

# SMART IRB Reliance Agreement Version 3.0

# High-Level Summary of Key Changes in Version 3.0 (as compared to Versions 1.0/2.0)

This document provides a high-level overview of key **changes**, or differences, in the terms of Version 3.0 of the SMART IRB Reliance Agreement (“Agreement”) as compared to the prior Versions 1.0/2.0. For a more detailed description of the key changes, see the **Detailed Summary of Key Changes in Version 3.0**.

* Eligibility to participate in the Agreement: Eligibility requirements have been made more flexible in that (1) while an Assurance is still required, it can be with any Common Rule agency (it does not have to be an FWA); and (2) an institution is no longer required to maintain policies for oversight of its exempt research.
* Exemption Determinations and Exempt Research:The Agreement more comprehensively addresses reliance on another institution or IRB for an Exemption Determination (a determination that Research is exempt from some or all Common Rule requirements). Specifically, the Agreement now provides that:

### Exemption Determinations must be conducted in accordance with the Common Rule;

### Reviewing IRBs will perform any required Limited IRB Reviews in connection with same; and

### The Agreement’s provisions on Local Considerations and Other Considerations, review of proposed changes to the Research, and review/notification/reporting of noncompliance apply to Exemption Determinations and Exempt Research.

* Withdrawal of Reviewing IRB:Reviewing IRBs may now withdraw from providing review and oversight for significant cause, such as a Relying Institution’s ongoing, uncorrected breach of Agreement terms.
* Reliance processes and policies: When federal regulatory or federal agency processes and policies for initiation of reliance, determination of the Reviewing IRB/Reviewing IRB Institution, or conduct of the reliance relationship apply, they override the correlating processes and terms of the Agreement. Their application must generally be documented by the parties. In the absence of such federal processes or policies, the Agreement (1) recommends (but no longer mandates) certain processes for initiation of reliance and determination of the Reviewing IRB/Reviewing IRB Institution; and (2) deems the SMART SOPs applicable by default to govern the conduct of the reliance relationship unless the parties document a different set of SOPs.
* Education, training and qualifications: The obligation to ensure adequate qualifications for Personnel (including IRB members) now applies to Reviewing IRB Institutions as well as Relying Institutions. Institutions no longer need to provide one another with documentation of individual Personnel/IRB member qualifications; general descriptive information about qualification requirements is sufficient.
* Dispute resolution: The Agreement now requires good faith cooperation by the parties to try to resolve concerns, and encourages (but does not require) informal dispute resolution.
* Notification of federal for-cause investigations: Participating Institutions must now notify other institutions with whom they are in a reliance relationship of certain for-cause compliance investigations of the notifying institution or its Personnel by federal human subjects research regulatory or funding agencies.
* Insurance: Participating Institutions that are private institutions may now rely on self-funded liability coverage to satisfy the Agreement’s insurance requirement. All government/public institutions (whether federal, state, or local) are now exempted from the Agreement’s insurance requirement.
* Indemnification:Entering indemnification agreements continues to be optional; however, the Agreement now contains a new SMART IRB Indemnification Addendum for Participating Institutions that wish to join it. The SMART IRB Indemnification Addendum does not override separate indemnification agreements entered by a Participating Institution prior to joining the Addendum.
* HIPAA:Rather than the Reviewing IRB determining how HIPAA authorization forms/language and waivers/alterations of HIPAA authorization are addressed, a Relying Institution now decides whether it will provide such forms/language and obtain such waivers/alterations or whether it will ask the Reviewing IRB to do so.Local Considerations identified by a Relying Institution will also drive whether HIPAA authorization forms/language are merged into research consents and whether waivers/alterations are approvable.Relying Institutions providing authorization forms/language or obtaining waivers/alterations are responsible for the compliance of those forms/language or waivers/alterations with HIPAA’s requirements.
* Standard of review for Research not subject to federal human subjects regulations: The Agreement now requires the Reviewing IRB to apply Common Rule standards (e.g., criteria for approval) to the review of such Research, unless a different standard is agreed upon and documented by the Reviewing IRB and Relying Institution. The provision only concerns review standards; external reporting is not required.
* Consent forms/scripts: Reviewing IRBs must now consider a Relying Institution’s requests for institution-specific modifications to consent forms/scripts that are necessary to address legal or regulatory issues, federal agency-specific requirements, or institutional requirements.
* Identification and communication of “Other Considerations”:The Agreement newly addresses responsibility for identifying and communicating certain federal laws, regulations, and requirements to the Reviewing IRB. Relying Institutions must identify and communicate not only Local Considerations but also applicable requirements of federal laws and regulations and of federal departments or agencies that are not readily apparent from a Research protocol or from other documents submitted to the IRB or that are specific to a Relying Institution (“Other Considerations”). Such requirements that are readily apparent from the submission are expected to be identified by the Reviewing IRB.
* Reports to funding agencies, sponsors, and other authorities: Any reports of unanticipated problems, serious or continuing noncompliance, or suspensions or terminations of IRB approval required to be made to a funding agency, sponsor, or other authority than a federal human subjects research regulatory agency will now be the sole responsibility of the Relying Institution.
* Termination:A Participating Institution whose Assurance is suspended, restricted, terminated, or expires, or if serving as a Reviewing IRB/Reviewing IRB Institution, whose IRB registration is lost or lapses, now has 60 (or up to 90 if agreed by other affected institutions) business days to fully reinstate its Assurance/IRB registration before its participation in the Agreement is terminated. (No new studies can be initiated.)
* Electronic Joinder Agreements:Joinder Agreements for Version 3.0 of the Agreement will be electronic and will be executed using electronic or digital signatures.