NOTES

Common Sense: Rethinking the New Common Rule's Weak Protections for Human Subjects

Since 1991, the Federal Policy for the Protection of Human Subjects, known as the "Common Rule," has protected the identifiable private information of human subjects who participate in federally funded research initiatives. Although the research landscape has drastically changed since 1991, the Common Rule has remained mostly unchanged since its promulgation. In an effort to modernize the Common Rule, the Federal Policy for the Protection of Human Subjects Final Rule ("Final Rule") was published on January 19, 2017. The Final Rule, however, decreases human-subject protections by increasing access to identifiable data with limited administrative oversight. Accordingly, the Final Rule demands reconsideration. This Note conducts a comparative analysis of the Final Rule and the Health Insurance Portability and Accountability Act Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule"). Ultimately, this Note argues that a revised Final Rule should incorporate a modified version of the Privacy Rule that in turn provides human subjects with legally enforceable rights, remedies, and control over how information about them is used.

> *The voluntary consent of the human subject is absolutely essential.*
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> —The Nuremberg Code[1]

INTRODUCTION

In his 2015 State of the Union address, former president Barack Obama announced the Precision Medicine Initiative ("PMI"), an interagency program that relies on patient-powered research to accelerate biomedical discoveries.[2] Precision medicine is defined as treatment and prevention tailored to the individual,[3] with consideration of the "variability in genes, environment, and lifestyle for

1. 2 TRIALS OF WAR CRIMINALS BEFORE THE NUERNBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, at 181 (1949).

2. Barack Obama, U.S. President, Remarks by the President in State of the Union Address (Jan. 20, 2015), https://obamawhitehouse.archives.gov/the-press-office/2015/01/20/remarks-president-state-union-address-january-20-2015 [https://perma.cc/X8AM-24AZ].

3. *The Precision Medicine Initiative*, OBAMA WHITE HOUSE, https://obamawhitehouse.archives.gov/node/333101 (last visited Aug. 5, 2018) [https://perma.cc/ZUT7-7EKJ] ("[M]ost medical treatments have been designed for the 'average patient.' As a result of this 'one-size-fits-all' approach, treatments can be very successful for some patients but not for others.").

each person."[4] In theory, precision medicine enables clinicians and researchers to better understand the complex structure underlying a patient's condition and more accurately predict which health strategies will be most effective.

Precision medicine's effectiveness depends on the availability of data—more data increases the likelihood of accurate results and accelerates scientific discoveries. Following PMI's 2016 launch, the National Institutes of Health ("NIH") received $130 million "to build a national, large-scale research participant group."[5] To achieve this goal, NIH launched the All of Us Research Program ("All of Us"), which aims to gather data from "one million or more people living in the United States."[6] All of Us began beta testing in June 2017, and national enrollment launched on May 6, 2018.[7]

All of Us, and precision medicine generally, highlights a significant shift toward a participatory research model where human subjects "increasingly expect to be *partners* in research."[8] Although accelerating the speed and volume of data collection is a win for science, this model necessitates greater protections for human subjects. Human subjects demand "greater choice over how their information is used" and require privacy and security over the identifiable private

4. Nat'l Insts. of Health, *What Is Precision Medicine?*, GENETICS HOME REFERENCE, https://ghr.nlm.nih.gov/primer/precisionmedicine/definition (last visited Aug. 5, 2018) [https://perma.cc/HHH7-T7BW].

5. *About the* All of Us *Research Program*, NAT'L INSTS. HEALTH, https://allofus.nih.gov/about/about-all-us-research-program (last visited June 15, 2018) [https://perma.cc/UY2V-DDUJ]; *NIH Announces National Enrollment Date for All of Us Research Program to Advance Precision Medicine*, NAT'L INSTS. HEALTH (May 1, 2018), https://www.nih.gov/news-events/news-releases/nih-announces-national-enrollment-date-all-us-research-program-advance-precision-medicine [https://perma.cc/L3YB-ZDAZ]. Forty-five thousand participants enrolled in All of Us during the beta phase. Heather Landi, *NIH's All of Us Program Hits Milestone with National Enrollment to Launch May 6*, HEALTHCARE INFORMATICS (May 1, 2018), https://www.healthcare-informatics.com/article/population-health/nih-s-all-us-program-hits-milestone-national-enrollment-launch-may-6 [https://perma.cc/6H9E-8X3S].

6. *About*, NAT'L INSTS. HEALTH, https://allofus.nih.gov/about (last visited Sept. 15, 2018) [https://perma.cc/M9AD-T96H].

7. *Beta Testing Begins for NIH's All of Us Research Program*, NAT'L INSTS. HEALTH (June 5, 2017), https://allofus.nih.gov/news-events-and-media/announcements/beta-testing-begins-nihs-all-us-research-program [https://perma.cc/P7TG-YKAQ].

8. *See* Kathy L. Hudson & Francis S. Collins, *Bringing the Common Rule into the 21st Century*, 373 NEW ENG. J. MED. 2293, 2293 (2015) (emphasis added).

information they volunteer.[9] When trust is broken, research comes to a halt.[10]

Promulgated in 1991, the Federal Policy for the Protection of Human Subjects, known as the "Common Rule," protected human subjects' identifiable private information, and it remained mostly unchanged for roughly a quarter century.[11] Recognizing the need to modernize the Common Rule, sixteen federal departments and agencies[12] published the Federal Policy for the Protection of Human Subjects Final Rule ("Final Rule") on January 19, 2017, after much analysis and vetting.[13] The Final Rule, however, does not strengthen human-subject protections: the regulation reduces administrative oversight, fails to adopt privacy standards, and broadens the scope of participants' consent.

The Final Rule does not safeguard human subjects' interests and information and accordingly demands reconsideration. By contrast, the Health Insurance Portability and Accountability Act ("HIPAA") provides an example of a participant-centric approach.[14] HIPAA's Standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") not only limits the use and disclosure of protected

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9. KATHY HUDSON ET AL., PRECISION MED. INITIATIVE WORKING GRP., THE PRECISION MEDICINE INITIATIVE COHORT PROGRAM – BUILDING A RESEARCH FOUNDATION FOR 21ST CENTURY MEDICINE 81 (2015), https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/pmi-working-group-report-20150917-2.pdf [https://perma.cc/L97Y-7XVN] [hereinafter PRECISION MEDICINE INITIATIVE].

10. *See id.* at 3 (explaining that "maintaining trust is a critical component to a successful, ongoing, and collaborative relationship").

11. Protection of Human Subjects, 45 C.F.R. § 46.101 (2017). The Common Rule was promulgated in 1991 and amended in 2005. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7149 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46). The Common Rule has not been amended since 2005. *Id.*

12. As listed in the Federal Register, the sixteen federal departments and agencies are as follows: Department of Homeland Security; Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Social Security Administration; Agency for International Development; Department of Housing and Urban Development; Department of Labor; Department of Defense; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; Department of Health & Human Services ("HHS"); National Science Foundation; and Department of Transportation. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7149. This Note cites to the HHS provisions in the Code of Federal Regulations at 45 C.F.R. pt. 46.

13. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7152. The sixteen departments and agencies announced an Interim Final Rule that delays the effective and general compliance date of the Final Rule by six months to July 19, 2018. *See* Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects, 83 Fed. Reg. 2885, 2885 (Jan. 22, 2018) (to be codified at 45 C.F.R. pt. 46). The delay is intended to provide regulated entities additional time to prepare to implement the Final Rule. *See id.*

14. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C. (2012)).

health information ("PHI") but also provides rights and remedies to human subjects.[15] In essence, where the Final Rule underregulates, the Privacy Rule overregulates.

This Note comparatively analyzes the Final Rule and Privacy Rule, positing a revised regulation that strengthens human-subject protections with legal force. Part I provides an overview of the original Common Rule and changes in the research landscape. Part II analyzes the text of the Final Rule in light of public comments on proposed changes to the Common Rule then considers the legal and ethical consequences of the Final Rule. Part III compares the Privacy Rule and the Final Rule to illustrate their differences and complexities. Finally, Part IV reimagines the Final Rule as a protective regulation—rather than a compilation of administrative requirements—that affords human subjects legally enforceable rights, remedies, and control over how information about them is used.

I. COMMON COURTESY: AN OVERVIEW OF HUMAN-SUBJECT PROTECTIONS IN THE UNITED STATES

Human subjects, quite literally the subjects of research, are living individuals about whom a researcher obtains "data through . . . identifiable private information."[16] Identifiable private information is private information from which the human subject's identity "may readily be ascertained by the investigator or associated with the information."[17] A human subject provides this information for "a specific purpose" with a reasonable expectation that the information "will not be made public."[18]

In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research published the Belmont Report, which identified three ethical principles underlying human-subject research.[19] *Respect for persons* acknowledges human subjects' autonomy and requires consent as a prerequisite to research.[20] *Beneficence* obliges researchers to maximize benefits to society while minimizing risks of harm to human subjects.[21] *Justice* demands

15. HIPAA Privacy Rule, 45 C.F.R. pts. 160, 164 (2017); *see infra* Part III.

16. 45 C.F.R. § 46.102(f).

17. *Id.*

18. *Id.*

19. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH 4–6 (1979), https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf [https://perma.cc/BF8C-LRPQ] [hereinafter BELMONT REPORT].

20. *Id.* at 4.

21. *Id.* at 5.

fairness in balancing the benefits conferred and burdens imposed through research.[22] Even with modern advances in research and technology, these ethical principles remain valid. The Belmont Report influenced both the original Common Rule[23] and the new Final Rule.[24]

Despite their ethical foundations, both rules fail to adequately protect human subjects' identifiable private information. The Common Rule was a "very clunky policy instrument."[25] The Final Rule, though more refined, decreases protections as a result of increased access to identifiable private information.[26] This Part details changes in the research regulatory regime from the Common Rule (1991) to the Final Rule (2017).

