

We, the undersigned, are investigators participating in the NIH Health Care Systems Research Collaboratory, which conducts large pragmatic trials conducted in partnership with and embedded in health care systems. Many of the trials conducted in the Collaboratory are comparative effectiveness research that may use FDA regulated drugs and devices. We applaud the proposed rule to allow for a waiver or alteration of informed consent for clinical investigations posing no more than minimal risk to a human participant and including appropriate safeguards.

We agree about the broad benefits described in the proposed rule—healthcare advances, reduction in burden from harmonizing FDA’s regulations with the Common Rule, and reduced burden and costs for the IRB—and articulate some more specific benefits below.

1. The proposed rule may help enable a Learning Health System (LHS) in which clinicians are able to continually learn from data collected at the point of care to improve both individual care and public health (Committee on the Learning Health Care System in America and Institute of Medicine 2013). Waiving consent for minimal risk research allows for more research to be accomplished with less burden in pursuit of the goal of a LHS.

2. We agree with the proposed rule’s statement that it will facilitate the “investigators’ ability to conduct minimal risk clinical investigations that could contribute substantially to the development of products to diagnose or treat diseases or other conditions, without compromising subjects’ rights, safety, or welfare.” By allowing a waiver of consent for minimal risk research, patients can more readily be prospectively randomly assigned to different treatments that are thought to be in clinical equipoise in order to gather evidence on the comparative risks, burdens, and benefits of the interventions in real-world settings.

3. As noted in the proposed rule, FDA regulations requiring informed consent for investigational use of drugs were developed in 1962, and the 21st Century Cures Act of 2016 encourages a more modern consideration of how data can be used in a clinical setting. Taking this one step further, the modern technical sector has been using data to advance knowledge and understanding for decades; and yet, in the clinical realm, the evidence regarding the risks, burdens and benefits of drugs and devices remains inadequate (Tricoci et al. 2009). Consequently, clinicians must base some of their treatment decisions on inferior and imprecise information. Updating rules to ease certain regulations around informed consent will result in more and better data on which to base clinical treatment decisions.

Thank you for the opportunity to comment on the proposed rule.

Sincerely,
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