

# SMART IRB Reliance Agreement Version 3.0

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

The purpose of this document is to detail 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. This document does not identify terms of the Agreement to which Version 3.0 merely makes **clarifications** to better convey the original intended meaning of the term. Many of the language revisions in Version 3.0 are in the nature of clarifications rather than changes or are to improve the organization or readability of the Agreement.

## Changes to Eligibility to Participate in the Agreement (Section 1)

* FWA No Longer the Only Form of Assurance Accepted (Section 1.1). Unless it is an Independent IRB Organization, an institution must still maintain an Assurance of compliance with the Common Rule to participate in the Agreement, but the Assurance can be with any federal Common Rule agency (such as an Assurance issued by the U.S. Department of Defense).
* Institutional Oversight of Exempt Research No Longer Required (Section 1.1).Version 3.0 no longer requires institutions to maintain policies for oversight of research that is exempt from the Common Rule. How institutions oversee exempt research is beyond the scope of the Agreement.

## Changes to Scope and Application of the Agreement (Section 2 and Certain Related Sections)

### Exemption Determinations and Exempt Research

* + Exemption Determinations and Associated Limited IRB Review More Comprehensively Addressed (Section 2.1.2 and related Section 5.4.2). Institutions may continue to use the Agreement to obtain determinations from another institution or IRB that Research is exempt from some or all Common Rule requirements. When they do, the Agreement now explicitly provides that Exemption Determinations will be conducted in accordance with the Common Rule and that the Reviewing IRB will perform any Limited IRB Review that is required as part of the Exemption Determination.
  + Local Considerations and Other Considerations Applicable to Exemption Determinations (Sections 5.4.2 and 6.6). When an Exemption Determination is requested, a Relying Institution must identify and communicate, and a Reviewing IRB/Reviewing IRB Institution must consider, any Local Considerations and Other Considerations (see below) and other local information to the extent such considerations or information are relevant to the Federal Policy’s criteria for exemption (e.g., where an exemption is limited to research involving adults, the Reviewing IRB/Reviewing IRB Institution needs to know and consider who is a child under the Relying Institution’s state law).
  + Review of Proposed Changes and Review, Notification, and Reporting of Noncompliance Applicable to Exempt Research (Sections 5.4.2, 5.10, 6.3, and 6.13). With respect to Research that has been determined exempt, Reviewing IRBs/Reviewing IRB Institutions must review proposed changes to the Research to determine whether the Research is still eligible for exemption and whether a new Limited IRB Review is required. Reviewing IRBs/Reviewing IRB Institutions must also review potential noncompliance with the Federal Policy or with the terms of the Exemption Determination that could disqualify the Research from the relevant exemption. The Reviewing IRB/Reviewing IRB Institution must notify the Relying Institution of the Reviewing IRB’s/Reviewing IRB Institution’s decisions, findings, and actions regarding the same, including a determination that a Report of serious and/or continuing noncompliance to federal human subjects officials is required. For its part, a Relying Institution must notify the Reviewing IRB/Reviewing IRB Institution of such potential noncompliance or if it determines that such a Report is required in connection with the exempt Research. A Relying Institution must also notify the Reviewing IRB/Reviewing IRB Institution of proposed changes to exempt Research.
* Reviewing IRBs May Withdraw from Providing Review (Section 2.5.2.2).For significant cause, such as a Relying Institution's ongoing and uncorrected failure to comply with its obligations under the Agreement, a Reviewing IRB may withdraw from providing review and oversight of Research for the Relying Institution, with 60 business days’ prior written notice and explanation provided to the Relying Institution.

## Changes to Collaborative Processes for Consideration of Reliance Requests, Determination of the Reviewing IRB/Reviewing IRB Institution, and Determination of Applicable Policies and Procedures (Section 3)

