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HOW DID YOU KNOW THAT? PROTECTING PRIVACY INTERESTS OF
RESEARCH PARTICIPANTS VIA CERTIFICATES OF
CONFIDENTIALITY[†]

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I. INTRODUCTION

“Hey Chase, I heard you have HIV.”¹ One can imagine the look of shock on Chase’s face when Charlie, a friend, said this to him. Chase, although denying the statement and carrying on with his day, could not deny the rush of thoughts and questions running through his mind: “How could Charlie have found out?” “Does he know my doctors, my nurses, my pharmacists?” “Did he hack my computer?” “I’m always so careful, how could this have happened?” Indeed, Chase was, and is, careful as it relates to his health information, including his HIV status. Chase was diagnosed as HIV-positive three years ago after a severe accident required him to receive a blood transfusion. The transfused blood however was not appropriately screened and contained traces of HIV.²

After being diagnosed, Chase became very concerned about protecting his privacy to ensure that others did not know that he had HIV. Chase was concerned that if people found out he was HIV-positive his personal relationships might suffer and he may face stigmatization. Further, Chase believed his employer would discriminate against him and his coworkers would ostracize him. Chase took a number of steps to ensure that any information regarding his HIV-positive status would remain private: Chase purchased his own insurance plan so he could visit physicians that were not within his employer’s insurance network, filled his medications at pharmacies well away from his home and social network, and never spoke of his HIV status, searched for HIV-related information on the internet, or read HIV-related educational materials. So how could Charlie possibly have found out?

Upon being diagnosed with HIV, Chase received an informed consent document related to his treatment and care. The informed consent document included details of an ongoing research study investigating patients’ blood to assess for vitamin deficiencies associated with treatment. Chase consented to having his blood assessed for the purposes of the ongoing research study. In addition, Chase checked a box on the informed consent document

1. HIV refers to the Human Immunodeficiency Virus. For more information regarding HIV, see *HIV/AIDS*, NAT’L INST. ALLERGY & INFECTIOUS DISEASES, <http://www.niaid.nih.gov/topics/hivaids/Pages/Default.aspx> (last updated Oct. 22, 2015).

2. See *HIV/AIDS: The Basics*, NAT’L INST. HEALTH, <http://www.aidsinfo.nih.gov/education-materials/fact-sheets/19/45/hiv-aids-the-basics> (last updated Sept. 15, 2015) (HIV is spread via the blood, semen, vaginal fluids, or breast milk of an HIV infected person).

indicating that he agreed to have his blood stored for use in future unforeseen research.

Charlie's brother Grayson,³ a molecular geneticist researching HIV, was the recipient of vials of Chase's deidentified blood sample from a biorepository. Immunological markers extracted from Chase's blood responded to a new therapy Grayson was investigating. To determine whether the immune response identified in Chase's blood was specific to any demographic characteristics, Grayson used genotyping methodologies to identify highly polymorphic short tandem repeats across the Y chromosome (Y-STRs).⁴ The Y-STR haplotypes were then cross-referenced with public genetic genealogy databases to identify Chase's surname.⁵ Grayson reported this information to the state public health office (where Charlie worked) when compelled to identify all persons whose blood he was researching that were HIV positive. Had the biorepository and Grayson obtained a Certificate of Confidentiality, such disclosure would be barred.⁶

This hypothetical highlights the threat to privacy incurred by rapid advances in medical research, specifically genetic research. Answering novel medical hypotheses requires investigators to have robust and demographically diverse biospecimens and genetic data to facilitate their research. Doing so, however, requires adequate participation by human subjects willing to consent to the donation and use of their biospecimens and genetic data for future unforeseen research. Advances in scientific methodologies and technologies are critical to enhancing the common good; they allow a deeper understanding of the etiology of diseases and facilitate the development of improved therapies. However, these advances pose informational risks associated with the re-identification of individuals. Mitigating the privacy concerns associated with potential re-identification in future unforeseen research without impeding innovative research presents a conundrum to both the medical and legal communities. Any strategy to address these concerns must appropriately balance a research participant's privacy with potential ethical and legal

3. Chase, Charlie, and Grayson are fictional characters created solely for the purposes of this paper.

4. Melissa Gymrek et al., *Identifying Personal Genome by Surname Inference*, 339 SCIENCE 321, 321-24 (2013).

5. *Id.* at 322.

6. 42 U.S.C. § 241(d) (2012).

obligations of researchers to notify research participants of any incidental findings that may impact his or her health.⁷

Current federal regulations, including the Common Rule and the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, do not adequately address privacy concerns related to the re-identification of research participants in future unforeseen research. Further, the current regulatory framework intended to safeguard and maintain the privacy of research participants employs divergent definitions of what constitutes identifiable information. Scholars maintain that the inconsistencies between the Common Rule and the Privacy Rule result in gaps in privacy protections and confusion among researchers and research participants.⁸ As such, the question exists as to whether harmonizing the Common Rule and the Privacy Rule will ensure the privacy of research participants' identifiable information without impeding future unforeseen research.

In July 2011, the U.S. Department of Health and Human Services (HHS) released an Advanced Notice of Proposed Rulemaking (ANPRM), titled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators," which proposed to modify the rules governing research involving human subjects.⁹ The ANPRM recognized the informational risks posed by the collection and secondary analysis of potentially identifiable data and that assurance of adequate protections for identifiable information is critical to an individual's willingness to participate in research.¹⁰ Likewise, the ANPRM recognized that the advances in scientific technologies—along with the increased access to and volume of data—demonstrate that what constitutes identifiable and

7. See Susan M. Wolf et al., *The Law of Incidental Findings in Human Subjects Research: Establishing Researchers' Duties*, 36 J.L. MED. & ETHICS 361, 363 (2008) (defining an incidental finding as "a finding concerning an individual research participant that has potential health or reproductive importance and is discovered in the course of conducting research but is beyond the aims of the study").

8. Mark A. Rothstein, *Research Privacy under HIPAA and the Common Rule*, 33 J.L. MED. & ETHICS 154, 154 (2005).

9. Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512–31 (July 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, and 164, and 21 C.F.R. pts. 50 and 56).

10. *Id.* at 44,524.

deidentified data is fluid.¹¹ Thus, much of the data once considered deidentified is potentially identifiable.¹²

Given the advances in genetic and information technologies that make deidentification of biospecimens nearly impossible and re-identification of health data easier, the ANPRM notes the importance of having uniformity between the Common Rule and the Privacy Rule.¹³ To do so, the ANPRM envisions that the Common Rule adopts the Privacy Rule standards for what constitutes identifiable information: limited data sets and deidentified information.¹⁴ The ANPRM also suggests the implementation of an absolute prohibition against re-identification of deidentified data.¹⁵

The ANPRM contemplates a much-needed revision to federal regulations governing future unforeseen research using potentially identifiable information. The ANPRM suggests that, by modifying the standards of what constitutes identifiable and deidentified information for research purposes, additional privacy protections may be afforded to research participants. While protecting research participant privacy is critical, the proposed adoption of the Privacy Rule definitions of identifiable and deidentified information by the Common Rule will impede advances in medical research. Moreover, the proposed prohibition against the re-identification of deidentified information by researchers is premature. This is due to the current lack of normalized and consistent empirical data demonstrating the likelihood of re-identification using presumably de-identified data, regulations governing privacy tort causes of action for re-identification, and the discovery and return of incidental findings from research.