A. The Common Rule

Promulgated in 1991, the Common Rule aimed to "promote uniformity, understanding, and compliance with human subject protections."[27] Fifteen federal departments and agencies codified the Common Rule in different regulations using identical language.[28] The regulation covered all human-subject research "conducted, supported or otherwise subject to regulation" by any federal department or agency that codified the rule.[29]

The Common Rule provided two critical protections to human subjects: (1) Institutional Review Board ("IRB") requirements and (2) informed consent requirements.[30] This Section provides a brief overview of these two protections.

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22. *Id.*

23. *See Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html (last visited Aug. 5, 2018) [https://perma.cc/9GZL-D9LA] [hereinafter *Common Rule*].

24. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7151 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46) ("The changes that are being implemented in the final rule continue to be shaped by those principles . . . .").

25. Jocelyn Kaiser, *U.S. Abandons Controversial Consent Proposal on Using Human Research Samples*, SCI. MAG. (Jan. 18, 2017, 4:15 PM), http://www.sciencemag.org/news/2017/01/update-us-abandons-controversial-consent-proposal-using-human-research-samples [https://perma.cc/F4FR-WQ2L] (quoting Kathy Hudson, former NIH official).

26. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7202, 7209, 7213.

27. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,935 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).

28. The Department of Labor, a signatory to the Final Rule, did not adopt the Common Rule. *Common Rule*, *supra* note 23.

29. Protection of Human Subjects, 45 C.F.R. § 46.101 (2017).

30. *Id.* §§ 46.107–.117.

1. IRB Requirements

The IRB is an administrative body comprising diverse members established to protect human subjects' interests.[31] The Common Rule granted the IRB authority to approve, modify, or disapprove research activities subject to regulation.[32] Before research could take place, the IRB ensured that the research plan satisfied seven requirements, including adequate informed consent documents and sufficient protocols for monitoring, collecting, and storing human-subject data.[33] The IRB also determined whether privacy measures were "adequate with respect to the informational risks of the study."[34] If the study was not approved by the IRB, it could not proceed.[35]

The Common Rule provided the IRB with three written procedural requirements.[36] First, the IRB conducted both initial and continuing review of research and reported its findings to the researchers and their respective institutions.[37] Next, the IRB determined which research activities "require[d] review more often than annually" and which activities "need[ed] verification . . . that no material changes [had] occurred since previous IRB review."[38] Finally, the IRB ensured that researchers reported proposed changes to studies that were already approved.[39]

The IRB reviewed research, and satisfied the requirements above, through either convened or expedited review.[40] Research subject to a convened review required approval from a majority of IRB

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31. *See id.* §§ 46.107–.115. IRB diversity promotes respect for its advice in protecting human subjects. *Id.* § 46.107(a) (listing IRB membership requirements).

32. *Id.* § 46.109(a). "Research subject to regulation, and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (for example, Investigational New Drug requirements administered by the Food and Drug Administration)." *Id.* § 46.102(e).

33. *Id.* § 46.111(a)(4)–(6).

34. *Id.* § 46.111(a)(7); *see* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,978 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).

35. *See OHRP Expedited Review Categories (1998)*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/regulations-and-policy/guidance/categories-of-research-expedited-review-procedure-1998/index.html (last visited June 15, 2018) [https://perma.cc/EN2R-FLTF]. Researchers and their institutions cannot override IRB decisions. *Id.*

36. 45 C.F.R. § 46.103(b)(4).

37. *Id.*

38. *Id.*

39. *Id.*

40. *See* Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators, 76 Fed. Reg. 44,512, 44,513 (July 26, 2011) (to be codified at 45 C.F.R. pts. 46, 160, 164).

members.[41] Expedited review was available for "certain kinds of research involving no more than minimal risk and for minor changes in approved research."[42] Under an expedited review, the IRB chairperson or another experienced member conducted the review and could approve or modify, but not disapprove, the research.[43] Research could only be disapproved in accordance with the Common Rule's nonexpedited procedures for IRB review.[44]

2. Informed Consent

Informed consent is a voluntary agreement to participate in research[45] and requires that researchers provide "sufficient opportunity" for human subjects to decide without "coercion or undue influence" whether to participate.[46] Under the Common Rule, unless the human subject gave "legally effective informed consent," researchers could not conduct research on the human subject.[47]

Common Rule compliance required informed consent protocols to meet eight basic elements.[48] Of relevance, researchers needed to provide human subjects with a statement explaining the research, including the purpose, procedures, and expected duration.[49] Researchers analyzing identifiable data from a completed study for another purpose usually needed to obtain additional informed consent and additional IRB approval.[50] Next, the Common Rule required a

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41. 45 C.F.R. § 46.108(b); *see Convened IRB Review*, JOHNS HOPKINS MED., https://www.hopkinsmedicine.org/institutional_review_board/guidelines_policies/guidelines/convened_review.html (last visited June 15, 2018) [https://perma.cc/XB4C-9TTW]. At least one member must have primary concerns in a nonscientific area. 45 C.F.R. § 46.108(b).

42. 45 C.F.R. § 46.110. Under the Common Rule, minimal risks meant "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." *Id.* § 46.102(i). The secretary of HHS publishes (and can amend with consultation) a list of categories of research that qualify for expedited review. *Id.* § 46.103(b)(4); *see OHRP Expedited Review Categories (1998)*, *supra* note 35.

43. 45 C.F.R. § 46.110.

44. *Id.* Nonexpedited review procedures are set forth in 45 C.F.R. § 46.108(b).

45. Philip Hamburger, *The New Censorship: Institutional Review Boards* 297 (Univ. of Chi. Law Sch. Pub. Law & Legal Theory Working Papers, Paper No. 95, 2005) ("[R]esearchers must get permission not only from the IRB but also from the persons they study.").

46. 45 C.F.R. § 46.116. Although the Common Rule does not define coercion or undue influence, the Belmont Report provides helpful context. *See* BELMONT REPORT, *supra* note 19, at 7. Coercion is "an overt threat of harm" to obtain compliance; undue influence is an improper award to obtain compliance. *Id.*

47. 45 C.F.R. § 46.116.

48. *Id.* § 46.116(a)(1)–(8).

49. *Id.* § 46.116(a)(1).

50. *See* Hamburger, *supra* note 45, at 298–99. If the already collected data are de-identified, the Common Rule does not govern their secondary use. 45 C.F.R. § 46.101(b)(4).

statement describing how researchers would maintain the human subjects' identifiable private information, if applicable.[51] Finally, researchers were required to provide a statement that human-subject participation was voluntary and that "refusal to participate [would] involve no penalty or loss of benefits."[52]

Regardless of the IRB review type, basic informed consent requirements were mandatory.[53] The IRB could, however, waive or alter informed consent requirements for specific studies.[54] Waiving or altering was appropriate when the IRB determined that the following conditions were present: (1) there was minimal risk[55] of harm to human subjects; (2) the waiver did not negatively affect human subjects; (3) research could not be carried out without the waiver; and (4) additional information would be provided to human subjects after participation.[56]

B. An Impetus for Change

In a 2015 town hall meeting, Jerry Menikoff, Director of the Office for Human Research Protections ("OHRP"), stated: "The way we do research has changed . . . [but] most portions of the [Common] Rule have not changed a great deal in many, many decades."[57] As a result of this stagnation, the Common Rule inadequately protected human subjects' interests and information. Further, researchers faced administrative burdens when applying Common Rule provisions in a modern research environment. This Section discusses the factors necessitating updates to human-subject protections by examining regulatory problems, discrepancies in judicial enforcement, and recent ethical controversies in research.

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51. 45 C.F.R. § 46.116(a)(5).

52. *Id.* § 46.116(a)(8). Human subjects can withdraw informed consent at any time for any reason. *See id.*

53. *See OHRP Expedited Review Categories (1998)*, *supra* note 35 (explaining that informed consent requirements, waivers, alterations, or exceptions apply whether there is convened IRB review or expedited IRB review).

54. 45 C.F.R. § 46.116(d).

55. *Id.* § 46.393(d) ("Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.").

56. *Id.*

57. Jerry Menikoff, Dir., Office for Human Research Prots., Town Hall Meeting on Common Rule NPRM (Oct. 20, 2015), http://www.hhs.gov/ohrp/humansubjects/regulations/transcriptoct20townhall.html [https://perma.cc/DQ2N-F6L3] ("The Common Rule has been around for 25 years, but the precursor versions of it were not all that different and those actually date back decades before that . . . .").

1. Common Problems

The Common Rule was both structurally and procedurally deficient.[58] Structural problems stemmed from the disconnect between current research practices and the regulatory regime created in 1991. Technology, "including imaging, mobile technologies, and the growth in computing power," has modernized the collection and storage of human-subject information and facilitates combining, mining, and sharing human-subject data in ways that "were simply not possible, or even imaginable, when the Common Rule was first adopted."[59] Re-identification—the process by which anonymized personal data are matched with their true owner—implicates privacy concerns.[60] The Common Rule required IRBs to review protection plans and determine their adequacy "with respect to the informational risks of [the] study," but IRBs were not designed to evaluate privacy risks, and they had little expertise in privacy matters.[61] Further, even if a privacy violation occurred, the Common Rule did not provide a private right of action or other options for corrective action.

Public engagement in research has also changed since the Common Rule's inception. Research is no longer paternalistic; it is increasingly participatory.[62] Human subjects "want to play an active role in research, particularly related to health."[63] For example, patients in the clinical setting are no longer passive recipients of medical treatment and advice.[64] Instead, over the past half century, patients more actively participate in decisions about their health and health care.[65] The participatory model "emerged alongside a broader trend in American society, facilitated by the widespread use of social media, in which Americans are increasingly sharing identifiable personal

58. *See* Alan R. Fleischman, *Regulating Research with Human Subjects—Is the System Broken?*, 116 TRANSACTIONS AM. CLINICAL & CLIMATOLOGICAL ASS'N 91, 91 (2005) (explaining the existing system is "strain[ed] under the weight of a changed research environment and inadequate resources").

59. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,938 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46); Jacob Metcalf & Kate Crawford, *Where Are Human Subjects in Big Data Research? The Emerging Ethics Divide*, BIG DATA & SOC'Y, Jan.–June 2016, at 6, http://journals.sagepub.com/doi/full/10.1177/2053951716650211 [https://perma.cc/VWD2-NZQJ].

