Purpose: This document is intended to help Participating Institutions identify and understand the differences across the versions of the SMART IRB Agreement and Joinder Agreement; note that purely technical fixes, for example to address typographical errors, are not tracked in this document

The SMART IRB Agreement and Joinder Agreement are periodically reviewed and may be amended from time to time in accordance with the terms of the SMART IRB Agreement (section 8.4 Amendment), and as described in the SMART IRB FAQs ("Amendments to the SMART IRB Agreement").

Minor changes such as to aid clarity may be made as needed by the SMART IRB Executive Committee. Participating Institutions will be notified and provided opportunity to comment when any material changes are under consideration.

Not all amendments will require re-execution of Joinder Agreements by Participating Institutions. It will be determined, on an amendment-by-amendment basis, whether Participating Institutions must re-execute the Joinder Agreement. When re-execution is not required, the amendment will go into effect on its specified effective date without further action.

SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement (SMART IRB Agreement)

The current version of the SMART IRB Agreement is always available for download at SMARTIRB.org.

V1.0 Sample of the Agreement, originally posted by National Center for Advancing Translational Science (NCATS) to https://ncats.nih.gov/expertise/clinical/smartirb for reference in advance of sign-on.

V1.1 September 05, 2016. The original version of the SMART IRB Agreement first available for institution sign-on via the SMART IRB Joinder platform.

V1.2 October 17, 2016. Non-material changes:

- Added SMART IRB logo to the header.
- Added "National Institutes of Health" after NCATS in the 2nd paragraph: "Developed under an award from the National Center for Advancing Translational Sciences ("NCATS"), the National Institutes of Health (NIH), the Agreement sets forth the respective authorities, roles, and responsibilities of the parties when a Ceded Review (defined in Exhibit A) is determined to be acceptable by Participating Institutions in accordance with the process set forth herein."
- Added a footer that reads: "ANY ATTEMPTED REVISION(S)/MODIFICATION(S) TO THIS AGREEMENT BY A PARTICIPATING INSTITUTION WILL BE NULL AND VOID, AND UNENFORCEABLE."

V2.0 CURRENT VERSION October 1, 2020. Material changes:

The revisions reflected in SMART IRB Agreement v2.0 were required to enable the National Institutes of Health (NIH) to sign the Agreement. A summary of the changes is outlined below; additional detail may be found in the SMART IRB Agreement Version 2.0 Cover Memo and FAQs.

- **Insurance (Section 4.10)**: Exempts Relying Institutions that are federal agencies from the requirement to maintain liability coverage for their activities under the Agreement.

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- **Conflicts of Interest (Sections 5.8 and 6.6)**:
    - 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.
    - Removes 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.

- **Congruence review (Section 5.15)**:
    - Provides 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.
    - 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 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 new Section 8.10 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 includes 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 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.

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SMART IRB Joinder Agreement

For an institution to join the SMART IRB Agreement, a representative from the institution uses the SMART IRB Joinder platform to generate a pre-filled, institution-specific Joinder Agreement. To date, changes to the Joinder Agreement have predominately been made to align the Joinder Agreement document and the online Joinder process. Note: a sample of the SMART IRB Joinder Agreement (clearly marked SAMPLE) is provided at the end of the SMART IRB Agreement when that document is downloaded from the SMART IRB website (see above); this sample document will match the current Joinder Agreement in version # and content.

V1.0 Sample Joinder Agreement, originally posted by NCATS for reference in advance of sign-on; available at https://ncats.nih.gov/expertise/clinical/smartirb.

V1.1 September 05, 2016. The original version of the SMART IRB Joinder Agreement first available for institution sign-on via the SMART IRB Joinder platform.

