NIH Revisions to the SMART IRB Agreement:
SMART IRB Agreement v2.0 (Final)
Frequently Asked Questions

Background about SMART IRB Agreement v2.0:

1. **Q. Why are the revisions to the SMART IRB Agreement reflected in SMART IRB Agreement v2.0 necessary?**
    A. The National Institutes of Health (NIH) requested revisions to the SMART IRB Agreement to enable NIH to become a signatory to the Agreement. Version 2.0 includes language required by NIH related to: liability coverage, conflict of interest, and non-interference with requirements of law. Version 2.0 also includes certain revisions regarding the provision for congruence review of grants and contracts with applications to the IRB.

2. **Q. How will 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. SMART IRB Agreement v1.0 was not written to reflect these requirements. The specific requirements relate to liability coverage and conflict of interest disclosure.

    SMART IRB Agreement v2.0 changes select provisions in SMART IRB Agreement v1.0 to be compliant with 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. It will also allow other sites and institutions to utilize the SMART IRB platform if the NIH is serving as the Reviewing IRB.

Insurance:

3. **Q. How does the addition of the footnote in Section 4.10, Insurance, affect the Agreement's insurance provision?**
    A. The footnote states that federal agencies are not required to maintain liability coverage for their activities under the SMART IRB Agreement. NIH, for example, follows, among other processes, 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.

4. **Q. Can NIH provide additional detail specifying which people affiliated with NIH are (or are not) covered under NIH's federal liability coverage?**
    A. NIH is not able to provide additional detail, due to the complexity of federal law and policy, and the unknown facts of a hypothetical event, that would determine

coverage for any specific case. An example of a federal statute governing liability coverage is the Federal Tort Claims Act (FTCA), 28 U.S.C. §§1346(b), 2401(b), 2671-80 et seq. You should speak to your institution's legal counsel if you have additional questions or interest regarding the FTCA. This Department of Justice website may be helpful as an introductory resource: https://www.justice.gov/civil/federal-tort-claims-act-litigation-section.

Conflicts of interest:

Sections 5.8 and 6.6 of SMART IRB Agreement v2.0 provide that when a federal agency is a Relying Institution, it will provide a conflict of interest assurance to the Reviewing IRB that agency personnel may participate in the Research. Information about the NIH Intramural Research Program's conflict of interest policies and processes (with links/citations to those policies and the underlying laws/regulations) can be found in the document titled "FAQ on the Conflict of Interest Policies of the NIH Intramural Research Program for SMART IRB." That document addresses questions about what information NIH can and cannot disclose to the Reviewing IRB.

5. **Q. Under SMART IRB Agreement v2.0, 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. No, 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 (although nothing prevents an IRB from taking other actions not specific to a confict of interest, such as limiting the number of participants that a site or institution, including the NIH, may enroll).

6. **Q. Under SMART IRB Agreement v2.0, if a Reviewing IRB concludes that it cannot rely upon the conflict of interest assurances from a Relying Institution that is a federal agency, can the Research be withdrawn from Ceded Review with respect to that agency?**
    A. Yes. Some Reviewing IRBs may not be able to rely upon a conflict of interest assurance from a federal agency (for example, if the Reviewing IRB's policies *require* the IRB to obtain specific information about investigators' financial interests or to manage financial interests that are below *de minimis* thresholds or that do not otherwise constitute conflicts under relevant policies). In response to public comment on this issue, SMART IRB Agreement v2.0 provides that a Reviewing IRB that has agreed to serve as the IRB of record for a federal agency but that subsequently concludes that the conflict of interest assurances from agency are not sufficient for it to rely upon may so inform the federal agency, and the Research will be withdrawn from Ceded Review (without an IRB approval or disapproval) with respect to that agency. Note that the Agreement does not require any IRB to serve as a Reviewing IRB for a federal agency (or any

other Participating Institution) in the first instance (e.g., Sections 2.2 and 3.2).

