

2014

HIPAA-Cratic or HIPAA-Critical: U.S. Privacy Protections Should Be Guaranteed by Covered Entities Working Abroad

Grace Fleming

Follow this and additional works at: <https://scholarship.law.umn.edu/mlr>



Part of the [Law Commons](#)

Recommended Citation

Fleming, Grace, "HIPAA-Cratic or HIPAA-Critical: U.S. Privacy Protections Should Be Guaranteed by Covered Entities Working Abroad" (2014). *Minnesota Law Review*. 331.
<https://scholarship.law.umn.edu/mlr/331>

Note

HIPAA-Cratic or HIPAA-Critical: U.S. Privacy Protections Should Be Guaranteed By Covered Entities Working Abroad

*Grace Fleming**

Privacy is a threatened right. Phone calls, emails, and even the conversations of heads of state are no longer reliably private.¹ Health and medical histories contain some of our most personal and sensitive information and privacy in this realm is of paramount importance. Privacy concerns in health care and medical research are intensified by the growth of electronic medical records and the rise of the Internet.² At the touch of a button, information can be transferred around the globe. Therefore, it is no surprise that privacy issues have dominated health information discussions in the last half-century.³ The Health Insurance Portability and Accountability Act (HIPAA) is designed to address these privacy issues, but because approximately one-third of U.S.-based clinical trials are now conducted outside of the United States,⁴ these protections may not extend

* J.D. Candidate 2014, University of Minnesota Law School; M.A. Candidate in Bioethics 2014, University of Minnesota; B.A. 2010, New York University. Thanks to Professor Amy Monahan for her guidance in writing this Note. Thanks also to Gordon Apple for introducing me to this gray area in the law. Sincere thanks to the editors and staff of the *Minnesota Law Review* for their efforts and support in getting my Note to publication. Thanks to my parents, my sister, and my friends Nalle and Teddy for all their support during Law School. Finally, thanks to the Produce Department at Red Owl Grocery. Copyright © 2014 by Grace Fleming.

1. David E. Sanger & Mark Mazzetti, *Allegation of U.S. Spying on Merkel Puts Obama at Crossroads*, N.Y. TIMES, Oct. 24, 2013, <http://www.nytimes.com/2013/10/25/world/europe/allegation-of-us-spying-on-merkel-puts-obama-at-crossroads.html>.

2. See BARRY R. FURROW ET AL., LIABILITY AND QUALITY ISSUES IN HEALTH CARE 259 (Thomson West, 6th ed. 2008).

3. See *id.* at 265.

4. See Seth W. Glickman et al., *Ethical and Scientific Implications of the Globalization of Clinical Research*, 360 NEW ENG. J. MED. 816, 816 (2009). This study used the online registry at ClinicalTrials.gov to look at recruitment in industry-sponsored phase three clinical trials as of November 2007 for

beyond U.S. borders. The globalization of research has triggered debates about researchers' ethical obligations concerning privacy among large research universities, non-profit organizations, and other U.S. entities covered by HIPAA.⁵ As the number of off-shore clinical trials grows, HIPAA must change to reflect this emerging globalized health and biomedical research industry. To address the challenges of worldwide threats to privacy and the growing importance of health information privacy to all people, U.S. entities must be required to follow HIPAA, both at home and abroad.

In the United States, patients, providers, and researchers are increasingly aware of the potential damage caused by a breach of privacy.⁶ Such breaches have included medical records improperly discarded in dumpsters,⁷ patients' HIV statuses revealed without patient consent,⁸ and private health records sent to patients' employers.⁹ Outside of the United States privacy is also a growing issue. Leading up to the May 1, 2011 capture of Osama Bin Laden in Abbottabad, Pakistan, the Central Intelligence Agency (CIA) reportedly implemented a sham campaign in which a physician went from house to house gath-

twenty of the largest U.S.-based pharmaceutical companies. The study found that around one third of the trials (157 of 509) were at that time conducted totally outside the United States and found that a majority of study sites (13,521 of 24,206) were also outside the United States. The authors wrote that many of these trials were being conducted in developing countries.

5. See Carol Bova, *Reframing the Influence of the Health Insurance Portability and Accountability Act on Research*, 141 CHEST 782, 785 (2012); see also, e.g., *International Research*, DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM (Aug. 3, 2011), http://irb.duhs.duke.edu/wysiwyg/downloads/41_International_Research_5-31-2011_revision_8-3-2011.pdf.

6. See FURROW ET AL., *supra* note 2, at 268 (suggesting that concerns about privacy in the health industry are a reality and consumers are increasingly vulnerable to breaches of their health information either deliberately or accidentally that can come from either an external breach of security or within the health care organization itself); Daniel J. Oates, Comment, *HIPAA Hypocrisy and the Case for Enforcing Federal Privacy Standards Under State Law*, 30 SEATTLE U. L. REV. 745, 745 (2006) (discussing a 1995 privacy catastrophe where the daughter of a hospital employee took names and phone numbers from medical records of recent emergency room patients and called falsely telling them they had contracted AIDS).

7. See, e.g., Jonathan Rodriguez, *Private, Medical Information Left Out in a Dumpster*, WNCT9 (June 29, 2012), <http://www.wnct.com/story/210130221/private-medical-information-left-out-in-a-dumpster>.

8. See, e.g., *Doe v. Medlantic Health Care Gr., Inc.*, 814 A.2d 939, 942 (D.C. Cir. 2003).

9. See *Herman v. Kratche*, No. 86697, 2006 WL 3240680, at *1 (Ohio Ct. App. 2006).

ering DNA under the guise of giving vaccinations.¹⁰ This blatant violation of patient privacy, wherein a physician collected patient DNA without consent and gave it to the CIA, negatively reflects on the entire medical profession—from physicians, to researchers, to international humanitarian aid workers. The mistrust fostered by such a breach inevitably hinders the aims of improved global health, research, and international relations.¹¹

Congress passed the Health Insurance Portability and Accountability Act (HIPAA) in 1996 to provide standards for the use, collection, and disclosure of Protected Health Information (PHI).¹² In the United States, HIPAA covers all information collected about patients by covered entities that falls under the definition of PHI.¹³ This includes diagnoses, medical records, and the patient's address and phone number.¹⁴ Hospitals, physicians, third party payers, and staff all have a legal duty to protect that information.¹⁵ The Department of Human Research Protections (DHRP) in the U.S. Department of Health and Human Services (HHS) has not provided guidance as to whether HIPAA's requirements apply to research institutions, drug and device companies, or any other U.S.-based research sponsor otherwise covered when conducting international clinical trials. The Secretary of Health and Human Services Advisory Committee on Human Research Protections asked the HHS to develop and publish guidelines about HIPAA's application in international research, but as of 2013 this guidance has not been produced.¹⁶ Beginning in the 1980s, clinical trials began

10. Les F. Roberts & Michael J. VanRooyen, *Ensuring Public Health Neutrality*, 368 NEW ENG. J. MED. 1073, 1073 (2013).

11. *Id.* at 1075.

12. 45 C.F.R. § 160.103 (2013) ("Health information means any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.").

13. Protected Health Information is information that identifies, or could be used to identify an individual and is created by a healthcare provider, health plan, employer, or healthcare clearinghouse that relates to that individuals past, present, or future physical or mental health or payment for the provision of healthcare. *See id.*

14. *Id.*

15. *See* 45 C.F.R. § 164.502(a) (2013).

16. *See Secretary's Advisory Committee on Human Research Protections Appendix H*, OFF. FOR HUM. RES. PROT., U.S. DEP'T OF HEALTH AND HUM.

moving abroad because there are substantially fewer regulatory requirements than those applicable in the United States.¹⁷ This movement raises questions about the legal and ethical requirements for clinical researchers and research sponsors that are based in the United States but working overseas.¹⁸

This Note points out the holes in U.S. privacy laws governing the obligations of U.S.-covered entities performing research abroad. It discusses the debate about HIPAA's application outside the United States and concludes that HIPAA should apply to U.S. entities working internationally. Part I provides a brief background of HIPAA, including what it does and why it was enacted. This background section then discusses current attempts to deal with the gray areas in this law and generally explains the notion of standards of care in research. Part II analyzes barriers to implementing HIPAA overseas, discusses how these barriers can be mitigated, and employs an ethical argument in favor of the United States implementing HIPAA abroad. Part III outlines governmental guidance that would solve this ambiguity and guarantee privacy protections for all human research subjects. It confronts practical barriers to implementation and explains that health information privacy is a fundamental human right. HIPAA privacy protections are a necessary part of all human subjects research in this increasingly global world and the government must respond to this gap by expanding privacy protections.

I. AN INTRODUCTION TO HIPAA AND THE DEBATE ON ITS APPLICATION ABROAD

HIPAA was the first federal rule to protect the privacy of health information and guarantee patient access to that information.¹⁹ HIPAA recognizes privacy as a fundamental right.²⁰ However, it is still unclear whether this right must be recognized by U.S. organizations when they work outside of the country.²¹ Part A introduces HIPAA's requirements and the

SERVS. (Jan. 6, 2014), <http://www.hhs.gov/ohrp/sachrp/appendixh.html>.

