

Western New England Law Review

Volume 29 29 (2006-2007)

Issue 2 SYMPOSIUM: *THE POLITICS OF
HEALTH LAW*

Article 9

1-1-2007

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Recommended Citation

Matthew B. Drexler, *HEALTH LAW—PRIVACY IN MEDICAL RESEARCH: A BOTCHED EXPERIMENT*, 29 W. New Eng. L. Rev. 535 (2007), <http://digitalcommons.law.wne.edu/lawreview/vol29/iss2/9>

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HEALTH LAW—PRIVACY IN MEDICAL RESEARCH: A BOTCHED EXPERIMENT

INTRODUCTION

A few months ago, Alexis's physician diagnosed her with a rare, incurable, hereditary disease.¹ A few days ago, Alexis lost her job as a premier television news anchor. The only link between the two events was her participation in a medical research experiment. Alexis assumed her health information would remain confidential, and never imagined that it would end up in the hands of her employer.

Medical research is booming in the United States.² Along with the boom has come the increased circulation of protected health information (PHI), sometimes to unauthorized recipients.³ Hospital-based research requires that a patient's PHI be viewed by hundreds of individuals, including physicians, nurses, x-ray technicians, billing clerks, hospital administrators, insurance companies, research sponsors, and other data specialists.⁴ Often, a patient or research participant has no idea that his or her health information is being shared so widely.⁵ Currently, the medical research industry attempts to protect the privacy of medical research participants by policing itself, using either Institutional Review Boards (IRBs) or

1. Alexis, a hypothetical character, guides this journey through the medical research process as it winds through issues including federal regulations, informed consent, and the legal process.

2. From 1995 to 2002, "federal funding for research has more than doubled." Eve E. Slater, *IRB Reform*, 346 *NEW ENG. J. MED.* 1402, 1402 (2002). Privately sponsored research has experienced similar growth. *Id.*; see also Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 *J. HEALTH CARE L. & POL'Y* 175, 175 (2004) (finding that nearly nineteen million people currently participate in clinical research trials).

3. "Health information" is information that is created or received and "[r]elates to the past, present, or future physical or mental health or condition of an individual." 45 C.F.R. § 160.103 (2005). "Protected health information" is health information that can assist in identifying an individual and is "(i) transmitted by electronic media; (ii) maintained in electronic media; or (iii) transmitted or maintained in any other form or medium." *Id.*

4. Charity Scott, *Is Too Much Privacy Bad for Your Health? An Introduction to the Law, Ethics, and HIPAA Rule on Medical Privacy*, 17 *GA. ST. U. L. REV.* 481, 483 (2000) (finding that during a typical hospital stay as many as 400 people may have access to a patient's medical records).

5. Standards for Privacy of Individually Identifiable Health Information, 65 *Fed. Reg.* 82,462, 82,466 (Dec. 28, 2000) (codified at 45 C.F.R. §§ 160, 164).

privacy committees, located within the walls of research institutions.⁶

Failing to inform medical research participants of material PHI disclosure practices not only violates ethical research principles,⁷ it also exposes medical researchers to liability. This Note argues that those conducting medical research are liable in tort when they fail to properly protect research participants by informing them of the privacy risks associated with their participation in the research. Medical research participants must be adequately informed of common PHI disclosure practices along with the risks of such disclosures.

Part I develops the profile of a hypothetical research participant, Alexis, introduced above. Part II addresses the role of IRBs, focusing on the doctrine of informed consent. This Part also discusses authorizations for the release of PHI under the Health Insurance Portability and Accountability Act (HIPAA).⁸ Part III discusses the impacts of technology on PHI and the increased use of business associate agreements in outsourcing both administrative functions and medical monitoring, illustrating common mistakes that lead to the disclosure of PHI to unauthorized recipients. Part IV argues that the medical community's reliance on IRBs, privacy boards, and the doctrine of informed consent fails to adequately protect privacy interests and advocates for the extension of a legal liability standard to protect the privacy interests of research participants. Part V discusses familiar theories of legal liability used to compensate research participants whose PHI has been mishandled or disclosed to unauthorized recipients. By way of illustration, this Part concludes with a brief application of the negligence standard of liability to provide a remedy for Alexis.

6. "[An] IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated." DEPT OF HEALTH & HUMAN SERVS. (HHS), OFF. OF HUMAN RESEARCH PROTECTIONS, PROTECTING HUMAN RESEARCH SUBJECTS: INSTITUTIONAL REVIEW BOARD GUIDEBOOK (1993) [hereinafter HHS IRB GUIDEBOOK], available at http://www.hhs.gov/ohrp/irb/irb_chapter1.htm.

7. See *infra* Part II.

8. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

I. THE HYPOTHETICAL

Alexis had been doing very well for herself in the competitive news anchor market; however, she began to notice subtle changes in her mood and behavior. As these symptoms persisted, she eventually contacted her physician, Dr. Brohman,⁹ who performed a genetic consultation¹⁰ and diagnosed Alexis with Huntington's disease.¹¹

Huntington's disease is a progressive neurological disorder, which leads to death approximately fifteen years after onset of symptoms.¹² As the disease progresses, those afflicted with Huntington's will experience involuntary body movements, difficulty making eye contact, hesitant or slurred speech, and dementia.¹³ Alexis learned that her prognosis was grim. There is no known cure for Huntington's disease and no drug therapy is currently available to meaningfully delay progression of the disease or alleviate its symptoms.¹⁴

When Alexis first learned of her diagnosis, the effects of the disease on her career, family, and reputation were at the forefront of her thoughts. Alexis's position as a prominent news anchor and community personality prevented her from disclosing her illness. In fact, Alexis's employer made the decision to hire her based on her potential for long-term employment.¹⁵ While Alexis struggled to cope with the news of her illness, she also wondered if there was some way that she could provide the medical community with valuable information to advance scientific understanding of her incurable disease.

9. Dr. Brohman is a fictitious person.

10. A genetic consultation provides information and resources for those at risk for genetic disorders. U.S. NAT'L LIBRARY OF MED., NAT'L INST. OF HEALTH, DEP'T OF HEALTH & HUMAN SERV., GENETICS HOME REFERENCE, HANDBOOK: YOUR GUIDE TO UNDERSTANDING GENETIC CONDITIONS 88 (2006), available at <http://ghr.nlm.nih.gov/dynamicImages/understandGenetics.pdf>.

11. Huntington's disease is a "hereditary disease that begins with occasional jerks or spasms" leading to "gradual loss of brain cells . . . and mental deterioration." THE MERCK MANUAL OF MEDICAL INFORMATION 553 (2d ed. 2003).

12. J. Stephen Huff, *Huntington Chorea*, EMEDICINE, Mar. 9, 2005, <http://www.emedicine.com/emerg/topic254.htm>.

13. MayoClinic.com, Huntington's Disease, <http://www.mayoclinic.com/health/huntingtons-disease/DS00401/DSECTION=2&> (last visited Feb. 18, 2007); see also Huff, *supra* note 12 (describing further symptoms of Huntington's disease).

14. Medline Plus, Huntington's Disease, <http://www.nlm.nih.gov/medlineplus/ency/article/000770.htm#Treatment> (last visited Feb. 18, 2007); Huff, *supra* note 12.

15. Alexis's employer believes that television viewers are comfortable with familiar faces reporting the news. See Patricia Sullivan, *ABC News Anchor was a Voice of the World*, WASH. POST, Aug. 8, 2005, at A1, available at LEXIS (stating that Peter Jennings was "a familiar face in millions of households for more than 40 years," enjoying top world news "ratings for eleven of the past twenty years").

Dr. Brohman began researching and identifying available clinical trials¹⁶ related to Huntington's disease and presented Alexis with a trial sponsored by GenoPharm Solutions, Inc. (GenoPharm),¹⁷ a major pharmaceutical and genetic research corporation.¹⁸ While reading a consent form that would allow Alexis to participate in the clinical trial, Alexis noticed that she would not receive financial compensation for her participation; however, she discovered that Dr. Brohman would receive \$8,000 for enrolling Alexis in the trial.¹⁹

After learning that she could help others afflicted with Huntington's by participating in a clinical research study, Alexis was eager to participate. She assumed, like many participants, that her status as a research participant would remain confidential.

Unfortunately, Alexis's admirable intentions were met with the mishandling and disclosure of her private health information, a risk she certainly would have avoided had she been fully informed. As it happened, a disgruntled data specialist, having access to medical records of research participants, broadcast Alexis's medical records, along with the records of hundreds of other research participants, via

16. Clinical trials investigate new drugs, medical devices, treatments, or surgical processes through prevention trials, diagnostic trials, or screening trials. Among the most common are those clinical trials focusing on treatments. Cinead R. Kubiak, *Conflicting Interests & Conflicting Laws: Re-Aligning the Purpose and Practice of Research Ethics Committees*, 30 BROOK. J. INT'L L. 759, 770 (2005).

17. GenoPharm is a fictitious corporation.

18. A physician will often suggest a clinical trial focusing on the specific condition of a patient. Kubiak, *supra* note 16, at 768. However, prospective participants can also begin their own investigation into available clinical trials by searching the Internet. Most Internet searches that seek information on clinical trials lead to the National Institutes of Health (NIH) clinical trials website containing a comprehensive list of available clinical trials, which may be sorted by condition, symptom, disease, sponsor, and location. See generally ClinicalTrials.gov, Information on Clinical Trials and Human Research Studies, <http://www.clinicaltrials.gov> (last visited Feb. 18, 2007).

19. Kevin W. Williams, *Managing Physician Financial Conflicts of Interest in Clinical Trials Conducted in the Private Practice Setting*, 59 FOOD & DRUG L.J. 45, 68 (2004). In the institutional setting, payments to physicians and researchers enrolling patients into clinical trials range from \$2,000 to \$5,000. *Id.* In private practice, "pharmaceutical companies may pay \$7,000 to \$8,000 per patient enrolled in a standard, intensive 48-week protocol." *Id.* Dr. Brohman may justify a portion of this amount as financial compensation for Bay General Hospital and for his own research group's time and effort involved in tracking Alexis's progress through the course of the study. See *id.* However, Alexis did not know that Dr. Brohman and the hospital received a significant portion of that amount purely as an incentive to enroll patients in the clinical trial. *Id.* (commenting that typical contracts with pharmaceutical companies usually provide payments for overhead costs associated with the clinical trial as well as supplying a significant portion for profit).

e-mail, to several news networks.²⁰ The data, which included information about Alexis's participation in the research experiment, quickly became available to her co-workers, her colleagues at competing networks, and her own network managers. Afterwards, Alexis lost her job and her group health insurance, and suffered irreparable damage to her reputation. Dismayed, Alexis must now consider her options.