* Specific Acknowledgment of Federally Mandated Processes (Section 3.1).For Research subject to federal regulatory or funding agency processes for initiation of reliance or for determination of the Reviewing IRB/Reviewing IRB Institution (such as Research subject to the Common Rule’s single IRB provisions or the NIH Single IRB Policy), such Mandated Processes will override the correlating processes set out in the Agreement. Participating Institutions only need to document among themselves when a Mandated Process applies if such documentation does not exist elsewhere (for example, in the grant documents).
* In the Absence of Federally Mandated Processes, Agreement Recommends But Does Not Require a Particular Process for Initiation of Reliance Requests or Determination of Reviewing IRB (Section 3.2). The Agreement continues to include detailed processes to guide Participating Institutions when they are not subject to Mandated Processes in initiating reliance requests and determining the Reviewing IRB, but these processes are now recommendations, not requirements. Participating Institutions have flexibility to use alternate processes for these matters. Regardless what processes are used, however, Participating Institutions that extend their Assurances to Research that is not federally funded continue to be required to inform the proposed Reviewing IRB/Reviewing IRB Institution if their Assurance is applicable to the Research.
* Specific Acknowledgement of Federally Mandated Policies (Section 3.4.1). For Research subject to federal funding agency policies for the conduct of the reliance relationship once it is established (such as research funded by the U.S. Department of Veterans Affairs or U.S. Department of Defense), such Mandated Policies will override the correlating terms set out in the Agreement.
* In the Absence of Federally Mandated Policies, Agreement Recommends But Does Not Require SMART IRB SOPs (Section 3.4.2). The Agreement continues to recommend that Participating Institutions use and follow the SMART IRB SOPs for the conduct of the reliance relationship once it is established, when they are not subject to Mandated Policies. Participating Institutions retain flexibility to use alternate policies and procedures to govern the conduct of the reliance relationship; however, if they do, the Agreement provisions override any such alternate policies and procedures in the event of any conflict.
* Documentation of Applicable Policies Is Required; Deemed Application of SMART IRB SOP (Section 3.4.3).Participating Institutions must not only communicate but now also must document among themselves what policies and procedures for the conduct of the reliance relationship will apply to their instance of reliance (Mandated Policies, SMART IRB SOPs, or alternate policies and procedures). If they do not document the applicable policies and procedures, the SMART IRB SOPs will be deemed to apply unless any Mandated Policies apply.

## Changes to General Responsibilities of Participating Institutions (Section 4)

* All Institutions Responsible for Ensuring Training and Requiring Compliance (Section 4.1). Just as Relying Institutions must do, Reviewing IRB Institutions must ensure that their Personnel have adequate education, training, qualifications, and resources to perform their obligations, and must require their Personnel to comply with applicable laws, regulations, policies, and the Agreement. For Reviewing IRB Institutions, these responsibilities also apply with respect to their IRB members.
* No Obligation To Provide Documentation of Individual Personnel or IRB Member Education/Training/Qualifications (Section 4.1).Participating Institutions no longer need to provide documentation to other Participating Institutions of individual Personnel or IRB member education, training or qualifications. Participating Institutions must still provide descriptive information about such education, training or qualifications if requested by another Participating Institution, but the information can be provided in a general/summary fashion (such as what training all IRB members are required to take).
* Obligation To Correct Noncompliance and Resolve Concerns in Good Faith (Sections 4.2, 4.3, and 4.6.2). Participating Institutions must correct noncompliance with applicable laws, regulations, policies, and the Agreement. In regard to potential noncompliance with or breach of the Agreement terms, affected Participating Institutions must work with one another in good faith to try to resolve concerns, and may attempt to resolve them through third-party consultations or other means, without waiving any rights under the Agreement.
* Notification of Federal For-Cause Investigations Required (Section 4.6.1).Participating Institutions must notify other Participating Institutions with whom they are then in a reliance relationship of any for-cause compliance investigations of the notifying institution or its Personnel by the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), National Institutes of Health (NIH), or other federal human subjects research regulatory or funding agencies, when the investigation is related to the Research under review or for which an Exemption Determination was provided or when the investigation could affect the conduct or the integrity of such Research, the rights or welfare of participants, or the Reviewing IRB/Reviewing IRB Institution’s authority or ability to perform its review and oversight obligations.
* Self-Funded Liability Coverage Meets Insurance Requirement; No Insurance Requirement for Government/Public Institutions (Section 4.9). Participating Institutions that are private institutions may rely on self-funded liability coverage (instead of or in addition to traditional insurance policies) to satisfy the Agreement’s insurance requirement. All government/public institutions (whether federal, state, or local) are exempted from the Agreement’s insurance requirement.

## Changes to Indemnification Provisions (Section 4.10 and Exhibit C - SMART IRB Indemnification Addendum)

* New SMART IRB Indemnification Addendum Provided as Option for Participating Institutions Seeking 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 addresses allocation of financial liability or responsibility between a Reviewing IRB/Reviewing IRB Institution and a Relying Institution resulting from their activities under the Agreement. Whether a Participating Institution elects to join the SMART IRB Indemnification Addendum has no effect on the institution’s eligibility to participate in the Agreement. If a Participating Institution joins the SMART IRB Indemnification Addendum, separate indemnification agreements entered by that Participating Institution prior to joining the SMART IRB Indemnification Addendum will continue to apply to Covered Activities initiated under those separate agreements. Participating Institutions that join the SMART IRB Indemnification Addendum can also agree among themselves to limit its scope to certain studies, and they remain free to enter separate indemnification agreements for other studies outside that scope. Note that public institutions, including federal departments and agencies, may join the SMART IRB Indemnification Addendum, but in the case of federal departments and agencies specifically, the Agreement and the Addendum exempt federal departments and agencies from providing indemnification to other Participating Institutions.

