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

Roger L. Jansson, M.P.H., M.P.A.

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.¹ 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.² Two outraged parents filed separate negligence actions when their children developed elevated lead levels in their blood while participating in the research program.³ 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.⁴

In *Grimes v. Kennedy Krieger Institute*,⁵ 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

1. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 811–12, 820–21 (Md. 2001) (explaining that the intervention consisted of five different levels of lead abatement achieved by removal of dust, paint, or soil).

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.⁶ 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,⁷ a standard of care seemingly higher than that provided by the federal regulations.⁸ The court later clarified that "any risk" means "any articulable risk beyond the minimal kind . . . inherent in any endeavor."⁹ It remains unclear whether this definition sets a higher standard of care than the federal regulations, or merely interprets allowable risk under the regulations.¹⁰

The *Grimes* decision is part of a larger trend in which injured research subjects have filed lawsuits against researchers.¹¹ These high-profile lawsuits have generated intense media attention.¹² 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.*

8. See 45 C.F.R. §§ 46.401–409 (2001).

9. *Grimes*, 782 A.2d at 862.

10. See *infra* notes 162–63.

11. See Mary R. Anderlik & Nanette Elster, *Lawsuits Against IRBs: Accountability or Incongruity?*, 29 J.L. MED. & ETHICS 220 (2001); Complaint, *Gelsinger v. Trustees of the Univ. of Pa.*, Phila. County Court of Common Pleas (Sept. 18, 2000), available at <http://www.sskrplaw.com/links/healthcare2.html> (alleging deficiencies in informed consent in a gene therapy experiment) (last visited Jan. 3, 2003); Complaint, *Robertson v. McGee*, Northern District of Oklahoma (Jan. 29, 2001) No. 01CV00G0H(M), available at <http://www.sskrplaw.com/gene/robertson/complaint-new.html> (alleging negligence for failure to follow the federal regulations in a study of a cancer vaccine) (last visited Jan. 3, 2003); Complaint, *Wright v. Fred Hutchinson Cancer Research Ctr.*, Kitsap County Court, Washington (No. 01-2-008376) (March 29, 2001), available at <http://www.sskrplaw.com/gene/wright/complaint1.html> (last visited Jan. 3, 2003) (bringing class action regarding an experimental bone marrow transplant for cancer).

12. See Michael D. Lemonick & Andrew Goldstein, *At Your Own Risk*, TIME, Apr. 22, 2002, at 46; S.G. Stolberg, *The Biotech Death of Jesse Gelsinger*, N.Y. TIMES MAGAZINE, Nov. 28, 1999, at 136; D. Wilson & D. Heath, *The Blood Cancer Experiment*, SEATTLE TIMES, Mar. 11, 2001, at A1.

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When human subjects are harmed, the most likely source of liability for researchers is based in negligence.¹³ There are two initial considerations when determining whether human research subjects can bring negligence actions against researchers.¹⁴ 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 Rule¹⁵ 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).

14. See W. PAGE KEETON ET AL., *PROSSER AND KEETON ON THE LAW OF TORTS* § 30, at 164–65 (5th ed. 1984).

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.¹⁶ In contrast, the FDA regulations apply to research involving experimental drugs, biological products, and medical devices that are subject to FDA approval.¹⁷ 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.¹⁸ 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.¹⁹ 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.²⁰ Later, doctors and scientists of the World Medical Association adopted the Declaration of Helsinki and set international guidelines for biomedical research by physicians.²¹ In 1966, the Public Health Service developed internal policy guidelines requiring peer review of all research involving human subjects.²²

16. 45 C.F.R. § 46.101 (2001).

17. 21 C.F.R. §§ 50.1, 56.101 (2001).

18. See KEETON ET AL., *supra* note 14, § 30 at 164–65.

19. See Leonard H. Glanz, *The Influence of the Nuremberg Code on U.S. Statutes and Regulations*, in THE NAZI DOCTORS AND THE NUREMBERG CODE, 183–200 (George J. Annas & Michael A. Grodin eds., 1992).

20. The Nuremberg Code (1949), *reprinted in* SOURCE BOOK IN BIOETHICS 11–12 (Albert R. Jonsen et al. eds., 1998).

21. World Medical Association, *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects* (1964), *reprinted in* SOURCE BOOK IN BIOETHICS 13–15 (Albert R. Jonsen et al. eds., 1998).

