

REVIEWING THE REVIEW BOARDS: WHY INSTITUTIONAL REVIEW BOARD LIABILITY DOES NOT MAKE GOOD BUSINESS SENSE

I. INTRODUCTION

In modern decades, the use of humans as participants in medical research studies has increased. An estimated “20 million Americans [are] tak[ing] part in more than 41,000 clinical trials.”¹ With the recent rise in human research, there has been a concomitant increase in the prevalence and utility of committees overseeing human research activities.² One type of oversight committee is the Institutional Review Board (IRB).³ Federal regulations established IRBs as bodies associated with a given research institution that review and approve research activities conducted by that institution.⁴ IRBs are charged with protecting the rights of research subjects and ensuring that certain health and safety requirements are met, both before the research commences and during the research period.⁵ In 1998, there were an estimated three to five thousand IRBs in the United States.⁶ The National Institutes of Health’s (NIH) Bell Report found that the annual workload of 491 IRBs included an estimated 284,000 reviews.⁷

In addition to the increase in human-subject research, there has also been an increase in injured research subjects filing suit against the researchers conducting the studies and the affiliated research institutions.⁸ Given the rise in research protocols and the associated need for IRB review, it is only a matter of time before injured research subjects

1. Tom Abate, *Experiments on Humans: Business of Clinical Trials Soars, But Risks Unknown*, S.F. CHRON., Aug. 4, 2002, at A1.

2. See generally Micheale C. Christian et al., *A Central Institutional Review Board for Multi-Institutional Trials*, 346 NEW ENG. J. MED. 1405, 1405 (2002) (discussing the increased workload of IRBs and the attendant problems with inadequate review of research protocols).

3. See generally Protection of Human Subjects, 45 C.F.R. § 46 (2003); Protection of Human Subjects, 21 C.F.R. §§ 50, 56 (2004) (providing a framework for the establishment, function, and duties of IRBs).

4. 45 C.F.R. § 46; 21 C.F.R. §§ 50, 56.

5. See generally 45 C.F.R. §§ 46.108–.109.

6. OFF. OF THE INSPECTOR GEN., INSTITUTIONAL REVIEW BOARDS: A TIME FOR REFORM, U.S. Dep’t of Health and Human Servs., Pub. No. OEI-01-97-00193, at 3 (U.S. Gov’t Printing Off., 1998).

7. Christian et al., *supra* note 2, at 1405 n.2 (citation omitted). Of the 284,000 reviews, 105,000 were initial reviews, 116,000 were annual reviews, and 63,000 were amendments to the original approved proposals. *Id.* The study also found that annual full-board meeting time ranged from nine to fifty hours and that the average time devoted to discussion of the initial review of a protocol was twenty-one minutes for low-volume IRBs and three minutes for high-volume IRBs. *Id.*

8. See *infra* Parts II.D and E.

regularly target IRBs—both as board members and individuals—as defendants in liability suits.⁹ As the gatekeepers of human research studies, the question arises about what duty, if any, IRBs owe to human subjects who have been injured in a research study which the IRB approved.¹⁰

This Note explores IRB liability and the question of the potential duty IRBs owe to injured research subjects. In Part II, this Note details government regulation of human-subject research and provides examples of historical and current research trials and negligence actions involving human subjects.¹¹ Part III discusses the potential for IRB liability.¹² Part IV considers how corporate law principles of liability apply to IRBs and suggests ideas to improve IRB operation and function.¹³

II. HISTORY OF FEDERAL REGULATIONS REGARDING HUMAN-SUBJECT RESEARCH AND CASES INVOLVING INJURED RESEARCH SUBJECTS

A. *History of Human-Subject Research*

The first heavily publicized use of human-subject research occurred during World War II when the Nazis conducted medical experiments on German concentration-camp prisoners.¹⁴ In some concentration camps, doctors infected healthy prisoners with yellow fever, smallpox, typhus, cholera, and diphtheria to study those diseases.¹⁵ Hundreds of prisoners died unnecessarily as a result of those Nazi studies.¹⁶

Despite its strong condemnation of Nazi human experimentation, the United States has not been immune to human research abuses. In 1963, researchers at the Jewish Chronic Disease Center Hospital in Brooklyn injected live cancer cells into elderly nursing home patients, most of

9. Mary R. Anderlik & Nanette Elster, *Lawsuits Against IRBs: Accountability or Incongruity?*, 29 J.L. MED. & ETHICS 220, 224 (2001). “IRB members—both individually and as a board—may be exposed to legal liability for any failures, deliberate or otherwise, associated with the human subjects research they are charged with approving and monitoring.” *Id.*

10. *Id.*

11. *See infra* Part II.

12. *See infra* Part III.

13. *See infra* Part IV.

14. *See generally* Jay Katz, *Human Sacrifice and Human Experimentation: Reflections at Nuremberg*, 22 YALE J. INT’L L. 401 (1997).

15. ALLEN M. HORNBLUM, *ACRES OF SKIN: HUMAN EXPERIMENTS AT HOLMSBURG PRISON* 75 (1998).

16. *Id.*

whom were senile.¹⁷ The nursing home residents were not told the reason for the injections, nor were they aware of their participation in any study.¹⁸

Similarly, another study in New York employed unsuspecting subjects.¹⁹ Researchers at Willowbrook, a facility for mentally disabled children and adults, intentionally infected patients with hepatitis so the researchers could study a vaccine for the disease.²⁰ Parents of the children involved were coerced into allowing their children to be injected with hepatitis because the parents believed their children would inevitably become infected by joining the facility's general patient population.²¹

Perhaps the most egregious abuse committed in the name of research was the notorious Tuskegee Syphilis Study, where researchers studied the effects of untreated syphilis in a group of African-American men, without their knowledge, for over twenty years.²² Although medical advances created a successful treatment for syphilis, it was not offered to the subjects.²³

17. Harold Y. Vanderpool, *Introduction and Overview: Ethics, Historical Case Studies, and the Research Enterprise*, in *THE ETHICS OF RESEARCH INVOLVING HUMAN SUBJECTS: FACING THE 21ST CENTURY* 1, 9 (Harold Y. Vanderpool ed., 1996).

Patients in the Jewish Chronic Disease Center Hospital study were not told about the experiments. *Hyman v. Jewish Chronic Disease Hosp.*, 206 N.E.2d 338 (N.Y. 1965). The study only came to the public forefront because a board member of the institution wanted to ascertain whether the patients involved had been injured, and sued to gain access to the patients' medical records. *Id.*

Despite the fact that the researcher's medical license was suspended and he was put on probation by the Board of Medical Examiners, the researcher was elected President of the American Association of Cancer Research only five years later. B.A. Preminger, *The Case of Chester M. Southam: Research Ethics and the Limits of Professional Responsibility*, 65(2) *THE PHAROS OF ALPHA OMEGA ALPHA* 4 (Spring 2002); see also MATTHEW BENDER & CO., INC., *TREATISE ON HEALTH CARE LAW*, § 23.01 (2003).

18. BENDER, *supra* note 17, at § 23.01.

19. *Id.*

20. *Id.* In the 1950s and 1960s, hepatitis was endemic among the Willowbrook patients. *Id.* Researchers vaccinated children and then infected them with hepatitis upon admission to the facility to determine if the vaccine was effective. *Id.* Although the parents of the children consented, they had been told by the researchers that the children would get the disease anyway when they joined the general hospital population. *Id.* The vaccine proved to be effective, yet there was no guarantee of this result at the time the children were vaccinated. *Id.*

21. *Id.*

22. William J. Curran, *The Tuskegee Syphilis Study*, 289 *NEW ENG. J. MED.* 730 (1973). In 1932, there was no effective treatment for syphilis. BENDER, *supra* note 17, at § 23.01. Physicians affiliated with the United States Public Health Service studied 400 African-American males in Alabama who had syphilis. *Id.* The subjects, who believed that they were receiving adequate care, were not told that they were research subjects. *Id.* When penicillin was recognized as an effective treatment for syphilis, it was not offered to the men. *Id.* Rather, the researchers continued with the study to observe the natural progression of the disease and, consequently, the men were not given available treatments and suffered unnecessarily. *Id.*

23. *Id.*

B. Government Regulation of Human-Subject Research

Realizing that research abuses would continue, national and international governments intervened to enact a set of rules to regulate research involving human subjects.²⁴ In 1945, in response to the Nazi concentration-camp experiments, judges of the international military tribunal conducted the Nazi Doctors' Trial at Nuremberg²⁵ and issued a verdict.²⁶ Known as the Nuremberg Code,²⁷ the verdict established ten principles for the conduct of research involving human subjects.²⁸ In addition, doctors and scientists of the World Medical Assembly adopted the Declaration of Helsinki.²⁹ The Declaration set international guidelines for biomedical research conducted by physicians.³⁰

The United States followed international example, beginning with the NIH establishing internal policies regarding research with human subjects, which were the first of their kind in the nation.³¹ These policies were later codified as federal regulations issued by the Department of Health,

24. See *infra* Parts II.B and C.

25. *War Crimes Tribunals, An In Depth Analysis From: Issues and Controversies on File*, at <http://www.facts.com/icof/nurem.htm> (last visited Feb. 8, 2004). Following World War II, the victorious allies (the United States, France, Great Britain, and the Soviet Union) established an international military tribunal at Nuremberg, Germany and commenced international war-crimes trials. *Id.* Prosecutors from these countries investigated the Nazi Germans' involvement in "crimes against humanity" and consequently entered a verdict against these individuals. *Id.* The verdict later became known as the Nuremberg Code.

