requirement is well-advised to reduce peer pressure for quid pro quo arrangements. In addition, there are insider trading rules that bar disclosure of confidential information from interested persons to disinterested persons.¹⁴³ The Model Business Corporation Act defines a disinterested or “qualified director” as:

[A]ny director who does not have either: (1) a conflicting interest respecting the transaction; or (2) a familial, financial, professional, or employment relationship with a second director who does have a conflicting interest ..., which relationship would, in the circumstances, reasonably be expected to exert an

¹⁴⁰ IRB Records, 45 C.F.R. § 46.115(2) (2007).

¹⁴¹ Resnik, *supra* note 35, at 145 (citing Adil E. Shamoo, *Institutional Review Boards (IRBs) and Conflict of Interest*, 7 ACCOUNTABILITY IN RES. 201 (1990)).

¹⁴² 18B AM. JUR. 2d *Corporations* § 1281 (2007) (“If a director of a corporation necessary to constitute a quorum is interested in the proceedings, the corporate act may be void, or voidable at the instance of the corporation or stockholders, without regard to the question of actual injury or detriment.”) (Citations omitted).

¹⁴³ 17 C.F.R. § 240.10b5-2 (2007) (duties of trust or confidence in misappropriation insider trading cases).

influence on the first director's judgment when voting on the transaction.¹⁴⁴

This definition recognizes that unethical practices can also occur when an interested person is present during voting, has contact with a subject outside the discussion area, or witnesses, or has access to details of how people voted. An analogous rule for research would help bar influence from outside meetings.

3. The Rules Inadequately Address Interests Outside the Research Institution

A final difficulty is that the regulations do not adequately address conflicts of interest between research interests and outside revenue interests. The rules apply to "cooperative research projects," that is, "those projects covered by this policy, [and] which involve more than one institution."¹⁴⁵ As such, "each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy," but "may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort."¹⁴⁶ Thus, under the regulations, a research institute, by having an interest with another institution that is not federally funded and playing "don't ask - don't tell," may stretch its ethical boundaries. One commentator noted the problem this way:

IRBs at academic medical centers that approve protocols for obtaining informed consent and collecting and sending tissue and medical information to private biobanks introduce problems of accountability for participants and conflicts of interest for the institution. In an increasingly common model for collaboration with the private sector, IRBs at hospitals not only have approved open-ended consent without time limits, but

¹⁴⁴ MODEL BUS. CORP. ACT § 8.62(d) (2003).

¹⁴⁵ 45 C.F.R. § 46.114 (2007).

¹⁴⁶ *Id.*

also have renounced ethical oversight of particular research projects.¹⁴⁷

These practices can lead to unethical behavior in several ways even though all involve ethical internal operations. First, a research institution can use legitimate investment practices to garner investment income, regardless of the ethical practices of the other party. An analogy would be investments in cosmetic companies that perform animal testing, which some believe is improper or unethical. Second, the research institution can sell tissue to private biobanks and research institutions that engage in unethical acts. The scandal over UCLA's Willd Body Program is such an example.¹⁴⁸ Lastly, as noted above, the federal regulations apply only when the research institution conducts federally-funded research. Thus, the research institution can fund unethical research practices outside the facility, such as those performed by private researchers on prisoners, without running afoul of the rules.¹⁴⁹

E. THE INADEQUATE PROTECTION OF PERSONAL DATA

1. The Inadequate Protection of Privacy

i. The Inadequacy of Federal Regulations

Another concern that has grown with the scale of medical research is the privacy of research subjects and donees. Although the federal regulations recognize the need for privacy, they are inadequate. For one, the regulations do not specifically define the scope of a person's privacy and do not require privacy of the research subject's personally identifiable information.¹⁵⁰ The regulations leave these tasks to the IRB unless the organization is also subject to the Health Insurance Portability

¹⁴⁷ Winickoff, *supra* note 38, at 1180 (noting instances of institutions sending tissue to companies that systematize and standardize the collection of clinical specimens).

¹⁴⁸ Wilson, *supra* note 102.

¹⁴⁹ See, e.g., NAT'L ACADEMY OF SCIENCES, ETHICAL CONSIDERATIONS FOR RESEARCH INVOLVING PRISONERS, 73 (2006) (With regard to "[t]he restrictiveness of the DHHS regulations regarding prisoners, ... research institutions are only required to abide by DHHS-promulgated regulations when they conduct research funded by the DHHS.").

¹⁵⁰ Criteria for IRB approval of research, 45 C.F.R. § 46.111(a)(7) (2007).

and Accountability Act (HIPAA).¹⁵¹ At best, the regulations require the IRB to “describ[e] the extent, if any, to which confidentiality of records identifying the subject will be maintained” in the informed disclosure statement.¹⁵² Since each IRB is independent with immediate responsibility to the research organization, there is a potential for wide discrepancy of what researchers or organizations will do to protect a subject’s privacy.¹⁵³

Another problem is the complex flowchart process that grants exceptions to various forms of research and allows access to the research subject’s personally identifiable information. For example, the federal regulations apply “to all research involving human subjects.”¹⁵⁴ To place personally identifiable information in perspective, the regulations define a human subject as “a living individual about whom an investigator . . . obtains (1) [d]ata . . . or (2) [i]dentifiable private information.”¹⁵⁵ The problem here is that the regulations address the subject’s privacy as needing protection only from the investigator.¹⁵⁶

¹⁵¹ *Id.* (“In order to approve research covered by this policy the IRB shall determine that . . . [w]hen appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”). Organizations covered by HIPAA are specifically regulated in the use and disclosure of protected health information beyond mere IRB requirements. *See* 45 C.F.R. § 164.508(a)(1) (2007) (“[A] covered entity may not use or disclose protected health information without an authorization that is valid under this section.”).

¹⁵² 45 C.F.R. § 46.116(a)(5) (2007) (listing basic requirements for informed consent).

¹⁵³ Resnik, *supra* note 35, at 143 (“[An] institution [with a conflict of interest] may fail to fulfill its primary ethical or legal obligations to research subjects, the research profession, or the public.”) (citing ADIL E. SHAMOO & DAVID B. RESNIK, RESPONSIBLE CONDUCT OF RESEARCH, 139-62 (2003)).

¹⁵⁴ 45 C.F.R. § 46.101(a) (2007).

¹⁵⁵ 45 C.F.R. § 46.102(f) (2007).

¹⁵⁶ 45 C.F.R. § 46.102 (f)(2) (“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.”). *See also* U.S. Dep’t of Health and Human Serv., Human Subject Regulations Decision Charts, Chart 1, Sept. 24, 2004, <http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm> (noting that “[t]he research is not research involving human subjects, and 45 C.F.R. Part 46 does not apply,” if “the information [is not] individually identifiable.”).

To avoid the strictness of the rules, an organization can ‘code’ the research subject’s personally identifiable information and keep the code away from the investigator.¹⁵⁷ Oddly, this only has to apply “until the [research subjects] are deceased.”¹⁵⁸ Another recommendation is to store individual identifiers in “a repository or data management center that prohibits the release of individual identifiers to the investigator under any circumstances, until the individuals are deceased.”¹⁵⁹ This still fails to protect the research subject’s privacy from anyone else. A better recommendation is to code the samples, encrypt the uncoded data, and then store the encrypted data outside the research center. That way, no one can use the data without the de-encryption key, even if they have access.

