MEDICAL RESEARCH LITIGATION AND MALPRACTICE TORT DOCTRINES:
COURTS ON A LEARNING CURVE

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I. CASE OVERVIEW ........................................ 6
II. A NEED FOR CLARITY: RESEARCH VERSUS MEDICAL PRACTICE ............................. 13
III. CONFUSION IN THE COURTS ......................... 19
   A. Research Injuries as Medical Malpractice .... 19
   B. Research Injuries as Ordinary Negligence ... 28
   C. Research as Distinct from Medical Practice ... 30
IV. ADAPTING CIVIL CAUSES OF ACTION TO THE RESEARCH CONTEXT ...................... 33
   A. Contract ............................................. 33
   B. Property ............................................ 35
   C. Negligence .......................................... 37
   D. Breach of Fiduciary Duty .......................... 41
      1. Investigators: Not Fiduciaries ............... 41
      2. Physician-Fiduciaries As Investigators .... 47
         a. Conflicts of Obligation .................. 49
         b. Conflicts of Interest .................... 51
V. INFORMED CONSENT AND BATTERY ................. 52
   A. Battery .............................................. 53
   B. Informed Consent .................................. 63
      1. Duty of care: scope of disclosure .......... 64
      2. Injury ........................................... 68
         a. Emotional Distress ....................... 70
         b. Dignity and Injuries .................... 73

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INTRODUCTION

Human clinical research trials, by which corporations, universities, and research scientists bring new drugs, devices, and procedures into the practice and marketplace of medicine, have become a huge and rapidly growing business. The National Institutes of Health (NIH) has doubled its spending over the past five years, most recently reaching about $27 billion in the 2003 fiscal year. Meanwhile, in the private sector, the top twenty pharmaceutical companies have more than doubled their investment in research and development over the past seven years. Maintaining their current levels of profit and productivity will require these firms to launch between twenty-four and thirty-four new drugs per year, a feat that will require aggressive efforts to bring drugs to market, via an approval process requiring human clinical trials, as quickly and efficiently as possible. To date, as many as twenty million Americans are estimated to have participated in such trials. As these numbers expand, so do trial sites. Whereas a decade ago about eighty percent of human clinical research trials for pharmaceuticals were conducted at academic medical centers, that figure has now dropped by half, as large numbers of private practice physicians enter the world of clinical research.

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3 Karine Morin, et al., Managing Conflicts of Interest in the Conduct of Clinical Trials, 287 JAMA 78, 78 (2002); see also, Abate, supra note 2, at A1 (stating "... In 1990, drug companies spent about $8.4 billion on research and development. By 2001, their R&D spending had risen nearly fourfold to $30 billion ... Biotech firms spent $5.7 billion on R&D in 1993. ... By 2001, they were pumping $15.7 billion into the effort.").
4 See Morin et al., supra note 3, at 78.
5 Noah, supra note 1, at 361.
6 See Jason L. Klein & Robert A. Fleischman, The Private Practicing Physician-Investigator: Ethical Implications of Clinical Research in the Office Setting, 32 HASTINGS CENTER REPORT 22, 22 (2002) (noting that "[I]n 1991, 80 percent of pharmaceutical industry money for clinical research went to investigators in academic medical center. ... In 1998, that figure dropped by half, to only 40 percent. ... As a result, thousands of private physicians have become physician-investigators, and their patients have become patient-subjects.").
7 Id.
For many years human clinical trials were remarkably free of controversy, even if not entirely free of scrutiny. In 1974, in the wake of several well-publicized research abuses, Congress created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research to formulate ethical principles and practical recommendations for the protection of human research subjects. Their deliberations produced the 1979 Belmont Report that, in turn, helped to guide the Institutional Review Boards (IRBs) created to review the ethics of federally funded research. In 1981, the Common Rule unified the human subject protection system across the spectrum of federal agencies and departments, further specifying the composition and operation of IRBs. Under those rules, institutions and researchers were largely free to proceed with a minimum of interference.

In the past few years, however, that placid picture has changed. The federal government, via federal agencies such as the Office of Human Research Protections (OHRP, formerly known as the Office of Protection from Research Risks) has disciplined numerous institutions for rules violations. The Justice Department, via

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10 See Goldner, supra note 9, at 98-99.

11 See id. at 98-99; see also Broad, supra note 9, at 35.

12 See Goldner, supra note 9, at 99-100.

13 See generally Paul E. Kalb & Kristin Graham Koehler, Legal Issues in Scientific Research, 287 JAMA 85 (2002) (noting that in 2000 ‘former DHHS Secretary Donna Shalala announced an ‘aggressive effort’ to improve education of clinical investigators, plans to provide clearer guidance on informed consent and conflicts of interest, and a series of other initiatives designed to improve compliance with the rules governing scientific research, particularly research on human subjects.”).


In May 1999 the Office for Protection of Research Risks (OPRR) briefly suspended the multiple project assurances (MPA) for all human subjects research at Duke University as a result of IRB deficiencies; this halted all federally sponsored research involving human subjects there until an acceptable corrective action plan was instituted. The OPRR and the Department of Veterans Affairs (VA) deactivated the MPA at the West Los Angeles VA Medical Center in March 1999,
the False Claims Act, has pursued research violations in cases where federal funds have been misused.\textsuperscript{15}

Probably the greatest upheaval has come from tort litigation.\textsuperscript{16} Medical researchers experienced relatively few lawsuits until the 1990s, when two events triggered a flurry of claims. The first was a report issued in 1995 by President Clinton’s Advisory Committee on Human Radiation Experiments, documenting widespread abuses during the 1940s, ‘50s, ‘60s, and even into the ‘70s, as government agencies and others conducted research involving radiation on a host of unsuspecting citizens.\textsuperscript{17} A number of suits followed those revelations.\textsuperscript{18} The second event was the 1999 death of Jesse Gelsinger, an eighteen-year-old who participated in gene transfer studies at the University of Pennsylvania.\textsuperscript{19} Allegedly the


\textsuperscript{17} See generally Alice Dembner, \textit{Lawsuits Target Medical Research}, \textit{B. GLOBE}, Aug. 12, 2002, at A1, available at \url{http://maillist.linuxmednews.org/pipermail/mednews/2002-August/000201.html} (last visited Sept. 21, 2003) (noting that medical researchers have long enjoyed relative immunity from lawsuits and the “increased federal prosecution of research fraud”).


\textsuperscript{19} See discussion infra Part I.

study’s risks were too great and the disclosures too limited.\textsuperscript{20} Since then a flurry of lawsuits have been filed, highlighting a variety of scenarios and diverse causes of action.\textsuperscript{21} With the rapid growth of medical research, a continued burgeoning of litigation can be anticipated.

Part I of this Article will review general trends in this emerging litigation, and Part II will lay some conceptual groundwork, discussing fundamental differences between research and ordinary medical practice. The pivotal distinction does not lie in the allegedly greater level of uncertainty characterizing research, but rather in its very different focus. Whereas ordinary medical treatment and even innovative treatment aspire to benefit the individual patient, research aims to gain generalizable knowledge, typically via protocols that, by the very essence of medical science, cannot aim to promote the benefit of any particular research subject. Research can thus subordinate the individual to a broader goal.

In light of this distinction, Part III shows that courts have not yet formulated an adequate theoretical basis for addressing the distinctive issues of research. On one hand, many courts regard research-related injuries as simply a genre of medical malpractice—an error that misunderstands the fundamental difference between research and ordinary practice. On the other hand, the relatively few courts that do clearly distinguish between research and medical practice have commonly made the mistake of placing research injuries into the realm of ordinary negligence—thereby failing to appreciate that researchers have far greater duties of care toward their subjects than the routine prudence that ordinary citizens owe fellow citizens.

After exploring courts’ confusion, this Article will review the available causes of action for addressing injuries that arise through human clinical research. Part IV will show that familiar causes of action may require adaptation before they can be appropriately applied to the research context. These include breach of contract, negligence, and property offenses. Another tort doctrine, breach of fiduciary duty, is not immediately applicable in research, because investigators must not be deemed fiduciaries of research subjects. However, when a standard physician-patient relationship—which


\textsuperscript{21} See discussion infra Part I.
is fiduciary—adds a research component, significant challenges emerge.

Two other causes of action deserve special consideration. Because deficiencies of information and consent comprise the most prevalent issues in research litigation, Part V examines battery and informed consent, concluding that both must be substantially modified before they can be suitably applied to human clinical research.

Overall this Article argues that, if familiar medical malpractice doctrines are applied uncritically to research injuries the dangers are, in the first place, that research participants may sometimes be left without appropriate remedy for their injuries. Reciprocally, investigators, sponsors, and others conducting research may be subjected to inappropriate or unfair standards of liability. Thus, this Article argues that human clinical trials need tort doctrines specifically adapted to the research setting.

I. CASE OVERVIEW

Case law regarding clinical research is relatively limited. Many of the cases introduced in this Part will be explored in greater detail below.

Some of the most well-known cases arise from research conducted under United States government auspices, some of it on troops and some on civilians. For instance, from 1953 to 1966, the CIA allegedly “financed a wide-ranging project... concerned with the research and development of chemical, biological, and radiological materials capable of employment in clandestine operations to control human behavior.” The program consisted of some 149 sub-projects which the Agency contracted out to various universities, research foundations, and similar institutions. At least 80 institutions and 185 private researchers participated. These studies aimed “to counter perceived Soviet and Chinese advances in brainwashing and interrogation techniques.” In one

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24 Id. at 162; see generally Scott, 562 F. Supp. at 476. Scott also discusses alleged abuses pursuant to the MKULTRA program. Id.
such experiment an Army serviceman was secretly given LSD,\(^{26}\) leading to personality disturbances, hallucinations, memory loss, and ultimately to divorce and discharge from the military.\(^{27}\) In another project, soldiers were directly exposed to radiation during nuclear bomb testing.\(^{28}\) However, in neither case were courts inclined to intervene in military decisions, citing broader societal interests\(^{29}\) and the need for military discipline.\(^{30}\)

In \textit{Begay v. United States},\(^{31}\) an array of government entities including the Bureau of Mines, the U.S. Geological Survey, the Public Health Service, and the Atomic Energy Commission undertook a long-term study of Navajo Indians who worked in uranium mines, to ascertain the kind and magnitude of danger from long-term exposure to uranium.\(^{32}\) Even after the dangers became fairly clear, the Indian miners were not informed, lest they cease working and thereby jeopardize the research.\(^{33}\) The court chose not to intrude upon the agencies' decision-making discretion.\(^{34}\)

In a related group of cases, military and other government agencies collaborated with civilian medical institutions. Many projects sought information about both the hazards and the potential medical value of radiation for the human body.\(^{35}\) From 1960-1972, for instance, the Department of Defense sponsored a study in


\(^{29}\) \textit{See id.} at 1239-40 (holding that "the interests of the society as a whole are advanced by holding certain individuals acting in special capacities free from legal action. ... Military service appears to be a situation where the Court would not independently grant a new cause of action under the Constitution.").

\(^{30}\) \textit{See Stanley}, 483 U.S. at 689. The Supreme Court found that Congress did not invite judicial "intrusion into military affairs." \textit{Id.} at 683. Justice Brennan in his dissent noted that initially the government invoked national security to cover its actions but that, by the time the Court ruled on the case, the military was primarily invoking military discipline. \textit{Id.} at 689 (J. Brennan, dissenting).

\(^{31}\) 768 F.2d 1059 (9th Cir. 1985).

\(^{32}\) \textit{id.} at 1060-61.

\(^{33}\) \textit{id.} at 1062, 1064-65.

\(^{34}\) \textit{id.} at 1064 (noting that "Congress wanted to prevent the courts from deciding in tort actions the policy and regulatory types of decisions that have been delegated to the agencies.").

\(^{35}\) \textit{Final Report of the Advisory Committee on Human Radiation Experiments}, stock number 061-001-00-848-9 (October 1995). As of October 15, the executive summary from this report is available at \url{http://tis.eh.doe.gov/ohre/roadmap/ohre/report.html}. 
which mainly poor, black cancer patients were subjected to total body radiation. Though the research aimed to understand the potential effects of radiation on soldiers in the battlefield, the patients were falsely told they were being treated for their cancer. In another study the Army Corps of Engineers ordered human subjects to be injected with plutonium to evaluate its long- and short-term effects. The unwitting patients included Janet Stadt, a forty-one year-old with scleroderma who, in 1946, was injected with 6.5 micrograms of plutonium and followed thereafter with periodic evaluations until her death thirty years later—a death preceded by severe bone degeneration and laryngeal cancer. In a 1953 experiment the Army Chemical Corps injected a psychiatric patient with a mesca-line derivative, completely unbeknownst to him or his family. The patient died immediately but the government concealed the truth until many years later, whereupon the Second Circuit determined that the family could recover additional compensation for the patient’s true damages.

Some cases featured straightforward medical, as opposed to military, research. One such project was conducted initially at the Brookhaven National Laboratory in the early 1950s, and then again in the early 1960s at the Massachusetts Institute of Technology and Massachusetts General Hospital. According to the federal district court, 140 patients with glioblastoma multiforme, a deadly form of brain cancer, were subjected to highly experimental treatment without their knowledge or consent. In a 1963 project sponsored

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37 Id. at 802.
39 Id.
40 Barrett v. United States, 689 F.2d 324, 326 (2nd Cir. 1982).
41 Id. at 332-33.
43 Id. at 54. The “boron neutron capture therapy” treatment involved surgical craniotomy, followed by the (attempted) injection of a boron compound into the circulation that served the tumor, followed by radiation with a stream of neutrons intended to destroy the cancer without damaging surrounding brain tissue. Id. at 54-55.
jointly by the United States Public Health Service and the American Cancer Society, live cancer cells were injected into debilitated elderly patients at a chronic disease hospital, likewise without their knowledge or consent.\textsuperscript{45} While it was already known that people with cancer have reduced ability to reject foreign cells, this study aimed to learn whether reduced immune function was directly due to the cancer, or instead attributable to cancer patients' more general debilitated state.\textsuperscript{46} It was hoped that injecting live cancer cells into weakened non-cancer patients would answer the question.\textsuperscript{47}

In virtually all these instances the litigation arose many years after the actual events.\textsuperscript{48} Hence, the respective courts focus heavily on procedural issues, such as whether fraudulent concealment should toll the statute of limitations.\textsuperscript{49} In \textit{Heinrich ex rel. Heinrich v. Sweet},\textsuperscript{50} the case involving 140 patients with glioblastoma multiformae, the federal district court found that for claims filed in New York, the state's definition of "fraudulent concealment" was not satisfied because that state requires affirmative acts of concealment.\textsuperscript{51} The statute of limitations had therefore expired for the New York cases.\textsuperscript{52} However, the litigation for Massachusetts plaintiffs could proceed because the Massachusetts definition holds that mere silence is fraudulent if a fiduciary such as a physician knows his patient has a cause of action.\textsuperscript{53}

\textsuperscript{45} Hyman v. Jewish Chronic Disease Hosp., 251 N.Y.S.2d 818, 820 (1964) rev'd, 206 N.E.2d 338 (N.Y. 1965). The subsequent litigation concerned not the merits of the scientific trial or the lack of informed consent, but rather, whether the director of the hospital should have access to otherwise private patient records. \textit{Id.} at 339. The appellate court thought not, but was overturned by the New York Court of Appeals on the ground that, since the corporation the director was responsible for might be liable, he is entitled to see them. \textit{Id.} The court also noted various moves that could shield patients' privacy. \textit{Id.}

\textsuperscript{46} \textit{Hyman}, 251 N.Y.S.2d at 820.

\textsuperscript{47} See \textit{id.}


\textsuperscript{52} See \textit{id.} at 304.

\textsuperscript{53} Id. at 304; see also Anderson v. George H. Lanier Mem'l Hosp., 982 F.2d 1513, 1519-20 (11th Cir. 1993); Barrett v. United States, 689 F.2d 324, 329-30 (2nd Cir. 1982); Mink v. Univ. of Chi., 460 F. Supp. 713, 720 (N.D. Ill. 1978); Bibeau v. Pac. N.W. Research Found., 980 F.
Because so many of these experiments were carried out under government auspices, a second common issue was whether qualified immunity would protect government workers from liability.\textsuperscript{54} A federal district court in Ohio summarized the relevant statute: "Section 1983, enacted in 1871, provides a right of action for parties deprived of their constitutional or federal statutory rights by actions taken 'under color of state law.' Section 1983 thus holds public officials who violate an individual's rights under the Fourteenth Amendment liable for that violation."\textsuperscript{55} In general, the statute attempts to reconcile two objectives: to protect public officials from the fear of being sued for every error of judgment, thus diverting their attention from their public duties, and at the same time, to recognize that violations of constitutional rights cannot be tolerated simply because they are committed by government officials.\textsuperscript{56} Hence, a section 1983 claim\textsuperscript{57} can potentially succeed if: [1] a constitutional or statutory right was violated; [2] the right was clearly established at the time of the events; [3] a reasonable person in that situation would have known that the defendant's conduct violated such a right.\textsuperscript{58}


\textsuperscript{56} Cincinnati Radiation, 874 F. Supp. at 807.


\textsuperscript{58} Heinrich v. Sweet, 62 F. Supp. 2d 282, 312 (D. Mass. 1999) (Heinrich III); see Ande v. Rock, 647 N.W.2d 265, 272-73 (Wis. Ct. App. 2002), cert. denied, 650 N.W.2d 840 (Wis. 2002); cert. denied sub nom. Ande v. Fost, 537 U.S. 1107 (2003), c.f. Barrett v. United States, 689 F.2d 324, 331 (2nd Cir. 1982) (establishing a slightly different test for a valid § 1983 test, namely that (1) the defendants subjected them to the deprivation of a federally protected right, (2) the defendants were acting under color of state law, and (3) plaintiffs are "persons" as that term is used in the statute with reference to injured parties); United States v. Stanley, 483 U.S. 669 (1987) (holding that a serviceman who unwittingly partici-
Aside from government and military research, research by private institutions and scientists has also prompted litigation. *Mink v. University of Chicago,*69 for instance, concerned women who were secretly given diethylstilbestrol (DES) during the early 1950s as an experiment to try to prevent miscarriage.60 *Karp v. Cooley*61 examined the adequacy of informed consent in a 1969 artificial heart implantation.62 *Burton v. Brooklyn Doctors Hospital*63 involved a 1950s evaluation of high-level oxygen used in the care of premature infants.64 Even though the practice was already suspected of causing blindness, infants were enrolled without their parents’ knowledge or consent, resulting in the plaintiff’s blindness.65 In *Anderson v. George H. Lanier Memorial Hospital,*66 poor, mostly illiterate patients undergoing surgery for cataracts were not told that their intraocular lens implants were experimental, and they were unable to read the consent forms they signed.67

64 460 F. Supp. 713 (N.D. Ill. 1978).
65 Id. at 715. The plaintiffs maintained that their daughters were at increased risk for cancer as a result of the experiment. Id.
67 Id. at 832.
69 982 F.2d 1513 (11th Cir. 1993).
70 Id. at 1515-16; see e.g., Frier v. JOLAB Corp. 607 A.2d 1111 (Pa. Super. Ct. 1992) (Patient sued hospital to recover for injuries sustained following implantation of intraocular lens, alleging failure to obtain informed consent for his participation in a clinical investigation); Kus v. Sherman Hosp., 644 N.E.2d 1214 (Ill. App. Ct. 1995); compare Research Roundtable, The “USF Case”: The University of South Florida ("USF") and Tampa General Hospital Agree to a $3,800,000 Payment in Settlement of a Lawsuit Over the Informed Consent Document in a Clinical Research Study, available at http://researchroundtable.com/USFcase.htm (last visited Nov. 21, 2003); see also Diaz v. Hillsborough County Hosp. Auth., 2000 WL 1682918 (M.D. Fla. 2000) (Economically poor, mostly Spanish-speaking, plaintiffs alleged that the consent forms they were provided prior to enrolling in obstetrics research were too sophisticated for their reading skills. None of the women alleged that they or their babies were harmed, nor did they deny that the research was IRB-approved. Nevertheless, when the case was certified as a class action, defendants determined it would be too costly to defend, and settled for $3.8 million.).
In Moore v. Regents of the University of California, the physician who removed a patient's spleen for therapeutic purposes discerned that the patient's cells could be developed into a lucrative cell line. Thereafter the patient was told to return repeatedly—under the ruse that it was for his benefit—so that the physician could continue to gather various tissue samples for research and commercial purposes.

Unlike many of the foregoing cases, the most recent spate of litigation does not typically feature completely unconsented research. Rather, the newer cases allege inadequate consent, mainly a failure to reveal information that might have prompted plaintiffs to decline to participate or to disenroll early.

In Grimes v. Kennedy Krieger, public health researchers attempted to determine whether less intensive procedures for removing lead from older housing in low-income neighborhoods might be sufficiently safe for children, while also inexpensive enough to encourage landlords to undertake appropriate clean-up rather than tearing down such buildings and thereby reducing the availability of low-cost housing. The study involved testing three lead abatement techniques, which in turn meant following the children who lived in the homes under study. Allegedly, the investigators permitted children to stay in a lead-borne environment even while lead levels in their blood rose, without informing the children's parents promptly enough.

Kernke v. The Menninger Clinic Inc. featured a psychiatric patient who, during testing of a new drug, became increasingly depressed and psychotic. He absconded from the institution and months later was found dead of exposure. Ande v. Rock was a complex case involving not a treatment intervention but a question

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67 Id. at 481. Although the California Supreme Court did not agree that the taking of these tissues constituted conversion of property, it did find a breach of fiduciary duty and of the duty to obtain informed consent. Id. at 497.
68 782 A.2d 807 (Md. 2001).
69 Id. at 821.
70 Id. at 811-12.
71 See id. at 828-29.
73 Id. at 1349-50.
74 Id. at 1351.
about whether results of prenatal diagnostic testing should be made available to parents, even in the absence of proven treatment for the illness.78

A flurry of still more recent cases followed the 1999 death of Jesse Gelsinger during a gene transfer study.79 Most of these cases claim informed consent was inadequate, alleging injuries such as wrongful death, fraud, negligence, emotional distress and the like.80 Additionally a number of these suits attempt to institute novel tort causes for breach of the right to be treated with dignity, consistent with the Nuremberg Code and the Declaration of Helsinki, and for violations of the federal rules that govern human research protections.81

II. A Need For Clarity: Research Versus Medical Practice

If courts are to take a systematic, jurisprudentially well-founded approach to research-related injuries and injustices, they need a clear concept of what research is and how it differs from

78 See id., at 274-75. Among other holdings the Wisconsin appellate court found that, because no physician-patient relationship had been established, there could be no medical malpractice claims, such as for breach of informed consent. Id. at 269.
80 See id.; see generally, Jeffrey H. Barker, Commentary: Human Experimentation and the Double Facedness of a Merciless Epoch, 25 N.Y.U. REV. L. & SOC. CHANGE 603, 618-19 (1999) (noting that "informed consent procedures, properly followed, are troublesome, time-consuming, and may even threaten proprietary information valuable to the biotech companies," and that researchers in the Jesse Gelsinger case may have bypassed informed consent procedures so that he would not choose to leave the trial).
ordinary medical practice. That clarity has long been available in
the literature of research ethics, although, as seen below, courts
seem unfamiliar with it.