V1.2 September 20, 2016. Non-material change:

- Removed the checkbox under the following statement at the end of the document: "I understand and affirm that Participating Institutions are strongly encouraged to use and follow the SMART IRB Standard Operating Procedures ("SMART IRB SOPs") for research covered under the Agreement, and that if institutions do not use the SMART IRB SOPs, they must communicate to each other and the Research Personnel the policies and procedures that will apply to the ceded Research." We determined that an institution official/signatory sufficiently signals agreement to the terms of the Joinder Agreement by signing the document.

V1.3 October 17, 2016. Non-material changes:

- Added the SMART IRB logo to the header.
- Added the new footer language: "ANY ATTEMPTED REVISION(S)/MODIFICATION(S) TO THIS AGREEMENT BY A PARTICIPATING INSTITUTION WILL BE NULL AND VOID, AND UNENFORCEABLE." to align with the SMART IRB Agreement (see above).
- Updated the "Notices" section to remove the "free text" fields and accommodate auto-fill from the Joinder platform "Institution Registration," allowing this information to be entered during the registration process and pre-populated in the Joinder Agreement.

V1.4 November 23, 2016. Non-material changes:

- Updated the Point of Contact (POC) section/language to clarify and more closely align with the language and terms of the SMART IRB Agreement: that one Point of Contact (POC) is required, and that Institutions may include an Alternate POC (optional).
    - ORIGINAL LANGUAGE:

      Point(s) of Contact. Each institution must identify and establish at least one individual who will serve as the contact person responsible for communicating on behalf of the institution with respect to matters concerning the initial and ongoing implementation of this Agreement.

      Alternate Point(s) of Contact (POC):

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The Alternate POC is the person who can make or facilitate determinations on behalf of the institution regarding IRB reliance requests and provide local context information to a Reviewing IRB.

- NEW LANGUAGE:
  Point(s) of Contact: Each institution must identify and establish at least one individual who will serve as a Point of Contact (POC).

  Point of Contact (POC): The POC is an individual responsible for day-to-day implementation of this Agreement at the institution (for example, making determinations on behalf of the institution regarding requests for Ceded Review or providing local context information to a Reviewing IRB). The POC will be listed on the SMART IRB website.

  Alternate Point of Contact (POC) (optional):
  An institution may provide an Alternate POC who can be contacted if the POC is not available or to whom the POC may delegate certain functions. The Alternate POC will be listed on the SMART IRB website.

- Removed the "Additional POCs" free text fields in the document, as all POC information for the Joinder Agreement is now entered in the Joinder platform during the registration process.
- Added to the "Notices" language, to provide an example of the type of notice that would be provided to the individual(s) listed.
  - ORIGINAL LANGUAGE:

    Notices: All written notices and other communications required under the Agreement from any other Participating Institution to the undersigned institution may be made in hard copy or electronic form and shall be delivered to the following address(es):
  - NEW LANGUAGE:

    Notices: All written notices and other communications required under the Agreement from any other Participating Institution to the undersigned institution (e.g., regarding termination of participation) may be made in hard copy or electronic form and shall be delivered to the following address(es):

V1.5 December 8, 2016. Non-material change:

- Slight update to the "Notices" language, to align with the language in "Institution Registration" section of the Joinder platform, and provide additional guidance regarding appropriate individuals/roles to fulfill this function. The example information provided in V1.4 was shifted to a tool tip in the Joinder platform.

  ORIGINAL LANGUAGE:

  Notices: All written notices and other communications required under the Agreement from any other Participating Institution to the undersigned institution (e.g., regarding termination of participation) may be made in hard copy or electronic form and shall be delivered to the following address(es):

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- NEW LANGUAGE:

  Notices: All written notices and other communications required under the Agreement may be made in hard copy or electronic form and shall be delivered to the following address(es). This may be the IO, a POC, legal counsel, or other HRPP personnel.

V2.0 CURRENT VERSION October 1, 2020. Material change**:**

- Reflects an update to the Joinder Agreement version number and date to correspond with SMART IRB Agreement v2.0. Institutions joining SMART IRB Agreement v2.0 must sign and execute Joinder Agreement v2.0.

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.