22. Surgeon General, Public Health Service to the Heads of the Institutions Conducting Research with Public Health Service Grants, 8 February 1966 (“Clinical research and investigation involving human beings”) (ACHRE No. HHS-090794-A), *reprinted in* ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT OF THE ADVISORY COMMITTEE ON HUMAN RADIATION EXPERIMENTS 100 (1996).

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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).

24. National Research Act of 1974, Pub. L. No. 93-348, § 102, 88 Stat. 342 (1974).

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).

26. The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, U.S. Dep’t of Health, Educ., & Welfare, Pub. L. No. (OS) 78-0012 (1978).

27. *Id.* at 4.

28. *Id.* at 4–20.

29. *Id.*

30. See 45 C.F.R. §§ 46.101–124 (2001).

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).

rights of human subjects of [biomedical and behavioral] research.”³² 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).³³ In 1991, this regulation was adopted by other federal departments and agencies as the Common Rule.³⁴ 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 to all research regardless of the funding source.³⁵ The HHS Office for Human Research Protections (OHRP) enforces institutional compliance with the Common Rule.³⁶

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.³⁷ 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.³⁸ 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.³⁹ The informed consent

32. Public Health Service Act, 42 U.S.C. §§ 201 et. seq., as amended by The Health Research Extension Act of 1985, Pub. L. No. 99-158 (Nov. 20, 1985).

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 IRBs⁴³ to independently review research⁴⁴ protocols that involve human subjects,⁴⁵ and sets forth the requirements for the review of research⁴⁶ 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)

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).

57. Sharona Hoffman, *Continued Concern: Human Subject Protection, The Institutional Review Board, and Continuing Review*, 68 TENN. L. REV. 725, 727 (2001); see Anderlik & Elster, *supra* note 11, at 223.

58. See, e.g., *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

59. See *infra* Part II.B.

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the breach caused injury to the subject; and (4) a cognizable injury.⁶⁰ Health care providers are subject to tort liability under two alternate negligence actions: informed consent and medical malpractice.⁶¹ These alternate causes of action correspond to two distinct interests of patients: self-determination and competent care.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 consent⁶³ 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.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.⁶⁵ Before providing treatment, the physician must obtain consent by disclosing and explaining all information that is necessary for the patient's decision,⁶⁶ which typically includes the nature and purpose of the treatment, expected benefits, foreseeable risks, reasonable alternatives, and foreseeable risks of forgoing treatment.⁶⁷ Lack of informed consent is generally treated as professional negligence, and is based on a physician's professional duty

60. See KEETON ET AL., *supra* note 14, § 30 at 164–65. Proving causation and cognizable injury is beyond the scope of this Comment.

61. See, e.g., *Thomas v. Wilfac, Inc.*, 65 Wash. App. 255, 261, 828 P.2d 597, 601 (1992).

62. See Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 127–28 (1986).

63. See, e.g., *Backlund v. Univ. of Wash.*, 137 Wash. 2d 651, 653–54, 975 P.2d 950, 951–52 (1999).

64. See generally Nancy King, *Consent and the Courts: The Emergence of the Legal Doctrine*, in A HISTORY AND THEORY OF INFORMED CONSENT 114–50 (Ruth R. Faden & Tom L. Beauchamp eds., 1986).

65. *Id.* at 29.

66. See, e.g., *Truman v. Thomas*, 611 P.2d 902, 905 (Cal. 1980) (en banc).

67. See generally John H. Derrick, Annotation, *Medical Malpractice: Liability for Failure of Physician to Inform Patient of Alternative Modes of Diagnosis or Treatment*, 38 A.L.R. 4th 900 (1985); W.M. Moldoff, Annotation, *Malpractice: Physician's Duty to Inform Patient of Nature and Hazards of Disease or Treatment*, 79 A.L.R. 2d 1028 (1961).

to provide patients with the appropriate information before they consent to treatment.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.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.⁷⁰ In medical malpractice, the standard of care is usually derived from expert testimony by the medical profession.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.⁷² Recently courts have begun to develop a specialized analysis for negligence causes of action in human subject research.⁷³ To bring a successful negligence claim against researchers,⁷⁴ a plaintiff must first establish that the defendant owed a

68. Faden & Beauchamp, *supra* note 64, at 29.

69. *Id.*

70. See BARRY R. FURROW ET AL., HEALTH LAW 269 (2d ed. 2000).

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).