That the federal medical research regulations have not kept pace with the greater risks associated with personally identifiable information serves to exacerbate this issue. From its inception in 1996, HIPAA has had gaps in protecting personally identifiable information and personal health information.¹⁶⁰ It took until 2002 for the Department of Health and Human Services (DHHS) to issue the final rules for the “Standards for Privacy of Individually Identifiable Health Information.”¹⁶¹ Unfortunately, the law only focuses on persons receiving health care, or organizations in the health care profession.¹⁶² Just as the Florida informed consent law does not apply to medical research, neither do the HIPAA protection laws. The covered organizations are health care providers, health care plan providers, and health care clearinghouses and employers.¹⁶³ Consequently, disclosures of health information to providers of other services, such as non-health care insurance policies or

¹⁵⁷ Rina Hakimian, Powerpoint Presentation, *Human Specimen Repositories: Requirements of 45 C.F.R. Part 46, Ethical and Regulatory Aspects of Use of Tissue Samples for Research*, slides 23, 25, Oct. 28, 2004, <http://www1.va.gov/resdev/programs/pride/conferences/docs/Hakimian-Tissue-Banks.ppt> (stating “research does not involve human subjects because investigators cannot readily ascertain the identity of the individuals” if the “[p]erson(s) doing coding of data/samples and person(s) holding codes are not part of research team.”).

¹⁵⁸ *Id.* at slide 21.

¹⁵⁹ *Id.* at slide 22.

¹⁶⁰ Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002) (to be codified at 45 C.F.R. pts. 160 and 164).

¹⁶¹ *Id.*

¹⁶² Definitions, 45 C.F.R. § 160.103 (2007).

¹⁶³ *Id.*

off-the-shelf health care products, are not protected. This is not to say that the DHHS thinks research subjects lack any protection. Instead, they note that “manufacturers that receive identifiable health information and misuse it may be subject to action taken under other *consumer protection* statutes by other federal agencies, such as the Federal Trade Commission.”¹⁶⁴ This is simply not effective. The Federal Trade Commission (FTC) merely issues rules concerning financial and consumer privacy.¹⁶⁵ Since research subjects are volunteers, there is no commercial transaction involved (which is necessary for the FTC to have jurisdiction), nor would medical researchers be recording the credit card numbers or purchases of research subjects. Thus, the FTC laws do not protect the privacy of research subjects as pertaining to the research.

Furthermore, if the DHHS was alluding to other laws, these provide indirect protection at best. For example, there are three federal laws that provide protection against the electronic taking of information. The Computer Fraud or Abuse Act (CFAA) makes it illegal for a person to knowingly access a protected computer without authorization and obtain anything of value.¹⁶⁶ The CFAA, however, does not apply to anything less than intentional acts taken with open access systems. The CFAA applies where the user sends an email (intent to access) knowing the email contains a virus, and believes the virus is harmless, but the virus causes computers to crash and shuts down a business.¹⁶⁷ CFAA would not apply where a person was trying to find his lost file on the company network (no intent to defraud), opens a file and learns private information about others in the company.¹⁶⁸

Another possible law is the Electronic Communications Privacy Act (ECPA).¹⁶⁹ Title I of the ECPA requires an intentional, real-time taking of wire, oral, or electronic communication information. While originally targeted for people skilled at telephone wire-tapping, recent case law has interpreted the ECPA to cover the Internet. One case provided for a right

¹⁶⁴ Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182, 53,187 (Aug. 14, 2002) (emphasis added).

¹⁶⁵ See FTC, *Privacy Initiatives*, <http://www.ftc.gov/privacy/> (last visited Mar. 2, 2007).

¹⁶⁶ 18 U.S.C. § 1030(a)(4) (2007).

¹⁶⁷ See *United States v. Morris*, 928 F.2d 504 (2d Cir. 1991).

¹⁶⁸ See Haeji Hong, *Hacking through the Computer Fraud and Abuse Act*, 24 U.C. DAVIS L. REV. 283 (1998).

¹⁶⁹ 18 U.S.C. § 2510 (2002).

of action against an Internet traffic monitoring company that used a “cookie” placed in client software to intercept personally identifiable information from people visiting the client website.¹⁷⁰ In fact, this case applied to demographic information including medical conditions and medications. A second case applied the ECPA to an Internet service and email provider intercepting client emails.¹⁷¹

These cases notwithstanding, the ECPA does not apply to information stored on a computer so it would narrowly apply to a medical research institute. The affected server would have to operate a program for collecting health related information and be tainted with code for intercepting personally identifiable information or emails. As there is little incentive in medical research for this type of information interception, the ECPA has little application to protecting the personally identifiable information of research subjects.

The Stored Communication Act (SCA) prohibits the intentional unauthorized access to, or use of, stored *electronic communications* such as voicemail, email, or other stored records of communications.¹⁷² While the term is broad under the statute, “electronic communications” does not include cookies or database files. Further, the SCA does not prohibit the copying or use of non-electronic records. Thus, written informed consent documents may lack extensive legal protection for the personally identifiable information they contain. The SCA would protect the electronically stored personally identifiable information in image form, collected for example, with the research subject’s electronic signature.

A new problem arises where the subject looks at a paper version and a non-image signature digitizer while the clerk, who controls the process, is the only one who sees the image. First, the subject cannot verify that the paper document is the same as the electronic image until after the electronic image is printed, and that is not until after complete execution of the document. Second, the clerk clicks the digital image to place the initials in the “Yes” or “No” block, but the subject cannot see what the clerk is doing. Thus, the process fails to give the subject proper informed consent before executing each initial or signature. To remain unsusceptible to challenge, the clerk must remain diligent to show and

¹⁷⁰ *In re Pharmatrak*, 329 F.3d 9 (1st Cir. 2003).

¹⁷¹ *U.S. v. Councilman*, 373 F.3d 197 (1st Cir. 2004).

¹⁷² 18 U.S.C. § 2701(a) (2007) (emphasis added).

explain the electronic image of the informed consent document to the subject *before* saying “sign here,” on the non-image digitizer, and allow the subject to see what block is selected. Dual monitor setups are inexpensive, yet would allow the clerk and subject to sit face to face.

ii. Inadequacy and Inconsistency in State Laws

While inconsistent, and inadequate in some cases, state laws are still the best effective protection of personally identifiable information of a research subject. As one example, Minnesota provides broad protection of personally identifiable information in state medical research.¹⁷³ Unfortunately, the Minnesota law applies only to “individuals who are the subject of research by the state authority.”¹⁷⁴ Subjects in private research are at the discretionary whim of the research operator. While Pennsylvania has a similarly worded law, the context is quite different.¹⁷⁵ The Pennsylvania law applies to persons involved in “[i]nvestigation of methods for the more precise detection and determination of alcohol and controlled substances in urine and blood samples.”¹⁷⁶ The law does not apply to persons subjected to other forms of medical research. A notably strong provision with the Minnesota and Pennsylvania laws, however, is that they bar persons with the information from being compelled to identify such individuals in any state civil, criminal, administrative, legislative, or other proceeding.¹⁷⁷

North Dakota, on the other hand, has a more protective law, but one that is somewhat less restrictive on disclosure. The North Dakota law is more protective because it applies to all information (genetic, demographic or health related), oral or recorded in any medium, taken by or received by “a health care provider, health researcher, health plan, health oversight authority, public health authority, employer, health or life insurer, school or university.”¹⁷⁸

Just like the Minnesota and Pennsylvania laws, the North Dakota law also bars a public health authority from disclosing protected health information except as authorized by law.¹⁷⁹ Such an instance might be

¹⁷³ MINN. STAT. § 254A.09 (2006).