26. *Id.*

27. Ezekiel J. Emanuel et al., *Scandals and Tragedies of Research with Humans*, in *ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH* 1, 2 (2003).

28. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS 181–82 (U.S. Gov't Printing Off., 1949).

The Nuremberg Code sets forth many of the basic principles governing ethical research conduct for experiments involving humans. *Id.* The first provision explicates that "[t]he voluntary consent of the human subject is absolutely essential." *Id.* at 181. Other provisions deal with several major tenants—human consent issues (the capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved) and minimization of risk and harm, favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the subject to resign at any time. *Id.* at 182; see also Office for Protection from Research Risks, *Institutional Review Board Guidebook*, at <http://www.hhs.gov/ohrp.irb> (last modified June 21, 2004) [hereinafter IRB Guidebook].

29. World Medical Assembly, *Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects* (1964), available at <http://www.cirp.org/library/ethics/helsinki/> (last visited Oct. 28, 2004). The Declaration of Helsinki was first adopted by the 18th World Medical Assembly (WMA) in Helsinki, Finland, in 1964. IRB Guidebook, *supra* note 28, at Intro., Part A. The Declaration was subsequently revised by the 29th WMA in Tokyo, Japan, in 1975 and again in 1989, by the 41st WMA in Hong Kong. *Id.*

30. See Lori A. Alvino, Note, *Who's Watching the Watchdogs? Responding to the Erosion of Research Ethics by Enforcing Promises*, 103 COLUM. L. REV. 893, 896 (2003).

31. IRB Guidebook, *supra* note 28, at Intro., Part A.

Education, and Welfare (now the Department of Health and Human Services (DHHS))³² in July of 1974.³³ In that same year, Congress enacted the National Research Act of 1974.³⁴ The Act created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (National Commission).³⁵ The purposes of the National Commission were to study the problems attendant to human-subject research and propose guidelines for the protection of human subjects.³⁶ To oversee human-subject protection, the National Commission also established the Office for the Protection of Research Risks (OPRR) (now the Office for Human Research Protections (OHRP)) within the NIH.³⁷

In 1978, the National Commission published the Belmont Report.³⁸ The critical contribution of the Belmont Report was the establishment of three ethical principles: (1) respect for persons,³⁹ (2) beneficence,⁴⁰ and (3) justice.⁴¹ Today, these three principles serve as a foundation for the federal

32. The Department of Health, Education and Welfare was created under President Eisenhower on April 11, 1953. U.S. Dep't of Health and Human Servs., *Historical Highlights*, at <http://www.os.dhhs.gov/about/hhshist.html> (last visited Sept. 30, 2004). In 1979, the Department of Education Organization Act separated the Department of Health, Education and Welfare into two different departments: the Department of Education and the Department of Health and Human Services. *Id.* For the purposes of this Note, the term Department of Health and Human Services (DHHS) will be used to refer to the previously-existing Department of Health, Education and Welfare and the current Department of Health and Human Services. For a general history, see the Department of Health and Human Services webpage, at <http://www.os.dhhs.gov/about/hhshist.html> (last visited Sept. 30, 2004).

33. *Id.*; see Protection of Human Subjects, 39 Fed. Reg. 18,914 (May 30, 1974) (codified as amended at 45 C.F.R. § 46 (2003)).

34. National Research Act of 1974, Pub. L. No. 93-348, § 201, 88 Stat. 342 (1974).

35. *Id.*

36. *Id.* § 202(a). The National Commission met from 1974 to 1978. IRB Guidebook, *supra* note 28, at Intro., Part A. It issued reports and recommendations regarding basic ethical principles for conducting biomedical and behavioral research involving human subjects to ensure that research was conducted accordingly. *Id.*

37. In June 2000, the protection of human research subjects was transferred from the Office for the Protection of Research Risks (OPRR) to the Office for Human Research Protections (OHRP), which is housed under the Office of the Secretary of Health and Human Services. See 65 Fed. Reg. 37,136-03 (June 13, 2000).

38. U.S. Dep't of Health, Educ., & Welfare, *Nat'l Comm'n 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*, available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm> (last visited Oct. 28, 2004). The Report was named after the Belmont Conference Center at the Smithsonian Institution where the discussions regarding the contents of the report were held. IRB Guidebook, *supra* note 28, at Intro., Part B.

39. "Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy." IRB Guidebook, *supra* note 28, at Intro., Part B.

40. "Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm." *Id.*

41. "Justice requires that the benefits and burdens of research be distributed fairly." *Id.*

regulations governing human-subject research.⁴² Each principle has been enlivened into federally codified human research safeguards: respect for persons translated into informed consent; beneficence is viewed as risk-benefit assessment; and justice is explained as fair selection of research subjects.⁴³

Seeing the need for explicit federal guidance, in 1981 the DHHS revised the regulations for protecting human subjects and codified them at Title 45, Part 46 of the Code of Federal Regulations.⁴⁴ In 1991, wanting even more concrete federal safeguards, the DHHS adopted the Federal Policy for the Protection of Human Subjects as part of the revisions.⁴⁵ These collective regulations became known as the “Common Rule”⁴⁶ and have been promulgated by the seventeen federal agencies that conduct, support, or regulate human-subject research.⁴⁷

The Common Rule is a set of federal regulations that incorporates the ethical principles and guidelines of the Belmont Report and standardizes human-subject protections among the different federal agencies and departments.⁴⁸ Additional protections for vulnerable populations—pregnant women, handicapped or mentally disabled persons, prisoners, and children—have also been adopted by the DHHS.⁴⁹ The responsibility

42. *Id.*

43. *Id.* In keeping with its congressional mandate, the National Commission also distinguishes between “practice” and “research.” *Id.* The Belmont Report is thus divided into two parts: (1) the distinction between practice and research and (2) ethical principles. *Id.* Practice involves enhancing the well-being of an individual through interventions that have a reasonable chance of success. *Id.* Medical or behavioral practice encompasses diagnosis, preventive treatment or therapy. *Id.* Research includes actions designed to test a hypothesis, make conclusions, and contribute to the generalizable knowledge. *Id.* Research is usually described in a protocol, detailing the objective and procedures employed. *Id.* “[E]xperimental procedures do not necessarily constitute research.” *Id.* It is also possible for practice and research to occur concurrently. *Id.*

44. 45 C.F.R. § 46.

45. IRB Guidebook, *supra* note 28, at Intro., Part A.

46. Ezekiel J. Emanuel et al., *Ethical and Regulatory Guidance for Research with Humans*, in ETHICAL AND REGULATORY ASPECTS OF CLINICAL RESEARCH, *supra* note 27, at 25, 27.

47. IRB Guidebook, *supra* note 28, at Chap. 2, Part A. These federal agencies and departments are: (1) Department of Agriculture, (2) Department of Energy, (3) National Aeronautics and Space Administration, (4) Department of Commerce, (5) Consumer Product Safety Commission, (6) International Development Cooperation Agency, (7) Agency for International Development, (8) Department of Housing and Urban Development, (9) Department of Justice, (10) Department of Defense, (11) Department of Education, (12) Department of Veterans Affairs, (13) Environmental Protection Agency, (14) Department of Health and Human Services, (15) National Science Foundation, (16) Department of Transportation, and (17) Central Intelligence Agency. *Id.*

48. 45 C.F.R. §§ 46.101–124.

49. See 45 C.F.R. § 46, Subpart B (establishing guidelines for research related to fetuses, pregnant women, and in vitro fertilization); Subpart C (establishing guidelines for research involving prisoners); Subpart D (establishing protections for children as research subjects).

of enforcing institutional compliance with the Common Rule has been delegated to the OHRP.⁵⁰

C. *The Common Rule*

There are three essential requirements of the Common Rule: (1) assurances, (2) institutional review boards, and (3) informed consent.⁵¹ First, any institution that conducts federally funded human research must submit a written assurance to the sponsoring agency that its researchers will comply with all of the requirements of the Common Rule.⁵²

Second, the Common Rule mandates that all research institutions that receive federal funds for human research establish one or more IRBs.⁵³ IRBs are composed of at least five members with varying backgrounds.⁵⁴ An IRB reviews the proposed research protocols and informed consent forms in light of institutional commitments and regulations, applicable law, and standards of professional conduct and practice.⁵⁵ As such, an IRB needs members with expertise in these different areas; an IRB cannot consist entirely of members of one profession,⁵⁶ and at least one member must not be affiliated with the institution in any way.⁵⁷

In reviewing research, an IRB is allowed to approve, require modifications of, or disapprove research protocols,⁵⁸ and must notify the

50. IRB Guidebook, *supra* note 28, at Chap. 2, Part A.

51. *See generally* 21 C.F.R. §§ 50, 56; 45 C.F.R. § 46.

52. 45 C.F.R. § 46.103(b)(1) (requiring “[a] statement of principles governing the institution in the discharge of its responsibilities for protecting the rights and welfare of human subjects of research conducted at or sponsored by the institution, regardless of whether the research is subject to federal regulation.”).