72. See *infra* notes 77–79 and accompanying text.

73. See *infra* notes 80–94 and accompanying text.

74. The liability of research institutions and IRB members is beyond the scope of this Comment. For cases holding hospitals or institutions liable, see *Gregg v. Kane*, 1997 WL 570909, at *6 (E.D. Pa. 1997) and *Kus v. Sherman Hosp.*, 644 N.E. 2d 1214, 1221 (Ill. App. Ct. 1995). See also *Fritter v. Iolab Corp.*, 607 A.2d 1111, 1114–15 (Pa. Super. Ct. 1992) (“[F]ederal regulations specifically

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duty of care.⁷⁵ Although many possible sources of this duty exist,⁷⁶ 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.⁷⁷ 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.⁷⁸ Courts did not accept clinical research as a necessary endeavor until the 1930s.⁷⁹

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*,⁸⁰ 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.”). There is no precedent for holding IRB members liable for negligence. However, there is split authority on whether state peer review statutes designed to encourage peer review by providing physicians who serve on committees with immunity for decisions to discipline their peers will protect IRB members from liability. *Compare* *Konrady v. Oesterling*, 149 F.R.D. 592, 598 (D. Minn. 1993) (holding that an IRB was not a peer review committee under the Minnesota peer review statute, and that the records were not protected), *with* *Doe v. Ill. Masonic Med. Ctr.*, 696 N.E.2d 707, 711 (Ill. App. Ct. 1998) (holding that documents used by hospital IRB in the course of a medical study come within the scope of privilege of the Illinois peer review statute). *See also* VA. CODE ANN. § 8.01-44.1 (Michie 2001) (explicitly providing civil immunity to IRB members in Virginia).

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).

77. *See, e.g.*, *Brown v. Hughes*, 30 P.2d 259, 262–63 (Colo. 1934).

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.⁸¹ The distinction between clinical practice and research has also been a difficult and complex problem in regulatory and ethical codes.⁸² Early discussions of research ethics and regulation often distinguished between “therapeutic” and “nontherapeutic” research,⁸³ although many commentators have argued that this distinction is illogical and confusing.⁸⁴ The Common Rule abandoned this distinction, simply referring to “research,” but some courts continue to refer to “nontherapeutic research” in their opinions.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.⁸⁶ In *Whitlock v. Duke University*,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.⁸⁸ The *Whitlock* court adopted the Common Rule as the standard of care for informed consent in human subject research,⁸⁹ but it did not reach the question of whether a duty of

81. See Karine Morin, *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).

82. See ROBERT J. LEVINE, *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”).

83. *Id.* at 8 (explaining that the original Declaration of Helsinki distinguished “nontherapeutic” non-clinical research from “therapeutic” clinical research).

84. *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).

85. See, e.g., *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

86. *Whitlock v. Duke Univ.*, 637 F. Supp. 1463 (M.D.N.C. 1986), *aff'd*, 829 F.2d 1340 (4th Cir. 1987).

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).

88. *Id.* at 1471. In dicta, the court also considered standards of disclosure under the Nuremberg Code and the Declaration of Helsinki. *Id.* at 1470–71.

89. See *id.* at 1471.

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care is implied by the Common Rule because it found that the Common Rule's standard of care was not breached.⁹⁰

In 2001, Maryland's high court held in *Grimes* that there are several potential sources of duty that researchers owe to human subjects.⁹¹ 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.⁹² 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.⁹³ 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."⁹⁴

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.⁹⁵ A duty to aid or protect someone is typically found in relationships involving dependence or mutual dependence.⁹⁶ The relationship between a researcher and human subjects is analogous to the special, fiduciary relationship between physicians and patients.⁹⁷

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-passenger; (2) innkeeper-guest; (3) landowner-invitee; and (4) certain custodial relationships).

96. *See id.* cmt. b.