Recognizing that modifications to the rules governing future unforeseen research are needed to safeguard research participant privacy and encourage participation, this author does not suggest that no changes are required. Rather, this author suggests the delay of the proposed harmonization of the Common Rule and the Privacy Rule until the legislature further investigates and fully considers the implications of a sweeping prohibition against re-identification. In the interim, federal entities supporting research

11. *Id.*

12. *Id.*

13. *Id.* at 44,525.

14. *Id.*

15. *Id.* at 44,526.

should use an already existing safeguard to enhance research participant privacy: Certificates of Confidentiality.¹⁶

II. BIOREPOSITORIES, GENETIC INFORMATION, AND PRIVACY

A biorepository is a stored collection of genetic samples that can be linked with medical and genealogical or lifestyle information from specific populations, which is gathered using a process of generalized consent.¹⁷ Although proscribing to one definition, biorepositories differ in their functionality. A biorepository may collect its own biospecimens and data in order to conduct research or rely on researchers at multiple sites to perform biospecimen collections, which the biorepository then aggregates for future research use.¹⁸ Some biorepositories¹⁹ also serve a dual purpose in that they conduct their own research while also aggregating and distributing data to investigators.²⁰

Biorepositories are a critical resource for medical research,²¹ including genome-wide association studies that facilitate the identification of genetic markers of disease.²² In 1998, the National

16. See PRESIDENTIAL COMM'N FOR THE STUDY OF BIOETHICAL ISSUES, PRIVACY AND PROGRESS IN WHOLE GENOME SEQUENCING 1, 39 (2012), available at http://bioethics.gov/sites/default/files/PrivacyProgress508_1.pdf (identifying confidentiality as “restricting access to information or data to groups of specifically authorized recipients”).

17. See SEC'Y'S ADVISORY COMM. ON GENETICS, HEALTH, AND SOC'Y, POLICY ISSUES ASSOCIATED WITH UNDERTAKING A NEW LARGE U.S. POPULATION COHORT STUDY OF GENES, ENVIRONMENT, AND DISEASE 1, 16 (Mar. 2007), available at http://osp.od.nih.gov/sites/default/files/SACGHS_LPS_report.pdf.

18. Susan M. Wolf et al., *Managing Research Results and Incidental Findings in Genomic Research Involving Biobanks & Archived Datasets*, 14 GENET MED. 361, 361–84 (2012).

19. See *CPMC FAQs*, CORIELL INST. FOR MED. RESEARCH, <http://cpmc1.coriell.org/about-the-cpmc-study/cpmc-faqs> (last visited Nov. 5, 2015).

20. William McGeeveran et al., *Deidentification and Reidentification in Returning Individual Findings from Biobank and Secondary Research: Regulatory Challenges and Models for Management*, 13 MINN. J. L. SCI. & TECH. 485, 488 (2012).

21. Laura M. Beskow & Elizabeth Dean, *Informed Consent for Biorepositories: Assessing Prospective Participants' Understanding and Opinions*, 17 CANCER EPIDEMIOLOGY, BIOMARKERS & PREVENTION 1440, 1440 (2008).

22. Stephen J. O'Brien, *Stewardship of Human Biospecimens, DNA, Genotype, and Clinical Data in the GWAS Era*, 10 ANN. REV. GENOMICS & HUMAN GENETICS 193, 193–94 (2009).

Bioethics Advisory Commission²³ estimated that approximately 282 million human biospecimens²⁴ were being stored in the United States. In addition, the number of stored biospecimens was increasing at a rate of 20 million cases per year.²⁵ Biorepositories are also diverse in the types of biospecimens stored (e.g., lung or brain tissue) and in the disease states they target.²⁶ Given the number and diversity of samples stored, biorepositories are a valuable resource to researchers attempting to understand and develop treatments for a broad spectrum of medical conditions.

Advances in genetic medicine, including whole genome sequencing,²⁷ have expanded research capabilities to identify genetic markers of disease. To facilitate research in this area, a number of federal agencies, including the National Institutes of Health (NIH) have developed genetic data repositories, including the database of Genotypes and Phenotypes (dbGaP) to investigate genetic factors associated with disease.²⁸ The dbGaP stores genetic information, including whole genome sequence data.²⁹ Access to deidentified genotypes and phenotypes of research participants is controlled³⁰ and researchers seeking access must submit research requests, which are reviewed by NIH Data Access Committees.³¹ Further, the NIH has implemented policies and procedures for researchers to adhere to in order to protect the privacy and confidentiality of genetic information.³²

While critical in facilitating research advances in genetic medicine, the collection, storage, and use of genetic information

23. NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE 1 (Aug. 1999), available at <http://govinfo.library.unt.edu/nbac/hbm.pdf>.

24. *Id.* at 13. (“[T]he term ‘specimen’ refers to an individual quantity of material; several specimens can be obtained from one case, or individual, and several specimens can be obtained from one tissue biopsy or blood drawing.”).

25. *Id.*

26. Kimberly J. Cogdell, *Saving the Leftovers: Models for Banking Cord Blood Stem Cells*, 39 U. MEM. L. REV. 229, 234 (2009) (citing Lori B. Andrews, *Harnessing the Benefits of Biobanks*, 33 J.L. MED. & ETHICS 22, 23 (2005)).

27. *See* PRESIDENTIAL COMM'N, *supra* note 16, at 16 (identifying whole genome sequencing as “a technique that determines the complete sequence of DNA in an individual’s cells.”).

28. *Id.* at 57; *see also* dbGaP, NAT'L CTR. FOR BIOTECHNOLOGY INFO., <http://www.ncbi.nlm.nih.gov/gap> (last visited Nov. 5, 2015).

29. *Id.*

30. *Id.* (citing Letter from Kathleen Sebelius, Secretary, Dep't of Health and Human Services, to Amy Gutmann, Chair, Presidential Comm'n for the Study of Bioethical Issues (May 16, 2012)).

31. *Id.*

32. *Id.*

stored in repositories for future unforeseen research raises privacy concerns. Indeed, although there is a general comfort amongst the public with respect to the sharing of genetic information in repositories, privacy ranks among research participants' highest concerns.³³ Previous empirical research demonstrates that privacy concerns are central to participation in large cohort studies.³⁴ For example, although 60% of people surveyed indicated that they would participate in studies where their data was stored, 91% indicated that they would be concerned about their privacy.³⁵ In addition, studies demonstrate that potential research participants are comfortable with the sharing of their data within the research community, but expressed concerns about access to their data by employers and insurance companies.³⁶

Current federal regulations seek to mitigate the privacy concerns of research participants associated with the collection, storage, and use of their biospecimens and genetic information in future unforeseen research. Thus, the Common Rule and the Privacy Rule provide guidelines to investigators regarding the conduct of research to ensure that research participants are making an informed decision about their participation and that information is deidentified to protect research participants' privacy. As described below, however, concerns exist as to the procedures used to deidentify research participants' health information and the lack of uniformity between the Common Rule and the Privacy Rule as to what constitutes deidentified health information.