II. PROTECTING PARTICIPANTS IN THE MEDICAL RESEARCH COMMUNITY: INSTITUTIONAL REVIEW BOARDS & THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT

The opportunity for physicians to conduct medical research involving human subjects is a "privilege and not a right."²¹ Modern ethical principles have developed over time and researchers must now adhere to these principles while conducting clinical trials.²² The Nuremberg Code, resulting from the trials of war criminals charged with performing research on involuntary human subjects in Nazi Germany, provides that "voluntary consent of the human subject is absolutely essential. . . . [A] person . . . should be so situated as to be able to exercise free power of choice."²³ The Belmont Report,²⁴ written in 1979 by the National Commission for the Protec-

20. The disgruntled employee had just received a poor performance evaluation. Armed with access to vast amounts of sensitive health information on thousands of patients and with access to an e-mail program, this employee had sufficient resources and motivation to wreak havoc on the employer, and as a result, Alexis. See Amy M. Jurevic, *When Technology and Health Care Collide: Issues with Electronic Medical Records and Electronic Mail*, 66 UMKC L. REV. 809, 832 (1998) (commenting that e-mail communications allow instantaneous communication to be broadcast to the world); see also *id.* at 809 (citing Doug Stanley & Craig Palosky, *Medical Records Not So Secure*, TAMPA TRIB., Feb. 18, 1997, at 1) (noting that the identities of 4,000 patients with AIDS were sent to two news organizations).

21. Steven Peckman, *A Shared Responsibility for Protecting Human Subjects*, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION 16, 17 (Robert J. Amdur & Elizabeth A. Bankert eds., 2d ed. 2006).

22. A comprehensive review of the ethical underpinnings of human subject research is beyond the scope of this Note. For a well-developed article on the ethical underpinnings of research, see Kubiak, *supra* note 16, at 771-85 (providing analysis of the Nuremberg Code, the Declaration of Helsinki, the Belmont Report, and the international ethical guidelines established by the Council for International Organizations of Medical Science in conjunction with the World Health Organization).

23. THE NUREMBERG CODE, 2 TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW No. 10, at 181-82 (1949), reprinted in NAT'L INSTITUTES OF HEALTH, REGULATION AND ETHICAL GUIDELINES, available at <http://ohsr.od.nih.gov/guidelines/nuremberg.html>.

24. NAT'L COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND

tion of Human Subjects of Biomedical and Behavioral Research, provides ethical guidelines for researchers at all federally funded institutions.²⁵ The Belmont Report requires respect for an individual's autonomy—the right to make a choice free from obstruction.²⁶ In addition, the Belmont Report recognizes the need to balance the benefit to society that this research can provide against the risks to individual research participants.²⁷

Currently, the medical research community relies on the supervisory role of IRBs and the doctrine of informed consent to protect research participants from the risks and potential abuses of medical research.²⁸ In addition, the Health Insurance Portability and Accountability Act (HIPAA)²⁹ and its complementary Privacy Rule protect the private health information of health care consumers, including research participants.³⁰

A. Institutional Review Boards

The National Research Act of 1974 created Institutional Review Boards (IRBs) in response to concerns about research abuses at medical schools and hospitals.³¹ IRBs conduct reviews of pro-

GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979) [hereinafter BELMONT REPORT], available at <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>.

25. Kubiak, *supra* note 16, at 777.

26. BELMONT REPORT, *supra* note 24, at Part B(1).

27. *Id.* at Part B. An experiment designed to benefit society at large may cause measurable harm to the individual research participants. To address these situations, the Belmont Report expresses that the protection of beneficence extends not only to the overall research enterprise but also to individual research participants. *Id.* at Part B(2). Beneficence can be stated as complements: "(1) do not harm and (2) maximize possible benefits." *Id.* Beneficence is stated easily enough; however, actual practice demonstrates that beneficence is sometimes difficult.

28. Abuses in human subject research are not new. See generally JAMES H. JONES, BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT (1993) (explaining that federally funded researchers informed African-American men that they would be treated for their condition; however, researchers clearly intended to withhold treatment to study the extended effects of syphilis); U.S. DEP'T OF ENERGY, ASSISTANT SEC'Y FOR THE ENV'T, SAFETY, & HEALTH, HUMAN RADIATION EXPERIMENTS: THE DEPARTMENT OF ENERGY ROADMAP TO THE STORY AND RECORDS (1995), available at <http://www.eh.doe.gov/ohre/roadmap/roadmap/index.html> (describing de-classified information that reveals that many research participants did not consent to federally funded research on the effects of radiation exposure).

29. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

30. 45 C.F.R. §§ 160, 164 (2005).

31. National Research Act of 1974, Pub. L. No. 93-348, § 474, 88 Stat. 343 (codified as amended in scattered sections of 5, 39, and 42 U.S.C.).

posed research protocols³² and must review and approve all human subject research conducted within a research institution.³³ Since the adoption of federal legislation related to human subject protections, each federally funded institution that chooses to conduct human-subject research must maintain an IRB and create an environment that “supports the highest ethical standards” for the protection of human subjects.³⁴ In fact, the IRB is the only entity “in the research process that exist[s] solely to protect human subjects.”³⁵

IRBs are regulated by both the U.S. Department of Health and Human Services (HHS) and the U.S. Food and Drug Administration (FDA).³⁶ HHS regulations, often termed the Common Rule, apply to federally funded human subject research,³⁷ whereas FDA regulations apply to research studying drugs, devices, and other products regulated by the FDA, regardless of federal funding status.³⁸ With respect to IRB functions, the Common Rule and the FDA regulations are parallel.³⁹

32. Protocol is defined as “[a] precise and detailed plan for the study of a bio-medical problem or for a regimen of therapy.” *STEDMAN’S MEDICAL DICTIONARY* 1466 (27th ed. 2000).

33. HHS IRB GUIDEBOOK, *supra* note 6, at 5-7; *see also* Peckman, *supra* note 21, at 17.

34. Peckman, *supra* note 21, at 17.

35. Mark R. Yessian, *Reflections from the Office of the Inspector General, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION*, *supra* note 21, at 9, 10. To be effective in their task of protecting human subjects, IRBs must function independently of the pressures of the research institution and retain the “ultimate authority for the approval of research with human subjects,” which is not always the case. Peckman, *supra* note 21, at 19.

36. 45 C.F.R. § 46 (2005) (HHS: Informed Consent and IRBs); 21 C.F.R. § 50 (2006) (FDA: Informed Consent); 21 C.F.R. § 56 (2006) (FDA: IRBs).

37. 42 U.S.C. § 289(a) (2000) (IRB approval required for all research utilizing federal funds).

38. *See generally Appendix B: Significant Differences in FDA and HHS Regulations for the Protection of Human Subjects, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION*, *supra* note 21, at 515.

39. For example, each IRB consists of at least five individuals with at least one member who has a primary interest in science and at least one member who has a primary interest in a non-scientific area. 45 C.F.R. § 46.107; 21 C.F.R. § 56.107. It is worth noting that the “non-scientific” position is not defined and may be filled by a member of the hospital administration (risk management, quality assurance, or compliance) or perhaps an attorney not affiliated directly with the hospital. 45 C.F.R. § 46.107; 21 C.F.R. § 56.107. An IRB may also invite individuals with specialized training, knowledge, or expertise to assist with reviews that require additional perspective. 45 C.F.R. § 46.107; 21 C.F.R. § 56.107.

B. *Informed Consent*

Essentially, an IRB reviews research protocols⁴⁰ and ensures that informed consent documents provide research participants with material information.⁴¹ Informed consent, in the context of medical research, requires that research participants receive a “description of any reasonably foreseeable risks or discomforts to the subject.”⁴² An informed decision cannot be made unless information regarding the “purpose, methods, risks, benefits, and alternatives to the [proposed] research” is disclosed.⁴³ The Common Rule and FDA regulations addressing informed consent require that “such consent [be obtained] only under circumstances that provide the prospective subject . . . sufficient opportunity to consider whether or not to participate and that . . . the possibility of coercion or undue influence [be minimized].”⁴⁴ Informed consent, operating effectively, ensures that individuals make an informed decision, allowing the individual to determine whether they will participate in a clinical trial.

Modern practice requires uniformity in research trials. Study sponsors, such as pharmaceutical corporations or device manufacturers, submit protocols and informed consent forms directly to the IRB without significant preparation or revision by the medical researchers or physicians who actually conduct and supervise the trials.⁴⁵ After all, most medical research is conducted at multiple research sites,⁴⁶ and studies must be conducted uniformly to promote efficiency and reliability of research data.⁴⁷ However, the presence of multi-site research does not excuse an IRB from its primary responsibility of ensuring that research participants are fully informed of all material risks.⁴⁸

40. 45 C.F.R. §§ 46.108-.111; 21 C.F.R. §§ 56.108-.111.

41. 45 C.F.R. § 46.116; 21 C.F.R. § 50.20.

42. 45 C.F.R. § 46.116.

43. Ezekiel J. Emanuel et al., *What Makes Clinical Research Ethical?*, 283 JAMA 2701, 2706 (2000).

44. 21 C.F.R. § 50.20.

45. Sanford Chodosh, *A Unified Human-Research Protection Program*, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION, *supra* note 21, at 13, 14.

46. Kubiak, *supra* note 16, at 788. Research centers consist of “hospitals, academic centers, managed care organizations, federal and state government agencies, and corporations, including pharmaceutical and device manufacturers.” *Id.*

47. Chodosh, *supra* note 45, at 15.

48. *Id.*

C. Health Insurance Portability and Accountability Act⁴⁹

When research requires the collection of medical data, “federal regulations unquestionably require that . . . IRB[s] approve the conditions for access to . . . medical record[s] and the procedures for protecting confidentiality.”⁵⁰ Title II of HIPAA focuses on protecting the health information that health care institutions obtain and store. The administrative simplification provisions in Title II require HHS to establish national standards for electronic health care transactions.⁵¹ The regulations associated with HIPAA that protect personally identifiable PHI⁵² are commonly referred to as the Privacy Rule.

