Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions

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RESEARCHER LIABILITY FOR NEGLIGENCE IN HUMAN SUBJECT RESEARCH: INFORMED CONSENT AND RESEARCHER MALPRACTICE ACTIONS

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Abstract: Two sets of federal regulations, the “Common Rule” and Food and Drug Administration (FDA) regulations, govern human subject research that is either federally-funded or involves FDA regulated products. These regulations require, inter alia, that: (1) researchers obtain informed consent from human subjects, and (2) that an Institutional Review Board (IRB) independently review and approve the research protocol. Although the federal regulations do not provide an express cause of action against researchers, research subjects should be able to bring informed consent and malpractice actions against researchers by establishing a duty of care and standard of care. Researchers owe human subjects a duty of care analogous to the special relationship between physicians and patients. The federal regulations should provide the minimum standard of care for informed consent in human subject research, and complying with them should be a partial defense. In contrast, expert testimony should establish the standard of care for researcher malpractice, and IRB approval should be a partial defense.

In 1993, the Kennedy Krieger Institute (KKI), a prestigious research institute associated with Johns Hopkins University, initiated a two-year research program in Baltimore to study the effectiveness of methods used to reduce lead exposure in children. The researchers measured the extent to which the children’s blood became contaminated with lead, and compared those blood levels with the measurements of lead dust in the children’s homes over the same period of time. Two outraged parents filed separate negligence actions when their children developed elevated lead levels in their blood while participating in the research program. The parents alleged that they were not fully informed of the study’s risks, and that the researchers violated a duty to warn them when the children’s blood-lead levels became elevated.

In Grimes v. Kennedy Krieger Institute, the Circuit Court for Baltimore City granted KKI’s motion for summary judgment on the ground that the researchers and institution had no legal duty to the

2. Id. at 812.
3. Id. at 825–29.
4. Id.
5. 782 A.2d 807, 832 (Md. 2001).
plaintiffs. Both plaintiffs appealed, and Maryland's high court held that there are several potential sources for a duty of care that researchers owe to human subjects, and that the breach of such duties may result in negligence. The Grimes court also held that a parent cannot consent to a child's participation in nontherapeutic research that poses "any risk" to the subject, a standard of care seemingly higher than that provided by the federal regulations. The court later clarified that "any risk" means "any articulable risk beyond the minimal kind... inherent in any endeavor." It remains unclear whether this definition sets a higher standard of care than the federal regulations, or merely interprets allowable risk under the regulations.

The Grimes decision is part of a larger trend in which injured research subjects have filed lawsuits against researchers. These high-profile lawsuits have generated intense media attention. This period of increased legal and public scrutiny of the research enterprise will likely lead to a dramatic rise in lawsuits by human subjects. However, few cases have generated reported decisions; thus the case law interpreting tort liability of researchers is scarce. Yet, in the near future many state courts will be faced with the task of developing an approach for dealing with negligence claims in human subject research.

6. Id. at 858.
7. Id.
9. Grimes, 782 A.2d at 862.
10. See infra notes 162-63.
When human subjects are harmed, the most likely source of liability for researchers is based in negligence. There are two initial considerations when determining whether human research subjects can bring negligence actions against researchers. First, is there a duty of care owed to human research subjects? Second, if so, what is the standard of care?

This Comment argues that state courts should recognize that researchers owe human subjects a duty of care rooted in informed consent and researcher malpractice. Part I describes the existing federal regulations and the elements of negligence. Part II explores the special relationship between a researcher and subject as a potential source for the duty of care researchers owe to human subjects. Part III examines the standard of care in negligence actions by research subjects for informed consent and researcher malpractice. Part IV argues that researchers owe a duty of care to human subjects, and that plaintiffs can establish a standard of care in negligence actions against researchers for informed consent and researcher malpractice actions. The federal regulations governing human subject research provide the best standard of care for informed consent, and complying with them should provide a partial defense. Further, expert testimony under the medical malpractice model provides the best standard of care for researcher malpractice, although Institutional Review Board (IRB) approval should provide a partial defense.

I. HUMAN SUBJECT RESEARCH AND NEGLIGENCE

Two sets of federal regulations govern human subject research: the Common Rule and Food and Drug Administration (FDA) regulations. The Common Rule applies to research funded by federal departments.

13. Other potential sources of liability including battery, contract-related claims, fraud and misrepresentation, strict liability in product liability cases, and constitutional claims are beyond the scope of this Comment. For a discussion of other bases of liability, see Jay M. Zitter, Annotation, Recovery for Nonconsensual Human Medical Experimentation, 2002 A.L.R. 5th 11 (2002). In addition, many injuries to human subjects may simply be adverse events, which are also beyond the scope of this Comment. For a discussion of other compensation systems for human subjects, see President’s Commission for the Study of Ethical Problems in Medicine & Biomedical & Behavioral Research, Compensating for Research Injuries: The Ethical & Legal Implications of Programs to Redress Injured Subjects (1982).


15. The Common Rule is a set of federal regulations issued to protect human subjects. The Common Rule is explained in detail at infra notes 31–51 and accompanying text.
and agencies that conduct, support, and regulate human subjects research. In contrast, the FDA regulations apply to research involving experimental drugs, biological products, and medical devices that are subject to FDA approval. In order for injured subjects to successfully bring negligence actions against researchers, they must first prove that the researcher owed a duty to the subject, and that the duty was breached. The federal regulations governing human subject research do not provide an express cause of action for negligence. Therefore, an independent duty must exist at common law in order for researchers to be held negligent.

A. The Common Rule and FDA Regulations

The federal regulations currently governing human subject research are rooted in the international guidelines and codes that arose after human subjects were abused in the Twentieth Century. After World War II and Nazi medical experiments, American judges developed the Nuremberg Code, setting forth ten ethical principles that provided a foundation for the protection of human subjects. Later, doctors and scientists of the World Medical Association adopted the Declaration of Helsinki and set international guidelines for biomedical research by physicians. In 1966, the Public Health Service developed internal policy guidelines requiring peer review of all research involving human subjects.

18. See Keeton et al., supra note 14, § 30 at 164–65.
By the mid-1970s, several highly publicized American research abuses23 led Congress to enact the National Research Act of 1974,24 which created the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research (National Commission).25 In 1978, the National Commission published The Belmont Report,26 setting forth three ethical principles27—respect for persons, beneficence, and justice—that later served as the foundation for the federal regulations governing human subject research. Each principle translated into a particular application to protect human subjects: "respect for persons" translated into "informed consent," "beneficence" into "risk-benefit assessment," and "justice" into "selection of subjects."28 The Belmont Report deliberately set a high standard of disclosure for informed consent in the research setting, stating that "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 hands of a clinician for needed care."29

The Federal Policy for the Protection of Human Subjects, known as the Common Rule, is a set of federal regulations that incorporates the ethical principles and guidelines of The Belmont Report.30 With minor variations, it applies to all federal departments and agencies that conduct, support, and regulate human subject research.31 The Common Rule was developed under the Public Health Service Act's mandate "to protect the

23. See, e.g., Henry K. Beecher, Ethics and Clinical Research, 274 NEW ENG. J. MED. 1354, 1354–60 (1966) (publicizing 22 examples of unethical research protocols); JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1993) (recounting the infamous study in which hundreds of African-American men with syphilis were left untreated for decades to gain scientific knowledge about progression of the disease).


25. Id. at § 203 (charging the National Commission with identifying the basic ethical principles underlying all research involving human subjects and developing research guidelines from those principles).


27. Id. at 4.

28. Id. at 4–20.

29. Id.


31. See ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, supra note 22, at 425–38 (explaining minor variations of the Common Rule across federal departments and agencies).
The regulation that formed the basis for the Common Rule was originally adopted in 1981 by the Department of Health, Education, and Welfare (DHEW), a predecessor to the Department of Health and Human Services (HHS). In 1991, this regulation was adopted by other federal departments and agencies as the Common Rule. The Common Rule applies to federally-funded research on human subjects, and to research conducted at institutions that have contractually agreed through a Federal Wide Assurance (FWA) to apply the Common Rule regardless of the funding source. The HHS Office for Human Research Protections (OHRP) enforces institutional compliance with the Common Rule.

