



SMART IRB

Master Common Reciprocal Institutional Review Board Authorization Agreement Version 2.0 NIH Final Revisions

Introduction

The SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (termed the SMART IRB Agreement or the Agreement) was launched in 2016 after iterative development and extensive collaboration with government agencies, academic medical centers (including all Clinical and Translational Science (CTSA) hubs and many of their affiliates), and industry partners. To date, the SMART IRB Agreement has almost 800 signatories, and the SMART IRB platform provides a robust online reliance system (ORS) to support reliance requests, numerous resources to train and educate the regulatory and investigator community, including a publicly-available learning center, and a highly functional harmonization steering committee (HSC) facilitating the alignment of policies and processes related to single IRB review.

Over the past year, SMART IRB leadership and representatives from the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) have engaged in discussions regarding revisions to the SMART IRB Agreement required to enable NIH to sign the Agreement and allow the NIH Intramural Research Program to take advantage of the efficiencies provided by the SMART IRB platform. NIH proposed revisions to the SMART IRB Agreement in four areas: **liability coverage, conflicts of interest, congruence review of grants and contracts with applications to the IRB, and non-interference with requirements of law**. In accordance with the terms of the Agreement, all Participating Institutions were provided the opportunity to review and comment on the proposed revisions (termed SMART IRB Agreement Version 2.0 or SMART IRB Agreement v2.0) that were posted on April 2, 2020; comments were received through June 8, 2020. During this time, feedback was also welcomed from prospective signatory institutions. Forty respondents commented on the proposed revisions. The majority of respondents indicated that their institution conducts collaborative research with NIH intramural researchers.

Final Revisions

NCATS and SMART IRB leadership have reviewed the community's feedback and explored multiple options for addressing the comments received, particularly the comments on the NIH proposed revisions related to conflict of interest. The final SMART IRB Agreement v2.0 reflects a few modifications and clarifications from the revisions as initially proposed, including, importantly, a provision allowing Research to be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to a federal agency if a Reviewing IRB determines that it cannot rely upon the conflict of interest assurances provided by the agency. Because NIH has indicated that it has no authority to deviate under applicable laws, regulations, and agency policies, more substantial modifications to the proposed revisions were precluded.

By way of high-level summary, the final SMART IRB Agreement v2.0 adopts or modifies the NIH



proposed revisions as follows:

- **Insurance (Section 4.10):** The final SMART IRB Agreement v2.0 retains the proposed revision to exempt Relying Institutions that are federal agencies from the requirement to maintain liability coverage for their activities under the Agreement.

- **Conflicts of Interest (Sections 5.8 and 6.6):**
 - The final SMART IRB Agreement v2.0 retains the proposed revision that Relying Institutions that are federal agencies will provide the Reviewing IRB with assurances that the agency has completed the conflict of interest analyses required under applicable federal laws and policies and that the participation of agency Research Personnel is permissible and consistent with federal law. No specific disclosures of financial interests or information about whether or how the agency has managed any conflicts of interest will be provided to the Reviewing IRB.
 - The final SMART IRB Agreement v2.0 also retains the proposed revision to remove reference to the authority of a Reviewing IRB to impose additional more stringent conflict of interest prohibitions or management plans with respect to Relying Institutions that are federal agencies.
 - However, if a Reviewing IRB cannot rely upon the assurances provided by a Relying Institution that is a federal agency, the final SMART IRB Agreement v2.0 allows the Research to be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that federal Relying Institution. This is a change from the initial proposal, which would have limited the ability for Research to be withdrawn from Ceded Review due to differences in approach to conflict of interest to non-federal Relying Institutions.

- **Congruence review (Section 5.15):**
 - The final SMART IRB Agreement v2.0 restores Section 5.15 providing for the Reviewing IRB to review the congruence of grant applications and contract proposals for human subjects research with the Research submitted for IRB review and approval when such congruence review is required by applicable law or regulation or by the funding agency or sponsor. This is a change from the initial proposal, which would have deleted Section 5.15.
 - The final SMART IRB Agreement v2.0 also slightly revises Section 5.15 to reflect that congruence review may be required by laws/regulations other than the Common Rule (such as state laws) or by the funding agency or sponsor.
 - The final SMART IRB Agreement v2.0 also adds additional language stating that U.S. federal agencies when serving as the Reviewing IRB will not perform a grant congruence review and that the responsibility for that review will remain with the Relying Institution.

- **Non-interference with requirements of law (Section 8.10):**



- The final SMART IRB Agreement v2.0 retains and clarifies the proposed new Section 8.10, which states that the Agreement does not require Participating Institutions to take any actions that would be in violation of applicable law, regulation, or other federal or state requirements (such as agency funding terms and policies).
- The final SMART IRB Agreement v2.0 also adds to Section 8.10 an obligation for a Participating Institution to notify other affected Participating Institutions if it determines that compliance with the Agreement would cause it to be in violation of one of these other requirements. Section 8.10 also now provides for withdrawal of the Research from Ceded Review if a mutually agreeable alternative approach to address the Agreement provision at issue cannot be worked out.

Additional information about and explanations for the provisions in the final SMART IRB Agreement v2.0 are available in the [SMART IRB Agreement Version 2.0 FAQs](#) and in the [FAQ on the Conflict of Interest Policies of the NIH Intramural Research Program for SMART IRB](#).

Joining SMART IRB Agreement v2.0

SMART IRB Agreement v2.0 will be posted to the SMART IRB website and enabled for joining as of October 1, 2020.

New institutions wishing to join SMART IRB will sign SMART IRB Agreement v2.0.

Any current Participating Institution that will serve as a Reviewing IRB for an NIH Institute or for which an NIH Institute will serve as the Reviewing IRB will need to sign SMART IRB Agreement v2.0.

Future Versions of the SMART IRB Agreement

In keeping with the approach to the original agreement development, SMART IRB leadership is collecting additional feedback on the Agreement from the research community, including representatives from Participating Institutions, other government agencies, and additional stakeholders. A number of issues, such as indemnification, clarification of HIPAA terms, and updates for the Revised Common Rule will be addressed in the next iteration of the SMART IRB Agreement (Version 3.0), which will be made available for review and public comment.

Questions

We greatly appreciate all who took the time to provide feedback on SMART IRB Agreement v2.0. Your opinion matters and is crucial to keeping this treaty style agreement between institutions strong and current.

SMART IRB is here to support you. Please reach out to your Ambassadors and/or the Help Desk with any questions.