¹⁷⁴ *Id.*

¹⁷⁵ 71 PA. STAT. ANN. § 1690.104(a)(8) (2007).

¹⁷⁶ *Id.*

¹⁷⁷ *See id.*; MINN. STAT. § 254A.09 (2006).

¹⁷⁸ N.D. CENT. CODE § 23-01.3-01(7)(a) (2007).

¹⁷⁹ N.D. CENT. CODE § 23-01.3-02 (2007).

for epidemiological or statistical studies for an IRB approved biomedical research project, with the data coded to protect the identity of the patient.¹⁸⁰ The drawback of the law is that the research subject or donee cannot prevent the disclosure, even in the rare circumstance where other information in conjunction with the coded disclosure is sufficient to effectively make the patient's identity public.

The rules may vary even within a state as to the make-up of research review committees. Members of the New Hampshire Committee for the Protection of Human Subjects "oversee research conducted in department-funded programs that serve people with mental illness, developmental disabilities, and substance abuse or dependence disorders." Members must be "qualified . . . in safeguarding the privacy and confidentiality of medical records information used for [] research," and in "protecting human subjects in research."¹⁸¹ IRB members, on the other hand, must merely be "qualified . . . in safeguarding the privacy and confidentiality of vital records information that is used for [] health-related research."¹⁸² A New Hampshire IRB member is not required to have qualifications for "protecting human subjects in research."

As to the disclosure of health related information, New Hampshire law is likewise bifurcated. The definition of protected health information is broad. In form, the New Hampshire law includes oral, written, electronic and visual forms of the health information.¹⁸³ In detail, the law covers all information pertaining to the person's physical or mental health, including services received and products purchased. The law even covers information which could be used to "reasonably [] reveal the identity of that individual."¹⁸⁴

However, the New Hampshire law then limits the protection depending on whether treatment is involved. The law reads in part that "[a]ll releases of [protected health] information shall be consistent with [HIPAA]."¹⁸⁵ Since HIPAA covers only medical treatment, a person in Moore's position would likely be covered, since he was undergoing treatment, but someone in the *Greenberg* plaintiffs' position would not

¹⁸⁰ *Id.*

¹⁸¹ N. H. REV. STAT. ANN. § 171-A:19-a(I)-(II) (2007).

¹⁸² N.H. REV. STAT. ANN. § 126:24-e(II) (2007).

¹⁸³ N.H. REV. STAT. ANN. § 141-C:2(XII-a) (2007).

¹⁸⁴ *Id.*

¹⁸⁵ N.H. REV. STAT. ANN. § 126:24-d (2007).

be covered because they were not yet being treated. The New Hampshire law infers a stopgap, though, in that “all proposed releases of vital records information . . . for the purposes of health-related research [shall] be reviewed and approved by the institutional review board . . . before the requested information is released.”¹⁸⁶ Consequently, the protection of health-related research information of someone in the position of the *Greenberg* plaintiffs has only the discretionary protection of the IRB.

Thus, while the Minnesota and North Dakota laws provide blanket disclosure protection, New Hampshire leaves the definition of privacy and confidentiality to the review committee establishing the records handling procedures. Unfortunately, this vagueness allows a potential for inconsistent protection based on the level of concern the IRB members have for protecting the research subjects.

2. *The Inadequate Protection of DNA Data*

Although personally identifiable information is still in vogue for demographic classification, it readily avails itself to identify theft. The certainty of DNA has led to a significant rise in its role and use for trace and remains identification and familial genotyping in the last twenty-plus years. DNA “fingerprinting” was in use as early as 1985 with criminal convictions by 1988.¹⁸⁷ Even so, in 1990 the *Moore* court downplayed DNA testing, saying that “locating . . . the relevant gene is often like a needle in a haystack.”¹⁸⁸ Ironically, that same year, the FBI was establishing its Combined DNA Index System (CODIS) for solving violent crimes.¹⁸⁹ The Genome Project raised the number of identified human genetic markers to the hundreds in the mid-1990s.¹⁹⁰ By 2005,

¹⁸⁶ *Id.*

¹⁸⁷ See Tresa Baldas, *First DNA Conviction Case Returns*, NAT’L L.J., Feb. 12, 2004. See also Robert A. Belair, DNA Fingerprinting, Microsoft Encarta Online Encyclopedia, (2006)http://encarta.msn.com/encyclopedia_761579857/DNA_Fingerprinting.html.

¹⁸⁸ *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 482 n.2 (Cal. 1990) (citing OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELL 42 (1987)).

¹⁸⁹ FBI, CODIS BROCHURE at 1, <http://www.fbi.gov/hq/lab/pdf/codisbrochure.pdf> (last visited Oct. 22, 2007) (“CODIS began as a pilot software project in 1990 serving 14 state and local laboratories.”).

¹⁹⁰ George Cahill, *A Brief History of the Human Genome Project*, in MORALITY AND THE NEW GENETICS: A GUIDE FOR STUDENTS AND HEALTH CARE

this number had reached into the thousands.¹⁹¹ Researchers now believe there are at least 30,000 genes in the human genome.¹⁹² Fifteen markers is now the minimum standard for evidentiary proof of identification.¹⁹³ As genotype data, this represents an enormous amount of personally identifiable information. At present a person can carry volumes of DNA data on a portable flash drive.¹⁹⁴ As personally identifiable information, there is a need for secure protection of DNA information.

In certain circumstances, the federal regulations bar a federally funded medical researcher from knowing the identity of the tissue donee.¹⁹⁵ Consequently, the samples are coded and stripped of personally identifiable information. Only the code-holder, who under the federal regulations cannot be a researcher, is supposed to have that information.¹⁹⁶ The role of the code-holder is to break the code should (1) the research reveal previously unknown medically significant information about the donee, or (2) allow for removal of the sample if the donee withdraws as provided for by section §46.116(a)(8) of the regulations. Otherwise, there is little regulation of the code-holder.

The lack of regulation and ready availability of both DNA testing and enormous data storage presents many privacy concerns. As noted above, the federal regulations do not apply to state or privately funded

PROVIDERS 1, 15 (Bernard Gert et al. eds., 1996) (“Daniel Cohen of Paris with a number of international collaborators have identified 191 markers along the 42 million bases of [chromosome] #21.”).

¹⁹¹ Annie Finnegan, *Human Genome: What Mapping Really Means*, WebMD, June 27, 2000,

<http://www.medicinenet.com/script/main/art.asp?articlekey=51044>.

¹⁹² See *infra* note 194.

¹⁹³ Joan Capuzzi Giresi, *DNA Technology Goes Wal-Mart: Genetics Lab Proves Paternity, Catches Criminals and Entertains the Masses*, PENN. ARTS & SCIENCES MAGAZINE, Nov. 16, 2006, at 22.

¹⁹⁴ It takes about three gigabytes to store one entire human genome. See Human Genome Project, Genome FAQs File, (Aug. 1, 2006)

http://www.ornl.gov/sci/techresources/Human_Genome/faq/faqs1.shtml. Many portable flash memory devices are capable of holding four or more gigabytes of data. See also, 2.5-inch flash drive holds 461 GB, Sept. 12, 2007, <http://www.linuxdevices.com/news/NS4331778531.html> (noting that while “16 GB flash cards are still considered novel,” one maker has crammed “461 GB of flash memory into a standard 2.5-inch hard drive form-factor.”).

