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**Ex Officio**

Elisa A. Hurley, PhD

Submitted electronically at <https://www.regulations.gov>

December 23, 2022

Robert M. Califf, MD  
Commissioner of Food and Drugs  
Food and Drug Administration  
19903 New Hampshire Avenue  
Silver Spring, MD 20993

RE: Docket No. FDA-2021-N-0286 for "Protection of Human Subjects and Institutional Review Boards."

Dear Dr. Califf,

Public Responsibility in Medicine and Research (PRIM&R) appreciates the opportunity to comment on the Food and Drug Administration (FDA)'s Proposed rule on "Protection of Human Subjects and Institutional Review Boards," published in the *Federal Register* on September 28, 2022.

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. Through educational programming, professional development opportunities, and public policy initiatives, PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science.

PRIM&R applauds the FDA for issuing the proposed rule to harmonize FDA regulations for institutional review boards (IRBs) and human subjects protections with the revised Common Rule. We believe that harmonization will indeed achieve its intended goal of streamlining the review of research and reducing regulatory burden, especially in cases where both sets of regulations apply.

Below are PRIM&R's responses to the questions listed in the *Federal Register* notice.

Q1 *Comment on whether FDA's proposed new basic element of informed consent at § 50.25(a)(9) would provide adequate notice to potential subjects regarding the possible future research use of their information and biospecimens or whether the Common Rule's provision at*

*45 CFR 46.116(b)(9) would better inform potential subjects about the possible future use of their information and biospecimens in research.*

PRIM&R understands that given the FDA mandate and the pace at which innovative medical products are being developed, adopting the revised Common Rule provisions for the basic element of informed consent at 45 CFR 46.116(b)(9) would be limiting and could likely be rendered obsolete sooner rather than later. However, PRIM&R disagrees with that rationale and believes that the open-ended nature of the proposed new basic element of informed consent at § 50.25(a)(9) will in fact prove unduly burdensome to the regulated community. Although the proposed language appears to provide more flexibility regarding what an investigator tells a potential subject or their legally authorized representative about possible future uses of identifiable private information and biospecimens, it does not provide enough guidance to be helpful in the drafting of adequate consent forms. More importantly, the provision ignores the basic fact that researchers may not know, in advance, how data generated by their study will be used in the future. Thus, requiring the inclusion of such information in the informed consent is not feasible. ***Therefore, PRIM&R recommends that FDA harmonize with the Common Rule's provision at §46.116(b)(9), and not introduce the new proposed regulatory language at 21 CFR 50.25(a)(9)***

Q2 *Comment on whether the research community anticipates challenges in implementing FDA's proposed new element and whether an alternative approach could lessen such challenges.*

***See response to Q1 above***

Q3 *Comment on whether FDA's current policy adequately addresses screening, recruiting, or determining eligibility for an FDA-regulated clinical investigation, or if including the revised Common Rule provision at 45 CFR 46.116(g) would be useful for FDA-regulated clinical investigations.*

Given that the intent of harmonization of FDA regulations with the revised Common Rule is to streamline the review of research and reduce regulatory burden especially in cases where both sets of regulations apply, it is essential to implement a standardized regulatory approach to activities preparatory to research. A common definition and approach will provide the regulated community with much need clarity and serve to enhance efficiency of the regulatory process. ***Therefore, PRIM&R recommends that FDA include the revised Common Rule provision at 45 CFR 46.116(g).***

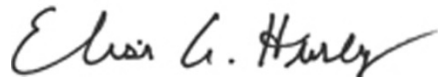
Q4 *Comment on whether this provision [at 45 CFR 46.117(c)(1)(i)] is relevant to FDA-regulated research and any examples of situations when it would be useful.*

PRIM&R believes that the Common Rule provision at 45 CFR 46.117(c)(1)(i) is indeed relevant to FDA-regulated research. For example, in clinical investigations of

FDA-regulated products for conditions that may be socially stigmatizing or that differentially affect minoritized populations (e.g., sexual minorities), any breach of confidentiality can have devastating effects on the research subjects. In such cases, even if the clinical intervention itself poses minimal risk to the subjects, but the potential harm ensuing from a breach of confidentiality is significant, a waiver of documentation of informed consent would increase protection of the rights and welfare of the research subject. ***Therefore, PRIM&R recommends that FDA adopt the Common Rule provision for waiver of documentation of informed consent at 45 CFR 46.117(c)(1)(i)***

Thank you again for the opportunity to comment on the proposed harmonized FDA regulations with the revised Common Rule. We hope our comments will be useful to the FDA in issuing a final rule. PRIM&R stands ready to provide any further assistance or input that might be of use. Please feel free to contact me at 617.303.1872 or [ehurley@primr.org](mailto:ehurley@primr.org).

Sincerely,

A handwritten signature in black ink that reads "Elisa A. Hurley". The signature is written in a cursive, flowing style.

Elisa A. Hurley, PhD  
Executive Director

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