Research must be distinguished on one hand from ordinary
medical treatment and on the other hand from clinical innovation.
Contrary to some scholars, research is not accurately distinguished
by greater uncertainty about the risks and benefits of an interven-
tion, or heightened concern about conflicts of interest as a physician
attends to issues beyond the needs of his immediate patient.82 After
all, in ordinary clinical care, uncertainties can permeate even the
most mundane treatments, such as when a physician may try one
hypertension drug and then another to see which works best for a
particular patient.83 More broadly, the standards of medical practice
shift constantly as new information shows which accepted inter-
ventions are, and which are not, genuinely useful.84 By the same token,
ordinary medicine can be permeated with conflicts of interest, as
commentators on managed care have been quick to point out.85

Uncertainties of clinical innovation can reach even further than
those of ordinary care as the physician modifies a procedure, puts
an existing drug to a new use, or tries some other significant devia-
tion from standard practice in hopes it will help a particular patient.
Innovation may be necessitated by the fact that no existing approach
will help that patient; other times the physician simply thinks he can

82 See Noah, supra note 1, at 570-71 (pointing to these three elements as key justifications for
why courts might want to require more rigorous informed consent requirements in the
research context).

83 See E. Haavi Moreim, A Dose Of Our Own Medicine: Alternative Medicine, Conventional
Medicine, and The Standards of Science, 31 J.L. MED. & ETHICS 222, 223 (2003), for a dis-
sussion of the uncertainties in routine medicine. See E. Haavi Moreim, Professional And
Clinical Autonomy in the Practice of Medicine, 69 Mt. Sinai J. Med. 370, 371 (2002) for a broad
literature discussion of the conflicts of interest for physicians in routine practice, particu-
larly those arising through various ways of remunerating physician services.

84 See J. Bruce Moseley et al., A Controlled Trial of Arthroscopic Surgery for Osteoarthritis of the
Knee, 347 New Eng. J. Med. 81, 81 (2002). Arthroscopic debridement or lavage for osteo-
arthrosis of the knee has been performed on more than 650,000 people per year, based mainly
on theoretical promise and two methodologically limited studies. Id. Only recently did a
gold-standard randomized, double-blind, placebo-controlled trial show that this pro-
cedure is no better than a sham surgery in which no surgical invasion of the knee took place.
Id. at 81, 85; see also David T. Felson & Joseph A. Buckwalter, Debridement and Lavage For

85 See E. Haavi Moreim, Balancing Act: The New Medical Ethics of Medicine's New
Economics 61 (1995); Marc Rodwin, Conflicts in Managed Care, 332 New Eng. J. Med. 604,
604-05 (1995); Dennis Thompson, Understanding Financial Conflicts of Interest, 329 New Eng.
Analyses of New Drugs Used in Oncology, 282 JAMA 1453, 1453, 1455 (1999).
improve on existing techniques or management strategies. However, the bare fact that an innovation elevates the uncertainties does not, of itself, render that innovation a form of research, even if one might rightly argue that innovations such as new surgical procedures or off-label drug uses ought to be validated by research before they become widely used.

Goals, not uncertainties, mark the basic difference between research on one side, versus ordinary practice or clinical innovation on the other. Ordinary and innovative practices both aim to benefit an individual patient. Ordinary care does so, essentially by definition as a physician diagnoses and treats his particular patient. In innovation, the physician pushes beyond standard boundaries because routine options may be inadequate or inappropriate for this person. But in either case the physician’s objective is to tune his care to the specific needs and interests of that individual. Indeed, innovation is often the ultimate in individualizing care, as the physician customizes therapy according to personal or situational idiosyncrasies.

The goal of research is fundamentally different. It does not aim to benefit any specific individual, but rather to advance generalizable knowledge and thereby to benefit broader populations. Any such advance, by the very essence of clinical medical science, requires that data be gathered systematically, typically according to a protocol that provides appropriate hypotheses, controls, definitions, procedures and endpoints. If facts are not gathered in a con-

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87 See Sam Horng & Franklin Miller, Is Placebo Surgery Unethical?, 347 NEW ENG. J. MED. 137, 137 (2002) (noting that “clinical trials are not designed to promote the medical best interest of enrolled patients and often expose them to risks that are not outweighed by known potential medical benefits”), see also Steven M. Grunberg & William T. Celotu, The Informed Role of Clinical Research in Clinical Care, 348 NEW ENG. J. MED. 1386, 1386 (2003) (noting that “the performance of clinical research has always been acknowledged to entail an essential conflict between the individualization of patient care and the standardization of the scientific method”).
88 See Morin, supra note 3, at 166-67 (contrasting Levine’s definition of research as “a class of activities designed to develop or contribute to generalizable knowledge [which] consists of theories, principles, or relationships for the accumulation of data on which they may be based] that can be corroborated by accepted scientific observation and inference” with Levine’s definition of medical practice as “a class of activities designed solely to enhance the well-being of an individual patient or client. . . . to provide diagnosis, preventive treatment, or therapy”), see also Robert Levine, supra note 86, at 24; cf. Spencelev v. M.D. Anderson Cancer Ctr., 936 F. Supp. 308, 398 (S.D. Tex 1996) (noting that “[t]he essence of research is that no current practice exists from which a standard of reasonable prudence could be derived.”).
sistent fashion according to specified rules, then they cannot add up to scientifically credible generalizations—and the project is unworthy of the name “clinical research.”

Note that this is not simplistically reducible to intent. The bare fact that a physician would like to draw general conclusions from his personal observations does not mean that he has undertaken research in any meaningful sense of the word. The crucial factor is the design and discipline of the activity. If the activity is designed “‘to test an hypothesis, permit conclusions to be drawn,’ and thereby to develop or contribute to generalizable knowledge, it is research.”

By implication, instead of attuning interventions to the peculiarities of each patient, the methodologies of research, such as randomization, double-blinding and placebo control, must often subordinate an individual enrollee’s personal interests and desires to the protocol. The patient may be exposed to the unknown hazards of a new treatment or reciprocally may receive only placebo instead of an active drug, even if he entered the study in hopes of getting that drug. Commonly a drug dosage cannot be raised or lowered even when such a change might suit the patient better, unless explicitly permitted by the protocol. The patient may be required to forego helpful medications altogether during a “washout” period, or may be precluded from treating side-effects with adjuvants such as decongestants or sleeping pills. He may have to remain in the hospital longer than he would otherwise need to, or

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90 See Goldner, supra note 9, at 113-14 (stating that “[o]n the issue of intent, there is little doubt that physicians may use innovative therapy for a number reasons [sic]: out of desperation because established procedures do not work; because they believe that the innovative therapy method is better; or because they believe that standard therapy is actually harmful or dangerous.”).


92 See Robert Levine, Informed Consent in Research and Practice, 143 ARCHIVES INTERNAL MED. 1229, 1231 (1983) (“the goal of research—the development of generalized knowledge—is advanced by working according to a detailed protocol.”).

93 Robert Levine, Uncertainty In Clinical Research, 16 L. MED. & HEALTH CARE 174, 178 (1988) (“the individualized dosage adjustments and changes in therapeutic modalities are less likely to occur in the context of a clinical trial than they are in the practice of medicine. This deprivation of the experimentation ordinarily done to enhance the well-being of a patient is one of the burdens imposed on the patient-subject in a clinical trial.”).
may experience unexpected, unpleasant side-effects. Thus, Jay Katz recommends that investigators tell prospective subjects very explicitly "that their therapeutic interest, even if not incidental, will be subordinated to scientific interest."

Several points should be emphasized about the nature and possibility of benefit in research. It is true that many research projects have in fact brought significant benefits to the projects' participants as well as to future patients. Indeed, there is evidence that people in research studies may fare better simply by being in a trial (e.g., via receiving closer attention). However, it is not the goal of any research protocol to benefit any specified individual. Rather, it is to learn information. Benefit to any given individual is thus by good fortune, not by design, even if it happens that many individuals in that study benefit.

Moreover, there is no advance assurance that anyone at all will benefit. "[O]f all drugs tested in the hope of approval by the Food and Drug Administration, about 80 percent fail." Even in Phase IV research, commonly designed to compare two approved and clearly effective approaches, a research subject may be assigned to a drug that is personally less effective for him, and thus may receive less

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94 Jay Katz, Human Experimentation and Human Rights, 38 ST. LOUIS U. L.J. 7, 14-15, 34 (1993) ("[I]n therapeutic encounters, unlike research encounters, physicians are expected to attend solely to the welfare of the individual patient before them... in clinical research, on the other hand, patient-subjects are also being used for the ends of science."); Morin, supra note 3, at 221 (stating research subjects should understand "that they do not place their trust in physicians to regain their health, but rather that they rely on a scientific experiment to yield valuable knowledge to make their participation meaningful.")

96 Emergency Care Research Institute, Should I Enter a Clinical Trial? A Patient Reference Guide for Adults With a Serious or Life-Threatening Illness, (February 2002), available at http://www.erci.org/documents/prg/prg.html; Miller & Rosenstein, supra note 93 at 1383; Miller & Brody, supra note 93, at 21-22; Larry Churchill et al., Assessing Benefits in Clinical Research: Why Diversity in Benefit Assessment Can Be Risky, 25 IRB: ETHICS & HUMAN RESEARCH 1, 3 (2003). But see Peppercorn JM, Wokes JC, Cook EF, Ioffe S, Comparison of Outcomes in Cancer Patients Treated Within and Outside Clinical Trials: Conceptual Framework and Structural Review, LANCASTER 2004 363, 363-70 ("Despite widespread belief that enrollment in clinical trials leads to improved outcomes in patients with cancer, there are insufficient data to conclude that such a trial effect exists. Until such data are available, patients with cancer should be encouraged to enroll in clinical trials' unquestioned role in improving treatment for future patients." Id. at 363).

97 Abate, supra note 2, at A1.
benefit than he would if he were simply receiving the ordinary
treatment of his choice.97

In research, subjects' individual needs and preferences can
only enter in either of two ways: via whatever flexibility a protocol
may have built in to accommodate personal variation and prefer-
ence or, if the study poses significant problems for an individual,
via removing that person from the study altogether. In this sense,
the interests of the individual constitute a "side constraint"98 of
the project. That is, deference to individuals is a limiting factor, not
the goal of the activity. Individual needs do not steer the study
overall.99

This does not mean, of course, that people cannot sign onto a
trial hoping for benefit, or that a research project can not provide
real benefits for some or even many enrollees. Neither does it mean
that an investigator cannot rightly say to a prospective enrollee that
a given research study might help him. Indeed, a trial may offer
hope for those who have none, or might bring improved treatments
for those whose disease has few or no other options—even if it will
not be known until the trial is over whether the new intervention
really is better. The important point is that any plausibly predicted
benefit is never aimed specifically at this or that individual.

97 See Paul Appelbaum et al., INFORMED CONSENT: LEGAL THEORY AND CLINICAL PRACTICE
237-40 (1987) for further discussion of the ways in which research can subordinate
the personal interests of individuals to the broader goal of gaining general knowledge. Appel-
bbaum et al., supra note 93, at 20-21; See also Charles Fried, MEDICAL EXPERIMENTATION:
PERSONAL INTEGRITY AND SOCIAL POLICY 47, 52 (1974); Paul Appelbaum et al., The Therapeu-
tic Misconception: Informed Consent in Psychiatric Research, 5 INT'L J. & PSYCHIATRY 319,
320-21 (1982).

98 See Robert Nozick, ANARCHY STATE AND UTOPIA 32 (1974). The author notes that "in
contrast to incorporating rights into the end state to be achieved, one might place them as
side constraints upon the actions to be done. . . . The rights of others sustain the contras-
ts upon your actions. . . . The side-constraint view forbids you to violate these moral
constraints in the pursuit of your goals." Id. at 29. Further, he notes that a specific side
constraint upon action toward others expresses the fact that others may not be used in the
specific ways the side constraint excludes. Side constraints express the inviolability of
others. Id. at 32.

99 Miller & Brody, supra note 93, at 19-28. As noted by Miller and Brody, this view contrasts
with an alternative in which the researcher is thought to owe his patient the best available
treatment. Id. This approach, in which the researcher has therapeutic duties under the
doctrine of "clinical equipoise," commits the so-called "therapeutic misconception," con-
flating research with clinical care and inviting research subjects erroneously to believe
research is inherently beneficial and indeed leaving them more vulnerable than ever to
potential exploitation. Id. Rather, argue Miller and Brody, research must be guided by a
very different ethic than that guiding clinical care. Id. at 21-22.
In sum, the distinction between research and ordinary or even innovative care is not a matter of uncertainties or the likelihood of benefit. Rather, it is a difference in objectives. As noted by Nancy King:

A research protocol is not treatment, no matter how much all parties wish it so. Treatment requires genuine attention to the best interests of the patient as an individual, including individual attention and individual tailoring or complete changing of any regimen for maximal efficacy. Even if the organization, scope, and duration of a clinical trial were compatible with these goals, the uncertainties and unknowns attendant upon use of an unproven intervention make individual tailoring almost meaningless, especially in early-phase trials. Moreover, the trialists’ mandate to collect data systematically makes individual tailoring largely incompatible with the development of generalizable knowledge.\footnote{Nancy M. P. King, Defining and Describing Benefit Appropriately in Clinical Trials, 28 J. L. Med. & Ethics 332, 339 (2000).}

III. CONFUSION IN THE COURTS

A. Research Injuries as Medical Malpractice

Across the fairly limited body of case law addressing clinical research, courts are often confused about the difference between re-

\footnote{Two recent cases have wrestled with the question whether health care providers' interventions constituted research or something else. In Ancheff v. Hartford Hospital, a hospital instituted a protocol for aggressively treating a particularly difficult bone infection. 790 A.2d 1087, 1089 (Conn. 2001). The plaintiff, who developed hearing and balance problems from antibiotics, claimed that the hospital had engaged in research without appropriate informed consent, on the grounds that a protocol was used, that it was 'radical,' that the hospital gathered data on patients’ progress while on the treatment, and shared this information with other health care providers. Id. at 1089-90. The hospital responded that this was simply a systematic implementation of the best available information, that there was no attempt to use control groups or to compare two research 'arms' to see which approach might be better, nor were there any other key features of research. Id. at 1071-72. The plaintiff tried repeatedly to enter the Belmont Report in its entirety into the record, a move the judge consistently denied as prejudicial because of its references to Nazi research and other abuses. Id. at 1070, 1079. By the time the plaintiff finally sought only to admit the Report's definition of "research" the court had had enough and permitted no further discussion of the matter. Id. at 1079-80. The state supreme court found no obvious error in this response: id. at 1080.}
research and standard medical practice. Many courts see research injuries as a variant of ordinary medical malpractice.\textsuperscript{101} As discussed just below, this approach is seriously problematic. Reciprocally, some other courts seem to regard research as simply a variant of ordinary negligence. As discussed following, this too is erroneous.

Courts' tendency to equate medical practice with research is understandable. After all, many research projects feature both treatment and research. For instance, a physician might bring a protocol trying the latest arthritis or hypertension drugs to his patients who suffer these ailments. Historically, early courts saw any sort of experimentation or innovation as essentially a form of malpractice because, by definition, these activities deviate from standard practice.\textsuperscript{102} Not until 1935 was there explicit recognition that deviation from routines can be legitimate.\textsuperscript{103} As explained by the Michigan Supreme Court, "[w]e recognize the fact that, if the general practice of medicine and surgery is to progress, there must be a certain amount of experimentation carried on; but such experiments must be done with the knowledge and consent of the patient or those responsible for him, and must not vary too radically from the accepted method of procedure."\textsuperscript{104}

Only considerably later do we see courts more explicitly addressing research situations. However, even while they recognize that research-based deviation from medical practice is not per se malpractice, courts nevertheless have often regarded research-based injuries as just another genre of medical malpractice.\textsuperscript{105}

\textit{Moore v. Regents of the University of California} \textsuperscript{106} is a salient example. Although John Moore's hairy cell leukemia genuinely required the removal of his spleen, Dr. David Golde thereafter repeatedly required Moore to return to Los Angeles from his home in Seattle so that Golde could remove blood, blood serum, skin,


\textsuperscript{102} Goldner, \textit{supra} note 9, at 71-72 (stating in the late 19th century and first half of the 20th century, courts "generally treated non-standard medical practice as improper experimentation; such cases included treatment of osteomyelitis with radio waves, treatment of impotency, hypertension, prostate and kidney disease with a compound surgical procedure, and a futile attempt to create a skin graft." (citations omitted).


\textsuperscript{104} Id.

\textsuperscript{105} See Jansson, \textit{supra} note 101, at 238-39.

bone marrow aspirate, and sperm samples under the pretext that these procedures were for the patient’s benefit and could only be performed at UCLA under Golde’s direction.\textsuperscript{107} In fact, virtually none of these post-splenectomy tissue-samplings were or even could have been medically helpful to Moore.\textsuperscript{108} Moore’s active treatment from Golde ended with the splenectomy.\textsuperscript{109}

\textsuperscript{107} Id., at 481.

\textsuperscript{108} Id. Moore was diagnosed in 1976. Id. See generally Harvey M. Golomb & James Vardiman, Hairy-cell Leukemia, in CANCER MEDICINE e5 2002, 2005 (Robert C. Bast Jr. et al. 2000). Other than splenectomy, only symptomatic treatments were available until 1984, when interferon-alpha became available. The author states “[a]lthough splenectomy was the indicated treatment in the 1970s to correct the effects of hypersplenism, by the early 1980s, recombinant interferon-alpha . . . was shown to be effective systemically.” Id. at 2002.

“The clinical course of HCL [hairy cell leukemia] is variable, but most often it is chronic . . . . Median survival was over 5 years prior to the introduction of effective systemic therapy . . . . Up to 10% of patients have mild disease, require no treatment, and have prolonged survival.” Id. at 2003 (citations omitted).

“Before the development of the newer systemic therapies that induce complete remissions, the intent of therapy had been to relieve symptoms and to prevent the frequent complications of the progressive disease.” Id. at 2004.

“Until the late 1980s, splenectomy was often the first therapeutic modality offered to patients with symptomatic cytopenias or splenomegaly. . . . Several investigators have retrospectively reviewed the results of splenectomy in patients with HCL and report an overall response rate of 80-100%, with hematologic complete remissions occurring in 40-60%.” Id. at 2005 (citing Herman J. Jansen, Splenectomy in Hairy Cell Leukemia, in 47 CANCER 2006 (1981); G. Flandrin, et al., Hairy Cell Leukemia: Clinical Presentation and Follow-up of 211 Patients, in 11 SEMINAR IN ONCOLOGY 458 (1984); Harvey M. Golomb & James W. Vardiman, Response to Splenectomy in 65 Patients With Hairy Cell Leukemia: An Evaluation of Spleen Weight and Bone Marrow Involvement, in 61 BLOOD 349 (1983); C.J.H. Ingoldsky, et al., Splenectomy For Hairy Cell Leukemia, 7 CLINICAL ONCOLOGY 525 (1981); A. S. Van Norman, et al., Splenectomy For Hairy Cell Leukemia, in 57 CANCER 644 (1986)).

Of special importance is the fact that almost none of the various tissues Golde harvested from Moore could even be used to monitor his wellbeing, because remissions in the splenectomy series are defined solely by improvement in peripheral blood cytopenias . . . . [A] complete remission requires a hematocrit above 36%, a neutrophil count above 1,000 per microliter, and a platelet count above 100,000 per microliter; a partial remission requires this degree of improvement in only one or two cell lines with persistent cytopenia in the other line(s); and no response is anything less than a partial response.

Id. at 2005.


After the operation, Moore ‘recover[ed] from the symptoms [he] had exhibited before,’ and although Golde ‘never used the word remission, Moore felt that he had ‘stabilized.’ Despite Moore’s apparent recovery, Golde requested that
Nevertheless, the California Supreme Court essentially treated the case as ordinary medical treatment and malpractice.\textsuperscript{110} The court found that the failure to disclose the research interest was a breach of informed consent and that a treating physician’s failure to reveal his personal interest was a breach of fiduciary duty.\textsuperscript{111} Unfortunately, the court regarded Golde’s repeated duplicitous invasions as though they were “treatment” and the research were simply another conflict of interest in the setting of ordinary medical care, analogous to a physician’s ownership of a pharmacy to which he might refer his patients.\textsuperscript{112}

That analysis is deeply problematic. First, the medically pointless tissue removals could not have been malpractice because they were not medical practice at all, if we accept Craft’s definition, discussed below, that medical treatment aims “to benefit or cure the patient.”\textsuperscript{113}

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Moore continued to see him periodically “so that Golde could continue to check up on the condition of the disease.” Moore traveled from his home in Seattle to Los Angeles approximately twelve times to visit Golde who, on each occasion, withdrew samples of ‘blood, blood serum, skin, bone marrow aspirate, and sperm.’ During this time, Golde and his research assistant were conducting research on Moore’s cells and planned to ‘benefit financially and competitively’ by exploiting the cells and their exclusive access to them by virtue of Golde’s ongoing physician-patient relationship with Moore.

In testimony,

Moore, at one point, mentioned that he could not afford to continue to travel to Los Angeles and suggested that he obtain his continuing care in Seattle. In response, Golde told Moore that he would obtain grant funds to pay for Moore’s trips. Later, when Moore expressed concern about the cost of accommodations, Golde offered to pay Moore’s expenses at a ‘luxurious hotel in Beverly Hills.’ On the first trip thereafter, Golde presented Moore with a ‘very elaborate and very complicated’ consent form purporting to ‘give away the rights to [the] cell line and products derived therefrom.’ Unaware of Golde’s development efforts, Moore signed the form giving his consent. On his next and last visit, Golde again asked Moore to sign a form. Moore, believing that Dr. Golde’s answers to his questions were ‘vague and . . . quite patronizing,’ signed the form explicitly withholding his consent by circling a box marked ‘I do not consent.’ Moore became suspicious and contacted an attorney as Golde repeatedly tried to persuade Moore to sign the form ‘in the correct fashion.’ Moore subsequently filed suit against the Regents, as patent holders, and against Golde and his research assistant.

\textit{Id.} at 130-31 (citations omitted).

\textsuperscript{110} \textit{See generally}, Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990), \textit{cert. denied} 504 U.S. 986 (1992).

\textsuperscript{111} \textit{Id.} at 480, 483, 485.

\textsuperscript{112} \textit{Id.} at 483-84 (citing Magan Medical Cl. v. California State Bd. of Med. Exam., 57 Cal. Rptr. 256 (1967)).

\textsuperscript{113} Craft v. Vanderbilt Univ., 18 F. Supp. 2d 786, 796 (M.D. Tenn. 1998).
Second, applying standard malpractice tort concepts to this situation significantly underrates the seriousness of Golde's offenses. Medical malpractice requires not just that the physician breach a duty of care, but that this breach cause an injury—typically a physical injury. While Moore was caused inconvenience, some personal expense, and the discomfort of needless punctures, these were hardly the most important injury, and under ordinary malpractice law these are at most only nominally compensable. The real injury was that Moore was exploited, completely without his knowledge or consent, for others' ulterior gain. Yet this dignitary offense is not typically deemed a compensable injury under malpractice law. And while the court did find that Dr. Golde breached his fiduciary duty as a physician to this patient, breaches of fiduciary duty do not ordinarily give rise to significant damage awards. They are usually addressed as problems of equity. At least within the sphere of medicine and malpractice, equity remedies are usually simple requirements to refrain from the suspect conduct in the future, to restore ill-gotten gains, or remedies of similar genre. In Moore's case the California Supreme Court denied that the gains Golde received from using Moore's tissues were "ill-gotten," as it denied Moore's property claim to the financial proceeds of the cell line. As a result, invoking standard medical mal-


115 Bergman, supra note 109, at 130.

116 For further discussion of what should be counted as injuries in research-related litigation, see discussion infra Part V.B.2.