The Privacy Rule encompasses more than just the requirements of the Common Rule and FDA regulations; however, in medical research, where both the Privacy Rule and the Common Rule or FDA regulations apply, the stricter requirements of each must be followed.⁵³ The Privacy Rule requires that research participants authorize, in writing, the disclosure of their PHI.⁵⁴ Medical researchers, however, often resent implementing provisions of HIPAA and its associated regulations.⁵⁵

Written authorization is most commonly sought using a Patient Authorization Form, also referred to as a Privacy Rule Authoriza-

49. Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C.).

50. Robert J. Amdur, *The Limits of Institutional Review Board Authority*, in INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION, *supra* note 21, at 30, 31.

51. See HHS, Ctrs. for Medicare & Medicaid Servs., Overview, <http://www.cms.hhs.gov/HIPAAGenInfo> (last visited Feb. 18, 2007).

52. 45 C.F.R. § 160.103 (2005) (defining individually identifiable health information as “any information, including demographic information collected from an individual, that . . . is created or received by a health care provider . . . [and] identifies the individual; or . . . with respect to which there is a reasonable basis to believe that the information can be used to identify the individual”).

53. Ellen Holt, *The HIPAA Privacy Rule, Research, and IRBs*, APPLIED CLINICAL TRIALS, June 2003, at 48, 50; available at <http://www.actmagazine.com/appliedclinicaltrials/data/articlestandard/appliedclinicaltrials/222003/58533/article.pdf>.

54. 45 C.F.R. § 160.103 (“Disclosure means the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information.”); 45 C.F.R. § 164.508 (requiring *written* authorization as a general rule). *But see* 45 C.F.R. § 164.512 (stating that authorization is not required when use and disclosure is required by law, public health, abuse or domestic violence, health oversight, judicial or administrative proceedings, law enforcement, crimes on premises, and emergencies).

55. Mary Durham, *How Research Will Adapt to HIPAA: A View from Within the Healthcare Delivery System*, 28 AM. J.L. & MED. 491, 492 (2002).

tion.⁵⁶ However, authorization is distinct from informed consent. Informed consent seeks an “individual’s [permission] to participate in the research [itself,]” whereas an authorization represents an individual’s permission to use or disclose PHI for research or medical purposes.⁵⁷ As discussed earlier, an informed consent form describes the research study and its anticipated risks and benefits.⁵⁸ Not insignificant to the informed consent requirements, however, is the duty to describe the methods used to protect the privacy of records.⁵⁹

Although the Privacy Rule requires that authorizations contain specific core elements,⁶⁰ it does not require that an authorization be separate from informed consent.⁶¹ An authorization, therefore, may be combined with an informed consent document.⁶² If an informed consent document is combined with an authorization to disclose PHI, the Common Rule and FDA regulations “require IRB review of the combined document.”⁶³ Thus, the IRB has the dual role of reviewing not only the research protocol contained in the informed consent, but also the authorization.⁶⁴ The Privacy Rule and IRBs both afford protection to research participants; however, an understanding of current practices in medical research is necessary to determine whether these protections are sufficient.

56. NAT’L INST. OF HEALTH, NIH PUBL’N. NO. 04-5529, HIPAA AUTHORIZATION FOR RESEARCH 1 (2004) [hereinafter HIPAA AUTHORIZATION FOR RESEARCH], available at <http://privacyruleandresearch.nih.gov/pdf/authorization.pdf> (listing core elements of research authorization and sample authorizations).

57. *Id.* at 1, 2-4.

58. *Id.*; see *supra* Part II.B.

59. See HIPAA AUTHORIZATION FOR RESEARCH, *supra* note 56.

60. 45 C.F.R. § 164.508 (2005) (stating that an authorization form must contain, among other items, identification of the PHI to be used or disclosed, identification of the persons authorized to make the use or disclosure, identification of the authorized recipients of the PHI, a description of each purpose for use or disclosure, an expiration date, and a statement related to the potential that the PHI is subject to re-disclosure by the recipient).

61. *Id.*

62. HIPAA AUTHORIZATION FOR RESEARCH, *supra* note 56, at 1.

63. *Id.*

64. Even if the informed consent and authorization remain separate, “[i]t is likely that IRBs will be primarily involved in acting on requests for waiver or alteration of the Authorization requirement.” NAT’L INST. OF HEALTH, NIH PUBL’N NO. 03-5428, INSTITUTIONAL REVIEW BOARDS AND THE HIPAA PRIVACY RULE 2 (2003), available at http://privacyruleandresearch.nih.gov/pdf/IRB_Factsheet.pdf. Since the authorization form must comply with core requirements, the eventual review of authorizations by independent review boards, such as an IRB or privacy board, is quite foreseeable. Holt, *supra* note 53, at 48.

III. CURRENT PRACTICES IN MEDICAL RESEARCH INCREASE DISCLOSURE OF PHI

Technology is prevalent in the practice of medicine⁶⁵ and healthcare institutions continue to aggressively pursue technological advancements in order to increase efficiency, facilitate worldwide communication, and reduce costs.⁶⁶ With the increasing need and ability to pass information quickly between agencies and health care entities, medical research requires increased privacy protection.⁶⁷

A. *Technology in Medical Research*

The most common operations using the protected health information of research participants are labeled “backroom,” or administrative, operations and include billing, insurance claims processing, and transcription.⁶⁸ Medical billing and transcription involve relatively simple technologies, such as the Internet and customized word processing and spreadsheet software.⁶⁹ Transcription of medical reports is big business, generating revenues in excess of \$15 billion per year.⁷⁰ However, the use of more sophisticated technology by medical researchers for non-administrative purposes, such as remote monitoring of a patient’s vital statistics, is now also prevalent.

Disease management is the most rapidly growing sector in health care and includes active monitoring of patient progress and coordination of care between multiple researchers.⁷¹ Newer technology enables a physician or researcher to remotely monitor health information, such as a patient’s heart rate.⁷² Advanced technologies, such as mobile-to-mobile or machine-to-machine (M2M)

65. See, e.g., Thomas R. McLean, *The Offshoring of American Medicine: Scope, Economic Issues and Legal Liabilities*, 14 ANN. HEALTH L. 205, 234-35 (2005) (describing mobile to mobile technology in patient monitoring and health care instructions).

66. Barbara Williams, *Virtual Web Wave of the Future: Integration of Healthcare Systems on the Internet*, 76 N.D. L. REV. 365, 365 (2000).

67. June Mary Zekan Makdisi, *Commercial Use of Protected Health Information Under HIPAA’s Privacy Rule: Reasonable Disclosure or Disguised Marketing?*, 82 NEB. L. REV. 741, 743 (2004).

68. McLean, *supra* note 65, at 229.

69. *Id.* at 231.

70. *Id.* at 230. Most aspects of medicine and research require the documentation of altered medical conditions, adjusted treatment orders, and billing adjustments based on those changes. *Id.*

71. *Id.* at 233.

72. *Id.* at 234-35.

devices, are becoming essential in monitoring medical conditions.⁷³ Also essential is the ability to perform administrative functions efficiently at low cost.

B. *Business Associates*

Although unknown to most research participants, it is common practice in the medical research community to use what are known as “business associates” to perform certain administrative operations in an effort to reduce costs or to streamline administrative processes.⁷⁴ A “business associate” is defined as a business or individual that contracts to perform administrative functions or services that require the disclosure of PHI.⁷⁵ HIPAA requires that the health care or research institution enter into an agreement with the business associate to safeguard identifiable health information used by or disclosed to the business associate.⁷⁶ Under a business associate contract, a business associate steps into the shoes of the health care institution and is, therefore, not permitted to use or disclose health information in any way that would violate the Privacy Rule.⁷⁷

Further cost savings in medical research are realized by using offshore business associates. Because of the economic incentives associated with “offshoring,” an increasing number of administra-

73. *Id.* Wireless communication devices, such as snap-on mobile phone accessories, are able to monitor heart rates and provide that information, by way of a radio transmitter, to a remote location where a medical researcher can analyze the data in real time using another mobile device, such as a personal digital assistant. See SONY ERICSSON, M2M: EXPANDING WIRELESS POSSIBILITIES 10 (2005), available at <http://www.sonyericsson.com/spg.jsp?cc=us&lc=en&ver=4002&template=ph1&zone=ph> (follow “M2M Brochure” link); see also Sony Ericsson, Facilitate Remote Care for Patients, http://www.sonyericsson.com/spg.jsp?cc=us&lc=es&ver=4002&template=pa1_5&zone=pa&prid=13&rid=15&lm=pa1&cid=140 (describing health care applications for M2M technology) (last visited Feb. 18, 2007).

74. HHS OFF. OF CIVIL RIGHTS, SUMMARY OF THE HIPAA PRIVACY RULE 3 (2003) [hereinafter SUMMARY OF THE HIPAA PRIVACY RULE], available at <http://www.hhs.gov/ocr/privacysummary.pdf>.

75. 45 C.F.R. § 160.103 (2005). A business associate may be located in the same town or in an international location, so long as the associate is not considered a member of the related health care entity. *Id.*

76. 45 C.F.R. §§ 164.502(e), 164.504(e).

