



SMART IRB Reliance Agreement Version 3.0

Frequently Asked Questions on Comment and Transition Processes

What is SMART IRB Reliance Agreement Version 3.0?

SMART IRB Reliance Agreement Version 3.0 is a new proposed (and renamed) version of the current SMART IRB Master Common Reciprocal Institutional Review Board Authorization Agreement. Once finalized, Version 3.0 will be the only version of the agreement open to join, and it will replace the current Versions 2.0 and 1.0, as explained further below.

SMART IRB Reliance Agreement Version 3.0 is intended to:

(1) address feedback received from current and potential Participating Institutions over the past several years, including on key terms to minimize barriers to participation and maximize the contexts in which the agreement can facilitate streamlined ethical and regulatory reviews of human subjects research.

(2) ensure that the agreement fully reflects the changes to IRB review requirements that were implemented in the 2018 Common Rule, including changes to the exemptions from IRB review and the concept of limited IRB review; and

(3) allow additional federal agencies, such as the U.S. Department of Veterans Affairs, the U.S. Department of Defense, the U.S. Department of Energy, and others to participate in the agreement (the National Institutes of Health joined Version 2.0).

Why is my institution being asked to review and comment on SMART IRB Reliance Agreement Version 3.0?

The current agreement (Versions 2.0 and 1.0) requires that material changes proposed to the agreement be open for written comments by Participating Institutions. Because SMART IRB Reliance Agreement Version 3.0 includes a number of such changes, SMART IRB leadership is providing Participating Institutions (as well as other stakeholders) the opportunity to review and comment on Version 3.0 before

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it is finalized. We are particularly interested in elements that are unclear and any terms that would prevent your institution from participating or continuing to participate. All comments received will be considered in determining whether further changes to Version 3.0 should be made before it is finalized.

Note that once finalized, Version 3.0 will replace Versions 2.0 and 1.0, which will no longer be available. Therefore, it is critical that your institution review Version 3.0 if it wishes to continue participation.

How does SMART IRB Reliance Agreement Version 3.0 differ from the current agreement?

SMART IRB leadership has prepared an [executive summary](#) of Version 3.0's key substantive changes to the current agreement, as well as a [redline](#) that shows all of the differences between Version 3.0 and the Version 2.0. (Note that the executive summary and redline are keyed to Version 2.0 and not Version 1.0.)

The executive summary is necessarily high-level and does not identify every proposed change or minor modification. It also does not identify the technical, organizational, and wording changes that are being proposed to enhance clarity in a number of provisions. Please review [SMART IRB Agreement Version 3.0](#) itself and the available [redline](#) for the complete set of changes.

How does my institution submit comments on SMART IRB Reliance Agreement Version 3.0?

SMART IRB leadership has prepared a [comment form](#) and requests all comments to be submitted using this form. The form has comment fields corresponding to each line of the agreement, and it can be submitted through the [SMART IRB Agreement page](#) on SMART IRB website. If necessary, comments can be emailed to help@smartirb.org, though we urge institutions to use the available form if possible.

How long does my institution have to submit comments on SMART IRB Reliance Agreement Version 3.0?

All comments must be submitted by **February 15, 2024**, in order to be considered.

What happens after the comment period closes?



SMART IRB leadership will review all comments received by the submission deadline and will work with the SMART IRB Harmonization Steering Committee, representatives from NCATS and other federal agencies, and members of the SMART IRB community as necessary to determine whether and which further changes to Version 3.0 should be made before it is finalized. If material changes are made at revision, those changes will be posted for further public comment.

Once ready, the final Version 3.0 will be posted (“go live”) on the [SMART IRB Agreement page](#), and Participating Institutions will be notified (through their Points of Contact, “POC”) that it has been posted and is available for signature. The POCs are listed on the [Participating Institutions list](#); please make sure that the POC contacts and their contact information for your institution is current (please email help@smartirb.org).

When the final SMART IRB Reliance Agreement Version 3.0 is posted (“goes live”), does my institution have to do anything to continue as a Participating Institution?

Yes. Your institution will need to execute (sign) a new SMART IRB Joinder Agreement in order to continue participating in the agreement. This is because the current agreement (Versions 2.0 and 1.0) requires re-execution of joinder agreements whenever the agreement is significantly amended. Version 3.0 constitutes a significant amendment of the agreement.

Once the final Version 3.0 is posted (“goes live”) on the [SMART IRB Agreement page](#), Participating Institutions will be given a reasonable period of time to execute a new SMART IRB Joinder Agreement. A Participating Institution that does not execute a new joinder agreement within that time period will be considered to have terminated its participation in the agreement.

Once the final SMART IRB Reliance Agreement Version 3.0 is posted (“goes live”), will my institution or other institutions be able to continue using Versions 2.0 or 1.0?

No. Version 3.0 will replace Versions 2.0 and 1.0, neither of which will be available.

How will this new agreement impact my institution’s existing research portfolio under Versions 2.0 or 1.0?



For participating institutions who sign on to Version 3.0, ongoing research/reliance arrangements initiated under Versions 2.0 or 1.0 will transition to the terms of Version 3.0. To ensure ongoing work is not disrupted, participating institutions will be granted a reasonable period of time from “go live” to execute the new SMART IRB Joinder Agreement.

Should an institution choose not to sign Version 3.0 by the indicated “go live” date, any ongoing research/reliance arrangements will no longer be covered under the SMART IRB Reliance Agreement (including Versions 1.0 and 2.0). However, an institution is able to sign on to Version 3.0 at any time.

Does executing a new SMART IRB Joinder Agreement mean that my institution must demonstrate that it has had a quality assessment of its HRPP within the five years prior to the date of the new SMART IRB Joinder Agreement?

No, current participating institutions do not need to demonstrate a quality assessment of their HRPP as long as participation in the agreement has been continuous since initially joining and the new joinder agreement is executed within the time period referenced above.

Does executing a new SMART IRB Joinder Agreement to participate in SMART IRB Reliance Agreement Version 3.0 mean that my institution is also agreeing to participate in the new SMART IRB Indemnification Addendum that is available through Version 3.0?

No. The decision to sign the new SMART IRB Indemnification Addendum is optional and entirely at the discretion of the Participating Institution. SMART IRB Reliance Agreement Version 3.0 does not require agreement to any indemnification agreements or terms. The new SMART IRB Indemnification Addendum is provided as an option for Participating Institutions who wish to use it. Such institutions must execute a separate SMART IRB Indemnification Addendum Joinder Agreement in order to participate in the SMART IRB Indemnification Addendum.