117 Moore v. Regents of Univ. of Cal., 793 P.2d 479, 486 (Cal. 1990).

118 Mertens v. Hewitt Assoc., 508 U.S. 248 (1993) (noting the types of "relief that were typically available in equity [include] injunction, mandamus, and restitution..."); see also Russell v. Northrop Grumman Corp., 921 F. Supp. 143, 145 (E.D.N.Y. 1996) (stating if monetary damages are "restitutionary in nature" they "will be considered equitable, not legal..."). Cf. Thomas R. McLean & Edward F. Richards, Managed Care Liability For Breach of Fiduciary Duty After Pogran v. Herdrich: The End of ERISA Preemption for State Law Liability for Medical Care, 53 HAM. L. REV. 1, 44 (2001) (noting that even under equity, monetary compensation for breach of fiduciary duty can be awarded to make injured parties whole). Although breach of fiduciary duty can be compensable, large monetary awards of the kind found in medical malpractice cases are not commonly found via equity. Id.

119 Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 497 (Cal. 1990).
practice theories to redress Moore’s injuries appears too limited, compared with the significance of the abuse.

A similar problem appears in *Kernke v. Menninger Clinic Inc.* A schizophrenic patient, voluntarily admitted to a psychiatric hospital, was told by his physician that he “would benefit from” participating in a research study. The patient signed a consent form, though his capacity to understand it was later questioned. Through a two-week “washout” period with no medication, followed by the experimental drug, the patient became increasingly depressed and psychotic, with worsening tardive dyskinesia, a significant neurologic side-effect. He wandered away from the institution, which then conducted only a limited search for him. Months later he was found in some woods a mile away, dead presumably from exposure.

The court dismissed via summary judgment all of the plaintiff’s claims other than medical malpractice—claims such as intentional infliction of emotional distress and fraudulent misrepresentation—on the ground that these were simply duplicative of the malpractice claim. “Kansas courts will not permit a plaintiff to ‘creatively classify’ a claim as something other than one for medical malpractice if the substance of the claim concerns the physician-patient relationship. . . . [E]ach of these additional claims involve [sic] the Menninger defendants’ care and treatment of Kenneth Kernke while he was a patient at the Menninger Clinic. . . . The essence of the claims simply does not extend beyond allegations that the Menninger defendants breached their duty of care to Kenneth Kernke.

It should by now be evident that this reasoning is misguided. Admittedly, some of Kernke’s care was routine medical practice, and some of his story, such as the failure to search for him following his disappearance, would rightly be addressed under familiar negligence and malpractice doctrines. But the bare fact that a physician has performed an intervention, or that it required some professional knowledge or skill, does not mean that intervention was medical.

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121 Id. at 1350.
122 Id. at 1350, 1356.
123 Id. at 1350.
124 Id. at 1351.
125 *Kernke*, 172 F. Supp. 2d at 1351.
126 Id. at 1353-54.
practice. Much of Kernke’s care was not ordinary medical practice. There was nothing “usual” or “standard” about the washout period or the experimental medication. These were governed by protocol, not customary practice. As in the previous cases, the court simply failed to appreciate the need for a third category—neither medical malpractice nor ordinary negligence, but a specific recognition of negligent research injuries.

Heinrich v. Sweet shares the same flaw. Patients with terminal brain cancer were subjected to “boron neutron capture therapy,” a highly experimental radiation-based treatment, allegedly without their knowledge or consent. Across the plethora of procedural and other rulings issued during the case, the federal district court expressly regarded this research as ordinary medical practice: “under the law of Massachusetts and New York, medical

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129 See discussion supra notes 42-54, and accompanying text.
130 118 F. Supp. 2d 73, 75 (D. Mass. 2000) (Heinrich V). The factual summaries of the Heinrich case provided by the district court differ markedly from those of the First Circuit. Once the case finally went to a jury after procedural issues were resolved, the jury found that informed consent duties had not been breached. Id. This fact is somewhat grudgingly acknowledged by the district court. Id. (Heinrich et al., Heinrich v. Sweet, 118 F. Supp. 2d 73, 83 (D. Mass. 2000) (Heinrich V)), but emphasized by the First Circuit (Heinrich v. Sweet, 2002 WL 1944863 (1st Cir. 8/27/2002) (Heinrich VI)).
131 44 F. Supp. 2d 408, 418-19 (D. Mass. 1999) (Heinrich I) (denying defendant’s motion to dismiss for lack of subject matter jurisdiction); 49 F. Supp. 2d 27, 36-38, 40, 42-43, 45-46 (D. Mass. 1999) (Heinrich II) (granting motions to dismiss on counts: III battery, IV intentional infliction of emotional distress, V strict liability for inherently dangerous acts, VI personal injury caused by exposure to toxic substances, IX civil responsibility for crimes against humanity, and denying motions to dismiss on counts: II civil fraud, VII absence of consent, VIII wrongful death claim, X negligence, XI negligent misrepresentation); 62 F. Supp. 2d 282,326 (D. Mass. 1999) (Heinrich III) (denying United States’ motion to dismiss, granting MIT’s motion for partial summary judgment, and granting in part and denying in part the Brookhaven defendant’s motion for summary judgment and motion to dismiss, Mass General’s motion for judgment on the pleadings and MIT’s motion to dismiss); 83 F. Supp. 2d 214, 224 (D. Mass. 2000) (Heinrich IV) (granting United States’ motion to dismiss based on the government contractor exception); 118 F. Supp. 2d 73, 92 (D. Mass. 2000) (Heinrich V) (granting defendant’s motion for reduction of jury verdict, ruling the correct wrongful death statute was the statute in effect when action arose, ruling the statute of limitations for wrongful death was tolled, and denying Massachusetts General’s motion for judgment as a matter of law on charitable immunity); 2002 WL 1944863 at 71 (1st Cir. 2002) (Heinrich VI) (affirming the district court’s judgment for the United states, vacating the jury verdict for the plaintiffs on the negligence and wrongful death claims, and entering judgment for the defendants Dr. Sweet and Massachusetts General (MGH)).
experimentation should be analyzed under the legal standards governing ordinary medical treatment.\textsuperscript{132}

To the extent that courts equate research with ordinary practice, they seem to be laboring under their own "therapeutic misconception," an assumption that somehow research, simply because it involves medical interventions, must be geared toward providing direct benefit for each patient, and that therefore the proper standard for assessing research interventions must be the same as for standard medical care.\textsuperscript{133} As should now be evident, courts ought instead to regard research as a fundamentally different kind of activity from standard medical practice.\textsuperscript{134}

In a related version of the same problem, courts seem equally confused about the difference between research and clinical innovation. As argued above, innovation is a genre of medical practice, not research, in that the physician modifies ordinary procedures in hopes of serving his individual patient better. The uncertainties may (or may not)\textsuperscript{135} be greater than in routine care, but the physician's focus is still on the individual patient. The modifications in that patient's care are not part of an attempt to gain generalizable scientific knowledge, nor are the patient's personal interests ever subordinated to the demands of a protocol.

\textit{Whitlock v. Duke University}\textsuperscript{136} exemplifies the courts' failure to distinguish innovation from research. The case featured a simulated deep-diving experiment in which volunteers were exposed to high atmospheric pressures of the type found at various depths under water.\textsuperscript{137} The plaintiff claimed that the organic brain damage he later developed was attributable to the research and that he had not been adequately warned about this possibility.\textsuperscript{138} Finding for the defendant, the court discussed the applicable informed consent

\begin{footnotesize}

\textsuperscript{133} See Appelbaum, et al, \textit{supra} note 97, at 321. See generally Appelbaum et al., \textit{supra} note 93, at 20.

\textsuperscript{134} Miller \& Brody, \textit{supra} note 93, at 20-23, 25 (discussing in detail the conceptual and ethical problems inherent in seeing research as a therapeutic enterprise).

\textsuperscript{135} See generally Noah \textit{supra} note 1, at 388 (explaining that the physician's intent is a factor in determining whether an activity is treatment or research).


\textsuperscript{137} Id., at 1467.

\textsuperscript{138} Id.
\end{footnotesize}
criteria, finding that although the issue had not been specifically addressed heretofore, a higher standard of information is required in so-called "nontherapeutic" clinical research, such as this experiment, than would apply to so-called "therapeutic" research.\textsuperscript{139}

Unfortunately, although the court ostensibly distinguishes between medical treatment and research, its decision was based on an important confusion, because the court misunderstood the main case on which its conclusion was based. \textit{Estrada v. Jaques}, which allegedly added "therapeutic research" to the ambit of North Carolina's medical informed consent statute, did not in fact concern research at all.\textsuperscript{140} Rather, it concerned innovation as a surgeon and a radiologist tried to treat a patient's blood clot with a procedure that had hardly been used elsewhere, and with which they themselves had no experience.\textsuperscript{141} These doctors were trying something new to help their patient, and given the complete absence of any effort to use a scientific protocol toward gaining generalizable knowledge, their treatment of this patient was not research.\textsuperscript{142} It was innovation. Hence, the real holding of \textit{Estrada} was simply that practicing physicians should inform patients when they want to help them via a new, untested procedure.\textsuperscript{143}

\textsuperscript{139} \textit{Id.} at 1471-72. The federal district court found that there was no mandate to warn the plaintiff about this alleged danger. \textit{Id.} at 1472. Because there was no evidence of any connection between deep diving and organic brain damage, it could not be deemed a foreseeable risk. \textit{Id.}

\textsuperscript{140} 321 S.E.2d 240, 243 (N.C. Ct. App. 1984).

\textsuperscript{141} \textit{Id.} at 253-54.

\textsuperscript{142} See generally Grimes v. Kennedy Krieger, 782 A.2d 807, 814 (Md. 2001) (finding that a greater measure of disclosure is required in "nontherapeutic research"). See also Heinrich ex rel. Heinrich v. Sweet, 62 F. Supp. 2d 282, 320 (D. Mass. 1999) (discussing some experiments would be "unconstitutional... without [a] full and fair disclosure of the nature of the experiments.").

\textsuperscript{143} It might also be noted that the court buys into a distinction between "therapeutic" and "nontherapeutic" research—arguably another error. See \textit{Brown}, supra note 9, at 34 (discussing the definition of "nontherapeutic research" as generally defined as "research which is purely scientific and without direct diagnostic or therapeutic value to the person subjected to the research" and "therapeutic research" as "research whose aim is essentially diagnostic or therapeutic for a patient.").

However, this distinction is arguably not credible. On the one hand, normal volunteers can benefit from nontherapeutic research—for instance by receiving medical check-ups, remuneration, the personal reward of providing an altruistic service, or the like. On the other hand, "therapeutic" research hardly carries any assurance of benefit. The subject may or may not receive any active intervention, and if he does, that intervention could cause more harm than good. Cf. Levine, supra note 9, 22-23 (observing that the 1964 Declaration of Helsinki, which introduced the distinction between "therapeutic" and "nontherapeutic" research, dis-
B. Research Injuries as Ordinary Negligence

A few courts have distinguished research from medical (mal)practice, but did not appreciate the implications of subsuming research injuries instead under the umbrella of ordinary negligence.

In *Craft v. Vanderbilt*,\(^{144}\) for instance, a mid-1940s study gave pregnant women a “vitamin drink” that, unbeknownst to them, contained radioactive iron isotopes.\(^{145}\) Although the objective was to learn more about how iron is absorbed during pregnancy, it was allegedly known at the time that radiation posed health risks.\(^{146}\) As with the radiation cases above, a central focus in litigation was on whether the statute of limitations expired.\(^{147}\) A federal district court found first that the Tennessee statute of repose for medical malpractice “does not apply to conduct that does not involve medical care,”\(^{148}\) which it defined as “actions . . . taken in an effort to benefit or cure the patient.”\(^{149}\) Since this study clearly did not aim to benefit the pregnant women, the rules of ordinary negligence applied rather than the (shorter) statute of repose for medical malpractice.\(^{150}\)

Similarly, in *Payette v. Rockefeller University*\(^{151}\) a student volunteered for three studies involving diet.\(^{152}\) After taking iodine injections and oral potassium iodide the student developed an enlarged thyroid and hypothyroidism.\(^{153}\) The court found that because this study was not medical practice, the adverse outcome could not be medical malpractice.\(^{154}\) Therefore, the applicable statute of limitations was the three-year limit of ordinary negligence, not the two and a half year term applicable to medical malpractice.\(^{155}\)

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\(^{144}\) 18 F. Supp. 2d 786 (M.D. Tenn 1998).

\(^{145}\) Id. at 789.

\(^{146}\) Id.

\(^{147}\) Id. at 796.

\(^{148}\) Id.

\(^{149}\) Craft, 18 F. Supp. 2d at 796.

\(^{150}\) Id. at 797. The court went on to find that the statute of limitations may have been tolled by fraudulent concealment because these physicians were in a fiduciary relationship with their patients, and because in Tennessee a fiduciary has “an affirmative duty to disclose, and that duty renders silence or failure to disclose known facts fraudulent.” Id.


\(^{152}\) Id. at 80.

\(^{153}\) Id.

\(^{154}\) Id. at 82.

\(^{155}\) Id. at 82.
phasize the difference, the court noted that the student was not seeking medical assistance by enrolling in the study, her relationship with the investigators was not that of physician and patient, and the interventions she received were not undertaken to diagnose and treat her.\textsuperscript{156} Hence, the court found, even though doctors were involved and performed medical procedures requiring professional skill, this was not medical practice, and thus could not be medical malpractice.\textsuperscript{157}

While the results in these cases initially seem reasonable, the underlying reasoning and implications may not be so attractive. These courts seem to assume that there are only two available standards by which to judge research mishaps—medical (mal)practice or ordinary negligence, with no special realm for research. Once they flatly reject the idea that clinical research is medical practice and relegate it to the realm of “ordinary negligence” as they adjudicate such matters as statute of limitation, then by implication these courts seem committed to the same reasoning for other issues, such as the standard of care.

However, judging research mishaps under the standards of ordinary negligence could be seriously problematic. On this approach, investigators in sophisticated clinical studies would owe their subjects nothing more than the same ordinary prudence that any citizen owes his fellow citizens—a standard quite likely too lenient. And yet, when the \textit{Craft} and \textit{Payette} courts go down the “ordinary negligence” path, this implication is precisely what follows.\textsuperscript{158}

Interestingly, a Wisconsin appellate court recently encountered this very issue. In \textit{Ande v. Rock}\textsuperscript{159} researchers used blood samples left over from routine newborn screening in a study to evaluate whether early nutrition interventions might help children with cystic fibrosis (CF).\textsuperscript{160} Computers processed the samples anonymously, using a relatively new test to detect CF, then revealed exactly half of

\textsuperscript{156} \textit{Payette}, 643 N.Y.S.2d at 81.

\textsuperscript{157} \textit{id}.

\textsuperscript{158} Perhaps these courts would apply their reasoning only to so-called “nontherapeutic” research. This would have two problems. First, as discussed below, the “therapeutic/nontherapeutic” distinction is not viable. See supra note 143. Second, as discussed just above, it is not actually superior to regard clinical research as simply a genre of medical (mal)practice. See supra Part II.


\textsuperscript{160} \textit{id}. at 269.
the positive test results. Parents of these children were invited to participate in the study, while the computer held the other, still-anonymous positive results in abeyance to serve as the control arm until two years later, when this group was then unmasked for comparison with the test group.

In the instant case, a family in the control group had already conceived a second child afflicted with CF before their first afflicted child had been medically diagnosed to have the disease. The computer “knew” the first child’s genetic condition from the beginning, the parents argued, and withholding this information deprived them of the opportunity to begin early treatment of their first child and avoid conceiving the second, diseased child. The court gave summary judgment to defendants on their medical malpractice claim, holding that because there was no medical practice, nor any physician-patient relationship between the investigators and the family, there were no duties beyond ordinary negligence.

While the result of this case may be appropriate, it begins to demonstrate the potential problems when courts believe that if research is not medical practice, then it must be nothing more than ordinary conduct. Researchers have many duties that go well beyond those of ordinary citizens in the affairs of daily life.

C. Research as Distinct from Medical Practice

In contrast to the foregoing cases, a few courts seem to understand that there are major differences among research injuries, medical malpractice, and ordinary negligence. In Barrett v. United States, when a psychiatric patient died immediately after being given an experimental mescaline derivative without his knowledge or consent, the government initially tried to pass off the patient’s death as ordinary medical malpractice—a simple overdose of an otherwise-appropriate medication. The Second Circuit found the

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163 Id.
164 Id. at 272.
165 Id.
166 Rev. 647 N.W.2d at 272.
167 Id. at 269. The court also dismissed the plaintiffs’ § 1983 claims on the ground that they could not show any constitutional right, such as a hypothetical property right to receive the test results, that had been violated. Id. Even assuming that the researchers’ withholding the test results constituted a violation of a protected liberty interest, this conduct would not rise to the level of violating a clearly established constitutional right, as required to establish a violation of § 1983. Id. at 384-85.
168 589 F.2d 324, 326 (2nd Cir. 1982).
contrary, holding that “[t]he gravamen of the FTCA claim is that the real reason Blauer died was not medical incompetence, but the fact that he was used as a human guinea pig.”167

In the same spirit the Southern District of Ohio found, when scientists exposed at least eighty-seven poor, uneducated, mostly black cancer patients to total body irradiation as part of an undisclosed military study, that the researchers “were not acting as physicians when they conducted experiments on unwitting subjects at Cincinnati General Hospital... Rather, the defendants were acting as scientists interested in nothing more than assembling cold data for use by the Department of Defense.”168

Additionally, the Eleventh Circuit declared, in a case where elderly, poor patients unknowingly received an experimental intracocular lens (IOL) implant, that “their claim is that they were never put on notice that they were the subjects of research... Under the ruse of removing cataracts, Dr. Torsch may have committed fraud on these appellants when he inserted experimental IOLs in their eyes.”169

Perhaps the clearest statement that research is different from ordinary treatment comes from a federal district court in Texas.170 Unlike the cases above, this case concerned patients who explicitly demanded to be in research.171 The plaintiffs, suffering from lymphoma, were in a trial that was discontinued.172 The court denied they had any valid claim to be enrolled in a new study.173

Research is not treatment. Experiments require measurements and conditions that may not be therapeutically significant. The disappointment of patient-participants is not the result of a wrong inflicted on them; they are frustrated in not receiving a potential cure, but they were permitted to have the drug for the purpose of research—the [M.D. Anderson Cancer Center's] purpose not theirs. They were the incidental, gratuitous beneficiaries of the re-

167 Id. at 329. The Second Circuit reversed the lower court's award of summary judgment on claims alleging civil rights violations under § 1983 and under the Federal Tort Claims Act. Id. at 333. Given the government's active concealing of its conduct, genuine issues of material fact existed as to whether the statute of limitations barred the cause of action; additionally, genuine issues of material fact existed as to whether defendants deprived the plaintiff of constitutional rights to life, liberty, due process, equal protection and the like. Id.


171 Id.

172 Id.

173 Id.
search. ... Research is not standard; it is speculation, approximation, and inquiry.174

From the foregoing, one lesson seems clear. Courts must begin to understand that research is different from ordinary medical practice, and even from innovative medical practice. Research injuries and missteps are not routine medical malpractice because research is not medical practice. Moreover, courts must understand that when research takes place in the context of also providing medical care, as with Kernke and Moore, it is important to distinguish which activities are part of the patient's medical treatment and which are part of the research. The former can rightly be addressed under traditional malpractice theories, but research should be addressed distinctively. At the same time, courts must also understand that neither is research ordinary conduct, nor its errors just a form of ordinary negligence.

Once this fundamental distinction is appreciated, it becomes evident that almost every cause of action commonly used to litigate health care injuries must be modified to accommodate the special features of research. A few, like contract and property, need relatively little adaptation to fit research. But a number of others, such as negligence and breach of fiduciary duty, need considerable change. These four are discussed in Part IV. Informed consent and its cousin, battery, are probably the dominant causes of action in research abuse. They will receive special attention in Part V.

Across this spectrum, the message is not that research injuries are somehow worse (or better) than medical malpractice, or that we need to augment (or diminish) the available causes of action against research errors. The message is simply that research is different, that courts need to be more knowledgeable and to think more clearly if they are to build an adequate foundation by which to guide conduct in this increasingly important realm.

174 Id. "Hospitals like Anderson may use experimental drugs in an exercise of compassion... Like research, compassion cannot be quantified... It is discretion with a degree of impulse far exceeding the limits implied by judgment... When research and compassion are the qualities of a medical decision, the processes of legal review are wholly inadequate." See also, Dahl v. HEM Pharm. Corp., 7 F.3d 1399, 1404 (9th Cir. 1993). Research participants sued to receive the year's worth of drug they had been promised in exchange for participating in a study of chronic fatigue syndrome. Id. The court found that a contract existed, and the participants were owed the drug in exchange for their contribution to the research. Id.
IV. ADAPTING CIVIL CAUSES OF ACTION TO THE RESEARCH CONTEXT

As discussed in this section, a number of familiar causes of action can be applied to medical research, but may require some modification.

A. Contract

For routine medical care, the physician-patient relationship ordinarily begins with a voluntary agreement—a contract. However, courts have largely governed the ensuing relationship under tort—a “contorts” approach, so to speak. Still, contract issues do sometimes arise. In *Penna v. Pirozzi*, for instance, the New Jersey Supreme Court implicitly relied on contract law to find fault with a physician who permitted a colleague to perform “ghost surgery” instead of doing the procedure himself. "A patient has the right to choose the surgeon who will operate on him and to refuse to accept a substitute... Correlative to that right is the duty of the doctor to provide his or her personal services in accordance with the agreement of the patient." In like manner the South Carolina Supreme Court was willing to recognize a breach of contract claim when a surgeon transfused blood into a Jehovah’s Witness patient who had explicitly refused it on numerous occasions. Hence, a jury could consider whether an express contract was created. Additionally, courts adjudicating claims for medical battery have regarded the informed consent document as a contract delimiting the scope of a

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175 Id. at 440.

176 Id. at 453-64.

177 Harvey v. Strickland, 566 S.E.2d 529, 534 (S.C. 2002). "We have previously recognized that an action may be maintained for breach of an express pre-treatment warranty to effect a particular result." Id.