97. *See, e.g.,* Angela R. Holder, *Do Researchers and Subjects Have a Fiduciary Relationship?*, 4 IRB: ETHICS & HUMAN RESEARCH 6–7 (1982).

1. *Physician-Patient Relationship*

In many states, the existence of a special physician-patient relationship is essential to negligence actions against physicians.⁹⁸ Physicians have been regarded as fiduciaries⁹⁹ of their patients and as such are expected to act in their patients' best interests.¹⁰⁰ This fiduciary duty arises out of the trust patients must place in a physician's skill, learning, and experience.¹⁰¹ 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.¹⁰² 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.¹⁰³ Consequently, medical malpractice law has included a mixture of contract and tort influences for over a century.¹⁰⁴

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.¹⁰⁵ 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

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.

103. See James L. Rigelhaupt, Jr., Annotation, *What Constitutes Physician-Patient Relationship for Malpractice Purposes*, 17 A.L.R. 4th 132 § 2 (1982).

104. See Gary T. Schwartz, *Medical Malpractice, Tort, Contract, and Managed Care*, 1998 U. ILL. L. REV. 885, 899 (1998).

105. Holder, *supra* note 97, at 6.

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that between a physician and patient.¹⁰⁶ The *Grimes* court stated that “the very nature of nontherapeutic research can, and normally will, create special relationships out of which duties arise.”¹⁰⁷

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.¹⁰⁸ These commentators have argued that the researcher-subject relationship is fiduciary, because a researcher’s specialized knowledge makes the subject dependent on the researcher.¹⁰⁹ 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.¹¹⁰

In addition, a researcher enters into a quasi-contractual relationship with the subject by obtaining the subject’s written informed consent.¹¹¹ 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.*,¹¹² the Ninth Circuit held that a consent form in a research protocol formed a unilateral contract.¹¹³ 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.¹¹⁴ Thus, there are significant similarities between the physician-patient and researcher-subject relationship that may impose similar duties of care.

106. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

107. *Id.* at 835–36.

108. See Holder, *supra* note 97, at 6–7; see also Delgado & Leskovic, *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 & Leskovic, *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).

114. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 843 (Md. 2001).

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 researchers¹²¹ and relied on expert testimony to determine whether the standard of care was met.¹²²

115. See KEETON ET AL., *supra* note 14, at 164–65.

116. See generally King, *supra* note 64, at 114–50.

117. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972).

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, *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, *supra* note 67.

121. See *infra* Part III.A.1.

122. See *infra* Part III.A.2.

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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.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,¹²⁴ not complying with environmental regulations on toxic waste,¹²⁵ and violating the Occupational Safety and Health Act (OSHA) regulations.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.¹²⁷ In most jurisdictions, an unexcused violation of a relevant federal statute or regulation constitutes negligence per se as a matter of law.¹²⁸ A minority of jurisdictions treat violations of statutes or regulations as evidence of negligence, creating a rebuttable presumption of negligence.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.¹³⁰ As early as

123. See RESTATEMENT (SECOND) OF TORTS § 285 (1965).

124. See generally Paul Sherman, *Use of Federal Statutes in Negligence Per Se Actions*, 13 WHITTIER L. REV. 831 (1992).

125. See generally Sheila G. Bush, *Can You Get There From Here?: Noncompliance with Environmental Regulations as Negligence Per Se in Tort Cases*, 25 IDAHO L. REV. 469 (1988/1989).

126. See John P. Ludington, Annotation, *Violation of OSHA Regulation As Affecting Tort Liability*, 79 A.L.R. 3d 962 (1977).

127. RESTATEMENT (SECOND) OF TORTS § 286 (1965).

128. See, e.g., *Sanchez v. Gale*, 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 *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 *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 *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 *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 *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

(proposing a regulatory compliance defense but permitting plaintiffs to overcome it by producing clear and convincing evidence that the regulation was inadequate).

131. Comment, *Legal Implications of Psychological Research with Human Subjects*, 1960 DUKE L.J. 265, 271 (1960).

132. 61 Cal. Rptr. 2d 260 (Cal. Ct. App. 1997).

133. *Id.* at 264 (involving spinal surgery using an experimental fixation device).

134. *Id.* at 273.