17. PETER BARTON HUTT ET AL., *FOOD AND DRUG LAW* 650 (Robert C. Clark et al. eds., 3d ed. 2007).

18. See *id.* at 818–20; Eve M. Brunts et al., *The International Clinical Trials Roadmap: Steering Clear of Legal and Practical Roadblocks*, *J. HEALTH & LIFE SCI. L.*, June 2012, at 1, 1; see also HUTT, *supra* note 17, at 650.

19. See FURROW ET AL., *supra* note 2, at 264.

20. *Id.*

21. See DEPT OF HEALTH & HUM. SERVS., *PROTECTING PERSONAL HEALTH INFORMATION IN RESEARCH: UNDERSTANDING THE HIPAA PRIVACY RULE*

reasons for its enactment. Part B explains that the confusion over HIPAA's application abroad needs to be formally addressed, and that the confusion stems from its inconsistent application in current practice and the history of standards of care abuse by U.S. research entities.

A. HIPAA'S HISTORY AND REQUIREMENTS

HIPAA was signed into law in 1996 in response to the expanding use of electronic health record technology and the increasing need for industry standardization in using electronic health records.²² HIPAA was enacted to address this growing use of electronic medical records and confront the many privacy and security issues arising from electronic transactions.²³

1. HIPAA Basics: Who is Covered and What is Required

HIPAA covers three groups ("covered entities"): (1) health plans, both individual and group plans that pay medical care costs; (2) health care clearing houses, entities that process information such as billing companies and community health management information systems; and (3) health care providers such as doctors, nurses, and therapists, and institutional providers such as hospitals.²⁴

HIPAA has two parts: the Privacy Rule and the Security Rule. The Privacy Rule applies to Protected Health Information in all forms—oral, written, and electronic.²⁵ The Privacy Rule standardizes how and for what reasons a covered entity can disclose a person's PHI.²⁶ It also outlines penalties for improper disclosure and misuse.²⁷ The Security Rule specifically addresses the issues of electronic PHI.²⁸ It mandates specific protections that covered entities must have for electronic medical rec-

(2003), [hereinafter DEP'T OF HEALTH & HUM. SERVS., UNDERSTANDING THE PRIVACY RULE], available at http://privacyruleandresearch.nih.gov/pdf/HIPAA_booklet_4-14-2003.pdf.

22. Young B. Choi et al., *Challenges Associated with Privacy in Health Care Industry: Implementation of HIPAA and the Security Rules*, 30 J. MED. SYS. 57, 58 (2006).

23. *Id.*

24. DEP'T OF HEALTH & HUM. SERVS., SUMMARY OF THE HIPAA PRIVACY RULE, 2-3 (2003), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

25. *Id.*

26. *Id.*

27. *Id.*

28. Choi, *supra* note 22, at 58.

ords. These include administrative safeguards and physical protections for computer systems and relevant facilities.²⁹ The Security Rule requires covered entities to monitor access to PHI and lays out specific requirements concerning contracts between covered entities and their business associates.³⁰ In addition, the Security Rule requires that covered entities have policies and procedures in place to ensure the health organization's compliance with HIPAA.³¹

Not all researchers and research institutions in the United States have to comply with HIPAA.³² However, a relationship with a covered entity folds an otherwise not covered entity under the jurisdiction of HIPAA.³³ For example, researchers commonly rely on covered entities for funding or as sources of individually identifiable health information that is included in research databases.³⁴ In other instances, a researcher employed by a covered entity may be bound by HIPAA in research endeavors undertaken as an employee.³⁵ This coverage varies according to the relationship of the researcher or research initiative to a covered entity.³⁶

2. How HIPAA Works and Who Enforces HIPAA

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) enforces HIPAA.³⁷ OCR investigates complaints of HIPAA violations, performs audits of covered entities, and does outreach and education to encourage compliance.³⁸ If there is a criminal violation, OCR works with

29. *Id.*

30. *Id.* A business associate is a person or organization, other than a covered entity's workforce, that provides services to a covered entity or performs certain functions on behalf of a covered entity and that work involves use or disclosure of identifiable health information. *Id.* This is most often claims processing, data analysis, utilization review, or billing. *Id.*

31. *Id.*

32. See DEP'T OF HEALTH & HUM. SERVS., UNDERSTANDING THE PRIVACY RULE *supra* note 21, at 1.

33. *Id.* at 6. For example, a University may be one legal entity that also includes an academic medical center. That hospital within the University that conducts covered activities, and the relationship it has with the University, means that the entire University is subject to HIPAA. *Id.*

34. *Id.* at 1.

35. *Id.*

36. *Id.*

37. See *Health Information Privacy*, HHS.GOV, <http://www.hhs.gov/ocr/privacy/index.html> (last visited Apr. 8, 2014).

38. See *Health Information Privacy: Enforcement Process*, HHS.GOV, <http://www.hhs.gov/ocr/privacy/hipaa/enforcement/>

the Department of Justice to enforce HIPAA.³⁹ For the most part, OCR works to achieve voluntary compliance through corrective actions and agreements with covered entities.⁴⁰ Civil penalties are only imposed if the violation was willful, and penalties are not imposed if the compliance failure resulted from reasonable cause and is rectified within a thirty-day grace period.⁴¹

HIPAA is crucial to protecting patient privacy and contains several requirements dedicated to achieving this goal. These protections have been largely successful and long-standing.⁴² The government should respond to the surge in international research and ambiguity of HIPAA's application abroad by expanding HIPAA protections to U.S. covered entities working abroad.

B. HIPAA'S APPLICATION ABROAD: CONFUSION IN CURRENT PRACTICES AND CURRENT APPROACHES TO STANDARDS OF CARE

HIPAA's statutory language and ethical considerations governing all human subject research has spurred debate among researchers and scholars about whether HIPAA applies internationally.⁴³ The government has offered conflicting clues on its approach to covered entities working abroad, resulting in a patchwork application of privacy laws in the academic research community. One thing, however, is clear: privacy is now expected in health settings.

1. Clues from HIPAA's Text and Governmental Guidance

HHS has not explained, answered, or elaborated on HIPAA's application in international research settings. HIPAA's text and previous HHS guidelines do, however, provide some clues. HIPAA does not cover foreign national beneficiaries receiving healthcare from the Department of Defense (DoD) or by any other federal agency or any agency acting on

process/index.html (last visited Apr. 8, 2014).

39. *Id.*

40. See FURROW ET AL., *supra* note 2, at 282.

41. *Id.*; see 45 C.F.R. § 160.401 (2013) ("Reasonable cause means an act or omission in which a covered entity or business associate knew, or by exercising reasonable diligence would have known, that the act or omission violated an administrative simplification provision, but in which the covered entity or business associate did not act with willful neglect.").

42. Choi et al., *supra* note 22, at 58.

43. Bova, *supra* note 5, at 785.

behalf of the DoD or federal agencies.⁴⁴ This narrow exclusion, combined with the broad definition of “individual” in the law suggests that foreign nationals are otherwise covered.⁴⁵ In addition, HIPAA focuses on covered entities and Protected Health Information rather than the nationality of research participants.⁴⁶ This has led some researchers and scholars to assume that HIPAA does apply in international settings.⁴⁷ International clinical trials can implicate the HIPAA Privacy Rule when data is transferred to the United States and the investigator or sponsor is a covered entity.⁴⁸ Therefore, many researchers argue that HIPAA is not required in international research as long as researchers de-identify data or never send the data back to the covered entity in the United States.⁴⁹ In 2004, however, a member of the Secretary’s Advisory Committee on Human Research Protection, Mark Barnes, noted that “there is nothing in the rule that says it only applies to Americans or American residents. It applies to all health information that’s identifiable and that is handled by a covered entity, which would include [researchers] who are abroad.”⁵⁰

The text and government statements do not definitively answer whether HIPAA applies in international research settings, allowing arguments on both sides. Consequently, it is necessary to consider the feasibility of applying HIPAA abroad to determine prescribed practices for research entities. These concerns ought to influence what kind of guidance the government should publish. Researchers currently face uncertainty, and a response from the government is necessary.

44. *Secretary’s Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

45. *Id.* (defining individual as “the person who is the subject of protected health information”); see 45 C.F.R. § 160.103 (2013).

46. DEP’T OF HEALTH & HUM. SERVS., UNDERSTANDING THE PRIVACY RULE, *supra* note 21, at 1.

47. *Secretary’s Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

48. Eve M. Brunts, *AHHA Seminar Materials J. Clinical Trials Update* AHHA-PAPERS P04250708 § VI. C. 1 (Apr. 25, 2007).

49. See, e.g., DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM, *supra* note 5, at 1; *HIPAA Authorization: International Language*, JOHNS HOPKINS MED. (Nov. 2010), http://www.hopkinsmedicine.org/institutional_review_board/hipaa_research/hipaa_international_language.

