PRIM&R
PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH



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Roger Severino, JD, MA
Director, Office for Civil Rights
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue, SW
Washington, DC 20201

RE: RFI, RIN 0945-AA00 (83 *Federal Register* 64302)

Dear Mr. Severino:

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Department of Health and Human Services (HHS)'s "Request for Information on Modifying HIPAA Rules to Improve Coordinated Care" published in the *Federal Register* on December 14, 2018.

PRIM&R is a nonprofit organization dedicated to advancing the highest ethical standards in the conduct of research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community, including members and staff of human research protection programs and institutional review boards (IRBs), investigators, and their institutions. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise understand the central importance of ethics to the advancement of science.

As the Office for Civil Rights (OCR) evaluates how to modify the HIPAA Rules to reduce regulatory burdens, facilitate more efficient care coordination and case management, and "promote the transformation to value-based health care" while safeguarding patient privacy, we urge it to use this opportunity to conduct a parallel evaluation of the HIPAA Rules as they are applied to research. A combined reconsideration of HIPAA in the clinical and research settings would be particularly relevant today, as the lines between research and clinical care are increasingly blurred. Consider, for example, emerging "learning healthcare systems," which are predicated on continuously collecting clinical care information to evaluate the comparative efficacy

and safety of various standard health care interventions and, ultimately, to improve patient care.

This is also an opportunity for the OCR to consider how the HIPAA Rules could be improved to better support the research enterprise in general. The research community has long argued that the application of the HIPAA Rules to covered entities that are involved in human subjects research is confusing, awkward, and overly burdensome, and does not obviously provide additional privacy protections for individuals who take part in research, above and beyond those provided by the Common Rule.[1] The lack of harmonization between the HIPAA Rules and the Common Rule in several key areas related to the protection of subjects in human research causes confusion for research participants and burdens for research institutions. Specific issues include:

- Different definitions of identifiability between the two sets of regulations.
- Differences in the scope of what each regulation covers. To take two examples: (1) HIPAA only covers PHI held by covered entities, whereas the Common Rule covers all institutions receiving federal research funding; and (2) HIPAA covers data from people until 50 years after their death, while the Common Rule covers only living people.
- The requirement, for covered entities, to obtain both authorization and informed consent for research, in order to be in compliance with both sets of regulations.
- Different requirements regarding waivers of these types of permission.
- The fact that HIPAA has different requirements for sharing PHI within a covered entity versus with an external entity, adding complexity when the entity is also covered by the Common Rule.

We elaborate on a few of these points below.

Regarding the two types of permission, a research informed consent document includes among other criteria, information required by the Common Rule about protecting privacy and confidentiality, while a HIPAA authorization includes the HIPAA specific details. Although not identical, there is much overlap between the requirements for each. Whether an institution uses a merged authorization/informed consent form or two free-standing documents, the situation is confusing and redundant. Moreover, institutions face additional burden in having to seek and to track these two types of permission. HHS should develop an approach that could be accommodated by a single description of the privacy and confidentiality protections.

[1] The Secretary's Advisory Committee on Human Research Protections (SACHRP), *SACHRP Recommendations on the Interpretation and Application of Exemption §_.104(d)(4), the "HIPAA Exemption"* (2017), https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-december-12-2017/index.html. Institute of Medicine (US) Committee on Health Research and the Privacy of Health Information, *The HIPAA Privacy Rule* (2009), https://www.ncbi.nlm.nih.gov/books/NBK9573/.

In terms of identifiability, HIPAA stipulates 18 specific identifiers that, individually, qualify information as identifiable, whereas the Common Rule defines identifiability in looser terms, specifically, whether the identity of a subject can be "readily ascertained" by an investigator or associated with private information about that subject. Among other problems, this means that research data might qualify as properly de-identified according to one set of rules, but not the other. This again creates confusion and burden that does not add to the protection of subjects in research.

Given the length of time the two regulatory schemes have co-existed, it is disappointing that no full-scale effort has been undertaken to harmonize and align their requirements.

As PRIM&R has argued previously, HIPAA provides a poor model for protecting individual's privacy in the context of research.[2] It was not designed with research data or research activities in mind. Furthermore, not all research institutions are considered "covered entities" bound by HIPAA—for example, the National Institutes of Health is not considered a covered entity. Many academic institutions may be hybrid entities in which only some components of their activities are covered by HIPAA. And finally, HIPAA allows a covered entity to decide whether or not to cover research information. This means that the privacy "protections" supposedly afforded by HIPAA are not applied consistently to all research data.

Thank you again for the opportunity to comment. As the OCR considers modifications to HIPAA, we urge it to consult with the research oversight community about how the HIPAA Rules might better facilitate important research while appropriately protecting research subjects' privacy interests. My PRIM&R colleagues and I are available to discuss our comments further, should that be of interest. Please feel free to contact me at 617.303.1872 or ehurley@primr.org.

Respectfully submitted,

Elisa A. Hurley, PhD
Executive Director

cc: PRIM&R Public Policy Committee, PRIM&R Board of Directors

[2] Public Responsibility in Medicine and Research, *Comments on Advance Notice of Proposed Rulemaking on Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators* (2011), https://www.primr.org/WorkArea/DownloadAsset.aspx?id=945.