III. DEIDENTIFICATION OF RESEARCH PARTICIPANT HEALTH INFORMATION

Experts in the field of health information privacy question the reliability of current deidentification procedures.³⁷ Deidentification refers to the process by which the identifiability of health

33. *Id.* at 43.

34. *Id.* (citing GENETICS & PUB. POLICY CTR., THE GENETIC TOWN HALL: PUBLIC OPINION ABOUT RESEARCH ON GENES, ENVIRONMENT, AND HEALTH (2009), available at http://www.pewtrusts.org/~media/legacy/uploadedfiles/phg/content_level_pages/reports/2009pcptownhallspdf.pdf).

35. *Id.* (citing David J. Kaufman et al., *Public Opinion About the Importance of Privacy in Biobank Research*, 85 AM. J. HUMAN GENETICS 643, 643-54 (2009)).

36. *Id.* (citing Amy L. McGuire et al., *DNA Data Sharing: Research Participants' Perspectives*, 10 GENETICS MED. 46, 46-53 (2008)).

37. Mark A. Rothstein, *Is Deidentification Sufficient to Protect Health Privacy in Research?*, 10 AM. J. BIOETHICS 3, 5 (2010).

information is reduced by the removal of certain data elements associated with an individual.³⁸ The process of deidentification varies depending upon the use of paper or electronic health records (EHR).³⁹ For paper records, the process can be labor intensive and time consuming as it involves manual deletion of individual information to remove identifiable health information.⁴⁰ Using this process of deidentification, individuals without any patient care responsibility modify sensitive health information without the knowledge, consent, or authorization of the patient.⁴¹ Further, there are no regulations governing who may deidentify identifiable health information or credentialing requirements for these persons.⁴²

In contrast to paper health records, the process of deidentifying EHRs is contingent upon the EHR system being used.⁴³ This process is complicated, as EHR systems generally do not have a one-click deidentification configuration. Thus, EHR systems' abilities to deidentify health information are reliant upon analyses of text boxes, scanned medical records (including laboratory reports and imaging data), and overt demographic characteristics.⁴⁴ As such, like with paper record deidentification, human intervention may be required.⁴⁵ In addition to the procedural complications associated with the deidentification of identifiable health information, the process is further complicated by inconsistencies between the Common Rule and the Privacy Rule as to what constitutes deidentified health information.

A. *The Common Rule*

Federal regulations governing human subjects research⁴⁶ are primarily based on recommendations from the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research.⁴⁷ Implemented by HHS, these

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.*

42. *Id.*

43. *Id.* (citing Ben Wellner et al., *Rapidly Retargetable Approaches to Deidentification in Medical Records*, 14 J. AM. MED. INFORMATICS ASS'N 564, 564-73 (2007)).

44. *Id.*

45. *Id.*

46. 45 C.F.R. §§ 46.101-46.505 (2014).

47. Marshall B. Kapp, *A Legal Approach to the Use of Human Biological Materials for Research Purposes* 10 RUTGERS J. L. & PUB. POL'Y 1, 5 (2013); see

regulations have since been adopted by fourteen other federal departments and agencies as the Common Rule.⁴⁸ The Common Rule applies to all human subjects research that is conducted, supported, or subject to regulation by any federal department or agency that makes the policy applicable to such research.⁴⁹

Federal regulations define a human subject as a living individual about whom an investigator conducting research obtains “(1) [d]ata through intervention⁵⁰ or interaction⁵¹ with the individual, or (2) [i]dentifiable private information.”⁵² The Common Rule requires investigators supported by federal funds to obtain and document the informed consent of individuals or their legally authorized representatives⁵³ prior to individuals participating in research.

Investigators seeking informed consent should only do so under circumstances that provide an individual with sufficient opportunity to consider whether he or she should participate in the study.⁵⁴ Informed consent documents and procedures must be written in language understandable to the individual and cannot include any exculpatory language requiring an individual to waive any of their legal rights or release the investigator, sponsor,

also Kenneth J. Ryan et al., U.S. DEP’T OF HEALTH & HUMAN SERVICES, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (1979).

48. See ANPRM, *supra* note 9, at 44,512.

49. 45 C.F.R. § 46.101(a) (2014); 45 C.F.R. § 46.102(d) (2014) (defining research as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.”).

50. *Id.* § 46.102(f) (defining intervention as including “both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.”).

51. *Id.* (identifying interaction as including “communication or interpersonal contact between investigator and subject.”).

52. *Id.* (defining private information as “information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.”).

53. *Id.* § 46.102(c) (defining legally an authorized representative as “an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.”).

54. *Id.* § 46.116.

institution, or its agents from liability for negligence.⁵⁵ Further, the possibility of coercion or undue influence to the individual should be minimized.⁵⁶

The Common Rule sets forth basic elements that investigators must include when seeking participation in a research study. Basic elements of informed consent include: a statement indicating that the study involves research, an explanation of the purposes of the research, the expected duration of participation, a description of the procedures to be followed, and identification of any experimental procedures.⁵⁷ Further, researchers must provide individuals with a description of any reasonably foreseeable risks⁵⁸ and/or benefits⁵⁹ associated with the study, as well as a disclosure of any alternative procedures or treatments that may be advantageous to the individual.⁶⁰ Individuals must also receive a description of how confidentiality will be maintained⁶¹ and an explanation of whom to contact with questions about the research, the individual's rights, and research-related injuries.⁶² With respect to research-related injuries, researchers must also provide individuals with information as to whether compensation or medical treatments are available if injury occurs.⁶³ Informed consent documents⁶⁴ must also include a statement that an individual's participation is voluntary, that they may withdraw from participation at any time, and that refusal to participate or withdraw will not result in any loss of benefits or penalties.⁶⁵

55. *Id.*

56. *Id.*

57. *Id.* § 46.116(a)(1).

58. *Id.* § 46.116(a)(2).

59. *Id.* § 46.116(a)(3).

60. *Id.* § 46.116(a)(4).

61. *Id.* § 46.116(a)(5).

62. *Id.* § 46.116(a)(7).

63. *Id.* § 46.116(a)(6).

64. *Id.* § 46.116(a)(8).

65. *Id.* § 46.116(b)(1–6) (there are additional elements of informed consent that shall be provided to individuals or their representatives, when appropriate, including “(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable; (2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent; (3) Any additional costs to the subject that may result from participation in the research; (4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject; (5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation

Central to research involving human subjects is the requirement that research protocols undergo Institutional Review Board (IRB) review and receive IRB approval.⁶⁶ IRBs are required to review, approve, disapprove, and, if necessary, require modification of a research protocol to secure approval.⁶⁷ Included in the IRB approval process of human subjects research is a review of the research protocol, including consent documents⁶⁸ required for participant inclusion. With respect to informed consent, an IRB assesses and determines whether the information provided to an individual complies with the regulations governing informed

will be provided to the subject; and (6) The approximate number of subjects involved in the study.”).