7. **Q. In the situation described in FAQ #6, as applied to the NIH (the Reviewing IRB concludes it cannot rely upon the conflict of interest assurances from NIH and the Research is withdrawn from Ceded Review with respect to NIH), can the Reviewing IRB continue to provide review of the Research for other Relying Institutions? In this situation, how will NIH's Policy on Use of a Single IRB for Multi-Site Research (NIH sIRB Policy) and the Revised Common Rule's single IRB requirement apply?**
    A. In this situation, the NIH Intramural Research Program can work with the funding applicant institution to seek an exception from NIH to the NIH sIRB Policy and an exception from the cooperative research provision of the Revised Common Rule. Note that with respect to an exception under the Revised Common Rule, there is currently (as of the date of these FAQs) no existing exception that would apply to this situation, and OHRP will need to be involved in consideration of the request. Alternatively, the NIH Intramural Research Program can choose not to participate in the Research. If exceptions are obtained or if the NIH Intramural Research Program chooses not to participate in the Research, the Reviewing IRB can continue as the Reviewing IRB for the other Relying Institutions involved in the Research. Note that the NIH Intramural Research Program may withdraw from the Research while an exception is sought, so as not to delay the review and approval of the Research for the other Relying Institutions.

8. **Q. Some organizations have voiced concerns that the language in Sections 5.8 and 6.6 of SMART IRB Agreement v2.0 relating to assurance to the Reviewing IRB of satisfaction of investigator conflict of interest policies from the NIH (such as from the NIH Intramural Research Program) is not compliant with AAHRPP standards regarding confict of interest. Is this aspect of SMART IRB Agreement v2.0 compliant with AAHRPP standards?**
    A. Yes. AAHRPP has affirmed that since investigators at the NIH, including the NIH Intramural Research Program, are legally bound to comply with policies that in effect prohibit the existence of a conflict (as defined in NIH policies), the NIH assurance that these policies are met is acceptable under AAHRPP's standards.

9. **Q. Some organizations have voiced concerns that the language in Sections 5.8 and 6.6 of SMART IRB Agreement v2.0 relating to assurance to the Reviewing IRB of satisfaction of investigator conflict of interest policies from Department of Health and Human Services (DHHS) agencies (such as from the NIH Intramural Research Program) is not compliant or consistent with the responsibilities of the IRB under the Common Rule and DHHS guidance (2004) on investigator financial conflict of interest. Is this aspect of SMART IRB Agreement v2.0 compliant/consistent with the Common Rule and DHHS guidance?**
    A. *This question is pending a formal response from OHRP and will be updated as soon as possible. That said, SMART IRB leadership believes that this aspect of*

10. **Q. How do the changes in the conflict of interest provisions reflected in SMART IRB Agreement v2.0 affect institutions that are not collaborating with a federal agency?**
    A. The changes do not affect the relationship between Reviewing IRBs and Relying Institution that are not federal agencies.

Congruence of Grant Applications/Contract Proposals:

11. **Q. The Revised Common Rule no longer requires an IRB to review the congruence of a federal grant application or contract proposal with the research submitted to the IRB. Why does SMART IRB Agreement v2.0 retain Section 5.15, Congruence of Grant Applications/Contract Proposals?**
    A. This provision is retained and slightly revised in response to public comments noting that such congruence review may still be required by laws/regulations other than the Common Rule (such as state laws) or by the funding agency or sponsor. The comments indicated that to the extent congruence reviews continue to be required, the community wishes to address the issue in the Agreement, rather than leaving it up to Participating Institutions to make arrangements among themselves regarding how such reviews will be performed. By its terms, the provision only applies when congruence review is required by applicable law or regulation or by the funding agency or sponsor. Notwithstanding the retention of the provision, the provision has been further modified to reflect that federal agencies that are serving as Reviewing IRBs will not perform congruence review; in such situations, the Relying Institution will need to perform any required congruence review.

Non-interference with requirements of law:

12. **Q. What change is effected through the new Section 8.10, No Violation of Law?**
    A. The new Section 8.10 in SMART IRB Agreement v2.0 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. We are not aware of any current conflict between the Agreement's terms and any of these other sources of requirements; however, NIH requires the Agreement to address the possibility that such a conflict could arise.