60. *See, e.g.*, Mats G. Hansson et al., *The Risk of Re-identification Versus the Need to Identify Individuals in Rare Disease Research*, 24 EUR. J. HUM. GENETICS 1553, 1555 (2016) ("It has been suggested that any re-identification may potentially harm study participants because it will release information on individual disease risks into the public domain.").

61. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,978.

62. *See* Hudson & Collins, *supra* note 8, at 2293.

63. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,938.

64. *See id.*

65. *See id.*

information."[66] Public databases ease re-identification; however, Americans expect to be involved in decisions on how the information they voluntarily provide might be shared in the future.[67]

IRB review and informed consent also faced procedural issues. IRBs at individual sites, or "local IRBs," were inconsistent.[68] They varied in "practices, resources, quality, and experience."[69] Inconsistencies led to unpredictable delays that were costly to researchers.[70] Further, research often took place at multiple sites. Multisite studies experienced long review periods, exclusion of some sites, and "substantial duplication of effort."[71] Inconsistent review processes made it difficult to predict if and when a study might proceed.[72] Once research began, IRBs tended to do little to monitor the actual performance of the study.[73]

Further, IRBs compounded the problem of "informed consent requirements."[74] First, the Common Rule required IRB approval of informed consent forms.[75] In multisite studies, local IRB review might have resulted in varied consent forms and different eligibility criteria.[76] Next, informed consent forms, essential to protect human subjects' autonomy, were onerous and burdensome for researchers.[77] Creating a form that not only complied with the Common Rule but also relayed scientific information in a comprehensible manner was "a formidable challenge."[78] Forms were unduly long—most were fifteen to twenty pages—and buried pertinent information deep in the consent form that human subjects might need to make an informed decision.[79] Rather

66. *Id.*

67. *See id.*

68. *See* Fleischman, *supra* note 58, at 96.

69. *Id.*

70. *See id.* ("Local IRBs have contributed to inordinate delays in initiating trials, exclusion of some sites from participation in a trial, substantial duplication of effort and extraordinary time commitments by core personnel and trial sponsors.").

71. *Id.*

72. *See id.*

73. *See id.* ("Assessment of performance is perhaps the most important problem facing the system for human subjects protection since there are no standard measures of outcome or performance for the system as a whole or to assess IRB performance or quality.").

74. Hamburger, *supra* note 45, at 298.

75. Criteria for IRB Approval of Research, 45 C.F.R. § 46.111(a)(4)–(6) (2017).

76. *See* Hamburger, *supra* note 45, at 298.

77. *See* Fleischman, *supra* note 58, at 96; Anvita Pandiya, *Readability and Comprehensibility of Informed Consent Forms for Clinical Trials*, 1 PERSP. CLINICAL RES. 98, 99 (2010) ("Besides giving medical information to the patient, the consent form must also convey complexities like trial design, randomization, placebo, possible risks and benefits, treatment options, rights to withdraw, and so forth.").

78. Pandiya, *supra* note 77, at 99.

79. *See id.*

than enhance human-subject protections, the Common Rule's consent requirements merely added administrative hurdles.

2. Cases and Controversies

Litigation and ethical controversies also influenced the debate over regulatory reform of human-subject protections. First, judicial opinions since the Common Rule's promulgation demonstrate conflicting approaches to human-subject protections. Although there are virtually no cases involving Common Rule violations,[80] some state and federal courts have addressed informed consent and secondary research.[81] The U.S. Court of Appeals for the Ninth Circuit worried that the lack of either notice or informed consent for secondary use might violate prevailing medical standards.[82] The Eighth Circuit, on the other hand, held that "individuals who make an informed decision to contribute their biological materials" no longer retain an ownership right "to direct or authorize the transfer of such materials to a third party."[83]

The most prominent support of regulatory reform came from a 2008 Arizona Court of Appeals case, which ended in an out-of-court settlement.[84] The Havasupai Tribe filed a lawsuit for misuse of volunteered blood samples.[85] As part of the out-of-court settlement, the Havasupai received $700,000, and researchers returned blood samples to the tribe.[86] Although the settlement did not create legal precedent, "it implied that the rights of research subjects can be violated when they are not fully informed about how their DNA might be used."[87]

Ethical controversies also sparked debates on research limits and human-subject protections.[88] In 1999, Jesse Gelsinger's death

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80. The Common Rule does not provide a private right of action or options for recourse.

81. *See infra* notes 82–83 and accompanying text. While these cases do not deal directly with research, they illuminate how courts addressed secondary use of personal data.

82. Norman-Bloodsaw v. Lawrence Berkeley Lab., 135 F.3d 1260, 1269 (9th Cir. 1998) ("One can think of few subject areas more personal and more likely to implicate privacy interests than of one's health or genetic make-up.").

83. Wash. Univ. v. Catalona, 490 F.3d 667, 673 (8th Cir. 2007).

84. Havasupai Tribe of Havasupai Reservation v. Ariz. Bd. of Regents, 204 P.3d 1063, 1066–67 (Ariz. Ct. App. 2008); *Havasupai Tribe and the Lawsuit Settlement Aftermath*, AM. INDIAN & ALASKA NATIVE GENETICS RESOURCE CTR., http://genetics.ncai.org/case-study/havasupai-Tribe.cfm?pdf=1& (last visited June 8, 2018) [https://perma.cc/223J-TY26].

85. *Havasupai Tribe of Havasupai Reservation*, 204 P.3d at 1066.

86. *See* Amy Harmon, *Indian Tribe Wins Fight to Limit Research of Its DNA*, N.Y. TIMES (Apr. 21, 2010), http://www.nytimes.com/2010/04/22/us/22dna.html [https://perma.cc/7GDN-F4SR].

87. *Id.*

88. *See* Joshua D. Smith et al., *Immortal Life of the Common Rule: Ethics, Consent and the Future of Cancer Research*, 35 J. CLINICAL ONCOLOGY 1879, 1879 (2017).

during a gene therapy trial sparked oversight concerns after subsequent media reports exposed the lead researcher's financial interest in the trial's outcome.[89] The case of Henrietta Lacks is another telling example.[90] HeLa cells, identified by the first two letters of Ms. Lacks's first and last names, shaped the future of medicine as the first cell lines to divide infinitely.[91] Ms. Lacks's husband orally consented to the harvesting of his wife's cells, but only after the researchers promised to give him the results of their findings.[92] The researchers neither informed the Lacks family of HeLa's influence on science nor shared profits derived from her unique cells.[93] When the Lacks's story was published in 2010, it sparked new debates on the ethics, limits, and protections of human subjects.[94]

II. FINAL SAY: THE NEW COMMON RULE AND ITS CONSEQUENCES

To address changes in research, the U.S. Department of Health & Human Services ("HHS") published an Advanced Notice of Proposed Rulemaking ("ANPRM") on July 26, 2011, seeking comments on modernizing the Common Rule.[95] HHS then published a Notice of Proposed Rulemaking ("NPRM") on September 8, 2015, reflecting some of the ANPRM's public feedback.[96] The NPRM sought comment on "proposals to better protect human subjects . . . while facilitating valuable research and reducing burden, delay, and ambiguity for investigators."[97]

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89. Robin F. Wilson, *The Death of Jesse Gelsinger: New Evidence of the Influence of Money and Prestige in Human Research*, 36 AM. J.L. & MED. 295, 295–96 (2010).

90. *See* REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).

91. Jane Dailey, *"The Immortal Life of Henrietta Lacks" by Rebecca Skloot*, CHI. TRIB. (Nov. 17, 2010), http://www.chicagotribune.com/lifestyles/books/chi-the-immortal-life-of-henrietta-111710-story.html [https://perma.cc/EK2Q-JXZL].

92. Rebecca Skloot, *Henrietta's Dance*, JOHNS HOPKINS MAG. (Apr. 2000), http://pages.jh.edu/jhumag/0400web/01.html [https://perma.cc/3TM3-9V3F].

93. *Id.*

94. *See* Smith et al., *supra* note 88, at 1879. After Lacks's story was published, informed consent "dominated discussion of the book," followed by the "welfare of the vulnerable and compensation." Laura M. Beskow, *Lessons from HeLa Cells: The Ethics and Policy of Biospecimens*, 17 ANN. REV. GENOMICS & HUM. GENETICS 395, 396 (2016). Further, "[d]iscussion in professional literature comprised a similar array of themes, including marked emphasis on informed consent, as well as commercialization and compensation; privacy and confidentiality; race, poverty, and health disparities; familial implications of genetic information; ownership of biospecimens; and trust in biomedical research." *Id.* at 396–97 (citations omitted).

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

96. *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,933 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).

97. *Id.*

In compliance with the Administrative Procedure Act, HHS requested and considered comments on the NPRM.[98] At the end of the comment period, interested parties submitted more than 2,100 comments.[99] While some comments supported efforts to enhance the Common Rule,[100] others found the NPRM "unnecessarily complex and hard to interpret."[101] After much deliberation, the Final Rule was published on January 19, 2017.[102] This Part provides an overview of the Final Rule, including proposed changes in the NPRM, comments on the NPRM, and potential consequences.

A. Proposed Changes, Comments, and the Final Rule

HHS proposed eight major changes to the Common Rule.[103] This Note addresses changes affecting identifiable private information in three broad categories: (1) reconsidering IRB review, (2) requiring privacy safeguards, and (3) improving consent. This Section provides an overview of these three proposed changes in the NPRM. This Section also discusses selected comments on the NPRM and analyzes the comments' influence on the Final Rule's text. The comments selected were submitted by well-known, reputable medical and research institutions and professional organizations. By examining the concerns and priorities of various parties, this Note's final recommendation offers a refined regulation that better balances the interests of human subjects and researchers.[104]

1. IRB Review

The NPRM proposed two significant changes to IRB review: single IRB review of multisite research and elimination of some

98. Administrative Procedure Act § 1, 5 U.S.C. § 551 (2012).

99. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7152 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

100. *Id.*

101. Jennifer K. Lodge & David H. Perlmutter, Washington University in St. Louis School of Medicine, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 5, 2016), https://research.wustl.edu/wp-content/uploads/2017/09/Common-Rule-Comment-Letter.pdf [https://perma.cc/MX5K-GD2T]; *see* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7152 (listing submitted comments on the proposed rule).