Until December 2001, the OHRP approved three types of assurances: Single Project Assurances (SPAs), applying to a single research activity at a single location; Multiple Project Assurances (MPAs), pertaining to multiple, often unrelated, research activities at a single location; and Cooperative Project Assurances (CPAs), encompassing multiple research activities at multiple locations. Alvino, *supra* note 30, at 899–900. After December 2001, a new type of assurance became available—the Federal Wide Assurance (FWA). *Id.* A valid FWA is kept on file with the OHRP and can be used to receive funds from any department or agency that subscribes to the Common Rule without filing any additional assurances. *Id.* FWAs streamline the process for researchers seeking approval; as such, SPAs, MPAs and CPAs will be replaced with FWAs as they expire. *Id.*

53. 45 C.F.R. §§ 46.103(b)(2), 46.107.

54. 45 C.F.R. § 46.107(a) (“The IRB shall be sufficiently qualified through . . . the diversity of its members, including consideration of race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”).

55. *Id.*

56. *Id.* § 46.107(b).

57. *Id.* § 46.107(d). In addition, an IRB member who has a conflicting interest is not allowed to participate in the IRB’s initial or continuing review of that research. *Id.* § 46.107(e).

58. 45 C.F.R. § 46.109(a).

investigators and the institution in writing of its decision regarding the proposed research activity.⁵⁹ If the IRB disapproves a research protocol, it must give a statement of the reasons for its decision and allow the investigator an opportunity to respond in person or in writing.⁶⁰ An IRB must also conduct continuing review of ongoing research at intervals appropriate to the degree of risk, but not less than once per year.⁶¹

Before approving research, the IRB must ensure that the following criteria are satisfied: (1) the risks to subjects are minimized; (2) the risks to subjects are reasonable relative to the anticipated benefits; (3) subject selection is equitable; (4) informed consent is sought from each prospective subject or a legal guardian thereof; (5) informed consent will be appropriately documented; (6) provisions exist for monitoring data to ensure subject safety; and (7) provisions exist to protect the privacy and confidentiality of subjects.⁶² In addition, an IRB or the affiliated institution should maintain documentation of the IRB's activities, including all research proposals reviewed, minutes of IRB meetings, records of continuing review, and correspondences between the IRB and investigators.⁶³

Last, the Common Rule requires informed consent, whereby an investigator must obtain legally effective informed consent before involving a human being as a research subject.⁶⁴ For consent to be considered valid, the prospective subject or her legal representative must have sufficient opportunity to consider whether to participate, and the consent information must be stated in language understandable to the subject or the representative.⁶⁵ Informed consent forms cannot include language that waives or appears to waive 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.⁶⁶ Each subject must also be provided with a description of the research; an explanation of risks, benefits, and alternatives; a discussion of confidentiality; a list of contact people; and a statement that participation is voluntary and may be discontinued at any time.⁶⁷

59. *Id.* § 46.109(d).

60. *Id.*

61. *Id.* § 46.109(e).

62. 45 C.F.R. § 46.111(a)(1)-(7).

63. 45 C.F.R. § 46.115.

64. 45 C.F.R. § 46.116.

65. *Id.*

66. *Id.*

67. 21 C.F.R. § 50.25(a), (b); 45 C.F.R. § 46.116(a), (b). The Food and Drug Administration

D. Negligence Actions by Injured Research Subjects

The Common Rule does not provide an express cause of action for researcher negligence.⁶⁸ To prove negligence, an injured subject must prove that there was a special relationship between the researcher and the subject that imposed a duty upon the researcher.⁶⁹ Looking to the medical context, there are two alternate negligence actions under which health care providers can be liable: informed consent⁷⁰ and medical malpractice.⁷¹ Researcher liability can be based on these same two causes of action.⁷²

(FDA) declined to adopt the Common Rule, but rather issued its own set of regulations for research involving human subjects. *See* 21 C.F.R. §§ 50, 56 (2004). These regulations established oversight for research involving experimental drugs, biological products and medical devices subject to FDA approval. *Id.* In contrast to the Common Rule, the FDA directives deal with only two main areas of regulation: informed consent and IRBs. *See* 21 C.F.R. § 50 (setting forth the requirements for informed consent, including special provisions for prisoners); 21 C.F.R. § 56 (establishing provisions for IRBs). For additional FDA regulations relevant to IRBs, *see* 21 C.F.R. § 312 (Investigational New Drug Application), 21 C.F.R. § 812 (Investigational Device Exemptions), and 21 C.F.R. § 860 (Medical Device Classification Procedures).

68. The Common Rule only provides that violating federal regulations may result in a loss of federal funding and, consequently, suspension or termination of research. 45 C.F.R. §§ 46.113–.123; *see also* 21 C.F.R. § 50.113 (regulating suspension or termination of IRB approval under the FDA).

69. *See* RESTATEMENT (SECOND) OF TORTS § 314a (1965) (describing four commonly recognized special relationships where an actor owes a duty to another: (1) common carrier-passenger; (2) innkeeper-guest; (3) landowner-invitee; and (4) certain custodial relationships); *see also* Roger L. Jansson, *Researcher Liability for Negligence in Human Subject Research: Informed Consent and Researcher Malpractice Actions*, 78 WASH. L. REV. 229, 236–38 (2003).

To prevail in a negligence action against a researcher, the injured subject must establish: (1) a duty is owed by the defendant; (2) the duty was breached; (3) the breach caused injury to the subject; and (4) a cognizable injury. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 30, at 164–65 (5th ed. 1984).

70. In the health care setting, obtaining a patient's informed consent before providing medical treatment is a general duty owed by physicians to patients. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 29 (1986). To establish negligence in medical informed consent actions, a plaintiff must prove that: (1) 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. *Id.* Lack of informed consent is usually treated as professional negligence, and arises from a physician's duty to provide patients with the necessary information before they consent to treatment. *Id.*

71. *Id.* Malpractice, or professional negligence, is a special kind of negligence whereby professional standards of care are applied to persons possessing or claiming to possess special knowledge or skill. *Id.* Medical malpractice occurs when a physician fails to exercise the required degree of care, skill, or diligence that is ordinarily possessed by a reasonable and prudent physician in the same medical specialty, acting under the same or comparable circumstances. *Id.* *See* 1 BARRY R. FURROW ET AL., HEALTH LAW § 6-2, at 269 (2d ed. 2000); *see, e.g.,* Thomas v. Wilfac, Inc., 828 P.2d 597, 601 (Wash. App. 1992). It is important to note that a physician's exoneration from liability for medical malpractice does not forestall a plaintiff's claim of failure to obtain informed consent, and vice versa. Backlund v. Univ. of Wash., 975 P.2d 950, 951–52 (Wash. 1999).

72. Thus, there are two distinct types of researcher negligence: informed consent and researcher

Injured research subjects usually sue under an ordinary negligence theory.⁷³ Most human-subject research claims allege that the plaintiff was not informed that she was participating in a research study and/or that the particular risk that occurred had not been explained to her.⁷⁴ Alternatively, there have been cases of “malresearch” (similar to medical malpractice) in which the allegation is physical injury due to negligent medical intervention during participation in a study.⁷⁵

Recently, courts have attempted to develop a specific analysis for causes of action in human-subject research. In *Whitlock v. Duke University*,⁷⁶ a North Carolina federal district court focused on the duty and standard of care for negligence actions based on informed consent under the Common Rule.⁷⁷ The court held that under the Common Rule, there is a heightened duty for disclosure of foreseeable risks that differs from that in the medical malpractice context.⁷⁸ The court concluded that

malpractice. Courts might choose to strictly follow or modify the standards used in the health care setting—for both informed consent and medical malpractice—when faced with an injured subject in the research context. *See supra* notes 70–71.

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

74. BENDER, *supra* note 17, at § 23.08. Usually with these types of allegations, the subject is also the investigator’s patient and the investigator did not make clear to the patient that the treatment was also research. *See, e.g.*, *Karp v. Cooley*, 493 F.2d 408 (5th Cir. 1974); *Sexton v. United States*, 644 F. Supp. 755 (D.D.C. 1986); *Schwartz v. Boston Hosp. for Women*, 422 F. Supp. 53 (S.D.N.Y. 1976); *Gaston v. Hunter*, 588 P.2d 326 (Ariz. Ct. App. 1978); *Burton v. Brooklyn Doctors Hosp.*, 452 N.Y.S.2d 875 (N.Y. App. Div. 1982); *Estrada v. Jaques*, 321 S.E.2d 240 (N.C. Ct. App. 1984).

75. *See, e.g.*, *Mink v. Univ. of Chicago*, 460 F. Supp. 713 (N.D. Ill. 1978); *Blanton v. United States*, 428 F. Supp. 360 (D.D.C. 1977); *Neuberg v. Michael Reese Hosp. & Med. Ctr.*, 377 N.E.2d 215 (Ill. App. Ct. 1978); *Brook v. St. John’s Hickey Mem’l Hosp.*, 368 N.E.2d 264 (Ind. Ct. App. 1977); *Field v. Mass. Gen. Hosp.*, 469 N.E.2d 819 (Mass. 1984); *Fiorentino v. Wenger*, 272 N.Y.S.2d 557 (N.Y. App. Div. 1966); *Salathiel v. New York*, 411 N.Y.S.2d 175 (Ct. Cl. 1978); *Barrett v. New York*, 378 N.Y.S.2d 946 (Ct. Cl. 1976).