178 See Sand v. Hardy, 379 A.2d 1014, 1026 (Md. App. 1977) (noting some courts have been willing to find that if a physician has warranted a certain result, the failure to achieve that outcome can be breach of contract).
physician's permissible intervention. If the physician’s interventions go substantially beyond that contract, battery may occur.\textsuperscript{181}

The investigator-subject relationship relies on contract significantly more. In Grimes v. Kennedy Krieger,\textsuperscript{182} the lead abatement study summarized above, the Maryland Court of Appeals identified contract law as one major basis for finding a special relationship between investigator and subject.\textsuperscript{183} After all, the court pointed out, the research arrangement has all the elements of contract law: offer, consideration, and mutual acceptance.\textsuperscript{184} The families received small financial compensation and some information about reducing lead exposure, while in exchange the researchers got data.\textsuperscript{185} Thus, the informed consent was seen as a contract creating duties.\textsuperscript{186}

The potential role of contract law in research is accentuated by the fact that the information and consent forms in research are usually far more detailed than for ordinary care,\textsuperscript{187} thereby creating a clearer set of reciprocal expectations. In Dahl v. HEM Pharmaceuticals Corporation\textsuperscript{188} for example, participants in a study of a drug for chronic fatigue syndrome, Ampligen, were promised that after the project was over, they would receive a year’s free supply of the drug.\textsuperscript{189} When the trial ended early and the drug company sponsoring the trial reneged on its promise, the plaintiffs prevailed on a contract theory.\textsuperscript{190} The Ninth Circuit observed that “[s]omehow the category of unilateral contracts appears to have escaped HEM’s notice. . . . The deal was, ‘if you submit to our experiment, we will give

\textsuperscript{181} Grabowski v. Quigley, 684 A.2d 610, 615-16 (Pa. Super. 1996) (“The dispositive issue in this battery claim is the nature and scope of Appellant’s consent. . . . This relationship is essentially contractual in nature. . . . [I]f a patient consents to a surgeon for the purpose of removing a tumor from his arm, a contract is entered into which requires the surgeon to remove the tumor. Therefore, he must not digress from that contract and also remove the patient’s appendix. In short, the surgeon must operate in accordance with the agreement made between the parties.”) (quoting Gray v. Grunagle, 223 A.2d 663, 663 (Pa. 1966); see also Taylor v. Albert Einstein Med. Ctr., 723 A.2d 1027, 1036 (Pa. Super. 1998) (emphasizing that battery is based on the scope of the informed consent contract).

\textsuperscript{182} 782 A.2d 807 (Md. 2001).

\textsuperscript{183} Id. at 858.

\textsuperscript{184} Id. at 843.

\textsuperscript{185} Id.

\textsuperscript{186} Id. at 818.


\textsuperscript{188} 7 F.3d 1390 (9th Cir. 1993).

\textsuperscript{189} Id. at 1401.

\textsuperscript{190} See id.
you a year’s supply of Ampligen at no charge.” As the court pointed out, the participants in this study “submitted themselves to months of periodic injections with an experimental drug, or un
knownst to them, mere saline solution, combined with intrusive and necessarily uncomfortable testing to determine their condition as the tests proceeded. . . . HEM sought to have them participate in its study so that it could obtain FDA approval for its new drug.” Accordingly, the company owed these people the benefit of their bargain.

These few examples do not constitute a trend, of course, yet the option of contract remedies for research injuries needs to be taken seriously. The elements of contract are all present, as the Grimes and Dahl courts noted and, as argued elsewhere, contract damages available in the health care context may be considerably greater than commonly believed. Moreover, to the extent that the informed consent contract marks the boundaries of battery in ordinary care—a subject discussed further below—then surely this line may have important implications for the application of battery in research.

B. Property

Like contract, property law is not among the obvious avenues to remedy research injuries. Yet it may have a legitimate even if limited role. For instance, when military-sponsored researchers exposed unwitting cancer patients to total body radiation, a federal district court authorized a property claim. As the court reasoned, when researchers concealed their misconduct they deprived the research subjects of the opportunity to exercise a tort cause of action—deemed a property right by the United States Supreme Court.

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191 Id., at 1404-05.
192 Dahl, 7 F.3d at 1404.
193 See id. at 1405.
194 See Bonin v. Vannaman, 929 F.2d 754, 763 (9th Cir. 1991) (denying contract claim as simply a means to avoid the statute of limitations).
196 See discussion infra Part VA.
198 Id., at 824-25.

the United States Supreme Court has recognized that a cause of action is a species of property protected by the Fourteenth Amendment’s Due Process clause. In fact, the Supreme Court, as far back as 1882, held that a vested
The Second Circuit was likewise willing to find a property claim in a research case. When a psychiatric patient died from a dose of mescaline derivative during clandestine government-sponsored research, the government concealed the truth for over two decades. Although the family sued and won shortly after the patient's death, the claims were for ordinary malpractice, not the more serious, higher-dollar claims that might have succeeded had the real circumstances of the man's death been known. When the family filed a second suit after discovering what had actually happened, the court agreed that their tort claim was a species of property right.

Other plaintiffs have been less successful invoking property rights. In *Ande v. Rock*, a Wisconsin appellate court found that parents of a child with cystic fibrosis had not successfully alleged any property right to receive the results of a prenatal test that had been undisclosed among a group of anonymous controls.

In *Moore v. Regents* the California Supreme Court denied that the tissues repeatedly taken from John Moore and used to create a...
lucrative cell line constituted conversion of property. The court’s rather pragmatic reasoning ranged from public health concerns over discarded tissue to the potential chilling effect on the progress of scientific research if property rights were attributed to surgically removed, ostensibly discarded body tissues. Nevertheless, with increasing public emphasis on privacy in health care and elsewhere, this ruling may not become commonplace. It is at least plausible that personal genetic information and other products of research may give rise to stronger property rights both within and outside the context of research.

C. Negligence

At the outset, we should acknowledge that even the most cutting-edge research often features elements of ordinary care, which should be addressed under the doctrines of routine medical malpractice. If a surgical procedure is involved, for example, it must be performed with standard techniques of antisepsis, the failure of which would be ordinary malpractice even if the surgery itself is experimental. If an experimental cancer chemotherapy is to be given in a specified dose, then an error in which a patient is repeatedly given vastly excessive doses would typically fall under standard negligence, since the problem does not lie with the research protocol, but rather with the provider’s basic practices in administering drugs. Innovation, too, should generally fall under ordinary malpractice standards, with special attention toward the medical justification for the specific innovation, the care with which it was executed, and the like. In essence, innovation should be governed by the long-recognized leeway for variation in medical practice, in-

\[26^\text{Id. at 481, 497.}\]
\[27^\text{See id. at 493-97 (discussing reasons for and against extending conversion liability).}\]
\[28^\text{See generally Greenberg v. Miami Children’s Hosp. Research Inst., 264 F. Supp. 2d 1064 (2003). In this case, which is not necessarily a reaffirmation of Moore, a group of people had donated tissue expressly so that a rare genetic disorder, Canavan disease, could be studied. Id. at 1067. Donors did not expect the scientists to license and profit from a genetic test. Id. at 1068. The court found that although the investigators did not breach any fiduciary duties, and there was no conversion of property, the plaintiffs did have a cause of action for unjust enrichment. Id. at 1072.}\]
\[29^\text{Institute of Medicine, To Erase a Human: Building a Safer Health System (Linda J. Kohn, et al. eds., Nat’l Acad. Press 1999) noting the death of Betsy Lehman, Boston Globe reporter who died of multiple chemotherapy overdoses).}\]
cluding, for example, the acceptance of different schools of thought, reputable minorities, the physician's best judgment, and the like.210

When research injuries are pursued as negligence torts, a major shift must be recognized. As in all tort litigation, three elements must be satisfied: duty of care, injury, and causation.211 However, special attention must be directed toward the first element, the standard of care the investigator owes the research subject. For research, that duty diverges strikingly from ordinary medicine, both in its content and sources.

The standard of care for medical practice emphasizes conformity to customary and prevailing practices, even while it accommodates variations.212 In contrast, research cannot be judged by its conformity to standard practice since it is, by definition, a deviation from those routines.213 Instead, research must first be judged by the content and implementation of the protocol that guides the study. Unlike the malpractice standard of care, research standards must reach beyond the conduct of individual actors, to encompass the protocol itself. An acceptable research protocol should satisfy the criteria of ethically and scientifically sound research. These should include scientific merit (i.e., a valid scientific question and valid research methods), risk minimization, and a favorable risk-benefit ratio (i.e., the risks to participants must be justified by the anticipated benefits of the study, whether to society overall or potentially to enrollees themselves).214 To expose human beings to excessive risk,


211 JOSEPH H. KING, JR., THE LAW OF MEDICAL MALPRACTICE 9 (2nd ed. 1986) (citing Restatement (Second) of Torts § 282 (1965)). The Restatement's formulation cites four elements, drawing a distinction between the existence of a duty and the breach of that duty. For present purposes, those two are united into a single element. Restatement (Second) of Torts § 282 (1965).

212 Phillip G. Peters Jr., The Quiet Demise of Deference To Custom: Malpractice Law at the Millennium, 57 WASH. & LEE L. REV. 163, 185-87 (2000). Admittedly, conformity to prevailing custom has its critics, and may be on the wane. See id. at 185. Nevertheless, it is likely that the profession will continue to set its own standards, and those standards will largely defer to what practicing physicians embrace. See id. at 186.

213 See supra Part II.

or even to moderate risk or mere inconvenience if the protocol is scientifically feeble, would arguably be negligence.\textsuperscript{214}

If the protocol is satisfactory, investigators' duty of care in implementing that protocol should include three elements. First, the investigator must enroll only eligible subjects. Enrolling ineligible people does not merely compromise the scientific integrity of the study and thwart its hoped-for benefits to future populations; it can also endanger subjects and deceive them by pretending that their participation contributes to science when, in fact, their ineligible participation may render their and other subjects' efforts and discomforts for naught if the study can no longer lead to scientifically valid conclusions.

Second, the investigator must honor enrollees' individual needs by appropriately using whatever flexibility the protocol affords for individualizing care, or if necessary by removing from the study any subject who is suffering undue harm. Some of the cases discussed above exhibit deficiencies of this sort. In *Kernke v. Menninger Clinic, Inc.*,\textsuperscript{215} physicians caring for a schizophrenic patient on a research protocol seemed inadequately attentive to the patient's deteriorating condition as they kept him in the study even while his depression, psychosis, and side-effects all grew markedly worse.\textsuperscript{216} Similarly, in *Burton v. Brooklyn Doctors Hospital*,\textsuperscript{217} a premature infant was kept in a study evaluating the effects of high-dose oxygen on vision even after it had become clear the infant's eyes were becoming damaged.\textsuperscript{218}

Third, the research duty of care requires ending the study if the harms to enrolled subjects have become unacceptable in light of anticipated benefits. Many of the higher-risk studies have Data and Safety Monitoring Boards (DSMBs) to assess research results at various intervals, to determine whether a study should be stopped or

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\textsuperscript{214} A feeble protocol could also be deceptive if, for instance, prospective subjects are told that their participation can benefit others when in fact that protocol is incapable of producing scientifically valid results.


\textsuperscript{216} See id. at 1350-51 (noting the decline evident in the patient's medical records and the patient's repeated requests to leave the study and facility). The court held, "as either the investigators of the M100007 study or as the physicians charged with Kenneth Kernke's care, each of the Menninger defendants owed Kenneth a duty of care." Id. at 1352-53.


\textsuperscript{218} Id. at 878 (noting that six consecutive examinations of the infant's eyes indicated continuing damage during the 28-day high oxygen portion of the study).
Those that do not should at least have a monitoring plan that can trigger review if accrued results reveal significant problems. On some views, a failure in this area may have been a fundamental problem in *Heinrich v. Sweet.* According to the federal district court, Dr. Sweet, the principal investigator,

had actual knowledge of the imprecision of the localization of the boron injections to the cancerous brain tissue and the related imprecision of the neutron radiation, with the result that unacceptably high degrees of radiation necrosis were occurring in these and other of his patients. In short, Sweet well knew during his care of these patients that his BNCT treatments were not helping them, and, in fact, were causing severe side effects unrelated to the progressive effect of the fatal brain tumors. He pressed ahead anyway, believing in complete good faith that such experimentation on dying patients held out hope for other cancer victims. However praiseworthy his goal, his conduct with respect to the patients involved here was, as the jury found, negligent.

As research cases are adjudicated, the derivation of the standard of care must likewise differ from routine malpractice. After all, malpractice standards are defined almost exclusively by the medical community, which is clearly inadequate for research.

One important source of the research duty of care derives from regulation. The Federal government’s Common Rule governs most human subjects research, and Institutional Review Boards (IRBs) are responsible to ensure that each project under their purview follows those rules. However, federal regulations only cover

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219 See Susan Ellenberg et al., *Data Monitoring Committees in Clinical Trials: A Practical Perspective* 1 (2002) for a detailed discussion of DSMBs’ purposes, composition, and functions.

220 See *Heinrich ex rel. Heinrich v. Sweet,* 118 F. Supp. 2d 73, 90-91 (D. Mass. 2000) (expressing regret that the court had no clear standards on which to rely when evaluating the conduct of the defendant in performing human experimentation).

221 *Id.* at 90-91 (citations omitted). It should be noted that in 2002, the First Circuit Court of Appeals issued a directed verdict for the defendant on the claim of negligence, on the ground that plaintiffs had not established the duty of care. See *Heinrich v. Sweet,* 308 F.3d 48, 70-71 (1st Cir. 2002). Moreover, the court noted that there was no evidence that the lives of patients with glioblastoma multiforme, an invariably fatal brain tumor, were shortened by the research. See *id.* at 62.

222 See Peters, supra note 211, at 165-66.

223 Southard v. Temple Univ. Hosp., 781 A.2d 101, 104 (Pa. 2001) (stating “while the FDA regulates the marketing and labeling of medical devices, it does not purport to interfere with the practice of medicine.”); see generally Brody supra note 9, at 31-54 (offering an overview and brief history of official policies governing research on human subjects throughout the world).

224 45 C.F.R. § 46.111 (2002). IRBs must ensure, for instance, that: risks to subjects are minimized; risks are reasonable relative to anticipated benefits; selection of subjects is equitable; informed consent is sought from each subject or legally authorized representative;
certain kinds of conduct such as informed consent, not the entire range of conduct and care appropriate for research. Hence, courts must also include other sources for defining investigators’ duties to their subjects.

Among those other sources, the broader scientific community may play an important role, for instance, in defining what constitutes sound scientific methodology. Additionally, the bioethics community may help to identify what kinds of risks are acceptable, and which may be too great to impose on human subjects. Courts themselves might introduce their own criteria if, for example, they find that an IRB has approved an unreasonably dangerous study. Even if only rarely, courts do sometimes supplant otherwise-applicable tort standards with their own judgments.

In sum, the substantive duty of care that physician-investigators owe their research subjects begins with familiar medical malpractice doctrines, because clinical research has elements of ordinary medical practice. However, conduct that is distinctive to research should be litigated under a research-focused standard of care based on defects in the protocol, failures to adhere to the protocol, breaches of research-specific informed consent, and the like.

D. Breach of Fiduciary Duty

1. Investigators: Not Fiduciaries

Research likewise diverges markedly from ordinary medical practice in the applicability of fiduciary doctrines. To be sure, the

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informed consent is appropriately documented; that data are appropriately monitored to ensure subjects' safety; subjects' privacy is appropriately protected; and vulnerable populations such as children and the mentally disabled are provided added levels of protection.

25 See Kalb & Koehler, supra note 13, at 87. Currently, federal regulations apply to research that receives federal funding, and to the entire spectrum of research in academic institutions that receive federal funding via “multiple project assurances.” Id. Companies using their own funds to sponsor trials for FDA approval must conform to FDA rules, which still require IRB surveillance. Id. But see: Rettig, supra note 14, at 139 (noting that some research escapes supervision altogether). For instance, since the FDA does not require approval of new surgical procedures, or off-label uses of drugs and devices (unless the manufacturer wants to change its labeling), research in those areas can escape supervision if it does not involve federal funding and is not undertaken at an institution that has assured the government it will supervise all research within its walls.

26 See T.J. Hooper v. N. Barge Corp., 60 F.2d 737, 740 (2d. Cir. 1932) (finding that failure to provide vessels with radars constituted a breach of reasonable prudence, even though it was not customary); Hellinger v. Carey, 519 F.2d 981, 903-04 (Wash. 1974) (finding professional ophthalmology standards insufficient to establish reasonable prudence).
concept of "fiduciary" is not entirely clear, and the standard physician-patient relationship is not always deemed fiduciary in the most classic sense. Courts have been reluctant to apply the full panoply of fiduciary responsibilities to physicians, for instance, and have often denied claims for breach of fiduciary duty as a separate cause of action against a physician.

Nevertheless, courts have felt free to call the standard physician-patient relationship fiduciary or at least a relationship of trust and confidence. The physician has knowledge and skills for

227 See Holder, supra note 209, at 225 (stating that the relationship between patient and physician is one known to the law as a "fiduciary relationship"... Any person such as a physician, attorney, priest, or other who enters into a relationship of trust and confidence with another has a positive obligation to disclose all relevant facts."). See also J.C. Shepheard, THE LAW OF FIDUCIARIES 29 (1981); William J. Curran & G. B. Muselye, The Malpractice Experience of Health Maintenance Organizations, 70 NW. U. L. Rev. 69, 76 (1975) (stating that generally, a fiduciary relationship is one in which "trust and confidence are reposed by one party in the influence or dominance of another, creating in the latter a duty to act with greater diligence and care than that required by a common negligence standard of due care."), Deborah A. DeMott, Beyond Metaphor: An Analysis of Fiduciary Obligation, 1988 Duke L.J. 879 (1988) (positing that the law of fiduciary obligation is situation-specific, elusive, and cannot be described exclusively by reference to contract principles); Feldman & Ward, supra note 175, at 18 (stating that "a fiduciary must "never take selfish advantage of his trust."), Francis Miller, Secondary Income From Recommended Treatment: Should Fiduciary Problems Constrain Physician Behavior?, in THE NEW HEALTH CARE FOR PROFIT: DOCTORS AND HOSPITALS IN A COMPETITIVE ENVIRONMENT 153, 154 (Bradford H. Gray ed., 1983) (noting that "[a]s fiduciaries, doctors owe a duty of loyalty to their patient's interests that requires them to elevate their conduct above that of commercial actors.").


229 See, e.g., Spoor v. Serota, 852 P.2d 1292, 1294-95 (Colo. Ct. App. 1992) (holding that the plaintiff's claim for breach of fiduciary duty was claim of claim for malpractice, as it presented issues identical to the malpractice claim); D.A.B. v. Brown, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (finding that the claim for breach of fiduciary duty was merely misstated claim for malpractice). As a specific example, several courts have been hesitant to require that physicians disclose financial conflicts of interest to their patients. Although the California Supreme Court required such disclosure in Moore, 793 P.2d at 485, several courts ruling on the financial conflicts implicit in managed care have not followed that lead. See, e.g., Neade v. Portes, 730 N.E.2d 496, 505-06 (III 2000) (declining to recognize a claim for breach of fiduciary duty where a physician did not disclose financial incentive plans); Bates v. Prudential Ins. Co. of Am., 724 N.Y.S.2d 3, 7 (N.Y. App. Div. 2001) (declining to recognize fiduciary duty on part of an insurance company towards an insured, and finding the relationship to be strictly contractual in nature). But see Shoa v. Esensen, 107 F.3d 625, 629 (8th Cir. 1997) (requiring disclosure of financial conflicts of interest in an ERISA case).

which the patient has significant need. The application of such knowledge and skills requires substantial exercise of discretion.231 When accepting a patient for care, the physician voluntarily and expressly undertakes to act primarily for the benefit of the patient and to refrain from exploiting the patient’s vulnerability for personal gain.232 The result is a relationship bearing the classic loyalty duties

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231 See Peter D. Jacobson & Michael T. Cahill, Applying Fiduciary Responsibilities in the Managed Care Context, 26 Am. J. L. & Med. 155, 160 (2000) (stating that “[t]he United States Supreme Court has noted that the central purpose of fiduciary law is to govern the exercise of discretion in making decisions that are not, and cannot be, controlled in advance by legal means.”).

232 A fiduciary relationship does not arise simply because one person needs or chooses to trust another, but because the latter agrees to this distinctive kind of arrangement. See e.g., Long v. Great West Life & Annuity Ins. Co., 957 P.2d 823, 824 (Wyo. 1998) (quoting Martinez v. Assoc. Fin. Sys. of Co., Inc., 891 P.2d 785, 790 (Wyo. 1995) as stating

    We have said that ‘[f]iduciary duty is not created by a unilateral decision to reposit trust and confidence; it derives from the conduct or undertaking of the purported fiduciary and have defined a fiduciary as ‘a person having duty, created by his own undertaking, to act primarily for another’s benefit in matters connected with such undertaking.’ . . . In describing fiduciary relationships, we have said: ‘Of the two essential kinds of fiduciary relationships, the first arises from specific legal relationships. ‘In cases of trustee and beneficiary, principal and agent, and the like, the relations are essentially fiduciary; and the inference or presumption follows of course.’ . . . The second is less susceptible of exact definition, being “implied in law due to the factual situation surrounding the involved transactions and the relationship of the parties to each other and to the questioned transactions.’

Johnson v. Brewer & Pritchard, P.C., 73 S.W.3d 193, 200 (Tex. 2002) (citing Restatement (Second) of Agency § 13 cmt. a (1958)) (citing the Restatement (Second) of Torts: The agreement to act on behalf of the principal causes the agent to be a fiduciary, that is, a person having a duty, created by his undertaking, to act primarily for the benefit of another in matters connected with his undertaking. Among the agent’s fiduciary duties to the principal is the duty to account for profits arising out of the employment, the duty not to act as, or on account of, an adverse party.
fiduciaries owe their beneficiaries. Physicians must place their patients' interests paramount, even above their own, and they must avoid conflicts of interest wherever possible.234

Physicians in ordinary practice cannot completely avoid conflicts of interest or conflicts of obligation.235 Every form of payment brings some form of conflict, for instance: a physician paid fee-for-service makes more money by providing unnecessary procedures; a physician paid by capitation235 may make more money by withholding services; and a salaried physician might want to see as few patients as possible. Nevertheless, familiar fiduciary obligations remain strong. The physician is to promote the patient's best interest, refrain from exploiting his vulnerability, and must generally avoid letting his own or others' interests supersede the patient's.236

without the principal's consent, the duty not to compete with the principal on his own account or for another in matters relating to the subject matter of the agency, and the duty to deal fairly with the principal in all transactions between them;)

Abele v. Sawyer, 747 So.2d 415, 417 (Fla. Dist. Ct. App 1999) (noting "[a] fiduciary relationship under Florida law is a legally imposed relationship which will be found to exist where a relation of trust and confidence exists between two parties, that is, where confidence is reposed by one party and a trust accepted by the other."); Greenberg v. Miami Children's Hosp. Research Inst., 264 F. Supp. 2d 1064, 1071, 1072 (S.D. Fla. 2003) (stating that "[t]his is a two-way relationship, and a fiduciary relationship will only be found when the plaintiff separately alleges that the plaintiff placed trust in the defendant and the defendant accepted that trust" and that a fiduciary relationship did not exist because the second element, acceptance of trust by defendants, had not occurred).

234 See Meinhard v. Salmon, 164 N.E. 545, 546 (N.Y. 1928) (noting that in the classic statement of fiduciary obligation the fiduciary "is held to something stricter than the morals of the market place. ...Not honesty alone, but the punctilio of an honor the most sensitive, is then the standard of behavior. ...Only thus has the level of conduct for fiduciaries been kept at a level higher than that trodden by the crowd.").

235 See generally E. HAAMI MORREIM, CONFLICTS OF INTEREST IN ENCYCLOPEDIA OF BIOETHICS 459-65 (Warren Thomas Reich ed., 1995). In a conflict of interest, the physician's (or fiduciary's) own personal interest is pitted against his obligations to the beneficiary. Id. at 459. In a conflict of obligation, the obligation to one party conflicts with an obligation to another party, without necessarily involving the physician's own personal interests. Id. at 459.