102. Protection of Human Subjects, 45 C.F.R. pt. 46 (2017).

103. *See* Menikoff, *supra* note 57. The proposed changes not discussed in this Note include regulating de-identified biospecimens, extending the Common Rule to clinical trials, and revising categories of exempt research. *See id.*

104. The analysis also informs the approach this Note posits in adopting a modified version of the Privacy Rule. *See infra* Parts III–IV.

continuing review.[105] These changes aimed to streamline IRB review, reduce inefficiencies, and hold independent IRBs directly responsible for compliance.[106]

First, the NPRM proposed a mandate for single IRB review of multisite research at U.S. institutions.[107] This mandate applied unless local laws required more than single IRB review or a federal department or agency determined single IRB review was not appropriate.[108] This change also provided Common Rule departments and agencies explicit "authority to enforce compliance" directly against independent IRBs "not operated by an assured institution."[109] This encouraged institutions to rely on a single IRB rather than various local IRBs.[110]

Second, the NPRM proposed eliminating continuing review for minimal risk studies, which usually qualify for expedited review.[111] The proposal also eliminated continuing review for studies "initially reviewed by a convened IRB . . . after the study reaches the stage where it involves" either analyzing data or "accessing follow-up clinical data from procedures that subjects undergo as part of standard care for their medical condition or disease."[112] In either case, an IRB could require continuing review but would have to document its rationale.[113] Overall, this proposed change aimed to make IRB operations more efficient.[114] By reducing continuing review, IRBs could, in theory, allocate more time to riskier studies involving human subjects.[115]

The proposal to mandate single IRB review of multisite research, one of the most commented-on proposals in the NPRM,

105. *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,937 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).

106. *Id.* at 53,981.

107. *Id.* at 53,983; *see also Single IRB Policy for Multi-site Research*, NAT'L INSTS. HEALTH, https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm (last visited Sept. 15, 2018) [https://perma.cc/F7TD-9QET] ("Historically, in many multi-site studies, each site has its own IRB which conducts an independent review of studies involving human research participants. The use of a single IRB of record for multi-site studies that are conducting the same protocol will help streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites.").

108. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,983.

109. *Id.*

110. *See* Menikoff, *supra* note 57.

111. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,985.

112. *Id.*

113. *Id.* at 53,986.

114. *Id.* at 53,984.

115. *See id.* at 53,936 ("Research that poses greater risk to subjects should receive more oversight and deliberation than less risky research."); Menikoff, *supra* note 57.

received over three hundred comments.[116] Approximately 130 supported the proposal, 140 opposed it, and the remaining had mixed views.[117] Supporters, including both individuals and scientific organizations,[118] believed the mandate reduced administrative burdens and costs.[119] On the other hand, research institutions tended to oppose the mandate and advocated for optional single-IRB review.[120] These opponents argued that the mandate increased administrative burdens and lessened human-subject protections because of "[d]ifferences in institutional policies and procedures, scopes of work at each site, and local cultures."[121]

In the end, the Final Rule adopted single-IRB review of multisite research.[122] Regulators made single-IRB review mandatory rather than optional because "systematic efficiencies have the best chance of occurring if single IRB review is required."[123] To provide flexibility in adjusting to the new model, the Final Rule adopts a delayed compliance date of three years from publication.[124]

Concerning eliminating some continuing review, the NPRM received approximately 120 comments, with roughly ninety-five comments supporting the proposal.[125] Supporters believed the proposal

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116. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7208 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

117. *Id.*

118. *Id.* Individual supporters are "those who were not providing comment in an official institutional capacity." *Id.*

119. *Id.*

120. *See, e.g.*, Sharon F. Terry, Genetic Alliance, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 2, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1806&attachmentNumber=1&contentType=pdf [https://perma.cc/D2WP-XNUB] [hereinafter Genetic Alliance Comment]. Other institutions that believed single IRB review should be optional included, but were not limited to, Vanderbilt University, Boston University, the University of Chicago, and Brown University. *See infra* notes 121, 135–136, 158.

121. David A. Savitz, Brown University, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 6, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1510&attachmentNumber=1&contentType=pdf [https://perma.cc/Q44Z-9HK5] ("The only scenario for which we see the mandate for use of a central IRB adding value is when a study involves identical procedures and involvement at each site. In these instances, however, it seems more appropriate for the funding agency to require the use of a single IRB.").

122. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7209.

123. *Id.*

124. *Id.*

125. *See, e.g.*, William T. Tucker, University of California System, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 4, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1062&attachmentNumber=1&contentType=pdf [https://perma.cc/9L6M-X4SA] ("[C]ontinuing review for minimal risk research imposes an administrative burden that does not

alleviated IRB administrative burdens, while opponents argued that continuing review importantly allowed researchers "to periodically re-evaluate the benefits, risks, methods, and procedures used in research activities."[126] With strong support, the Final Rule adopted the NPRM's change as proposed.[127]

2. Privacy Safeguards

To assure appropriate privacy and confidentiality protections of human subjects' identifiable private information, the NPRM proposed having several sets of standards promulgated by the secretary of HHS, allowing researchers to choose which standard to use.[128] The safeguards, published in the Federal Register, would involve minimal cost and effort to implement and would assure that data "posing informational risks to subjects would be protected according to appropriate standards."[129] If researchers met these safeguards, there would be no need for additional IRB review.[130] Additionally, compliance with the HIPAA Privacy Rule, which better addressed informational risks by restricting the use and disclosure of identifiable data, would also satisfy the Common Rule requirements.[131]

The NPRM received approximately 130 comments addressing privacy safeguards,[132] most of which supported the proposal.[133] Both

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result in the discovery of information or raise issues that require IRB review or investigator action.").

126. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7205.

127. *Id.*

128. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,979 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46).

129. *Id.*; *see* Menikoff, *supra* note 57 ("So the goal is that these would be common sense, easily implemented standards.").

130. *See* Menikoff, *supra* note 57 ("[T]he default position is that if the privacy standards . . . are met, there will be no need for additional IRB Review . . . .").

131. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,979; *see* Menikoff, *supra* note 57 ("An institution could abide by the HIPAA rules, so any institution that is bound by HIPAA is already meeting these standards."). The NPRM also listed eight additional statutes and acts that might be reasonable to include in the new Common Rule. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,979–80. The Privacy Rule is discussed in detail *infra* Part III.

132. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7202.

133. *Id.* Many comments expressed support through a form letter that included the following statement: "I endorse the following . . . [p]roposal to develop standards deemed sufficient to safeguard privacy in addition to those set forth in HIPAA." COUNCIL ON GOVERNMENTAL RELATIONS, ANALYSIS OF PUBLIC COMMENTS ON THE COMMON RULE NPRM 12 (2016), http://www.cogr.edu/sites/default/files/Analysis%20of%20Common%20Rule%20Comments.pdf [https://perma.cc/F8DK-CB3H]. The American Society for Investigative Pathology posted the form letter. *Comment Letter on the Notice of Proposed Rulemaking – Common Rule*, AM. SOC'Y FOR INVESTIGATIVE PATHOLOGY (Nov. 23, 2015),

supporters and opponents agreed, however, that "it was difficult to comment on the adequacy of privacy standards that had yet to be developed."[134] Those opposed also criticized incorporating HIPAA protections for various reasons.[135]

Some commenters linked privacy with protecting autonomy and suggested Congress create a statutory right of action to remedy informational harms.[136] Under the Common Rule, and under the NPRM's proposed changes, human subjects had virtually no options for recourse. One commenter explained that the United States' failure to require compensation for research-related injuries made it an outlier "in this respect in the international community."[137]

Despite majority support, the Final Rule did not adopt the privacy proposal in the NPRM.[138] Instead, the Final Rule "retains and

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http://www.asip.org/SciencePolicy/documents/ASIPCommentsNPRMCommonRule.pdf [https://perma.cc/CX3R-K3KC].

134. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7202; *see, e.g.*, Lois Brako, University of Michigan Human Research Protection Program, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 5, 2015), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1277&attachmentNumber=1&contentType=pdf [https://perma.cc/22DX-RNN6] [hereinafter University of Michigan Comment] ("Regarding . . . the yet-to-be-developed . . . privacy protections, we are unable to comment . . . as no specific standards are present."); Alexander E. Dreier, Yale University, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 6, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1749&attachmentNumber=1&contentType=pdf [https://perma.cc/R334-B67M] (requesting further clarification on privacy protections in the NPRM).

135. *See, e.g.*, Gordon R. Bernard, Vanderbilt University, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 5, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1188&attachmentNumber=1&contentType=pdf [https://perma.cc/2CCX-4N3A] (arguing the cost of implementing HIPAA would be tremendous and not add any value); University of Michigan Comment, *supra* note 134 ("[W]e know that HIPAA standards do not fit for all cases of human research and we would discourage the broader application of HIPAA or HIPAA-like standards."); Michael D. Rich, Rand Corporation, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 5, 2016), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1390&attachmentNumber=1&contentType=pdf [https://perma.cc/HW4X-FEA4] (explaining that researchers (1) are not well-versed in HIPAA and (2) could not make informed self-determinations that HIPAA would apply).

136. Jessica L. Roberts, University of Houston Law Center, & Valerie G. Koch, University of Chicago, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Jan. 5, 2015), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1348&attachmentNumber=1&contentType=pdf [https://perma.cc/X2SF-MS8B].