¹⁹⁵ 45 C.F.R. § 46.111(a)(7) (2007).

¹⁹⁶ 45 C.F.R. § 46.102(f) (2007).

organizations; and the HIPAA privacy regulations apply only to “health plans, health care clearinghouses, and certain health care providers.”¹⁹⁷ Thus, a federally-funded research organization could sell the tissue (and separately the personally identifiable information) to a private organization. That organization could then develop the tissue genotype and sell the genotype information and personally identifiable information to another organization. Armed with both the genotype and personally identifiable information, an insurer is in a position to deny health or life insurance coverage without the stigma of collecting samples or doing the testing. The sale of genotype and personally identifiable information also provides enormous targeted marketing opportunities for health-related products. While many people give their health information to marketing people without reservation, this is not the same situation as a donee that does not expect his or her genotype and personally identifiable information to become public information. Thus, coding the sample does not bar public access to the genotype, which, with the personally identifiable information of the donor, makes the genotype traceable to the donor.

F. FUNDING BASED CONFLICTS OF INTEREST

In the year following the *Belmont Report*, private medical research received about \$300 million dollars, while the public funded about \$5.1 billion dollars.¹⁹⁸ For 2007, the projected expenditure for combined private and medical research is about \$49 billion dollars and growing nearly 7% per year.¹⁹⁹ Federal government statistics predict that the combined private and public medical research will rise by 2015 to about \$81 billion dollars.²⁰⁰

However, from both ethical and statistical viewpoints, the source and magnitude of the money is a problem. Pharmaceutical funding is an important contributor to medical research of well over \$3 billion dollars

¹⁹⁷ Standards for Privacy of Individually Identifiable Health Information, 67 Fed. Reg. 53,182 (Aug. 14, 2002).

¹⁹⁸ U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2007 at 96 tbl.121 (2006) available at <http://www.census.gov/compendia/statab/tables/07s0121.xls>.

¹⁹⁹ *Id.* at 96 tbl. 122 available at <http://www.census.gov/compendia/statab/tables/07s0122.xls>.

²⁰⁰ *Id.*

annually.²⁰¹ The problem is that this places the researcher in an actual conflict of interest. From 1980 to 2004, the pharmaceutical contribution was only 10% of the total medical research expenditures.²⁰² Yet, “[s]ome studies have shown that 90% or more of publications sponsored by a pharmaceutical company favor that company’s products.”²⁰³ That private funding gets much better results than public funding is an unbelievable statistical anomaly. Stated differently, one commentator surmised that “[conflicts of interest] can bias the outcome of research... Pharmaceutical companies can use several tactics to achieve these results, including the suppression of research that yields negative results and biased interpretations for the data.”²⁰⁴ A real dilemma is that a conflict of interest in medical research “can undermine the public’s trust in the research enterprise, because research subjects, politicians and laypeople may view investigators . . . as biased or unethical.”²⁰⁵

There are two methods to avoid the conflict of interest conundrum. The preferred method would be for private funding to be monitored through public oversight, i.e., outside persons should staff IRBs. Another method might have pharmaceutical R&D contributions blended with federally-sponsored medical research funding and oversight.

III. BRINGING THE REGULATIONS UP TO DATE

A. CLOSE THE IRB ACCOUNTABILITY GAP

For the most part, IRBs perform admirably. As with any group, a few “bad apples” may unnecessarily taint the public perception of these groups. Of the hundreds of thousands of medical researchers and FDA regulated companies in the U.S., the FDA issued only 142 warning letters in 2006.²⁰⁶ This figure, however, may be askew because there are only some 200 FDA investigators to audit the estimated 350,000 medical

²⁰¹ *Id.*

²⁰² *Id.* at 96 tbl. 121.

²⁰³ Resnik, *supra* note 35, at 144.

²⁰⁴ *Id.* (internal citations omitted).

²⁰⁵ *Id.* (internal citations omitted).

²⁰⁶ *Search Warning Letters by Date and Export to Excel*, http://www.accessdata.fda.gov/scripts/wlcfm/export_report_excel.cfm (2007) (search criteria of 1/11/2006 to 12/31/2006).

research testing sites in the U.S.²⁰⁷ The actual number of violations could be much higher. Thus, the first measure of subject protection is the individuals of the IRBs who already have oversight responsibility and authority under the regulations.

Of real concern, however, is that the IRBs of the fourteen examples listed in Table I below approved the research that led to the violations and five deaths between 1996 and 2003. Fortunately, only one of the fourteen examples expressly involved members of an IRB. This still means, though, that the members of the thirteen other IRBs missed the signs found by the FDA auditors that could have stopped the research and perhaps saved lives. The continuing stream of violations and legal challenges indicate there are accountability loopholes that allow unethical behavior to continue unabated. There are at least two ways of closing the accountability gap.

One method expressly adopts the regulatory principle of independent, non-official audits, which the regulations permit.²⁰⁸ While many medical researchers and facilities are familiar with FDA and Joint Commission audits for accreditation, these have official sanctions, and are stressful to the organization, both in time and in personal resources. Faced with rising losses from sub-par manufacturing or service procedures, some corporations adopted an independent audit quality system in the 1990s. Many of these corporations found the independent audits useful for discovering compliance problems before they became serious. Medical device manufacturers are also familiar with this program as part of the 21 C.F.R. § 820 Quality System Regulations.²⁰⁹ There were at least four medical research related deaths from 1996 to 2003 in the U.S. These statistics strongly suggest that researchers must adopt strong preventive measures.

The second method addresses the personnel of the IRB. Just as large corporations often have many outside directors (and more now because of Sarbanes-Oxley), research organizations should require some portion of outside staffing of IRBs. The benefit is that just like outside directors, outside IRB members are less likely to have personal knowledge of non-

²⁰⁷ See Gardiner Harris, *Report Assails F.D.A. Oversight of Clinical Trials*, N.Y. TIMES, Sept. 28, 2007, at A1.

²⁰⁸ 45 C.F.R. § 46.109(e) (2007) (“An IRB ... shall have authority to observe or have a third party observe the consent process and the research.”).

²⁰⁹ 21 C.F.R. § 820.22 (2007) (procedures for conducting quality audits).

board members (i.e., researchers to the IRB), have conflicts of interest within the corporation (research organization), and they would decrease the likelihood that questions might go unasked. Such a program might have prevented the 1997 case of two IRB members and investigators conducting illegal clinical trials.²¹⁰

One last IRB regulation change addresses the role and governance of institutional review boards. The regulations expressly require an IRB to “conduct continuing review of research covered by this policy at intervals appropriate to the degree of risk, but not less than once per year.”²¹¹ However, the regulations also allow “an institution participating in a cooperative project [to] rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.”²¹² This rule is a loophole to the requirement that “each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy.”²¹³ Consequently, each IRB can operate as though the other IRB had primary oversight and attempt to shift the blame for adverse results. For example, in 2000, federal investigators criticized prison-cooperative studies by four universities with partial drug company funding for unacceptable risks in HIV-treatment, improper informed consent, and possible conflicts of interest, where one IRB named a prison doctor overseeing the research as the inmates’ advocate.²¹⁴ Just as companies using quality system audits trade auditors, the regulations should require that all IRBs involved in a cooperative project closely audit the outside research.