The Common Rule places the responsibility of obtaining informed consent directly on the researcher, and states that the researcher must minimize the possibility of coercion and that the research must provide the prospective subject with sufficient opportunity to consider whether to participate in the study. The elements of consent include an explanation of the purposes and procedures of the research, a description of any reasonably foreseeable risks and benefits, and a disclosure of alternatives. The consent process must also explain the confidentiality policy, state that participation is voluntary, explain whether any compensation is available if injury occurs, and provide information on whom to contact with additional questions. The informed consent


33. See ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, supra note 22, at 425.

34. Each department and agency has codified the Common Rule in different parts of the Code of Federal Regulations. When citing the Common Rule, this Comment always refers to the Health and Human Services (HHS) regulations at 45 C.F.R. §§ 46.101–24.

35. See 45 C.F.R. § 46.103 (setting forth the assurance system, which requires all institutions receiving federal funding to conduct research to provide formal assurance to Office for Human Research Protections (OHRP) (or other applicable agency designee) that it will develop a system to protect human subjects). In December 2000, OHRP developed a Federal Wide Assurance (FWA) to streamline the assurance process. See http://ohrp.osophs.dhhs.gov/irbasur.htm (last visited Jan. 3, 2003).

36. OHRP, located in the office of the Secretary of Health and Human Services since June 2000, was formerly known as the Office for the Protection from Research Risks (OPRR), which was located in the National Institutes of Health (NIH). See 65 Fed. Reg. 37,136 (June 13, 2000). Even though the Food and Drug Administration (FDA) is part of HHS, the FDA (not OHRP) oversees compliance with 21 C.F.R. sections 50 and 56. See 21 C.F.R. §§ 56.120–124.

37. 45 C.F.R. § 46.116.

38. Id. § 46.116(a).

39. Id.
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cannot include any exculpatory language that waives "any of the
subject’s legal rights, or releases or appears to release the investigator,
the sponsor, the institution or its agents from liability for negligence." 40
The Common Rule also sets forth circumstances where the requirements
for informed consent can be altered or waived. 41 In addition, the
Common Rule states that these informed consent requirements do not
preempt any federal, state, or local laws which require additional
information to be disclosed for informed consent. 42

The Common Rule also requires IRBs 43 to independently review research 44
protocols that involve human subjects, 45 and sets forth the
requirements for the review of research 46 and the criteria for its
approval. 47 The IRB must review the informed consent form for
compliance with federal requirements, 48 and must perform continuing
reviews at least once a year. 49 The criteria for IRB approval of research
include a determination that: (1) the risks to subjects are minimized, (2)
the risks to subjects are reasonable in relation to anticipated benefits, (3)
the selection of subjects is equitable, and (4) informed consent is sought
and documented. 50 In addition, the Common Rule allows expedited
review for certain kinds of research involving minimal risk, and for
minor changes in approved research. 51 Thus, the Common Rule places
the responsibility on IRBs to review and approve research protocols, and

40. Id. § 46.116; see also 21 C.F.R. § 50.20 (2001) (prohibiting exculpatory agreements
concerning negligence in clinical investigations regulated by the FDA).
41. 45 C.F.R. §§ 46.116(c)-(d) (listing circumstances where the IRB may allow the elements of
consent to be altered or waived).
42. Id. § 46.116(e).
43. Id. § 46.107 (requiring the IRB to include at least five members who possess the professional
competence necessary to review specific research activities, including at least one member who is
not affiliated with the institution).
44. Id. § 46.102(d) ("Research' means a systematic investigation, including research
development, testing and evaluation, designed to develop or contribute to generalizable
knowledge.").
45. Id. § 46.102(f) ("Human subject' means a living individual about whom an investigator
(whether professional or student) conducting research obtains (1) Data through intervention or
interaction with the individual, or (2) Identifiable private information.").
46. Id. § 46.109.
47. Id. § 46.111.
48. Id. §§ 46.109(b)-(c).
49. Id. § 46.109(e).
50. Id. § 46.111(a).
51. Id. § 46.110.
merely requires researchers to obtain informed consent of subjects and IRB approval.

The FDA developed a similar set of federal regulations in 1981 to oversee research involving experimental drugs, biological products and medical devices subject to FDA approval, even if it is privately funded.\(^{52}\) The FDA regulations also require informed consent,\(^{53}\) IRB review and approval.\(^{54}\) The most notable difference between the FDA regulations and the Common Rule is that the FDA regulations provide fewer exceptions to the informed consent requirements, and fewer waivers.\(^{55}\) Together, the Common Rule and the FDA regulations serve as guidelines for human subject research.

**B. Negligence Actions Against Researchers Generally**

The Common Rule does not provide an express cause of action for negligence. Instead, it merely states that violating the federal regulations may result in a loss of federal funding and thus suspension or termination of research.\(^{56}\) The OHRP has recently increased enforcement and temporarily suspended all human subject research at several prominent institutions for violations of the federal regulations.\(^{57}\)

However, researchers may be liable to injured subjects for their negligent actions.\(^{58}\) There may be a special relationship between the researcher and human subject that imposes a duty.\(^{59}\) In order to prevail in a negligence action against a researcher, an injured subject must prove that: (1) a duty is owed by the defendant; (2) the duty was breached; (3)...

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52. 21 C.F.R. §§ 50, 56 (2001). This Comment will use the term “Common Rule” to refer to 45 C.F.R. § 46 and the term “FDA regulations” to refer to 21 C.F.R. §§ 50 and 56. This Comment uses the term “federal regulations” to encompass both.
53. 21 C.F.R. §§ 50.20–50.27.
54. Id. §§ 56.103, 56.109, 56.111.
55. Compare 45 C.F.R. §§ 46.116(c)–(d) (2001) (Common Rule’s provisions for modification or waiver of consent requirements), with 21 C.F.R. § 50.23 (2001) (FDA regulations’ exceptions to consent requirements). Certain types of research typically fall outside both regulations and are beyond the scope of this Comment, such as surgery, dietary supplements and therapies, in-vitro fertilization, and stem cell research.
56. See 45 C.F.R. §§ 46.113, 46.123; see also 21 C.F.R. § 50.113 (FDA regulation on suspension or termination of IRB approval).
59. See infra Part II.B.
the breach caused injury to the subject; and (4) a cognizable injury.\textsuperscript{60} Health care providers are subject to tort liability under two alternate negligence actions: informed consent and medical malpractice.\textsuperscript{61} These alternate causes of action correspond to two distinct interests of patients: self-determination and competent care.\textsuperscript{62} Thus, a jury’s exoneration of a physician from liability for medical malpractice does not forestall a plaintiff’s claim for failure to obtain informed consent \textsuperscript{63} and vice versa. Researcher liability may also be based on these alternate causes of action, resulting in two distinct types of researcher negligence: informed consent and researcher malpractice.

Physicians’ obligation to obtain patients’ informed consent before providing medical treatment has become a general duty owed by physicians to patients.\textsuperscript{64} To establish negligence in medical informed consent litigation, the plaintiff must prove: (1) that the physician owed a duty to disclose information to the patient; (2) the physician breached the duty under the appropriate standard of disclosure; (3) the plaintiff was injured; (4) the injury was the result of an undisclosed outcome or risk; and (5) had the plaintiff been informed of the outcome or risk, the plaintiff would not have consented.\textsuperscript{65} Before providing treatment, the physician must obtain consent by disclosing and explaining all information that is necessary for the patient’s decision, which typically includes the nature and purpose of the treatment, expected benefits, foreseeable risks, reasonable alternatives, and foreseeable risks of forgoing treatment.\textsuperscript{66} Lack of informed consent is generally treated as professional negligence, and is based on a physician’s professional duty

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\bibitem{60} See Keeton et al., \textit{supra} note 14, § 30 at 164–65. Proving causation and cognizable injury is beyond the scope of this Comment.
\bibitem{63} See, e.g., Backlund v. Univ. of Wash., 137 Wash. 2d 651, 653–54, 975 P.2d 950, 951–52 (1999).
\bibitem{65} Id. at 29.
\bibitem{66} See, e.g., Truman v. Thomas, 611 P.2d 902, 905 (Cal. 1980) (en banc).
\end{thebibliography}
to provide patients with the appropriate information before they consent to treatment.\textsuperscript{68} Courts considering informed consent actions against researchers must determine how to establish the appropriate standard of care for informed consent in human subject research.

Professional negligence, or malpractice, is a special type of negligence in which professional standards of care have been developed for persons possessing or claiming to possess special knowledge or skill.\textsuperscript{69} Medical malpractice is the type of professional negligence most analogous to researcher malpractice, and is generally defined as a failure to exercise the required degree of care, skill and diligence ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances.\textsuperscript{70} In medical malpractice, the standard of care is usually derived from expert testimony by the medical profession.\textsuperscript{71} Courts considering researcher malpractice actions must determine how to establish the appropriate standard of care.