135. *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. *Id.*

137. 637 F. Supp. 1463, 1475 (D.N.C. 1986), *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); *see supra* notes 87–90 and accompanying text.

138. *Id.* at 1471.

139. 128 Wash. 2d 840, 913 P.2d 779 (1996) (involving research on the effects of high altitude on subjects).

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Rule's informed consent provision.¹⁴⁰ 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.¹⁴¹ 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.¹⁴² These defendants invoke the federal preemption doctrine, arguing that the primacy of federal law under the Supremacy Clause¹⁴³ 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.¹⁴⁴ In addition, many defendants have argued that compliance with federal regulations should be a complete defense to state tort liability.¹⁴⁵ However, few jurisdictions view regulatory compliance as a complete defense.¹⁴⁶ Most states allow juries to take a defendant's compliance with federal regulations into account, but instruct juries to treat federal safety standards as only a minimum floor of acceptable conduct.¹⁴⁷ While state courts have often been willing to treat violation of federal statutes or regulations as negligence per se, they have been reluctant to treat compliance as a complete defense.¹⁴⁸

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.

141. *See, e.g.,* *Chambers v. Osteonics Corp.*, 917 F. Supp. 624, 626 (S.D. Ind. 1996); *Kus v. Sherman Hosp.*, 644 NE.2d 1214, 1221 (Ill. App. Ct. 1995); *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr. 2d 852, 859–60 (Cal. App. 1994); *Mitchell v. Iolab Corp.*, 700 F. Supp. 877, 878–79 (E.D. La. 1988).

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.¹⁴⁹ In *Slater v. Optical Radiation Corp.*,¹⁵⁰ 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.”¹⁵¹ 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.”¹⁵² 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.¹⁵³ 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.¹⁵⁴ 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.¹⁵⁵ 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.¹⁵⁶

149. See, e.g., *Covey v. Surgidev. Corp.*, 815 F. Supp. 1089, 1095 (D. Ohio 1993); *Beach v. E.R. Squibb & Sons, Inc.*, 706 A.2d 26, 1998 WL 67744, at *2 (Del. Feb. 11 1998).

150. 961 F.2d 1330 (7th Cir. 1992).

151. *Id.* at 1333–34.

152. *Id.*

153. 45 C.F.R. § 46.101(f) (2001).

154. *Id.* § 46.116(e).

155. See, e.g., CAL. HEALTH & SAFETY CODE §§ 24170–24175 (West 2002); DEL. CODE ANN. tit. 16, § 5173 (2001); FLA. STAT. ANN. § 381.85 (West 2001); LA. REV. STAT. ANN. § 22:230.4 (West 2001); MO. ANN. STAT. § 630.115(8) (West 2001); WASH. ADMIN. CODE § 388-04 (2002).

156. See, e.g., CAL. PENAL CODE § 3524 (West 2002) (protecting prisoners in biomedical and behavioral research); D.C. CODE ANN. § 7-1305.09 (2002) (protecting mentally retarded persons in experimental research); MICH. COMP. LAWS ANN. § 330.1919[1] (West 2002) (protecting subjects in mental health research); MONT. CODE ANN. §§ 53-20-147 (2002) (protecting developmentally disabled persons in experimental research) and 53-21-147 (2002) (protecting mentally ill persons in experimental research). Some of these state statutes and regulations contain preemption clauses such that they do not apply to federally-funded research that is already subject to federal regulations. See, e.g., N.Y. PUB. HEALTH LAW § 2445 (McKinney 2001); VA. CODE ANN. § 32.1-162.20 (Michie 2001); WASH. ADMIN. CODE § 388-04-010 (2002).

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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.

157. 793 P.2d 479 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

158. *Id.* at 485.

159. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

160. *Id.* at 862.

161. 45 C.F.R. §§ 46.406–407 (2001).

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.").

163. See Loretta M. Kopelman, *Pediatric Research Regulations Under Legal Scrutiny: Grimes Narrows Their Interpretation*, 30 J.L. MED. & ETHICS 38, 47–48 (2002) (arguing that the court was merely interpreting ambiguities in the federal regulations governing research); see also Robert M. Nelson, *Nontherapeutic Research, Minimal Risk, and the Kennedy Krieger Lead Abatement Study*, 23 INSTITUTIONAL REVIEW BOARD: ETHICS & HUMAN RESEARCH 6, 7–11 (2001) (explaining that the court merely affirmed the minimum risk standard in the federal regulations).

