



November 14, 2023

To all SMART IRB Participating Institutions and Stakeholders:

Over the past several years, SMART IRB leadership has been working with the SMART IRB Harmonization Steering Committee, the National Center for Advancing Translational Sciences (NCATS) and other federal agency representatives, and members of the SMART IRB community to discuss possible changes to the current SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement.

I am writing now to share with you the culmination of these efforts: a proposed (and renamed) [SMART IRB Reliance Agreement Version 3.0](#) for your review and comment.

SMART IRB Reliance Agreement Version 3.0 is a significant amendment of the current agreement that is intended to (1) address feedback on the agreement collected from current and potential Participating Institutions over the past several years; (2) fully reflect the changes to IRB review requirements implemented in the 2018 Common Rule; and (3) allow additional federal agencies to participate in the agreement.

All current Participating Institutions and stakeholders have the opportunity to comment on SMART IRB Reliance Agreement Version 3.0. The deadline to provide comments is **February 15, 2024**.

A final version of SMART IRB Reliance Agreement Version 3.0 will subsequently be issued for execution (joinder). All current Participating Institutions will need to execute (join) the final SMART IRB Reliance Agreement Version 3.0 in order to continue participation. Therefore, it is critical that your institution review Version 3.0. We are particularly interested in elements that are unclear and any terms that would prevent your institution from participating or continuing to participate.

In order to facilitate your review of SMART IRB Reliance Agreement Version 3.0 and to provide further detail about the comment and transition process, SMART IRB leadership has prepared an [executive summary](#) of Version 3.0's key changes to the current agreement, a [redline](#) that shows the differences between Version 3.0 and the current agreement, a set of [FAQs](#) on the comment and transition periods, and a [comment form](#). Please share these documents, along with Version 3.0 itself, within your institution and with your legal counsel as

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appropriate and submit your comments via the [SMART IRB Agreement page](#) on the SMART IRB website on or before the deadline of **February 15, 2024**.

Please direct questions about SMART IRB Reliance Agreement Version 3.0 or about the comment and transition process to [the SMART ambassador for your region or to an ambassador at large](#), or contact help@smartirb.org. In addition, please ensure that your institutional Point(s) of Contact and their contact information as listed on the [Participating Institutions page](#) is current (please email help@smartirb.org).

Thank you for your attention to this announcement. On behalf of SMART IRB leadership, we look forward to your feedback, and we look forward to working with you.

Barbara E. Bierer, MD

Chairperson,
SMART IRB Executive Coordinating Committee