Because negligence actions against researchers have been rarely reported, there are two important issues that remain unexplored. First, do researchers owe a duty of care to human subjects? Second, if they do, how can subjects establish standards of care to assess whether researchers have breached that duty for informed consent and researcher malpractice?

II. DUTY OF CARE

Courts have historically treated researcher negligence actions as part of the medical malpractice framework.\textsuperscript{72} Recently courts have begun to develop a specialized analysis for negligence causes of action in human subject research.\textsuperscript{73} To bring a successful negligence claim against researchers,\textsuperscript{74} a plaintiff must first establish that the defendant owed a

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  \item \textsuperscript{68} Faden & Beauchamp, \textit{supra} note 64, at 29.
  \item \textsuperscript{69} Id.
  \item \textsuperscript{70} See \textsc{BARRY R. FURROW ET AL., HEALTH LAW} 269 (2d ed. 2000).
  \item \textsuperscript{71} Id. at 270; see Moringa v. Vue, 85 Wash. App. 822, 832, 935 P.2d 637, 642 (1997) (stating that expert testimony is required unless evidence is observable by lay persons and describable without medical training).
  \item \textsuperscript{72} See infra notes 77–79 and accompanying text.
  \item \textsuperscript{73} See infra notes 80–94 and accompanying text.
  \item \textsuperscript{74} The liability of research institutions and IRB members is beyond the scope of this Comment. For cases holding hospitals or institutions liable, see \textit{Gregg v. Kane}, 1997 WL 570909, at *6 (E.D. Pa. 1997) and \textit{Kus v. Sherman Hosp.}, 644 N.E. 2d 1214, 1221 (Ill. App. Ct. 1995). \textit{See also} \textit{Frieter v. Iolab Corp.}, 607 A.2d 1111, 1114–15 (Pa. Super. Ct. 1992) ("[F]ederal regulations specifically
duty of care. Although many possible sources of this duty exist, this Comment focuses on the special relationship between researchers and subjects, and analogizes it to the special relationship between physicians and patients.

A. Historical Treatment of Researcher Negligence Actions

Historically, courts have been reluctant to allow clinical research that deviates from accepted medical practice. Courts have relied on the medical malpractice framework to analyze negligence actions in human subject research. Early experimental deviations from medical standards of care were automatically considered malpractice, without regard to the level of care used or the experimental nature of the treatment. Courts did not accept clinical research as a necessary endeavor until the 1930s.

Analyzing human subject research as a separate negligence cause of action, apart from medical malpractice actions, is a relatively recent development. Halushka v. University of Saskatchewan, a 1965 Canadian case, was one of the first North American decisions to distinguish between medical practice and medical research. In the 1970s, mandated that the hospital assume the duty of obtaining informed consent.

75. See Keeton et al., supra note 14, at 164–65.

76. See Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 858 (Md. 2001) (stating that potential sources for the duty the researchers owe to subjects include: the special relationship between researcher and subject, the informed consent quasi-contract, an implied duty from the federal regulations, and duties from international codes).


78. See, e.g., Carpenter v. Blake, 60 Barb. N.Y. 488, 523–24, rev’d 50 N.Y. 696 (N.Y. Gen. Term 1871) (holding that an innovative treatment was negligent because it deviated from standard practice).

79. See Fortner v. Koch, 261 N.W. 762, 765 (Mich. 1935) (“[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”).

80. [1965] D.L.R.(2d) 436, 443–44 (“The duty imposed upon those engaged in medical research to those who offer themselves as subjects for experimentation is at least as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient.”).
there was a transition period in which courts blurred the distinction between causes of action based on traditional medical malpractice and those based on research.\textsuperscript{81} The distinction between clinical practice and research has also been a difficult and complex problem in regulatory and ethical codes.\textsuperscript{82} Early discussions of research ethics and regulation often distinguished between "therapeutic" and "nontherapeutic" research,\textsuperscript{83} although many commentators have argued that this distinction is illogical and confusing.\textsuperscript{84} The Common Rule abandoned this distinction, simply referring to "research," but some courts continue to refer to "nontherapeutic research" in their opinions.\textsuperscript{85}

Recently, courts have begun to develop a specialized analysis for negligence causes of action in human subject research. In 1986, a federal district court in the Middle District of North Carolina became the first American court to carefully address the duty of care and standard of care for negligence actions based on informed consent under the Common Rule.\textsuperscript{86} In \textit{Whitlock v. Duke University},\textsuperscript{87} the court held that under the Common Rule there is a heightened duty for disclosure of foreseeable risks that differs from the medical context.\textsuperscript{88} The \textit{Whitlock} court adopted the Common Rule as the standard of care for informed consent in human subject research,\textsuperscript{89} but it did not reach the question of whether a duty of

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  \item \textsuperscript{81} See Karine Morin, \textit{The Standard of Disclosure in Human Subject Experimentation}, 19 J. LEGAL MED. 157, 198–202 (1998) (discussing the transition from medical malpractice to a distinct cause of action in human subject research).
  \item \textsuperscript{82} See ROBERT J. LEVINE, \textit{ETHICS AND REGULATION OF CLINICAL RESEARCH} 3 (2d ed. 1986) (defining "research" as "a class of activities designed to develop or contribute to generalizable knowledge," whereas "practice of medicine" refers to "a class of activities designed solely to enhance the well-being of an individual patient or client").
  \item \textsuperscript{83} \textit{Id.} at 8 (explaining that the original Declaration of Helsinki distinguished "nontherapeutic" non-clinical research from "therapeutic" clinical research).
  \item \textsuperscript{84} \textit{Id.} at 8–10 (explaining that many types of research cannot be defined as therapeutic or nontherapeutic, such as placebo-controlled, double-blind drug trials in which nobody knows who is receiving placebo).
  \item \textsuperscript{85} See, e.g., Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 858 (Md. 2001).
  \item \textsuperscript{86} Whitlock v. Duke Univ., 637 F. Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987).
  \item \textsuperscript{87} 637 F. Supp. 1463 (M.D.N.C. 1986), aff'd, 829 F.2d 1340 (4th Cir. 1987) (involving an experienced diver in a simulated deep sea diving experiment to research high pressure nervous syndrome).
  \item \textsuperscript{88} \textit{Id.} at 1471. In dicta, the court also considered standards of disclosure under the Nuremberg Code and the Declaration of Helsinki. \textit{Id.} at 1470–71.
  \item \textsuperscript{89} See \textit{id.} at 1471.
\end{itemize}
care is implied by the Common Rule because it found that the Common Rule's standard of care was not breached.\(^9\)

In 2001, Maryland's high court held in *Grimes* that there are several potential sources of duty that researchers owe to human subjects.\(^9\) These include the special relationship between researcher and subject, the informed consent quasi-contract, implied duties from the federal regulations, and duties from international codes.\(^9\) Although the *Grimes* court concluded that researchers may owe human subjects a duty of care, it did not clearly articulate which of these sources the duty arises from.\(^9\) However, *Grimes* was the first case to explicitly state that "the very nature of nontherapeutic scientific research on human subjects can, and normally will, create a special relationship out of which duties arise."\(^9\)

B. A Source for the Duty of Care: The Special Relationship Between Researchers and Subjects

Although there are a number of potential sources of duty that researchers owe to human subjects, the special relationship between researchers and human subjects offers the most likely choice. In general, a person has no duty to aid someone unless he or she placed that person in danger or had a "special relationship" with the person that created a duty.\(^9\) A duty to aid or protect someone is typically found in relationships involving dependence or mutual dependence.\(^9\) The relationship between a researcher and human subjects is analogous to the special, fiduciary relationship between physicians and patients.\(^9\)

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90. *Id.* at 1475.
91. *Grimes*, 782 A.2d at 858.
92. *Id.*
93. See *id*.
94. *Id.* at 835–36.
95. See RESTATEMENT (SECOND) OF TORTS § 314A (1965) (describing four commonly recognized special relationships in which an actor is under a duty to another: (1) common carrier-passienger; (2) innkeeper-guest; (3) landowner-invitee; and (4) certain custodial relationships).
96. See *id.* cmt. b.
1. Physician-Patient Relationship

In many states, the existence of a special physician-patient relationship is essential to negligence actions against physicians. Physicians have been regarded as fiduciaries of their patients and as such are expected to act in their patients’ best interests. This fiduciary duty arises out of the trust patients must place in a physician’s skill, learning, and experience. Once the physician gains this trust, the physician assumes the duty of informing patients of the nature and hazards of their disease and treatment.