137. *Id.* In 2013, the United States failed to sign the seventh edition of the Declaration of Helsinki, a set of ethical principles regarding human experimentation developed by the World Medical Association that added the following provision: "[a]ppropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured." *Id.*

138. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7202.

acknowledges the IRB's role in ensuring that privacy safeguards are appropriate for the research studies that require IRB review."[139] Additionally, the Final Rule requires the secretary of HHS to issue guidance to assist IRBs in protecting human subjects' privacy and confidentiality.[140] The regulatory text explains that this approach avoids promulgating "a regulation that lack[s] sufficient specificity."[141] Further, the text states "IRBs have been responsible for evaluating such risks under the pre-2018 rule," and further guidance would make them more effective.[142]

3. Consent

The NPRM proposed tightening informed consent requirements to make the process of obtaining consent more meaningful by establishing a reasonable person standard.[143] Consent forms would be drafted "in a way that facilitates" a reasonable person's understanding "of the reasons why one might or might not want to participate."[144] In light of the reasonable person standard, the proposed changes included revising "unduly long [consent] documents."[145] Consent forms would provide essential information in a clear, organized, and sufficient manner to human subjects to assist their decisionmaking process.[146]

Further, to ensure that the proposed modifications did indeed change current practices, the NPRM mandated a "one-time posting requirement" for consent forms.[147] This way, drafters knew that their forms would be subject to public scrutiny.[148] By increasing transparency, regulators believed these changes would better protect

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139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.* The Final Rule also acknowledges that IRBs were not specifically designed to evaluate (1) risks to privacy and confidentiality and (2) the adequacy of safeguards to protect against those risks. *Id.*

143. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. 53,933, 53,936 (Sept. 8, 2015) (to be codified at 45 C.F.R. pt. 46); *see* Menikoff, *supra* note 57 ("[S]ome of the changes will require the document to provide essential information that a reasonable person would want to know . . . a standard bar from the legal world in terms of clinical consent in a nonresearch setting.").

144. Menikoff, *supra* note 57; *see* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,936.

145. Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,936.

146. *Id.*

147. *Id.*

148. *Id.*

human subjects—the ultimate goal of informed consent—and build trust.[149]

Another major change required consent "for the use of all biospecimens in research, whether or not they [were] deidentified."[150] In the context of secondary (or future) research, obtaining additional informed consent for the use of identifiable private information is burdensome.[151] As a result, the NPRM proposed broad consent as an alternative to informed consent.[152] With broad consent, human subjects would consent to unknown future research without additional informed consent.[153] Thus, human subjects would not be afforded another opportunity to decide whether they wanted their identifiable private information used in a particular way. To compensate for the loss in human-subject autonomy from broad consent, IRBs would not be permitted to waive consent if human subjects were asked to provide broad consent and declined.[154]

Approximately two hundred comments discussed the NPRM's proposal to "include information required by the Common Rule in the consent form and place other information in appendices."[155] Supporters (approximately 140 commenters) agreed informed consent documents should be shorter and easier to understand.[156] Approximately thirty-five commenters opposed the change because human subjects' decisionmaking process would not be improved and the lack of specific standards would make the provision impossible to implement.[157] Other commenters liked "the general idea of the proposal . . . [but] felt the

149. *Id.*; *see* Menikoff, *supra* note 57 ("[S]ome people think it's often lawyers trying to protect the institution [who] have written a document that's more helpful in terms of protecting institutions as oppose[d] to the goal of genuinely doing a good job in terms of informing the subject.").

150. Hudson & Collins, *supra* note 8, at 2294; *see* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,972.

151. *See* Federal Policy for the Protection of Human Subjects, 80 Fed. Reg. at 53,972 ("Critics of the existing rules have observed that the current requirements for informed consent for future research with pre-existing information and biospecimens are confusing and consume substantial amounts of investigators' and IRBs' time and resources.").

152. *Id.*

153. *Id.* at 53,973.

154. *Id.* at 53,975–76. The NPRM states that broad consent is different than informed consent; thus, broad consent forms should "ensure that the individual would be provided with sufficient information to make an informed decision about whether to agree to provide broad consent for a wide variety of research that may be unforeseen at the time in which consent is being sought." *Id.* at 53,973. The NPRM imposed strict IRB waiver requirements for secondary research and explicitly stated that waiver is intended to be "extremely rare." *Id.* at 53,976.

155. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7211 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

156. *Id.*

157. *Id.*

proposal should not focus on the length of a consent form, but rather on clarity and understandability."[158]

The Final Rule mandates six significant revisions to the requirements of informed consent[159] and adopts "almost verbatim" all proposals made in the NPRM to improve, clarify, and streamline informed consent.[160] Consistent with public comments, the Final Rule adopts an approach "emphasizing efforts to foster understanding overall rather than imposing specific length limitations on the entire consent forms."[161] This approach allows regulated research entities "to pursue different and innovative approaches to obtaining informed consent."[162]

With regard to broad consent, the NPRM received 475 comments, mostly in opposition to the proposal "that some type of consent (broad or specific) would be required for research with nonidentified biospecimens."[163] Approximately 150 comments addressed "the adequacy or inadequacy" of broad consent, or broad consent templates to be created by HHS.[164] Commenters also questioned whether broad consent was actually meaningful consent.[165]

The Final Rule makes broad consent a permissible option only for secondary research use of identifiable private information.[166] In response to public comments, the Final Rule requires a general description "of the types of research that may be conducted with identifiable private information" that a reasonable person would want or need to know.[167] Lastly, the Final Rule does not include the NPRM's

158. *Id.*; *see, e.g.*, Gloria Waters, Boston University, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Dec. 23, 2015), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-0597&attachmentNumber=1&contentType=pdf [https://perma.cc/3ALY-NRQZ] [hereinafter Boston University Comment] (suggesting consent documents be formatted in a list with bullet points to help human subjects make informed decisions).

159. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7210. The six major revisions include the following: (1) new requirements for content, organization, and presentation of information; (2) basic and additional elements of consent; (3) the elements of broad consent for the storage, maintenance, or secondary research use of identifiable private information; (4) changes in waiver or alteration criteria for consent; (5) a new provision that allows IRBs to approve a research proposal without individuals' informed consent in specific situations; and (6) a new requirement to post a copy of an IRB-approved version of the consent form on a federal website. *Id.*

160. *Id.* at 7213.

161. *Id.*; *see* Boston University Comment, *supra* note 158.

162. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7214.

163. *Id.* at 7218.

164. *Id.*

165. *Id.*

166. *Id.* at 7220.

167. *Id.* at 7221.

provision that the secretary of HHS establish broad consent templates.[168] Thus, institutions can create and tailor their own broad consent forms.[169]

B. New Consequences

The Final Rule differs considerably from the NPRM, reflecting "the power of the research institutions' lobby."[170] By increasing access to identifiable private information under broad consent and by limiting oversight, the Final Rule alleviates administrative burdens for both researchers and the IRB. As a result, "the research world will . . . be awash in unwittingly donated—and *not* anonymized" human-subject data.[171]

Accordingly, the Final Rule will likely have the unintended consequence of increasing privacy risks.[172] Concerning consent, the Final Rule allows researchers to choose between informed consent or broad consent, which creates a lose-lose situation.[173] Informed consent protects subject autonomy but, even with the Final Rule's streamlined informed consent documents, increases administrative burdens. On the other hand, broad consent for identifiable private information eliminates any incentive to de-identify human-subject data.[174] Further, even though broad consent does not replace informed consent, multiple bioethics scholars concluded in 2015 that broad consent "in many cases [is] optimal" and will likely be preferred by researchers because it significantly reduces administrative burdens.[175]

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168. *Id.* at 7222.

169. *Id.*

170. Timothy Caulfield & Blake Murdoch, *Genes, Cells, and Biobanks: Yes, There's Still a Consent Problem*, PLOS BIOLOGY 2 (July 25, 2017), journals.plos.org/plosbiology/article/file?id=10.1371/journal.pbio.2002654&type=printable [https://perma.cc/2SJL-5BWU].

171. John Conley, *Some Thoughts on the New Common Rule for Human Subjects Research*, PRIVACY REP. (Mar. 29, 2017), https://www.genomicslawreport.com/index.php/2017/03/29/some-thoughts-on-the-new-common-rule-for-human-subjects-research/ [https://perma.cc/HJ8A-6FXN].

172. *See* Roy A. Jensen, University of Kansas Cancer Center, Comment Letter on the Department of Health & Human Services Proposed Rule: Federal Policy for the Protection of Human Subjects (Dec. 28, 2015), https://www.regulations.gov/contentStreamer?documentId=HHS-OPHS-2015-0008-1157&attachmentNumber=1&contentType=pdf [https://perma.cc/A3YD-KP7J] [hereinafter University of Kansas Comment] (discussing privacy concerns).

173. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. at 7220.

174. *See* University of Kansas Comment, *supra* note 172.

175. Christine Grady et al., *Broad Consent for Research with Biological Samples: Workshop Conclusions*, 15 AM. J. BIOETHICS 34, 39 (2015). The bioethics scholars that took part in the workshop agreed that broad consent is optimal when the following three components are attached: (1) initial broad consent; (2) process of oversight and approval of future research activities; and (3) wherever feasible, an ongoing communication process. *Id.*

The primary risk raised by research is the unintended revelation of the human subject's identity.[176] Limited oversight and broad consent for secondary research compound this risk. First, the IRB and researchers often shirk their responsibility to ensure ethical research processes.[177] The American Association of Universities conducted a systematic review of reports that addressed problems with Common Rule compliance at universities.[178] The report concluded that human-subject protection has "not always been subject to the continuing review and monitoring it needs to ensure that it is functioning as well as this vital area of research protections requires."[179] The Final Rule only exacerbates this problem.

As informational risks rise, the new regulation does not provide any legally enforceable rights to human subjects to prevent, monitor, or remedy privacy violations.[180] The University of Kansas addresses this concern in its comment on the NPRM: "All human biospecimens and the information derived therefrom are deserving of the highest level of security. . . . The regulations have failed to address sanctions for the unauthorized re-identification of subjects."[181] Broad consent inhibits the ability of human subjects "to be truly informed about the objectives and details of the research" and does not respect human subjects' "values and personal preferences."[182] More problematically, broad consent inadequately protects human subjects against new and unpredictable regulatory changes.[183] Like the original Common Rule, the Final Rule is merely a compilation of requirements that lacks judicial relief.