236 See Donald M. Berwick, Quality of Health Care, 335 NEW ENG. J. MED. 1227, 1227 (1996). In capitation, the physician (or physician group) is typically paid a fixed amount per patient, per year, to provide a specified array of services. Id. The physician's payment thus is the same, regardless of how much care the patient needs. Id. See generally Steven D. Pearson et al., Ethical Guidelines for Physician Compensation Based on Capitation, 339 NEW ENG. J. MED. 889, 890-891 (1998) (discussing in detail the ethical complications of physician incentives).

Exceptions will occasionally be necessary, as where the physician might be obligated to breach a patient's confidentiality in order to warn an innocent third party of an imminent danger posed by the patient. See, e.g., Tarasoff v. Regents of Univ. of Cal., 551 P.2d 334, 345-46 (Cal. 1976) (holding that psychiatrists have a duty to warn prospective victims
In sharp contrast, the very nature of research precludes a fiduciary relationship between investigators and subjects. As pointed out above, by definition the researcher’s goal is not the betterment of any particular participant. It is the successful completion of the research according to the protocol, in hopes that the knowledge gained will help future patients. This is not a situation in which a basically sound fidelity requires a transient compromise, such as a decision whether to violate patient confidentiality to warn a third party that the patient poses imminent danger. Rather, a completely different allegiance permeates the relationship. The investigator’s entire purpose, his number one loyalty, is already pegged on something other than the patient. It is to the protocol.

This conclusion, that the investigator-subject relationship is not fiduciary, and cannot be, is sharply at odds with prior commentary. Karin Morin notes, for instance, that traditionally the physician-patient relationship and the investigator-subject relationship “both have been described as a fiduciary relationship.”237 Similarly, Angela Holder argues that because investigators must treat enrolled subjects with great care, deference, and loyalty, then the relationship must be fiduciary. She further suggests that, since courts are unlikely to excuse injury and unfairness to research participants on the ground that the investigator is not a fiduciary, this must be reason to conclude that the investigator is indeed a fiduciary.238

This reasoning runs backwards. Whereas the logical chain of reasoning says that a fiduciary relationship must exist before fiduciary duties can be imposed, Holder reasons in the opposite direction, using the fact that an investigator has duties to subjects to infer that the relationship must therefore be fiduciary.

There are two problems with this argument. First, it straightforwardly commits the classic logical fallacy known as “affirming the consequent.” In “affirming the consequent” one begins with the premise “if A is true, then B is true.” If one then conversely supposes that because B is true, then A must also be true, he is committing the fallacy. For example, it is clearly true that “if (A) it is raining heavily, then (B) the sky must be cloudy.” However, the

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when a patient presents a serious danger of violence to a third party). Nevertheless, on the whole, the physician must make the individual patient’s welfare his first priority.

(quoting Robert Levine, Ethics and the Regulation of Clinical Research, 98 Urb. & Schwarzenberg, 1986, as stating “[s]cholars on the subject of the ethics of medical research describe the relationship between investigator and subject as a fiduciary relationship.”)

238 Angela Holder, Do Researchers and Subjects Have a Fiduciary Relationship? 4 IRB 6 (1982).
reverse order is not necessarily true: "if (B) the sky is cloudy, then (A) it must be raining heavily." Here, Holder begins with "if (A) a relationship is fiduciary, then (B) certain loyalty duties apply," then affirms the consequent (B) "researchers have loyalty duties to their subjects" in order to conclude that (A) "researchers are fiduciaries toward their research subjects."

Second, Holder is simply incorrect to suppose that the duties owed by an investigator to a subject are in fact fiduciary kinds of loyalty. As argued above, they are not. The investigator does not owe his top loyalty to the subject in the same way a physician owes his to the patient. The investigator must focus on the protocol, even if he must also take great care not to harm individual patients in the process. This care, as argued above, is more a "side constraint" than a direct duty; it is a limit on what the researcher can do in pursuing the protocol, not the central focus of his activity.

Nevertheless, even if not fiduciary in nature, investigators do have important duties toward their subjects. Arguably, those duties begin with the standard of care discussed above under "negligence." Additionally, they include informational obligations, such as to make it clear that the relationship is not a traditional physician-patient kind of relationship. The investigator must emphasize to a prospective subject that the research does not aim to benefit

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239 Id. at 7. Interestingly, Holder acknowledges the odd implication that other major players in the research setting, such as nurses who may be under the same requirements to protect subjects' welfare, are not fiduciaries in research because they are not fiduciaries in ordinary care. Seemingly abdicating her earlier argument that the need to respect patients is what makes the investigator a fiduciary, Holder finds that "[t]he license to practice seems to confer the fiduciary obligation, not the particular interaction involving the research subject." Id. Holder's turnaround here is further evidence of the weakness of her conclusion. See also Grimes v. Kennedy Krieger, 782 A.2d 834, 842-843 (Md. 2001). The Maryland Court of Appeals repeatedly calls the investigator-subject relationship a "special relationship" carrying distinctive duties. Id at 843. But nowhere does the court call it "fiduciary." See id.

240 See generally Novick, supra note 98, at 32 (discussing side constraints and their application to other people).

241 See discussion supra Part IV.C.

242 Appelbaum et al., supra note 97, at 322 (noting that while Department of Health and Human Services requires an explanation of the purpose of the research, a description of applicable procedures (including experimental), and description of any reasonably foreseeable risks or discomforts, the guidelines do not address disclosure regarding methodology of the study, and asserting that inadequate understanding about the latter can impede the subject's ability to assess benefits and risks soundly).
him personally, even if it may happen to benefit him, and that the researcher has only limited control over what will happen, and will have limited options to modify the protocol to suit that patient’s needs and preferences. Because the investigator does not carry a primary loyalty to the subject, these disclosures have more of a of *caveat emptor* character than a preservation of fidelity, with the goal of empowering the subject with sufficient information to make a sound decision.

2. **Physician-Fiduciaries As Investigators**

Notwithstanding the foregoing discussion, fiduciary duties can nevertheless be present in the research setting. We must distinguish two situations: a pure research setting in which the patient’s only relationship with the investigator is as a research subject, and a mixed situation in which a pre-existing physician-patient relationship adds a research component. The former situation does not carry fiduciary duties, but in the latter mixed setting, a physician in a standard fiduciary relationship also functions as an investigator with respect to that same patient. It is a situation harboring substantial hazards, with abundant opportunities for the very problems that fiduciary duties are designed to combat.

The physician-investigator may be tempted to describe the research, or even to regard it, as a therapy aimed at this patient’s personal benefit, rather than as science-seeking protocol. If the

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241 Id. at 321. The mistaken assumption by research subjects that decisions about their care are being made with only their benefit in mind constitutes the “therapeutic misconception.”

242 See Charles Weijer & Paul Miller, *Therapeutic Obligation in Clinical Research*, 33 Hastings Center Report 3 (2003). Weijer and Miller focus on the latter, mixed physician/investigator role in order to conclude that investigators are fiduciaries. To be sure, the mixed situation carries a fiduciary role, but that is because the physician is a fiduciary. It does not follow from this that the investigator, per se, is a fiduciary.

243 See Klein & Fleischman, *supra* note 6, at 24 (noting that financial incentives in research “can and do influence supposedly unbiased investigators . . .”)

244 See Nancy Kass, et al., *Trust: The Fragile Foundation of Contemporary Biomedical Research*, 26 Hastings Center Report 25, 27 (1996) (noting some physicians have a “tendency . . . to inflate the potential benefits of research interventions . . . In one study, virtually all physicians thought their patients would benefit from investigational treatments, and 43 percent said they had ‘no doubts at all about benefits of treatment’ despite a statement in the consent form that benefit could not be assured . . . In another study, physicians consistently underestimated the likelihood of benefit from clinical trials.”); Doris T. Penman, et al., *Informed Consent for Investigational Chemotherapy: Patients’ and Physicians’ Perceptions, 2* Clinical Oncology 849, 855 (1984); Sudha Rajagopal et al., *Adjuvant Chemotherapy for Breast Cancer: Discordance Between Physicians’ Perception of Benefit and the Results of Clinical
patient experiences difficulties from the protocol, the physician may be tempted to accommodate his patient's needs beyond the flexibility permitted by the protocol, thereby endangering the protocol's scientific integrity. In extreme cases the physician may be tempted to exploit the vulnerable patient for his own gain, as by urging her to enroll or remain in a study so that he can fill the trial and enjoy benefits such as financial remuneration, scholarly publications, academic advancement, or increased prestige.\textsuperscript{247}

Moore v. Regents of the University of California\textsuperscript{248} illustrates the difficulties of such a mixed relationship. Since John Moore and Dr. Golde began with a standard physician-patient relationship to treat Moore's leukemia, Golde clearly owed Moore the same fidelity any physician owes his patient.\textsuperscript{249} Golde's surreptitious use of Moore as research fodder was thus a rank violation of his most fundamental obligations.\textsuperscript{250} It was not just a conflict of interest, but a fundamental change of priorities that took place without informing the patient. In contrast, had the relationship begun and continued solely as a research relationship, it would not have been fiduciary. Moore would have known the periodic removal of tissue samples was research, because the entire relationship would have centered on that purpose.

Whether or how the mixed physician-patient and investigator-subject relationship should be permitted is an important question this Article will not address. At the very least, however, the physician-investigator must carefully address conflicts of obligation and conflicts of interest. In a conflict of obligation, one's duty to one

\textit{Trials}, 12 J. CLINICAL ONCOLOGY 1296, 1303 (1994) (asserting that it is important for physicians to convey a realistic description of the potential benefit that can be expected to patients who are considering new treatments, as it has been shown that physicians tend to overestimate the true therapeutic gain).

\textsuperscript{247} See Grimes v. Kennedy Krieger, Inc., 782 A.2d 807, 815 n.6 (Md. 2001) (finding that the study's goal was not therapeutic in nature, but rather was for the purpose of calculating the minimal level of effective lead paint abatement); Klein & Fleischman, supra note 6, at 23.

\textsuperscript{248} 503 P.2d 479 (Cal. 1972).

\textsuperscript{249} Id. at 481 (noting that Golde was Moore's physician, and that Moore was under Golde's "care and treatment").

\textsuperscript{250} See id. at 485 (finding a breach of fiduciary duty where a physician does not disclose personal interests unrelated to the patient's health as part of an informed consent process); see also McCall v. Pacificare of Cal., Inc., 21 P.3d 1189, 1199 (Cal. 2001) (finding that a physician's fiduciary duty may be breached by permitting financial interests to affect treatment detrimentally or by failing to disclose financial interests).
party conflicts with his duty to some other party. In research, the investigator-based obligation to follow the protocol can conflict with the physician-based obligation to promote his patient’s best interests. In contrast, a conflict of interest pits one’s duties to others against his own personal interests. A physician-investigator’s opportunities to profit financially or professionally could conflict with his obligations to adhere to the protocol or to provide honest disclosures to enrollees.

a. Conflicts of Obligation

Where conflicts of obligation or of interest cannot be avoided, the usual remedy is disclosure. Since a physician-investigator is ineradicably in a potential conflict between his obligation to honor the protocol and his duties to the patient, he must explain that within the ambit of the research, the investigator’s first loyalty must be to the protocol, even if he will use any permissible leeway to accommodate that patient’s individual needs. As suggested by Kass and others:

Investigators . . . should make it clear that their primary loyalty is to future patients. While investigators also unequivocally have an obligation to minimize harm to subjects and to respect their wishes, patients who enroll as research subjects must understand this shift in loyalties that is inherent to the role of investigators, in contrast to that of patients’ personal physicians.

In that context, an interesting question concerns whether the physician is obligated to tell the patient each and every time the patient’s interest has in fact been subordinated to the protocol, regardless how minor the sacrifice, or whether it might be sufficient to make a generic initial disclosure that sometimes such trade-offs will occur. For instance, a particular patient might have fewer annoying side-effects with a lower dose of the study medication, yet the protocol may forbid reducing the dose. Perhaps a simple medication

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251 See Morrell, supra note 234, at 459-65 (in a conflict of interest, the physician’s (or other fiduciary’s) own personal interest is pitted against his obligations to the beneficiary. In a conflict of obligation, the obligation to one party conflicts with an obligation to another party, without necessarily involving the physician's own personal interests).

252 See id.

253 See Moore v. Regents of Univ. Cal. 793 P.2d 485; McCall v. Pacificare of Cal., Inc., 21 P.3d 1189, 1199 (Cal. 2001); Miller, supra note 227.

254 Kass et al., supra note 246, at 28; see also Katz, supra note 94, at 34; Goldner, supra note 9, at 122 (suggesting additions to the usual elements of informed consent, such as the possibility the research will subordinate the subject’s therapeutic interests to the scientific requirements of the project and the possibility of a significant change in the nature of the previously existing therapeutic relationship, if one existed).
that might ameliorate those side-effects is off-limits to avoid confounding the research results.

Generic disclosures might be adequate in the pure research context, because the research subject is not in a relationship that carries an expectation of pure dedication to the patient's own interest. However, in the mixed research and therapy setting the physician-patient relationship may be especially likely to engender a "therapeutic misconception" in which the patient assumes that each intervention, even if risky, is undertaken for his personal benefit. A one-time disclosure by the physician may not be sufficient to make clear the reality of ongoing trade-offs between the patient's personal interests and the protocol.

At the same time, it may be infeasible and perhaps not important to discuss every minor trade-off, particularly those that are unlikely to change the patient's mind about continuing her participation in the study. Moreover, in blinded studies the investigator does not know which intervention the patient is receiving, hence will be unable to discern when a patient is receiving a less effective or more onerous intervention than she might otherwise have.

Accordingly, a middle ground may be appropriate, such as a "materiality" standard in which the physician-investigator discloses whenever compromises of personal care might singly or cumulatively prompt the patient-subject to reconsider her participation in the study. This standard is familiar. In federally regulated clinical trials, subjects must be told that if information becomes available that may affect their willingness to continue, they will be informed and invited to make a decision. Here, the same standard would apply when the loyalty a patient expects from her own physician is subordinated to research demands. The physician should tell the patient-subject plainly when adherence to the protocol requires treatment that significantly differs from what would otherwise occur in a strictly therapeutic relationship. While similar to the standard caveat, this materiality standard is heightened because it invites the research participant to be vigilant not only to the risks of the research itself, but to the ways it may compromise her relationship with her physician.

\[^{25}\text{See Appelbaum et al., supra note 93, at 20.}\]

\[^{26}\text{45 C.F.R. § 46.116(b)(5) (2002).}\]
b. Conflicts of Interest

In conflicts of interest the patient's welfare may be pitted against the physician-investigator's own interests. Disclosure would seem to be the first-line safeguard because concealment is so tempting and potentially so pernicious. As Appelbaum and colleagues have observed, "it is decidedly not in investigators' self-interest for them to disabuse potential subjects of the therapeutic misconception. . . . Experienced investigators, as we have reported elsewhere, view the recruitment of research subjects as an intricate and extended effort to win the potential subject's trust." The American Medical Association echoes the point, "(t)he nature and source of funding and financial incentives offered to the investigators must be disclosed to potential participants as part of the informed consent process."

Another form of protection may be to engage someone other than the physician-investigator to provide the information for patients considering whether to enroll or continue in their physician's

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257 As noted above, "profit" can go beyond financial rewards to include professional and academic gains such as promotion, tenure, enhanced prestige and with these the opportunity to win grants, larger laboratory facilities, and the like. Even aside from such concrete conflicts, investigators may be intellectually, emotionally, and professionally invested in their research, with their sheer enthusiasm for a cherished project potentially obscuring any of its downsides.

258 Appelbaum, et al., supra note 93, at 23. The authors quote one study subject as saying: "(i) was almost as if they were courting me . . . everything was presented in the best possible light." Id.

259 Marin, supra note 3, at 83. The American Medical Association has also weighed in on this issue. See Managing Conflicts of Interest in the Conduct of Clinical Trials. CLEA Onlines 8(3)15, Rev. 112 (6) (t)he nature and source of funding and financial incentives offered to the investigators must be disclosed to a potential participant as part of the informed consent process. Disclosure to participants also should include information on uncertainties that may exist regarding funding of treatment for possible complications that may arise during the course of the trial. Physicians should ensure that such disclosure is included in a written informed consent. Available at http://www.amer-assn.org/ama/pub/category/3796.html (last visited Nov. 23, 2003).

It is interesting to note that in another context, courts have been surprisingly reluctant to require physicians to disclose conflicts of interest to their patients. In several cases featuring physicians in financial conflicts of interest, courts have refused to allow breach of fiduciary duty as a separate cause of action. See Neide v. Franco, 738 N.W.2d 299 (III. 2000) (declining to recognize a new cause of action for breach of fiduciary duty for failure to disclose HMO financial incentives on the grounds that it was duplicative of the medical malpractice claim), D.A.B. v. Brown, 570 N.W.2d 168, 171 (Minn. Ct. App. 1997) (finding that although the claim was based on a breach of fiduciary duty, the complaint actually sounded in medical malpractice where a physician had received compensation for prescribing drug).
research. A “neutral discloser”\textsuperscript{260} or research subject advocate\textsuperscript{261} might be better suited to present the relevant information and respond to questions that the patient might be embarrassed to pose to his own physician. Ideally, such a neutral person might be available throughout the research, to field questions or assist with concerns the patient may feel awkward posing directly to the physician.

In sum, those who serve purely as investigators are not fiduciaries, although they nevertheless have important duties toward subjects. By contrast, a physician providing treatment is a fiduciary. For those who add “investigator” to their relationship with patients, it means that breach of fiduciary duty could be a readily available cause of action if they do not carefully manage their conflicts of interest and of obligation.

V. INFORMED CONSENT AND BATTERY

A wide variety of harms can occur in the research setting. Some are distinctive to research, such as negligent research design. Others may be routine medical malpractice, as research often involves commonplace medical activities. In other cases an investigator fails in his duty to protect the people enrolled in his research, such as where the investigator fails to remove from the protocol a subject who is clearly being harmed by his participation. Notwithstanding these diverse examples, the most prevalent problems in research have stemmed from the consent process. In early litigation the problem was a complete lack of information and consent—classically, battery.\textsuperscript{262} More recently, litigants claim that information has been inadequate rather than absent.\textsuperscript{263} Both these scenarios deserve special attention. Battery in the research setting brings a very distinctive twist, while inadequate information in research must be conceived very differently from breach of informed consent in ordinary medicine.

\textsuperscript{260} See Appelbaum, et al., supra note 93, at 23. Similarly, independent consent or procedure monitors have been proposed. See Klein & Fleischman, supra note 6, at 25.


\textsuperscript{262} See discussion infra Part I.

\textsuperscript{263} See supra Part I.
A. Battery

When research is surreptitious and completely unconsented, as in the government-sponsored radiation studies during the mid-twentieth century, then battery—defined as unconsented, offensive touching,\(^{264}\)—seems an obvious claim. Yet courts permit only limited room for this tort in health care. As argued below, certain kinds of research conduct should be deemed a distinctive kind of battery, here dubbed “medical research battery.”

Historically, informed consent doctrine began in battery. Early cases involved surgical procedures to which the patient had not consented, or which went well beyond the agreed-on procedure.\(^{265}\) However, informed consent doctrine evolved away from battery during the 1960’s and ’70s when courts decided that, so long as the patient gave some sort of consent, the inadequacies of disclosure such as failing to mention a particular risk must be addressed as negligence.\(^{266}\) After all, the consequences of litigating defects of in-

\(^{264}\) “The law of battery provides protection against unauthorized touching of the human body. While most cases in which this protection is invoked involve touchings that are harmful, this is not a requirement to establish battery.... The law of battery also protects against touchings that are offensive, even if they do not inflict bodily harm.... In so doing, battery protects the purely dignitary interest in the body that it be free from offensive contact.” Meisel, supra note 114, at 211.

\(^{265}\) See Mohr v. Williams, 104 N.W. 12, 13 (Minn. 1905) (stating surgeon operated on the left rather than right ear, though the patient had only consented to surgery on the right ear); Rolater v. Strain, 137 P. 96, 97 (Okla. 1913) (noting a surgeon removed bone from foot despite patient’s express refusal); Schloendorff v. Society of New York Hosp., 105 N.F. 92, 93 (N.Y. 1914) (stating a patient who had consented only to an ether examination, but not to surgery, was subjected to surgery for removal of a fibroid tumor).

\(^{266}\) See Canterbury v. Spence, 464 F.2d 772, 783 (D.C. Cir. 1972) (noting that in regards to informed consent, the “disclosure requirement, on analysis, reflects much more of a change in doctrinal emphasis than a substantive addition to malpractice law”); Mink v. Univ. of Chicago, 460 F. Supp. 713, 716-17 (N.D. Ill. 1978):

The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. When the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present. However, when the patient consents to certain treatment and the doctor performs that treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.


See also Meisel, supra note 114, at 211; Morin, supra note 3, at 160 (stating “given the ‘absolute nature of battery,’ and because most cases arise from insufficient consent.
formed consent under battery could be unduly severe for physicians. For want of mentioning a single risk, the physician would in essence be accused of a crime or, at the least, of an intentional tort for which malpractice insurance provided no coverage. Moreover, battery requires no expert testimony, no finding that the procedure was performed negligently, and no causal connection between the battery and the injuries. One need only prove that the touching

virtually all jurisdictions now address the doctrine [of informed consent] under a negligence theory.

267 Trogon v. Fruchtman, 207 N.W.2d 297, 313 (Wis. 1973) (noting that informed consent cases differ significantly from the traditional concepts of battery in that physicians are acting in good faith and for the benefit of the patient and do not entail the intent to unlawfully touch the person of another, and while the result may not be what was desired, the act of the physician is not of the anti-social nature usually associated with assault and battery; furthermore, if a physician is found to have committed a battery, the physician’s malpractice insurance may not cover the liability. Therefore, the physician would have to pay the costs out of pocket for what is essentially an act of negligence).

268 Grabowski v. Quigley, 684 A.2d 610, 615 (Pa. Super. 1996) (commenting that when the theory of recovery is battery and not malpractice, one need not prove that surgery was performed negligently).

269 Gouse v. Cassel, 615 A.2d 331, 333 (Pa. 1992). “[T]he patient need not prove that a causal relationship exists between the physician’s or surgeon’s failure to disclose information and the patient’s consent to undergo surgery.” That is, under a theory of battery, the patient need not demonstrate that injury occurred as a result of the recommended treatment or as a result of not undergoing a course of treatment undisclosed by the doctor. See Grabowski v. Quigley, 684 A.2d at 615.

“[I]t is not necessary for a plaintiff to prove such specific medical findings under a theory of battery... It is the conduct of the unauthorized procedure which constitutes the tort.” Dutry v. Patterson, 741 A.2d 199, 203 (Pa. Super. 1999); see also Taylor v. Albert Einstein Med. Ctr., 723 A.2d 1027, 1035 (Pa. Super. 1998).