77. SUMMARY OF THE HIPAA PRIVACY RULE, *supra* note 74, at 3. HHS provides sample business associate agreements to assist health care entities. HHS Off. of Civil Rights, Sample Business Associate Contract Provisions, <http://www.hhs.gov/ocr/hipaa/contractprov.html> (last visited Feb. 18, 2007). HIPAA requires that health care institutions, and their business associates, maintain reasonable and appropriate safeguards to ensure the integrity and confidentiality of personal health information. Jurevic, *supra* note 20, at 815.

tive operations are being sent abroad for completion.⁷⁸ With the increase in medical monitoring comes an expanded reliance on outsourcing, resulting from the need to coordinate medical personnel, data, data analysis, and feedback.⁷⁹ In turn, an increased reliance on outsourcing expands the likelihood that a research participant's PHI will be disseminated to unauthorized recipients.⁸⁰

C. *Mishandled Health Information: The Risk of Using Business Associates*

The very nature of electronic medical records increases the risk that PHI will be mishandled or disclosed to an unauthorized recipient.⁸¹ Electronic records combine data stored in multiple computer systems; thus, large amounts of data can be accessed from a single location.⁸² Medical records contain a wealth of personal information, including an individual's family history, genetic test results, history of any prior drug use, and treatment of any sexually transmitted diseases.⁸³ Unfortunately, electronic storage of health records allows cross-referencing of medical data in ways not originally intended, permitting easy and inexpensive searching, data mining, and distribution of PHI.⁸⁴ Yet, despite the availability of information and the ease of filtering and sorting information, more

78. McLean, *supra* note 65, at 212-13. Offshoring is beneficial where a favorable wage-benefit differential exists, where cost effective telecommunications are present, and where numbers of educated, English-speaking individuals are concentrated in other countries. *Id.* at 212-15. Using these factors to identify favorable areas of the world to satisfy the needs of the medical research community, China, Russia, and India are "merging rapidly into the global labor market" for outsourcing. *Id.* at 215.

79. *Id.* at 233-37.

80. Barbara Von Tigerstrom, *Protection of Health Information Privacy: The Challenges and Possibilities of Technology*, 4 APPEAL 44, 46 (1998) (finding the number of uses of medical information to mean that the "widespread dissemination of personal information is inevitable, and this makes it difficult to control the use of such information").

81. Jurevic, *supra* note 20, at 812.

82. *Id.*

83. *Id.* at 808.

84. *Id.* at 812. For example, a banker who obtains access to state health records improperly secured (and therefore mishandled) may cross-reference a list of patients known to have cancer with the bank's loan register so that the loans of patients with cancer may be called in for immediate payment. *Id.* at 809 (citing E. Bartlett, *RMS Need to Safeguard Computerized Patient Records to Protect Hospitals*, 15 HOSP. RISK MGMT. 129, 132 (1993)).

established threats continue to expose medical information to unauthorized and unintended recipients.⁸⁵

The most common threat to health information privacy continues to be sabotage by disgruntled employees, including destruction of hardware and software, purposeful entering of incorrect data, deletion or alteration of data, or the planting of “logic bombs”—programs that destroy data or computer applications.⁸⁶ Human error, such as the loss of laptop computers used by healthcare workers and medical researchers, also leads to the disclosure of PHI.⁸⁷ Perhaps the most obvious, and egregious, example of disclosure of PHI to unauthorized sources is the selling of data contained in large databases.⁸⁸ In addition, researchers can encounter scenarios in which an offshore business associate threatens to post PHI on the Internet (a clear violation of HIPAA) in order to force resolution of a contract dispute.⁸⁹

Revisiting Alexis

Dr. Brohman chose to use a mobile device to monitor Alexis’s symptoms during the course of the clinical trial because GenoPharm desired to develop a drug remedy targeting specific symptoms of Huntington’s disease. The hospital hosting Dr. Brohman’s clinical

85. *Id.* at 809 (citing E. Bartlett, *RMS Need to Safeguard Computerized Patient Records to Protect Hospitals*, 15 HOSP. RISK MGMT. 129, 129-40 (1993)) (providing multiple examples of breaches of privacy with respect to medical records).

86. *Id.* at 809-12. Additional threats include physical problems with technology, such as outdated or fragile equipment, or physical theft by employees. *Id.* at 812. Hackers, who gain access to computer systems and browse for valuable information, may also gain access to PHI. *Id.* Trojan horses, programs that appear to perform a valid function but operate underneath to uncover confidential information such as network passwords or access paths to restricted data, can also be planted by hackers or disgruntled employees, without a noticeable impact on system performance. *Id.*

87. Carol Ann Quinsey, *Information Security—An Overview*, AM. HEALTH MED. INFO. MGMT. ASS’N, Aug. 2003, available at http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_021875.hcsp?dDocName=bok1_021875 (replacing Mary D. Brandt, *Information Security—An Overview*, AM. HEALTH MED. INFO. MGMT. ASS’N, June 1996).

88. Bob Sullivan, *Choice Point to Pay \$15 Million over Data Breach*, MSNBC.COM, Jan. 26, 2006, available at LEXIS. ChoicePoint, Inc., a data warehouse, settled charges for failing to protect consumers’ confidential personal information. *Id.* ChoicePoint sold information on 163,000 individual consumers and settled with the Federal Trade Commission to pay a \$10 million fine. *Id.* In addition, ChoicePoint will spend \$5 million to establish a fund to aid victims. *Id.* To date, this is the largest penalty imposed for failing to properly secure data. *Id.*

89. McLean, *supra* note 65, at 232 (finding that this scenario experienced by the University of California at San Francisco was not an isolated event, leading six states to contemplate banning outsourcing to avoid such situations).

trial entered into a business associate contract with an offshore company to provide administrative and patient monitoring services.⁹⁰ Alexis believed her medical information would remain in the hospital. She was unaware that her PHI would be outsourced to business associates. Because privacy of her medical condition was important to her, Alexis would not have participated in the clinical trial, had she been adequately informed.

IV. WHEN THE MEDICAL COMMUNITY FAILS TO ADEQUATELY INFORM RESEARCH PARTICIPANTS, A LEGAL STANDARD OF LIABILITY MUST BE APPLIED

After examining privacy interests in personal health information, this Part analyzes the current protections provided by the medical research community. This Part also argues that the protections provided by the medical research community, such as informed consent or IRB oversight of medical research, are insufficient. Therefore, applying legal standards of liability is necessary to protect research participants.

A. *Privacy Rights in Medical Records*

The Supreme Court addressed privacy in integrated medical systems in *Whalen v. Roe*.⁹¹ In *Whalen*, a state statute permitted the state to track the distribution of certain drugs by obtaining copies of prescriptions that contained personal information of those patients receiving them.⁹² In this case, the personal information was kept secure on an off-line computer that was locked in a room surrounded by a wire fence and monitored by an alarm system.⁹³ The Supreme Court recognized the various safeguards used to control access to personal information⁹⁴ and concluded that, in this case, no

90. See, e.g., PORTECK, SOLUTIONS FOR PROVIDERS 2, available at http://www.computedbilling.com/brochures/Providers_Brochure.pdf (last visited Feb. 18, 2007) (listing available services, including assisting clients with “process improvements, technology automation and offshore implementation”); Porteck, Contact Us, <http://www.porteck.com/contactus.htm> (last visited Feb. 18, 2007) (listing offices both in the United States and India); see also MedValue Offshore Solutions, Inc., Medical Claims Processing—Claim Indexing—HCFA Data Entry, <http://medvaluebpo.com> (last visited Feb. 18, 2007) (advertising processing and processing support services, including “HIPAA Compliance”).

91. *Whalen v. Roe*, 429 U.S. 589 (1977).

92. *Id.* at 592-94.

93. *Id.* at 594.

94. *Id.* at 607 (Brennan, J., concurring).

privacy interests were significantly infringed by the state statute.⁹⁵ However, the Court recognized a “threat to privacy implicit in the accumulation of vast amounts of personal information in [massive] computerized . . . files.”⁹⁶ The Court made clear that it was not required to decide the privacy issues arising specifically from unwarranted disclosures of private health information, whether intentional or unintentional.⁹⁷ In a concurring opinion, Justice Brennan recognized that an individual’s interest in preventing disclosure of personal information is a privacy right, even though it was not seriously invaded in the specific factual circumstances presented in *Whalen*.⁹⁸ Justice Brennan could not say, however, that different factual circumstances would not demonstrate a need for restrictions on the collection and disclosure of personal health information.⁹⁹ Rather, he recognized that the “central storage and easy accessibility of computerized data vastly increases the potential for abuse.”¹⁰⁰

As discussed above, significant technological advancements, enabling the efficient and widespread dissemination of medical records, have occurred since the Court decided *Whalen* in 1977.¹⁰¹ Therefore, it is unlikely that *Whalen* will shield the unauthorized disclosure of PHI from being considered a violation of privacy. In fact, Justice Brennan stated that broad dissemination would “clearly implicate constitutionally protected privacy rights.”¹⁰² Ultimately, *Whalen* left open the issue of the impacts of expanded technology on broad circulation of PHI.

In addition, the Privacy Rule¹⁰³ provides that individuals have the “right to adequate notice of the uses and disclosures” of their PHI.¹⁰⁴ The description of the disclosure of PHI must include sufficient detail so that a research participant is aware of both required

95. *Id.* at 597 (majority opinion) (finding that states are given “broad latitude in experimenting with possible solutions to problems of vital concern,” such as misuse of dangerous drugs).

96. *Id.* at 605.

97. *Id.* at 605-06.

98. *Id.* at 606 (Brennan, J., concurring).

99. *Id.* at 607.

100. *Id.*

101. *See supra* Part III.A.

102. *Whalen*, 429 U.S. at 606 (Brennan, J., concurring).

103. 45 C.F.R. §§ 160, 164 (2005).

104. Stacey A. Tovino, *The Use and Disclosure of Protected Health Information for Research Under the HIPAA Privacy Rule: Unrealized Patient Autonomy and Burdensome Government Regulation*, 49 S.D. L. REV. 447, 474 (2003) (quoting 45 C.F.R. § 164.520(a)(1)).

and permitted disclosures.¹⁰⁵ The requirement to inform an individual of the disclosures of PHI further supports the notion of a right to privacy in personal health information.¹⁰⁶

Further evidence of this right can be found both in the requirements of HIPAA and the doctrine of informed consent. After all, HIPAA establishes an authorization requirement to inform research participants of their privacy rights as well as the risks associated with the use and disclosure of PHI.¹⁰⁷ Informed consent only requires that individuals understand the potential risks of participation in the research protocol.¹⁰⁸ As previously discussed, authorization focuses on “making patients clearly understand how their information will be used for research activities, [and] the risk that [this] information could be re-disclosed by researchers and other recipients.”¹⁰⁹

B. *Authorization Forms Fail to Adequately Inform Research Participants of PHI Disclosure Risks*

If privacy notices describing the general use and disclosure of a research participant’s PHI are too lengthy, or if the sections containing research-specific disclosures are too abbreviated, an individual is unlikely to know whether his or her PHI will be used or disclosed while participating in the clinical trial.¹¹⁰ The Privacy Rule requires that research authorizations contain certain elements and statements.¹¹¹ For example, the name or identity of those who are authorized to use a research participant’s PHI must be disclosed.¹¹² Researchers must also identify potential risks associated with disclosures of PHI to individuals or entities outside the research institution, because those subsequent disclosures may no longer be protected by the Privacy Rule.¹¹³ Alarming, a general statement to the effect that PHI may no longer be protected once disclosed by a health care institution or research program is suffi-

105. 45 C.F.R. § 164.520(b)(1)(ii)(D).