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176. PRECISION MEDICINE INITIATIVE, *supra* note 9, at 5.

177. Dave Maass, *More Needs to Be Done to Strengthen Protection of Human Subjects in Scientific Experiments*, ELECTRONIC FRONTIER FOUND. (Jan. 7, 2016), https://www.eff.org/deeplinks/2016/01/more-needs-be-done-strengthen-protection-human-subjects-scientific-experiments [https://perma.cc/M7ZE-NVY6] ("[M]eaningful oversight . . . requires after-the-fact accountability.").

178. ASS'N OF AM. UNIVS., REPORT ON UNIVERSITY PROTECTIONS OF HUMAN BEINGS WHO ARE THE SUBJECTS OF RESEARCH 2 (2000).

179. *Id.*

180. Numerous public comments on the NPRM sought rights and remedies for human subjects. *See* University of Kansas Comment, *supra* note 172.

181. *Id.*

182. Isabelle Budin-Ljøsne et al., *Dynamic Consent: A Potential Solution to Some of the Challenges of Modern Biomedical Research*, BMC MED. ETHICS 2 (Jan. 25, 2017), https://bmcmedethics.biomedcentral.com/track/pdf/10.1186/s12910-016-0162-9 [https://perma.cc/W84K-X9SE] [hereinafter *Dynamic Consent: A Potential Solution*].

183. *Id.*

III. ANOTHER PRIVATE MATTER: AN ANALYSIS OF THE HIPAA PRIVACY RULE

In contrast to the Final Rule's weakened human-subject protections, the Privacy Rule provides stronger safeguards for participants. Although the Final Rule rejected Privacy Rule compliance, NPRM comments suggest components of the Privacy Rule would better protect human subjects.

As background, Congress enacted HIPAA in 1996[184] to protect patient health information "given emerging advances in information technology."[185] Under HIPAA's administrative simplification provision, Congress instructed HHS to submit "detailed recommendations on standards with respect to the privacy of individually identifiable health information."[186] Per this provision, HHS developed the Privacy Rule, "a set of national standards for the protection of certain health information."[187]

The Privacy Rule, promulgated in 2001 and amended in 2013, protects the use and disclosure of PHI.[188] PHI is individually identifiable health information transmitted by or maintained in electronic media or "any other form or medium."[189] The language in the Privacy Rule is nuanced. Individually identifiable health information is defined as a subset of health information[190] and includes an individual's demographic information, "created or received" by a covered entity[191] and related to the mental health, provision of health care, or payment of health care of an individual.[192]

Research is not a primary focus of the Privacy Rule.[193] Nonetheless, HHS included research provisions in the Privacy Rule to

184. Health Insurance Portability and Accountability Act (HIPAA) of 1996, Pub. L. No. 104-191, 110 Stat. 1936 (codified as amended in scattered sections of 18, 26, 29, and 42 U.S.C. (2012)).

185. Byrne v. Avery Ctr. for Obstetrics & Gynecology, P.C., 102 A.3d 32, 35 (Conn. 2014).

186. § 264, 110 Stat. at 2033.

187. *Id.*; HIPAA Privacy Rule, 45 C.F.R. pts. 160, 164 (2017).

188. 45 C.F.R. pts. 160, 164.

189. *Id.*

190. Health information is any information "created or received by a health care provider, health plan . . . , or health care clearinghouse" that relates to the mental health condition, health care, or payments of health care to an individual. *Id.* § 160.103.

191. Covered entities include health plans, health-care clearinghouses, and health-care providers "who transmit[ ] any health information in electronic form in connection with a transaction covered by this subchapter." *Id.*

192. *Id.*

193. COMM. ON HEALTH RESEARCH & THE PRIVACY OF HEALTH INFO.: THE HIPAA PRIVACY RULE, INST. OF MED. OF THE NAT'L ACADS., BEYOND THE HIPAA PRIVACY RULE: ENHANCING PRIVACY, IMPROVING HEALTH THROUGH RESEARCH 86 (Sharyl J. Nass et al. eds., 2009) [hereinafter BEYOND THE HIPAA PRIVACY RULE].

"remedy perceived shortcoming[s] of federal privacy protections in health research under the Common Rule."[194] The U.S. General Accounting Office ("GAO") prepared a report in 1999 detailing weak human-subject protections in anticipation of the Privacy Rule.[195] Specifically, the GAO reported that the typical complaint made by human subjects was "lack of privacy and confidentiality."[196] Further, the report documented investigations by the HHS Office for Protection from Research Risks.[197] These investigations found human-subject protection violations stemmed from "(1) research subject to IRB review and (2) research outside federal protection."[198] HHS considered this report, among other recommendations, when drafting the Privacy Rule's research protections.[199]

The Privacy Rule and the Final Rule were both reactions to the inadequate Common Rule. However, the Privacy Rule provides patients stronger privacy protections than the Final Rule. Importantly, it engages users of PHI in discussing how to secure and protect patient privacy and imposes penalties for privacy violations. The Privacy Rule, however, is not perfect. It is burdensome, formalistic, and, at times, too restrictive. The distinctions between the Privacy Rule and Final Rule inform this Note's final recommendation. This Part discusses legal rights and research provisions under the Privacy Rule as well as options for corrective action when privacy violations occur.

A. Legal Rights and Research Provisions

The Privacy Rule establishes legally enforceable rights for individuals who are the subject of PHI[200] and provides recourse to patients who fall victim to privacy violations. The Final Rule, in contrast, does not establish any rights.[201]

The Privacy Rule establishes the general right to authorize use or disclosure of PHI for research.[202] This general right is coupled with

194. *Id.* at 27.

195. U.S. GEN. ACCOUNTING OFFICE, MEDICAL RECORDS PRIVACY: ACCESS NEEDED FOR HEALTH RESEARCH, BUT OVERSIGHT OF PRIVACY PROTECTIONS IS LIMITED (1999).

196. *Id.* at 16.

197. *Id.* The Office for Protection from Research Risks is now OHRP. *Office for Human Research Protections*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/ohrp/ (last visited June 3, 2018) [https://perma.cc/6FH5-L6HD].

198. BEYOND THE HIPAA PRIVACY RULE, *supra* note 193, at 163.

199. *Id.*

200. HIPAA Privacy Rule, 45 C.F.R. §§ 164.508, .520, .528 (2017).

201. Instead, the Common Rule (and Final Rule) "[safeguard] the rights and welfare of human subjects." Protection of Human Subjects, 45 C.F.R. § 46.103(b)(1).

202. 45 C.F.R. § 164.508.

the right to adequate notice of use and disclosure of PHI and the right to an accounting of disclosures of PHI.[203] These rights increase awareness "of persons or entities . . . in possession of [PHI]."[204]

An authorization must include six core elements as well as statements that adequately put an individual sharing PHI on notice.[205] Of particular relevance, the authorization must be "specific and meaningful" and provide notice of the individual's right to revoke the authorization in writing.[206] Further, the authorization must include a description of each purpose of the requested use or disclosure.[207] Under this requirement, PHI research must be study specific.[208] Unspecified future research is invalid under the Privacy Rule.[209]

The Privacy Rule permits waiver of authorization in whole or in part by an IRB or privacy board.[210] A privacy board consists of diverse members that "review the effect of the research protocol on the individual's privacy rights and related interests."[211] Unlike the Final Rule, the Privacy Rule does not require an IRB or privacy board to review authorization forms.[212]

Unauthorized PHI use requires "the information be used and disclosed under strict conditions that safeguard individuals' confidentiality."[213] Thus, the Privacy Rule sets "complex standards" for IRBs and privacy boards to apply in determining waiver of authorization.[214] The IRB and privacy board must determine that the following are true: (1) the use or disclosure of PHI involves no more than a minimal privacy risk; (2) "[t]he research could not practicably be

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203. *Id.* §§ 164.520, 164.528.

204. BEYOND THE HIPAA PRIVACY RULE, *supra* note 193, at 51.

205. 45 C.F.R. § 164.508(c)(1)–(2). The six core elements are as follows: (1) a description that identifies the requested information in a "specific and meaningful fashion"; (2) the name or other specific identification of the person or entity authorized to make the requested information; (3) the name or other specific identification of the persons or entity to which the requested information may be disclosed; (4) a description of the purpose for which the information is requested; (5) an expiration date or expiration event that relates to the individual or the purpose for which the information is requested; and (6) a dated signature of the patient or the patient's representative with a description of the representative's authority to act on behalf of the patient. *Id.* § 164.508(c)(1)(i)–(vi).

206. *Id.* § 164.508(c)(1)(i), (vi).

207. *Id.* § 164.508(c)(1)(iv).

208. BEYOND THE HIPAA PRIVACY RULE, *supra* note 193, at 164–65.

209. *Id.*

210. 45 C.F.R. § 164.512(i)(1)(i)(A)–(B).

211. *Id.* § 164.512(i)(1)(i)(B)(1). At least one member of the privacy board must not be affiliated with the covered entity or research sponsor. *Id.* § 164.512(i)(1)(i)(B)(2). Further, no member of the privacy board can have a conflict of interest. *Id.* § 164.512(i)(1)(i)(B)(3).

212. *Id.* § 164.508(c)(1)(iv).

213. BEYOND THE HIPAA PRIVACY RULE, *supra* note 193, at 167.

214. *Id.* at 168.

conducted without the waiver or alteration"; and (3) "the research could not practicably be conducted" without the PHI.[215] Covered entities can rely on waiver approved by a single IRB or privacy board with jurisdiction.[216]

Authorization is more explicit than consent and the nuance is critical: authorization grants permission to use or disclose PHI whereas consent signifies an agreement to participate in research.[217] Authorization is a detailed document that provides the "how, why, and to whom the PHI will be used and/or disclosed for research."[218] In contrast, informed consent documents include a description of the study, anticipated risks and benefits, and how the confidentiality of records will be protected, among other things.[219] Voluntary consent is not sufficient under the Privacy Rule unless "it also satisfies the requirements of a valid authorization."[220] Authorization allows patients to know and direct how information about them is being used. Thus, the Privacy Rule prohibits one hallmark of the Final Rule: broad consent for unspecified future research.[221]

The Privacy Rule, like HIPAA generally, produces a "heightened awareness" for patient privacy,[222] but heightened awareness comes with costs.[223] The Privacy Rule, like the Final Rule, improperly balances patients' and researchers' interests. The difference, however, is the Privacy Rule is overly protective of patients whereas the Final Rule is too relaxed on researchers. The rights granted under the Privacy Rule—authorization, notice, and accounting of disclosures—create extra bureaucracy and expense. A 2017 survey conducted by the Association of Academic Health Centers found researchers "overwhelmingly believe that the HIPAA Privacy Rule has had a

215. 45 C.F.R. § 164.512(i)(2)(ii)(A)–(C).

