



October 2, 2026

Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Submitted electronically via Regulations.gov

Re: Comment on the Proposed Rule, FDA-2026-N-2886, "Modification of Certain Terminology in Title 21; Reopening of the Comment Period."

To the Office of the Commissioner:

Public Responsibility in Medicine and Research (PRIM&R), which has more than 3,200 active members throughout the research enterprise, appreciates the opportunity to respond to the proposed rule, FDA-2026-N-2886, "Modification of Certain Terminology in Title 21."

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 ethics and oversight community. PRIM&R seeks to ensure that all stakeholders in the research enterprise appreciate the central importance of ethics to the advancement of science. Our perspective is informed by the experiences of professionals responsible for implementing federal research regulations across academic, healthcare, government, and independent research institutions.

The FDA explained the need for the proposed rule as follows: "to modify certain terminology in Title 21 of the Code of Federal Regulations (CFR) to comply with Executive Order (EO) 14168, 'Defending Women From Gender Ideology Extremism and Restoring Biological Truth to the Federal Government,' issued on January 20, 2025. Specifically, this proposed rule, if finalized, will remove the term 'gender' wherever it appears and either replace it with the term 'sex,' or delete reference to gender, as applicable, along with other editorial changes to improve readability."

PRIM&R represents institutional review board (IRB) professionals, researchers, research administrators, institutional officials, and others responsible for the ethical oversight of research. Our members interpret federal research protections across institutions nationwide. Their work depends on a regulatory system that is clear, consistent, and predictable.

The proposed rule amends many parts of Title 21; however, the primary focus of our response addresses § 56.107(a) and (b), which govern IRB composition. Changing the IRB composition requirements, as proposed by the FDA, would directly impact human research protections.

The IRB community, including IRB administrators and members, complies with the regulations set forth in Title 21 regarding IRB composition. In full, 21 CFR § 56.107 IRB Membership of Title 21 of the Code of Federal Regulations states, “Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects.”¹

Removing “gender” presents a substantive change to how institutions ensure IRB composition includes individuals with “varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution.”

Section 2(a) of the January 20, 2025, Executive Order states, “‘Sex’ shall refer to an individual’s immutable biological classification as either male or female. ‘Sex’ is not a synonym for and does not include the concept of ‘gender identity.’”² By the EO’s own definition, sex and gender are two distinct considerations, and the FDA should continue to recognize this distinction in its regulations.

Replacing “gender” with “sex” in § 56.107(a) and (b) narrows how institutions interpret appointments of IRB members, limiting the range of characteristics, perspectives, and experiences that are critical to thorough and effective IRB review.

The real, lived experiences of committee members help inform an IRB’s collective understanding of complex ethical considerations, such as privacy concerns, stigma, discrimination, and potential harms to research participants. These perspectives are necessary for all research and are particularly relevant when reviewing research involving populations that may face unique risks or vulnerabilities that require deeper protections. Gender, specifically, is a crucial consideration for IRB composition. It is a multidimensional construct that directly impacts individual and population-level health outcomes.

The proposed change should not inadvertently diminish institutions’ ability to consider these perspectives when establishing IRB membership and fulfilling their responsibilities to protect the rights and welfare of research subjects.

¹ <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-A/part-56/subpart-B/section-56.107>

² <https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/>

Further, a narrower range of perspectives represented in the review of research protocols could cause delays and increase costs, as IRBs will be required to seek external consultation to ensure complete and adequate review of research activities. This scenario will be especially problematic for research where gender is salient (reproductive and maternal health, conditions with gendered presentation or treatment, behavioral research, research involving gender-diverse populations).

We welcome the opportunity to provide additional information or work collaboratively with the FDA to foster rigorous research that benefits the American public. Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink that reads "Ivy Tillman". The script is cursive and fluid, with the first letters of each word being capitalized and prominent.

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