106. In addition, the term “Privacy Rule” may, by its name, stress the recognition and importance of a *privacy* right and conclude that its provisions are aimed to protect a patient’s, or research participant’s, privacy interest in identifiable health information.

107. See *supra* Part II.C. (explaining requirements of authorization under HIPAA).

108. See *supra* Part II.B. (describing the doctrine of informed consent).

109. Tovino, *supra* note 104, at 474.

110. *Id.* at 476.

111. 45 C.F.R. § 164.508(c) (2005).

112. *Id.* § 164.508(c)(1)(ii).

113. *Id.* § 164.508(c)(2)(iii).

cient to satisfy the Privacy Rule's requirement to warn of the re-disclosure risk.¹¹⁴ HIPAA does not require researchers to explain to patients or research participants the associated risks of re-disclosure or to identify those who may actually receive re-disclosed PHI.

Examining a sample authorization form provided by HHS raises serious doubt as to whether a prospective research participant can accurately gauge the risks of PHI disclosure when viewed in light of actual practices in the medical research environment.¹¹⁵ The following language has been deemed acceptable by HHS: "Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission."¹¹⁶ The language eviscerates the entire concept of privacy to the extent that the text appears to articulate privacy rights, only to take them away.

Further confusion arises because some individual research institutions use separate authorization forms while others combine the authorization with an informed consent form.¹¹⁷ In either event, authorization forms, or portions of consent forms seeking authorization, "fumble when attempting to convey [potential loss of privacy caused by subsequent disclosures] . . . and the patient reading the form may fail to understand that the recipient of her information is not required by the Privacy Rule to protect her information."¹¹⁸

General language, such as "reasons we might use or share your health information are: [t]o do the research described above [and] . . . [f]or treatment, payment, or health care operations," does not accurately inform a prospective research participant of actual dis-

114. Tovino, *supra* note 104, at 466 (commenting that HIPAA merely requires that the authorization form contain re-disclosure language).

115. HIPAA AUTHORIZATION FOR RESEARCH, *supra* note 56, at 2.

116. *Id.* However, case law is absent to determine whether reliance on HHS form language shields entities from liability stemming from re-disclosure of PHI. See PARTNERS HEALTHCARE SYSTEM, GENERAL CONSENT FORM TEMPLATE 8-9 (2005), available at <http://healthcare.partners.org/phsirb/consfrm.htm> (follow the "General Consent Form Template" hyperlink) ("Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside of Partners, we cannot promise that it will remain private.").

117. Clinical research programs at Massachusetts General Hospital, for example, use a single consent and authorization form. *E.g.*, PARTNERS HEALTHCARE SYSTEM, *supra* note 116.

118. Tovino, *supra* note 104, at 467.

closure practices, especially those involving business associates in offshore locations.¹¹⁹ Authorization and consent forms that use terminology such as “research purposes” to encompass actual practices of disclosing PHI neither inform nor warn a prospective research participant about known risks of mishandled PHI inherent in medical research. When medical researchers fail to adequately inform participants of risks, a negligently injured plaintiff commonly looks to the doctrine of informed consent to establish that researchers owed the plaintiff a duty of care.

C. *Informed Consent in the Research Community*

In *Moore v. Regents of the University of California*, the Supreme Court of California expanded the doctrine of informed consent when it held that “a physician has a . . . duty to disclose all information [that is] material to the *patient’s* decision,” and all information “that may affect the *physician’s* professional judgment.”¹²⁰ In *Moore*, the patient-subject was instructed to return to the hospital to provide additional tissue samples.¹²¹ The plaintiff complied, believing that such samples were necessary in the ordinary course of his leukemia treatment.¹²² The plaintiff had no reason to believe that the additional tissue would be used solely to benefit researchers in making a profit.¹²³

By requiring informed consent in instances that might affect a researcher’s professional judgment, *Moore* demonstrates an apparent willingness to expand informed consent beyond the physical risks associated with the trial to include harms to dignity and economic interests. Failure to disclose such interests might expose those involved in medical research to either a lack of consent claim, or allegations of breach of the physician’s fiduciary duty to inform the patient-subject of material risks inherent in the research experiment.¹²⁴ Arguably, a physician’s professional judgment may not affect the risk of a research participant’s PHI being mishandled.

119. PARTNERS HEALTHCARE SYSTEM, *supra* note 116, at 9-10 (explaining that those people outside of the institution who may access PHI are “[p]eople or groups that we hire to do certain work for us, such as data storage companies, our insurers, or our lawyers[;] [f]ederal and state agencies . . . [t]he sponsor(s) of the research study, and people or groups it hires to help perform this research study”).

120. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (emphasis added).

121. *Id.* at 481.

122. *Id.*

123. *Id.*

124. *Id.* at 483.

Nonetheless, a non-physical risk can still be material to a patient's decision to participate in research and should therefore be disclosed.

D. *Establishing a Legal Basis to Protect Research Participants*

In addition to the *Moore* decision, several other courts have addressed privacy rights in the context of medical research.¹²⁵ These cases demonstrate that a legal standard of liability is needed to supplement the medical research community's continued reliance on informed consent and IRB oversight. In *Greenberg v. Children's Hospital Research Institute*, researchers obtained patents for genes studied in the research of Canavan's Disease, a relatively rare, but fatal, inherited brain disorder.¹²⁶ Parents allowed tissue and autopsy samples to be taken from their children who were afflicted with the disorder; however, the parents did not know that the researchers intended to commercialize their research results.¹²⁷ The court held that researchers have no duty to disclose financial or commercial conflicts of interest and that no fiduciary duty exists between "researchers" and "research participants."¹²⁸ The court reasoned that the researchers were merely recipients of tissue donations, classifying the research participants as "donors" who lacked a special relationship to the researchers.¹²⁹ The court further reasoned that since the parents did not enjoy a special relationship with researchers, no fiduciary duty existed between the researchers and the families.¹³⁰

Greenberg is distinguishable from many medical research situations. The situation in *Greenberg* is best described as a "research collaboration gone sour" and does not reflect the typical research relationship.¹³¹ The parents in *Greenberg* provided financial support and assisted researchers in identifying similarly situated families and recruiting them to the research trial.¹³² These parents contributed efforts toward the research itself; so, in the court's eyes, the parent-plaintiffs were more appropriately classified as research

125. See, e.g., *Greenberg v. Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1067 (S.D. Fla. 2003); *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 811-12 (Md. 2001); *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990).

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

127. *Id.* at 1068.

128. *Id.* at 1070-72.

129. *Id.* at 1070-71.

130. *Id.* at 1070.

131. *Id.* at 1066.

132. *Id.* at 1067.

collaborators.¹³³ Based on this classification, the court suggested that the parents could have protected their interests in preventing the commercialization of research findings.¹³⁴ The *Greenberg* decision appears to excuse the exploitation of research participants who have donated themselves, their tissues, or their financial resources for the advancement of science.¹³⁵ The case would create a dangerous precedent if its holding were to extend to all medical research situations.

In contrast, a research participant who is continually monitored using disease management technology or who is in an ongoing relationship with researchers must be treated differently. Unlike the *Greenberg* and *Moore* participants, continually monitored participants make an ongoing contribution to the clinical trial, and so they cannot be aptly described as mere tissue donors. Furthermore, unlike the parents in *Greenberg*, these participants are directly affected research participants and are not accurately classified as research collaborators since they do not assist in recruiting participants or contribute financial resources. Most research participants, like continually monitored participants, are presumably not in a position to protect their financial or commercialization interests from the competing interests of medical research sponsors.

The Court of Appeals of Maryland¹³⁶ has also addressed informed consent in research. *Grimes v. Kennedy Krieger Institute* involved a Johns Hopkins University research program that measured the effects of various lead abatement strategies in certain classes of dated homes undergoing partial lead modifications.¹³⁷ The effectiveness of the lead abatement was measured by analyzing lead levels in the bloodstream of otherwise healthy children over the course of two years.¹³⁸ Landlords received public funding, in the form of grants or loans, and were encouraged to rent their dwellings to families with young children.¹³⁹ The consent agree-

133. *Id.* at 1072-73.

134. Kevin C.J. Oberdorfer, Note, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 GEO. L.J. 365, 366 (2004).

135. See Christopher Jackson, *Learning From the Mistakes of the Past: Disclosure of Financial Conflicts of Interest and Genetic Research*, 11 RICH. J.L. & TECH. 4, 24 (2004).

136. The Court of Appeals of Maryland is the highest court in the State. See Court of Appeals of Maryland, <http://www.courts.state.md.us/coappeals>.

137. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 811-12 (Md. 2001).

138. *Id.* at 812.

139. *Id.*

ment used by researchers did not explain that the research was designed to measure lead abatement or that the “researchers intended that the children be the canaries in the mines.”¹⁴⁰

Apparently, the IRB at Johns Hopkins University found nothing wrong with the proposed research protocol or the fact that research participants were not informed of the risks involved.¹⁴¹ In fact, despite the requirement that an IRB ensure the safety of human research participants, the IRB at Johns Hopkins University assisted researchers in circumventing safety requirements.¹⁴² *Grimes* illustrates that IRBs may not offer adequate protection—the IRB was able, but apparently unwilling, to protect research participants. Rather, it looked beyond the interests of research participants to assist researchers.