Courts have also viewed the special relationship between physicians and patients as express or implied contracts. Although a physician has no duty to treat a patient until entering into a consensual transaction, once the physician enters into this relationship the physician is obligated to treat the patient at a certain standard of care. Consequently, medical malpractice law has included a mixture of contract and tort influences for over a century.

2. Researcher-Subject Relationship

If a medical researcher is also the subject’s treating physician, courts may view the dual physician/researcher-patient/subject relationship as “special” under traditional principles of medical malpractice. However, it is less clear whether courts would view researchers who are not a subject’s treating physician as owing a special duty to the research subject. Grimes was the first case to explicitly hold that the researcher-subject relationship itself constitutes a “special relationship” similar to

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98. See, e.g., Anderson v. Houser, 523 S.E.2d 342, 345 (Ga. Ct. App. 1999) (reasoning that doctor-patient privity establishes the legal duty to conform to a standard of conduct and is essential to medical malpractice claims).

99. See, e.g., Carson v. Fine, 123 Wash. 2d 206, 218, 867 P.2d 610, 617 (1994) (en banc) (recognizing that the physician-patient relationship is a fiduciary one).

100. See, e.g., Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972) (stating that the doctor’s fiduciary duty of disclosure requires informed consent).

101. See, e.g., Moldoff, supra note 67, at § 1.

102. See FURROW, supra note 70, at 265.


105. Holder, supra note 97, at 6.
that between a physician and patient. The Grimes court stated that "the very nature of nontherapeutic research can, and normally will, create special relationships out of which duties arise." Although the Grimes court did not cite any authority for holding that a special relationship exists between researchers and subjects, commentators have noted that there are several similarities between the research-subject and physician-patient relationship. These commentators have argued that the researcher-subject relationship is fiduciary, because a researcher's specialized knowledge makes the subject dependent on the researcher. Similar to the medical malpractice context, the risk that researcher negligence could cause a subject bodily injury might lead a court to impose special duties of care and disclosure on the researcher.

In addition, a researcher enters into a quasi-contractual relationship with the subject by obtaining the subject's written informed consent. This quasi-contractual relationship might serve as the basis for a special relationship similar to that of physician and patient. In Dahl v. Hem Pharmaceuticals Corp., the Ninth Circuit held that a consent form in a research protocol formed a unilateral contract. The Grimes court took this contract analysis a step further and held that the informed consent agreements in research protocols may constitute bilateral contracts that create special relationships between researchers and subjects. Thus, there are significant similarities between the physician-patient and researcher-subject relationship that may impose similar duties of care.

107. Id. at 835-36.
108. See Holder, supra note 97, at 6-7; see also Delgado & Leskovac, supra note 62, at 107-12 (arguing that the researcher has a fiduciary duty with the human subject, similar to that in the typical physician-patient relationship).
109. See Delgado & Leskovac, supra note 62, at 107-12.
110. See Grimes, 782 A.2d at 846 (stating that recruitment of otherwise healthy subjects into potentially hazardous study conditions for the purpose of creating statistics for testing scientific hypotheses "would normally warrant or create such special relationships as a matter of law").
111. See 45 C.F.R. § 46.117 (2001) (requiring a written informed consent form unless the IRB waives the requirement in exceptional circumstances).
112. 7 F.3d 1399 (9th Cir. 1993).
113. Id. at 1404-05 (allowing plaintiff to continue receiving the study drug even after the sponsor had ended the study, based on a reliance argument in contract law).
III. STANDARD OF CARE

Once a plaintiff in a negligence action establishes that the defendant owes the plaintiff a duty of care, the court must determine whether the defendant met the standard of care.\(^{115}\) Courts considering informed consent and malpractice actions against researchers must determine the standard of care that researchers owe subjects in each action. In both informed consent and researcher malpractice actions, there are two potential sources for the standard of care: federal regulations and expert testimony.

A. Standard of Care for Informed Consent in Research

Physicians’ obligation to obtain patients’ informed consent before providing medical treatment has become a general duty owed by physicians to patients.\(^ {116}\) The informed consent requirement in medicine is based on a respect for the patient’s autonomy and right to self-determination.\(^ {117}\) As early as 1914, Justice Cardozo articulated this principle in an oft-quoted opinion: “Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . . .”\(^ {118}\) In order to meet the standard of care for informed consent, the physician must obtain, disclose, and explain all of the information necessary for a patient to decide.\(^ {119}\) This typically includes discussing the nature and purpose of the treatment, its expected benefits, foreseeable risks, and reasonable alternatives, as well as the foreseeable risks of forgoing treatment.\(^ {120}\) Courts faced with determining the standard of care in researcher informed consent actions will most likely consider the federal regulations and expert testimony. Typically, courts have adopted the federal regulations as the standard of care for informed consent actions against researchers\(^ {121}\) and relied on expert testimony to determine whether the standard of care was met.\(^ {122}\)

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\(^{115}\) See KEETON ET AL., \textit{supra} note 14, at 164–65.

\(^{116}\) See generally King, \textit{supra} note 64, at 114–50.


\(^{118}\) Schloendorff v. Soc’y of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914).

\(^{119}\) See, e.g., Truman v. Thomas, 611 P.2d 902, 905 (Cal. 1980) (en banc).

\(^{120}\) See generally John H. Derrick, Annotation, \textit{Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment}, 38 A.L.R. 4th 900 (1985); Moldoff, \textit{supra} note 67.

\(^{121}\) See infra Part III.A.1.

\(^{122}\) See infra Part III.A.2.
1. **Using the Federal Regulations to Establish the Standard of Care in Researcher Informed Consent Actions**

Courts have held that a statute or administrative regulation can provide the standard of care if a duty of care exists at common law.\(^\text{123}\) Violations of federal statutes and regulations have served as the basis for negligence actions in many areas of law. These include violating safety standards for drugs, medical devices, and pesticides,\(^\text{124}\) not complying with environmental regulations on toxic waste,\(^\text{125}\) and violating the Occupational Safety and Health Act (OSHA) regulations.\(^\text{126}\) Courts can adopt an administrative regulation as the standard of care if the administrative regulation’s purpose is: (1) to protect a class of persons including the person whose interest was invaded, (2) to protect the particular interest invaded, (3) to protect that interest against the kind of harm which has resulted, and (4) to protect that interest against the particular hazard from which the harm results.\(^\text{127}\) In most jurisdictions, an unexcused violation of a relevant federal statute or regulation constitutes negligence per se as a matter of law.\(^\text{128}\) A minority of jurisdictions treat violations of statutes or regulations as evidence of negligence, creating a rebuttable presumption of negligence.\(^\text{129}\)

Although state courts are not required to adopt federal regulations as the standard of care in tort litigation, commentators have argued that state courts should give federal standards more weight.\(^\text{130}\) As early as

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123. See Restatement (Second) of Torts § 285 (1965).
128. See, e.g., Sanchez v. Galey, 733 P.2d 1234, 1242 (Idaho 1986) (reasoning that violation of OSHA regulations constituted negligence per se); see also Steagall v. Dot Mfg. Corp., 446 S.W.2d 515, 518 (Tenn. 1969) (stating that violation of the Federal Hazardous Substances Act may result in negligence per se).
129. Sherman, supra note 124, at 877–84 (comparing approaches to negligence per se in various states).
130. See Lars Noah, Rewarding Regulatory Compliance: The Pursuit of Symmetry in Products Liability, 88 Geo. L.J. 2147, 2152 (2000) ("Although not formally obligated to adopt relevant federal regulations as particularizing the standard of care in tort litigation, at least absent preemption, courts should take them more seriously than they do at present."); see also Richard Ausness, The Case for a "Strong" Regulatory Compliance Defense, 55 Md. L. Rev. 1210, 1253–54 (1996)
1960, one commentator proposed that the standard of care for human subject research should be at least partly based on applicable statutes and regulations. \(^{131}\) In 1997, a California court took the lead and held in \textit{Daum v. SpineCare Medical Group} \(^{132}\) that the federal regulations designed to protect human research subjects provided the standard of care for informed consent in a negligence action against a researcher. \(^{133}\) The \textit{Daum} court held that the human subject could successfully use the FDA regulations to prove the elements of negligence per se. \(^{134}\) Further, the court held that the trial court should have instructed the jury on negligence per se based on the defendant's violation of the federal regulations on informed consent. \(^{135}\) Thus, the \textit{Daum} court derived the standard of care for informed consent from the federal regulations, and limited the role of expert testimony to whether the standard was met. \(^{136}\)

Several other courts have relied on the federal regulations to establish the standard of care for informed consent in human subject research. The federal district court in \textit{Whitlock} held that the Common Rule established the standard of care for an informed consent claim against researchers in North Carolina, \(^{137}\) and stated that there is a heightened standard of disclosure of foreseeable risks in research than in the medical context. \(^{138}\) Further, the Supreme Court of Washington adopted the Common Rule as the standard of care for informed consent in \textit{Vodopest v. MacGregor}, \(^{139}\) holding that University of Washington researchers violated the Common Rule by requiring subjects to waive their legal rights to bring negligence actions in the consent form, a requirement that violates the Common


\(^{133}\) \textit{Id.} at 264 (involving spinal surgery using an experimental fixation device).

