

July 14, 2025

Department of Health and Human Service (DHHS)  
200 Independence Avenue SW  
Washington, DC 20201

Submitted Electronically

**RE: Response to Request for Public Comment, Document Identifier: 0990-0278-30D, Agency Information Collection Request. 30-Day Public Comment Request, Federalwide Assurance (FWA) Form (90 *Federal Register* 25058)**

To whom it may concern:

Public Responsibility in Medicine & Research (PRIM&R), is a non-profit organization dedicated to advancing the highest ethical standards in research. Since 1974, PRIM&R has served as a professional home and trusted thought leader for the research protections community. PRIM&R appreciates the opportunity to comment on the proposed changes and offers its responses to the four specific questions proposed by DHHS.

**Question**

*“With this revision, OHRP is seeking to remove information from the FWA form to adopt the changes for assurances at [45 CFR 46.103](#) of the 2018 Requirements and reduce burden on respondents.*

*(1) removing the Pre-2018 Common Rule requirement that institutions provide a statement of ethical principles;”*

**Comment:**

While clarity in ethical principles is key for institutions regardless of FWA status, the reduction to the amount of information required is indeed appropriate. Removal of this item is unlikely to affect protections.

**Question**

*“(2) removing the Pre-2018 Common Rule requirement that an institution designate one or more IRBs to review the research to which the FWA applies;”*

**Comment:**

IRB composition requirements and ethical expectations are clearly outlined in the Common Rule. Collection of designation of all specific IRBs is now an extraneous step and can improve application turnaround if removed.

**Question**

***“3) removing “check the box”, or the option for U.S. institutions to voluntarily apply the Common Rule, or the Common Rule and subparts B, C, and D of the HHS regulations at [45 CFR part 46](#), to all of an institution's nonexempt human subjects research regardless of the source of support;”***

**Comment:**

As an anticipated step since 2018, removing the “box” from the form will likely lead to less confusion from entities that were not familiar with the prior requirement. The change promotes and allows flexibility in review and reporting burden. Furthermore, entities that desire uniformity within their practices are not prohibited from *applying* the federal standards to all research, even if research is not *subject* to the federal requirements. This allows both situational and institutional choice for appropriate research protections. PRIM&R encourages this action and suggests continued guidance from OHRP on how institutions can operationalize this change.

**Question**

***“(4) eliminating the requirement for institutions outside the U.S. to provide procedural standards they apply for human subjects research when assuring compliance with the Terms of the Federalwide Assurance.”***

Institutions outside of the U.S. that commit to terms within the FWA are subject to the same standards as all domestic FWA – holding entities. The articulation of procedural standards does not necessarily result in additional protections for human subjects. Institutional accountability is still implied despite the removal of the proposed sections.

In conclusion, PRIM&R is encouraged by the movement toward reduction in administrative burden by the removal of items referenced in questions 1-4 above. The aforementioned FWA form sections may be duplicative for institutions already required to form operating procedures and resource the infrastructures that ensure IRB review of research with human subjects.

Any anticipated time savings and resource allocation must be repurposed and focused on measures that support research participant safety. This includes appropriate staffing and useful oversight to consistently guide IRBs, enhance trust, and continue to support ethical discoveries.

We thank HHS for the opportunity to comment.

Sincerely,



Ivy R. Tillman, EdD, CIP  
Executive Director  
Public Responsibility in Medicine and Research (PRIM&R)