



**NIH Proposed Revisions to the SMART IRB Agreement:
Draft SMART IRB Agreement v2.0
Frequently Asked Questions**

1. Q. Why are the revisions to the SMART IRB Agreement reflected in the draft SMART IRB Agreement v2.0 being proposed?

- A. Representatives from the National Institutes of Health (NIH) National Center for Advancing Translational Sciences (NCATS) have requested revisions to the SMART IRB Agreement to enable NIH to become a signatory to the Agreement. Version 2.0 includes language requested by NIH related to: insurance, conflicts of interest, congruence review of grants and contracts with applications to the IRB, and non-interference with legal obligations.

2. Q. How will the changes proposed in the draft SMART IRB Agreement v2.0 allow NIH to collaborate with extramural organizations?

- A. Federal Agencies, including the research arm of NIH—the NIH Intramural Research Program—must follow laws that apply specifically to federal agencies.

The SMART IRB Agreement v1.0 was not written to reflect these statutory requirements. The specific requirements relate to indemnification coverage and conflict of interest disclosure.

The draft SMART IRB Agreement v2.0 changes select provisions in the SMART IRB Agreement v1.0 to be compliant with statutory requirements that apply to federal agencies and will allow the NIH Intramural Research Program to take advantage of the efficiencies provided by the SMART IRB platform.

Insurance:

3. Q. How does the proposed addition of the footnote in Section 4.10, Insurance affect the Agreement's insurance provision?

- A. The proposed footnote states that Federal agencies do not—and will not be required to—maintain insurance coverage for their activities under the SMART IRB Agreement. NIH is requesting this change because it follows Federal statutory requirements for determinations of liability coverage and thus cannot assure that all people affiliated with NIH and conducting research involving human subjects under the NIH Federalwide Assurance (FWA) will be included under NIH's federal liability coverage.



Conflicts of interest:

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.](#)"

4. Q. Under the proposed changes, will a Reviewing IRB be able to impose additional, more stringent prohibitions or management plans related to conflicts of interest of Federal agency research personnel?

A. The proposed changes to the conflict of interest sections of the SMART IRB Agreement would mean that a Reviewing IRB may *not* impose additional, more stringent prohibitions or management plans with respect to research personnel of Relying Institutions that are Federal agencies.

5. Q. In the current SMART IRB Agreement, if the Reviewing IRB and Relying Institution cannot agree on an approach to a conflict of interest, the Research can be withdrawn from Ceded Review without IRB approval or disapproval with respect to the Relying Institution. Will such withdrawal be permissible under the proposed changes where the Relying Institution is a Federal agency?

A. No. If the Reviewing IRB has agreed to be the IRB of record, there are no provisions for withdrawal of Research from Ceded Review due to disagreement on approach to conflict of interest if the Relying Institution is a Federal agency. Therefore, a Reviewing IRB must accept the Federal agency's assurance. Note that the Agreement does not require any IRB to serve as a Reviewing IRB for a Federal agency (or otherwise).

6. Q. How do the proposed changes in conflict of interest provisions affect institutions that are not collaborating with a Federal agency?

A. The changes would not affect the relationship between Reviewing IRBs and Relying Institution that are not Federal agencies.

Congruence of Federal Grant Applications/Contract Proposals:

7. Q. Why will Section 5.15, Congruence of Federal Grant Applications/Contract Proposals be removed from the SMART IRB Agreement?

A. NIH is requesting that this section be deleted because the revised Common Rule no longer requires these congruency reviews. Note that this is not a substantial change from the current version of the SMART IRB Agreement in that a congruence review is only required when mandated by federal regulations or oversight agencies. However, deleting the section means that if other federal regulations or if oversight agencies require congruency reviews, those reviews would no longer be addressed in the SMART IRB Agreement; the affected Participating Institutions would have to make arrangements among themselves regarding how such reviews will be performed.



Non-interference with Legal Obligations:

8. Q. What change is being proposed through the new Miscellaneous, Section 8.10, No Violation of Law section of the SMART IRB Agreement?

- A. NIH is requesting this new section to explicitly state 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.”

Reporting:

9. Q. How will reporting of noncompliance and unanticipated problems be handled by NIH?

- A. NIH indicates that if the NIH is the reviewing IRB, it will report noncompliance or unanticipated problems to the Office of Human Subjects Protections (OHRP) and/or the Food & Drug Administration (FDA), as applicable. If reports are required to the funding agency or sponsor or any other oversight authority, those will be the responsibility of the Relying Institution. NIH intends to accomplish this by triggering 5.13 only as to a relying institution’s reporting obligations to a sponsor, funding agency, and other oversight authority. This clarification will be added to the SMART IRB FAQs to specify the process by which NIH will implement reporting to agencies.