50. *Thompson To Hear Recommendations to Ease Researchers’ HIPAA Concerns*, FDA COMPLIANCE EXPERT (July 28, 2004), <http://prod-admin1.tmg.atex.cniweb.net:8080/preview/www/2.3427/2.3465/1.116184>.

2. Institutions of Higher Education Approach to HIPAA Internationally Exemplifies the Patchwork of Compliance by Covered Entities Abroad

Research programs at universities across the United States apply HIPAA abroad in different ways, suggesting that the lack of government clarification on this issue has important effects on research and, as such, necessitates an immediate response. For example, Duke University's policy acknowledges that whether HIPAA applies to international research is an unanswered question.⁵¹ It notes that once individually identifiable information reaches U.S. soil under a covered entity like Duke, it becomes subject to HIPAA protections.⁵² In addition to recognizing the debate over HIPAA's application abroad, Duke's policy also notes that it may be difficult to apply HIPAA in an international setting.⁵³ With this in mind, they offer researchers the option of requesting that the Institutional Review Board (IRB) approve modifications or waivers of HIPAA requirements entirely.⁵⁴

Johns Hopkins takes a similar approach, requiring HIPAA protections when international research data is transmitted to a covered entity in the United States.⁵⁵ Likewise, they suggest that research teams in foreign countries may alter Johns Hopkins' standard HIPAA privacy language requirements in consent forms as long as they obtain IRB permission.⁵⁶ IRBs offer another check on the ethical practices of researchers and the protection of research participants' rights.⁵⁷ Yale University documents indicate that HIPAA *may* apply when conducting international research if the information gathered is returned to the University.⁵⁸ The University recommends that data be

51. DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM, *supra* note 5, at 1.

52. *Id.*

53. *Id.*

54. *Id.*

55. JOHNS HOPKINS MED., *supra* note 49.

56. *Id.* This may be to respond to language or educational barriers. 21 C.F.R. § 56.102 (2013) ("Institutional Review Board (IRB) means any board, committee, or other group formally designated by an institution to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.").

57. 21 C.F.R. § 56.102 (2013).

58. *Conducting Research Internationally*, YALE UNIV. OFF. OF RES. ADMIN., <http://researchadministration.yale.edu/ora-services/conducting-research-internationally> (last visited Apr. 8, 2014).

de-identified before the investigator returns to Yale.⁵⁹

In contrast, the Human Research Protection Program at University of California Los Angeles simply notes in its guidelines that HIPAA does not apply overseas or in foreign countries.⁶⁰ Basic privacy protection measures still apply, but research subjects do not have to sign an authorization to allow access to their PHI.⁶¹

Duke seems to approach the situation cautiously by explaining that there is debate about HIPAA's application abroad while noting the importance of privacy.⁶² Despite requiring researchers to provide equivalent protections to research subjects abroad as they would to research subjects in the United States, both Duke and Johns Hopkins allow waivers from general HIPAA requirements.⁶³ In contrast, UCLA denies that HIPAA applies at all.⁶⁴ Universities are hubs of knowledge and are often leaders in research. These patchwork recommendations suggest that HHS guidance is necessary and important to ensuring the universal, standardized application of human subject protections.

3. Standards of Care in Research

Standards of care in research represent the degree of care a "reasonable" and "prudent" researcher and research organization must exercise.⁶⁵ These standards are meant to protect human subjects research participants from abuse. Contemporary human subjects protections began in 1947 with the adoption of the Nuremberg Code, a set of standards developed by the Nuremberg tribunal to judge Nazi experimentation on individuals during World War II.⁶⁶ This Code provided the basic principles that led to similar recommendations from the World Medical

59. *Id.*

60. *HIPAA Frequently Asked Questions*, UCLA OFF. OF THE HUM. RES. PROT. PROGRAM, <http://ora.research.ucla.edu/OHRPP/Pages/HIPAAFAQ.aspx> (last visited Apr. 8, 2014).

61. *Id.*

62. DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM, *supra* note 5, at 1.

63. *Id.*; JOHNS HOPKINS MED., *supra* note 49.

64. UCLA OFF. OF THE HUM. RES. PROT. PROGRAM, *supra* note 60.

65. Peter Moffett & Gregory Moore, *The Standard of Care: Legal History and Definitions: The Bad and Good News*, 12(1) W.J. EMERGENCY MED. 109, 109 (2011).

66. *45 CFR 46-FAQs*, HHS.GOV, <http://answers.hhs.gov/ohrp/categories/1562> (last visited Apr. 8, 2014).

Association in the 1964 Declaration of Helsinki.⁶⁷ Following several publicized abuses by U.S. researchers, the U.S. government passed the National Research Act in 1974 covering human subjects research and created the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (“Commission”).⁶⁸ The Commission produced the Belmont Report, which provided three ethical guiding principles for research: respect for persons, beneficence, and justice.⁶⁹ The Belmont Report led to the adoption of federal guidelines.⁷⁰

The “Common Rule” represents the federal policy for the protection of human subjects research that has been adopted by several federal government agencies.⁷¹ It requires that

When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. . . In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy.⁷²

In recent years, the research community has debated the standard of care owed to research subjects in developing countries.⁷³ The Declaration of Helsinki was revised in 2000 to endorse the view that every trial participant, no matter where the trial was located, is entitled to the “worldwide best standard of care.”⁷⁴ This decision suggests that a lower standard of care is unethical.⁷⁵ It violates researcher’s obligations to trial participants and creates a double standard for the rich and poor.⁷⁶ Despite the Declaration’s language, many public, private, nation-

67. *Id.*

68. *Id.*

69. THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH, THE NAT’L COMM’N FOR THE PROT. OF HUM. SUBJECTS OF BIOMEDICAL & BEHAVIORAL RES. (Apr. 18, 1979), available at <http://www.hhs.gov/ohrp/policy/belmont.html>.

70. *Federal Policy for the Protection of Human Subjects (“Common Rule”)*, HHS.GOV, <http://www.hhs.gov/ohrp/humansubjects/commonrule/index.html> (last visited Apr. 8, 2014).

71. *Id.*

72. 45 C.F.R. § 46.101(h) (2013).

73. R K Lie et al., *The Standard of Care Debate: The Declaration of Helsinki Versus the International Consensus Opinion*, 30 J. MED. ETHICS 190, 190 (2004).

74. *Id.*

75. *Id.*

76. *Id.*

al, and international groups have concluded that in some circumstances, it is ethical to use a different standard of care in different countries.⁷⁷ Standards of care address what is *legally* required, but also encourage the research community to consider what *ought* to be required. This debate often discusses standards in clinical therapies, but not the standards of protection for research participant information.⁷⁸ Because privacy standards of care abroad is a gray area in U.S. law, it is important to consider not only whether requiring HIPAA is feasible, but also whether failing to do so violates research ethics.

As clinical research moves beyond U.S. borders and guidelines remain vague, clinical researchers and research sponsors must confront a set of moral concerns around their legal and ethical requirements.⁷⁹ Many universities and other covered entities conduct research overseas and admit their confusion in whether HIPAA applies in those endeavors.⁸⁰ In addition, the concept of global health has come to the forefront in the last decade as influenza and AIDS illustrate the importance of global health initiatives and international cooperation and understanding.⁸¹ Finally, medical records are increasingly electronic. The ease of electronic transfer and collection of data heightens privacy concerns.⁸² As overseas research increases, so does the importance of resolving this confusion. A guidance document should clarify that HIPAA applies to a covered entity working in the United States *and* abroad, despite roadblocks to implementation. Covered entities would then be on notice that HIPAA's protections apply outside the United States, giving all research subjects a guaranteed level of protection for personal and medical information.

Expanding HIPAA's application faces barriers to implementation. HIPAA requirements add costs to research.⁸³ Applying U.S. federal law in other countries raises issues of extraterritorial application of U.S. law and conflicts of law between U.S. privacy laws and privacy laws that exist in the host country.⁸⁴ Researchers may be concerned about translating an

77. *Id.*

78. *See, e.g., id.*

79. *See* Bova, *supra* note 5; Glickman et al., *supra* note 4.

80. *See supra* Part I.B.2.

81. *See supra* Part I.B.3.

82. *See* FURROW ET AL., *supra* note 2, at 259.

83. *See infra* Part II.A.2.

84. *See infra* Part II.A.1, II.A.3.

American-based privacy theory in countries with different cultural values and languages, the effect of added requirements on the progress of research, and practical issues of enforcing HIPAA abroad.⁸⁵ Part II explains these barriers and suggests ways to mitigate them. A government decision expanding HIPAA's application will decrease uncertainty and expand an improved standard of care concerning privacy to all persons participating in research with U.S. covered entities, whether in the United States or abroad.

II. LEGAL AND ETHICAL ANALYSIS OF THE FEASIBILITY OF OVERSEAS APPLICATION OF U.S. PRIVACY STANDARDS

The Secretary's Advisory Committee on Human Subjects Research asked for further guidance on HIPAA's application abroad.⁸⁶ Part A presents potential barriers to expansion abroad and how these barriers can be mitigated. Part B discusses the ethical implications of applying HIPAA overseas, concluding that research ethics and standards of care require implementation of privacy protections abroad.

