

February 25, 2025

To all SMART IRB Participating Institutions and Stakeholders:

## On behalf of SMART IRB leadership, I am delighted to share the final **Version 3.0 of the SMART IRB Reliance Agreement**, which has been posted for your review on the [**SMART IRB Agreement page**](https://smartirb.org/agreement/) of our website. We expect Version 3.0 will be available for joinder on March 17, 2025.

## As you are aware, Version 3.0 is the culmination of several years of effort and engagement on the part of the SMART IRB team, the SMART IRB Harmonization Steering Committee, the National Center for Advancing Translational Sciences (NCATS) and other federal agency representatives, and many other members of the SMART IRB community. The final Version 3.0 reflects feedback from two rounds of public comments and countless contributions from every corner of our community, for which we are truly grateful. We believe Version 3.0 will ensure that our Agreement is fully consistent with current regulations and reliance practices, and enable more federal agencies and other parties to join.

## To support review and joinder of Version 3.0, we have prepared both a **high-level** and a **detailed summary** of the differences between Version 3.0 and Versions 1.0/2.0. We have also prepared a **redline** comparing Version 3.0 to Version 2.0. Finally, we have created a **list of operational differences** between Version 3.0 and Versions 1.0/2.0 to assist current Participating Institutions who may be subject to both Version 3.0 and Versions 1.0/2.0 with respect to different reliance requests or different reliance partners in understanding how their day-to-day, on-the-ground responsibilities differ between the applicable versions. To facilitate your review, we have packaged these materials together in a single ZIP file.

## To that end, ***current*** Participating Institutions should pay careful attention to the **transition plan** for Version 3.0 to ensure they are aware of which reliance requests and relationships may remain under Version 1.0/2.0 and which will require joining Version 3.0. Note that Version 3.0 will be the only version of the Agreement open for ***new*** institutions to join. The transition plan also contains information for current Participating Institutions about shifting to the new optional SMART IRB Indemnification Addendum.

## We will also be updating and adding many other [**resources**](https://smartirb.org/resources/) to accompany Version 3.0, including the SMART IRB Standard Operating Procedures, the Letter of Acknowledgment templates, the Implementation Checklist and various other checklists. We will communicate further once these are all available. Please take a look and let us know if there are other resources you would like to see.

## We hope you will share Version 3.0 and all of these supporting materials within your institution and with your legal counsel as appropriate in preparation to join Version 3.0 in the near future.

## 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)

## As always, we deeply appreciate your commitment and engagement with respect to SMART IRB and the SMART IRB Reliance Agreement, and we look forward to welcoming new members to our SMART IRB community.

### Barbara E. Bierer, MD

Chairperson,

SMART IRB Executive Coordinating Committee