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.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.¹⁶⁵ The professional practice standard, adopted in over twenty-five states,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.¹⁶⁷ The “reasonable person” standard, growing in popularity and approaching a majority position,¹⁶⁸ bases the appropriate scope of disclosure on what a “reasonable person” would want to know, regardless of professional practice.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.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 *Stewart v. Cleveland Clinic Foundation*,¹⁷¹ expert testimony was used to determine whether the standard of care set by the federal regulations was met.¹⁷² The defendant argued that the informed consent for a clinical trial

164. 45 C.F.R. § 46.116(a); see *supra* notes 37–42 and accompanying text.

165. See 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).

166. See FURROW, *supra* note 70, at 318.

167. *Id.* at 318.

168. *Id.* at 318–19.

169. *Id.* at 319.

170. *Id.*

171. 736 N.E.2d 491 (Ohio Ct. App. 1999).

172. *Id.* at 501.

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complied with the Common Rule,¹⁷³ while the plaintiff provided a contradictory expert report.¹⁷⁴ 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.¹⁷⁵ 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.¹⁷⁶ 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.¹⁷⁷ 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.¹⁷⁸

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,¹⁷⁹ they do not impose specific requirements on researchers beyond obtaining the subjects' informed

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.

consent¹⁸⁰ and IRB approval.¹⁸¹ The federal regulations place the responsibility of weighing risks and approving research on IRBs, not on researchers.¹⁸² 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.¹⁸³ 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.¹⁸⁴ Indeed, the *Grimes* court accused the IRB of abdicating its responsibility by helping the researchers to “miscast the characteristics of the study”¹⁸⁵ and by “aid[ing] researchers in getting around federal regulations.”¹⁸⁶ 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 claims¹⁸⁷ 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,¹⁸⁸ and have ignored or rejected researcher malpractice actions based on expert testimony.¹⁸⁹

180. 45 C.F.R. § 46.116 (2001).

181. *Id.* § 46.111.

182. *See supra* notes 43–51 and accompanying text.

183. *See supra* notes 43–51 and accompanying text.

184. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001); *see supra* notes 1–8 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 & Leskovic, supra* note 62.

189. *See, e.g., Maxwell J. Mehlman, How Will We Regulate Genetic Enhancement?*, 34 WAKE FOREST L. REV. 671, 705–06 (1999). *But see* Edward Marshall, *Medical Malpractice in the New*

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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.¹⁹⁰

In the medical malpractice model, the standard of care is usually derived from expert testimony by members of the medical profession.¹⁹¹ The appropriate standard of care arises out of the complex interactions of professional leaders, journals, peer discussions and meetings.¹⁹² Thus, standards of care emerge gradually through the interplay of numerous comments from various professional sources once a practice becomes generally accepted.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.¹⁹⁴ To prove medical malpractice, the plaintiff must normally show that the defendant health care provider violated the standard of care through expert testimony.¹⁹⁵ Very few cases have allowed patients to recover when the defendant health care provider complied with the standard of practice.¹⁹⁶ Thus,

Eugenics: Relying on Innovative Tort Doctrine To Provide Relief When Gene Therapy Fails, 35 GA. L. REV. 1277, 1303–08 (2001) (arguing that the medical malpractice model should be used to establish the standard of care for gene therapy research, similar to how it has been used to establish standards of care for innovative medical treatments that lack customary standards of care).

190. See FURROW, *supra* note 70, at 269.

191. *Id.* at 270.

192. *Id.* at 271–76.

193. In determining the standard of care for medical specialists, most jurisdictions have moved from a locality rule to a national standard. See Jay M. Zitter, Annotation, *Standard of Care Owed to Patient By Medical Specialist as Determined by Local, “Like Community,” State, National, or Other Standards*, 18 A.L.R. 4th 603 §3 (1982) (listing cases that recognize that a specialist has the duty to possess and exercise that degree of skill and care ordinarily employed, under similar circumstances, by the members of his specialty in good standing, located in the same locality or community) and 18 A.L.R. 4th 603 § 6 (listing medical malpractice cases in which courts adopt standards of care based on national or nongeographic standards of similar specialists). The standard of care for general practitioners, interns, and residents is usually still based on the local or similar community standard. See, e.g., *Bahr v. Harper-Grace Hosps.*, 497 N.W.2d 526 (Mich. Ct. App. 1993).