In order to recover in an action for battery, a plaintiff need only prove that the required disclosure did not occur, and thus no consent was given. In a battery action, there is no need to prove that knowledge of the undisclosed information would have changed the patient’s treatment decision, to demonstrate that the patient suffered any remediable harm as a result of the nondisclosure, or to introduce extensive expert testimony. In addition, many defenses to negligence, such as an emergency situation or invocation of the therapeutic privilege, are unavailable to a physician charged with battery. For these reasons, battery generally is viewed as more favorable to patients, and the move from battery to negligence has been characterized as an attempt to protect physicians from liability for minor disclosure failure. Krause, supra note 266, at 309.
was unconsented and offensive. Additionally, a battery claim can expose a physician to punitive damages.\textsuperscript{270}

Following that transition, many courts have been reluctant to find a cause of action for battery in health care—even where a plaintiff was ostensibly subjected to undisclosed research—so long as there was some sort of consent. Thus, in *Heinrich v. Sweet*, in which brain cancer patients allegedly were unwittingly injected with a boron compound prior to radiation,\textsuperscript{271} the federal district court denied a claim for battery.\textsuperscript{272} The court found the plaintiffs did not contend there was no consent.\textsuperscript{273} Rather, they said the consent was inadequately informed, hence a matter of negligence rather than battery.\textsuperscript{274}

\textsuperscript{270} "However, expert opinion as to community standard is not required in a battery count, in which the patient must merely prove failure to give informed consent and a mere touching absent consent. Moreover a doctor could be held liable for punitive damages under a battery count, and if held liable for the intentional tort of battery he might not be covered by his malpractice insurance." Perry v. Shaw, 106 Cal. Rptr. 2d 70, 73 (Cal. Ct. App. 2001) (citing Cobbs v. Grant, 104 Cal. Rptr. 505, 512 (Cal. 1972)).

See also Shultz, supra note 114, at 225.

On the one hand, a general consent to treatment given without awareness of risks, prognoses, and options was seen as an insufficient basis upon which to authorize treatment, even medically defensible treatment. Yet to hold that such informed consent was invalid, thereby subjecting doctors to actions for battery, threatened to yield unacceptably harsh results. Given the absolute nature of battery, the narrowness of its defenses, and the breadth of its remedies, doctors could end up paying significant damages after providing faultless medical treatment, simply because some minor informational aspect of the consent process was questioned. \textit{id.}

See also Howard v. Univ. of Med., 800 A.2d 73, 80 (N.J. 2002) (noting that even where an operation is perfectly performed with good medical results, nominal and punitive damages may be available if proper consent was not obtained); Trognin v. Fruchtman, 207 N.W.2d 297, 313 (Wis. 1973) (opining that a physician’s breach of informed consent should not be treated as conventional battery; the latter is essentially a criminal act, potentially warranting punitive damages that must be paid out of pocket—unfair to impose on a physician for a simple failure to inform).

\textsuperscript{271} See *Heinrich v. Sweet*, 49 F. Supp. 2d 27, 27 (D. Mass. 1999) (Heinrich II). The Heinrich plaintiffs alleged that the "United States government conspired to conduct extensive, unproven and dangerous medical experiments on over 140 terminally ill patients, without their knowledge or consent" by subjecting them to experimental boron neutron capture therapy. \textit{id.}

The facts in this case are not altogether clear. Although the initial description of the case is of completely undisclosed research, a jury subsequently found in favor of defendants on the informed consent claim. See *Heinrich v. Sweet*, 308 F.3d 48, 70-71 (1st Cir. 2002) (Heinrich VI).


\textsuperscript{273} \textit{id. at} 38.

\textsuperscript{274} \textit{id.} (stating the "[p]laintiffs have not alleged that their decedents were unwilling participants in the BNCT trials . . . . Rather, the crucial allegation in the plaintiffs’ case is that
In a similar vein, the Louisiana Supreme Court refused to find battery when a surgeon, after promising that he would do a hernia repair using a mesh material, simply ignored his promise and performed a very different procedure. The court cited the state statute, emphasizing the legislature’s determination that negligence rather than battery must govern a failure to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent. “We therefore reject a battery-based liability in lack of informed consent cases (which include no-consent cases) in favor of liability based on breach of the doctor’s duty to provide the patient with material information concerning the medical procedure.”

Nevertheless, battery continues to play a role in the litigation of adverse health care events. Although the classic definition con-

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their decedents would not have consented to the experiments had they been given full information. As such, the plaintiffs’ action is one for lack of informed consent, and therefore the motion to dismiss the battery claim is GRANTED.”

Notwithstanding this ruling, the court later noted a particularly moving example of what surely appears to be battery.

The most poignant of Sweet’s medical hubris is found in the testimony of Marie Denning, Eileen Sienkiewicz’s sister. . . . She testified that she visited her sister in Mass General shortly before the latter’s death. . . . She found her sister struggling feebly against the nurses, begging them not to give her any more boron neutron injections. . . . Marie Denning went to see Dr. Sweet and asked him to discontinue the treatments. . . . His response was to say ‘Your sister’s been through a lot and for the good of mankind . . . this will help.’


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Id. at 452-53 (emphasis omitted). However, the court noted:

Nevertheless, the doctor’s breach of duty cannot be fairly said to have resulted in no injury whatsoever . . . . While we have herein rejected battery as the basis for analyzing liability in lack of informed consent cases, some of the damages generally awarded in battery cases are applicable in our discussion of damages in this case . . . . [T]he doctor’s breach of duty caused plaintiff to undergo a medical procedure to which the patient expressly objected and for which the doctor failed to provide adequate information in response to the patient’s request, thereby causing damages to plaintiff’s dignity, privacy and emotional well-being. See id. at 455.

The state of Pennsylvania has adopted a curious mix of informed consent and battery. On the one hand, the state officially recognizes only battery and not informed consent as the applicable tort where information has been inadequate. Courts apply the doctrine exclusively to surgery and other invasive procedures, on the ground that “[i]t is the invasive nature of the surgical or operative procedure involving a surgical cut and the use of surgical instruments that gives rise to the need to inform the patient of risks prior to surgery.” Morgan v. MacPhail, 704 A.2d 617, 620 (Pa. 1997). Additionally, the informed consent statute in Pennsylvania requires informed consent before performing radiation, chemo-
cerns offensive unconsented touching, courts commonly recognize a “medical battery” action in three main scenarios. The first is a complete lack of consent. For instance, when pregnant women were given diethylstilbestrol (DES) to prevent miscarriage without

therapy, blood transfusion, inserting a surgical device, or administering an experimental therapy. Krause, supra note 266, at 310.

Pennsylvania also honors the battery tradition that no injury is required, and no causation need be shown between the failure to disclose and whatever injuries are incurred. See Dutry v. Patterson, 771 A.2d 1255, 1258 (Pa. 2001) (maintaining the premise that an informed consent claim sounds in battery); Dutry v. Patterson, 741 A.2d 199, 203 (Pa. Super. 1999); Taylor v. Albert Einstein Med. Ctr., 723 A.2d 1027, 1035 (Pa. Super. 1998).

On the other hand, Pennsylvania uses a patient-based disclosure standard, in which the physician is obligated to disclose “material facts, risks, complications and alternatives to surgery which a reasonable man in the patient’s position would have considered significant in deciding whether to have the operation . . . .” Gouse v. Cassel, 615 A.2d 331, 333 (Pa. 1992).

Tennessee follows a somewhat similar approach, emphasizing battery as the cornerstone of the duty to disclose. See Shadrick v. Coker, 963 S.W.2d 726, 732 (Tenn. 1998); Cardwell v. Bechtol, 724 S.W.2d 739, 745 (Tenn. 1987).

278 The Restatement (Second) of Torts, § 18, states that “[a]n act is subject to liability to another for battery if (a) it acts intending to cause a harmful or offensive contact with the person of the other or a third person . . . .” In comment (c) to section 18 the meaning of “contact with another person” is more fully explained. As noted therein, “[i]t is not necessary that the contact with another’s person be directly caused by some act of the actor. All that is necessary is that the act intend to cause the other, directly or indirectly, to come in contact with a foreign substance in a manner which the other would reasonably regard as offensive.” Fritter v. IOLAB Corp., 607 A.2d 1111, 1115 (Pa. Super. 1992). See also Mink v. Univ. of Chicago, 460 F. Supp. 713, 718 (N.D. Ill. 1978) (citing Restatement (Second) of Torts).

“[I]nformed consent is not effectively obtained, the defendant’s departure from the standard of care is not negligence but battery because ‘the doctrine of battery [is] applicable to cases involving treatment performed without informed or knowledgeable consent.’ . . . As observed in Landford v. York . . . malpractice ‘is based on lack of care or skill in the performance of services contracted for, and [battery] on wrongful trespass on the person regardless of the skill employed. The assertion of one is the denial of the other.’” Cardwell v. Bechtol, 724 S.W.2d at 739 (citing Landford v. York, 357 S.W.2d 525, 528 (Tenn. 1970)).

279 Several courts have used the term “medical battery” to characterize unconsented medical treatment. See Taylor v. Johnston, 985 P.2d 460, 465 (Alaska 1999) (concluding that a medical battery claim may lie if a person falsely claiming to be a doctor touches a patient); Hernandez v. Schitteck, 713 N.E.2d 203, 207 (Ill. App. 3d 1999) (holding “[i]njury in medical battery case is allowed when the patient establishes a complete lack of consent to medical procedures performed, when the treatment is against the patient’s will and, or when the treatment is ‘substantially at variance with the consent given’”); Gragg v. Calandra, 696 N.E.2d 1282, 1287 (Ill. App. 2d 1991) (recognizing both a negligence and battery action to address lack of consent for medical procedures); Kus v. Sherman Hosp., 644 N.E.2d 1214, 1220 (Ill. App. 2d 1995) (noting that “medical battery is a valid legal claim in this state”); Harvey v. Stockland, 566 S.E.2d 529, 534 (S.C. 2002) (recognizing a viable cause of action for medical battery when physicians administered post-operative blood transfusions to a Jehovah’s Witness patient, despite multiple prior refusals).
their knowledge or consent, ultimately increasing the risk of cancer in their daughters, a federal district court was willing to find battery even though the women themselves were not injured.\textsuperscript{260} "The essence... of the question in a battery case involving a physician is what did the patient agree with the physician to have done, and was the ultimate contact by the physician within the scope of the patient's consent."\textsuperscript{261}

Second, battery has been found where a procedure is substantially different from or beyond that to which the patient consented (in essence, a substitution of one treatment for another). In Karl J. Pizzalotto, M.D., Ltd. v. Wilson,\textsuperscript{262} for instance, a patient had agreed to conservative surgery but instead received an unwanted, unconsented hysterectomy. Similarly, in Russell v. Murphy,\textsuperscript{263} the patient expressly wanted local anesthesia but instead received general anesthesia.\textsuperscript{264}

\textsuperscript{260}Mink v. Univ. of Chicago, 460 F. Supp. 713, 718-19 (N.D. Ill. 1978)

\textsuperscript{261}Id. at 718 (citing Cathemer v. Hunter, 558 P.2d 975, 978 (Ariz. Ct. App. 1976)) (alteration in original).

\textsuperscript{262}See also Lojk v. Quandt, 706 F.2d 1456, 1458 (7th Cir. 1983), cert. denied, 106 S.Ct. 822 (1986) (psychiatric patient at VA hospital subjected to electro-convulsive therapy without his competent, knowledgeable consent); Lloyd v. Kull, 329 F.2d 168, 170 (7th Cir. 1964) (surgeon removed a mole without consent during surgery for completely different purpose); Perry v. Shaw, 106 Cal. Rptr. 70, 72 (2001) (surgeon hired to remove excess skin after major weight loss did a breast implant completely without consent); Curtis v. Jaskey, 759 N.E.2d 962, 963 (Ill. App. Ct. 2001) (obstetrician performed an episiotomy that had been explicitly rejected); Gragg v. Calandra, 696 N.E.2d at 1285 (Ill. App. Ct. 1998) (court found potential battery in case featuring unwanted heart surgery followed by unwanted life support); Roberson v. Provident House, 576 So.2d 992, 992 (La. 1991) (quadruple patient repeatedly received indwelling urinary catheters against his express refusal); Harvey v. Strickland, 566 S.E.2d at 531-32 (surgeon transfused blood into Jehovah's Witness patient who had expressly refused).


\textsuperscript{264}Russell v. Murphy, 86 S.W.3d 745, 747 (Tex. App.--Dallas 2002).

\textsuperscript{265}Id. at 747; see also Cobbs v. Grant, 502 P.2d 1, 7 (Cal. 1972) "Where a doctor obtains consent of the patient to perform one type of treatment and subsequently performs a substantially different treatment for which consent was not obtained, there is a clear case of battery."

In Gaskin v. Goldman, 520 N.E.2d 1085, 1094 (Ill. App. Ct. 1988), a dentist extracted five more teeth than the patient agreed to have removed: "[R]ecovers under a battery theory in medical malpractice cases is also allowed where 'the treatment is either against the patient's will or substantially at variance with the consent given' (citing Woodley v. Henderson, 418 A.2d 1123, 1133 (Me. 1980)). See also Cathemer v. Hunter, 558 P.2d 975 (Ariz. App. 1976) (hip surgery significantly different from that which the patient was led to believe he would receive); Benton v. Snyder, 825 S.W.2d 409 (Tenn. 1992) (surgeon did more extensive surgery than that to which the patient consented, resulting in sterility); Penn v. Havnc, 210 N.W.2d 640, 646, 648 (Iowa 1973) (patient had agreed to have two, but not four, vertebrae fused); Hernandez v. Schiltz, 713 N.E.2d 203, 205 (Ill. App. Ct. 1999).
Third, courts are willing to find battery when a different doctor is substituted for the one the patient agreed would perform the procedure ("ghost surgery"). Thus, when a patient's kidney stone surgery was performed by a different doctor in the physician's medical group, the New Jersey Supreme Court, noting that it is unacceptable to mislead patients as to the identity of their physician, held that the substitution constituted battery. The latter two scenarios, in which something to which the patient did not consent is...
substituted for something to which he did consent (a different procedure, a different doctor), emphasize that battery is a matter of agreements and boundaries. The consent marks a boundary, outside of which the physician may not go without further consultation and agreement.

In the special case of undisclosed research, a very distinctive kind of substitution takes place, one that arguably is even more offensive than the typical instances of medical battery discussed above. It is a substitution of goals.

As emphasized in Part II, clinical research pursues a fundamentally different goal from ordinary medical care. While medical practice seeks to benefit the individual patient, research seeks generalizable scientific knowledge via activities in accordance with a protocol. Therefore, when patients are subjected to research without their knowledge or consent, the investigator has covertly made a profound change of goals. Whereas the patient believes his personal welfare is the primary goal, the real goal is now to benefit society by following the protocol, even sometimes contrary to the patient’s best interest.

At the same time, the physician has also shifted his relationship with the patient from a fiduciary physician-patient relationship to a nonfiduciary investigator-subject connection. Accordingly, where research is substituted for or added to treatment and the investigator has not clearly informed the patient, courts should recognize “medical research battery” as a cause of action with the full panoply of battery damages, including punitive damages.

287 See discussion supra Part II.

288 Some courts have already applied battery to the research setting. In Kas v. Sherman Hospital, 644 N.E.2d 1214, 1220 (Ill. App. Ct. 1995), a court was willing to apply “medical battery” in the research setting. The physician/investigator’s study was approved by the Institutional Review Board (IRB), but thereafter the physician removed from the consent form the language indicating that the intraocular lens the patient would receive was experimental, instead portraying the lens as routine and well-accepted. Id. at 12. The Illinois appellate court held that “[c]learly, the medical battery claim is warranted under existing law.” Id. at 1220.

Another court also identified the possibility of battery in the research setting. Whitlock v. Duke University, 637 F. Supp. 1463 (M.D.N.C. 1986), aff’d, 829 F.2d 1340 (4th Cir. 1987), featured an allegation that organic brain disease was caused by participation in a research project subjecting volunteers to simulated deep-diving. Id. at 1466. The district court noted that, although inadequate information is normally a matter of negligence, “if the failure to provide adequate information is the result of fraudulent misrepresentation, the action may sound in battery.” Id. at 1467. In this case, however, the court found the plaintiff had not established either injury or a failure to inform. See also Fritter v. IOLAB Corp., 607 A.2d 1111, 1113-15 (Pa. Super. Ct. 1992) (holding that hospital that was active
Note that this modified battery tort would not apply to clinical innovation, which, as noted above, still focuses on the best interests of the individual. Innovation may feature significant uncertainty, and a number of courts have held that physicians should inform patients when an intervention is untested. One can further argue that innovators have an obligation to undertake research to test the participant in research protocol on an experimental intraocular lens could be liable for technical battery).

See supra Part II.

Courts are divided over the question of whether a physician must reveal that his proposed intervention is not well-tested. Some courts have mandated disclosure. For example, an Arizona appellate court held "that when a physician contemplates a novel or investigational procedure he must inform his patient of the novel or investigational nature of the procedure... Absent this, he has committed a battery." Gaston v. Hunter, 588 P.2d 326, 351 (Ariz. Ct. App. 1978) (finding battery for failure to disclose to the patient that a procedure was investigational).

The Tenth Circuit agreed.

We recognize that there are many considerations that may influence a doctor’s decision on the amount of radiation to be administered in any given case. However, our legal system requires that the treatment to be administered must be within the bounds of recognized medical standards in order to overcome legal challenges such as that presented in this case. Accordingly, in order for a physician to avoid liability by engaging in drastic or experimental treatment, which exceeds the bounds of established medical standards, his patient must always be fully informed about the experimental nature of the treatment and of the foreseeable consequences of that treatment.

Ahern v. Veterans Admin., 537 F.2d 1098, 1102 (10th Cir. 1976) (deciding a case where cancer patient received several times the usual dose of radiation, in hopes of rapid tumor shrinkage).

Sec also Salgo v. Leland Stanford Jr. Univ. Bd. of Trust., 317 P.2d 170, 180 (Cal. 1957) (noting that physicians who use an experimental approach on patients must disclose that fact, but noting also that merely departing from a manufacturer’s recommendations does not, per se, constitute experimentation); Estrada v. Jaques, 521 S.E.2d 240 (N.C. Ct. App. 1984) (surgeon and radiologist attempted to treat a patient’s blood clot with a highly experimental steel coil embolization procedure); Retkwa v. Orentreich, 584 N.Y.S.2d 710, 712-13 (N.Y. App. Div. 1992) (patient should have been told that injectable silicone was not approved by the FDA as an injectable substance); Corrigan v. Methodist Hosp., 874 F. Supp. 657, 658 (E.D. Pa. 1995) (information about investigational status of pedicle screws in orthopedic surgery is relevant); Shadrick v. Coker, 663 S.W.2d 726 (Tenn. 1989) (patient should have been told about investigational status of pedicle screws before orthopedic surgery).

On the other hand, in several cases in which orthopedists used a device called a pedicle screw in an off-label fashion, courts held that doctors were not obligated to disclose the device’s investigational status. See Blazenski v. Cook, 787 A.2d 910, 919 (N.J. Super. Ct. App. Div. 2001) (“What is clear is that the FDA’s concern is to regulate the marketing and labeling of medical devices, not to intrude upon the practice of medicine or redefine the doctrine of informed consent”); Southard v. Temple Univ. Hosp., 781 A.2d 101, 104 (Pa. 2001) (“while the FDA regulates the marketing and labeling of medical devices, it does not purport to interfere with the practice of medicine”); See also Noah, supra note 1, at 372.
safety and effectiveness of their innovations. Nevertheless, innovation does not modify the basic commitment of the physician to pursue this individual patient’s best interest. Hence, a physician’s failure to disclose that his intervention is new and untested, unlike a failure to disclose that a patient has been enrolled in systematic research, should be deemed a matter of inadequate informed consent, not medical research battery.

As a practical matter, battery will probably remain limited as an avenue of tort remedy, even in research. First, in the current era, a complete failure to inform someone that he has been participating in research rather than in standard care is probably relatively rare. Between the recent spate of lawsuits and flurry of government penalties for failures to adhere to regulations, the research community has become quite keenly sensitized to the importance of information and consent. Still, some areas may not be so well-marked. Surgical specialties, for instance, could at some point come under increased scrutiny. Because surgical procedures and off-label uses of approved drugs and devices are not regulated by the Food and Drug Administration (FDA), it is sometimes difficult to distinguish between, on the one hand, an innovation that is repeated for a number of patients and then evaluated by retrospective chart review (not regarded as research in federal regulations) versus research, on the other hand. As litigators and the public become more sensitized to the thinness and ambiguity of this line, it would not be surprising to see surgical specialties come under increasing scrutiny and, in some instances, be accused of undertaking research without proper IRB and informed consent procedures.

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291 Id. at 372.73.


293 45 C.F.R. § 46.101(b)(4).

294 Two recent cases provide evidence that physicians are not always clear about what constitutes research. In one, the National Naval Medical Center suspended all orthopedic and radiology research on patients after discovering that a study of shoulder injuries had not been submitted for approval. See Lawrence K. Altman, Naval Center Halts Research During Inquiry About Ethics, N.Y. Times (Oct. 27, 2003), available at http://www.nytimes.com/2003/10/27/national/27ETH.html. In the other, a physician at a state mental hospital undertook research-related interventions without obtaining informed consent and prior to obtaining regulatory review. See Ellen Barry, Drugs of 4 Patients Subbed Without OK, Boston (Nov. 10, 2003) available at http://www.boston.com/news/local/articles/2003/11/10/drugs_of_4_patients_subbed_without_ok/.
Second, battery as an intentional tort is not ordinarily covered by a physician-investigator’s liability insurance. To the extent that this removes an important “pocket” into which a plaintiff might reach, battery becomes less attractive as a cause of action, even though in principle it can permit lucrative punitive damages.

B. Informed Consent

For research undertaken during the current era of federal supervision and mandatory informed consent, the most prevalent complaints concern inadequate, not absent, information. If battery applies to a complete failure to disclose, breach of informed consent would apply when a researcher has openly invited someone to enter a research protocol but insufficiently described its nature, uncertainties, risks or alternatives.

Admittedly, even here the conceptual distinctions are not tidy. If the inadequacy of disclosure effectively masks the fact that the project is research or significantly understates the extent to which the overall course of care is research, it could be a covert attempt to nudge the person to enroll and the proper complaint could potentially be battery. Similarly, if a researcher has failed to describe viable standard treatment alternatives, leaving the patient with an incorrect impression that his only option is the research protocol, then again battery might be an appropriate complaint. Even though the patient’s entry into the research would not be covert, the investigator would have achieved the same result: surreptitiously limiting or removing choice about whether to enter into research.

Aside from such relatively uncommon scenarios, breach of informed consent will be the leading complaint in the research setting. However, an informed consent tort for the research setting cannot be simplistically imported from conventional medical malpractice doctrine. As a negligence tort, breach of informed consent requires the usual elements of negligence—breach of the duty of care, injury, and causality. As we will see, however, all three elements must be substantially overhauled for research.

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26 See discussion supra Part I.