The IRB at the University of Pennsylvania has also been the target of criticism for its faulty protection of participants in a genetic research experiment.¹⁴³ In 1999, Jesse Gelsinger participated in a genetic research experiment studying the effects of a liver disease treatment.¹⁴⁴ Although Gelsinger’s physicians were successfully managing his condition, he consented, at the age of eighteen, to participate in a gene therapy experiment, allegedly without being properly informed of its risks, which resulted in a fatal immune system reaction.¹⁴⁵ Gelsinger did not expect the research to produce a direct benefit; after all, his disease was under control.¹⁴⁶ Even though the *Gelsinger* matter eventually settled out of court, the impact on the medical research community has been staggering.¹⁴⁷ Informed consent had yielded to the pressures of research, not in an obscure research institution or foreign country lacking protections

140. *Id.* at 813. Historically, canaries were used to determine whether dangerous levels of toxic gases existed in mines because canaries are particularly susceptible to certain toxic gases. *Id.*

141. *Id.*

142. *Id.* at 813-14.

143. Complaint—Civil Action at ¶¶ 86-93, *Gelsinger v. Trs. of the Univ. of Pa.*, No. 000901885 (Ct. Com. Pl., Philadelphia County, Sept. 18, 2000), available at <http://www.sskrplaw.com/links/healthcare2.html>; see also Paul Gelsinger, *Forward* to INSTITUTIONAL REVIEW BOARD: MANAGEMENT AND FUNCTION, *supra* note 21, at xv, xviii.

144. See Complaint—Civil Action at ¶ 1, *Gelsinger v. Trs. of the Univ. of Pa.*, *supra* note 143.

145. *Grimes*, 782 A.2d at 839.

146. *Gelsinger*, *supra* note 143, at xv, xviii.

147. The FDA halted eight other gene therapy research projects at other institutions after discovering “a number of serious problems in the . . . informed consent procedures and . . . a lapse in the researchers’ ethical responsibilities to experimental subjects.” *Grimes*, 782 A.2d at 838.

for human research participants, but at a highly prestigious research institution in the United States.¹⁴⁸ As the facts in *Grimes* and the situation leading to Jesse Gelsinger's death illustrate, the "scientific and medical communities cannot . . . assume sole authority to determine ultimately what is right and appropriate."¹⁴⁹

Revisiting Alexis

Alexis feels misled. She intended to help scientists and physicians study Huntington's disease. Instead, she was seriously and negatively affected by the disclosure of her PHI. Because the medical community's reliance on the doctrine of informed consent and IRB oversight has failed to adequately protect Alexis, she now must seek protection through the legal system.

V. PROTECTING PARTICIPANTS BY HOLDING MEDICAL RESEARCHERS LIABLE

Legal remedies can compensate research participants for the effects of the unauthorized disclosure of PHI. However, for there to be an entitlement to a legal remedy, a duty must first exist between researchers and research participants. A discussion of legal duty is presented below. This Part also identifies those individuals or entities that are subject to liability for failing to protect research participants by not adequately informing them of PHI disclosure practices and risks.

A. Establishing a Duty Between Researchers and Participants

Before a research participant may seek a legal remedy for harm suffered as a result of the disclosure of PHI, the participant must first establish that the defendant-researcher owed him or her a duty.¹⁵⁰ Where a researcher provides medical treatment to a research participant, the researching physician also has a doctor-patient relationship with the research participant, and therefore owes a duty of care to the patient-subject.¹⁵¹ A medical researcher, even if not a participant's treating physician, may still owe a duty of care to the research participant as the research participant "looks to the

148. *Id.* at 839 (citing Jeffrey H. Barker, *Human Experimentation of a Merciless Epoch*, 25 N.Y.U. REV. L. & SOC. CHANGE 603, 617 (1999)).

149. *Id.* at 817.

150. Noah, *supra* note 2, at 208.

151. *Id.*

investigator as an expert and places his trust in the investigator's expertise."¹⁵²

The court in *Grimes* held that research normally creates "special relationships" resulting in duties, the breaches of which may ultimately result in liability.¹⁵³ Other paths to establishing a legal duty between a researcher and research participant exist. For instance, a duty can arise by virtue of a relationship, by contract, or directly from a statute, regulation, or rule.¹⁵⁴

1. Nature of Research Relationships

According to *Grimes*, there is no bright-line rule that establishes when a special relationship exists between a researcher and participant.¹⁵⁵ Instead, the court used a fact-driven analysis to hold that "such research agreements can, as a matter of law, constitute 'special relationships' . . . [and] . . . that, *normally*, such special relationships are created between researchers and the human subjects used by the researchers."¹⁵⁶ The *Grimes* court stated that "the very nature of . . . scientific research on human subjects can, and normally will, create special relationships out of which duties arise."¹⁵⁷ The court justified its holding: "[W]e know of no law, nor have we been directed to any applicable [law] . . . that provides that the parties to a scientific study . . . cannot be held to have entered into special relationships with the subjects of the study."¹⁵⁸

2. Contractual Relationships

A duty can also arise by contract. The *Grimes* court held that informed consent agreements can constitute contracts.¹⁵⁹ The court explained that by having a research participant sign a consent form, both the researcher and research participant expressly make representations, creating a bilateral contract.¹⁶⁰ The *Grimes* court found that a consent agreement suggests that a research participant agrees to participate in the research study, expecting that she will be "informed of all the information necessary for [her] to freely choose

152. *Id.*

153. *Grimes*, 782 A.2d at 819.

154. *Id.* at 842 (citing *Bobo v. State*, 697 A.2d 1371, 1375-76 (Md. 1997)).

155. *See id.*

156. *Id.* at 858 (emphasis added).

157. *Id.* at 834-35.

158. *Id.* at 834.

159. *Id.* at 844.

160. *Id.* at 843.

whether to participate . . . and [will] receive promptly any information that might bear on [her] willingness to continue to participate in the study.”¹⁶¹ Information regarding the risk of mishandled PHI may directly influence an individual’s choice to participate in a research study.

3. Statutes and Regulations

A duty can also arise from the requirement to comply with statutes or regulations.¹⁶² For example, federal regulations guiding federally funded research impose standards of care in medical research.¹⁶³ The HHS and FDA regulations require adherence to “sound ethical principles,”¹⁶⁴ including informing patients of “all risks that are reasonably foreseeable” or those that are well known.¹⁶⁵ Although the federal regulations do not create a private right of action, the regulations recognize the existence of a common law duty to inform research participants.¹⁶⁶

Federal regulations further contemplate that a research participant will retain certain legal remedies. For example, researchers are prohibited from including language in the informed consent that would waive legal rights or “release the investigator, the sponsor, the institution or its agents [i.e., business associates] from liability.”¹⁶⁷ Therefore, by not disclosing risks, such as actual PHI disclosure practices that would reasonably affect an individual’s decision to participate in research, those responsible for research studies could violate the very regulations that presume that, in addition to the research investigator, “the [research] institution or its IRB—could be liable in negligence for injury to a research subject.”¹⁶⁸

Failure to comply with the provisions contained within HIPAA’s Privacy Rule also creates a basis for establishing a special relationship or duty, akin to the relationships and duties defined by the HHS and FDA regulations. HIPAA requires health care entities to comply with the standards set forth by HHS “to protect the

161. *Id.*

162. *Id.* at 846.

163. *Id.*; *see also* 45 C.F.R. § 46.101 (2005) (HHS protections for human research subjects); 21 C.F.R. § 50.1 (2005) (FDA protections for human research subjects).

164. *Grimes*, 782 A.2d at 848.

165. *Id.* (citing *Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1471, *aff’d*, 829 F.2d 1340 (4th Cir. 1987)).

166. Noah, *supra* note 2, at 216 (citing 21 C.F.R. § 50.20; 45 C.F.R. § 46.116).

167. 45 C.F.R. § 46.116; *see also* 21 C.F.R. § 50.20.

168. Noah, *supra* note 2, at 216.

security, confidentiality, and integrity of health information.”¹⁶⁹ Failure to adequately protect PHI, or to adequately supervise business associates with respect to handing PHI, breaches a duty owed to research participants, exposing researchers to liability. Therefore, HIPAA’s Privacy Rule, as it relates to protecting PHI in medical research, establishes a special relationship between researchers and participants.¹⁷⁰ As a result, researchers have a duty to adequately protect PHI and inform research participants of the risks of PHI disclosure associated with participation in the clinical trial. The breach of these duties should result in liability.

B. *Failure to Inform Research Participants of PHI Disclosure Risks Exposes Multiple Parties to Liability*

Mishandling PHI in the medical research environment implicates multiple parties. Liability extends beyond those directly responsible for disclosing PHI to unauthorized recipients. In fact, causes of action for negligence can be pursued against those generally responsible for medical research: IRBs, individual IRB members, hospitals, business associates, research sponsors, and treating physicians.¹⁷¹

1. IRBs

Although tort lawsuits against IRBs are relatively rare, they have begun to increase.¹⁷² Research participants commonly encounter judgment-proof¹⁷³ researchers and must look “higher up the chain of research oversight for a more promising defendant.”¹⁷⁴ Given that IRBs, by regulation, may require additional disclosures from researchers that will meaningfully add to the protections of research participants, it follows that IRBs may be held liable for failing to request additional disclosures and for failing to investigate and warn participants of current research practices with respect to

169. Williams, *supra* note 66, at 373.

170. 45 C.F.R. §§ 160, 164.

171. See *infra* Part V.C. (using a claim of negligence to provide a remedy for Alexis).

172. Noah, *supra* note 2, at 207.

173. A debtor is judgment-proof if he or she is “unable to satisfy a judgment for money damages because the person . . . does not own enough property.” BLACK’S LAW DICTIONARY 861 (8th ed. 2004).