13. **Q. What violations or conflicts are addressed in the new Section 8.10?**
    A. The new Section 8.10 addresses potential conflicts between the terms of the Agreement and the requirements of applicable law, regulation, or other federal or state requirements. "Other federal or state requirements" is intended to include federal/state agency funding terms and policies. Conflicts with a Participating Institution's contractual obligations under other private contracts are not included; Participating Institutions are expected to manage any conflicts (or assure that there are no conflicts) with the terms of their other private

contracts on their own. Only when complying with the terms of the Agreement would cause a Participating Institution to violate an applicable law, regulation, or other governmental requirement is a Participating Institution eligible for consideration of an alternate approach (as described in FAQ #14 below).

14. **Q. What must a Participating Institution do if it determines that complying with a provision of the Agreement will cause it to be in violation of applicable law, regulation, or other federal or state requirements?**
    A. In this situation, the new Section 8.10 requires the Participating Institution to notify the other affected Participating Institutions and work with them to identify a mutually agreeable alternative approach to address the provision of the Agreement that is at issue. Such an approach might include identification of a different way to satisfy the Agreement provision (when possible) or a decision not to insist on the Participating Institution's performance of the Agreement provision (if acceptable to the other affected Participating Institutions). (Note that under Section 8.6 of the Agreement, a decision not to insist on performance of an Agreement term does not constitute a waiver of the Agreement by the other affected Participating Institutions). If a mutually agreeable approach cannot be identified, Section 8.10 requires that the Research be withdrawn from Ceded Review with respect to the affected Participating Institutions.

Reporting:

15. **Q. How will reporting of noncompliance and unanticipated problems be handled by NIH?**
    A. NIH has indicated that if 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 Section 5.13 of the Agreement only as to a Relying Institution's reporting obligations to a sponsor, funding agency, and other oversight authority. This clarification is included here to specify the process by which NIH will implement reporting to agencies.

Administrative issues and comment period:

16. **Q. If my institution has already joined SMART IRB Agreement v1.0, can my institution continue to use that Version 1.0?**
    A. Yes. However, note that an institution that serves as a Reviewing IRB for the NIH Intramural Research Program will need to sign Version 2.0, as will any Relying Institution for which the NIH Intramural Research Program IRB serves as the Reviewing IRB. Once Version 2.0 is finalized, any new institution that wishes to join SMART IRB and has not yet completed a Joinder will only have the option to

sign SMART IRB Agreement v2.0.

17. **Q. My institution is not serving as a Reviewing IRB for the NIH nor is it ceding IRB review to the NIH Intramural Research Program IRB. Does my institution need to sign SMART IRB Agreement v2.0?**
    A. No. However, note that if an institution wishes to serve as a Reviewing IRB for the NIH Intramural Research Program, it will need to sign SMART IRB Agreement v2.0, as will any Relying Institution for which the NIH Intramural Research Program IRB serves as the Reviewing IRB.

18. **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 SMART IRB Agreement v2.0?**
    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 Version 2.0 of the SMART IRB Agreement if they have already signed SMART IRB Agreement v1.0. 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.

19. **Q. Does my institution need to re-execute a Joinder Agreement to sign Version 2.0 of the SMART IRB Agreement?**
    A. Yes. Some of the changes included in SMART IRB Agreement v2.0—including the changes to the conflict of interest provisions—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.

20. **Q. If my institution re-executes a Joinder Agreement to sign SMART IRB Agreement v2.0 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 that the institution *first* joined SMART IRB rather than when an institution re-executes a joinder for an updated agreement.

21. **Q. If my institution signs SMART IRB Agreement v2.0, how will this affect reliance arrangements in place under earlier versions of the SMART IRB Agreement (Version 1.0 including Version 1.1 and 1.2)? 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 (which includes Version 1.1 and 1.2) 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 arrangement. For new reliance arrangements (put in place after Version 2.0 is 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.