76. 637 F. Supp. 1463 (M.D.N.C. 1986). The plaintiffs filed suit in the Middle District of North Carolina, naming the researcher and the University as defendants. *See id.* at 1463, 1465. The plaintiff sought to recover for injuries sustained by participating in the experiment. *Id.* at 1463. The study, conducted at Duke University, was a deep sea diving experiment designed to research high pressure nervous syndrome. *See id.* at 1465.

77. *Id.* at 1471–72, 1475.

78. *Id.* at 1471. The court considered whether to apply the North Carolina statute (N.C. GEN. STAT. § 90-21.13(a)) or the federal regulations (45 C.F.R. § 46.116(a)(2)) to the injured-subject claim. *Id.* The court, drawing from support in the Nuremberg Code and the Declaration of Helsinki, concluded that the appropriate standard would be the higher standard found in the federal regulations:

Two important differences to note between the Nuremberg Code and § 90-21.13 are that the subjective consent of the subject is always required under the Nuremberg Code whereas under § 90-21.13 a health care provider may escape liability if a reasonable person would have consented if the proper disclosure of information had been made; and more importantly for purposes of this case the Nuremberg Code requires the researcher to make known to the subject *all* hazards reasonably to be expected and the possible effects upon the health and person of the subject whereas § 90-21.13 only requires the health care provider to apprise the patient of the “usual and most frequent risks and hazards” of the procedure. . . . [T]he Court

the Common Rule was the appropriate standard of care for informed consent claims by human research subjects.⁷⁹

In *Grimes v. Kennedy Krieger Institute, Inc.*,⁸⁰ Maryland's highest court identified several potential sources of the duty researchers owe to human subjects.⁸¹ Those sources include the special relationship between the research investigator and the subject, the informed consent quasi-contract, the implied duties from the federal regulations, and duties from international codes.⁸² The *Grimes* court concluded that researchers may owe human subjects a duty of care, yet it did not explicate sufficiently which one of these sources gives rise to the duty.⁸³ *Grimes* was, however, the first case to hold that the researcher-subject relationship itself constitutes a "special relationship" comparable to the physician-patient relationship.⁸⁴

E. Recent Abuses in Human-Subject Research

While the case law regarding researcher negligence actions and the attendant duty of care is undeveloped and courts are struggling to deal with these issues, injury and even death of research subjects continues. For example, in September 1999 Jesse Gelsinger, a participant in a research study at the University of Pennsylvania's Institute for Gene Therapy, died from multiple organ-system failure, which was a result of the research treatment he received.⁸⁵ Following Gelsinger's death, his family filed a civil suit alleging negligence in performing the research treatment and lack of informed consent concerning a conflict of interest.⁸⁶ The conflict of

concludes the degree of required disclosure of risks is higher in the nontherapeutic context [i.e. research context] than required under § 90-21.13 [i.e. health care context].

Id.

79. *Id.* The court did not, however, reach the question of whether a duty of care is implied by the Common Rule because it found that the Common Rule's standard of care had not been breached by the researcher. *Id.* at 1475.

80. 782 A.2d at 858.

81. *Id.*; see also *infra* notes 104–09 and accompanying text.

82. 782 A.2d at 858.

83. *Id.*

84. *Id.* The 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." *Id.* at 834–35.

85. Anderlik & Elster, *supra* note 9, at 220. Gelsinger was involved in clinical research testing a new approach to treatment of ornithine transcarbamylase deficiency (OTC), a rare metabolic disorder. *Id.* He suffered a relatively mild form of OTC. *Id.* As part of the research, Gelsinger received injections of a virus which was to carry new genetic material into his system to treat the OTC. *See id.* The injected virus was the cause of Gelsinger's multiple organ-system failure, which ultimately led to his death. *Id.*

86. *Gelsinger v. Trs. of the Univ. of Penn.* (Phila. Cty. Ct. of C.P. filed Sept. 18, 2000), at

interest, whereby the researchers stood to financially gain from the successful use of a patent associated with the research, was not disclosed to the subjects.⁸⁷ In addition, the complaint alleged that the informed consent process did not fully disclose the risks; Gelsinger believed that the risks were minimal and the potential benefits were great.⁸⁸ In reality, the risks were significant and the possible benefits to the subject were not as pronounced as the financial benefit for the researchers.⁸⁹ The researchers also allegedly altered the IRB-approved FDA consent form by deleting information about the deaths and illnesses of monkeys in prior animal studies.⁹⁰

In July 2000, the University of Oklahoma Health Sciences Center in Tulsa was shut down because of inadequate protections for human research subjects during a cancer research study testing a melanoma vaccine.⁹¹ Injured subjects in the melanoma study filed suit in federal district court,⁹² naming the primary investigator and all members of the

<http://www.sskrplaw.com/links/healthcare2.html> (last visited Jan. 17, 2005). The Gelsingers named the trustees of the University, the primary investigator, the company sponsor, and the former medical school dean as defendants. *Id.* The complaint alleged that the virus used to carry the genetic material into Gelsinger's system was a more dangerous way than other possible means of transporting the genetic material. *Id.* Interestingly, the researchers patented the virus used in the research, suggesting a possible conflict of interest between the research subjects' well-being and the researchers' financial gain from use of the patent. *Id.*

87. Anderlik & Elster, *supra* note 9, at 220. The complaint alleged the following causes of action: wrongful death, assault and battery linked to a lack of informed consent, and common law fraud and misrepresentation associated with deficiencies in the informed-consent process. *Id.* The IRB that reviewed and approved the protocol was not, however, named as a defendant. *Id.* The parties reached a settlement on November 3, 2000. *Id.* at 221.

88. *Id.* at 220.

89. *Id.*

90. *Id.*

91. *Id.* at 221. The IRB at the Center approved the melanoma research protocol. *Id.* Many of the patients who enrolled in the study had advanced melanoma, a virulent form of skin cancer, and had been unresponsive to standard therapies. *Id.* The patients had been given life prognoses ranging from two to six months. *Id.* Ninety-four patients received the vaccine and twenty-six subjects died during the course of the study. *Id.* However, none of the deaths were attributed to the vaccine itself. *Id.*

The experiment attracted public attention because the study's nurse coordinator, Cheryl Lynn Mathias, contended that there were problems with quality control, patient care, reporting of adverse events, and adherence to the study's protocol. *Id.* Mathias's formal presentation to the head of the department of surgery and the director of the office of research triggered an outside audit. *Id.* The audit found violations of good manufacturing practice, good clinical practice, and FDA requirements. *Id.* Mathias persisted, approaching federal regulators with her concerns. *Id.* An investigator from the OHRP notified the University of Oklahoma of the serious allegations of noncompliance with protections for human subjects. *Id.* The OHRP found that the IRB regularly failed to continually review almost all research protocols, including the one in question. *Id.* It also found that the IRB lacked information regarding subject recruitment and enrollment, subject selection, privacy and confidentiality protections, and additional safeguards for vulnerable subject populations before approving the research. *Id.*

92. Vida Foubister, *Clinical Trial Patients Sue IRB Members*, 44(8) AM. MED. NEWS (Feb. 26,

IRB as individual defendants.⁹³ The plaintiffs contended that because the defendants failed to comply with federal regulations for the protection of human research subjects and notify the plaintiffs of this failure, “the plaintiffs’ involvement in the study was without their consent.”⁹⁴ Plaintiffs also claimed violations of both their constitutional privacy right “to be treated with dignity” and their due process liberty interest.⁹⁵ The court found that no private right of action existed for alleged violations of international laws, such as the Declaration of Helsinki⁹⁶ and the Nuremberg Code,⁹⁷ that protect human research subjects.⁹⁸ According to the court, the appropriate standard in the United States for conducting research on human subjects is contained in the Code of Federal Regulations; yet, even under the Code of Federal Regulations, the court found no private right of action.⁹⁹

Only a year later, in 2001, the OHRP investigated Johns Hopkins University (Johns Hopkins) because a healthy, twenty-four year old, Ellen Roche, died while participating in an asthma study.¹⁰⁰ The OHRP found the researcher at fault “for inadequately researching the drug used in the study.”¹⁰¹ In addition, the OHRP cited the Johns Hopkins IRB for

2001), at <http://www.ama-assn.org/amednews/2001/02/26/prsb0226.htm>.

93. *Robertson v. McGee*, No. 01CV60, 2002 WL 535045 (N.D. Okla. Jan. 28, 2002).

94. *Id.* at *2.

95. *Id.*

96. *See supra* notes 29–30 and accompanying text.

97. *See supra* notes 25–28 and accompanying text.

98. *Robertson*, 2002 WL 535045, at *2.

99. *Id.* at *3 (“Within 21 C.F.R. §§ 210, 211 and 45 C.F.R. § 46, there is a comprehensive enforcement scheme provided to the FDA, accordingly there is no private right of action enforceable under § 1983.”).

Interestingly, the IRB defendants claimed qualified immunity as state actors against the plaintiffs’ claim of not being treated with dignity. *Id.* at *4. The court affirmed that state actors performing discretionary functions can be shielded from liability under qualified immunity if their conduct does not violate clearly established statutory or constitutional rights which a reasonable person would have known. *Id.* The court did not reach the question of whether the IRB members had violated any rights, because they could find “no federal law which recognizes a constitutional right under 42 U.S.C. § 1983 ‘to be treated with dignity’ for persons who agreed to participate in a medical research project sponsored by a state university.” *Id.*

100. *Report on a Research Death Faults Review Board*, N.Y. TIMES, Aug. 31, 2001, at A16 [hereinafter *Report on Research Death*].