194. See, e.g., *Osborn v. Irwin Mem’l Blood Bank*, 7 Cal. Rptr. 2d 101, 128 (Cal. Ct. App. 1992) (stating that “professional prudence is defined by actual or accepted practice within a profession, rather than theories about what ‘should’ have been done”).

195. *But see Helling v. Carey*, 83 Wash. 2d 514, 521–22, 519 P.2d 981, 985 (1974) (determining ophthalmologist negligent as a matter of law even though he complied with the standards of the profession) (later legislatively overruled by WASH. REV. CODE § 4.24.290 (1988)).

196. See JOHN W. WADE ET AL., PROSSER, WADE AND SCHWARTZ’S CASES AND MATERIALS ON TORTS 180 (9th ed. 1994).

conforming with customary practice is generally a conclusive defense for a health care professional.¹⁹⁷

Recently in *Heinrich v. Sweet*,¹⁹⁸ the Court of Appeals for the First Circuit adapted the medical malpractice framework to human subject research.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.²⁰⁰ The *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 1960–61.²⁰¹ Although the research predated the modern federal regulations, the *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.²⁰² In addition, the *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.²⁰³ Thus, the *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

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, *The Role of Custom in Medical Malpractice Cases*, 51 IND. L.J. 528, 536–37 (1976). But see Philip G. Peters, *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).

198. 308 F.3d 48 (1st Cir. 2002).

199. *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).

200. *Id.* at 70–71.

201. *Id.* at 65–67.

202. *Id.* at 69.

203. *Id.* at 70.

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

204. See *supra* notes 97–101 and accompanying text.

relationships.²⁰⁵ 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,”²⁰⁶ 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.”²⁰⁷ 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.²⁰⁸ Plaintiffs should argue first that negligence in human subject research may result in bodily injury,²⁰⁹ 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.²¹⁰ Third, the researcher-subject relationship is initiated by an informed consent quasi-contract,²¹¹ similar to the patient-physician relationship.²¹² 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.²¹³ There is often less accepted scientific evidence and experience to establish what is safe in human subject research than in

205. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 858 (Md. 2001).

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”).

210. *See Holder, supra* note 97, at 6–7; Delgado & Leskovic, *supra* note 62, at 107–12.

211. *See supra* notes 111–14 and accompanying text.

212. *See supra* notes 102–04 and accompanying text.

213. *See Delgado & Leskovic, supra* note 62, at 69.

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medical practice.²¹⁴ 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.²¹⁵ Whereas physicians are primarily attempting to help patients,²¹⁶ researchers and subjects may have conflicting interests.²¹⁷ Indeed, the federal requirements for written informed consent²¹⁸ 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.²¹⁹ 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,²²⁰ and violation of federal regulations has served as the basis for negligence actions in many areas of law.²²¹ 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.

218. 45 C.F.R. § 46.116 (2001) (requiring a written consent form for research).

219. Whitlock v. Duke Univ., 637 F. Supp. 1463, 1471 (D.N.C. 1986); *see supra* notes 87–90 and accompanying text.

220. *See* RESTATEMENT (SECOND) OF TORTS § 285 (1965).

221. *See supra* notes 124–26 and accompanying text.

which has resulted, and (4) against the particular hazard from which the harm results.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.²²³ In particular, the *Daum* court found that the federal regulations are “intended to protect the rights and safety of subjects”²²⁴ and that human subjects are “within the class of persons for whose protection the [federal regulations] were enacted.”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.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.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.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.²²⁹ In *Vodopest v. MacGregor*,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,²³¹ because the

222. RESTATEMENT (SECOND) OF TORTS § 286 (1965).

223. *Daum v. SpineCare Med. Group*, 61 Cal. Rptr. 2d 260, 276 (Cal. Ct. App. 1997).