27 Kline, supra note 210, at 9.
1. **Duty of Care: Scope of Disclosure**

For ordinary medical care, states establish physicians’ duty of disclosure in one of two ways. The older approach is a classic negligence-based requirement that the physician adhere to prevailing practices by telling the patient what other physicians would disclose, a standard that must be established by expert testimony.298 About half the states299 have adopted a newer standard that emerged through a trinity of cases in 1972.300 It asks not what physicians do, but what patients need to know to make an informed decision. *Canterbury v. Spence*301 defined this as whatever information would be “material” to the patient’s “right of self-decision.”302 At the same time, even states with a patient-based standard do not generally base the disclosure duty on the vagaries of what any specific patient would want to know. Rather, nearly all embrace an “objective” standard, namely, what the reasonable and prudent patient in similar circumstances would want to know.303

Research requires a sharply different approach. Neither of the traditional malpractice standards is adequate for research. A physician-based standard could embrace little or no disclosure if physi-

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299 See Krause, supra note 266, at 311; Noah, supra note 1, at 367.


301 The Supreme Court of Connecticut voiced the transition well: the incongruity of making the medical profession the sole arbiter of what information was necessary for an informed decision to be made by a patient concerning his own physical well-being has led to various judicial and legislative attempts within the last decade to define a standard tailored to the needs of the patient but not unreasonably burdensome upon the physician or wholly dispensing with the notion that ‘doctor knows best’ in some situations. While the essential ambivalence between the right of the patient to make a knowledgeable choice and the duty of the doctor to prescribe the treatment his professional judgment deems best for the patient has not been fully resolved, the outline has begun to emerge. Logan v. Greenwich Hosp. Ass’n, 465 A.2d 294, 299 (Conn. 1983).


303 Id. at 786-87. Interestingly, although a number of states moved quickly to adopt the “patient-based” standard after 1972, several actually reversed course after physicians pressured state legislatures, including New York, Ohio, and Vermont. Logan v. Greenwich Hosp. Ass’n, 465 A.2d 294, 300 (Conn. 1983).

304 Not all states use this objective standard. See, e.g., Scott v. Bradford, 606 P.2d 554 (Oklahoma). For further discussion see Grant H. Morris, Dissing Disclosure: Just What The Doctor Ordered, 44 Am. J. Rev. 313, 331 (2002).
cientists’ prevailing practice were to keep patients in the dark. The “reasonable patient” standard has little applicability because the decision to enter research is highly individual. Research does not aim to benefit any individual patient, and people can have a wide variety of reasons for entering research, from altruism to financial gain to a desperate, last-ditch hope for cure. The Belmont Report itself came to this conclusion back in 1979, finding both of the conventional disclosure standards “insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care.”

Another problem with ordinary informed consent doctrine is its permission for physicians to opt out of disclosure on grounds of “therapeutic privilege,” withholding information if it would unduly traumatize the patient. In the research setting, any such exemption could be an open invitation for researchers to perpetuate the patient’s ignorance under the pretext that it’s “best” for him not to know he has been enrolled in research. Indeed, some commenta-

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As noted by some observers, even in ordinary medicine it may be nearly nonsensical to suppose that there is any way of discerning what “the” reasonable person would do in a given situation. Krause points out, “a review of empirical evidence by Twerski and Cohen suggests that juries may face an impossible task . . . . Reviewing the psychological literature regarding information processing and decision making, the authors argue that it is extremely difficult to predict how a person’s decision will change as more information is provided . . . . The authors argue that unless a fact finder completely knows the patient’s ‘base’ information and beliefs, as well as the order and manner in which the new information would have been presented by the physician, it is almost impossible to determine with any accuracy what the patient would have done.” Krause, supra note 266, at 310-20.


As should now be clear, this argument must fail because research by definition is not designed to benefit any particular individual, and it changes the physician-patient fiduciary relationship into a fundamentally nonfiduciary one. Even in the case of Phase IV trials, research cannot promise the individually optimal benefit, despite the fact that everyone can be expected to benefit by receiving one or the other treatment. After all, in Phase IV studies that compare proven treatments, it is not the research protocol that benefits the individual, so much as the treatments themselves.
tors argue that prospective subjects must be virtually assaulted with the emphasis that research is not treatment, lest they confuse the two.\textsuperscript{308}

Accordingly, research requires a distinctive standard of disclosure. It will be based heavily on federal regulations that require an array of facts to be disclosed, such as the purposes, duration and procedures of the research; any reasonably foreseeable risks or discomforts; potential benefits to the enrollee or to others; available alternatives to the research trial; and other specified information.\textsuperscript{309}

Additionally, the disclosure standard for research should include a subjective element in deference to individuals' varying needs for personally important information. Consent forms virtually always incorporate this element by inviting prospective enroll-

Under unusual conditions, such as the testing of emergency procedures, it may be acceptable to enter patients into research without their consent. However, this is not done because it is "best" for patients but rather because the research is important, there is no alternative, and the risk-benefit balance is acceptable. Protection of human subjects: informed consent and waiver of informed consent requirements in certain emergency research. 61 Fed. Reg. 51,498 (FDA Oct. 2, 1996). See also A.N. Shah & J. Sugrman, Protecting Research Subjects Under the Waiver of Informed Consent for Emergency Research: Experiences With Efforts To Inform the Community, 41 ANNALS EMERGENCY MED. 72, 73 (2003).

\textsuperscript{308} Appelbaum and colleagues suggest that beyond researchers' merely disclosing the standard litany of risks and benefits, it may be necessary to assault the beliefs that underlie the therapeutic distortions. Subjects may have to be told explicitly that scientific goals will have priority over therapeutic goals, that the investigator—because of his dual role as researcher and physician—will be unable to maintain an unaltered devotion to their well-being (or that, as Fried would say, the investigator cannot offer them personal care), and that various aspects of the study may turn out not to be in their best interests at all.

Appelbaum et al., supra note 97, at 328.

\textsuperscript{309} 43 C.F.R. § 46.11b; see also Phillip M. Boin, Surrogate Consent and the Incompetent Experimental Subject, 46 FOOD DRUGS COSM. L.J. 739, 743 (1991) (describing federal regulations regarding decision making).

The Maryland Supreme Court emphasized federal regulations as a source of informed consent duties in Grimes v. Kennedy Krieger Institute, 782 A.2d 807, 849 (Md. 2001). In this case, a special relationship out of which duties might arise might be created by reason of the federally imposed regulations. The question becomes whether this duty of informed consent created by federal regulation, as a matter of state law, translates into a duty of care arising out of the unique relationship that is researcher-subject, as opposed to doctor-patient. We answer that question in the affirmative. In this State, it may, depending on the facts, create such a duty.\textsuperscript{Id}

Recall that the research context differs from clinical innovation, where courts differ about the extent to which physicians must disclose the innovative character of an intervention. In Retik v. Onetouch, 584 N.Y.S.2d 710, 713 (N.Y. Sup. Ct. 1992), for instance, even though the court found that disclosure may be owed, the question would turn on whether a jury would find that physicians working with liquid silicone would have disclosed its investigational status.\textsuperscript{Id}
ees to ask questions. At the same time, such a subjective element should not usher in a requirement that investigators be mind-readers who can anticipate every distinctive concern that each potential research enrollee might have.

Given this tension, a reasonable standard of disclosure might have several elements. First, per the Belmont Report, a "reasonable volunteer" standard would require telling patients clearly that the study is not geared toward their personal benefit, and that their participation would be a voluntary activity dedicated to furthering scientific knowledge.\textsuperscript{311}

Second, many of the particulars that must be disclosed would be identified according to regulatory requirements,\textsuperscript{312} with the caveat that tort law should probably expect those requirements to be met whether or not the particular research project in question is technically subject to federal regulation.

Third, to balance subjects' need for personalized disclosure with investigators' need for clear expectations, the research standard of disclosure might include a rebuttable presumption. The information provided on the consent form should be presumed adequate except where the prospective enrollee has explicitly asked for additional information, as where someone might inquire about the physician's level of experience,\textsuperscript{313} or where a Jehovah's Witness might ask about the use of blood products.\textsuperscript{314} Once the physician is

\textsuperscript{310} 45 C.F.R. § 46.116(a)(7).

\textsuperscript{311} The Belmont Report, supra note 305.

\textsuperscript{312} E.g., 45 C.F.R. § 46.116. (1992).

\textsuperscript{313} Some courts have recognized a duty for physicians to provide information beyond the usual disclosure, even in the context of ordinary care. When a patient asks about the physician's level of experience, the physician is obligated to answer fully and truthfully. See, e.g., Howard v. Univ. of Med., 800 A.2d 73, 84-85 (N.J. 2002); Duttry v. Patterson, 741 A.2d 199, 202 (Pa. Super. Ct. 1999) reversal; Duttry v. Patterson, 771 A.2d 1258 (Pa. 2001); Johnson by Adler v. Kokemoor, 545 N.W.2d 495, 504 (Wis. 1996).


Other courts, however, have denied that physicians must affirmative volunteer information about their experience with the instant procedure. See Albany Urology Clinics, P.C. v. Cleveland, 528 S.E.2d 777, 779-80 (Ga. 2000); Ditto v. McCord, 947 P.2d 952, 954 (Haw. 1997).

\textsuperscript{314} As noted by the Arizona Supreme Court several decades ago, "because of the fiduciary relationship between physician and patient, the scope of disclosure required can be expanded by patient's instructions to physician." Hales v. Pittman, 576 P.2d 493, 497 (Ariz.
explicitly on notice that a particular kind of information is important to the prospective participant, his duty to disclose would expand to encompass it. This rebuttable presumption will prove important in assessing causality, an issue addressed below.

2. Injury

Standard medical malpractice litigation recognizes diverse injuries and causes of action, such as wrongful death, negligence, and the like. Fraud, for instance, could figure prominently in research litigation. Where researchers have either failed entirely to disclose that the project is research or have misdescribed risks, discomforts or other aspects of the research, courts have allowed fraud as a cause of action. Indeed, fraud can be linked with battery if the patient is induced to agree to a medical intervention, or to research, under false pretenses.

1973. Though the case concerned medical treatment rather than research, the court recognized the need for individualized information. See id.


320 See discussion of battery, supra Part V.A. On a realted note, fraudulent concealment has tolled the statute of limitations in some research cases, allowing claims to proceed that would otherwise have been long defunct. See e.g., Heinrich et al v. Heinrich v. Sweet, 62 F. Supp. 2d 282 (D. Mass. 1999) (Heinrich III) (finding that the Massachusetts, but not the New York, definition of fraudulent concealment was satisfied); Anderson v. George H. F. Supp. 713, 721 (N.D. Ill. 1978); Barret v. United States, 689 F. 2d 324, 333 (2nd Cir. 1982); Sadowski v. Cook, 983 S.W. 2d 726, 733 (Tenn. 1998). See also County of Cook v. Barrett, 344 N.E.2d 540, 550 (Ill. App. Ct. 1976). But see Bonin v. Vannaman, 929 P.2d 751 (Kan. 1996) (holding a doctor did not commit a fraud because he had no legal duty to reveal material facts to patient. Thus, the statute of limitations was not tolled); Rioux v. Poc. Northwest Research Found., 980 F. Supp. 349 (D. Or. 1997) (plaintiff failed to exercise due diligence to learn of the fraud).

321 Where a fiduciary relationship is involved, as between a treating physician and his patient, a number of jurisdictions are willing to construe mere silence as concealment. In some states, physicians are regarded as fiduciaries who have an affirmative duty to disclose to their patients when they believe the patient has a tort claim, even against the physician himself. See Heinrich et al v. Heinrich v. Sweet, 62 F. Supp. 2d 282 (D. Mass. 2000) where the District of Massachusetts court found that "Massachusetts imposes a fiduciary duty on doctors to disclose known possible causes of action to patients." Id. at 304.

In a subsequent ruling the court refined that holding to indicate that "there must be some evidence that the defendant knew or believed" that she had breached her professional duty. "Massachusetts imposes a fiduciary duty on doctors to disclose known possible"
Such standard causes of action should, of course, be equally available for research-related injuries, with suitable adaptation to the research setting, as proposed above. The more interesting question is whether special kinds of injuries should be recognized in research, beyond those ordinarily permitted for medical malpractice, to stand as the requisite injuries for an informed consent tort.

Arguably yes, once we appreciate the fact that research does not propose to benefit any specific enrollee, and thereby carries significant opportunities for exploitation of vulnerable people. At the extreme, research abuses that involve outright duping would seem particularly insulting to the dignity of the research subject who is being used for ulterior purposes—a difference in kind from the standard malpractice error that occurs in an effort to directly benefit a patient. But infractions need not be malicious or even intentional. Given the economic enormity of the clinical research business, pressures on researchers to complete trials quickly might sometimes lead to a less-than-meticulous informed consent process, thereby potentially camouflaging the purpose, risks, and uncertainties of the research. Even more commonly, investigators who are simply enthused about a project they genuinely believe will help humankind may unintentionally downplay the risks and disadvantages of their research, thereby presenting a distorted picture for potential subjects.

Unfortunately, existing tort law may be inadequate to identify the kinds of injuries that may be especially important in the research setting. After all, so long as courts consider a breach of informed consent in research to be simply another instance of informed consent as a medical malpractice tort, they will require—and will only

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Although fraudulent concealment can of course figure in ordinary medical malpractice actions, the research setting may present especially appropriate applications of this tort, particularly where treating physicians add research to their prevailing relationships with patients. Research carries more stringent requirements for disclosure; often higher levels of risk and uncertainty; and greater likelihood for conflicts of interest, all of which can tempt investigators to back away from the ample disclosure they owe prospective research participants.

13 See discussion supra Part II.
recognize—the kinds of injuries familiar in medical malpractice actions. Medical malpractice ordinarily requires some sort of physical injury in order to conclude that a remedy is warranted. Many jurisdictions recognize some non-physical injuries, such as emotional distress, but commonly even these must be linked to a physical injury or the threat of one. On this approach, if a duped or ill-informed research subject does not incur physical or other specifically accepted harms, there is no tort. And yet in research, such limits would seem seriously inappropriate. John Moore, who was surreptitiously coopted into David Golde’s lucrative research agenda, did not suffer significant physical or even economic damage. Yet he was profoundly wronged. Courts need to recognize that certain kinds of mistreatment in the research context can be injuries in themselves, quite regardless whether they cause further physical or other damage. Potential avenues include emotional distress and direct dignity harm.

a. Emotional Distress

Emotional distress, intentional or negligent, could particularly apply where someone has been surreptitiously entered into a research project or where the description of risks and inconveniences has been significantly understated. Courts have acknowledged emotional distress damages in research cases. Admittedly, there is no simple formula for applying this tort, since jurisdictions differ markedly on threshold questions such as whether a physical injury or the threat of one is required. Some jurisdictions do not require either, thus opening the door to an emotional distress tort for the sheer fact of being deceived about research, quite apart from

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314. Voerz, supra note 114 at 212; Shultz, supra note 114, at 224, 232. See also Brzoska v Olson, 365 A.2d 1355, 1362 (Del. 1976); Sargeant v Dowling, 701 So.2d 447, 455 (La. 1997); Sard v Hardy, 35 A.2d 1014, 1021 (Md. App. 1977) (discussing “physical self-determination”); Woolley v Henderson, 418 A.2d 1123, 1129 (Me. 1980) (discussing patients’ interest in “physical self-determination”).

315. See discussion infra section 8.B.12 b.


317.

318. See supra note 114 at 212; Price & Lemons, supra note 20, at 30; Shultz, supra note 114, at 278.
whether the project caused any further harm. Applicable case law comes largely from outside the research realm, however, and may need to be adapted to the special circumstances of research. ²²⁵

Battery cases have also sometimes brought emotional distress damages.²²⁶ For instance, when a patient discovered that his surgery had been performed by a doctor he had never met, the New Jersey Supreme Court found that “a jury could award damages for mental anguish resulting from the belated knowledge that the operation was performed by a doctor to whom the patient had not given consent.”²²⁷ Similarly, when a plaintiff’s husband received unwanted heart surgery, followed by life support against both the patient’s advance directives and the family’s express refusal, an Illinois court approved emotional distress damages.²²⁸

Interestingly, wrongful birth case law supports emotional distress damages for a failure to provide and the opportunity to make

²²⁵ In Malen v. Kaiser Foundations Hospitals, 616 P.2d 813, 819 (Cal. 1980), for instance, a physician mistakenly diagnosed a woman as having syphilis and indicated that her husband would need to be tested. The California Supreme Court found that physical injury is not required for a cause of action in negligent infliction of emotional distress. Id. at 930-31. In an analogous case, the Maine Supreme Court held that when a psychotherapist developed a personal relationship with the lover of her patient, the patient can recover damages for mental distress even without physical injury or an underlying tort. Rowe v. Bennett, 514 A.2d 802, 806 (Me. 1986). See also Willis v. Ashby, 861 A.2d 442, 447 (N.J. Super. Ct. App. Div. 2002) (death of otherwise healthy infant during botched cesarean delivery could warrant emotional distress damages).

A New York court awarded emotional distress damages when a couple’s embryo was mistakenly implanted in the uterus of another woman. Perry-Rogers v. Gobso, 723 N.Y.S.2d 28, 29 (N.Y. App. Div. 2001) (“Damages for emotional harm can be recovered even in the absence of physical injury when there is a duty owed by defendant to plaintiff, and a breach of that duty that result[s] directly in emotional harm.”); see also Perna v. Pirozzi, 457 A.2d 431, 438 (N.J. 1983) (“a jury could award damages for mental anguish resulting from the belated knowledge that the operation was performed by a doctor to whom the patient had not given consent.”). Another New York court concluded similarly regarding a mistaken diagnosis of cancer for a woman who, because she had previously had cancer, would foreseeably suffer severe distress upon receiving such a diagnosis. Martell v. St. Charles Hosp., 523 N.Y.S.2d 342 (N.Y. App. Div. 1987); see also Hecht v. Kaplan, 645 N.Y.S.2d 51 (W.V. App. Div. 1996).


In contrast, when patients filed suit after learning their dentist had AIDS, the Delaware Supreme Court found that there is no recovery for emotional distress in the absence of physical injury; mere fear of physical injury is not enough. Brzoska v. Olsen, 668 A.2d 1355, 1367 (Del. 1995). See Nancy Levit, Ethical Torts, 61 Geo Wash. L Rev. 136, 142-43, 170-72 (1992).
an informed, autonomous choice. In Berman v. Allan, an obstetrician’s failure to inform a pregnant woman about the option of amniocentesis led to the birth of a child with Down’s Syndrome—a child whose birth would have been averted, had the mother been informed in time to terminate her pregnancy. The court refused to recognize the child’s own claim for wrongful life and declined to award parents the broader costs of raising the child. However, it did accept an emotional distress claim, tied to a violation of the parents’ autonomy.

In failing to inform Mrs. Berman of the availability of amniocentesis, defendants directly deprived her and, derivatively, her husband of the option to accept or reject a parental relationship with the child and thus caused them to experience mental and emotional anguish upon their realization that they had given birth to a child afflicted with Down’s Syndrome. . . . We feel that the monetary equivalent of this distress is an appropriate measure of the harm suffered by the parents deriving from Mrs. Berman’s loss of her right to abort the fetus.

Other New Jersey courts have affirmed the point. “[T]he Court has repeatedly affirmed that the legal harm in a wrongful birth action is not the birth of the child, but the parents’ lost opportunity to decide for themselves whether to continue the pregnancy.” “In wrongful birth cases, there is no claim that the negligence of the physician caused the child’s impairments. . . . The sole claim is that negligence precluded the parents’ opportunity to decide whether to give birth to the impaired child in the first place. . . . Moreover, an award of damages for emotional distress has been recognized as one of the few avenues of redress for tortious conduct in this circumstance.”

Arguably, if the decision whether to bring a pregnancy to term is sufficiently important for the sheer deprivation of choice to warrant emotional distress damages, so might be the deprivation of a

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33 Id. at 8.
34 Id. at 13.
35 Id. at 14.
36 Id.
37 Berman, 404 A.2d at 14.
39 Geller v. Akawi, 818 A.2d 402, 411 (N.J. App. 2003), cert. denied, 827 A.2d 298 (N.J. 2003). The court continued: “In sum, the Court has expanded concepts of duty in order to specifically recognize a tort directed solely against parents, consisting of a deprivation of their right of choice through the absence of genetic counseling, and it has recognized a right of recovery for that tort.” Id. at 413.
decision whether to participate in research. Particularly where an ongoing physician-patient relationship is transformed into a profoundly different investigator-subject relationship, preempting the patient's opportunity to make his own decision could constitute a significant emotional injury.

b. Dignitary Injuries

In addition to standardly recognized injuries, courts arguably should recognize purely dignitary harms in the research context. Battery, discussed above, is perhaps the leading example of a dignitary tort. The plaintiff need not demonstrate any injury nor invoke expert witnesses. The lack of consent alone is sufficient if the touching is offensive. However, battery alone is inadequate to capture the problem of inadequate information in research. Battery, after all, requires touching,337 often construed in the medical context as surgery or some other concrete intervention.338

Because of such limitations, courts should go further. Even for ordinary medical care, a number of scholars have recommended that serious deficiencies of informed consent be deemed a distinct

337 Morris, supra note 303, at 336.
338 The state of Pennsylvania takes this constraint so literally that it will not permit an informed consent tort in any other kind of case, including cases in which physicians failed to inform patients about the risks and side-effects of medication. The only nonsurgical interventions that require informed consent are specified by statute: administering radiation or chemotherapy, administering a blood transfusion, inserting a surgical device, or administering an experimental therapy. See, e.g., Morgan v. MacPhail, 701 A.2d 617, 620 (Pa. 1997). Morgan stated:

The rationale underlying requiring informed consent for a surgical or operative procedure and not requiring informed consent for a non-surgical procedure is that the performance of a surgical procedure upon a patient without his consent constitutes a technical assault or a battery because the patient is typically unconscious and unable to object. . . . Appellants here argue that the traditional battery or assault-based theory should be abandoned in favor of a negligence standard. The basis for their argument is their assertion that a patient has the right to determine the scope and discretion of medical treatment no matter which form the treatment takes, whether surgical or non-surgical. The patient, appellants argue, has the right to make an informed choice as to electing to undergo a medical procedure after having been presented with the alternatives and the risks attendant to each alternative. This argument, however, flies in the face of the traditional battery theory. It is the invasive nature of the surgical or operative procedure involving a surgical cut and the use of surgical instruments that gives rise to the need to inform the patient of risks prior to surgery.

dignitary tort. Because standard informed consent doctrine usually limits recovery to cases featuring a physical or other separate injury, it can fail to honor human autonomy in cases where someone’s right to choose has been abused without demonstrable physical damage. If this is a problem in ordinary medicine, it is even more so in the research setting.

People who are imminently dying pose a particularly poignant illustration, because a requirement of physical injury is nearly impossible to satisfy. In Heinrich v. Sweet, the First Circuit ultimately determined that people with terminal brain cancer had no cause of action for wrongful death when they were allegedly subjected to experimental radiation treatments, because there was no evidence that the experiment hastened these patients’ already-imminent deaths. In cases like this, where the only documentable harm is deprivation of the right to make an informed choice, courts’ denial of dignitary violations as a distinct injury can effectively preclude recovery even in egregious cases.

Accordingly, per the recommendation above, courts should broaden the ambit of legally cognizable injuries to include dignitary harms. In addition to medical research battery, one such dignitary harm would be invasion of bodily integrity. The United States Supreme Court has emphasized that bodily integrity is a liberty interest protected by the Fifth and the Fourteenth Amendments. In essence, it is a civil rights claim that the plaintiff was denied due


340 Heinrich v. Sweet, 308 F.3d 48, 53 (1st Cir. 2002) (Heinrich VI). All the patients had glioblastoma multiforme, at the time a uniformly lethal brain tumor.