101. Daniel J. Powell, *Using the False Claims Act as a Basis for Institutional Review Board Liability*, 69 U. CHI. L. REV. 1399, 1404 (2002) (citing Letter from Patrick McNeilly, Compliance Oversight Coordinator, Division of Compliance Oversight, HHS, and Michael Carome, Director, Division of Compliance Oversight, HHS, to Edward Miller, Dean and Executive Chief Officer, Johns Hopkins Medicine, Chi Van Dang, Vice Dean for Research, The Johns Hopkins School of Medicine, and Gregory F. Schaffer, President, The Johns Hopkins Bayview Medical Center (July 19, 2001), available at http://ohrp.osophs.dhhs.gov/detrm_lettrs/jul01a.pdf (last visited Mar. 21, 2002)). “It appears that previous versions of textbooks had indicated that the drug used to induce asthma was toxic in humans, and that a more exhaustive review of the literature would have revealed that the

significant violations of federal regulations—the IRB did not “obtain adequate information to evaluate the risks of the research protocol, did not satisfactorily review ongoing research, failed to fully consider the needs of vulnerable subjects, and kept insufficient records of its meetings.”¹⁰² Due to these violations, the OHRP stopped all federally funded research at Johns Hopkins for several days until Johns Hopkins officials established a proposal addressing the OHRP’s concerns.¹⁰³

A Johns Hopkins-affiliated research institution, Kennedy Krieger Institute, Inc. (KKI), studied the effectiveness of varying degrees of lead paint abatement modifications on homes, using young children as the human research subjects.¹⁰⁴ The consent forms did not disclose that the child might accumulate lead in the blood, nor did the forms reveal that in order for the experiment to succeed it was necessary that the child remain in the house as the lead in the child’s blood increased or decreased, so that it could be measured.¹⁰⁵ Most egregiously, the Johns Hopkins University Joint Committee on Clinical Investigation (the Johns Hopkins IRB) suggested to the researchers “a way to miscast the characteristics of the study in order to avoid the responsibility inherent in non-therapeutic research involving children.”¹⁰⁶ The parents of two child-subjects brought two separate negligence actions alleging that KKI had a duty to warn the participants of the risks attendant to the research; the researchers breached this duty when they failed to warn parents in a timely manner or otherwise

research protocol should have been modified.” *Id.* (citing Letter from Chi Van Dang, Vice Dean for Research, Johns Hopkins University School of Medicine, and Gregory F. Shaffer, President, Johns Hopkins Bayview Medical Center, to Michael Carome, Division of Compliance Oversight, OHRP (July 13, 2001), available at <http://www.sunspot.net/bal-hopkinsletters.htmlstory> (last visited Feb. 7, 2002)).

102. Powell, *supra* note 101, at 1404.

103. *Id.* at 1404–05.

104. *Grimes*, 782 A.2d 807. The researchers anticipated that the children would accumulate lead in their blood from the lead-bearing dust, which would help researchers determine the extent to which the various partial abatement procedures worked. *Id.* at 812–13.

“There was no complete and clear explanation in the consent agreements signed by the parents of the children that the research to be conducted was designed” to use the extent of contamination in the children’s blood as a proxy for the effectiveness of the abatement procedures. *Id.* at 813.

105. *Id.* at 824–25.

106. *Id.* at 813. In a letter to the researcher, the IRB pointed out that “[f]ederal guidelines are really quite specific regarding using children as controls in projects in which there is no potential benefit” to the children (i.e., non-therapeutic research, which is research that promises no direct benefit to the participant). *Id.* at 814. Because of this, the IRB encouraged the researchers to change the consent form to indicate that the control group was “being studied to determine what exposure outside the home may play in total lead exposure.” *Id.* Thus, the consent form indicated that the controls were receiving some benefit in discovering “whether safe housing alone is sufficient to keep the blood-levels in acceptable bounds” (i.e., therapeutic research, which is research that promises a potential benefit to the participant). *Id.*

act to prevent the children's exposure to the known presence of lead.¹⁰⁷ The court held that informed consent agreements in a non-therapeutic research context can constitute contracts, as well as special relationships, giving rise to duties.¹⁰⁸ A breach of these duties by the researcher may also result in negligence claims.¹⁰⁹

III. ANALYSIS OF POTENTIAL IRB LIABILITY

While current case law is beginning to establish the existence of a duty of care owed by a researcher and the applicable standard of care that an injured research subject must establish to recover under either an informed consent or research malpractice theory, the same has yet to be established for an IRB that approved the research protocol.¹¹⁰ IRBs are less than ideal defendants because of the uncertainty that an injured research subject faces regarding the duty owed by and the standard of care imposed upon an IRB.¹¹¹ Consequently, there has never been a lawsuit filed against IRB members as a group for "negligent approval of a protocol" or any other claim of the sort.¹¹²

Yet, naming IRBs as defendants may be a way for injured plaintiffs to intimidate IRBs and undermine their credibility if IRB members must testify at trial.¹¹³ One legal scholar suggests that the decision to sue IRB

107. *Id.* at 818. Both claims alleged that KKI discovered lead hazards that could cause lead poisoning in the homes of the participating families. *Id.* The plaintiffs further contended that they were not fully informed of the risks of the research. *Id.*

108. *Id.* at 858.

109. Regarding parental consent, the *Grimes* court held that a parent cannot consent to a child's participation in non-therapeutic research that poses "any risk" to the subject: "We hold that in Maryland a parent, appropriate relative, or other applicable surrogate, cannot consent to the participation of a child or other person under legal disability in nontherapeutic research or studies in which there is any risk of injury or damage to the health of the subject." *Id.*

110. Anderlik & Elster, *supra* note 9, at 224. It might seem logical that if an IRB was to be sued, the usual negligence standard of care would be applied, i.e., what a reasonably prudent IRB member would have done in a similar situation. *Id.* Conceivably, though, this could become quite complicated given the diverse membership of the IRB. *Id.* Would an ethicist or philosopher IRB member be held to the same standard as a member who was a medical doctor or a lawyer? *Id.*

111. *Id.*

112. See *supra* Parts II.D and E; see also BENDER, *supra* note 17, at § 23.08.

However, a report by the National Commission on IRBs alluded to the possibility that an IRB member could be held personally liable for negligent approval of protocols. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, REPORT AND RECOMMENDATIONS: INSTITUTIONAL REVIEW BOARDS, DHEW Pub. No. (OS) 78-0008, at 82 (1978); see also 43 Fed. Reg. 56,174 (1978).

113. Anderlik & Elster, *supra* note 9, at 224.

members could be an efficient way for plaintiffs to cast the net as wide as possible and encourage settlement.¹¹⁴

Aside from the uncertainty of suing an IRB due to the lack of clear definitions of duty and standard of care, the question arises whether an injured research subject should be able to hold an IRB liable, as individual members or as a whole, for approving the research protocol *designed and performed* by an independent researcher that led to the subject's injury. In answering this question, several considerations are relevant.

First, state peer review statutes may preclude IRBs from incurring liability.¹¹⁵ If the language of the statute is broad enough it may apply to IRBs as it does to other peer review committees.¹¹⁶ These types of statutes may not only protect the IRBs and its individual members, but the statutes might also shield IRB records and documents from discovery or admission into evidence.¹¹⁷ For example, an Illinois court held that the state peer review statutes' definition of a peer review committee included IRBs; therefore, the IRB was not required to disclose documents requested by the plaintiffs.¹¹⁸

114. *Id.* (citing Foubister, *supra* note 92 ("It's a strategy [referring to suing IRBs] that causes more people to get upset, and therefore encourages institutions to settle quicker.")).

115. *See, e.g.*, VA. CODE ANN. §§ 8.01–44.1 (Michie 2001) (explicitly affording civil immunity to Virginia IRB members).

116. Medical Studies, 735 ILL. COMP. STAT. 5/8-2101 (1994) (exempting from disclosure documents used by hospitals and other providers in the course of medical research, to encourage candid and voluntary studies and programs used to improve hospital conditions and patient care or to reduce the rates of death and disease in Illinois).

117. *Doe v. Ill. Masonic Med. Ctr.*, 297 Ill. App.3d 240 (Ill. App. Ct. 1998) (holding that documents used by an IRB during a medical study were privileged under the Illinois Medical Studies Act).

118. *Id.* The court found that:

In addition to protecting all information used in the course of "internal quality control," the Act's plain language expressly protects all information used in the course of "medical study." . . . Therefore, we presume that the legislature clearly intended that the statute's purview was not restricted to peer review committees. The Act also limits the privilege to materials belonging to certain entities. Included among these are "committees of licensed or accredited hospitals." The IRB is such a hospital committee.

Id. at 243.

For an opposite result, see *Konrady v. Oesterling*, 149 F.R.D. 592 (D. Minn. 1993). The Minnesota statute in this case was narrower than the Illinois statute construed in *Illinois Masonic Medical Center*. *Id.* The Minnesota statute was expressly limited to peer review and the court found that it contained no privilege for medical study information: "An IRB . . . does not have *peer* review as its purpose. IRB's are part of a highly regulated scheme designed to protect the rights and safety of human subjects. . . . The IRB does not review peers, it reviews research, approves specific investigational device exemption applications, [and] monitors the investigation's progress . . ." *Id.* at 598.