224. *Id.* at 273.

225. *Id.*

226. *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1471 (D.N.C. 1986); *see also supra* notes 87–90 and accompanying text.

227. *Daum*, 61 Cal. Rptr. 2d at 273; *see supra* notes 132–35 and accompanying text.

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).

229. *See, e.g.*, *Chambers v. Osteonics Corp.*, 917 F. Supp. 624, 626 (S.D. Ind. 1996); *Kus v. Sherman Hosp.*, 644 N.E.2d 1214, 1221 (Ill. App. Ct. 1995); *Evraets v. Intermedics Intraocular, Inc.*, 34 Cal. Rptr. 2d 852 (Cal. App. 1994); *Mitchell v. Iolab Corp.*, 700 F. Supp. 877, 878–79 (E.D. La. 1988).

230. 128 Wash. 2d 840, 913 P.2d 779 (1996).

231. *Id.* at 857–62, 913 P.2d at 787–89.

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Common Rule prohibits such exculpatory agreements.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.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.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.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.²³⁶ For instance, in *Stewart v. Cleveland Clinic Foundation*,²³⁷ the defendant clinic argued that the informed consent form for a clinical trial complied with the Common Rule,²³⁸ while the plaintiff provided contradictory expert testimony.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.²⁴⁰ Similarly, the *Daum* court limited the use of expert

232. See *supra* note 40 and accompanying text.

233. 45 C.F.R. § 46.116(a); see *supra* notes 38–40 and accompanying text.

234. See King, *supra* note 65, at 29.

235. See FURROW, *supra* note 70, at 318.

236. *Id.* at 319.

237. 736 N.E.2d 491 (Ohio Ct. App. 1999).

238. *Id.* at 495.

239. *Id.* at 497.

240. *Id.* at 501.

testimony to determine whether the standard of care provided by the federal regulations was met.²⁴¹

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,²⁴² 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.²⁴³ 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.²⁴⁴ 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.²⁴⁵ 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 review²⁴⁶ and approval²⁴⁷ 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"²⁴⁸ and "reasonable in relation

241. *Daum v. SpineCare Med. Group*, 61 Cal. Rptr 2d 260, 279 (Cal. Ct. App. 1997).

242. *See supra* notes 149–52 and accompanying text.

243. *See, e.g., supra* notes 171–75 and accompanying text.

244. 45 C.F.R. § 46.116(e) (2001).

245. *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 485 (Cal. 1990), *cert. denied*, 499 U.S. 936 (1991).

246. 45 C.F.R. § 46.109 (2001).

247. *Id.* § 46.111.

248. *Id.* § 46.111(a)(1).

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to anticipated benefits, if any, to subjects and the importance of the knowledge that may reasonably be expected to result.”²⁴⁹ The IRB also must make technical decisions about the scientific merit of research protocols before approving the research.²⁵⁰ 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.²⁵¹ Early cases treated research that deviated from medical standards of care as negligent, without developing a specialized standard of care for research.²⁵² 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.²⁵³

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.²⁵⁴ Although the *Heinrich* court observed that “the bar to be surmounted in litigation over current charges of [researcher] malpractice is a demanding one,”²⁵⁵ the circuit court found that approval by committees similar to IRBs was a partial defense.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.²⁵⁷ Second, the federal regulations explicitly allow higher standards of care set by federal, state, or local laws.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.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 *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.²⁶⁰ Finally, even if the researcher obtained proper IRB approval before conducting the research, it is possible that the research was negligently performed,²⁶¹ or that the researcher deviated from the IRB-approved protocol. Juries should therefore consider IRB approval as evidence that the standard of

254. See *supra* notes 43–51 and accompanying text.

255. *Heinrich v. Sweet*, 308 F.3d 48, 71 (1st Cir. 2002).

256. See *supra* note 202 and accompanying text.

257. RESTATEMENT (SECOND) OF TORTS § 288C (1965).

258. 45 C.F.R. § 46.101(f) (2001).

259. *Id.* § 46.109(e); see note 49 and accompanying text.

260. See *supra* notes 185–86 and accompanying text.

261. See John Robertson, *The Law of Institutional Review Boards*, 26 UCLA L. REV. 484, 531 (1978).

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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.