174. Noah, *supra* note 2, at 209. Institutions having IRBs normally have significant financial resources derived from financial rewards related to research, whether received in the form of grants or similar compensation for housing a clinical trial within the walls of the institution. *Id.* at 210.

handling PHI.¹⁷⁵ Requiring additional efforts and disclosures to inform participants, or protect them from the risks of unauthorized disclosure of PHI, is an IRB duty.¹⁷⁶

Holding an IRB responsible is sound because research participants are also considered third-party beneficiaries¹⁷⁷ to research agreements and contracts, between the hospital, the IRB, and the researcher.¹⁷⁸ Such agreements elevate research participants to third-party beneficiary status because participants are, by design, intended to benefit from the IRB's protection.¹⁷⁹ To be sure, research participants reasonably rely on the IRB for protection from the risks inherent in research in exchange for their participation.¹⁸⁰ IRBs may argue, in defense, that they cannot effectively supervise clinical research or the risks associated with participation in research due to inadequate staffing or institutional support, financial or otherwise. However, such an explanation as to this factual finding is likely to "fail to persuade a jury."¹⁸¹

2. IRB members

Individual IRB members do not enjoy the same immunity for their participation on the IRB as those individuals who serve on institutional peer review boards and receive legal immunity in exchange for candid evaluations of hospital physicians.¹⁸² In fact, the *Grimes* court explained that it was "not aware of any general legal precept that immunizes . . . 'institutional volunteers' or scientific researchers from the responsibility for the breaches of duties arising in 'special relationships.'"¹⁸³ Therefore, individual members of an

175. 45 C.F.R. § 46.109(b) (2005); 21 C.F.R. § 56.109(b) (2006).

176. 45 C.F.R. § 46.109(b); 21 C.F.R. § 56.109(b).

177. A third-party beneficiary is "[a] person who, though not a party to a contract, stands to benefit from the contract's performance." BLACK'S LAW DICTIONARY, *supra* note 173, at 165.

178. Noah, *supra* note 2, at 209.

179. *Id.*

180. *Id.* at 210.

181. *Id.* at 219.

182. Health Care Quality Improvement Act of 1986, Pub. L. No. 99-660, §§ 411-12, 100 Stat. 3784, 3784-86 (codified at 42 U.S.C. § 11111-12 (2000)) (immunity from and standards for professional review); see also William P. Gunnar, *The Scope of a Physician's Medical Practice: Is the Public Adequately Protected by State Medical Licensure, Peer Review, and the National Practitioner Data Bank?*, 14 ANNALS HEALTH L. 329, 344-49 (2005) (discussing legal immunity in peer review and credentialing in hospitals).

183. *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 834 (Md. 2001).

IRB are subject to liability for failing to protect research participants by not informing them of the risks of mishandled PHI.

3. Hospitals

Patients who are treated and injured in a hospital can bring claims against a hospital when peer review credentialing committees¹⁸⁴ hire or retain a negligent physician.¹⁸⁵ By analogy, research participants should also be in a position to recover from a hospital when its IRB fails to properly review, approve, or monitor human subject research within its facility by failing to provide participants with all material information. Vicarious liability also extends to hospitals for the actions of its employees or business associates performing tasks requiring disclosure of PHI.¹⁸⁶ Healthcare institutions that choose to utilize business associates would “become [liable] . . . if another entity, such as a billing agent . . . transmits health information on their behalf.”¹⁸⁷

4. Business Associates

Business associates disclosing PHI, either intentionally or unintentionally, should also expect to face direct liability for injuries sustained from mishandled PHI, as business associates have contracted to protect participants’ health information.¹⁸⁸ If the disclosure of PHI results from an intentional act of an employee, a business associate may argue that the employee acted beyond the scope of employment.¹⁸⁹ That argument would certainly be at-

184. Peer review credentialing is a hospital’s internal process of admitting and retaining physicians by forming a committee of colleagues to provide candid evaluations of physicians. *See Grande v. Lahey Clinic Hosp.*, 725 N.E.2d 1083, 1085 (Mass. App. Ct. 2000) (explaining that peer review committees “promote uninhibited investigation and expression of opinion” because their members enjoy immunity from legal liability); *see also* MASS. GEN. LAWS ch. 111, § 204(a) (2003) (stating “the proceedings, reports and records of a medical peer review committee shall be confidential”).

185. Noah, *supra* note 2, at 211.

186. 45 C.F.R. § 164.530(b)(1) (2005) (“A covered entity must train all members of its workforce on the policies and procedures with respect to protected health information . . .”).

187. Williams, *supra* note 66, at 382.

188. 45 C.F.R. § 164.502(e)(1) (explaining that a covered entity may release PHI to a business associate only if the “covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information”); 45 C.F.R. § 164.504(e)(2)(ii)(D) (requiring that any agents of the business associate agree to the same conditions to protect PHI).

189. RESTATEMENT (SECOND) OF AGENCY § 219(2) (1958) (stating a “master is not subject to liability for the torts of his servants acting outside the scope of their employment”).

tempted in cases where a particular employee has acted on his own accord and not within the policies or procedures of the business. However, a more persuasive argument is that the employer is ultimately responsible because the employer failed to adequately supervise the employee. For example, failing to monitor external e-mail communications containing PHI may constitute a negligent act on behalf of a business associate.¹⁹⁰

5. Research Sponsors

Research sponsors, like the fictitious GenoPharm, may be held liable for failing to adequately inform research participants of the true risks inherent in current research practices. Since sponsors of multi-center research often take the responsibility of drafting the information and materials provided to research participants, it follows that research sponsors should be held liable for deficiencies in authorizations and informed consent agreements.¹⁹¹ Furthermore, research sponsors directly benefit from research subjects' participation. It is unfair, therefore, to allow research sponsors to avoid liability for failing to disclose material risks when sponsors are in a position to control the content of uniform authorizations.¹⁹²

6. Physicians

In cases where a researcher is also a treating physician, and a conflict of interest might alter his or her professional judgment, the physician-researcher has the highest level of fiduciary duty to the

190. *See id.* § 219(2)(b) (stating that an employer can be held liable for intentional torts of an employee acting outside the scope of employment if the employer is also negligent or reckless). In this case, the employer could have properly supervised or controlled e-mail transmissions of employees, especially those that contain PHI and those that appear to be transmitted to multiple recipients.

191. Kubiak, *supra* note 16, at 788.

192. However, since hospitals have differing methods for handling PHI in the healthcare setting, a research sponsor can argue that it lacks specific knowledge of actual disclosure practices and is not in a position to warn participants of associated risks. Nevertheless, a research sponsor who develops materials for participants must be required to disclose risks associated with common activities, such as exporting billing, data analysis, and medical monitoring operations. *See McLean, supra* note 65, at 215. In addition, there is an inherent conflict of interest in these situations, and therefore patients may be in even greater danger of remaining uninformed. For example, GenoPharm's goal is for patients to agree to participate in medical research so that it may receive FDA approval of its products. At the same time, if GenoPharm had made a full disclosure to Alexis of how her PHI would be traveling the globe, Alexis would likely not have participated in the research trial, especially since she was not receiving any personal or therapeutic benefit.

patient-subject.¹⁹³ Conflicts of interest are common to the medical research community,¹⁹⁴ especially where a researcher has “personal, financial, or political interests that undermine his or her ability to meet or fulfill his or her primary professional, ethical, or legal obligations.”¹⁹⁵ When a physician has personal interests unrelated to the patient’s health, the physician must disclose the presence and extent of these interests to the patient.¹⁹⁶ A common conflict of interest exists where a physician acts in the dual capacity as a primary care physician and a researcher, requiring the physician to “deftly balance his recommendations.”¹⁹⁷ However, even in cases where a medical investigator is acting solely as a researcher, a special relationship still exists.¹⁹⁸

C. *Using a Negligence Claim to Provide a Remedy*

The discussion below outlines a negligence cause of action based on a failure to protect research participants by not warning them of the common practices of PHI disclosure and the risks associated with these practices. To prove negligence, a plaintiff must establish the following elements by a preponderance of the evidence: (1) that the defendant owed a duty to the plaintiff, (2) that the defendant breached that duty, (3) that the plaintiff experienced actual harm or a legally recognized injury, (4) that the defendant was a cause in fact of the harm caused to plaintiff, and (5) that the defendant was the proximate cause of the plaintiff’s injury.¹⁹⁹

193. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (“[A] physician must disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect the physician’s professional judgment.”).

194. Jeffrey M. Drazen & Gregory D. Curfman, *Financial Associations of Authors*, 346 NEW ENG. J. MED. 1901, 1901-02 (2002) (explaining that the *New England Journal of Medicine* will refuse publication to physicians only in the event of *significant* financial interests in the manufacture of a product, versus the previous standard where *any* financial conflict would have resulted in withholding of publication).

195. ADIL E. SHAMOO & DAVID B. RESNIK, RESPONSIBLE CONDUCT OF RESEARCH 141 (2003).

196. *Moore*, 793 P.2d at 483.

197. Williams, *supra* note 19, at 69. Some research institutions have managed similar physician-researcher conflicts by utilizing third-party monitors. *Id.* at 73. Study enrollers explain to patients the amount and source of funding the physician will receive as a result of their participation in the clinical trial. Alternatively, consent monitors, employed by the IRB, can oversee the entire consent process. *Id.* at 73-74.

198. *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 846 (Md. 2001).

199. 1 DAN B. DOBBS, THE LAW OF TORTS § 114 (2001); see also RESTATEMENT (SECOND) OF TORTS §§ 281-282 (1965) (identifying elements for a negligence cause of action and the standard for negligence liability).

First, assuming a court finds that researchers and participants enjoy a special relationship that creates a duty on behalf of the researchers to adequately inform participants of the risks of PHI disclosure, the remaining elements of negligence must be demonstrated.²⁰⁰

Second, a research participant must establish that researchers breached their duty by failing to protect him or her as a research participant.²⁰¹ In a negligence action, failure to comply with the Common Rule, FDA regulations, or HIPAA will provide the necessary elements of duty, breach, and proximate cause, under the doctrine of negligence *per se*,²⁰² so long as the research participant is within the class of persons protected by the statute and the injury, or risk of injury, is of the type the statute seeks to prevent.²⁰³ Since the Common Rule and FDA regulations aim to protect research participants and because HIPAA was implemented to protect the PHI of consumers, it follows that research participants fall within the class of persons protected by each statute.²⁰⁴ These statutes also recognize the risk of compromising an individual's PHI; therefore, the statutes establish a duty to inform participants of risks related to PHI disclosure given common disclosure practices among researchers, business associates, and sponsors. When a researcher violates federal statutes designed to protect research participants, liability flows from the "breach of statute rather than from demon-

200. See *supra* Part V.A.

201. See *supra* Part V.A.

202. Cf. *Martin v. Herzog*, 126 N.E. 814, 815 (N.Y. 1920). "We must be on our guard, however, against confusing the question of negligence with that of the causal connection between the negligence and the injury." *Id.* at 816. "[T]he omission of a safeguard prescribed by statute . . . is held not merely some evidence of negligence, but negligence in itself." *Id.* at 815. A statute or regulation designed to protect "is not to be brushed aside as a form of words." *Id.* at 816; see also *Price v. Blood Bank of Del., Inc.*, 790 A.2d 1203, 1212-13 (Del. 2002) (finding "that the violation of a statute, or regulation having the force of statute, enacted for the safety of others is negligence in law or negligence *per se*").