Second, the obvious reason for imposing liability on an IRB would be to increase accountability for the IRB's actions.¹¹⁹ Yet it is not clear that increased IRB monitoring will result in a decrease in adverse events in human research.¹²⁰ In addition, the IRB is only a small part of the overarching framework for protecting human subjects. Institutions, sponsors, the government, and the clinical investigators who manage the studies also play critical roles.¹²¹ No amount of IRB scrutiny can safeguard against unexpected events, either due to the individual health of the particular subject or an oversight of an investigator.¹²²

Moreover, if liability against IRBs and its members were allowed, it would likely discourage people from becoming IRB members rather than motivating them to be more conscientious in reviewing and monitoring research protocols.¹²³ Membership on an IRB does not give a member a

119. Anderlik & Elster, *supra* note 9, at 225 (“Legal liability is a perfectly ordinary means for ensuring that people and institutions meet their responsibilities. . . . [L]awsuits may be one of the few ways of expediting the needed changes [in the IRB system], as fear can often be a motivating force.”); *see also* J. Savulescu, I. Chambers, & J. Blunt, *Does Setting Good Practice Standards for Research Ethics Committees Increase Their Legal Liability?*, 314 *BRIT. MED. J.* 1833 (1997).

120. Robert Steinbrook, *Improving Protection for Research Subjects*, 346 *NEW ENG. J. MED.* 1425, 1429 (2002) (quoting Helen McGough, director of the Human Subjects Division at the University of Washington in Seattle: “We have very poor data on the number of adverse events and whether there is any relation between the adverse events and the quantity and quality of IRB review.”).

121. *Id.* at 1425.

The IRB cannot be viewed as a substitute or surrogate for a responsible, well-trained, caring investigator. No matter how much we improve our system of checks and balances, the primary responsibility for full and thoughtful disclosure, enrollment without coercion, monitoring of the conduct of the trial, reporting adverse events, and confidentiality must remain with the local primary investigator.

Eve E. Slater, Editorial, *IRB Reform*, 346 *NEW ENG. J. MED.* 1402, 1403 (2002).

122. *See* Donald S. Kornfeld, Correspondence, *Institutional Review Boards Reform*, 347 *NEW ENG. J. MED.* 1285, 1286 (2002).

On the basis of my experience as a chairman of the IRBs at two major academic medical institutions for a total of 18 years, I would argue that serious risk to patients is more likely to be the result of human fallibility than of inadequate IRB procedures. Adequate IRB procedures could not have prevented the deaths of the student at the University of Rochester from an excessive dose of lidocaine, the volunteer at Johns Hopkins from the pulmonary damage inflicted by hexamethonium, the patient at the University of Pennsylvania from a genetically modified agent, or the nurse at Case Western Reserve from an overdose of methionine. These deaths were the result of a variety of human failings. The most zealous overhaul of IRB regulations and the expenditure of substantial sums to enforce them cannot avert the harm that results from unexpected events or is inflicted by an investigator's sociopathy, hubris, or carelessness.

Id.

123. Anderlik & Elster, *supra* note 9, at 225 (citing Foubister, *supra* note 92).

Why would I even want to risk the chance of being named in a lawsuit? . . . With the amount of research done at any major research university or academic medical center, there will be people who have adverse events and there will be people who die. If the default is as soon as that happens the IRB gets sued, there will be no more IRBs and there will be no more

greater chance of promotion or tenure, nor does it increase outside funding.¹²⁴ Additionally, IRB members do not get paid for their efforts, and reviewing research protocols requires a huge investment of time and energy.¹²⁵ As such, the pool of potential IRB members from which an institution can draw is limited.¹²⁶ This pool would become even smaller if liability for adverse research events was imposed upon IRB members.¹²⁷ Additionally, IRBs may become so risk-adverse that hardly any research will be approved.¹²⁸ Consequently, one could easily imagine that IRBs could also face lawsuits alleging damage to the careers and reputations of investigators whose protocols were rejected.¹²⁹

Third, statutory language throughout the federal regulations hints that the drafters did not intend to allow injured research subjects to impose liability on IRBs. Under section 46.116 of the Code of Federal Regulations, which addresses informed consent, research subjects cannot waive their legal rights or indemnify “the investigator, the sponsor, the institution or its agents from liability for negligence.”¹³⁰ One might argue that an IRB could fall under the exempted “agent” category.¹³¹ Yet, this language might also suggest that Congress purposefully excluded IRBs from its indemnification list; if Congress had wanted to include IRBs in this section, it easily could have listed IRBs as a group which subjects

research because you can't do research without IRBs.

Id.

124. *Id.* at 226.

125. *Id.*

126. See, e.g., H. Edgar & D.J. Rothman, *The Institutional Review Board and Beyond: Future Challenges to the Ethics of Human Experimentation*, 73 MILBANK Q. 489 (1995); D.F. Phillips, *Institutional Review Boards Under Stress: Will They Explode or Change?*, 276 JAMA 1623 (1996); S.B. Putney & S. Gruskin, *Time, Place and Consciousness: Three Dimensions of Meaning for U.S. Institutional Review Boards*, 92 AM. J. PUB. HEALTH 1067 (2002); L.E. Wolf, M. Croughan & B. Lo, *The Challenges of IRB Review and Human Subjects Protections in Practice-Based Research*, 40 MED. CARE 521 (2002).

127. Anderlik & Elster, *supra* note 9, at 225.

128. *Id.*

129. *Id.*

130. 45 C.F.R. § 46.116 reads, in part:

No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.

131. See RESTATEMENT (SECOND) OF AGENCY § 1(1), which provides: “Agency is the fiduciary relation which results from the manifestation of consent by one person to another that the other shall act on his behalf subject to his control, and consent by the other so to act.”

After selecting IRB members, the corresponding institution charges the IRB with the responsibility of protecting the rights and welfare of human subjects. See BENDER, *supra* note 17, at § 23.02(1). As such, the institution is consenting to the IRB's review and approval of research at that institution, and therefore entering into a fiduciary relation with the IRB as its agent. See *id.*

could not indemnify under section 46.116. Evidence suggests that the latter is true.¹³² Precisely because Congress did not specifically mention IRBs in this regulation, which discusses negligence actions and defendant targets, it is not likely that Congress contemplated IRBs as possible defendants in human research litigation.¹³³ This idea is further supported by the fact that section 46.116 and sections 46.107–.115, which establish IRBs,¹³⁴ were codified on the same day,¹³⁵ suggesting that the drafters clearly had IRBs and their role in mind when crafting the regulations. Therefore, because Congress did not see the need to prevent indemnification of IRBs, it is even more likely that Congress did not expect IRBs to be sued by injured research subjects.¹³⁶

IV. PROPOSED SCHEMA FOR ACTIONS AGAINST IRBS

A. *Duty of Care and the Business Judgment Rule*

Given the lack of case law dealing with IRB liability, it is instructive to look to a more established area of law for an answer to how to deal with IRB member liability.¹³⁷ Under corporate law, officers and directors have a duty of care¹³⁸ whereby they must “discharge their duties in good faith and with that degree of diligence, care and skill which ordinary prudent [persons] would exercise under similar circumstances”¹³⁹

132. See 45 C.F.R. § 46.116. Subsections 46.116(c) and (d) specify how an IRB may approve a consent procedure that excludes or alters informed consent in certain circumstances. Given that subsections 46.116(c) and (d) specifically mention IRBs, yet IRBs are not listed as parties which cannot be released from liability for negligence under section 46.116, it seems that Congress clearly did not want to include IRBs as parties released from liability. This could be interpreted to mean that Congress neither anticipated nor desired negligence actions to be brought against IRBs.

133. *Id.*

134. 45 C.F.R. §§ 46.107–.115.

135. See 45 C.F.R. §§ 46.107–.116. All the regulations were codified on June 18, 1991 and became effective August 19, 1991.

136. *Id.*

137. In the legal world, it is common to look to a separate area of law for answers in dealing with an area of law that is undeveloped or unsettled. For the remainder of the discussion, this Note will explain how corporate law principles used for board of directors liability can be useful in determining how IRB liability suits should be handled.

138. REV. MODEL BUS. CORP. ACT § 8.30(a) (1984) (stating this duty in a way that is typical of the law in most states: “A director shall discharge his duties as a director . . . (1) in good faith; (2) with the care an *ordinarily prudent person* in a like position would exercise under similar circumstances; and (3) in a manner he *reasonably believes* to be in the *best interests of the corporation*.”) (emphasis added).

139. *Francis v. United Jersey Bank*, 432 A.2d 814, 820 (N.J. 1981) (citing N.J. STAT. ANN. § 14(a) (1969)).

when acting on behalf of the corporation.¹⁴⁰ Under this duty of care, two types of fact patterns are possible: “(1) negligent specific decisions;¹⁴¹ . . . and (2) a failure of the board of directors to adequately supervise the operations of a corporation.”¹⁴²

The business judgment rule, however, provides a shield to officers and directors from their actions on behalf of the corporation.¹⁴³ The business judgment rule provides that a court will not find a breach of duty of care solely because the director’s decision was unwise.¹⁴⁴ Courts will not impose liability if three conditions are satisfied: (1) the officer or director had no conflict of interest in the matter decided;¹⁴⁵ (2) the officer or director adequately informed him or herself about the relevant facts of the decision;¹⁴⁶ and (3) the business decision was, in the director’s opinion, rational¹⁴⁷ and in the best interest of the corporation at the time that it was made.¹⁴⁸

140. *Id.*

141. *See, e.g.,* Litwin v. Allen, 25 N.Y.S.2d 667 (N.Y. Spec. Term. 1940) (holding bank directors liable for purchasing securities for the bank but giving the seller an option to buy the securities back at the same price and, in effect, risking a loss with no possible gain or interest derived from holding the securities); *see also* JOEL SELIGMAN, CORPORATIONS 141–43 (1995).