341 Id.

342 Mohr v. Williams, 104 N.W. 12, 14 (Minn. 1905) (citing Pratt v. Davis, 224 Ill. 300 (Ill. A.D. 1 Dist. 1906), aff’d, 279 N.E. 562 (Ill. 1906).

Under a free government, at least, the free citizen’s first and greatest right, which underlies all others—the right to the inviolability of his person; in other words, the right to himself—is the subject of universal acquiescence, and this right necessarily forbids a physician or surgeon, however skillful or eminent, who has been asked to examine, diagnose, advise, and prescribe...to violate, without permission, the bodily integrity of his patient by a major or capital operation, placing him under an anesthetic for that purpose, and operating upon him without his consent or knowledge.

See also Schendel v. Society of New York Hosp., 105 N.E. 92 (N.Y. 1914); Stadt v. Univ. of Rochester, 921 F. Supp. 1023, 1027 (W.D.N.Y. 1996); see generally Planned Parenthood of
process. Some courts use the language of privacy rather than bodily integrity, but the concept is essentially similar: competent adults should not be subjected to manipulation or invasion of their bodies or their persons without their consent. Thus, in many of the radiation cases courts found uninformed, unconsented research to be an invasion of bodily integrity.

Civil rights actions under statutes such as section 1983 might offer another kind of dignity injury where plaintiffs can show that constitutional rights such as the rights to life, liberty, property, and equal protection were violated by government actors who knew or should have known that they were committing a wrong. This cause of action has particularly figured in the radiation cases. However, notwithstanding some commentators’ recommendation that autonomy in decision-making be more broadly protected as an intrinsic good, these civil rights actions are limited to the conduct of government actors.


Krause, supra note 266, at 336.

Roe v. Wade, 410 U.S. 113, 153 (1973); Griswold v. Connecticut, 85 S.Ct. 1678, 1681-82 (1965); see, also, Messel, supra note 114, at 213 (noting that “[t]he right of privacy, as originally conceived, is the right to be let alone. This is the very interest that is infringed when a doctor performs therapy on a patient who has not received adequate information about the kinds of things required by the law of informed consent.”).

See Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (1914). The classic statement is that “every human being of adult years and sound mind has a right to determine what shall be done with his own body.” Id.

See Heinrich v. Sweet, 62 F. Supp. 2d 282, 313-14, 319-20 (D. Mass. 1999) (“Failure to provide adequate disclosure of a potentially deadly medical experiment to subjects who were induced to participate on the basis of fraud constitutes a procedural irregularity sufficient to trigger the protections of the Fifth Amendment. Moreover, the consequences in this case were needlessly severe.”).


See supra notes 55-58 and accompanying text.
Some observers would like to press dignity torts even further. During the late 1990s and early 2000s, a series of lawsuits against several major research institutions attempted to bring dignity torts into the research arena by arguing that the Nuremberg Code and the Declaration of Helsinki warrant a dignity tort when research subjects are inadequately informed about the protocol’s objectives and risks. More grandly stated, unconsented or inadequately informed participation in research might be deemed a crime against humanity. These suits typically also argued that violations of federal regulations governing the treatment of human research subjects should be seen as a tort against the research subjects, cast as third-party beneficiaries to those regulations.

Courts have not been receptive to importing international ethics codes into U.S. law. Just one court has indicated any willingness to regard the Nuremberg Code or the Declaration as U.S. law. The Maryland Court of Appeals, arguing that there is a special relationship between investigator and subject, acknowledged that although no United States court “has ever awarded damages to an

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253 See discussion supra notes 70-81 and accompanying text.

injured experimental subject, or punished an experimenter, on the basis of a violation of the Nuremberg Code,"\textsuperscript{355} nevertheless the Code was intended for international application and has never been rejected in the U.S.\textsuperscript{356} Even here, the court's interest in the Code appears as dicta rather than black-letter law.\textsuperscript{357}

Otherwise, courts have found that the Code and similar documents provide ideals, not hard law. One federal district court opined that, although international law is "an inseparable part of American jurisprudence . . . [i]n one of the cases cited by the plaintiffs recognizes a general private right of action under international law."\textsuperscript{358} Several other courts have likewise cited the Nuremberg Code and Helsinki Accords, but not as domestic law.\textsuperscript{359} Rather, these documents are typically cited in section 1983\textsuperscript{360} civil rights claims as evidence that surely people who committed research abuses such as the radiation research of the 1940s, '50s and '60s should have known that people have a right to be free from uncon- sented research. As noted by one court: "It is inconceivable to the Court that the . . . Defendants, when allegedly planning to perform radiation experiments on unwitting subjects, were not moved to pause or rethink their procedures in light of the forceful dictates of the Nuremberg Tribunal and the several medical organizations."\textsuperscript{361}

\textsuperscript{355} Id. at 835.

\textsuperscript{356} Id.; see also id. at 858 ("Additionally, we hold that governmental regulations can create duties on the part of researchers toward human subjects out of which 'special relationships' can arise. Likewise, such duties and relationships are consistent with the provisions of the Nuremberg Code."). The recent spate of research-related lawsuits carries on the same trend. See Robertson v. McGee, 2002 WL 535045, *5 (N.D. Okla. 1/28/02) (noting that "This Court agrees with other jurisdictions which have found that there is no private right of action for an alleged violation of international law for the protection of human research subjects under the Declaration of Helsinki and the Nuremberg Code . . . Moreover, the standard in the United States for conducting research on human subjects is contained in the Code of Federal Regulations and, thus, there is no need for the courts to resort to international law to impute a standard."). The Western District of Washington came to the same conclusion. See Wright v. Fred Hutchinson Cancer Research Ctr., 2002 WL 32124953 (W.D. WA. 2002).

\textsuperscript{356} Grimes, 782 A.2d at 856.


In that spirit, courts ruling on the latest cases have tended to discard the Nuremberg-based dignity claims as not cognizable under federal law.\textsuperscript{362}

Despite the current impediments to recognizing dignity torts and other special injuries in the research setting, there is reason to think that courts might evolve toward somewhat greater acceptance. At least one court has recognized dignitary injuries in ordinary medical care.\textsuperscript{363} When state statute required the Louisiana Supreme Court to deny battery in a case where the surgeon simply ignored his promise to use a specific surgical technique the patient had requested, the Court nevertheless held that

[i]his case is different from the usual lack of informed consent cases where the doctor failed to inform the patient of a material risk and the risk materialized to cause physical damages. Here, the doctor's failure to inform the patient adequately did not cause the patient to undergo a risk that materialized and caused physical damages. Rather, the doctor's breach of duty caused plaintiff to undergo a medical procedure to which the patient expressly objected and for which the doctor failed to provide adequate information in response to the patient's request, thereby causing damages to plaintiff's dignity, privacy and emotional well-being. The doctor, rather than explaining the advantages and disadvantages of the patient's express request, patronized his patient and mentally reserved the right to decide to disregard the patient's expressed wishes. Even the dissenting judge in the court of appeal noted that plaintiff is entitled to an award of damages for being deprived the opportunity of self-determination in regard to subjecting himself to an unwanted procedure.\textsuperscript{364}

The court went on to find that "[i]n this type of case, damages for deprivation of self-determination, insult to personal integrity, invasion of privacy, anxiety, worry and mental distress are actual and compensatory. The primary concern in this injury to the personality is vindication of a valuable, though intangible, right, the mere invasion of which constitutes harm for which damages are recoverable."\textsuperscript{365}

If such a purely dignitary injury can be acknowledged in ordinary medical care, surely it should be even more readily available in research, where a person seeking help for his illness can potentially be turned into a research subject without his full understanding and consent. In the case of \textit{Díaz v. Tampa General Hospital},\textsuperscript{366} such reason-

\begin{footnotes}
\item[362] See supra notes 353-59.
\item[363] See \textit{Taggart v. Dowling}, 701 So. 2d 447, 455 (La. 1997).
\item[364] Id. at 455-56.
\end{footnotes}
ing led to a high-dollar settlement in a case where no physical injury was ever claimed. Rather, plaintiffs argued that sophisticated consent forms were tantamount to inadequate informed consent for pregnant women whose socioeconomic and cultural status impeded their comprehending the information they were given.

In the final analysis, courts need to recognize that "patients can be harmed when they are prevented from making decisions about their own care, even when, or perhaps especially when, no physical harm occurs." When inadequacies of information have inappropriately steered a patient's decision about whether to participate in research, courts should be willing in at least some instances to see this as an injury in itself.

3. Causality

An informed consent tort does not require simply a breach of duty and an injury. The former must cause the latter. However, as with the duty and injury elements of the tort, causality takes on a distinctive twist in research. Even as informed consent doctrine evolved toward the patient-based disclosure standard in the early 1970s, courts favored an objective approach. Rather than expecting physicians to guess each patient's informational preferences,

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Plaintiffs were poor, uneducated, mostly Spanish-speaking women who said that they did not understand the three-page, IRB-approved consent form. In addition to conceding there was no injury, the plaintiffs also agreed that they had signed the consent form. When the case was certified as a class action, defendants determined they could not afford to defend the suit. A settlement of $3.8 million closed the case.

369 Krause, supra note 266, at 366. Krause goes on to note that "[i]t is particularly true with regard to the nondisclosure of treatment alternatives, especially when the treatment is in fact successful. Where nondisclosure of treatment alternatives leads to physical harm, it often can be characterized as a typical 'risk disclosure' case. But where no physical injury has occurred, only a cause of action protecting a 'dignitary' or 'process' right will permit recovery, and without recovery, there can be no vindication of the patient's claim in tort." Id. at 366-67.

370 Battery, in contrast, requires no causality. See discussion supra Part V.A.

371 See discussion supra Part V.B.
courts asked physicians only to disclose what the reasonable and prudent person in this patient’s situation would want to know.\(^{372}\)

Those same pivotal cases also instituted an objective standard for causality.\(^{373}\) It is a standard that most courts follow whether they use a physician-based or patient-based standard of disclosure. Thus, the inadequacy of disclosure is said to cause the injury only if the reasonable and prudent person in the patient’s position would have refused the intervention if given adequate information.\(^{374}\) Courts adopted this objective approach largely out of fairness to physicians who would otherwise be vulnerable to patients’ hindsight regrets,\(^{375}\) and out of deference to juries who would otherwise

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\(^{373}\) See id.

\(^{374}\) The Canterbury court found that causality should be assessed “in terms of what a prudent person in the patient’s position would have decided if suitably informed of all perils bearing significance.” *Canterbury*, 464 F.2d at 791; see also e.g., Lugentuah v. Dowling, 701 So.2d 447, 454 (La. 1997) (discussing the two aspects of causation: [1] “the plaintiff must prove, as in any other tort action, that the defendant’s breach of duty was a cause-in-fact of the claimed damages or, viewed conversely, that the defendant’s proper performance of his or her duty would have prevented the damages”; and [2] “the plaintiff must further prove that a reasonable patient in the plaintiff’s position would not have consented to the treatment or procedure, had the material information and risks been disclosed. . . . Causation is established only if adequate disclosure reasonably would be expected to have caused a reasonable person to decline treatment because of the disclosure of the risk or danger that resulted in the injury.”); Howard v. Univ. of Med., 800 A.2d 73, 79, 84 (N.J. 2002); Guehard v. Jabay, 452 N.E.2d 751, 757 (Ill. App. 2d 1983); Sard v. Hardy, 379 A.2d 1014, 1025 (Md. App. 1977) (“Under this rule, the patient’s hindsight testimony as to what he would have hypothetically done, though relevant, is not determinative of the issue.”); see also Krause, *supra* note 266, at 317.

\(^{375}\) Woolley v. Henderson 418 A.2d 1123, 1132 (Me. 1980).

We believe that the subjective test is an unsatisfactory gauge for determining causality in informed consent actions and, therefore, in accord with those courts that have squarely addressed this issue, we hold that causation should be judged by an objective standard. (citations omitted) . . . If a subjective standard were applied, the testimony of the plaintiff as to what he would have hypothetically done would be the controlling consideration. Thus, proof of causation under a subjective standard would ultimately turn on the credibility of the hindsight of a person seeking recovery after he had experienced a most undesirable result. Such a test puts the physician in ‘jeopardy of the patient’s hindsight and bitterness’ . . . Under the objective test, a causal connection exists between the defendant’s failure to disclose and the plaintiff’s injury only if a reasonable person in the position of the plaintiff would have declined the treatment had he been apprised of the risk that resulted in the harm. (citation omitted) [The patient’s hindsight testimony as to what he would have hypothetically done, though relevant, is not determinative of the issue.

See also Sard v. Hardy, 379 A.2d 1014, 1025 (2002); Canterbury v. Spence, 464 F.2d 772, 790-91 (D.C. 1972); Arena v. Gningar, 748 F.2d 547, 549 (Or. 1988).
confront difficult hypothetical questions about what this particular person might or might not have done if given different information.376

Unfortunately, this objective causality standard overlooks the obvious problem that even for ordinary medical care, people can weigh information very differently in light of their own values and then, ever so reasonably and prudently, come to markedly different decisions.377 However we might resolve this issue for ordinary care, courts should recognize a more subjective causality standard for research for two reasons.

First, it is neither "reasonable" nor "unreasonable" to enter a research study, as a one-size-fits-all judgment. As noted in Section II, unlike ordinary medical care, research does not aim to benefit any particular person. The protocol may hope to benefit groups of people, and individuals may hope for and receive a benefit. But benefiting any specific enrollee is never the goal of a research protocol.378 Since research cannot promise to promote any individual's self-interest, the across-the-board "reasonableness" judgments of the kind required for objective findings of causality make little sense. The decision is as individual as the decision whether or not to buy a lottery ticket.

Second, the only relatively assured outcome of research participation is the altruism of helping others (assuming the project is sci-
entifically meritorious and soundly designed). Here especially, the decision is intensely personal, and there can be no single, objectively "reasonable" or intrinsically "prudent" decision.

Case law favors this critique. In Zalazar v. Vercimak, a woman sought cosmetic surgery to remove bags under her eyes. Although she was illiterate, no one read to her the consent form describing the procedure's significant risks. An Illinois appellate court found that an objective, "reasonable patient" standard of causality should not be used in a case of aesthetic surgery. Unlike the situation in which a patient seeks needed medical treatment for an illness or injury,

"[t]he choice plaintiff made was a subjective, personal one that only she could make... We believe no expert or other third party could possibly assert how a reasonable person in the plaintiff's position would have weighed the risks and complications of the surgery, and whether such individual would have decided against or gone ahead with the four-lid blepharoplasty had the proper disclosures been made."34

The court continued: "Indeed, where a surgical procedure involves no medical benefit to the patient and the decision is so subjective, the admissibility of the expert's opinion is questionable."35

The Wisconsin Supreme Court has likewise rejected the objective causality standard in cases where a patient has withdrawn her prior consent. In Schreiber v. Physicians Ins. Company, a pregnant woman in labor repeatedly asked her physician to switch from vaginal delivery to cesarean. She previously had two cesarean deliv-

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34 See Katz, supra note 94, at 25 ("Respect for the subjects' human rights dictates that they know that the decision to participate in research entails making a gift for the sake of others.").
36 Id. at 1224.
37 Id.
38 See id. at 1226.
39 Id. at 1226 (also noting that "Unlike chiropractic, cobalt and X-ray treatments, and even tubal ligation, the procedure in this case involves no medically significant benefits to the patient and the alternative is simply to forgo the procedure. What kind of expert can objectively weigh the benefits and risks of such a procedure in determining what a so-called 'reasonable person' would have decided? We do not believe that such an expert can be found. Where no expert can objectively evaluate whether the failure to warn was the proximate cause of the patient's injury, no expert can be required.").
40 Zalazar, 833 N.E.2d at 1226.
42 Id.
43 Id. at 27.
eries and, although willing to try vaginal, experienced a level of pain that changed her mind.390

When a patient clearly withdraws a prior consent, the Court held, the physician is obligated to undertake a second informed consent conversation.391 More to the point, in such circumstances the objective standard of causality no longer applies.391 Rather, the patient’s own actions have made it clear what she would choose if given a second opportunity.392 The court emphasized that

[ ] applying the objective test to a case such as this would result in the evisceration of Janice’s actually expressed and understood choice of treatment in favor of what the hypothetical reasonable person would have chosen. When we actually know what was chosen based on the disclosure of all of the pertinent information, we need not engage in the hypothetical exercise of what the reasonable person would have chosen.393

If the foregoing discussion is correct, causality analysis should not treat research decisions like ordinary medical treatment decisions. They are highly personal, not suitably subjected to an evaluation of whether the “reasonable” person would think it “prudent” to enter research. Just as with a decision to have cosmetic surgery, the question is what the individual person would want.394

390 Id. at 28.
391 Id. at 27.
392 Schreiber, 588 N.W.2d at 27-28.
393 Id. at 34 (“It can lead to absurd results when the known and concrete choice of the actual person may well be ignored if it does not comport with what the hypothetical reasonable person would have chosen.”).
394 Id.

394 On this analysis, the Western District of Washington arguably erred in *Berman v. Fred Hutchinson Cancer Research Ctr.*, (W.D. Wash. Aug. 8, 2002) concerning a protocol in which two drugs were hoped to ameliorate the toxicity of chemotherapy in breast cancer patients. The plaintiff indicated that she was unlikely to be able to use any oral medications and was allegedly promised an intravenous (I.V.) form of the drug. Allegedly the cancer center was aware but failed to disclose that the I.V. form was no longer available. As it assessed various claims for breach of informed consent, the court found that as a matter of law the patient would not have agreed to enter the trial, had she been aware that the I.V. form of the drug was not available:

The Court’s inquiry is focused on a reasonably prudent patient in similar circumstances. The Court finds that, as a matter of law, a reasonably prudent prospective study participant would not have agreed to treatment with lethal doses of chemotherapeutic agents if she had been told that she would be deprived of the only potentially beneficial drug being tested in the protocol should she, as expected, be unable to tolerate its oral form. Id. at 6-7.

The court went on:

Even if focusing the causation analysis on the precise medication or procedure to which the patient was subjected without informed consent makes sense in the normal therapeutic treatment context, where the patient is being asked to take
Admittedly, there remains the concern that a subjective standard of causality could hold physicians hostage to patients’ bitter hindsight. However, several responses seem reasonable. First, the investigator should ensure that the prospective enrollee has ample opportunity to ask questions that could flag the issues he considers personally important. An animal-rights activist, given the opportunity to ask about any animal studies that preceded the trial he is being invited to enter, can place the investigator on notice that if this person is not given full disclosure on that issue, he may later be able to say that he would not have entered a trial, had he known more about its use of laboratory animals.995

Second, juries must routinely grapple with factual questions about litigants’ motives and intentions. After noting that the objective standard of causality does not adequately honor patients’ autonomy, the Oklahoma Supreme Court held that

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part in an experimental research study, the failure to disclose material aspects of one element of the protocol can invalidate the patient’s consent to participation in the study as a whole. In this case, it is undisputed that Hamilton died of RRT as a result of her participation in Protocol 681.1. Had defendants fully disclosed the material facts regarding the unavailability of intravenous PTX under the research protocol, Hamilton would not have agreed to the treatment which ultimately killed her.” Id. at 7.

The court’s conclusion, though perhaps faithful to the spirit of the “reasonable person” standard, seems hasty. As proposed by the defendants, this patient appeared desperate and might have entered the trial anyway. End-of-life research is surely one setting in which people have widely differing risk preferences. The very act of seeking out a research trial when one has a late-stage cancer untreatable by conventional means seems to indicate that one is willing to accept significant risks and discomforts for a relatively limited chance of benefit. It is not clear at all that someone such as the plaintiff would not be willing to enter a trial with the understanding that, if she could not adhere to its regimen, she would simply drop out. Yet as the court pointed out, other equally reasonable people in this person’s circumstances might have concluded that if the IV. drug were unavailable, there would be little point to entering the study. The upshot is that neither decision is “the” reasonable one, and it is at best a stretch to choose either as the single objectively correct standard for determining whether the lack of information in fact caused the person to make a different decision than she would otherwise have made.

**This measure is reasonable and common. Informed consent processes for research invite the subject to ask questions. 45 C.F.R. § 46.116(d)(7). Even in the context of ordinary care, some state statutes require that patients be given the opportunity to ask questions. In Oregon, for instance, the relevant statute requires, for informed consent, that the physician explain in general terms the procedure, the alternative procedures or methods, and the risks. See Aron v. Gingrich, 748 P.2d 547, 548 (Or. 1988) (citing OR. REV. STAT. § 677.007 (2003)).**

(2) After giving the explanation specified in subsection (1) of this section, the physician or podiatrist shall ask the patient if the patient wants a more detailed explanation. If the patient requests further explanation, the physician or podiatrist shall disclose in substantial detail the procedure, the viable alternatives, and the material risks unless to do so would be materially detrimental to the patient.
(This basic right to know and decide is the reason for the full-disclosure rule. Accordingly, we decline to jeopardize this right by the imposition of the 'reasonable man' standard. . . . Although it might be said this approach places a physician at the mercy of a patient's hindsight, a careful practitioner can always protect himself by ensuring that he has adequately informed each patient he treats.\(^{366}\)

Similarly, the Zalazar court ruling in the case of aesthetic surgery acknowledged that

We recognize that our holding today places a burden on a defendant-physician to probe the subjective decision-making process of cosmetic surgery plaintiff-patients complaining of lack of informed consent, but we deem the subjective standard preferable to the insurmountable burden that the objective standard poses for the plaintiff-patient in such cases. Also, we note that documentation of the informed consent procedure via video tape or other means would not appear to be unreasonably burdensome, considering the regularity with which photography is utilized in connection with surgical procedures.\(^{367}\)

Third, the plaintiff bears the burden of proof in tort litigation. As a practical matter, this will mean that if the plaintiff did not ask questions about special issues that were important to him personally, he can not readily cite those personal issues in asserting that his injury was caused by the defendant's failure to inform him regarding a matter about which he himself failed to ask. As Morin notes, causation issues cannot be resolved until the scope of the disclosure duty is circumscribed; only if the information should have been disclosed can it be said the patient's decision would have differed.\(^{368}\) If the plaintiff receives broad, otherwise adequate general information but then failed to ask questions about issues personally important to him, such as the use of animals in this research, he will be hard-pressed to argue the investigator had a duty of disclosure or breached that duty. At that point, the investigator's failure to disclose a specific fact that went beyond the general duty to disclose would not be the cause of the patient's injury. Thus, even under a subjective standard the plaintiff must antecedently have made it clear that he wanted certain kinds of additional information, if he is to successfully claim he has been harmed for lack of that information.

\(^{366}\) Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1980); see also Noah, supra note 1, at 366.


\(^{368}\) See Morin, supra note 3, at 165.
VI. Conclusion

As the energy and financing behind human clinical trials increase, litigation will assuredly increase alongside. Courts will need considerable guidance to understand that, just as clinical research differs from ordinary medical practice, research litigation differs importantly from ordinary medical malpractice litigation. Familiar tort doctrines such as negligence, battery, and informed consent simply do not fit the realities of research and, if they are applied thoughtlessly in this emerging body of cases, the danger is great that research participants will be left without appropriate compensation for very real injuries, and reciprocally that investigators may be subjected to unfair standards of liability. Courts need to recognize clinical research as a distinct area of medical activity and to attune tort doctrines specifically to its nuances.