216. *Id.* § 164.512(i)(2)(iv)(A).

217. *HIPAA Authorization for Research*, NAT'L INSTS. HEALTH (Apr. 2004), https://privacyruleandresearch.nih.gov/pdf/authorization.pdf [https://perma.cc/C4SL-L79G].

218. BEYOND THE HIPAA PRIVACY RULE, *supra* note 193, at 315.

219. *Id.* at 164.

220. *What Is the Difference Between "Consent" and "Authorization" Under the HIPAA Privacy Rule?*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/for-professionals/faq/264/what-is-the-difference-between-consent-and-authorization/index.html (last visited Feb. 20, 2018) [https://perma.cc/SD3Y-N54K].

221. *Compare* 45 C.F.R. § 164.508(c)(1)(i) (authorization must be "specific and meaningful"), *with* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7220 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46) (broad consent is permissible for secondary research).

222. Neil Chesanow, *Is HIPAA Creating More Problems than It's Preventing?*, MEDSCAPE (Sept. 16, 2013), https://www.medscape.com/viewarticle/810648 [https://perma.cc/3MTG-6LBV] (quoting George D. Lundberg, MD, Editor at Large, Medscape).

223. *See* BEYOND THE HIPAA PRIVACY RULE, *supra* note 193.

negative impact on the scope, pace, and cost of research."[224] The survey also characterized the Privacy Rule as having a negative impact on recruiting research participants.[225] While continuous monitoring and communication better protect patients' information and promote trust, at times they can be impractical, ineffective, and inefficient.[226]

B. A Novel Approach to Privacy Violations

The Privacy Rule requires covered entities to protect PHI.[227] If an individual believes a covered entity violated his privacy rights, he might take one of two corrective paths. The first path involves filing a complaint with the Office for Civil Rights ("OCR") of HHS.[228] OCR can act on complaints only if a covered entity violated the Privacy Rule and the complaint was filed within 180 days of the violation.[229] If OCR determines the covered entity violated HIPAA, it can impose civil and criminal penalties.[230] The second path involves making a state law negligence claim.[231] This might seem odd because the Privacy Rule (and HIPAA generally) does not provide a private right of action. Thus, an individual affected by a privacy breach may not bring a civil claim against a covered entity under HIPAA. Further, the Privacy Rule

224. MINDY J. STEINBERG & ELAINE R. RUBIN, THE HIPAA PRIVACY RULE: LACKS PATIENT BENEFIT, IMPEDES RESEARCH GROWTH 10 (2009). Fifty-four respondents from twenty-seven institutions responded to the survey. *Id.* at 2. Relevant findings included the following: (1) 59.1% of respondents believed the Privacy Rule had a negative or strongly negative impact on the scope of research, while only 7.5% said the impact was positive or strongly positive; (2) 81.3% of respondents reported their institution had a designated official to assist researchers with Privacy Rule issues; and (3) 76.6% of respondents said their IRB had assumed additional responsibilities to address the Privacy Rule, of which 62.3% characterized the impact of these additional responsibilities as negative or strongly negative, 20.8% said there was no impact on the IRB, and 11.3% said the impact was positive or strongly positive. *Id.* at 3–5.

225. *Id.* at 9. The survey found that 45.3% of respondents believed the Privacy Rule had a negative or strongly negative impact on subject recruitment; 48.1% rated the impact on the cost of recruiting participants as negative or strongly negative. *Id.*

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

227. HIPAA Privacy Rule, 45 C.F.R. § 164.530(c) (2017).

228. *What to Expect*, U.S. DEP'T HEALTH & HUM. SERVS., https://www.hhs.gov/hipaa/filing-a-complaint/what-to-expect/index.html (last visited Feb. 20, 2018) [https://perma.cc/MKK4-GB3F].

229. *Id.*

230. *Id.*

231. Four elements are required to establish a prima facie case of negligence: (1) existence of a legal duty that defendant owed to plaintiff; (2) defendant's breach of duty; (3) plaintiff's sufferance of injury; and (4) proof that defendant's breach caused the injury. *Negligence*, WEX LEGAL DICTIONARY, https://www.law.cornell.edu/wex/negligence (last visited Aug. 6, 2018) [https://perma.cc/5FRA-UGGR].

preempts any contrary provision of state law.[232] Recent decisions by state courts, however, held HIPAA is the standard industry practice for health-care providers and may form the basis for state law negligence claims involving disclosure of patient medical records.[233] Under this path, state courts create what looks like a de facto private right of action under HIPAA.

For example, consider the Connecticut Supreme Court's landmark decision in *Byrne*.[234] In *Byrne*, the plaintiff instructed Avery Center (a covered entity) not to release her medical records to the estranged father of her child.[235] When the father filed paternity actions against the plaintiff and subpoenaed Avery Center for the plaintiff's medical records, Avery Center mailed the documents to the court without notifying the plaintiff.[236] As a result, the plaintiff alleged she suffered harassment and extortion threats from the father "since he viewed her medical records."[237] The Connecticut Supreme Court declared that HIPAA does not preempt state negligence or negligent infliction of emotional distress claims against covered entities.[238] Further, HHS regulations implementing HIPAA, such as the Privacy Rule, may inform the applicable standard of care in certain circumstances.[239]

At least ten other states have also recognized that courts may look to HIPAA when considering the relevant standard of care for state negligence claims brought by individuals.[240] Of the state courts that have addressed this novel approach, only Ohio courts have found HIPAA neither provides a private right of action nor establishes the

232. 45 C.F.R. § 160.203. The Privacy Rule defines "contrary" as impossible to comply with both state and federal requirements or when "[s]tate law stands as an obstacle" in executing the Privacy Rule. *Id.* § 160.202.

233. *See, e.g.*, Byrne v. Avery Ctr. for Obstetrics & Gynecology, P.C., 102 A.3d 32, 48 (Conn. 2014); *see also infra* notes 257–263.

234. 102 A.3d at 48.

235. *Id.* at 36.

236. *Id.*

237. *Id.*

238. *Id.* at 48.

239. *Id.*

240. *See* I.S. v. Wash. Univ., No. 4:11CV235SNLJ, 2011 WL 2433585, at *4 (E.D. Mo. June 14, 2011); Harmon v. Maury County, No. 1:05 CV 0026, 2005 WL 2133697, at *3 (M.D. Tenn. Aug. 31, 2005); Fanean v. Rite Aid Corp., 984 A.2d 812, 823 (Del. Super. Ct. 2009); Young v. Carran, 289 S.W.3d 586, 588–89 (Ky. Ct. App. 2008); Bonney v. Stephens Mem'l Hosp., 17 A.3d 123, 128 (Me. 2011); Yath v. Fairview Clinics, N.P., 767 N.W.2d 34, 49–50 (Minn. Ct. App. 2009); Acosta v. Byrum, 638 S.E.2d 246, 252–54 (N.C. Ct. App. 2006); Sheldon v. Kettering Health Network, 40 N.E.3d 661, 670 (Ohio Ct. App. 2015); Sorensen v. Barbuto, 143 P.3d 295, 299 n.2 (Utah Ct. App. 2006); R.K. v. St. Mary's Med. Ctr., Inc., 735 S.E.2d 715, 722–24 (W. Va. 2012).

standard of care associated with state tort claims.[241] Nonetheless, it is clear that a growing number of states are finding covered entities liable for improper uses and disclosures of PHI. The court decisions from these states force covered entities to safeguard individuals' PHI and enhance public trust.[242]

IV. LESSONS LEARNED: RETHINKING HUMAN-SUBJECT PROTECTIONS

Despite the Final Rule's promulgation, this Note proposes a solution to address the same challenges HHS unsuccessfully attempted to remedy with the new regulation. In doing so, this solution incorporates lessons learned from both public comments received on the NPRM and the text of the Privacy Rule, offering a refined regulation that better balances the interests of human subjects and researchers. Section IV.A considers alternative forms of consent that promote autonomy and transparency while reducing administrative burdens. Section IV.B then establishes rights and remedies to protect human subjects' interests and identifiable information.

A. Rethinking Consent and Transparency

The Final Rule poses two different methods to obtain consent for secondary research use of identifiable private information: informed consent and broad consent. [243] These two alternatives unequally balance the interests of human subjects and researchers. Informed consent protects subject autonomy but, even with the Final Rule's streamlined informed consent documents, increases administrative burdens. Broad consent, on the other hand, allows data sharing but does not provide meaningful choice to research subjects. The NPRM comments indicate the need for efficient and cost-effective research,[244] which does not make authorization under the Privacy Rule viable. Accordingly, rather than choosing between informed and broad consent or an authorization, the Final Rule should require researchers to choose between dynamic or tiered consent.[245]

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241. *See Sheldon*, 40 N.E.3d at 670 ("The Ohio federal cases . . . stand for the undisputed proposition that Congress did not create a private, statutory right of action to enforce HIPAA's terms.").

242. *See supra* note 240 and accompanying text.

243. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7220 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

244. For this reason, authorization under the Privacy Rule is likely not a viable option because of its restrictive nature.

245. *See* Genetic Alliance Comment, *supra* note 120 (explaining benefits of dynamic consent).