A. BARRIERS TO COMPLIANCE WITH HIPAA AND MITIGATING THOSE BARRIERS

The potential consequences of applying HIPAA abroad should be considered and weighed against potential consequences of *failing* to issue guidance. The barriers to applying HIPAA overseas include the extraterritorial application of U.S. law, cost, conflicts of law, translation problems, and the potential for hindering research.

1. Extraterritorial Application of U.S. Law

Congress has the power to enforce its laws beyond the territorial boundaries of the United States,⁸⁷ but there is a presumption that federal legislation applies only within the Unit-

85. See *infra* Part II.A.4–5.

86. OFF. FOR HUM. RES. PROT., DEP'T OF HEALTH AND HUM. SERVS., *supra* note 16.

87. The presumption against extraterritorial application of U.S. law may be rebutted if it is clear that the law is intended to apply outside of the United States. See *Foley Bros. v. Filardo*, 336 U.S. 281, 283 (1949) (noting that it is not a question whether Congress has the power to extend the Eight Hour Law to work performed in foreign countries).

ed States.⁸⁸ This presumption relies on the idea that most legislation is meant to cover domestic rather than foreign issues.⁸⁹ *Morrison v. National Australia Bank Ltd.* suggests that this presumption is difficult to circumvent.⁹⁰ This may present a significant barrier to the application of HIPAA abroad.

Several considerations may present an exception to the presumption when it comes to HIPAA enforcement. If HHS produces guidance explicitly indicating that HIPAA applies abroad, the presumption can be rebutted.⁹¹ As research and other U.S. endeavors become global, the need for extraterritorial application of U.S. laws becomes more apparent.⁹² The presumption against extraterritorial application can be overcome with new guidance from HHS responding to this issue and clarifying that HIPAA must apply abroad.⁹³ This guidance docu-

88. *Morrison v. Nat'l Austl. Bank Ltd.*, 561 U.S. 247. (2010).

89. See *Smith v. United States*, 507 U.S. 197, 204 (1993).

90. *Morrison*, 130 S. Ct. at 2877 (noting that unless Congress expressly writes a law to the contrary, the presumption is that a law is meant to apply only within the United States).

91. *Foley Bros.*, 336 U.S. at 285 (“The canon of construction which teaches that legislation of Congress, unless a contrary intent appears, is meant to apply only within the territorial jurisdiction of the United States . . .”).

92. See, e.g., Trey Childress, *Wal-Mart and the Foreign Corrupt Practices Act*, CONFLICTOFLAWS.NET (Apr. 24, 2012), <http://conflictoflaws.net/2012/wal-mart-and-the-foreign-corrupt-practices-act/>.

93. Agencies often use alternative measures to explain policy preferences than the traditional note and comment process as required by the Administrative Procedure Act. These include legal opinions from agency counsel; management policies; guidance documents; manuals; instruction memoranda; and regulatory guidance letters. Sam Kalen, *The Transformation of Modern Administrative Law: Changing Administrations and Environmental Guidance Documents*, 35 *ECOLOGY L.Q.* 657, 659–60 (2008). This provides the agency with a flexible way to communicate with regulated parties. Jill E. Family, *Administrative Law through the Lens of Immigration Law*, 64 *ADMIN. L. REV.* 565, 566 (2012). Guidance documents are official “statement[s] of general applicability and future effect, other than [regulations]” that set forth “a policy on a statutory, regulatory, or technical issue or an interpretation of a statutory or regulatory issue.” Sean Croston, *The Petition Is Mightier than the Sword: Rediscovering an Old Weapon in the Battles over “Regulation Through Guidance,”* 63 *ADMIN. L. REV.* 381, 382 (2011) (quoting Office of Management and Budget, Final Bulletin for Agency Good Guidance Practices, 72 *Fed. Reg.* 3432, 3434 (Jan. 25, 2007)). Guidance documents may proclaim an agency’s general policies and interpretations, but they cannot set forth binding legal requirements. They can be practically binding in the effect they have on how the agency enforces the policy and the difficulty that ensues for regulated parties to challenge the guidance. *Id.* The enforceability and ability to challenge guidance documents in court is beyond the scope of this Note, but given that this would be an interpretation of current HIPAA regulations, it would likely fall neatly into what a guidance document is meant to be. *Id.*

ment would interpret the existing HIPAA regulations as applying overseas.

2. Cost of HIPAA Compliance

HIPAA has been called a fiscal bottleneck for biomedical research.⁹⁴ There were many concerns about cost at the outset of HIPAA's implementation.⁹⁵ HIPAA's implementation costs include training staff on HIPAA compliance and bolstering security of information both in the physical sense and in the technological arena.⁹⁶ In addition, covered entities incur costs in three direct ways: (1) creating new forms for patients regarding privacy practices, (2) appointing or hiring persons to be in charge of HIPAA compliance, and (3) needing revisions in business associate contracts.⁹⁷ Indirect costs include time and energy spent in compliance.⁹⁸ Finally, there are continual costs to maintain HIPAA compliance by training and re-training employees and maintaining the systems for protecting privacy as technology and systems change.⁹⁹

HIPAA has been a part of U.S. law for over a decade.¹⁰⁰ Startup costs for HIPAA compliance were significant.¹⁰¹ The cost of maintaining compliance, however, has been less significant than predicted,¹⁰² and the cost of noncompliance can be

94. Jocelyn Kaiser, *Privacy Rule Creates Bottleneck for U.S. Biomedical Researchers*, 305 SCI. 168, 168 (2004).

95. *See id.*; Peter Kilbridge, *The Cost of HIPAA Compliance*, 348 NEW ENG. J. MED. 1423, 1423 (2003).

96. Kilbridge, *supra* note 95, at 1423.

97. *Id.*

98. *See* Arthur R. Williams et al., *HIPAA Costs and Patient Perceptions of Privacy Safeguards at Mayo Clinic*, 34(1) JOINT COMMISSION J. ON QUALITY & PATIENT SAFETY 27, 30 (Jan. 2008).

99. *Id.*

100. *See* 45 C.F.R. § 160.103 (2013).

101. *See* Williams et al., *supra* note 98, at 30.

102. *See id.*; *see also* Peter A. Winn, *Confidentiality in Cyberspace: The HIPAA Privacy Rules and the Common Law*, 33 RUTGERS L.J. 617, 679–80 (2002).

The most likely explanation of the increase in costs associated with the implementation of the HIPAA Privacy Rules appears to be the fact that, in recent years, many healthcare providers have invested significant resources in increasingly accessible computerized health information networks without maintaining appropriate safeguards to protect medical information as the accessibility of health information increased. As we have seen, traditional standards for confidentiality that involved only modest costs when information was stored in locked file cabinets, or in main frame computers, now present much more difficult and expensive information management problems in

high. Actors operating abroad could face monetary costs if HHS decides to use the vagueness of the law to enforce HIPAA abroad.¹⁰³

All covered entities in the United States should already be in compliance, thus requiring their overseas researchers to comply with HIPAA protocols should not significantly increase costs.¹⁰⁴ Some argue that HIPAA compliance would slow and diminish research in the United States, but others see this reaction as “alarmist.”¹⁰⁵ Research in the United States has continued.¹⁰⁶ Much of the infrastructure that allows for continued compliance of covered entity researchers in the United States could be used when those covered entities operate overseas.¹⁰⁷ The infrastructure of compliance is already familiar to most actors; therefore new cost of compliance barriers are foreseeable and will not unfairly stunt research.

There are increasing financial consequences for non-compliance in the United States. In 2009, the maximum penalty was increased from \$25,000 to \$1.5 million.¹⁰⁸ A recent case

the context of vast national electronic health networks. Thus, the high cost estimates associated with the HIPAA Privacy Rules appear to be due simply to the exponential growth in the use of electronic health information by the health care industry without a concomitant investment in compliance with previously existing duties of confidentiality.

Id.

103. *HITECH Act Enforcement Interim Final Rule*, HHS.GOV, <http://www.hhs.gov/ocr/privacy/hipaa/administrative/enforcementrule/hitechenforcementifr.html> (last visited Apr. 8, 2014) (noting a maximum penalty of \$1.5 million for violations).

104. While many were concerned with start-up costs, maintaining compliance has been less strenuous. *See* Williams et al., *supra* note 98, at 32 (noting that “added into annual operating costs, and spread over the patient census, the average privacy cost per patient visit (\$0.90) and per patient (\$4.00) appears modest . . . [M]odest expense (cost) and improved patient information are both achievable . . .”). In addition, HIPAA might lead to cost saving in an institution. *See* Jerry LaMartina, *Cost vs. Benefits of HIPAA Is Unclear, but Change in Procedures Is a Certainty*, KAN. CITY BUS. J., May 19, 2002, <http://www.bizjournals.com/kansascity/stories/2002/05/20/focus6.html> (“Standardized electronic transactions could save businesses an estimated \$10 billion to \$15 billion during 10 years . . .”). It could logically follow that maintaining compliance overseas would not create a significant increase in costs.