66. *Id.* § 46.111 (identifying the criteria necessary for IRB approval and stating “(a) In order to approve research covered by this policy the IRB shall determine that all of the following requirements are satisfied: (1) Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes. (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility. (3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons. (4) Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by § 46.116. (5) Informed consent will be appropriately documented, in accordance with, and to the extent required by § 46.117. (6) When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. (7) When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (b) When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.”).

67. *Id.* § 46.109(a).

68. *Id.* § 46.109(b).

consent.⁶⁹ An IRB may also waive the requirement for an investigator to obtain a signed consent document if the research presents no more than a minimal risk⁷⁰ or the only record linking the individual and research is the consent document, which may pose the sole potential risk and harm of a breach of confidentiality.⁷¹ Following approval, the research protocol is then subject to continuing IRB oversight and formal review at least once a year.⁷² Thus, the Common Rule is designed to “safeguard the welfare of human research subjects, including the privacy of the subjects and the confidentiality of their data.”⁷³ To do so, the Common Rule provides guidance to investigators to ensure that consent documents are prepared in a manner that discloses all potential risks, including privacy and confidentiality risks, to research participants to allow them to make an informed decision about their participation.

B. HIPAA Privacy Rule

HIPAA⁷⁴ is the federal law most related to medical privacy as it sets forth policies, procedures, and guidelines⁷⁵ for maintaining the privacy and security of individually identifiable health information.⁷⁶ With respect to research participant protection in future unforeseen research, including genetic research and potential re-identification, the most significant of the HIPAA rules is the Privacy Rule. The major goal of the Privacy Rule is to ensure that an individual’s health information is adequately protected while also facilitating the flow of health information critical to

69. *Id.*

70. *Id.* § 46.117(c)(2).

71. *Id.* § 46.117(c)(1).

72. *Id.* § 46.109(e).

73. *See* Rothstein, *supra* note 8, at 155.

74. The Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 110 Stat. 1936, enacted August 21, 1996.

75. *Id.*; *see also* PRESIDENTIAL COMM’N, *supra* note 16, at 62.

76. 45 C.F.R. § 160.103 (2014) (defining individually identifiable health information as “information that is a subset of health information, including demographic information collected from an individual, and: (1) Is created or received by a health care provider, health plan, employer, 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; and (i) That identifies the individual; or (ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual.”).

providing and promoting high-quality health care.⁷⁷ To do so, the Privacy Rule defines circumstances in which a patient's health information, including any identifiable information, may be used or disclosed by covered entities.⁷⁸ Covered entities refer to health plans, health care clearinghouses, or health care providers that transmit health information in electronic form.⁷⁹ Since its enactment, the Privacy Rule has been expanded to include business associates⁸⁰ of covered entities that may be subject to liability for disclosing health information.

Pursuant to the Privacy Rule, use and disclosure of an individual's health information is prohibited unless authorized by the individual⁸¹ or if it is to be used for treatment, payment, or health care operations.⁸² A covered entity must also make reasonable efforts to limit the use and disclosure of health information to the minimum amount necessary to accomplish the purpose of its use, disclosure, or request.⁸³ There are exceptions, however, in which a covered entity is not required to obtain an individual's authorization for use and disclosure of his or her health information, including but not limited to: public health activities,⁸⁴ health oversight activities,⁸⁵ judicial and administrative proceedings,⁸⁶ law enforcement,⁸⁷ and research.⁸⁸ However, in order for health information to be used for research purposes, an investigator must obtain documentation that an alteration or waiver of an individual's authorization has been approved by an IRB⁸⁹ or privacy board.⁹⁰

77. U.S. DEP'T OF HEALTH & HUMAN SERVS., *Summary of the HIPAA Privacy Rule*, 1 (2003), available at <http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf>.

78. 45 C.F.R. § 164.502 (2014) (identifying the uses and disclosures of PHI (protected health information) by covered entities).

79. *Id.* § 160.103.

80. *Id.*

81. *Id.* § 164.508 (identifying the uses and disclosures of PHI which require patient authorization).

82. *Id.* § 164.506 (identifying the permitted uses and disclosures of PHI to carry out treatment, payment or health care operations that do not require patient authorization).

83. *Id.* §§ 164.502(b) and 164.514(d).

84. *Id.* § 164.512(b).

85. *Id.* § 164.512(d).

86. *Id.* § 164.512(e).

87. *Id.* § 164.512(f).

88. *Id.* § 164.512(i).

89. *Id.* § 164.512(i)(1)(A).

90. *Id.* § 164.512(i)(1)(B).

By having only limited exceptions in which an individual's authorization for use and disclosure is not required, the Privacy Rule seems comprehensive in its approach to maintaining the privacy of an individual's health information. However, it actually only applies to covered entities and business associates. Thus, individually identifiable health information that is held by other entities or individual researchers is not protected by the Privacy Rule. Further, health information that is deidentified is not subject to the Privacy Rule.

C. Disparity Between the Common Rule and the Privacy Rule

Although intended to be complementary,⁹¹ the standards for what is considered to be human subjects research (due to the identifiability of information) under the Common Rule do not align with those defining what constitutes identifiable and deidentified information under the Privacy Rule. The Privacy Rule is only applicable to individually identifiable health information.⁹² Thus, the Privacy Rule does not apply and authorization for use and disclosure are unnecessary if health information is deemed to be unidentifiable.⁹³

The Privacy Rule does however have strict standards regarding the deidentification of health information.⁹⁴ Health information is considered deidentified if there is no reasonable basis to believe that the information can be used to identify an individual.⁹⁵ Thus, health information is considered deidentified if an individual, with appropriate statistical and scientific expertise, determines that the risk is very small that information could be used, alone or in combination with other available information, to identify an individual.⁹⁶ Further, health information may be deemed deidentified following the removal of eighteen specified identifiers, including but not limited to: name, telephone number, Social Security number, full face photo, and postal address.⁹⁷

91. *How Do Other Privacy Protections Interact with the Privacy Rule?*, NAT'L INSTS. OF HEALTH (Feb. 2, 2007), http://privacyruleandresearch.nih.gov/pr_05.asp.

92. *See* Rothstein, *supra* note 8, at 156.

93. *Id.*

94. *Id.*

95. 45 C.F.R. § 164.514(a) (2014).

96. *Id.* § 164.514(b)(1)(i).