Dynamic consent is a personalized, online platform that facilitates both the consent process and ongoing communication between researchers and human subjects.[246] This platform allows human subjects to express how they want information about them used, to change those choices, and to track and audit any changes.[247] Further, human subjects can choose "when and how they are contacted in cases in which [recontact] is needed for secondary research purposes."[248] Dynamic consent does not aim to replace human interaction; instead, the platform seeks to make the process straightforward, interactive, and ongoing.[249] Human subjects are treated as partners, rather than one-time contributors.[250]

Dynamic consent also benefits researchers. First, the technology streamlines recruitment and enables efficient recontact.[251] Recruitment costs in research are high, and "recruitment rates into publicly funded studies are relatively low."[252] Dynamic consent platforms can automatically select human subjects willing to be involved in research; platforms can also identify, approach, and recruit human subjects for new studies.[253] Further, when the scope of research changes or data are sought for secondary research, dynamic consent allows researchers to easily contact human subjects to make an additional informed

246. *Dynamic Consent: A Potential Solution*, *supra* note 182; *see* Hawys Williams et al., *Dynamic Consent: A Possible Solution to Improve Patient Confidence and Trust in How Electronic Patient Records Are Used in Medical Research*, JMIR MED. INFORMATICS, Jan.–Mar. 2015, at 184, 186 ("The implementation of Dynamic Consent through a convenient computer-based interface allows for the possibility of using videos, animation, and other formats to increase the communication to the patients, including the presentation of lay summaries of research results.").

247. Jane Kaye et al., *From Patients to Partners: Participant-Centric Initiatives in Biomedical Research*, 13 NATURE REVS. GENETICS 371, 373 (2012).

248. *Id.*

249. *See* Isabelle Budin-Ljøsne et al., *Genome Sequencing in Research Requires a New Approach to Consent*, 135 J. NOR. MED. ASS'N 2031, 2032 (2015) (explaining that dynamic consent promotes interest in participation and promotes discussion and reflection on research processes).

250. Biobanks in the United Kingdom provide an example of dynamic consent. The Ensuring Consent and Revocation ("EnCoRe") project is a web-based platform that allows human research subjects to have an "interactive relationship with the custodians of biobanks and the research community." ENCORE, http://www.hpl.hp.com/breweb/encoreproject/ (last visited Aug. 6, 2018) [https://perma.cc/N2MU-SQCN]. EnCoRe provides real-time feedback to human subjects on how data are used, and human subjects can provide or revoke consent for further studies. *Id.*

251. *See* Jane Kaye et al., *Dynamic Consent: A Patient Interface for Twenty-First Century Research Networks*, 23 EUR. J. HUM. GENETICS 141, 142 (2015) [hereinafter *Dynamic Consent*] ("Maintaining contact with participants helps researchers to deal with many of the ethical and legal problems that emerge from unforeseen circumstances. . . . Dynamic consent makes it easy to contact participants and to provide readily accessible information so that people can make their own informed decision.").

252. *Id.* at 144.

253. *See id.*

decision.[254] This platform makes recruitment and communication less costly, reducing paperwork and staff time.

Next, dynamic consent improves transparency and risk management at low cost and effort. By contrast, the Final Rule eliminates some continuing review of research in order to alleviate similar administrative burdens.[255] With dynamic consent, technology allows researchers to be continuously apprised of privacy risks human subjects are willing to take and which data may or may not be used.[256] In doing so, dynamic consent promotes and preserves public trust and accountability.

Despite its beneficial effects, dynamic consent might be problematic for human subjects of lower socioeconomic status given its reliance on technology. As such, tiered consent provides an alternative to protect human-subject autonomy. Tiered consent is a "consent model in which participants are given a set of options allowing them to select how they want to participate in the research."[257] Under this approach, human subjects might be asked to choose from a list of disease categories (e.g., cancer or mental illness) or research methodologies (e.g., genetic analysis or medical record review) at the time of initial consent.[258] Alternatively, human subjects might be asked to designate areas of research for which their data may not be used.

Tiered consent is considered by many to be a research best practice.[259] Arguably, however, this form of consent could become complicated and administratively burdensome. Still, tiered consent is no more onerous than informed consent and should be used as an alternative when dynamic consent is not feasible. Further, studies

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254. *See id.*

255. *See* Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7205 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

256. *Dynamic Consent*, *supra* note 251, at 144–45.

257. *The Informed Consent Resource*, NAT'L HUM. GENOME RES. INST., https://www.genome.gov/27559022/informed-consent-glossary/ (last visited June 21, 2018) [https://perma.cc/4S5R-MS9L].

258. Christian M. Simon et al., *Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models*, 13 GENETICS MED. 821, 825 (2011).

259. In 2003, the RAND Corporation examined existing human tissue resources and identified best practices for obtaining consent, among other research protocols. Elisa Eiseman et al., *Case Studies of Existing Human Tissue Repositories*, RAND CORP. (2003), https://www.rand.org/content/dam/rand/pubs/monographs/2004/RAND_MG120.pdf [https://perma.cc/4UJ3-XSYX]. After examining twelve different human tissue repositories, six of which incorporated tiered consent and one that partially incorporated tiered consent, the RAND Corporation recommended and identified tiered consent as a best practice (when informed consent is unavailable) to address privacy, ethical concerns, and consent issues. *Id.*

indicate human subjects prefer tiered consent over traditional consent processes.[260]

Dynamic consent and tiered consent allow human subjects greater choice and control over how information about them is used. In today's data-rich environment, research must be cost effective and protective, as indicated in the NPRM comments. As such, dynamic consent and tiered consent provide better options for human subjects and researchers.

B. Establishing Rights and Remedies

Human subjects must be afforded rights and remedies to protect their identifiable private information. The Final Rule declines to adopt much-needed privacy protections and instead continues to allow IRBs to review protection plans.[261] The Privacy Rule, like HIPAA generally, provides an existing framework that protects PHI better than the Final Rule protects identifiable private information. A revised Final Rule should adopt the HIPAA privacy standards without the requirement for authorization, which is in line with the comments received on the NPRM.

The Privacy Rule establishes the general right to authorize use or disclosure of PHI for research, the right to adequate notice of use and disclosure of PHI, and the right to an accounting of disclosures of PHI.[262] Many NPRM comments opposed HIPAA standards because these additional rights increase oversight, costs, and paper trails.[263] Accordingly, rather than human subjects authorizing identifiable private information use, human subjects should consent to research via dynamic or tiered consent, as discussed previously. Dynamic consent, specifically, can alleviate the costs and concerns connected with these forms.[264] The right to disclosure and accounting, however, must remain

260. In a focus-group session with patients from a genetic epilepsy study, researchers analyzed perceptions of traditional consent versus tiered consent. Amy L. McGuire et al., *DNA Data Sharing: Research Participants' Perspectives*, 10 GENETICS MED. 46, 49–51 (2008). Under traditional consent, the focus group chose between unrestricted data release or withdrawal, a "take it or leave it approach." *Id.* at 49. The focus group unanimously consented to unrestricted data release, "albeit with some reluctance." *Id.* at 50. Under a tiered consent approach, the focus group was given several options, including release to public access or release to a restricted database. *Id.* Only one participant agreed to unrestricted data access. *Id.* The remaining participants consented to release into a restricted database "in the interest of paranoia for the future." *Id.*

261. Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7202 (Jan. 19, 2017) (to be codified at 45 C.F.R. pt. 46).

262. HIPAA Privacy Rule, 45 C.F.R. §§ 164.508, 164.520, 164.528 (2017).

263. For a list of comments opposing the Privacy Rule, see *supra* note 135.

264. As explained previously, dynamic consent and technology can alleviate administrative burdens on researchers. *See supra* Section IV.A.

to promote trust and transparency. The disclosure and accounting provisions in the Privacy Rule should be replicated exactly in a revised Final Rule.

Further, unlike the Final Rule, the Privacy Rule provides options for corrective action. Under the Privacy Rule, OCR handles research complaints involving human subjects, and a revised Final Rule should follow identical procedures.[265] OCR review is proper and appropriate to protect human subjects because OCR already has the experience addressing research complaints under the Privacy Rule.[266] OCR review and investigations promote compliance and better protect human subjects' identifiable private information.

More importantly, the Privacy Rule's novel approach provides human subjects judicial relief when privacy violations occur. While a statutory private right of action is ideal to protect human subjects, recent common law developments under state tort doctrine provide an alternative antidote to informational harms.[267] As discussed, HIPAA does not provide a private right of action, yet state courts are increasingly finding that HIPAA may provide the standard of care in a negligence action against a covered entity for privacy violations.[268] By adopting the Privacy Rule, a revised Final Rule would provide human subjects, for the first time, the opportunity to establish a prima facie case of negligence for privacy violations.[269] Concurrently, in order for a revised Final Rule to achieve maximum efficacy, more courts need to recognize a de facto private right of action under HIPAA. Until a statutory private right of action appears, a de facto private right of action provides human subjects the opportunity to have their day in court.

CONCLUSION

Meaningful research thrives on large amounts of data. Having more data increases the likelihood of accurate results and accelerates discoveries. In the process of data collection, however, human subjects' interests must be considered.

Today's data-rich environment increasingly exposes human subjects to informational harms. The Final Rule, enacted to protect human subjects, prioritizes the interests of researchers over the

265. *See What to Expect*, *supra* note 228.

266. *See id.*

267. *See supra* note 241 and accompanying text.

268. *See supra* note 241 and accompanying text.

269. *See supra* note 231 (explaining the elements of a prima facie case of negligence).

interests of human subjects. The Final Rule's changes to human-subject protections—reducing IRB oversight, failing to adopt privacy standards, and approving broad consent for secondary research—do not favor human subjects. Rather, they principally alleviate researchers' administrative burdens and costs.

Success in research is contingent on trust. When trust fails, research comes to a halt. To uphold and foster trusting relationships, human subjects must be treated as partners in research. As such, the Final Rule must be transformed into a protective regulation that affords human subjects certain rights, remedies, and control over how information about them is used. Human subjects must be offered meaningful choices when consenting to studies. Further, human subjects must have rights and remedies throughout the entire research process in case privacy violations occur. Regulators and researchers need to revisit the official title of the Final Rule: Federal Policy for the Protection of *Human Subjects*.

*Ahsin Azim**

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