105. *See* George J. Annas, *HIPAA Regulations—A New Era of Medical-Record Privacy?*, 348 NEW ENG. J. MED. 1486, 1489 (2003).

106. *See Trends, Charts, and Maps*, CLINICALTRIALS.GOV (Nov. 9, 2012), <http://www.clinicaltrials.gov/ct2/resources/trends> (stating that there are currently 162,059 clinical trials registered on clinicaltrials.gov in the U.S.).

107. *See supra* Part I.B.2.

108. Amanda McGrory-Dixon, *HHS Toughens HIPAA Violation Penalties*,

involving a HIPAA violation by a former UCLA employee was the first to lead to incarceration.¹⁰⁹ In that case, a UCLA researcher was sentenced to jail time for looking at patient records he did not have the authorization to view.¹¹⁰ This signals the importance of privacy in health records. While it is unclear whether HIPAA applies, if HHS were to interpret the language of HIPAA as reaching covered entities abroad, the stakes are high for noncompliance.

3. Conflicts of Law

Several researchers have concluded that HIPAA must not apply internationally because there would be serious conflict of law issues.¹¹¹ These researchers suggest that the foreign laws of the country hosting the researchers would trump the application of HIPAA.¹¹² For example, the European Union (EU) has its own law protecting privacy of personal data.¹¹³ This law applies generally to all EU members, requiring them to protect the “right to privacy with respect to the processing of personal data” and restrict the flow of information between member states.¹¹⁴

Comparing the EU law with HIPAA suggests that conflicts of law may be a barrier to applying HIPAA in other countries because the EU privacy law has some significant differences from the HIPAA privacy rule. For example, the term “personal data” is broader than the definition of PHI under HIPAA.¹¹⁵ The EU Directive defines personal data to include any information related to an identified or identifiable natural person.¹¹⁶ In addition, the definition of processing is also broadly defined

BENEFITSPRO (Apr. 9, 2013), <http://www.benefitspro.com/2013/04/09/hhs-toughens-hipaa-violation-penalties>; see also *HITECH Act Enforcement Interim Final Rule*, *supra* note 103.

109. Pamela Lewis Dolan, *HIPAA Violation Leads to Jail Time*, AMEDNEWS.COM, June 7, 2010, <http://www.amednews.com/article/20100607/business/306079969/6/>.

110. *Id.*

111. *Secretary's Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

112. *Id.*

113. See, e.g., European Parliament and the Council of the European Union, Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995, 1995 O.J. (L 281) 31 (Nov. 23, 1995), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31995L0046:en:HTML>.

114. *Id.* at art. 1.

115. *Id.*

116. *Id.* at art., 2 § a.

to mean any operations on personal data including collection, recording, storage, use, disclosure, or destruction beyond the disclosure and misuse provisions of HIPAA.¹¹⁷ The entity controlling this data is called a “controller” which may at first sound like a covered entity.¹¹⁸ However, the EU Directive’s definition of “controller” is not limited to healthcare providers and business associates considered by HIPAA.¹¹⁹ Finally, in order for a controller to transfer data to a third country, that third country must ensure an “adequate level of protection,”¹²⁰ and the EU has determined that the United States does not fulfill this criterion.¹²¹ To remedy this, the U.S. Department of Commerce worked with the European Commission to develop a safe harbor provision where U.S. organizations can be deemed to have an adequate level of protection.¹²² Differing national privacy requirements may make ensuring HIPAA compliance more complicated when researching outside of the United States

Despite the potential for conflicts of law, this does not automatically preclude HIPAA’s application abroad. Researchers may work with their IRB to come up with a solution when there is more than one applicable law.¹²³ In addition, if a research institution or covered entity does a lot of research in a region, they may be able to determine what a combination of HIPAA with the local privacy laws requires, and use that for every study done under the name of that covered entity.¹²⁴ HIPAA was designed to minimize conflicts of law among the states.¹²⁵ Covered entities or states may require more protec-

117. *Id.* at art. 2, § b.

118. *See id.*

119. *Id.* at art. 2, § d. A controller includes any natural or artificial person, public authority, agency, or anything else that processes personal data.

120. *Id.* at art. 25, § 1.

121. *See Commission Decisions on the Adequacy of the Protection of Personal Data in Third Countries*, EUROPEAN COMMISSION (2011), http://ec.europa.eu/justice/data-protection/document/international-transfers/adequacy/index_en.htm (last visited Apr. 8, 2014).

122. Brunts et al., *supra* note 18, at 20.

123. Basic HHS Policy for Protection of Human Subjects, 45 C.F.R. § 46.101 (2013). Institutional Review Boards must approve proposed non-exempt research before beginning research involving human subjects.

124. Brunts et al., *supra* note 18, at 20.

125. *HIPAA Frequent Questions “How Does the HIPAA Privacy Rule Reduce The Potential for Conflict With State Laws?”* HHS.GOV, <http://www.hhs.gov/hipaafaq/state/401.html> (last visited Apr. 8, 2014).

tions for individually identifiable health information or create greater privacy rights.¹²⁶ HIPAA is designed to be a floor, making it a baseline of protections from which to build upon.¹²⁷ If the covered entity is working in a country that requires greater protections than HIPAA, they will have to follow that country's laws. But if the country has a lower privacy standard or none at all, then the covered entity should provide HIPAA's basic level of protections, regardless of the research participant's citizenship and location of the trial.

4. Translation of an American-Based Theory of Privacy

Differing cultural norms around privacy and human rights may generate ethical incongruence. Translating HIPAA rights and requirements to a culture that may not share the same concepts of privacy constitutes a potential barrier to implementation.¹²⁸ This has given rise to discourse centering on the validity of applying an American-based theory of research ethics in a different culture,¹²⁹ and confronting the potential of "medical-ethical imperialism."¹³⁰ The application of an American-based theory of privacy overseas through HIPAA may be challenged as culturally inappropriate.¹³¹

In contrast to the idea that privacy concepts embedded into western culture and codified in HIPAA are difficult or non-translatable in international settings is the issue of practicing double standards for U.S.-based research and research abroad.¹³² Translational issues and cultural differences are a traditional problem in all parts of international research¹³³ but they need not hinder research progress. Cultural divides may

126. *Id.*

127. *Id.*

128. See Salla Sariola & Bob Simpson, *Theorising the 'Human Subject' in Biomedical Research: International Clinical Trials and Bioethics Discourses in Contemporary Sri Lanka*, 73 SOC. SCI. & MED. 515, 516 (2011) (suggesting that the philosophies underpinning bioethics are reflective of Anglo-American rather than universal values).

129. Carel B. IJsselmuiden & Ruth Faden, *Research and Informed Consent in Africa—Another Look*, 326 NEW ENG. J. MED. 830, 830 (1992).

130. *Id.* Medical ethical imperialism involves the imposition of solutions culturally appropriate for one society onto another society assuming that those solutions represent moral absolutes. See Charles F. Gilks, *Ethical Imperialism*, 322 NEW ENG. J. MED. 200, 200 (1990).

131. IJsselmuiden & Faden, *supra* note 129, at 830.

132. *Id.*

133. S.R. Benatar, *Reflections and Recommendations on Research Ethics in Developing Countries*, 54 SOC. SCI. & MED. 1131, 1135 (2002).

be bridged if a researcher invests skill, time and interest in breaking down those walls.¹³⁴ For example, it has been noted that in Uganda the western concept of informed consent has faced the problems of (i) socioeconomic inequalities between researchers and subjects, which results in subjects feeling they have no choice when asked to participate in a research study; (ii) colonialism, which instills divides in power and trust between researchers and subjects; and (iii) erosion of the Ugandan health care system, which left many with a suspicion that HIV was brought to Africa by foreigners.¹³⁵ Researchers should be informed of these things before attempting to achieve required informed consent of research participants. When discussing privacy, anthropologists indicate that it is typical of African culture that individuals perceive themselves as extensions of the family.¹³⁶ They see themselves as an intermediaries between ancestors and future generations, not as individual persons in their own right who makes decisions only for themselves.¹³⁷ This might mean that privacy, as well as informed consent, cannot be translated to a culture that makes decisions as a community. It is important to understand these barriers before beginning research. Anthropologic literature involving local health care authorities and the continued assistance of an ethics committee is useful.¹³⁸

In addition, literature on doctor-patient and scientist-subject interactions in western countries notes that differences in culture and class between the two limits the effectiveness of communication, but no one suggests that there be varied standards based on such differences.¹³⁹ While privacy is not necessarily defined the same across all cultures, fears of cultural imperialism may be allayed by making it clear that only U.S. firms are expected to adhere to HIPAA guidelines. HIPAA was designed as a base of privacy protection able to protect persons regardless of their differences, and moving research abroad should not change this standard.

5. Increasing Requirements and the Slowing of Research

Complying with HIPAA may require added time and re-

134. *Id.*

135. *Id.* at 1134.