97. *Id.* § 164.514(b)(2)(i) (identifiers include (1) names; (2) geographical subdivisions smaller than a state except for the first three digits of a ZIP code; (3) all elements of dates (except year) that relate to birth date, admission date, and discharge date; (4) telephone numbers; (5) FAX numbers; (6) e-mail addresses;

Because full compliance with the Privacy Rule's deidentification procedures would lead to the deletion of some information that is valuable for research purposes, the Privacy Rule only allows for a limited data set to be accessed for research.⁹⁸ The limited data set removes direct identifiers but allows for the retention of certain data elements, including date of service and zip code,⁹⁹ provided that the covered entity enters into a data use agreement with the recipient of the partially identifiable information that indicates permitted uses and disclosures.¹⁰⁰

According to guidance from the HHS Office for Human Research Protections (OHRP), obtaining identifiable private information or identifiable specimens for research purposes qualifies as human subjects research under the Common Rule.¹⁰¹ Obtaining identifiable private information or specimens includes, but is not limited to, the use, study, or analysis for research of identifiable private information or specimens provided to investigators from any source, including those that were already in the possession of the investigator.¹⁰² Further, research involving biospecimens "obtained prospectively from living people . . . falls within the definition of human subjects research" as it involves an "intervention or interaction"¹⁰³ with a living person.¹⁰⁴

Private information or specimens are not considered to be individually identifiable, when they are unable to be linked to specific individuals, directly or indirectly, by an investigator via coding systems.¹⁰⁵ Therefore, research involving coded human

(7) social security numbers; (8) medical record numbers; (9) health plan beneficiary numbers; (10) account numbers; (11) certificate or license numbers; (12) vehicle identifiers, including license-plate numbers; (13) device identifiers and serial numbers; (14) URLs (web locators); (15) Internet protocol (IP) address numbers; (16) biometric identifiers; (17) photographic and comparable images; and (18) any other unique identifying number, characteristic, or code.); *see also* Rothstein, *supra* note 37, at 4.

98. *Id.* § 164.514(e)(1).

99. *Id.* § 164.514(e)(2).

100. *Id.* § 164.514(e).

101. *Guidance on Research Involving Coded Private Information or Biological Specimens*, U.S. DEP'T OF HEALTH & HUMAN SERVS. (Oct. 16, 2008), <http://www.hhs.gov/ohrp/policy/cdebiol.html>.

102. *Id.*

103. *See* definitions of intervention and interaction, *supra* notes 50–51.

104. Leslie E. Wolf, *Advancing Research on Stored Biological Materials: Reconciling Law, Ethics, and Practice*, 11 MINN. J.L. SCI. & TECH. 99, 130 (2010).

105. *See* OHRP Guidance on Research Involving Biological Specimens, *supra* note 101.

biospecimens¹⁰⁶ does not constitute human subjects research if the biospecimens were not collected specifically for the research program proposed at the time of collection via interaction or intervention with living individuals.¹⁰⁷ In addition, for research involving coded human biospecimens to be excluded from human subjects research, an investigator must not be able to readily ascertain the identity of the individual to whom the coded biospecimens pertain.¹⁰⁸ Research using existing biospecimens may also be exempt from federal regulation if the biospecimens are publicly available or if the information is recorded in such a manner that subjects cannot be identified, directly or indirectly, via linked subject identifiers.¹⁰⁹

The OHRP guidance recognizes that the Common Rule creates a lower identifiability standard than does the Privacy Rule.¹¹⁰ The OHRP guidance notes that “some coded information, in which the code has been derived from identifying information linked to or related to the individual, would be individually identifiable under the Privacy Rule, but might not be individually identifiable under [the Common Rule].”¹¹¹

Although the deidentification provisions under the Common Rule are admittedly less stringent than those of the Privacy Rule, incorporating the provisions regarding what constitutes deidentified information in the Privacy Rule into the Common Rule—as suggested in the ANPRM¹¹²—would impede medical research, specifically genetic research. This inference is consistent with the 2009 report by the Institute of Medicine (IOM) focusing on the Privacy Rule as it relates to health research.¹¹³ According to the IOM, the Privacy Rule as currently implemented “impedes

106. *Id.* Under the OHRP guidance, coded is defined as “(1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and (2) a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.”

107. *Id.*

108. *Id.*

109. 45 C.F.R. § 46.101(b)(4) (2014).

110. *See* OHRP Guidance on Research Involving Biological Specimens, *supra* note 101.

111. *Id.*

112. *See* ANPRM, *supra* note 9, at 44,525.

113. INST. OF MED., *Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health Through Research*, 250 (Sharyl J. Nass et al. eds., 2009) [hereinafter “IOM”].

important health research”¹¹⁴ as it creates “barriers to research and leads to biased research samples, which generate invalid conclusions.”¹¹⁵ In doing so, the Privacy Rule does not “protect privacy as well as it should”¹¹⁶ as it “overstates the ability of informed consent to protect privacy rather than incorporating comprehensive privacy protections.”¹¹⁷

In addition to the IOM report, commentators have further elucidated the impediments that the Privacy Rule deidentification provisions have on medical research. Information privacy scholars such as Cate note that the deidentification provisions of the Privacy Rule are “useless for most medical research because researchers require access to information about the patient’s medical history . . . or other data prohibited under the deidentification standard.”¹¹⁸ Likewise, McGeeveran and colleagues indicate that biorepositories and investigators performing unforeseen future research are less likely to be considered covered entities or business associates subject to HIPAA.¹¹⁹ Therefore, harmonization between the Privacy Rule and the Common Rule would “introduce additional regulatory burdens because these entities would effectively be required to comply with both the [Privacy Rule] and the Common Rule.”¹²⁰

Because harmonization of the Common Rule and the Privacy Rule is likely to impede medical research, the question remains as to the best means of protecting research participants’ privacy interests to facilitate participation in medical—and especially genetic—research. The Presidential Commission for the Study of Bioethical Issues suggests that entities funding genetic research as well as policy makers outline details regarding access to and the permissible use of information to donors.¹²¹ Further, the IOM suggests that Congress authorizes HHS to develop an approach that “enhances privacy protections” and facilitates “greater use of data with direct identifiers removed . . . and implement legal sanctions to prohibit unauthorized re-identification of information that has had direct identifiers removed.”¹²² The implementation of

114. *Id.* at 2.

115. *Id.*

116. *Id.*

117. *Id.*

118. Fred H. Cate, *Protecting Privacy in Health Research: The Limits of Individual Choice*, 98 CAL. L. REV. 1765, 1789 (2010).

119. See McGeeveran, *supra* note 20, at 506.

120. *Id.*

121. See PRESIDENTIAL COMM’N, *supra* note 16, at 6.

122. See IOM, *supra* note 113, at 30.

an absolute prohibition against re-identification of deidentified health information has also been proposed as a way to enhance research participant privacy in the ANPRM.¹²³

IV. WE ARE NOT READY FOR A PROHIBITION ON RE-IDENTIFICATION

As noted above, given the inconsistencies between the Common Rule and the Privacy Rule, the ANPRM proposes a complete prohibition on the re-identification of deidentified health information to protect research participant privacy. The lack of uniformity that currently exists in the federal regulations as to what constitutes deidentification coupled with advances in genetic research make it unsurprising that concerns exist related to potential re-identification. Scholars maintain that deidentification assumes that third parties lack certain information about individuals, which precludes re-identification.¹²⁴ Ohm contends that technologists and regulators alike have embraced the belief “that they could robustly protect people’s privacy by making small changes to their data,” but Ohm argues that this belief “is deeply flawed.”¹²⁵ Re-identification may occur due to adversaries legally or illegally obtaining information from a variety of sources,¹²⁶ including those that are publicly available,¹²⁷ such as voter registration records, commercially available databases, and hospital discharge records.¹²⁸ As such, some scholars, including Ohm, suggest that re-identification may be possible regardless of how much identifying information has been removed.¹²⁹

123. See ANPRM, *supra* note 9, at 44,526.

124. Sharona Hoffman and Andy Podgurski, *Balancing Privacy, Autonomy, and Scientific Needs in Electronic Health Records Research*, 65 SMU L. REV. 85, 105 (2012).