\(^{134}\) \textit{Id.} at 273.

\(^{135}\) \textit{See id.} at 279 ("Instead of being able to try the case based on the statutes and regulations governing clinical trials, the Daums were forced to engage in a battle of experts over the duty of disclosure.").

\(^{136}\) \textit{Id.}

\(^{137}\) 637 F. Supp. 1463, 1475 (D.N.C. 1986), \textit{aff'd}, 829 F.2d 1340 (4th Cir. 1987) (holding that the defendant did not violate the standard of care provided by the Common Rule, because the risk of organic brain damage was not foreseeable); \textit{see supra} notes 87-90 and accompanying text.

\(^{138}\) \textit{Id.} at 1471.

\(^{139}\) 128 Wash. 2d 840, 913 P.2d 779 (1996) (involving research on the effects of high altitude on subjects).
Rule's informed consent provision. Similarly, courts have held that the FDA regulations set the standard of care for obtaining a patient's informed consent before implanting experimental medical devices. Thus, there appears to be an emerging trend among courts to use the federal regulations as the standard of care for informed consent in human subject research.

Defendants have argued that complying with federal safety standards should shield them from state tort liability. These defendants invoke the federal preemption doctrine, arguing that the primacy of federal law under the Supremacy Clause overrides state tort law. Defendants have successfully employed the preemption doctrine to overcome claims by injured consumers involving federally regulated cigarette labels, medical device labels and designs, and motor vehicle designs. In addition, many defendants have argued that compliance with federal regulations should be a complete defense to state tort liability. However, few jurisdictions view regulatory compliance as a complete defense.

Although no courts have explicitly addressed whether complying with the federal requirements for informed consent is a complete defense in researcher negligence actions, several courts have granted summary judgment to defendants for compliance with the federal regulation.

140. Id. at 857-62, 913 P.2d at 787-89.
142. See Ausness, supra note 130, at 1225-37.
143. U.S. CONST. art. VI, cl. 2.
144. See Ausness, supra note 130, at 1225-37 (reviewing federal preemption of state product liability claims).
145. See id. at 1239-47 (reviewing regulatory compliance as a defense).
146. Id.
147. See Paul Dueffert, The Role of Regulatory Compliance in Tort Actions, 26 HARV. J. ON LEGIS. 175, 176, 186-88 (1989); see also RESTATEMENT (SECOND) OF TORTS § 288c (1965) (“Compliance with a legislative enactment or an administrative regulation does not prevent a finding of negligence where a reasonable man would take additional precautions.”).
148. See Noah, supra note 130, at 2151-52.
requirements for disclosure of risks. In *Slater v. Optical Radiation Corp.*, Judge Posner, writing for the Seventh Circuit Court of Appeals, observed that when the risks are adequately explained to the research subject, “he cannot complain that the risks materialized.” Further, Judge Posner cautioned that “[i]f experimental procedures are subject to hindsight evaluation by juries, so that failed experiments threaten to impose enormous tort liability on the experimenter, there will be fewer experimental treatments, and patients will suffer.” Thus, under *Slater*, defendants could argue regulatory compliance as a defense.

However, complying with the federal requirements for informed consent should not be viewed as a complete defense because the federal regulations explicitly state that they do not affect state or local laws in general. Further, the federal regulations specifically state that the informed consent requirements do not preempt any federal, state, or local laws which require additional information to be disclosed for informed consent. Thus, states can set higher standards of care for informed consent in human subject research without violating the federal regulations. Several states have specific statutes or regulations addressing human subject research that could provide a standard of care for informed consent. Although these laws usually adopt the identical requirements as the Common Rule, some states have enacted statutes or regulations providing additional protections to certain groups deemed vulnerable when participating as human subjects, such as prisoners, the mentally ill, and developmentally disabled persons.

150. 961 F.2d 1330 (7th Cir. 1992).
151. *Id.* at 1333–34.
152. *Id.*
154. *Id.* § 46.116(e).
At least two courts have imposed higher standards of care than those in the federal regulations for informed consent in human subject research without relying on state statutes or regulations governing human subject research. The Supreme Court of California, in *Moore v. Regents of the University of California,*\(^{157}\) held that medical researchers must disclose conflicts of interest under state law on informed consent,\(^{158}\) even though the federal regulations do not mention conflicts of interest. Further, the Maryland high court in *Grimes* arguably set a higher standard of care than the Common Rule for informed consent.\(^{159}\) After holding that researchers may owe duties to human subjects, the *Grimes* court further held that parents cannot consent to their children's participation in nontherapeutic research that involves "any articulable risk beyond the minimal kind of risk that is inherent in any endeavor."\(^{160}\) The federal regulations, however, allow research that poses greater than minimal risks for children in certain situations.\(^{161}\) Thus, it is unclear whether this ancillary holding established a higher standard of care for parental consent in children's research,\(^{162}\) or was merely an attempt to interpret the level of risk allowed under the federal regulations.\(^{163}\)

In sum, there are few state statutes, regulations, or judicial decisions that set higher standards of care for human subject research than those in the federal regulations. Although the federal regulations allow states to provide additional protections to human subjects, the trend at this point appears to be for courts to adopt the federal regulations as the standard of care for informed consent.

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\(^{158}\) Id. at 485.


\(^{160}\) Id. at 862.


\(^{162}\) See Lainie Friedman Ross, *In Defense of the Hopkins Lead Abatement Studies*, 30 J.L. MED. & ETHICS 50, 54 (2002) ("At trial, the legal and moral authority of parents to enroll their children in certain types of nontherapeutic research should be reaffirmed.").

2. Using Expert Testimony to Evaluate the Standard of Care for Informed Consent

Even if the federal regulations provide the standard of care for informed consent, expert testimony may be required to determine whether researchers breached the standard of care. The federal regulations require researchers to disclose certain elements of consent, including an explanation of the purposes and procedures of the research, a description of any reasonably foreseeable risks and benefits, and a disclosure of alternatives.\textsuperscript{164} Courts must develop tests to decide whether researchers adequately met these federal requirements for disclosure. Currently, there are two different tests for establishing the appropriate standard of disclosure in medical informed consent actions: (1) the professional practice standard; and (2) what the "reasonable person" would want to know.\textsuperscript{165} The professional practice standard, adopted in over twenty-five states,\textsuperscript{166} requires expert testimony to establish the scope of a reasonable disclosure, based on what a reasonable practitioner would have disclosed in a similar situation.\textsuperscript{167} The "reasonable person" standard, growing in popularity and approaching a majority position,\textsuperscript{168} bases the appropriate scope of disclosure on what a "reasonable person" would want to know, regardless of professional practice.\textsuperscript{169} The trier of fact may determine what a "reasonable person" would want to know without expert testimony, but expert testimony may still be needed to clarify the nature of the treatment and its probability of risk.\textsuperscript{170}

Thus, even if the federal regulations are used to establish the standard of care for informed consent in human subject research, expert witnesses will most likely be required to help factfinders determine whether the researcher complied with the standard of care. For instance, in \textit{Stewart v. Cleveland Clinic Foundation},\textsuperscript{171} expert testimony was used to determine whether the standard of care set by the federal regulations was met.\textsuperscript{172} The defendant argued that the informed consent for a clinical trial

\textsuperscript{164} 45 C.F.R. § 46.116(a); see supra notes 37–42 and accompanying text.
\textsuperscript{165} \textit{See} \textit{King, supra} note 64, at 30–34 (also noting that a third "subjective" standard has been proposed in legal commentary, based on what the particular patient wants to know).
\textsuperscript{166} \textit{See} \textit{FURROW, supra} note 70, at 318.
\textsuperscript{167} \textit{Id.} at 318.
\textsuperscript{168} \textit{Id.} at 318–19.
\textsuperscript{169} \textit{Id.} at 319.
\textsuperscript{170} \textit{Id.}
\textsuperscript{171} 736 N.E.2d 491 (Ohio Ct. App. 1999).
\textsuperscript{172} \textit{Id.} at 501.
complied with the Common Rule, while the plaintiff provided a contradictory expert report. The Stewart court held that a genuine issue of material fact existed as to whether the informed consent form complied with the federal requirements, and allowed the jury to decide. In sum, courts have generally adopted the federal regulations as the standard of care for informed consent, and have used expert testimony to determine whether the standard was breached.