203. RESTATEMENT (THIRD) OF TORTS § 14 (Tentative Draft No. 1, 2001) ("An actor is negligent [per se] if, without excuse, the actor violates a statute that is designed to protect against the type of accident the actor's conduct causes, and if the accident victim is within the class of persons the statute is designed to protect."); see *id.* § 15 (excused statutory violations are not negligence: reasonable care in an attempt to comply with statute, confusing statutory requirements, etc.).

204. See 45 C.F.R. §§ 46.101-124 (2006) (HHS Common Rule); 21 C.F.R. § 50.20 (2006) (FDA informed consent); 21 C.F.R. §§ 56.101-124 (2006) (FDA institutional review boards).

strative proof of how the [researcher] was at fault.”²⁰⁵ In fact, it is unnecessary to show that a researcher’s “actions were unreasonable, [or] how they foreseeably exposed the plaintiff to an undue risk of harm.”²⁰⁶

Healthcare institutions providing support for research activities will attempt to defend a statutory violation.²⁰⁷ For example, a hospital may argue that its statutory violation is excused because it has taken reasonable measures to comply with federal privacy regulations but that full compliance is cost-prohibitive.²⁰⁸ With little case law testing this defense, it is difficult to examine its merit given the federal requirement to comply with the Common Rule, FDA regulations, and HIPAA. In any event, “[court] opinions tend to start with a discussion of IRB negligence in failing to protect a research subject from injuries and then work backwards to announce, or more often simply assume, the existence of a duty of care,” leaving less room for a compliance defense.²⁰⁹

Third, actual damages must be proven.²¹⁰ The damages need not be the physical harm²¹¹ most often encountered in informed consent claims.²¹² The harm experienced in the event of unauthorized disclosure of PHI is comparable to the harm experienced in tort claims of assault, damage to reputation, and libel or slander.²¹³

205. David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 ARIZ. ST. L.J. 1003, 1010 (2004) (discussing negligence per se excuses available to manufacturers in products liability contexts).

206. *Id.*

207. See RESTATEMENT (THIRD) OF TORTS, § 15.

208. See P. Greg Gulick, *E-Health and the Future of Medicine: The Economic, Legal, Regulatory, Cultural, and Organizational Obstacles Facing Telemedicine and Cybermedicine Programs*, 12 ALB. L.J. SCI. & TECH. 351, 384 (2002).

209. Noah, *supra* note 2, at 214.

210. 1 DOBBS, *supra* note 199, § 114.

211. 2 DOBBS, *supra* note 199, § 311 (commenting that private information published to others may be an invasion of privacy and emotionally harmful, therefore allowing a cause of action to seek damages resulting from purely emotional harms unaccompanied by a physical injury). Even if claims in negligence are not successful, remedies can be found in “rules of privacy invasion or breach of confidence.” *Id.*; see also *id.* § 460 (discussing rights in personality, or reputation, to address privacy invasions that result in economic damages to the plaintiff).

212. See, e.g., *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 812-13 (Md. 2001) (exposing healthy children to anticipated accumulation of lead in blood stream); see also *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 481 (Cal. 1990) (taking samples of blood, serum, skin, bone marrow, and sperm from patient unaware that tissues were used for research purposes); *supra* notes 144-45 and accompanying text (describing the death of Jesse Gelsinger, a research participant).

213. See *supra* note 211.

Fourth, a research participant must demonstrate cause in fact, or actual cause.²¹⁴ In medical research, multiple actors often share responsibility for inflicting a single indivisible injury—in this case, the effects of mishandled PHI.²¹⁵ Even though it may be difficult for a plaintiff to apportion responsibility among several tortfeasors, joint and several liability²¹⁶ becomes a useful tool to force defendants to apportion fault amongst themselves.²¹⁷ Joint and several liability prevents a defendant, such as an IRB, from being excused merely because the harm could have occurred in the absence of the IRB's failure to warn the plaintiff of risks inherent in current research disclosure practices.²¹⁸ Therefore, an IRB can remain as a defendant because the IRB can be considered either a cause in fact or a substantial factor in the disclosure of a research participant's PHI.²¹⁹

Finally, proximate cause must be determined.²²⁰ Proximate cause focuses on whether liability should be extended because the risk of harm was foreseeable.²²¹ A violation of a statute or federal regulation, such as HHS, FDA, or HIPAA regulations, establishes proximate cause because the statute itself explicitly identifies the necessary foreseeable plaintiffs (research participants) and the foreseeable risks (loss of a privacy interest in PHI).²²²

Generally, the foreseeability of the manner in which the injury occurs is irrelevant, as is the extent of the injury. However, an intervening cause or act may terminate liability if the act itself is sig-

214. 1 DOBBS, *supra* note 199, § 114.

215. For example, a hospital may have acted negligently in selecting a business associate and the business associate may have been negligent or reckless in disclosing PHI to unauthorized recipients.

216. “Joint and several liability” is defined as “[l]iability that may be apportioned either among two or more parties or to only one or a few select members of the group [B]ut a paying party may have a right of contribution and indemnity from nonpaying parties.” BLACK’S LAW DICTIONARY, *supra* note 173, at 933.

217. See *Landers v. E. Tex. Salt Water Disposal Co.*, 248 S.W.2d 731, 734 (Tex. 1952) (finding that without imposing joint liability, “the plaintiff [would be] in no better position to produce the required proof of the portion of the injury attributable to each of the defendants”).

218. The issue is whether the release of PHI would have occurred but for the negligent act of the individual or entity. RESTATEMENT (THIRD) OF TORTS § 26 cmt. b (Tentative Draft No. 2, 2002) (but-for standard for factual cause).

219. See *id.* § 26 cmt. j (explaining that when the but-for test fails and the release of PHI still would have occurred, a party may still be a cause in fact of the injury if the party is determined to be a substantial factor in causing the injury).

220. 1 DOBBS, *supra* note 199, § 114.

221. *Palsgraf v. Long Island R.R. Co.*, 162 N.E. 99, 100-01 (N.Y. 1928).

222. RESTATEMENT (THIRD) OF TORTS § 14 (Tentative Draft No. 1, 2001).

nificant.²²³ Such a cause would relieve a defendant of liability because the causal link between the defendant's negligent act and the eventual harm would have been broken by the intervening cause. A defendant, such as an IRB member, may attempt to establish that an act of disclosing PHI by a business associate is an intervening act that supersedes any liability. However, the risk of a business associate negligently or recklessly disclosing PHI to an unauthorized recipient that results in a loss of career, loss of insurance coverage, damage to reputation, and economic damage, is the very same risk of failing to warn a research participant of common practices related to the disclosure of their PHI in medical research.²²⁴ Therefore, those involved in research should not be permitted to place blame on the actions of a business associate in an effort to escape liability.

Revisiting Alexis

Alexis sought to advance scientific understanding of an incurable disease. However, she suffered damage to her reputation and lost her career because her disease was disclosed to her employer and members of her community as a direct result of her participation in the clinical trial. The medical research community relied on informed consent, authorization, and IRB oversight to protect Alexis. When these measures failed, Alexis was forced to pursue a legal remedy.

In addition to possible contractual claims, Alexis should succeed in a negligence cause of action against those involved in the clinical trial, including the hospital, its IRB, individual IRB members, business associates, the research sponsor, and her physician, both as her treating physician and as a medical researcher. The medical researchers had a duty to inform Alexis of disclosure risks. They breached this duty by not informing Alexis of the risks material to her as a research participant. Alexis will be successful in establishing that those involved in the clinical trial were an actual cause of her injury. Alexis can also establish that she was both a foreseeable

223. BLACK'S LAW DICTIONARY, *supra* note 173, at 234 (stating that an intervening cause is "[a]n event that comes between the initial event in a sequence and the end result, thereby altering the natural course of events that might have connected a wrongful act to an injury").

224. *Derdiarian v. Felix Contracting Corp.*, 414 N.E. 2d 666, 671 (N.Y. 1980) (finding that an intervening act does not sever liability "and relieve an actor of responsibility, where the risk of the intervening act occurring is the very same risk" associated with the defendant's negligent act).

plaintiff and that the risks of mishandled PHI were foreseeable, making it fair to allow Alexis to recover damages.

CONCLUSION

The issue of liability condenses to one essential fact: most research participants are not informed of everything that they need to know to make an informed decision to participate in a clinical trial. Warning prospective participants of the risks associated with modern practices of disclosing PHI must be a universal practice. To properly inform participants of the true risks associated with participating in medical research, the medical research community must disclose actual business practices common to the industry. Prospective participants are the only ones who can make a truly informed decision whether to participate in medical research after balancing the benefits they expect to receive, if any, against the risks associated with participating in medical research.

Such additional disclosures will not likely have a chilling effect on research participation. In fact, an increase in confidence in the medical research community may result. The medical or legal communities can hardly condemn being forthright with all research-related risks in an effort to protect participants. If plaintiffs succeed in obtaining judgments against medical researchers, either the costs of medical research will increase, or the willingness of individuals to participate in research will decrease. Either event would require adjustments in the protections provided to research participants. However, not permitting research participants to recover damages resulting from unauthorized disclosure of PHI, merely because they chose to advance scientific knowledge by participating in a clinical trial, comes dangerously close to revisiting the distrust in medical research that led to the very developments designed to protect human research participants.

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* I would like to recognize the staff of the *Western New England Law Review* for their support, motivation, and critique. In particular, I would like to recognize Tracie Kester for her multiple reads and suggestions and Professors Katharine Van Tassel and Barbara Noah for their motivation and energy. It is fair to say that all remaining errors, mistakes, or omissions are entirely my own. I would also like to thank my family and friends who continually impress me with their commitment and support, especially, my wife, Teresa, and the kids.