B. IMPROVING INFORMED CONSENT

Legal challenges over conflicts of interests in medical research have multiple bases. Moore’s challenge was to recover for the offense of being misled through informed consent that there was no commercial or financial value to his blood and bodily substances. The Gelsingers’ basis for recovery was that the informed consent document misled their son. The *Greenberg* plaintiffs were likely offended on two counts. First, they

²¹⁰ Steve Stecklow & Laura Johannes, *Test Case: Drug Makers Relied on Clinical Researchers Who Now Await Trial*, WALL ST. J., Aug. 15, 1997, at A1.

²¹¹ 45 C.F.R. § 46.109(e) (2007).

²¹² 45 C.F.R. § 46.114 (2007).

²¹³ *Id.*

²¹⁴ Sydney P. Freedberg, *Safety Fears Stop Inmate Research*, ST. PETERSBURG TIMES, Aug. 29, 2000, at 1A.

were informed of the patent after they funded the research, and they were charged for testing after funding the research. While the *Catalona* suit was not directly one of a conflict of interest, the informed consent disclosure had a major role in the court's decision. Consequently, researchers should consider these six steps to improve the disclosure and prevent conflict of interest based violations and challenges:

- (1) The researcher must completely disclose the researcher's commercial interest in the research to the research subject, the tissue donee, or at least the person authorizing excision of the tissue.
- (2) The disclosure must name the entity of the commercial interest and state the current value and the estimated value of the contribution of the research to the commercial interest at a reasonable time after the research, as disclosed to the researcher.
- (3) The researcher must name all commercial medical interests funding the researcher or research organization.
- (4) The researcher must name all commercial medical interests the researcher has or hopes to establish through the research on the research subject or tissue.
- (5) The researcher must disclose all commercial medical interests in the patient's or research subject's research as they occur.
- (6) The researcher must disclose the conflict of interest before executing a binding agreement, as the subsequent withdrawal of the patient or research subject might have deleterious effects on the value of the agreement.

Viewed from the circumstances of the research subject, there are three facets for discussion.

1. Complete Disclosure with Opt-Out Notification

Some opine that the current informed consent regulations hamper the interests of both researchers and research subjects. Researchers find the informed consent too limiting, in part, because the narrow regulatory scope assumes that the research subject is always nearby to give consent. However, the informed consent program also causes problems for

research subjects. One problem is that researchers do not have to disclose “minimal risk” research, and the research subject does not decide, and is not told, what constitutes “minimal risk.” The regulations take the position that the researchers and research organizations understand these issues better than the research subject and leave the decision of what constitutes “minimal risk,” and the disclosure decision, to the researchers and research organizations.

This is the same paternalistic view that caused the judicial creation of the informed consent requirement. Research subjects today both want to know, and in many cases are better informed now to understand, the risks and make research related decisions. Thus, whether the information is “harmful” to the patient is both ridiculous and irrelevant. Physicians and researchers who do not fully disclose the required informed consent information risk legal challenges from research subjects, as well as official sanction by research administrators (as employers) and the FDA.

This discussion is not to dismiss implied consent. The solution, however, is for more disclosure so that the range of informed consent by patients and research subjects is broader. Even though researchers cannot know what future research might discover, the disclosure can be made in conjunction with an “opt-out” research program. Suppose that the researchers in *Moore* did not need Moore to come back and provide more tissue. Had they sent a certified letter with return receipt, they might have avoided the trouble with Moore had they (1) informed Moore of their initial findings, and (2) disclosed that they would proceed with the further research, unless (3) Moore contacted them within a stated time (e.g., 10-days) with an express denial (opt-out) of permission.²¹⁵ To invoke implied consent, the researcher would have to (1) include notice of the opt-out program in the initial informed consent disclosure, and (2) send the opt-out notice to the patient or research subject at the time of discovery.

2. *Disclosing Conflicts of Interest*

The research subject’s second problem is that researchers in some jurisdictions are not required to disclose conflicting interests. Even if the

²¹⁵ The researcher would have had to also disclose the conflict of interest, but that could have been part of the initial informed consent.

researcher's interest in pursuing the research, and potential profit, do not create an actual conflict of interest, the cases of *Moore*, *Greenberg* and *Gelsinger* show that the plaintiff's legal cause of action was *the failure of disclosure of the financial interest*. While Moore's case appears to have had a greater personal profit motive than the plaintiffs in the *Greenberg* case, Moore succeeded precisely because the physician failed to disclose his personal financial interest in Moore's tissue.

Although such disclosures are personal to the researcher, they are not any more personal than the disclosures made by politicians (both incumbent and putative). The disclosure rules for politicians arose because politicians have to make decisions based on personal financial interests. The ongoing violations and inconsistency in state and private disclosure laws mandate closing the disclosure gap.

3. *Qualifying Discloseable Conflicts of Interest*

The research subject's third problem is the qualification of a conflict of interest, which when required, has two components: a monetary value and a time of valuation. California defines a discloseable conflict of interest as \$10,000 at the time of disclosure.²¹⁶ This requirement, however, suffers from three weaknesses. First, researchers, patients, and research subjects may disagree on the value necessary for disclosure. Researchers may consider the disclosure limit too low, while patients and research subjects may consider the limit too high. While this is facially a legislative issue, rather than a regulatory issue, the true issue is not a numerical value. The real problem, and the second weakness of a California-type rule, is that the disclosure rule fails to appreciate that the true conflict of interest is in the motivation of the future worth of the conflict of interest, not the present value. When people make growth-type investments, they do not consider the present value of the investment as strongly as the potential for future value. There is not a reason to believe that researchers are any different when considering work-related investment potentials. Even if the researcher discloses the present value of the conflict of interest, the disclosure fails to provide a true indication of motivation behind the research.

Thus, even the California disclosure rule fails because patients and research subjects are not told of the true magnitude of a researcher's

²¹⁶ CAL. HEALTH & SAFETY CODE § 24173(c)(11) (2007).

conflict of interest. This is possible only by the researcher disclosing the motivation for engaging in the conflict of interest—the reasonably expected value of the research at a designated point of time, perhaps one or more years later at the expected completion of the study with the valuation based on past research. Investors make comparative investment decisions regularly, and such decisions are not beyond sharing with the patient or research subject when potentially the health, safety and life of the patient or research subject are at stake.

Critics would argue this is impossible because of the speculative nature of both research and investments. As pointed out above, however, a disclosure of a present value is irrelevant when the motivation of the researcher is in the future value of the conflict of interest, and such decisions are routine for investors.

Another difficulty with the disclosure rule is that researchers are not required to disclose a new conflict of interest. The *Greenberg* court argued that requiring “researchers [to] constantly evaluate whether a discloseable event has occurred . . . would give rise to a type of dead-hand control that research subjects could hold because they would be able to dictate how medical research progresses.”²¹⁷ However, a researcher is well aware that signing an assignment, employment agreement, or other contract is a discloseable event for creating an actual conflict of interest. Unlike the Gelsinger’s Dr. Wilson, a researcher is in a better position to show that a patient or research subject was properly informed if the research subject understands the researcher’s motivation. Finally, failure to disclose the conflict of interest may be construed as a breach of fiduciary duty or unjust enrichment, and are what gave Moore and the *Greenberg* plaintiffs their court victories.