Administrative issues and comment period:

10. Q. How can my institution provide feedback on the proposed NIH changes to the SMART IRB Agreement?

- A. You may provide feedback via [this form](https://smartirb.org/agreement/), accessible via the SMART IRB website at <https://smartirb.org/agreement/>. The draft of the revised SMART IRB Agreement (SMART IRB Agreement v2.0) will be available for comment from April 2, 2020 to May 31, 2020, with the possibility that the timeframe for feedback will be extended if needed.

11. Q. If my institution has already joined the SMART IRB Agreement, when Version 2.0 of the SMART IRB Agreement is finalized, can my institution continue to use the prior version of the SMART IRB Agreement?

- A. Yes. However, NIH requests that all current and new institutions transition to Version 2.0. Note that an institution that serves as a Reviewing IRB for an NIH Institute will need to sign Version 2.0, as will any Relying Institution for which an NIH Institute serves as the Reviewing IRB. Any new institution that wishes to join the SMART IRB Agreement after Version 2.0 has been finalized will only have the option to sign on to the SMART IRB Agreement Version 2.0.

12. Q. Will studies for which an NIH IRB serves as the Reviewing IRB for extramural research (e.g., the National Cancer Institute Central IRB and All of Us IRB) be transitioned to the SMART IRB Agreement?

- A. There are no current plans for extramural research reviewed by an NIH IRB (e.g.,



by the NCI Central IRB or All of Us IRB) to transition to the SMART IRB Agreement.

13. Q. My institution is not serving as a Reviewing IRB for the NIH nor is it ceding IRB review to an NIH Institute. Does my institution need to sign version 2.0 of the SMART IRB Agreement?

A. No. However, NIH requests that all institutions that signed version 1.0 of the SMART IRB Agreement (which includes version 1.1 and 1.2) transition to version 2.0. Note that if an institution wishes to serve as a Reviewing IRB or Relying Institution for the NIH participating in that research study, it will need to sign onto version 2.0.

14. Q. My institution might serve as a Reviewing IRB for both the NIH engaged in Research and for other institutions engaged in that Research that are not Federal agencies. Would all of the institutions engaged in that Research need to sign on to Version 2.0 of the SMART IRB Agreement?

A. No. Although the Reviewing IRB and the NIH will need to sign Version 2.0 of the SMART IRB Agreement to establish a reliance arrangement, the other Relying Institutions that are not the NIH would not need to sign on to version 2.0 of the SMART IRB Agreement if they have already signed the current SMART IRB Agreement. Note that the Reviewing IRB and each Relying Institution should track and record which version of the SMART IRB Agreement is applicable to the reliance arrangement with that Relying Institution.

15. Q. Does my institution need to re-execute a Joinder Agreement to sign onto Version 2.0 of the SMART IRB Agreement?

A. Yes. Some of the proposed NIH changes to the SMART IRB Agreement—including the changes to the conflict of interest provisions—are significant substantive changes and thus require Participating Institutions to execute a new joinder to document acceptance of the new terms. The SMART IRB joinder system will capture which version(s) of the SMART IRB Agreement an institution has signed and display that information as part of the [Participating Institutions](#) list on its website, as well as within the Online Reliance System.

16. Q. If my institution re-executes a Joinder Agreement to sign onto Version 2.0 and my institution has an IRB, is my institution required to have undergone or initiated an assessment of the quality of its human research protection program (HRPP) within 5 years of the execution of the new joinder (Section 1.2, HRPP Quality)?

A. No. The 5-year timeframe required in the Agreement will be tied to the date the institution first joined SMART IRB rather than when an institution re-executes a joinder for an updated agreement.

17. Q. If my institution signs onto version 2.0 of the SMART IRB Agreement, how will this



affect reliance arrangements in place under earlier versions of the SMART IRB Agreement? Does my institution need to document which version of the SMART IRB Agreement covers each of our reliance arrangements in effect?

- A. Institutions should continue to use version 1.0 for reliance arrangements in place prior to any institution's transition to version 2.0, regardless of whether the institution serves as the Reviewing IRB or Relying Institution in the reliance arrangement. For new reliance arrangements (put in place after Version 2.0 becomes available to join), the Reviewing IRB and each Relying Institution should track and record which version of the SMART IRB Agreement is applicable to the reliance arrangement with that Relying Institution.