## Changes to HIPAA Provisions (Section 4.4)

* Relying Institutions Determine How HIPAA Authorization Forms and Waivers of HIPAA Authorization are Addressed.Relying Institutions that are HIPAA Covered Entities determine whether they will provide their own HIPAA authorization forms and obtain their own HIPAA waiver determinations for Research or whether they will request the Reviewing IRB Institution/Reviewing IRB to provide such forms and perform such determinations. Reviewing IRB Institutions/Reviewing IRBs that are federal departments or agencies, that are not HIPAA Covered Entities, or that otherwise do not provide such forms or perform such determinations (whatever the reason) are not obligated to agree to a request. Even when the Reviewing IRB Institution/Reviewing IRB agrees to provide such forms or perform such determinations, Local Considerations (if any) identified by the Relying Institution drive whether the HIPAA authorization form is merged into the research informed consent form and whether a waiver of HIPAA authorization is ultimately approvable. The party providing an authorization ensures that the form contains HIPAA’s required elements and statements for an authorization and that the form permits the use and disclosure of Protected Health Information as necessary for the Research.
* Reviewing IRBs/Reviewing IRB Institutions Are Not Required To Ensure Compliance of a HIPAA Waiver/Alteration of Authorization Obtained by a Relying Institution. Just as a Reviewing IRB/Reviewing IRB Institution has no obligation to ensure that a HIPAA authorization supplied by a Relying Institution complies with HIPAA’s requirements for an authorization, Version 3.0 explicitly acknowledges that a Reviewing IRB/Reviewing IRB Institution has no obligation to ensure that a HIPAA waiver/alteration of authorization obtained by a Relying Institution complies with HIPAA’s requirements for such a waiver/alteration or for documentation of the same.

## Changes to Reviewing IRB Responsibilities (Section 5)

* Common Rule as Standard for Research Not Subject to Federal Human Subjects Regulations (Section 5.4.1.2).When reviewing Research that is not federally funded, FDA-regulated, or otherwise subject to federal human subjects protection regulations, the Reviewing IRB will apply Common Rule standards to the review (e.g., Common Rule criteria for approval of the Research), unless a different standard is agreed upon and documented by the Reviewing IRB and Relying Institution. Note that this provision does not require the parties to comply with the Common Rule’s provisions on external reporting to federal departments or agencies.
* Reviewing IRBs Must Consider Certain Requests To Customize Consent Form/Scripts (Section 5.6).The Reviewing IRB will consider a Relying Institution’s requests for institution-specific modifications to consent forms/consent scripts that are necessary to address legal or regulatory issues, federal agency-specific requirements, or institutional requirements, i.e., matters from which there is no flexibility for the Relying Institution to deviate.

## Changes to Relying Institution Responsibilities (Section 6)

* Relying Institutions Responsible for Identifying and Communicating Both Local Considerations and Other Considerations (Section 6.6). Version 3.0 continues Relying Institutions’ responsibility to communicate local factors to the Reviewing IRB but newly addresses responsibility for certain federal factors as well. Under Version 3.0, Relying Institutions must identify and communicate to the Reviewing IRB/Reviewing IRB Institution both:

* + Local Considerations: applicable requirements of state or local laws and regulations, institutional policies, local standards, and other local factors; and
  + Other Considerations: 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 (e.g., a federal records confidentiality requirement that applies only to a Relying Institution contributing records to the Research where the submission does not indicate that protected records are contemplated).

Reviewing IRBs are expected to identify readily apparent requirements of federal laws and regulations and federal departments or agencies (e.g., federal requirements for confidentiality of educational records in a public-school-based protocol contemplating review of student health and disciplinary files).

* Relying Institutions Responsible for Reports to Funding Agencies, Sponsors, and Other Authorities (Section 6.16 and the related Section 5.13.3). Reviewing IRBs will generally continue to make any required reports of unanticipated problems, serious or continuing noncompliance, and suspensions or terminations of IRB approval to federal human subjects research regulatory agencies (e.g., OHRP, FDA). However, any and all other reports or notifications of such events that may be required to a funding agency, sponsor, or other authority, will be the Relying Institution’s sole responsibility.

## Changes to Other Provisions (Sections 7 and 8)

* Grace Period for Termination of Participation for Loss of Assurance or IRB Registration (Section 7.2.1.3).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, has 60 business days (or up to 90 business days if agreed by other affected institutions) to fully reinstate its Assurance/IRB registration before its participation in the Agreement is terminated. The Participating Institution may not participate in new studies/activities during this period.
* Provision for Electronic Joinder Agreements (Section 8.1).Joinder Agreements for Version 3.0 of the Agreement will be electronic and will be executed using electronic or digital signatures.