C. CONSISTENCY IN REGULATION

1. Standardized Disclosure Requirements

The fourth problem for research subjects is the lack of standardized disclosure requirements. Although states and individuals have considerable rights under the Federal Constitution, consistency in medical research regulation is an important national interest. From a

²¹⁷ *Greenberg v. Miami Children’s Hosp.*, 264 F. Supp. 2d 1064, 1070-71 (S.D. Fla. 2003).

viewpoint of the national economy, medical research will soon be an \$80 billion dollar business.²¹⁸ Inconsistency in state and private regulation allows researchers in one facility to perform acts that might be unethical in other facilities. Through this inconsistency, a facility in a regulated state can engage in a partnership with a facility in an unregulated facility using funds subject to regulation for conduct prohibited in its facility. From a research subject viewpoint, a person living in a regulated state (e.g., California) seeking research-related treatment out of state (e.g., Florida) may be subjected to unethical conduct prohibited in the home state. Forcing a person to make such a choice is unethical since the researcher in the unregulated state is taking advantage of the person who can be presumed to know their home state laws, but not the inconsistency in state research regulations. Thus, consistency in medical research regulations is imperative.

2. Using Codes of Ethics as Regulation

Even if the regulations are not timely improved, other options are available. In pressing their case against Dr. Matalon, the *Greenberg* plaintiffs relied on the American Medical Association Ethics Code for physicians and medical researchers.²¹⁹ Section E-2.08 provides that:

[p]otential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials . . . [and] [h]uman tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material.²²⁰

The Court rejected this argument, however, finding that the AMA Code of Ethics did not apply. The provision was not part of the contract binding the parties.²²¹ Moreover, the AMA is not a governing body. The AMA is only an advisory body whose opinions a state may adopt or disregard. While Dr. Matalon was a medical doctor, Florida law exempted medical researchers from the same standards as physicians

²¹⁸ U.S. CENSUS BUREAU, STATISTICAL ABSTRACT OF THE UNITED STATES: 2007 at 96 tbl.122 (2006), available at <http://www.census.gov/compendia/statab/tables/07s0122.xls>.

²¹⁹ *Greenberg*, 264 F. Supp. 2d at 1071 n.2.

²²⁰ *Id.* See also, AM. MED. ASS'N, CODE OF ETHICS § E-2.08 (2007) (governing the commercial use of human tissue).

²²¹ *Greenberg*, 264 F. Supp. 2d at 1071.

who treat people.²²² Had the court read this requirement to apply, the plaintiffs would have been the intended third-party beneficiaries of the provision.

Short of Florida changing the law, the AMA should change Section E-2.08 to make the requirement mandatory and apply the Code of Ethics to both physicians and medical researchers. Even without the force of law, it would assert pressure on states to adopt the standard, especially those states that defer to national standards. Federal legislation could also require medical researchers receiving federal funds to follow this provision, irrespective of whether the medical researcher performs treatment. As the federal government wholly or partially funds a significant portion of U.S. medical research, such a requirement would cover medical research in many states that did not adopt the revised Code of Ethics.

Another example of professional regulation that could provide a model for medical researchers is the American Bar Association's conflict of interest rules.²²³ These Codes require both a disclosure, and that the attorney advise the client to seek a second opinion. ABA Model Rule 1.8(a) provides an example for instances when an attorney acquires an interest in a client's business or other financial interest. The lawyer must fully disclose the terms in writing to the client, using terms "reasonably understood by the client."²²⁴ The client must also be told of, and given "a reasonable opportunity to seek the advice of independent legal counsel on the transaction."²²⁵

Just as other professions recognize an interest in the outcome is a conflict of interest, so should the medical research disclosure requirements. Yet, the informed consent disclosure requirements do not address the business relationship between the patient or research subject and researcher.²²⁶ An application of ABA Model Rule 1.8(a) to the

²²² *Id.* at 1069 ("Medical consent law does not apply to medical researchers." (citing FLA. STAT. ANN. § 760.40)).

²²³ Resnik, *supra* note 35, at 148 ("An increasing number of professions, including law, real estate, banking, brokering, accounting, engineering, and journalism require that professionals disclose [conflicts of interest] to clients or other relevant parties.").

²²⁴ See MODEL RULES OF PROF'L CONDUCT, R. 1.8(a) (2004).

²²⁵ *Id.*

²²⁶ 45 C.F.R. § 46.116 (2007) (basic elements of informed consent).

disclosure requirements (i.e., disclosing the interest and suggesting that the patient or research subject seek outside advice) would help to improve and broaden the informed consent of the patient or research subject.

Other examples of conflict of interest rules come from the corporate world. Section 206 of the Sarbanes-Oxley Act of 2002 requires that, “[t]he CEO, Controller, CFO, Chief Accounting Officer or person in an equivalent position cannot have been employed by the company’s audit firm during the 1-year period preceding the audit.”²²⁷ A second example is a tax law requirement that the compensation committee setting performance goals of employees subject to the excess compensation law “must be . . . comprised solely of two or more outside directors.”²²⁸ These rules seek to help prevent undue influence or favoritism through association of the members on the corporate board. While these conflict of interest requirements may seem unnecessary to many researchers, the amount of money used in research has grown too significantly to ignore.

D. TRUSTS TO BALANCE THE INTEREST

1. The Biobank Trust

Another way to avoid conflicts of interest and possible ethical violations by institutional review boards and medical researchers would be to place the ethically challenging assets of medical research in trust outside the direct control of the research organization or researcher. At the front end of medical research are the tissue samples; while at the finished end are the products of the research.

In *The Charitable Trust as a Model for Genomic Biobanks*, David and Richard Winickoff proposed a charitable trust that would operate by having the tissue donor transfer his or her property interest in their tissue to the trust, and to appoint a trustee who would have legal fiduciary duties over the donated tissue.²²⁹ The best justification for such a model

²²⁷ 15 U.S.C. § 78j-1(l) (1) (4) (2007).

²²⁸ 26 U.S.C. § 162(m) (2007) and 26 C.F.R. § 1.162-27(e)(3)(i) (2007).

²²⁹ Winickoff, *supra* note 38, at 1182 (citing George G. Bogert, *THE LAW OF TRUSTS AND TRUSTEES*, 323-29 (West Publishing, 2d ed. 1992)). A transfer of ownership over tissue cannot occur until tissue removal. Otherwise the research institution would own that part of the person, which is illegal. For a regular

is that, “[i]n a charitable trust, the general public acts as the beneficiary.”²³⁰ In this way, the charitable trust, as trustee, has a fiduciary duty and legal power both to transfer *possession* of the research tissue to the research organization and to ensure that the research organization meets the ethical regulations. Furthermore, since the charitable trust has legal power over the tissue, researchers have a readily and legally available authorization to proceed with other, newly-discovered research.

Another justification the Winickoff article provides is that “[t]he charitable trust is a promising legal structure for handling such a set of obligations, for promoting donor participation in research governance, and for stimulating research that will benefit the public.”²³¹ This is true, however, only to the extent that the informed consent-trust document provides for the ethical handling of the research. For example, the charitable trust must assure that the donor’s informed consent was sufficient to meet the criteria for further research where a donor may have expressed distain for one form of the research, or the researcher has a possible or actual conflict of interest. Thus, while the charitable trust is a feasible platform for medical research, the informed consent document must be consistent from jurisdiction to jurisdiction, and the charitable trust must provide sufficient review to assure the donor that unethical acts do not occur. Such a scenario is best possible if the federal regulations provide for these requirements in conjunction with the existing federal enforcement oversight.

