



SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement Version 2.0 NIH Proposed Revisions

Introduction:

The SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (termed the SMART IRB 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 over 700 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 Agreement to enable NIH to sign on to the SMART IRB Agreement. The proposed revisions reflected in SMART IRB Agreement version 2.0 (SMART IRB Agreement v2.0) have been proposed by NIH. In accordance with Section 8.4 of the current SMART IRB Agreement, these proposed changes are now being provided for review and comment to all current and prospective signatory institutions.

Proposed NIH Revisions:

The proposed SMART IRB Agreement v2.0 revises the following sections of the agreement:

Responsibilities of the Participating Institution(s)

Section 4.10, Insurance: Adds a footnote to specify that statutory requirements for Participating Institutions that are Federal agencies apply to insurance coverage for activities under the SMART IRB Agreement. The current SMART IRB Agreement applies the requirement to maintain coverage to all Participating Institutions but allows those that are government agencies to cite self-insurance mechanisms and/or laws limiting governmental liability in lieu of providing documentation of insurance coverage. The proposed change clarifies that NIH must follow Federal statutory requirements for determinations of liability coverage and therefore, NIH cannot assure that all people affiliated with NIH and conducting research involving human subjects under the NIH Federalwide Assurance will be included under NIH's federal liability coverage.

Responsibilities of the Reviewing IRB(s) and Reviewing IRB Institution(s)

Section 5.8, Conflicts of Interest: Reflecting parallel changes to Section 6.6 (see below), creates terms for IRB consideration of conflicts of interest for Relying Institutions that are Federal agencies are required to comply with Federal statutory and regulatory requirements. Specifically:

- Specifies that Relying Institutions that are Federal agencies would provide the Reviewing IRB with *assurances* that they have completed conflict of interest reviews



under existing relevant policies and federal laws. Additional information provided by NIH about its conflict of interest processes is included below.

Section 5.15, Congruence of Federal Grant Applications/Contract Proposals: Deletes this section because the revised Common Rule no longer requires this congruence review.

Responsibilities of the Relying Institution(s)

Section 6.6, Conflicts of Interest: As described in connection with Section 5.8:

- The assurances would indicate that participation of agency Research Personnel is permissible and consistent with relevant policies and Federal statutory requirements. Consistent with Federal law, no specific disclosures of conflicts of interest or information about how the agency has managed any conflicts can be made available.
- Removes references to a Reviewing IRB's authority to impose additional more stringent prohibitions or management plans with respect to Relying Institutions that are Federal agencies.
- Also specifies that the ability to withdraw research from ceded review due to the inability of the Reviewing IRB and Relying Institution to reach a mutual agreement regarding a management plan applies only to non-federal Relying Institutions

Additional information about the NIH Intramural Research Program's conflict of interest policies processes can be found in the document titled, "[FAQ on the Conflict of Interest Policies of the NIH Intramural Research Program for SMART IRB.](#)"

Miscellaneous

Section 8.10, No Violation of Law: Adds a new section stating that "Nothing in this Agreement will be construed to require a Participating Institution to take any action in violation of its legal obligations or responsibilities."

Comment and Revision Process Timeline:

On April 1, 2020, SMART IRB Agreement v2.0 will be posted for public comment on the [SMART IRB website](#) for a two-month period. SMART IRB leadership will work with legal counsel to incorporate appropriate edits based on comments received. Should further feedback be necessary, the proposed further edits to SMART IRB Agreement v2.0 will be reposted for an additional comment period of at least 30 days. Upon completion of this process, the SMART IRB Agreement v2.0 will be posted to the SMART IRB website and enabled for joining. Current resources in the SMART IRB Learning Center will be updated and additional resources relating to potential revisions will be added.

From that point forward, new institutions wishing to join the SMART IRB will sign SMART IRB Agreement v2.0. After a date to be determined, NIH requests that all signatory institutions sign the SMART IRB Agreement v2.0. The original SMART IRB Agreement, versions 1.0 (which includes version 1.1-1.2) will no longer be available.



Future Versions of the SMART IRB Agreement

In keeping with the approach to the original agreement development, SMART IRB leadership is collecting additional feedback from the research community, including representatives from Participating Institutions, other government agencies, and additional stakeholders on the current SMART IRB Agreement. 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

Thank you for taking the time to provide feedback. 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.