125. Paul Ohm, *Broken Promises of Privacy: Responding to the Surprising Failure of Anonymization*, 57 UCLA L. REV. 1701, 1706–07 (2010).

126. See Hoffman, *supra* note 124, at 105 (citing George T. Duncan et al., STATISTICAL CONFIDENTIALITY: PRINCIPLES & PRACTICE 37 (2011)).

127. See Ohm, *supra* note 125, at 1737.

128. Bradley Malin & Latonya Sweeney, *How (not) to protect genomic data privacy in a distributed network: Using trail re-identification to evaluate and design anonymity protection systems*, 37 J. BIOMEDICAL INFORMATICS 179 (2004); Latonya Sweeney, *K-anonymity: A model for protecting privacy.*, 10 INT’L J. UNCERTAINTY, FUZZINESS, & KNOWLEDGE-BASED SYS. 557 (2002).

129. See Leslie E. Wolf et al., *Certificates of Confidentiality: Protecting Human Subject Research Data in Law and Practice*, 14 MINN. J.L. SCI. & TECH. 11, 76 (2013) (citing Ohm, *supra* note 125, at 1704)).

Despite concerns about possible re-identification, empirical data assessing the re-identification of individuals is conflicting, non-normalized, and contingent upon the number of identifying characteristics available. For example, previous studies estimate that between 63%¹³⁰ and 87%¹³¹ of the United States population can be identified based on factors including gender, date of birth, and zip code. In contrast, in a study performed by the HHS Office of the National Coordinator for Health Information Technology, only two out of 15,000 individuals (0.01%) were able to be re-identified following deidentification of their health information pursuant to the Privacy Rule.¹³² This data are consistent with Sweeney's contention that approximately 0.04% of records complying with the deidentification requirements of the Privacy Rule are at risk for re-identification.¹³³

Given the inconsistencies in the empirical research, implementing a sweeping rule that precludes re-identification of deidentified health information in research is premature. Further, such a rule is premature due to a lack of legislation governing privacy tort causes of action such as the public disclosure of private facts that research participants may have against researchers conducting unforeseen future research. Moreover, the ANPRM's proposed rule prohibiting re-identification does not account for the discovery and return of incidental findings¹³⁴ that may protect the health and well-being of research participants.

A. A Cause of Action Against Researchers?

The first issue with respect to the implementation of a broad prohibition against re-identification for research purposes of deidentified health information is in determining whether a research participant may have a cause of action against a researcher for disclosure of his or her health information. In doing

130. Philippe Golle, *Revisiting the uniqueness of simple demographics in the U.S. population*, IN PROCEEDING OF THE FIFTH ACM WORKSHOP ON PRIVACY IN THE ELECTRONIC SOCIETY, 77–80 (2006).

131. Latonya Sweeney, *Uniqueness of simple demographics in the U.S. Population* (Carnegie Mellon U., Data Privacy Working Paper No. 3, 2000), available at <http://dataprivacylab.org/projects/identifiability/paper1.pdf>.

132. DEBORAH LAFKY, *THE SAFE HARBOR METHOD OF DE-IDENTIFICATION: AN EMPIRICAL TEST* (2009).

133. NAT'L COMM. ON VITAL & HEALTH STATISTICS, REPORT TO THE SECRETARY OF HEALTH AND HUMAN SERVICES ON ENHANCED PROTECTIONS FOR USES OF HEALTH DATA 36 n.16 (Dec. 19, 2007), available at <http://www.ncvhs.hhs.gov/wp-content/uploads/2014/05/071221lt.pdf>.

134. See Wolf, *supra* note 7.

so, the research participant must first establish that the researcher owed the research participant a duty.¹³⁵ With respect to clinician-researchers that are treating the research participant, the clinician-researcher also has a physician-patient relationship with the research participant and owes him or her a duty of care, including maintaining his or her privacy.¹³⁶ The duty to maintain privacy also extends to health care workers that come into contact with patients and/or research participants.¹³⁷

Although not focused on research participants specifically, the Court of Appeals for the First District of California in *Urbaniak* did identify that a patient has a cause of action against a health care worker for public disclosure of private facts.¹³⁸ Urbaniak disclosed his HIV-positive status for the sole purpose of alerting a nurse of the need to take precautions in handling medical equipment contaminated with his blood.¹³⁹ The court determined that the circumstances underlying Urbaniak's disclosure of his HIV status and subsequent cause of action were governed by the concept of "improper use of information properly obtained."¹⁴⁰ The court noted that in health care, disclosure of a patient's health information constitutes improper use "when it will subvert a public interest favoring communication of confidential information by violating the patient's reasonable expectations of privacy."¹⁴¹ Further, the court indicated that the evidence supported the notion that Urbaniak reasonably anticipated privacy upon his disclosure and that, by enforcing such an expectation, "the courts will simultaneously foster needed disclosures of HIV-positive status"¹⁴² Thus, disclosure of a patient's HIV status is a private fact in which disclosure may be deemed offensive and objectionable to a reasonable person.¹⁴³

In addition to potential liability against clinician-researchers and health care workers for re-identification and disclosure of health information, scholars maintain that a cause of action may exist against non-treating researchers as well. According to Noah, a non-treating researcher may owe a duty to a research participant if

135. Barbara A. Noah, *Bioethical Malpractice: Risk and Responsibility in Human Research*, 7 J. HEALTH CARE L. & POL'Y 175, 208 (2004).

136. *Id.*

137. *Urbaniak v. Newton*, 226 Cal. App. 3d 1128 (Cal. Ct. App. 1991).

138. *Id.* at 1135-36.

139. *Id.*

140. *Id.* at 1140 (citing *White v. Davis*, 533 P.2d 222, 235 (Cal. 1975)).

141. *Id.*

142. *Id.* at 1141.

143. *Id.* at 1138.

the research participant “looks to the investigator as an expert and places his trust in the investigator’s expertise.”¹⁴⁴ In such a case, the duty would appear to include “not only an obligation to act reasonably under the circumstances but also a duty to take whatever steps are necessary to protect the [research participant’s] best interests.”¹⁴⁵

Drexler expands upon Noah’s theoretical framework by relying on the Maryland Court of Appeals decision in *Grimes v. Kennedy Krieger Institute, Inc.* in which the Court noted that “the very nature of . . . scientific research on human subjects can, and normally will, create special relationships out of which duties arise.”¹⁴⁶ Likewise, Drexler contends that a researcher’s duty can arise out of contract as informed consent agreements can constitute contracts.¹⁴⁷ Further, Drexler suggests that failure to comply with the provisions dictating the use and disclosure of health information under the Privacy Rule may also create a basis for establishing a special duty between a researcher and a research participant and subsequent liability.¹⁴⁸

Noah and Drexler are correct in their assertions about potential liabilities for researchers, which may include privacy violations due to the unauthorized disclosure of health information. It is important to note however that such liability regarding the Privacy Rule would only attach to the researcher if he or she were a member or a business associate of a covered entity. Noah and Drexler’s notions of liability fail to extend the privacy tort of public disclosure of private facts to researchers performing unforeseen future research, as they are unlikely to be members of a covered entity or business associates. Thus, the theoretical framework that Noah and Drexler have built for potential researcher liability does not extend to the unknown researcher or the re-identification of deidentified health information.