2. *The Public Trust Repository*

Another option to resolve the conflict of interest issue would be to place the ownership interest in the proceeds into a trust. Unlike the biobank, this interest is independent of the tissue. As an extension of the public financing of the research, the public-trust repository would hold an

tissue donee, the tissue donee transfers ownership of the tissue to the research institution. Here, the tissue donee would transfer ownership to the trust.

²³⁰ *Id.* at 1182.

²³¹ *Id.* at 1182 (citing David E. Winickoff, *Governing Population Genomics: Law, Bioethics, and Biopolitics in Three Case Studies*, 43 *JURIMETRICS* 187, 201 (2003)); Karen Gottlieb, *Human Biological Samples and the Laws of Property: The Trust as a Model for Biological Repositories*, in *STORED TISSUE SAMPLES: ETHICAL, LEGAL AND PUBLIC POLICY IMPLICATIONS* 182-204 (University of Iowa Press ed., 1998)).

ownership interest in the research funded by the signatory parties, such as federal, state, or private financing. As a non-government, publicly-accountable entity, the public-trust repository could invest its assets and dispense funds for public or private health care matters according to its charter. A modification of this approach would grant an interest to tissue donors through the informed consent document. One scenario would provide for tissue donors to receive a share of the profits, which balances the conflict of interest of researchers.

A drawback of either plan is the enormous costs associated with the administration and distribution of proceeds. Publicly-traded corporations, however, work daily and profitably with determining the fractional interests of shareholders and distributing dividends each quarter. Just as Fannie Mae and Freddie Mac are publicly traded quasi-public entities in the mortgage industry, a donors' public trust repository has the same capacity to provide tissue and public participation through private ownership in the medical research industry.

E. PROTECTION OF PERSONAL INFORMATION

While the federal regulations have some provisions for handling personally identifiable information, as described above, these are weak and susceptible to abuse. The HIPAA regulations apply only to health care providers, health plans, health information clearinghouses, business associates, and the workers for those organizations. Other federal laws only apply to consumer transactions, financial data, and improper access to computers. Since the informed consent documents must have the research subject's signature, the informed consent documents, and the personally identifiable information they contain, are in written form. While other federal laws apply to electronic collection of information, these laws do not protect the privacy of the research subject through the personally identifiable information in written form. Thus, state law, which is inconsistent from state to state, is all that protects the privacy of research subjects. Consequently, the best option would be for the federal regulations to provide guidelines for encryption and storage of personally identifiable information.

Private DNA testing and DNA databases are becoming commonplace but are not subject to federal privacy requirements.²³² To address the

²³² An Internet query showed over 20 U.S. firms, with one website listing eight affiliated companies performing genetic testing. *See, e.g.*,

concern that genetic information might be used for discriminatory purposes, members of the Human Genome Project drafted the first Genetic Privacy Act in 1994.²³³ As envisioned, the Genetic Privacy Act seeks to “protect individual privacy while permitting genetic analysis for medical and identification purposes and legitimate research” by allowing the individual to “control identifiable DNA samples or genetic information about [the] individual.”²³⁴ As national legislation, the Genetic Privacy Act would apply to all tissue taken for DNA sampling. The person collecting the sample would have to inform the donor, both verbally and in writing, of his or her rights, and obtain the donor’s written permission to collect the sample.²³⁵ The donor would have the right to restrict access to the sample, and stipulate “instructions regarding maintenance and destruction of [the] DNA samples.”²³⁶ Specific rules would apply to DNA sample collection and research on “minors, incompetent persons, pregnant women, and embryos.”²³⁷ The Act would also publicize these controls to the medical, scientific, business, law enforcement communities, and the general public. When Congress did not pass this legislation, “President Clinton signed an executive order . . . prohibiting every federal department and agency from using genetic information in any hiring or promotion action.”²³⁸ The order prohibits federal employers from requiring or requesting genetic tests as a condition to employment, “to evaluate an employee’s ability to perform his or her job,” or use genetic information as a basis for employee classification or deny advancement based on “a genetic

<http://www.genetree.com/sorensongenomics/dna-partners.asp> (last visited: Feb. 24, 2007).

²³³ GEORGE J. ANNAS ET AL., GUIDELINES FOR PROTECTING PRIVACY OF INFORMATION STORED IN GENETIC DATA BANKS (1995) *available at* http://www.ornl.gov/sci/techresources/Human_Genome/resource/privacy/privacy1.html.

²³⁴ Anne Adamson, *Genetic Privacy Act Introduced*, 6 HUMAN GENOME NEWS (Mar.-Apr. 1995), *available at* http://www.ornl.gov/sci/techresources/Human_Genome/publicat/hgn/v6n6/4genetic.shtml.

²³⁵ *Id.*

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ Human Genome Program, U.S. Dep’t of Energy, *Genetics Privacy and Legislation*,

http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (last visited Oct. 21, 2007). *See* Exec. Order No. 13,145, 64 Fed. Reg. 6,877 (2000).

predisposition for certain illnesses.”²³⁹ The order also placed genetic information with privacy protections on par with health related information.

Congress still did not act. Then, in 2001, the EEOC learned that Burlington Northern Santa Fe Railroad was secretly testing its employees for genetic conditions, including carpal tunnel syndrome, diabetes, and alcoholism.²⁴⁰ Thereafter, Congress introduced four bills during 2001 and 2002 to proscribe this activity. None of these bills passed.²⁴¹

In 2003, Congress introduced four bills, at least one of which passed in the Senate, but failed to clear the House.²⁴² However, on January 16, 2007, an updated version of the 2003 bills was re-introduced into the House as H.R. 493, the Genetic Information Nondiscrimination Act of 2007.²⁴³ The bill would prohibit genetic discrimination by employers and health insurance providers, and limit their ability to use and collect genetic information.²⁴⁴ In April 2007, the House passed the bill by a nearly unanimous vote, 420-3.²⁴⁵ While this bill would help protect the privacy of genetic information, it remains to be seen how the Senate will respond.

Finally, other factors associated with DNA studies regard storage of DNA samples and results, and whether and how these samples might be used for genealogy and tracing genetic heritage. As one solution, the National Research Council suggested “an international organization to serve as a trustee and fund-holder for all the sampled populations.”²⁴⁶ This solution is troubled, however, by the international divergence of privacy laws. Since the data protection laws of the U.K. differ from

²³⁹ Human Genome Program, U.S. Dep’t of Energy, *Genetics Privacy and Legislation*,

http://www.ornl.gov/sci/techresources/Human_Genome/elsi/legislat.shtml (last visited Oct. 21, 2007).

²⁴⁰ *Id.*

²⁴¹ *Id.*

²⁴² *Id.*

²⁴³ H.R. 493, 110th Cong. (2007).

²⁴⁴ Electronic Privacy Information Center, *Genetic Privacy*, <http://www.epic.org/privacy/genetic/> (last visited Oct. 20, 2007).

²⁴⁵ H.R. 493.

²⁴⁶ Winickoff, *supra* note 38, at 1182 (citing NAT’L RES. COUNCIL, EVALUATING HUMAN GENETIC DIVERSITY 67 (1997)).

those of Germany, and both differ from the U.S. protections described above, such an organization would have difficulty providing informed consent and handling personally identifiable information in ways that conform to all the different privacy laws.