Generally, these kinds of decisions are protected from liability under the business judgment rule. *Id.* For further discussion on the business judgment rule, see *infra* notes 143–48 and accompanying text.

142. SELIGMAN, *supra* note 141, at 142. When directors are charged with a failure to adequately supervise, the business judgment rule is not normally available as a defense. *Id.* at 141–43.

143. *See generally id.* at 167–213.

144. *Id.* at 167.

145. Interest in a transaction is defined as being a party to the transaction, being related to a party, or otherwise having some financial stake in the transaction’s outcome that is adverse to the corporation’s stake. *See* A.L.I., PRIN. CORP. GOV., § 4.01(c) (1993). Where an interest is shown, the business judgment rule will not apply; any evidence of self-dealing by the director deprives the director of the business-judgment shield. *Id.*

The business judgment rule aims to protect honest cases, even if mistaken, of business judgment. *Id.* The rationale against self-dealing is that if a director has engaged in self-dealing, then he has not judged his decision on behalf of the corporation, but rather on behalf of his own objectives. *Id.* Self-dealing is not what the business judgment rule was designed to protect. *Id.*

146. Informed decisionmaking means that the director gathered a reasonable amount of information about the decision before he made it. *See id.* Directors must educate themselves “prior to making a business decision, of all material information reasonably available to them.” Aronson v. Lewis, 473 A.2d 805, 812 (Del. 1984).

Under the informed decision requirement, most courts will hold that a director loses the benefit of the rule only if he was *grossly negligent* in the amount of information he obtained. STEVEN L. EMANUEL, CORPORATIONS 183 (2000). Thus, *ordinary* negligence in gathering information, will not be enough to impose liability. *Id.* Furthermore, a court will usually consider all of the surrounding circumstances (e.g., whether the decision had to be made in an extremely short period of time). *Id.*

147. A rational decision is one in which the director rationally believes his or her business judgment was in the corporation’s best interest. *See* A.L.I., PRIN. CORP. GOV., § 4.01(c)(3). Not only must the director actually believe that his or her decision was in the corporation’s best interest, but this belief must also be rational. *Id.* Rational is a different, lower standard than *reasonable*. *Id.* Rational

In conjunction with the business judgment rule, the duty of care only operates in the most egregious cases to impose liability.¹⁴⁹ First, actual business decisions made by a director or officer will not be second-guessed by a court as long as the decisions are rational, made in good-faith, and based on reasonable information.¹⁵⁰ Therefore, imposition of liability for breach of duty of care only arises where the director has failed to comply with reasonable procedures for making business decisions.¹⁵¹ Second, most courts will impose liability only for “gross negligence” or “recklessness,” even if the director’s procedures are inadequate.¹⁵²

There are three rationales for using the business judgment rule to limit directors’ liability. First, innovation and risk-taking are essential to the growth and prosperity of the business industry.¹⁵³ Without the business judgment rule preventing liability, risks would not be taken and the industry would never expand.¹⁵⁴ Second, courts are ill-suited for judging whether a business decision was a rational one and, consequently, there is an increased potential for improper outcomes without the business judgment rule.¹⁵⁵ Third, directors are, by their very nature, in poor positions to spread the costs of unfortunate outcomes or losses in the

implies that the decision must be totally beyond the bounds of reasonableness. *Id.* Therefore, a decision that most people would agree is not a good idea may still be protected as rational under the business judgment rule. *Id.*

148. SELIGMAN, *supra* note 141, at 167. Under the business judgment rule, a court does not scrutinize the subjective decision itself. *Id.* Therefore, if a director makes a good faith effort to obtain the facts and makes a decision which is unwise, the director will likely not be liable for breach of the duty of care; the business judgment rule will protect the director. *Id.* at 167–70. On the other hand, a director who makes an unwise decision on behalf of the corporation, without attending board meetings or attempting to ascertain the facts, will likely be found to have breached the duty of care. *Id.*

149. *See generally id.* at 167–213.

150. EMANUEL, *supra* note 146, at 173–74.

151. *Id.*

152. *Id.*

153. *Id.* at 182. It is in the interest of the corporation for the directors to take rational risks on the corporation’s behalf. *Id.* If directors were not shielded from liability by the rule, they would be more conservative and risk-adverse, causing the overall economic performance of corporations to decline. *Id.*

Or, it is quite possible that if liability was imposed upon directors in all cases, it would be harder to find persons willing to serve in directorships. *Id.* Certainly, “no man of ordinary prudence would accept a trust surrounded by such perils.” *Godbold v. Branch Bank*, 11 Ala. 191, 199 (1847).

154. EMANUEL, *supra* note 146, at 182.

155. *Id.* Directors must engage in “risk/benefit calculus” when making business decisions. *Id.* Judges are not trained in this type of calculus, especially judging from hindsight. *Id.* Consequently, judges may reach inappropriate conclusions if they are allowed to evaluate business decisions. *Id.* “A reasoned decision at the time made may seem a wild hunch viewed years later against a background of perfect knowledge.” *Joy v. North*, 692 F.2d 880, 886 (2d Cir. 1982). In addition, even if courts were suited to make these kinds of decisions, courts would not have the time required to engage in this calculus in every situation. EMANUEL, *supra* note 146, at 182.

ordinary course of practice, as opposed to company shareholders who can diversify their investments to prevent devastating losses if one investment has a bad outcome.¹⁵⁶

B. Application of Corporate Law Principles to IRBs

There are clear parallels between corporate boards of directors in the business context and IRBs in the research context.¹⁵⁷ Given the large size of both corporations and research institutions, it would be impractical for every member of a research institution or shareholder of a corporation to be involved in every decision that affected the institution or the business.¹⁵⁸ As such, board members are appointed and entrusted to oversee the progress and well-being of the larger institution or corporation and make important decisions on behalf of the members or shareholders.¹⁵⁹

Therefore, the rationales behind applying the business judgment rule to corporations might readily justify using some variation of the business judgment rule in research institutions conducting human-subject research.¹⁶⁰ First, research institutions are charged with creating and perfecting new means for diagnosing and treating the health and wellness of human beings.¹⁶¹ Yet, progress cannot be made without taking risks, using innovation, and trying new, albeit “unheard of,” techniques when developing research breakthroughs.¹⁶² Second, courts are not in a position to judge whether the approval of a research protocol that resulted in injury was rational given the relevant information; judges rarely have the scientific background and knowledge to understand the gravity of the proposed research, let alone determine if it was warranted in the given

156. EMANUEL, *supra* note 146, at 182. The point of holding directors liable is to spread the cost of the loss among more people. *Id.* But directors are poor cost-spreaders because directors, at best, only serve a few companies and cannot recoup the loss into the price charged for services—as opposed to other lines of work where the costs can easily be spread across many clients. *Id.* As a result, shareholders are in a better position than directors to spread the risk of business misjudgment by diversifying their portfolios. *See generally Joy*, 692 F.2d 880.

157. *Compare supra* notes 153–56 and accompanying text, *with infra* notes 160–65 and accompanying text (explaining the rationales behind the business judgment rule in the corporate law context and how these rationales are similar to those in the human-subject research context).

158. *See generally* EMANUEL, *supra* note 146, at 51–53.

159. *Id.*

160. *See generally* BENDER, *supra* note 17, at § 23.01(1).

161. *See, e.g., Barnes Jewish Hospital, Mission, Vision and Values*, available at <http://www.barnesjewish.org/groups/default.asp?NavID=357> (last visited Oct. 29, 2004) (“We take exceptional care of people By advancing medical knowledge and continuously improving our practices.”).

162. This can be paralleled to the first rationale for applying the business judgment rule—using innovation and risk-taking—to promote the growth and prosperity of the business industry. *See supra* note 153.

situation.¹⁶³ Third, IRB members have no ability to spread the costs of an unwise decision because they receive no compensation for serving as IRB members, nor are the members likely to have the resources to compensate injured subjects.¹⁶⁴

Consequently, IRB members can be likened to corporate board members and, accordingly, should receive protection from liability under some variant of the business judgment rule.¹⁶⁵ Applying the three prongs of the business judgment rule to the research context, courts should not impose liability upon an IRB member if: (1) the IRB member had no conflict of interest in the approved protocol; (2) the IRB member adequately informed him or herself about the relevant facts, risks, and possible consequences surrounding the proposed research; and (3) the approval of the research was, in the IRB member's opinion, rational¹⁶⁶ and in the best interest of the research institution or research subjects at the time that it was made. This principle will hereinafter be referred to as the IRB judgment rule.

