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PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

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Jerry Menikoff, MD, JD
Director, Office for Human Research Protections
US Department of Health and Human Services
1101 Wooton Parkway, Suite 200
Rockville, MD 20852

RE: Document ID number HHS-OPHS-2018-007 *Federal Policy for the Protection of Human Subjects: Proposed Six Month Delay of the General Compliance Date While Allowing the Use of Thee Burden-Reducing Provisions During the Delay Period* (83 *Federal Register* 17595)

Dear Dr. Menikoff:

Public Responsibility in Medicine and Research (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, in particular, members and staff of human research protection programs (HRPPs) and institutional review boards (IRBs). 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.

We appreciate the efforts of the federal agencies, led by the Department of Health and Human Service's Office for Human Research Protections, to modernize and revise the Federal Policy for the Protection of Human Subjects, or Common Rule. And we are pleased to have this opportunity to comment on the proposal to delay the general compliance date for the revised rule for an additional six months, to January 21, 2019, while allowing institutions to take advantage of three burden-reducing provisions during the delay period.

PRIM&R endorses the proposal, but **our support is predicated on an understanding that the delay will give the agencies time to produce much-needed guidance and make it available to the regulated community far enough in advance of the compliance**

date to be useful in guiding institutions' implementation plans, ideally at least three months in advance. A primary stated reason for the release of an interim final rule in January 2018 delaying the original compliance date six months was to allow the agencies time to publish guidance. We are pleased that in issuing this delay, the agencies heard concerns from the regulated community that there was insufficient guidance available to enable successful and effective implementation of and compliance with the rule by January 2018. However, to date, no guidance has been published. We urge the agencies to take advantage of the additional delay to issue guidance prior to the January 2019 compliance date, and in a timeframe that will allow institutions to make the required changes to their systems, processes, and procedures. We encourage the agencies to expedite the process by making use of existing resources, such as the recommendations already developed by the Secretary's Advisory Committee on Human Research Protections (SACHRP).

Because time between now and January is short, and based on our understanding of the regulated community's most urgent needs, we suggest the following four areas be prioritized for guidance:

1. The new requirement at §__.116(a)(5)(i) that informed consent begin with a "concise and focused presentation of key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research." Guidance is needed on what constitutes "key information" and on how that information can best be presented so that it is both concise and informative regarding the reasons one might or might not want to participate. In addition, guidance is needed regarding when "informed consent begins," since there can be many conversations that appropriately precede a formalized consent process for research.

2. New exemption category 3 at §__.104(d)(3)(i), involving "benign behavioral interventions." Specifically, the community needs examples, decision trees, or other tools to help with the determination of whether a human subjects research activity may qualify as a "benign behavioral intervention" and hence may be considered exempt under this category.

3. New exemption category 4 at §__.104(d)(3)(i), the "HIPAA Exemption," according to which research using identifiable private information may be exempt as long as that information or its collection is covered by HIPAA. This is the first time a reference to HIPAA privacy protections is referenced in the Common Rule. We thus agree with SACHRP that "the application of this new exemption… is complex and without sufficient guidance, research institutions, IRBs, and the general public may have difficulty

understanding the circumstances under which the HIPAA Exemption may and may not be relied upon as an exemption from Common Rule requirements."[1]

4. Limited IRB review. Four exemption categories (exemptions 2, 3, 7, and 8) make use of the new concept of "limited IRB review," and exemption categories 7 and 8, having to do with storage, maintenance, and secondary use of private identifiable information and identifiable biospecimens, require it. Though limited IRB review mostly involves ensuring adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, in some places, limited IRB review also involves review of how broad consent is obtained, documented, and followed. Since this is a new concept in the rule, guidance regarding options for operationalizing limited IRB review and how IRBs should understand what makes such a review "limited" is needed.

Finally, we do not believe that the agencies should prioritize the creation of guidance on broad consent, as we share the community's concerns that, among other things, that option will require mechanisms for tracking consent and refusals to consent that are logistically burdensome or even prohibitive for many institutions. As such, this provision is not likely to be used by most of the regulated community.

Thank you again for the opportunity to comment on this NPRM and provide input into this important process. Like many in the regulated community, we look forward to its completion. I and my PRIM&R colleagues are available to discuss PRIM&R's recommendations or provide additional information about how and why the creation of guidance prior to the compliance date is crucial for the regulated community to effectively implement the revised Common Rule, 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

[1] https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-b-december-12-2017/index.html