IV. CONCLUSION

Just as Congress has standardized consumer protection against deceptive transactions and the handling of financial information, it is time for Congress to standardize the protection of research subjects. Regulations developed during the 1970s and 1980s sought to protect the physical and mental health, safety, and welfare of the research subject. The regulations relied on the principle that the research subject was a present and informed part of the research. Since then, there have been significant technical and societal advances that create conflicts of interests. Genes are now patentable and an essential element of medical research. Medical research funding is now in the many billions of dollars, creating significant employment opportunities for researchers capable of raising such funds. Finally, outcome-based funding has become so lucrative so as to create apparent, if not actual and disturbing, conflicts of interest. In short, medical research now has two motives—the altruistic goal of public betterment and the employment and financial betterment of the medical researcher.

At the time of development of the regulations, the concern was that researchers might not disclose the risks of research out of paternalism or ignorance of ethical considerations. Now, the commercial conflicts of interest in research have become a risk factor for the physical or mental illness or death of a research subject. Adding to these dangers is the risk that personally identifiable information may find its way into the public or be used for fraudulent purposes.

Research subjects need complete disclosure, from both the researcher and the research organization, revealing the role of outside and commercial interests to the research. Even if the researcher or the research organization lacks a present economic interest in the outcome or source of funding, the commercial funding of private research brings both the appearance of a conflict of interest and, according to statistics, an actual conflict of interest.

While researchers want to protect their own privacy, research subjects are not asking for any more information than the public already demands from politicians, who also have conflicts of interests. While there is a distinction in the office between a medical researcher and a politician, both persons are tasked with the trust of the public. Medical researchers are not likely to desire the diminished reputation suffered generally by persons in the fields of politics and law that results from breach of trusts by a few members of each field. Researchers must learn to recognize a potential conflict of interest disclose it to the research subject.

Additional concerns arise because of inconsistencies in state research and privacy laws. These inconsistencies affect the success of interstate cooperative research, the treatment received by out of state research subjects, and how private organizations behave toward research subjects.

While biotechnology research, whether performed at the federal, state, or private level, is an academic pursuit, it is also a business. Researchers and research organizations have a fiduciary duty to their research organization, the validity of the research, and to the research subjects. This duty requires them to give all parties a complete and timely disclosure of all risks and conflicts of interests. As an industry that generates hundreds of billions of dollars annually and hundreds of thousands of jobs, the ethical performance of biotechnology on a nationwide scale is important to the health, safety and welfare of the subjects, the validity of the research, and—from its rapidly increasing growth—the economic vitality of the nation.

V. Appendix

TABLE I—SELECTED FDA VIOLATIONS 1995-2006²⁴⁷

<i>YEAR</i>	<i>DESCRIPTION OF VIOLATION</i>
1995	A Veterans Affairs investigator failed to get informed consent on four subjects. ²⁴⁸
1996	A Missouri university thoracic surgeon failed to get informed consent from at least 78 open-heart surgery patients while doing research for an article. ²⁴⁹
1996	A 19-year-old university student died after a research project bronchoscopy that failed to follow proper protocols and minimize risk to subjects. ²⁵⁰
1997	Two IRB members and investigators conducted illegal clinical trials. They were found guilty of theft and fraud of millions of dollars and sent to prison. ²⁵¹
1999	A Boston investigator failed to disclose sizable financial payments from drug companies, fabricated invoices, & double billed work. ²⁵²
2000	A 9-month-old boy died at a hospital during a study designed to test a heartburn remedy on children. The informed consent document misleadingly stated the study drug was approved for use in children. ²⁵³

²⁴⁷ A generic search page is available at <http://www.fda.gov/foi/warning.htm>.

²⁴⁸ Philip J. Hilts, *V.A. Hospital is Told to Halt All Research*, N.Y. TIMES, Mar. 25, 1999, at A25.

²⁴⁹ Josh Flory, *Surgeon Cited for Improper Heart Research*, COLUMBIA-MISSOURI TRIBUNE, May 2, 1999, available at <http://archive.showmenews.com/1999/may/19990502news01.htm>.

²⁵⁰ Dan McGuire, *Rochester Death Halts MIT-Funded Study*, THE TECH, Apr. 9, 1996, available at <http://www-tech.mit.edu/V116/N17/rochester.17n.html>.

²⁵¹ Steve Stecklow and Laura Johannes, *Test Case: Drug Makers Relied on Clinical Researchers Who Now Await Trial*, WALL ST. J., Aug. 15, 1997, at A1.

²⁵² Alison Bass, *Drug Companies Enrich Brown Professor*, BOSTON GLOBE, Oct. 4, 1999, at A1.

²⁵³ *Death of Infant is Linked to Hospital Study of a Drug*, ASSOCIATED PRESS, Apr. 27, 2000.

2000	A medical center investigator developing new arteries through investigational use of genetic material in subjects with significant cardiovascular disease, but who were not candidates for traditional therapy, enrolled ineligible subjects, failed to follow key subject safeguards, and failed to report the death of a subject as required. ²⁵⁴
2000	A university investigator was cited for repeatedly, and deliberately, violating federal regulations while conducting biological and investigational new drug studies. ²⁵⁵
2000	A prisoner study at four separate U.S. prisons had unacceptable risky drug research, improper informed consent, and possible conflicts of interest. ²⁵⁶
2001	A healthy 24-year old employee volunteer died in an asthma study at Johns Hopkins University in Baltimore Maryland. The university and researcher received unfavorable citations for inadequate review of study design, failure to provide continuing oversight of the asthma study, inadequate subject consent forms, failure to report side effects of the drug used in an earlier patient, and use of a drug unapproved for humans. ²⁵⁷
2002	A healthy retired nurse volunteer died from of an overdose administered during an Alzheimer's disease study. ²⁵⁸

²⁵⁴ Michael Lasalandra, *Human Gene Therapy Trials Placed under the Microscope*, BOSTON HERALD, May 4, 2000 at 10.

²⁵⁵ Omer Gillham & Jeff Martin, *FDA Seeks to Ban Oklahoma Doctor from Research*, TULSA WORLD, Jul. 26, 2001.

²⁵⁶ Sydney P. Freedberg, *Safety Fears Stop Inmate Research*, ST. PETERSBURG TIMES, Aug. 29, 2000, at 1A.

²⁵⁷ Linda Bren, *Human Research Reinstated at Johns Hopkins, with Conditions*, FDA CONSUMER, Sept.-Oct. 2001, at 11.

²⁵⁸ Susan Okie, *A Death During Research*, WASH. POST, Jan. 12, 2002, at A3.

2003	A 60 year-old subject died while participating in the multi-site Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trials experiment following many serious violations and failure to adequately protect human subjects. ²⁵⁹
2006	Cardiologist was permanently barred from conducting medical research after failure to timely report a subject's 2002 death, use of non-approved physicians for implantation surgery, use of unapproved subjects in the study, failure to maintain screening and enrollment logs and backdating of logs, failure to timely report adverse events, and failure to maintain control over subject records. ²⁶⁰

²⁵⁹ Alliance for Human Research Protection, *Lawsuit Filed re: ALLHAT Hypertension Research Death of Human Subject*, <http://www.ahrp.org/infomail/03/07/17.php> (Jul. 17, 2003).

²⁶⁰ Sheryl Kornman, *UA Doctor Barred from Research on Humans*, TUCSON CITIZEN, May 31, 2006, at 6A.