As such, the privacy concerns of potential research participants regarding the public disclosure of their health information are not mitigated by potential privacy tort causes of action with respect to unforeseen future research under Noah and Drexler. In contrast, the privacy torts only protect research participants’ privacy interests

144. See Noah, *supra* note 135, at 208.

145. *Id.* at 208–09.

146. Matthew B. Drexler, *Health Law – Privacy in Medical Research: A Botched Experiment*, 29 W. NEW ENG. L. REV. 535, 558 (2007) (citing *Grimes v. Kennedy Krieger Inst.*, 782 A.2d 807, 834–35 (Md. 2001)).

147. *Id.* (citing *Grimes*, 782 A.2d at 844).

148. *Id.* at 559–60.

if they have a physician-patient relationship with a clinician-researcher or if they are engaged in an ongoing research study with a non-clinician investigator. Thus, prior to the enactment of a complete prohibition on the re-identification of deidentified health information in unforeseen future research, additional rules are required to determine privacy tort causes of action a research participant may have against an unknown researcher. Further, enactment of a complete prohibition on re-identification may compromise the health of research participants and have a chilling effect on research.

B. Compromising Health and Research by Precluding Re-Identification

A complete prohibition on the re-identification of research participants' deidentified health information in unforeseen future research may have a negative impact on the health of research participants. As medical science and technologies advance, there will be greater opportunities to assess biospecimens for molecular signatures of disease and responses to therapy. For example, biospecimens may be assessed to determine genetic aberrations that may lead to cancers and/or neurodegenerative diseases.

Identifying and subsequently reporting incidental findings¹⁴⁹ of research to treating physicians may assist in beginning a research participant on preventative courses of therapy to lessen the likelihood of acquiring diseases and/or help to mitigate the deleterious effects of diseases. Likewise, characterizing responses of research participants' biospecimens to alternate courses of treatment (e.g., immune responses to new antiretroviral therapies) may facilitate a longer and/or improved quality of life in addition to reducing the adverse effects of certain treatments. A sweeping rule that prohibits the re-identification of deidentified information will prevent research participants from having access to incidental findings that may be beneficial to their health.

A complete prohibition on the re-identification of research participants' deidentified information may also have a chilling effect on medical, including genetic, research. This chilling effect may be due to concerns about the potential of incurring liability due to re-identification and the ethical obligations of researchers to report incidental findings. Such confusion may make researchers hesitant to use genetic methodologies and research techniques or to pursue studies that have the likelihood of producing incidental findings. The ethical obligations to report incidental findings are

149. See Wolf, *supra* note 7.

rooted in the principles of beneficence and respect for persons in ethics.¹⁵⁰ Because beneficence requires researchers to take efforts to “maximize possible benefits and minimize possible harms,”¹⁵¹ returning incidental findings could be beneficial to research participants by providing the opportunity to prevent or minimize future harms to their health.¹⁵² Further, respect for persons also supports a researcher’s ethical obligation that incidental findings should be disclosed if the findings would be useful to the research participant in making autonomous medical decisions.¹⁵³

In addition to ethical dilemmas, a complete prohibition on the re-identification of deidentified information may also have a chilling effect on research, as it would conflict with the potential legal obligations of researchers to return incidental findings. Although no current law exists regarding a legal obligation to return incidental findings, legal scholars suggest “we may be standing at the precipice of legal liability for failing to adequately return [incidental findings].”¹⁵⁴ Such liability may arise due to failure to return incidental findings at all or returning some incidental findings but not those that may be critical for a research participant’s health.¹⁵⁵

Although not currently in place, legal obligations regarding the return of incidental findings appear to be forthcoming. With respect to genetic research, the Presidential Commission for the Study of Bioethical Issues recommended that researchers be required to make individuals “aware that incidental findings are likely to be discovered . . . [and] whether these findings will be communicated, the scope of communicated findings, and to whom the findings will be communicated.”¹⁵⁶ In addition, the

150. Elizabeth R. Pike et al., *Finding Fault? Exploring Legal Duties to Return Incidental Findings in Genomic Research*, 102 GEO. L.J. 795, 804 (2014).

151. *Id.* (citing Belmont Report, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 44 Fed. Reg. 23,192, 23,194 (Apr. 18, 1979) (codified at 45 C.F.R. pt. 46)).

152. *Id.* (citing Franklin G. Miller et al., *Incidental Findings In Human Subjects Research: What Do Investigators Owe Research Participants?*, 36 J.L. MED. & ETHICS 271, 277 (2008)).

153. *Id.* (citing Annelien L. Bredenoord et al., *Disclosure of Individual Genetic Data to Research Participants: The Debate Reconsidered*, 27 TRENDS IN GENETICS 41, 44 (2011)).

154. *Id.* at 812–13 (citing Wolf, *supra* note 7, at 365 (“[A] a legal trend may be emerging toward recognizing an obligation on the part of a researcher to provide a research participant with information acquired from a study, when that information has clinical implications for the participant.”)).

155. *Id.* at 813.

156. *See* PRESIDENTIAL COMM’N, *supra* note 16, at 9.

Commission recommended that funding agencies support studies evaluating the “proposed frameworks for offering return of incidental findings and other research results” derived from genetic research.¹⁵⁷ As the push towards an ethical obligation to return incidental findings develops into a research standard, the ethical obligation may give rise to a legal duty.¹⁵⁸ Thus, a broad prohibition on the re-identification of deidentified information would directly contravene any legal obligations to return incidental findings to research participants as researchers would be barred under the prohibitive rule.

C. *Certificates of Confidentiality: The Near-Term Solution*

It is widely accepted that researchers have an obligation to protect the confidentiality of research participants’ information.¹⁵⁹ Harmonizing the provisions of the Privacy Rule with the Common Rule related to identifiable and deidentifiable health information and/or a broad prohibition against re-identification does little to enhance research participants’ privacy and may impede research. Further, doing so may also compromise research participants’ health. In the near term, to better protect research participants’ privacy and to continue to facilitate unforeseen future research, including genetic research, Certificates of Confidentiality should be used.

Certificates of Confidentiality were originally authorized as part of the Comprehensive Drug Abuse Prevention and Control Act of 1970.¹⁶⁰ Certificates of Confidentiality were required for research on drug abuse because drug abuse “involve[d] illegal activities . . . [therefore] reliable statistics [could not] be obtained on the actual extent of drug abuse.”¹⁶¹ Subsequent amendments to the authorizing statute allow for the use of Certificates of Confidentiality to protect confidentiality in biomedical, behavioral, and clinical research.¹⁶² The current statute authorizes research

157. *Id.*

158. See Pike, *supra* note 150, at 813.

159. See *Institutional Review Board Guidebook Chapter III: Basic IRB Review*, OFFICE OF HUMAN RESEARCH PROTS., (1993), http://www.hhs.gov/ohrp/archive/irb/irb_chapter3.htm.

160. Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, 84 Stat. 1236, 1241 (1970).

161. H.R. Rep. No. 91-1444 (1970), *reprinted in* 1970 U.S.C.C.A.N. 4566, 4572.

162. Health Omnibus Programs Extension of 1988, Pub. L. 100-607, 102 Stat. 3048 (1988).

investigators to protect the privacy of research participants who are the subject of the research by withholding identifiable information from all persons not connected with the research.¹⁶³ Further, the statute indicates that investigators authorized to protect research participant privacy “may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”¹⁶⁴

The confidentiality protections afforded by Certificates of Confidentiality are promulgated within the statute; however, HHS regulations dictate the identifying characteristics protected by a Certificate of Confidentiality¹⁶⁵ and the required contents for an application of confidentiality.¹⁶⁶ Included in the required contents of an application is that research participants be informed that a Certificate of Confidentiality has been issued.¹⁶⁷ Thus, Certificates of Confidentiality may encourage individuals to participate in research as they ensure research participants that their privacy will be maintained because researchers cannot be compelled to disclose identifiable information in specified proceedings.¹⁶⁸

Certificates of Confidentiality are also a useful tool for unforeseen future research using biospecimens and genetic data.¹⁶⁹ Indeed, the NIH encourages biorepositories and recipient investigators of biospecimens and/or genetic information to consider obtaining a Certificate of Confidentiality depending on the “nature and sensitivity of the identifiable data associated with the biospecimen.”¹⁷⁰ Rather than recommending that recipient investigators obtain a Certificate of Confidentiality, HHS/NIH

163. 42 U.S.C. § 241(d) (2006).

164. *Id.*

165. 42 C.F.R. § 2a.2(g) (2013) (defining identifying characteristics as “the name, address, any identifying number, fingerprints, voiceprints, photographs or any other item or combination of data about a research subject which could reasonably lead directly or indirectly by reference to other information to identification of that research subject.”).

166. *Id.* C.F.R. § 2a.4.

167. *Id.* § 2a.4(j).

168. *Id.* § 2a.4(i); *see also* Wolf, *supra* note 129, for a comprehensive review of reported and unreported cases involving Certificates of Confidentiality.

169. *See Frequently Asked Questions on Certificates of Confidentiality*, NAT’L INSTS. OF HEALTH (Apr. 14, 2015), <https://grants.nih.gov/grants/policy/coc/faqs.htm>.

170. *National Cancer Institute Best Practices for Biospecimen Resources*, OFFICE OF BIOREPOSITORIES AND BIOSPECIMEN RESEARCH, NAT’L INSTS. OF HEALTH, NAT’L CANCER INST. 42 (2011), <http://biospecimens.cancer.gov/bestpractices/2011-NCIBestPractices.pdf>.

should require that Certificates of Confidentiality be obtained for all research conducted using biospecimens and genetic data.

Concerns may exist as to how research participants will be informed that a Certificate of Confidentiality has been issued for the use of their biospecimens/genetic data in unforeseen future research. To ensure that research participants are aware that their biospecimens/genetic data are protected by a Certificate of Confidentiality from compelled disclosure when used for purposes other than the primary study, modified informed consent documents may be employed. The informed consent document for a primary study that requests consent for unforeseen future uses of a research participant's biospecimens/genetic data would also include the NIH Certificate language indicating that the storage site (biorepository) will maintain a Certificate of Confidentiality for their biospecimens/genetic data. The informed consent document would also specify that biospecimens/genetic data will not be released to investigators for research purposes unless the investigator is also issued a Certificate of Confidentiality. In doing so, biorepositories and investigators would ensure that research participant privacy is adequately protected from compelled disclosure.

In addition to compelled disclosure, Certificates of Confidentiality, upon issue, allow investigators to “withhold the names and other identifying characteristics of individuals who are the subject of such research from any person . . . not connected with the conduct of such research.”¹⁷¹ Thus, Certificates of Confidentiality afford privacy protection to research participants by precluding their information from being shared with employers and insurers, a concern expressed by potential research participants.¹⁷²

Certificates of Confidentiality may also provide research participants a privacy tort cause of action for the public disclosure of private facts. If the biorepository requires that a recipient investigator obtain a Certificate of Confidentiality in order to obtain biospecimens and/or genetic data, disclosure of identifiable information by the recipient investigator would constitute a disclosure of private facts about the research participant. The disclosure would be an improper use of information that was properly obtained, because the biorepository required the recipient

171. 42 C.F.R. § 2a.3(b) (2013).

172. See PRESIDENTIAL COMM'N, *supra* note 16, at 36, (citing Amy L. McGuire et al., *DNA Data Sharing: Research Participants' Perspectives*, 10 GENETICS MEDICINE MED. 46, 50–51 (2008)).

investigator to have a Certificate of Confidentiality in order to access the biospecimen/genetic data. Thus, assuming that the disclosure would be offensive and objectionable to a reasonable person, a research participant would likely have a cause of action. Although a Certificate of Confidentiality protects a research participant's identity from being shared, it does not preclude the potential for discrimination based on health information. Protections against discrimination by employers and insurers for research participants are afforded under the Genetic Information Nondiscrimination Act of 2008 (GINA).¹⁷³ GINA makes it unlawful to refuse to hire, discharge, or deprive any employee of employment opportunities based on their genetic information.¹⁷⁴ Likewise, it is unlawful for an employer to request or acquire genetic information about an employee¹⁷⁵ unless specified conditions are met (e.g., an employee voluntarily provides written authorization).¹⁷⁶ With respect to health insurance, GINA makes it unlawful for insurers to use genetic information to make coverage, eligibility, or premium determinations; from obtaining genetic information for underwriting purposes; and from requesting or requiring genetic testing or information.¹⁷⁷ Thus, coupled with GINA, Certificates of Confidentiality offer protections regarding the disclosure of health information, including genetic information, and potential discrimination due to disclosure from employers and health insurers.

V. CONCLUSION

Current federal regulations including the Common Rule and the Privacy Rule do not adequately address privacy concerns related to re-identification of research participants' in unforeseen future research. In an effort to address research participant privacy concerns, the ANPRM proposed harmonization between the Common Rule and the Privacy Rule¹⁷⁸ and a prohibition on the re-identification of deidentified information.¹⁷⁹ These proposals however will impede medical research and are premature due to a lack of legislation governing privacy tort causes of action for re-identification as well as the discovery and return of incidental

173. 42 U.S.C. §§ 2000ff-1-11 (2013).

174. *Id.* §§ 2000ff-1(a)(1-2).

175. *Id.* §§ 2000f-1(b).

176. *Id.* §§ 2000f-1(b)(1-2) (2013).

177. 29 U.S.C. § 1182 (2013).

178. *See* ANPRM, *supra* note 9, at 44,525.

179. *Id.* at 44,526.

findings from research. Certificates of Confidentiality provide an effective alternative to these other proposals. Requiring Certificates of Confidentiality for all unforeseen future research using biospecimens and genetic data would afford added privacy protections for research participants by precluding disclosure of identifiable information.