136. *See* IJsselmuiden & Faden, *supra* note 129, at 830.

137. *See id.*

138. *See* Benatar, *supra* note 133, at 1135, 1137.

139. *See id.*

sources that would slow the pace of research in clinical trials abroad.¹⁴⁰ HIPAA would require that resources and time be spent explaining privacy rights, training researchers and clinical staff on HIPAA, and setting up safeguards to protect privacy of research subjects.¹⁴¹

The need for data can be immediate. In some cases, it is necessary to give research speed a high priority. For example, data on HIV transmission, hepatitis B, or multi-drug-resistant tuberculosis is critical and time sensitive to those infected and to those who may become infected.¹⁴² Adding these regulatory requirements might hinder the research¹⁴³ and slow progress in the effort to end the global epidemics of these potentially fatal illnesses.

There are many urgent health needs, and many of these are rampant in developing countries outside of the United States.¹⁴⁴ The question ought not be whether this research needs to be done in haste, but whether that urgency warrants reducing ethical standards because of the added time, expense, and effort that increasing privacy protections would require.

The pace at which research findings are actually implemented in the form of new drugs, technologies, and vaccines does not support reduced ethical standards.¹⁴⁵ For example, the hepatitis B vaccine was approved for use in the United States in the late 1970s.¹⁴⁶ Replicating these trials in Africa was important because there can be different responses in different groups.¹⁴⁷ The argument that the urgency of the research findings was so great as to prevent the researchers from complying with ethical standards required in the United States is unsupported because even if the vaccine was effective it was unlikely

140. See IJsselmuiden & Faden, *supra* note 129, at 830.

141. See *supra* Part I.A (describing the requirements of HIPAA compliance).

142. See, e.g., Press Release, AVAC, Continued Investment in HIV Prevention Research Can Speed Development of New Options To Help End the AIDS Epidemic (June 30, 2013), available at <http://online.wsj.com/article/PR-CO-20130630-900440.html> (explaining the urgent need for research in this area).

143. *Id.*

144. *The Top 10 Global Health Issues To Watch in 2013*, INTRAHEALTH.ORG, (Jan. 15, 2013), available at <http://www.intrahealth.org/page/the-top-10-global-health-issues-to-watch-in-2013>.

145. See IJsselmuiden & Faden, *supra* note 129, at 830.

146. See *Hepatitis B*, CTRS. FOR DISEASE CONTROL AND PREVENTION (May 7, 2012), <http://www.cdc.gov/vaccines/pubs/pinkbook/hepb.html>.

147. See *id.* (discussing how serologic markers of hepatitis B can vary depending on whether the infection is acute or chronic).

to be rapidly used and disbursed following this positive finding.¹⁴⁸ The inevitable lag between research findings and action cripples the argument for decreasing ethical standards in the face of urgency for results.¹⁴⁹

The debate over whether HIPAA applies to covered entities working abroad is exacerbated by the lack of specific guidance from HHS.¹⁵⁰ In addition, institutions of higher education that are often leaders in the research field supply a varied patchwork of conclusions regarding HIPAA's implications in international research.¹⁵¹ Potential consequences of applying HIPAA abroad include issues of extraterritorial application of U.S. law, added costs, conflicts of law, and translation of privacy to different cultures. While these are not to be ignored, they can be mitigated with a flexible approach. Moreover, the consequences of *not* applying HIPAA are grave.

B. ETHICAL ANALYSIS OF PRIVACY STANDARDS

Costs of not issuing guidance to require compliance with HIPAA overseas include both monetary and ethical considerations. This section argues that implementing HIPAA abroad is an ethically necessary solution because it would significantly add to the propriety of U.S. researchers working abroad, and that HIPAA is a baseline of privacy protections that ought to be guaranteed by every covered entity.

1. Past Abuses in Standards of Care and Current Standards of Care in Research Highlight the Need for Equity and the Importance of Privacy for All Persons

The AZT trials conducted in the 1990's in Africa are a blemish on U.S. research history in the context of standard of care issues. These trials, conducted in Africa, involved research on antiretrovirals in preventing transmission of HIV from mother to child.¹⁵² Although there were established therapies,

148. See Hilton Whittle et al., *Observational Study of Vaccine Efficacy 14 Years After the Trial Vaccination in Gambian Children*, 325 *BMJ* 7364 (Sept. 4, 2002), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC124550/>.

149. See *id.*

150. See *Secretary's Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

151. See DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM, *supra* note 5; JOHNS HOPKINS MED., *supra* note 49; UCLA OFF. OF THE HUM. RES. PROT. PROGRAM, *supra* note 60; YALE UNIV. OFF. OF RES. ADMIN., *supra* note 58.

152. See Peter Lurie & Sidney M. Wolfe, *Unethical Trials of Interventions To Reduce Perinatal Transmission of the Human Immunodeficiency Virus in*

there was a placebo control arm to the study.¹⁵³ The placebo control arm was defended by researchers, “arguing that the subjects are treated at least according to the standard of care in these countries, which consists of unproven regimens or no treatment at all.”¹⁵⁴ Using the host country’s standard of care (which may be *no* standard at all, as in this case), led to outcry against the study’s design.¹⁵⁵

In August 2011, the families of children who died during a meningitis drug trial in Nigeria received their first payments following a settlement with the sponsor.¹⁵⁶ “[Eleven] children died in the trial: five after taking the drug Trovan and six after taking an older antibiotic [that was] used for comparison in the clinical trial. Others suffered blindness, deafness and brain damage.”¹⁵⁷ A panel of Nigerian medical experts concluded that the study violated international law by testing an unapproved drug on children and failing to obtain authorization from the Nigerian government for the trial.¹⁵⁸ Criticism remains that research moves overseas to avoid U.S. regulatory protections and capitalize on less demanding requirements abroad,¹⁵⁹ and the President’s Commission on Bioethics has stated that there is still much room for improvement to protect research subjects.¹⁶⁰

The Common Rule states that to gain approval from the IRB there must be “adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.”¹⁶¹ Privacy protections must be at least equivalent for those govern-

Developing Countries, 337 NEW ENG. J. MED. 853 (1997).

153. *Id.* at 855.

154. *Id.*

155. *Id.* (arguing that any acceptance of the standard of care that does not conform to the standard in the sponsoring country leads to a “double standard” in research).

156. Donald G. McNeil, Jr., *Nigerians Receive First Payments for Children Who Died in 1996 Meningitis Trial*, N.Y. TIMES, Aug. 11, 2011, <http://www.nytimes.com/2011/08/12/world/africa/12nigeria.html>.

157. *Id.*

158. Joe Stephens, *Panel Faults Pfizer in '96 Clinical Trial in Nigeria*, WASH. POST, May 7, 2006, <http://www.washingtonpost.com/wp-dyn/content/article/2006/05/06/AR2006050601338.html>.

159. See Stacey B. Lee, *Informed Consent: Enforcing Pharmaceutical Companies' Obligations Abroad*, 12(1) HEALTH & HUM. RTS.: INT'L J. 15, 15 (2010), available at <http://www.hhrjournal.org/2013/08/26/informed-consent-enforcing-pharmaceutical-companies-obligations-abroad/>.

160. See President’s Commission Releases Report on Human Subjects Protection, BIOETHICS.GOV, <http://bioethics.gov/node/559> (last visited Apr. 8, 2014). This includes greater transparency and accountability. *Id.*

161. 45 C.F.R. § 46.111(a)(7) (2013).

ment agencies that have adopted the Common Rule. The Declaration of Helsinki, requires that

The right of research subjects to safeguard their integrity must always be respected. Every precaution should be taken to respect the privacy of the subject, the confidentiality of the patient's information and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.¹⁶²

These documents suggest that privacy is a contemplated protection for research subjects both in the United States and abroad. Yet, the U.S. government has not taken steps to explicitly state that HIPAA is required by all U.S. covered entities working overseas and the varied understanding of the nation's research universities illustrates that this question must be addressed. These examples indicate that the United States has faced standards of care issues in the past and has favored expansion of rights of human subjects. This approach of expanding rights should be furthered in the realm of privacy by adopting HIPAA's standards that give practical steps to improve privacy protections for all human subjects.

2. Lowered Standards of Care Decrease the Propriety of U.S. Researchers and Hinder International Research

The consequences of reducing ethical standards are great. International noncompliance could lead to the loss of patient, research subject, or public's trust that HIPAA aimed to achieve.¹⁶³ Surveys and evidence suggest that patients value HIPAA privacy regulations and the rights that come with them.¹⁶⁴ Potential costs of ethical transgressions in standards of care abroad include loss of integrity in research and international relations.¹⁶⁵ U.S. health work abroad has seen major ethical transgressions that have damaged the reputation of U.S. sponsored initiatives. For example, following the false hepatitis vaccination scheme to attempt to find Osama Bin Laden, a campaign against the polio vaccine and those aid workers who

162. *World Medical Association Declaration of Helsinki*, Bulletin of the World Health Org. 374 (2001), available at [http://www.who.int/bulletin/archives/79\(4\)373.pdf](http://www.who.int/bulletin/archives/79(4)373.pdf).