B. **Standard of Care for Researcher Malpractice**

Medical malpractice is the type of professional negligence most analogous to researcher malpractice, and is generally defined as a failure to exercise the required degree of care, skill and diligence ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances. The liability of health care providers for medical malpractice is governed by (1) state statutes and (2) expert testimony under medical malpractice law that varies from state to state. Although courts could determine the standard of care for researcher malpractice actions by using the federal regulations, no court has taken this approach because the federal regulations only impose general requirements on conducting research. At least one court has relied on expert testimony to establish the standard of care in researcher malpractice actions.

1. **Using the Federal Regulations to Establish the Standard of Care for Researcher Malpractice**

No courts have used the federal regulations to establish the standard of care for researcher malpractice outside the context of informed consent claims. Although the federal regulations are intended to protect the rights and safety of human subjects, they do not impose specific requirements on researchers beyond obtaining the subjects' informed

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173. *Id.* at 495.
174. *Id.* at 497.
175. *Id.* at 501.
176. *See Furrow*, *supra* note 70, at 269.
177. *Id.*
178. Heinrich v. Sweet, 308 F.3d 48, 70 (1st Cir. 2002).
179. *See supra* note 32 and accompanying text.
consent and IRB approval. The federal regulations place the responsibility of weighing risks and approving research on IRBs, not on researchers. Thus, unlike in informed consent, the federal regulations do not provide a specific standard of care for researcher malpractice actions.

However, it is possible that IRB approval could provide a partial defense in researcher malpractice claims, even though no courts have explicitly addressed this issue. IRB approval requires that an independent group of IRB members with professional competence determine, inter alia, that the research had scientific merit, risks were minimized, and the benefits outweighed the risks. Obtaining IRB review may therefore provide evidence of due care in researcher malpractice actions. But, it should be noted that the Grimes court allowed a negligence action against the researchers to proceed even though the researchers had obtained IRB approval. Indeed, the Grimes court accused the IRB of abdicating its responsibility by helping the researchers to “mischaracterize the characteristics of the study” and by “aid[ing] researchers in getting around federal regulations.” Thus, not all courts have found IRB approval to be a partial defense to researcher malpractice actions.

2. Using Expert Testimony to Establish the Standard of Care for Researcher Malpractice

Most negligence actions against researchers to date have been based on informed consent claims rather than researcher malpractice, so there is little case law to determine the standard of care for researcher malpractice. Consequently, most commentators have focused on informed consent issues in human subject research, and have ignored or rejected researcher malpractice actions based on expert testimony.

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181. Id. § 46.111.
182. See supra notes 43–51 and accompanying text.
183. See supra notes 43–51 and accompanying text.
185. Grimes, 782 A.2d at 813.
186. Id. at 814.
187. See supra notes 132–41 and accompanying text.
188. See Morin, supra note 81; see also Delgado & Leskovac, supra note 62.
Nevertheless, expert testimony could be used to establish the standard of care for a reasonable researcher in the same research specialty acting under the same or similar circumstances, similar to the medical malpractice model.\textsuperscript{190}

In the medical malpractice model, the standard of care is usually derived from expert testimony by members of the medical profession.\textsuperscript{191} The appropriate standard of care arises out of the complex interactions of professional leaders, journals, peer discussions and meetings.\textsuperscript{192} Thus, standards of care emerge gradually through the interplay of numerous comments from various professional sources once a practice becomes generally accepted.\textsuperscript{193} Once the standard of care is established by expert testimony, courts merely enforce the standard in tort suits rather than determining what the standard "should" be.\textsuperscript{194} To prove medical malpractice, the plaintiff must normally show that the defendant health care provider violated the standard of care through expert testimony.\textsuperscript{195} Very few cases have allowed patients to recover when the defendant health care provider complied with the standard of practice.\textsuperscript{196} Thus,
conforming with customary practice is generally a conclusive defense for a health care professional.\textsuperscript{197}

Recently in \textit{Heinrich v. Sweet},\textsuperscript{198} the Court of Appeals for the First Circuit adapted the medical malpractice framework to human subject research.\textsuperscript{199} The First Circuit vacated a jury verdict for the plaintiffs on the negligence claim and reversed in favor of the defendants, noting that evidence that the physician had breached the standard of care was flawed.\textsuperscript{200} The \textit{Heinrich} court relied on expert testimony to determine the standard of care in researcher malpractice, and held that the plaintiffs’ expert testimony lacked adequate foundation to show that the research violated the standard of care at the time it was performed, in 1960–61.\textsuperscript{201} Although the research predated the modern federal regulations, the \textit{Heinrich} court noted that the research received three levels of review by administrative committees at the hospital, and that “approval by these various committees is very compelling evidence” that the trials complied with the standard of care.\textsuperscript{202} In addition, the \textit{Heinrich} court observed that adequate informed consent is a partial defense to researcher malpractice claims, but admitted that there are situations in which deviating from the research protocol described in informed consent could lead to independent negligence.\textsuperscript{203} Thus, the \textit{Heinrich} court adapted the medical malpractice model to establish the standard of care in researcher malpractice.

In sum, although there is a trend for courts to adopt the federal regulations as the standard of care for informed consent actions against

\begin{footnotes}
\footnotetext[197]{Although the medical profession is in the unusual position of setting its own legal standards of conduct, merely by adopting its own medical practices as the standard, this privilege is based in part on the reasoning that physicians set those standards with “primary regard to protection of the public rather than to such considerations as increased profitability.” See Rossell v. Volkswagen of Am., 709 P.2d 517, 522, 523 (Ariz. 1985); see also Richard N. Pearson, \textit{The Role of Custom in Medical Malpractice Cases}, 51 IND. L.J. 528, 536–37 (1976). But see Philip G. Peters, \textit{The Quiet Demise of Deference to Custom: Malpractice Law at the Millenium}, 57 WASH. & LEE L. REV. 163, 170 (2000) (observing that judicial deference to physician customs is gradually eroding, with twelve states expressly rejecting deference to physician customs and another nine adopting a standard of care based on the reasonable physician).}
\footnotetext[198]{308 F.3d 48 (1st Cir. 2002).}
\footnotetext[199]{\textit{Id.} at 52–53 (explaining that the medical malpractice case was brought in 1995 for the deaths of two patients given an experimental treatment for brain cancer over four decades ago, in medical trials only recently made public).}
\footnotetext[200]{\textit{Id.} at 70–71.}
\footnotetext[201]{\textit{Id.} at 65–67.}
\footnotetext[202]{\textit{Id.} at 69.}
\footnotetext[203]{\textit{Id.} at 70.}
\end{footnotes}
researchers, limiting the scope of expert testimony to determining whether the federally-established standard was breached, no courts have adopted the federal regulations as the standard of care for researcher malpractice. Rather, courts such as the First Circuit in Heinrich have used expert testimony to establish the standard of care in researcher malpractice actions and viewed IRB approval as a partial defense.

IV. INJURED RESEARCH SUBJECTS SHOULD BE ABLE TO BRING INFORMED CONSENT AND RESEARCHER MALPRACTICE ACTIONS AGAINST RESEARCHERS

An injured research subject should be able to successfully bring a negligence action against a researcher by establishing that the researcher owes the subject a duty of care based on the special relationship between a researcher and subject. Once the injured research subject has demonstrated that a duty of care exists, courts must determine whether the researcher has violated the standard of care. A plaintiff should be able to establish that the federal regulations are the standard of care for informed consent in human subject research, using expert testimony to determine if the federal requirements for informed consent have been met. Violating the federal requirements for informed consent should result in a finding of negligence, and compliance with the federal regulations should provide a partial defense. Further, a plaintiff should be able to establish the standard of care for other researcher malpractice actions by using expert testimony, similar to the medical malpractice model. Failure to obtain IRB approval before proceeding with human subject research protocols should result in a finding of negligence, and IRB approval should provide a partial defense.

