

November 13, 2024

# To all SMART IRB Participating Institutions and Stakeholders:

# On behalf of SMART IRB leadership, I am pleased to provide an update on the proposed SMART IRB Reliance Agreement Version 3.0 that we shared for public comment last fall.

# During the comment period (November 15, 2023 to February 15, 2024), we received 250 unique comments from 54 different institutions. 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, we have considered all comments and have made a number of substantive changes to the draft agreement with the goal to enable more parties to join.

# As a result of those efforts, I share with you now a [**revised SMART IRB Reliance Agreement Version 3.0**](https://smartirb.org/assets/files/SMARTIRBAGREEMENTv3.0_DRAFT_FOR_2ndCOMMENT.docx) and ask you to submit any final comments via the [SMART IRB Agreement page](https://smartirb.org/agreement/) on the SMART IRB website by December 13, 2024. In particular, we are interested in comments on the changes we have made from the previous draft of Version 3.0, with a focus on any such changes that are unclear or that would prevent your institution from participating or continuing to participate in the agreement.

# In order to facilitate your review, we have prepared a [**summary**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_SUMMARYOFCHANGES.docx) of the key changes we made to Version 3.0 based on the public comments, [a [**redline**](https://smartirb.org/assets/files/SMARTIRBAGREEMENTv3.0_DRAFT_FOR_2ndCOMMENT_REDLINED.docx) that shows the differences between the revised Version 3.0 and the previous draft of Version 3.0,] a set of [**FAQs**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_FAQS.docx) responding to questions and issues raised in the public comments (including questions about the plan for transitioning current Participating Institutions from Versions 1.0/2.0 to Version 3.0), and a [**comment form**](https://hms.az1.qualtrics.com/jfe/form/SV_a2GdNSw7iDh1Ejk). As previously, please share these documents, along with the revised Version 3.0 itself, within your institution and with your legal counsel as appropriate and submit your comments via the [**SMART IRB Agreement page**](https://smartirb.org/agreement/) on the SMART IRB website on or before the deadline noted above. As the transition plan for current Participating Institutions has changed, please pay particular attention to the information within the [**FAQs**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_FAQS.docx) on that plan.

# If you have any questions, please direct them to [**the SMART ambassador for your region or to an ambassador at large**,](https://smartirb.org/ambassadors/) or contact [**help@smartirb.org**.](mailto:help@smartirb.org)

# At the close of this second comment period, we will consider any comments received, discuss with federal agency representatives any impact of the public comments on issues previously negotiated with those agencies, and make any additional warranted changes. We will then issue the final SMART IRB Reliance Agreement Version 3.0 for execution (joinder).

# Once issued, Version 3.0 will be the only version of the agreement open for **new** institutions to join. In certain – but not all – instances, detailed further in the [**FAQs**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_FAQS.docx) linked above, **current** Participating Institutions will need to join Version 3.0 as well. However, Versions 2.0 and 1.0 will remain active for some institutions. *Note that this is a change from the plan communicated previously, based on significant comments we received from the community about the transition to Version 3.0.* We will provide additional guidance to assist with the transition when we issue Version 3.0 for execution.

# We deeply appreciate your commitment and engagement with respect to SMART IRB and the agreement revision process to date, and we look forward to your further feedback.

Barbara E. Bierer, MD

Chairperson,

SMART IRB Executive Coordinating Committee