163. See Annas, *supra* note 105, at 1486 (arguing that the public policy rationale for protection of privacy is that patients will be less likely to disclose details necessary for proper medical care if they do not trust their physicians to keep the information secret, and HIPAA is a way to ensure these principles in the electronic age).

164. See Williams et al., *supra* note 98, at 30.

165. See Lurie & Wolfe, *supra* note 152, at 855.

administer it has been launched.¹⁶⁶ Unarmed volunteers, all over Pakistan, Somalia, and Afghanistan are being targeted for assassinations and their important vaccines being refused.¹⁶⁷ This same distrust of western medicine and vaccination resulted following a research trial of a meningitis drug.¹⁶⁸

Standards of care for research subjects can vary, and the government has set guidelines in the past to address these issues.¹⁶⁹ Privacy is now a part of the accepted standard of care and should be recognized as such. Upsetting the public or research community with poor research practices can end a project, waste money for the host organization, and damage the integrity of the research organization as a whole. It is in the best interests of researchers and research organizations alike to follow HIPAA standards when overseas.

3. The Potential Costs to Research Participants in Studies Using Lower Privacy Standards is Great

Beyond the financial costs and potential standard of care conflicts is the human cost of not applying HIPAA overseas. Before HIPAA was written, the American medical community witnessed unauthorized use of medical records for blackmail, harassment, job exclusion, and discrediting of persons.¹⁷⁰ HIPAA was enacted in 1996 to address the public's fears as electronic medical records increased the threat of these invasions of privacy.¹⁷¹ These fears are just as real in any country. Research could implicate a particularly stigmatized subject like HIV status, or it may involve private medical histories. Leaving people vulnerable to abuse is the human cost of non-compliance. There should be an obligation to protect information collected about medical histories, diagnoses, and other PHI so that this information can't be used to harm participants or their families, whether they are U.S. citizens or not.

166. See Emma Green, *Five Global Health Concerns*, THE ATLANTIC, Oct. 5, 2013, <http://www.theatlantic.com/events/archive/2013/10/five-global-health-concerns/280304/>.

167. *Id.*

168. See McNeil, *supra* note 156.

169. See Part II.B.1.

170. The story of Thomas Eagleton is a good example in which his medical records were used to discredit his campaign as Vice President. See *The Thomas Eagleton Affair Haunts Candidates Today*, NPR (Aug. 4, 2012), <http://www.npr.org/2012/08/04/157670201/the-thomas-eagleton-affair-haunts-candidates-today>; see also *supra* notes 2–4.

171. See Choi et al., *supra* note 22, at 58.

Research subjects often do not have any say in determining standards of care. In worst-case scenarios, standards are determined by the financial limitations that these research subjects live with because their government cannot afford the high prices set by drug and device companies and medical industry.¹⁷² Standards of care should reflect the laws of the entity's home country, not the power asymmetries of the subject country.¹⁷³ While our laws may not specifically require the application of HIPAA abroad, the spirit of the laws we do have, including the Common Rule, and the ethical transgressions that led to the creation of international standards of care, do require the application of HIPAA abroad.

III. ISSUING GUIDANCE TO IMPLEMENT HIPAA ABROAD

Universities and other research organizations are unsure of the privacy requirements for studies conducted overseas.¹⁷⁴ Standards of care in international research are a constantly developing area and privacy is becoming part of that standard, ripe for recognition.¹⁷⁵ To require HIPAA compliance internationally, HHS must issue guidance. Part A explains what guidance from HHS should look like. Part B discusses overcoming barriers to implementing HIPAA abroad. Part C argues that privacy is a fundamental right, and that basic privacy protections for research subjects is part of that right.

A. WHAT GUIDANCE FROM HHS OUGHT TO LOOK LIKE

HHS must issue guidance clarifying that the scope of HIPAA reaches covered entities working overseas. This guidance should state:

HIPAA privacy protections apply to covered entities working abroad. All covered entities must comply with the following basic privacy protections:

1. Covered entities must have a set of policies in place for compliance with HIPAA.¹⁷⁶
2. There must be a system of training of covered entity

172. See Lurie & Wolfe, *supra* note 152, at 855.

173. See Marcia Angell, *The Ethics of Clinical Research in the Third World*, 337 N. ENG. J. MED. 847, 848 (1997).

174. See *supra* Part I.B.2.

175. See Lie et al., *supra* note 73, at 190.

176. See, e.g., 45 C.F.R. § 164.530(i)(1) (2013) (describing policies and procedures).

staff on compliance and on the importance of privacy.¹⁷⁷

3. International patients or research participants should receive notice of privacy practices in their own language, so they know how their information might be used or disclosed.¹⁷⁸

4. Covered entities must have appropriate administrative, technical, and physical safeguards to protect against unauthorized disclosures.¹⁷⁹

5. Covered entities should work with their IRB to meet these basics and adapt them to their host country and population's needs.

This guidance document would allow flexibility in working with the IRB to reach acceptable standards of care and privacy policies without sacrificing HIPAA's requirements and research participants' right to privacy. It would also mean that all covered entities would clearly know that HIPAA applies abroad and that they are required to consider and protect human subjects' privacy in the United States and abroad.

The Secretary's Advisory Committee on Human Research Protections has suggested that IRB alterations of HIPAA's authorization requirements, which involve research subjects giving permission for the use of their information in the study, might be sought.¹⁸⁰ This would be a "boiled down" version of the elements of authorization.¹⁸¹ The approach from universities in response to this debate¹⁸² is a good example of potential compromise. IRBs and covered entities can work together to determine how to best protect PHI with the baseline requirements of HIPAA as a framework. HIPAA has standards but is also a law that allows for flexibility for covered entities to take into account their costs, size, and level of risk for security breach of PHI.¹⁸³ A covered entity may use any security measures, as long as they reasonably and appropriately implement HIPAA standards.¹⁸⁴ This should make it easier for covered entities to work with IRB's to implement HIPAA and protect the privacy

177. See, e.g., *id.* § 164.530(b)(1) (describing standards for training).

178. See, e.g., *id.* § 164.520 (outlining notice of privacy practices for protected information).

179. See, e.g., *id.* § 164.530(c)(1) (describing standards for safeguards).

180. See *Secretary's Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

181. *Id.*

182. See *supra* Part I.B.2.

183. See 45 C.F.R. § 164.306(b).

184. *Id.*

of all persons in research or treatment while also taking into account the differing needs of researchers and populations.

Basic HIPAA protections for patient or research participants' health histories should be maintained as researchers work with their IRB to determine which safeguards are necessary given the nature of the research. HHS guidance should be rigid in its principle of privacy protection for research subjects, but flexible in building upon HIPAA's baseline protections, a process through which a research entity and IRB may find solutions to the varying issues involved in international research. With this clarifying guidance document, covered entities would not have to deal with uncertainty as to whether protections apply abroad and those research subjects with whom they work would be guaranteed protection of private personal and medical information.¹⁸⁵

Although this guidance would simply extend basic privacy protections to all persons participating in research with U.S. covered entities, the potential barriers to implementation discussed in Part II.A should be considered. These include extraterritorial application of U.S. law, costs associated with compliance, conflicts of law, translational issues, and the effect of the regulation on the pace of research. In addition, practical concerns including who will enforce the law and how research participants will be able to understand the law are important.

B. OVERCOMING BARRIERS TO APPLYING HIPAA OVERSEAS

As explained in Part II.A, there are several barriers to implementing HIPAA abroad, but with planning and use of current HIPAA infrastructure, these barriers are surmountable. Extraterritorial application of U.S. law issues can be avoided quickly, if HHS issues guidance that HIPAA should apply abroad.¹⁸⁶ Additional costs to research organizations for implementing HIPAA overseas is a legitimate concern.¹⁸⁷ Yet, HIPAA has been a part of U.S. law for over a decade,¹⁸⁸ and every covered entity in the United States should already be in compliance. Requiring overseas researchers to follow the same proto-

185. See Choi et al., *supra* note 22, at 58.

186. See *Foley Bros. v. Filardo*, 336 U.S. 281, 283 (1949) (noting that it is not a question whether Congress has the power to extend the Eight Hour Law to work performed in foreign countries).

187. See Kilbridge, *supra* note 95, at 1423.

188. Congress enacted HIPAA in 1996. See The Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-91, 110 Stat. 1936.

col should not overwhelm those organizations.¹⁸⁹

Conflicts of law may arise when applying a U.S. standard overseas, but HIPAA is designed to be a floor and a baseline of protections from which to build up.¹⁹⁰ If a covered entity is working in a country that requires more than HIPAA, they will have to follow that country's laws, but if the country has a less thorough privacy rule or none at all, then the covered entity should provide this basic level of protection, regardless of citizenship. Researchers may work with their IRB to come up with the privacy plan to both adequately protect participant privacy and comply with all laws.¹⁹¹

Privacy concepts important to a western culture and codified in HIPAA may not be effective in international settings, but practicing double standards for U.S.-based research and research abroad is not the solution.¹⁹² Translational issues and cultural differences are a traditional problem in all international research,¹⁹³ but if a researcher invests skill, time and interest in understanding those differences there should not be a conflict.¹⁹⁴ HIPAA was designed as a base of privacy protection without regard to differences, and where privacy translation is an issue, a researcher may work with their IRB to find a solution to comply with HIPAA without insulting local culture.¹⁹⁵

HIPAA compliance will require added time and resources that may slow the pace of research in overseas clinical trials.¹⁹⁶ But reducing ethical standards to potentially increase the pace of discovery would not directly lead to faster implementation of new drugs, technologies, or vaccines.¹⁹⁷ While reduced pace is a risk, it does not warrant a decreased standard of care.