A. Establishing the Duty of Care For Human Subject Research

A plaintiff who participates in a research study should be able to establish a duty of care against researchers. Although the duty arising from the researcher-subject relationship has rarely been addressed by the courts, plaintiffs should be able to successfully establish that researchers owe a duty of care to human subjects that resembles the special physician-patient relationship. Grimes is the first case to explicitly hold that researchers owe duties to human subjects based on special

204 Grimes is the first case to explicitly hold that researchers owe duties to human subjects based on special

See supra notes 97-101 and accompanying text.
relationships. The *Grimes* court stated that "the very nature of nontherapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise," and noted that no laws preclude "the parties to a scientific study" from entering into "special relationships with the subjects of the study that can create duties." Plaintiffs should be able to rely on *Grimes* as persuasive authority that the special relationship between researchers and subjects exists even outside of Maryland.

Further, plaintiffs should be able to establish that researchers owe subjects a duty of care by emphasizing the similarities between the researcher-subject relationship and the physician-patient relationship. Plaintiffs should argue first that negligence in human subject research may result in bodily injury, creating a duty similar to that imposed in medical malpractice. Second, the researcher-subject relationship is fiduciary in nature because the subject is dependent on the researcher’s specialized knowledge. Third, the researcher-subject relationship is initiated by an informed consent quasi-contract, similar to the patient-physician relationship. Drawing on these similarities, injured research subjects should be able to successfully establish that researchers owe an affirmative duty of care to human subjects based on the special relationship that exists between researchers and subjects.

Although it can be argued that the researcher-subject relationship is distinguishable from the physician-patient relationship because researchers can potentially have little to no personal interaction with human subjects, the researcher-subject relationship arguably imposes a higher duty of care. Research often involves unforeseeable and unknown risks, increasing the subject’s dependence on the researcher’s specialized knowledge. There is often less accepted scientific evidence and experience to establish what is safe in human subject research than in

206. *Id.* at 834–35.
207. *Id.*
208. *See supra* Part II.B.
209. *See Grimes*, 782 A.2d at 846 (stating that recruitment of otherwise healthy subjects into potentially hazardous study conditions for the purpose of testing scientific hypotheses "would normally warrant or create such special relationships as a matter of law").
211. *See supra* notes 111–14 and accompanying text.
212. *See supra* notes 102–04 and accompanying text.
medical practice. Further, the research subject often has less chance of receiving a direct benefit than medical patients, and is often acting out of altruism rather than self-interest. Whereas physicians are primarily attempting to help patients, researchers and subjects may have conflicting interests. Indeed, the federal requirements for written informed consent prior to research have been held to be more stringent than the unwritten consent implied in the physician-patient relationship, and to create a higher standard of disclosure of foreseeable risks. Thus, courts should find that researchers owe a duty of care to their subjects.

B. Establishing the Standard of Care for Human Subject Research

Plaintiffs should be able to bring two types of professional negligence actions against researchers: informed consent, and researcher malpractice. The federal regulations governing human subject research should provide the minimum standard of care for informed consent. Violating the federal requirements for informed consent should result be deemed negligence, and researchers’ compliance with them should be a partial defense. In contrast, plaintiffs should be able to establish a standard of care for researcher malpractice actions through expert testimony, and researchers who obtain IRB approval should be allowed a partial defense.

1. Establishing the Standard of Care for Informed Consent in Research

A standard of care may be established by administrative regulations, and violation of federal regulations has served as the basis for negligence actions in many areas of law. Courts may adopt the standard of care from federal regulations that protect: (1) a class of persons whose interest is invaded, (2) the particular interest that is invaded, (3) against the harm

214. See id.
215. Id.; see National Commission, supra note 26 and accompanying text.
216. See, e.g., Rossell v. Volkswagen of Am., 709 P.2d 517, 522–23 (Ariz. 1985); see also supra note 197.
217. See Morin, supra note 81, at 213; see also Delgado & Leskovac, supra note 62, at 69.
221. See supra notes 124–26 and accompanying text.
which has resulted, and (4) against the particular hazard from which the harm results.\textsuperscript{222} The Daum court held that the federal regulations provide the standard of care for informed consent in human subject research because they meet these four elements of negligence per se.\textsuperscript{223} In particular, the Daum court found that the federal regulations are "intended to protect the rights and safety of subjects"\textsuperscript{224} and that human subjects are "within the class of persons for whose protection the [federal regulations] were enacted."\textsuperscript{225}

Several courts have used the federal regulations to determine the standard of care for informed consent in human subject research. The Whitlock court adopted the Common Rule as the standard of care for informed consent, and held that there is a heightened standard of disclosure for informed consent in the research context.\textsuperscript{226} Similarly, the Daum court held that violations of the federal regulation's requirements for informed consent result in negligence per se, and limited the role of expert testimony to whether the federal standard was met.\textsuperscript{227} Courts have found that the federal regulations provide detailed, clear guidelines for courts and juries to assess whether a subject's informed consent conformed to the higher standard of care owed by researchers.\textsuperscript{228}

In addition, other courts have relied on the FDA regulations to set the standard of care for obtaining a patient's informed consent before implanting experimental medical devices.\textsuperscript{229} In Vodopest v. MacGregor,\textsuperscript{230} the Supreme Court of Washington held that researchers violated the Common Rule by requiring subjects to waive their legal rights to bring negligence actions in the consent form,\textsuperscript{231} because the

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\begin{itemize}
  \item \textsuperscript{222} Restatement (Second) of Torts § 286 (1965).
  \item \textsuperscript{223} Daum v. SpineCare Med. Group, 61 Cal. Rptr. 2d 260, 276 (Cal. Ct. App. 1997).
  \item \textsuperscript{224} Id. at 273.
  \item \textsuperscript{225} Id.
  \item \textsuperscript{226} Whitlock v. Duke Univ., 637 F. Supp. 1463, 1471 (D.N.C. 1986); see also supra notes 87–90 and accompanying text.
  \item \textsuperscript{227} Daum, 61 Cal. Rptr. 2d at 273; see supra notes 132–35 and accompanying text.
  \item \textsuperscript{228} See, e.g., United States v. Najarian, 915 F. Supp. 1460, 1473 n.21 (D. Minn. 1996) (observing that "the requisites of 'informed consent' are detailed in the FDA's Regulations" and holding, inter alia, that 21 C.F.R. §§ 50.20–50.27 is not void for vagueness).
  \item \textsuperscript{230} 128 Wash. 2d 840, 913 P.2d 779 (1996).
  \item \textsuperscript{231} Id. at 857–62, 913 P.2d at 787–89.
\end{itemize}
Common Rule prohibits such exculpatory agreements.\textsuperscript{232} Courts have thus recognized that both the Common Rule and FDA regulations provide a workable standard of care by which to measure a research subject's informed consent.

Even though the federal regulations provide a detailed standard of care for informed consent, expert testimony will most likely be necessary to determine whether a particular researcher complied with the standard of care. The Common Rule sets forth specific elements of informed consent, including explaining the purposes and procedures of the research, describing the reasonably foreseeable risks and benefits, and disclosing the alternatives.\textsuperscript{233} Courts currently apply two different tests for establishing the appropriate scope of disclosure in informed consent actions: (1) the professional practice standard; and (2) what the "reasonable person" would want to know.\textsuperscript{234} Jurisdictions using the professional practice standard should rely on expert testimony to determine the scope of disclosure for each of the elements of informed consent, based on what a reasonable researcher would have disclosed in a similar situation.\textsuperscript{235} Jurisdictions using the "reasonable person" standard should allow the trier of fact to determine the scope of disclosure for each of the elements of informed consent that a "reasonable person" would want to know, but should use expert testimony to clarify the purposes, procedures, and foreseeable risks of the research.\textsuperscript{236} For instance, in \textit{Stewart v. Cleveland Clinic Foundation},\textsuperscript{237} the defendant clinic argued that the informed consent form for a clinical trial complied with the Common Rule,\textsuperscript{238} while the plaintiff provided contradictory expert testimony.\textsuperscript{239} The court held that a genuine issue of material fact existed as to whether the informed consent complied with the federal requirements, and allowed the jury to consider expert testimony in determining whether the researchers complied with the federal regulations.\textsuperscript{240} Similarly, the \textit{Daum} court limited the use of expert