Using the business judgment rule as a model would create the perfect balance between shielding an IRB from liability when it exercises correct judgment on the one hand, and imposing liability upon the IRB when it violates one of the business judgment tenets on the other hand. From a policy standpoint, this would increase IRB accountability while only imposing liability when the duty of care was not met. For example, applying the IRB judgment rule to *Gelsinger*,¹⁶⁷ the IRB should not be held liable for negligent research treatment and lack of informed consent because it was the researchers who altered the original consent forms so they no longer complied with federal regulations.¹⁶⁸ If, however, the Gelsingers could prove that the IRB did not properly inform itself regarding research activities or use the requisite rational judgment in its

163. The second rationale can be likened to courts' inability to judge whether a business decision was a rational one. *See supra* note 154.

164. The third rationale is similar to the business director's failure to spread the costs in the ordinary course of practice. *See supra* note 155.

165. *See supra* note 157 and accompanying text.

166. It is quite possible to use a "reasonable person" standard, as opposed to the "rational" standard. However, this Note uses the lower, rational standard given the likeness between the business and research contexts and the compelling need to encourage research developments. *See supra* note 147.

167. *Gelsinger*, *supra* note 86.

168. *Id.* The researchers allegedly altered the consent form approved by the FDA by deleting information about deaths and illnesses of monkeys in prior animal studies. *See supra* note 90 and accompanying text.

continued review of the research study, the IRB might be held liable under the IRB judgment rule.

In the situation involving the Oklahoma Health Sciences Center,¹⁶⁹ the OHRP found that the IRB lacked information regarding “subject recruitment and enrollment, subject selection, privacy and confidentiality protections, and additional safeguards for vulnerable subject[.]” populations before approving research.¹⁷⁰ Clearly this is a violation of the second prong of the IRB judgment rule, whereby an IRB must be adequately informed before approving the research project; therefore, liability should be imposed.

Applying the IRB judgment rule to the *Roche*¹⁷¹ case, the IRB should not be liable for approving the research protocol. Given the information in the approved proposal, the IRB was not likely to know the toxicity of the drug used in the study—specifically because the researchers did not disclose this information in their proposal.¹⁷² A rational IRB would likely have approved the research absent any showing of danger to the subjects.

Employing the IRB judgment rule in the *Grimes*¹⁷³ case would impose liability on the IRB because its members clearly violated the third prong of rationality and consequently breached their duty of care. It was not rational for the IRB to approve the protocol because it was obviously aware of the risks inherent in the study, as evidenced by its suggestion to miscast the study’s characteristics to avoid the responsibility associated with non-therapeutic research involving children.¹⁷⁴

C. Alternatives for Improving IRB Operation and Function Without Imposing Liability

In recent years, IRBs have been harshly accused of “reviewing too many protocols, reviewing protocols too quickly, having insufficient expertise, and providing too little training” for new members.¹⁷⁵ There are several ways to improve the function and accountability of IRBs without imposing liability. First, the role and responsibility of the IRB should be defined more clearly in federal statutes.¹⁷⁶ The statutes should explicate

169. See *supra* notes 91–99 and accompanying text.

170. Anderlik & Elster, *supra* note 9, at 221.

171. See *supra* notes 100–03 and accompanying text.

172. See *supra* note 101 and accompanying text.

173. *Grimes*, 782 A.2d 807; see also *supra* notes 104–09 and accompanying text.

174. See *supra* note 106 and accompanying text.

175. Steinbrook, *supra* note 120, at 1426.

176. Anderlick & Elster, *supra* note 9, at 225–26.

whether IRBs should be held responsible for ensuring ethical research behavior or whether IRBs are merely acting as one step in realizing and addressing problematic components of research.¹⁷⁷ Second, an increase is needed in the resources devoted to protecting research subjects to contend with the growth of federal and private clinical research expenditures.¹⁷⁸

Third, an increase in the number and types of IRBs would improve the current system.¹⁷⁹ Educational programs for investigators and IRB members, additional staff, and programs for the protection of research subjects directed by senior officials could be beneficial as well.¹⁸⁰ Furthermore, institutions, especially those with multi-center studies, could increase the use of external review boards.¹⁸¹ Fourth, IRBs could increase the membership of unaffiliated members to better represent the human-subject population.¹⁸² Finally, accreditation programs for the protection of research subjects could be imposed in a more standardized manner to encompass all institutions performing human-subject research.¹⁸³

177. *Id.*

178. *Id.* “From 1995 to 2000, the budget of the National Institutes of Health (NIH) doubled. President George W. Bush requested \$27.3 billion for the NIH in fiscal year 2003, a 33 percent increase over the \$20.5 billion budget for fiscal year 2001.” Steinbrook, *supra* note 120, at 1426. If the resources for IRBs do not increase at a rate greater than the current one, it is unreasonable to expect IRBs to review and approve the increased number of proposed research protocols. *Id.*

179. *See* Steinbrook, *supra* note 120, at 1428–29. Institutions such as Johns Hopkins and Duke University have increased both their spending and the number of IRBs to correct serious problems with their programs for protecting research subjects. *Id.* at 1428. “Between 1999 and 2002, 7 of the 11 medical schools with the largest amount of NIH support for research established additional IRBs.” *Id.*

180. *Id.*

181. *Id.* The work load for participating institutions could be decreased by using external boards to review the overall research protocols for multi-center studies. *Id.* External review boards could also review certain types of protocols for single-center studies to lessen the IRBs workload or an external review board could be established to review a frequent type of study or to review certain studies that might require different expertise. *Id.*; *see also*, W.J. Burman, R.R. Reves, D.L. Cohn & R.T. Schooley, *Breaking the Camel's Back: Multicenter Clinical Trials and Local Institutional Review Boards*, 134 ANNALS INTERNAL MED. 152 (2001).

182. *See* Steinbrook, *supra* note 120, at 1428. “Current federal regulations require that each IRB have ‘at least one member who is not affiliated with the institution’” and that the board not be entirely comprised of one profession. *Id.*; *see supra* notes 56–57 and accompanying text. However, the National Bioethics Advisory Commission (NBAC) contends that one member may not be enough to avoid institutional bias, “especially because some IRBs have 15 to 21 members.” Steinbrook, *supra* note 120, at 1428. The NBAC recommends that IRB members who represent the perspective of the research participants and are not affiliated with the institution should represent 25% of the IRB membership. *Id.*

183. Steinbrook, *supra* note 120, at 1427. “The Joint Committee on Accreditation of Healthcare Organizations . . . [has] accredited health care organizations for years.” *Id.* Since the early 1980s, accreditation programs for the protection of human research subjects have been recommended, but these programs were only initiated in earnest in 2001. *Id.* “Two private organizations are involved . . . [First], the National Committee for Quality Assurance [NCQA] which accredits managed-care organizations and has started an accreditation program for the medical centers of the Department of Veterans Affairs.” *Id.* The program was created in response to the failure of the West Los Angeles

V. CONCLUSION

Since the egregious violations that occurred during World War II, society has realized the need for regulation of research involving human subjects.¹⁸⁴ Both international and national principles have been established to ensure that researchers adhere to minimum standards to protect the interest and dignity of human research subjects.¹⁸⁵ In the United States, IRBs were created to oversee and approve protocols for research involving human participants.¹⁸⁶ IRBs are responsible for protecting the rights of those participants, both before the research commences and during the research period.¹⁸⁷ With the recent rise in suits alleging lack of informed consent or injury associated with research studies against researchers and their affiliated institutions, it will only be a matter of time before IRB members are commonly named as defendants in such suits. Therefore, establishing a framework for addressing IRB liability—whether that be the IRB judgment rule or an equivalent substitute—is indispensable.

This Note proposes that IRBs be treated like corporate directors, allowing courts to apply a business judgment rule variant to cases alleging IRB member liability. Provided that an IRB member is a disinterested party to the approved research protocol; has made him or herself adequately informed about the relevant facts, risks, and possible consequences surrounding the proposed research; and his or her approval of the research was, in the IRB member's opinion, rational¹⁸⁸ and in the best interest of the research institution or the human subjects at the time that it was made, the IRB member should be shielded from liability if

Veterans Affairs Medical Center to improve research subject protections, and the resulting suspension of research involving human subjects there in March 1999. *Id.* Currently, the NCQA offers accreditation only to Veterans Affairs institutions, but hopes to expand to accredit other institutions as well. *Id.* Second, the Association of American Medical Colleges and six other groups founded the Association for the Accreditation of Human Research Protection Programs (AAHRPP). *Id.* at 1428. Currently, accreditation under the AAHRPP is voluntary, but in time, it is hoped that accreditation under the AAHRPP could become standard practice. *Id.*; see also INSTITUTE OF MEDICINE, *Preserving Public Trust: Accreditation and Human Research Participant Protection Programs*, Washington, D.C. (National Academy Press, 2001); NCQA, *VA Launch First Ever Accreditation Program for Human Research Protection* (Aug. 28, 2001), available at <http://www.ncqa.org/communications/news/vahrpaplaunch.htm>; AAHRPP "Open for Business," *Ready to Accept Applications for Accreditation* (Feb. 26, 2002), available at http://www.aahrpp.org/nr_02-26-02.htm.

184. See *supra* Part II.A.

185. See *supra* Parts II.A, B, and C.

186. See *supra* Part II.A.

187. See *supra* Part II.A.

188. See *supra* note 166.

there is an adverse consequence resulting from the approved research study. In addition, there are more constructive ways of ensuring that IRBs are functioning in accordance with federal regulations and promoting the welfare of research subjects that do not require the imposition of liability for adverse research outcomes.¹⁸⁹

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189. *See supra* Part IV.C.

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