Finally, in addition to the issues with HIPAA application discussed above are the practical difficulties in beginning to require HIPAA compliance overseas. The OCR at HHS may audit a covered entity, but they also accept complaints from anyone

189. See *supra* note 104.

190. See LaMartina, *supra* note 104.

191. Protection of Human Subjects, 45 C.F.R. § 46.101 (2013). Institutional Review Boards must approve proposed non-exempt research before beginning research involving human subjects. *Id.*

192. See IJsselmuiden & Faden, *supra* note 129, at 830.

193. See Benatar, *supra* note 133, at 1134–35.

194. See *id.* at 1134–36.

195. See *id.* at 1134.

196. See, e.g., IJsselmuiden & Faden, *supra* note 129, at 831–33 (discussing researchers' obligations when conducting research in developing countries).

197. See *id.* at 830.

who feels their privacy rights have been violated.¹⁹⁸ There is a main office in Washington, D.C., and several smaller investigator offices throughout the country.¹⁹⁹ The current complaint process is focused on persons in the United States, and its expansion may prove difficult. Yet with proper planning these practical difficulties can be avoided.

OCR works to achieve voluntary compliance through corrective actions and agreements with covered entities.²⁰⁰ This collaboration between covered entities and OCR would likely continue. The enforcement process is largely complaint driven.²⁰¹ As there is no private right of action,²⁰² international research subjects or persons being treated abroad would not be able to sue over a HIPAA violation, but they could file complaints with OCR.²⁰³ OCR would work towards voluntary compliance with the covered entity to improve their privacy protections globally.²⁰⁴ Complaints may be submitted electronically or in writing, and the OCR offices are adamant that anyone may file a complaint, including noncitizens.²⁰⁵ In addition, while it may be more difficult for persons outside the United States to learn about the OCR process, it is not impossible.²⁰⁶ The information is on the internet and available globally,²⁰⁷ and covered entities would be required to explain these options as part of their privacy policy provided to each research participant before beginning a study. Resource limits for researchers and research subjects, including reduced access to computers or the internet, present a problem to the proper filing of complaints. Self-enforcement and voluntary compliance will be even more important in the context of research abroad. In addition, the IRB and the Ethics Committee should play a role in ensuring privacy protections and HIPAA compliance.²⁰⁸

198. See *Health Information Privacy: How To File a Complaint*, HHS.GOV, <http://www.hhs.gov/ocr/privacy/hipaa/complaints/index.html> (last visited Apr. 8, 2014).

199. *Id.*

200. See FURROW ET AL., *supra* note 2, at 282.

201. *Id.*

202. *Id.*

203. See *Health Information Privacy: How To File a Complaint*, *supra* note 198.

204. See FURROW ET AL., *supra* note 2, at 282.

205. *Id.*

206. See *id.*

207. *Id.*

208. See Benatar, *supra* note 133, at 1137 (arguing the importance of ethics committees).

C. PRIVACY AS A FUNDAMENTAL HUMAN RIGHT

In the 1890s, future Supreme Court Justice Louis Brandeis argued that privacy had become essential to the individual, but “modern enterprise and invention have, through invasions upon his privacy, subjected him to mental pain and distress, far greater than could be inflicted by mere bodily injury.”²⁰⁹ As personal information becomes more readily available and valuable,²¹⁰ many are afraid that individual privacy is an unachievable goal.²¹¹ Even though privacy seems to be slipping away, it is a fundamental human right.²¹² It is recognized by the Universal Declaration of Human Rights,²¹³ the Declaration of Helsinki,²¹⁴ and the International Covenant on Civil and Political Rights.²¹⁵ Privacy in health is essential to human dignity. The paradox in current health care privacy practices is that U.S. researchers may either disregard the dignities of our neighbors for scientific gain, or risk accusations of cultural imperialism by granting them the same rights we expect within our own borders. The fluidity of information in the modern age has diminished the rigidity of borders and the function of laws that cover only that information within them. Privacy may be more difficult to achieve, but there remains a moral imperative to enforce privacy in health as a basic human right by guaranteeing protection of private information in research in all cases. Expanding HIPAA to cover international research would achieve this goal.

209. Samuel D. Warren & Louis D. Brandeis, *The Right to Privacy*, 4 HARV. L. REV. 193, 196 (1890).

210. PHI covers any personal information, including identity indicators which can be valuable. See 45 C.F.R. § 160.103 (2013).

211. See, e.g., Jean-Louis Gassée, *NSA Files Show Privacy Does Not Exist*, THEGUARDIAN.COM (Aug. 5, 2013), <http://www.theguardian.com/technology/blog/2013/aug/05/nsa-privacy-surveillance-monday-note>.

212. See, e.g., Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III) (Dec. 10, 1948) (“No one should be subjected to arbitrary interference with his privacy. . . .”); see also Dominic Rushe, *UN Advances Surveillance Resolution Reaffirming ‘Human Right to Privacy’*, THEGUARDIAN.COM (Nov. 26, 2013), <http://www.theguardian.com/world/2013/nov/26/un-surveillance-resolution-human-right-privacy>.

213. Universal Declaration of Human Rights, *supra* note 212.

214. *World Medical Association Declaration of Helsinki*, Bulletin of the World Health Org. 374 (2001), available at [http://www.who.int/bulletin/archives/79\(4\)373.pdf](http://www.who.int/bulletin/archives/79(4)373.pdf).

215. International Covenant on Civil and Political Rights, Dec. 16, 1966, S. Exec. Rep. 102-23, 999 U.N.T.S. 171.

CONCLUSION

The expansion of electronic record keeping, the ease of information sharing, and the rise of clinical trials overseas has highlighted the importance of privacy of health information and the need for heightened scrutiny of privacy practices of U.S. entities working abroad.²¹⁶ Privacy has developed into a widely recognized basic right.²¹⁷ Parallel to these increased concerns over privacy is the international expansion of clinical research by U.S. organizations.²¹⁸ Regulations to protect this right have lagged behind the expansion of operations as globalization of healthcare proceeds unabated.

While HIPAA requires basic privacy protections of health information by all covered entities in the United States,²¹⁹ when those covered entities leave the United States, HIPAA may no longer apply.²²⁰ Interpretations vary widely—some believe HIPAA does not apply abroad while others think it attaches to covered entities regardless of where they work.²²¹ This confusion contributes to an ineffective patchwork of privacy protections.²²²

To achieve clarity, the basic protections guaranteed by HIPAA should be part of the legal and ethical requirements for research or treatment performed by U.S. covered entities both in the United States and internationally. While there are difficulties inherent in expanding HIPAA application overseas, these barriers are not insurmountable and the consequences of failing to provide privacy protections can be great. The De-

216. FURROW ET AL., *supra* note 2, at 265.

217. *Id.* at 268–69 (suggesting that privacy is a value on which our society is built, but it is also necessary for the effective delivery of care, and a breach of health privacy can have implications beyond physical health including loss of a job, alienation of family and friends, loss of health insurance, and public humiliation).

218. See Glickman et al., *supra* note 4, at 816.

219. See Choi et al., *supra* note 22, at 58.

220. See *Secretary's Advisory Committee on Human Research Protections Appendix H*, *supra* note 16.

221. See *id.*

222. See, e.g., DUKE UNIV. HEALTH SYS. HUM. RES. PROT. PROGRAM, *supra* note 5 (providing policies for international research to Duke investigators); JOHNS HOPKINS MED., *supra* note 49 (describing John Hopkins' standard practices); UCLA OFF. OF THE HUM. RES. PROT. PROGRAM, *supra* note 60 (outlining HIPAA research); YALE UNIV. OFF. OF RES. ADMIN., *supra* note 58 (providing guidance on various rules, regulations, and policies specific to international research).

partment of Health and Human Services must issue guidance documents establishing that HIPAA's requirements extend to covered entities whether they are in the United States or abroad. This guidance should reflect the basic ideals of HIPAA, guaranteeing protection of patient information, including physical and technical safeguards, as well as organizational policies and staff training, while allowing for flexibility to work with their IRB to accommodate the needs of research teams and research populations. With this guidance document, covered entities would not have to deal with uncertainty as to whether protections apply abroad, and those research subjects they work with would be guaranteed a level of protection for personal and medical information in an increasingly global world with graver consequences for breaches of privacy.