\textsuperscript{232} See supra note 40 and accompanying text.
\textsuperscript{233} 45 C.F.R. § 46.116(a); see supra notes 38-40 and accompanying text.
\textsuperscript{234} See King, supra note 65, at 29.
\textsuperscript{235} See \textit{Furrow}, supra note 70, at 318.
\textsuperscript{236} Id. at 319.
\textsuperscript{237} 736 N.E.2d 491 (Ohio Ct. App. 1999).
\textsuperscript{238} Id. at 495.
\textsuperscript{239} Id. at 497.
\textsuperscript{240} Id. at 501.
testimony to determine whether the standard of care provided by the federal regulations was met.\footnote{Daum v. SpineCare Med. Group, 61 Cal. Rptr 2d 260, 279 (Cal. Ct. App. 1997).}

However, complying with the federal regulations’ informed consent requirements should only be a partial defense for researchers. Although several courts have granted summary judgment to defendants for complying with the federal requirements for disclosure of risks,\footnote{See supra notes 149–52 and accompanying text.} there are several reasons why such compliance should not be a complete defense. First, expert testimony will usually be required to determine whether the informed consent was adequate under the federal regulations, thereby precluding summary judgment.\footnote{See, e.g., supra notes 171–75 and accompanying text.} Second, the federal regulations explicitly state that the informed consent requirements do not preempt applicable federal, state, or local laws that require additional information to be disclosed.\footnote{45 C.F.R. § 46.116(e) (2001).} Thus, courts must consider whether state laws set higher standards for informed consent and whether the researcher’s actions violated them. For example, the Supreme Court of California held that researchers must disclose conflicts of interest under state law, even though the Common Rule does not require it.\footnote{Moore v. Regents of Univ. of Cal., 793 P.2d 479, 485 (Cal. 1990), cert. denied, 499 U.S. 936 (1991).} Assuming that state or local laws do not require higher standards for informed consent, plaintiffs should be able to establish the Common Rule as the standard of care for informed consent in human subject research. Violating the federal requirements should result in a finding of negligence, and compliance should only be a partial defense.

2. Establishing the Standard of Care for Researcher Malpractice

The federal regulations require researchers to obtain IRB review\footnote{45 C.F.R. § 46.109 (2001).} and approval\footnote{Id. § 46.111.} before obtaining informed consent and conducting research on human subjects. The federal regulations do not, however, provide a specific standard of care for the conduct of research. The criteria for IRB approval generally requires that the IRB determine, inter alia, that “risks to subjects are minimized”\footnote{Id. § 46.111(a)(1).} and “reasonable in relation
to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.” The IRB also must make technical decisions about the scientific merit of research protocols before approving the research. Thus, the federal regulations place the primary responsibility of risk-benefit analysis and approval of research on IRBs, and do not provide detailed standards of care for the actual conduct of research in researcher malpractice. However, obtaining IRB approval could become part of the standard of care for researcher malpractice, in which case conducting research without IRB approval could result in researcher malpractice.

Setting the federal regulations aside, plaintiffs should be able to successfully establish the standard of care in researcher malpractice actions through expert testimony, similar to the medical malpractice model. The standard of care in medical malpractice is generally established by expert testimony, and is defined as a failure to exercise the required degree of care, skill, and diligence ordinarily possessed by a reasonable and prudent physician in the same medical specialty acting under the same or similar circumstances. Early cases treated research that deviated from medical standards of care as negligent, without developing a specialized standard of care for research. Courts should adapt the medical malpractice model to establish a specialized standard of care in researcher malpractice actions, using expert testimony to determine the degree of care, skill and diligence ordinarily possessed by a reasonable and prudent researcher in the same research specialty acting under the same or similar circumstances. The First Circuit adopted this approach in Heinrich using expert testimony to establish the standard of care for researcher malpractice, and holding that the plaintiffs failed to show that the applicable standard of care was breached.

Although the federal regulations do not provide a specific standard of care for researcher malpractice, obtaining IRB approval should only be a partial defense. IRB approval demonstrates that an independent group of IRB members with professional competence determined, inter alia, that the research had scientific merit, the benefits outweighed the risks, and the informed consent form was in compliance with federal

249. Id. § 46.111(a)(2); see supra notes 43–51 and accompanying text.
250. Id. § 46.111(a)(1) (stating IRBs must determine that research protocols use “procedures which are consistent with sound research design”).
251. See FURROW, supra note 70, at 269.
252. See supra notes 77–79 and accompanying text.
253. See supra notes 198–203 and accompanying text.
requirements.\textsuperscript{254} Although the \textit{Heinrich} court observed that "the bar to be surmounted in litigation over current charges of [researcher] malpractice is a demanding one,"\textsuperscript{255} the circuit court found that approval by committees similar to IRBs was a partial defense.\textsuperscript{256} If the researcher complied with the federal regulations and obtained IRB approval, it should at least be evidence of meeting the standard of care for researcher malpractice.

There are several reasons why IRB approval should only create a rebuttable presumption of due care in research malpractice actions, rather than serving as a complete defense. First, complying with the federal requirement of obtaining IRB approval will not necessarily prevent a finding of researcher malpractice if a reasonable person would have taken additional precautions.\textsuperscript{257} Second, the federal regulations explicitly allow higher standards of care set by federal, state, or local laws.\textsuperscript{258} Consequently, courts must evaluate whether other laws set higher standards of care than those required to obtain IRB approval. Third, IRB approval itself may be flawed if the researcher provided inaccurate information about the risks and benefits of the research, or failed to provide information about adverse events for annual continuing review.\textsuperscript{259} The IRB relies on the researcher's training and honesty when reviewing and approving research protocols. It is always possible that this reliance could be misplaced.

Further, the IRB itself may not have adequately performed the IRB review. For instance, the \textit{Grimes} court criticized the IRB's performance in approving the research, and allowed a negligence action against researchers to proceed because the IRB approval was flawed.\textsuperscript{260} Finally, even if the researcher obtained proper IRB approval before conducting the research, it is possible that the research was negligently performed,\textsuperscript{261} or that the researcher deviated from the IRB-approved protocol. Juries should therefore consider IRB approval as evidence that the standard of

\textsuperscript{254} See supra notes 43–51 and accompanying text.

\textsuperscript{255} Heinrich v. Sweet, 308 F.3d 48, 71 (1st Cir. 2002).

\textsuperscript{256} See supra note 202 and accompanying text.

\textsuperscript{257} RESTATEMENT (SECOND) OF TORTS § 288C (1965).

\textsuperscript{258} 45 C.F.R. § 46.101(f) (2001).

\textsuperscript{259} \textit{Id.} § 46.109(e); see note 49 and accompanying text.

\textsuperscript{260} See supra notes 185–86 and accompanying text.

care for researcher malpractice was met, but should ultimately assess the value of that evidence in the context of expert testimony.

Thus, courts should adopt the federal regulations as the standard of care for informed consent in human subject research, using expert testimony to establish whether the standard of care for informed consent was breached. Researchers who violate the federal requirements for informed consent should be held liable, although researchers who comply with these requirements should be granted a partial defense. Because the federal regulations do not provide detailed standards of care for researchers conducting research, plaintiffs should be able to establish the standard of care in researcher malpractice through expert testimony. Researchers who proceed without IRB approval should be held liable, while researchers who obtain IRB approval should only be entitled to a partial defense.

CONCLUSION

Injured human subjects are becoming more likely to sue researchers. Although the case law on human subject research is just beginning to emerge, plaintiffs should be able to successfully establish negligence claims against researchers by establishing a duty of care based on the special relationship between researchers and subjects. Having established that researchers owe human subjects a duty of care, injured research subjects should be able to bring negligence actions against researchers based on informed consent and researcher malpractice. Research subjects should be able to establish the federal regulations as the minimum standard of care in informed consent, and use expert witnesses to determine whether the federal requirements for informed consent were violated. Violating the standard of care for informed consent in the federal regulations should result in a finding of negligence, and researchers who comply with the regulations should be allowed a partial defense. Although the federal regulations do not provide a specific standard of care for researcher malpractice, research subjects should be able to establish specialized standards of care for researcher malpractice through expert testimony, similar to the traditional medical malpractice model. Failure to obtain IRB approval should result in a finding of negligence, and IRB approval should only be a partial defense.