

# SMART IRB Reliance Agreement Version 3.0

# Key Operational Differences Between Version 3.0 and Versions 1.0/2.0

Pursuant to the transition plan for moving Participating Institutions to Version 3.0 of the SMART IRB Reliance Agreement (“Agreement”), a Participating Institution may be under different versions of the Agreement for different studies, and a Reviewing IRB Institution may be under different versions of the Agreement with respect to different Relying Institutions in the same study. The purpose of the list below is to highlight key operational differences between Version 3.0 and Versions 1.0/2.0 of the Agreement in order to assist Participating Institutions, and Reviewing IRB Institutions in particular, to identify the differences they will need to manage day-to-day as part of the transition.

## Setting Up the Reliance Relationship

* Agreement Term/Section:Documentation of Applicable Federal Regulatory or Agency Processes for Initiation/ Consideration of Reliance Requests and Selection of Reviewing IRB (V3.0, Section 3.1)
  + Versions 1.0/2.0:No requirement to document when such federal regulatory or agency processes apply.
  + Version 3.0:Reviewing IRB Institution and Relying Institution must document among themselves when such federal regulatory or agency processes apply unless such documentation exists elsewhere (e.g., in grant documents).
* Agreement Term/Section:Documentation of Applicable Policies and Procedures for Conduct of the Reliance Relationship (V3.0, Section 3.4.3)
  + Versions 1.0/2.0:No requirement to document what policies and procedures apply.
  + Version 3.0:Reviewing IRB Institution and Relying Institution must document whether any federal agency policies and procedures apply and, if not, what policies and procedures they will follow; if they do not document, the SMART IRB SOPs will apply.

## Exchange of Information

* Agreement Term/Section:Documentation of Training for Individual Personnel (V3.0, Section 4.1)
  + Versions 1.0/2.0:Documentation of individual Personnel training must be provided on request.
  + Version 3.0:Documentation of individual Personnel or IRB member training not required to be provided; general description of applicable training requirements is sufficient.
* Agreement Term/Section:Documentation of Insurance Coverage (V3.0, Section 4.9)
  + Versions 1.0/2.0:Documentation of self-funded liability coverage suffices for public (governmental) institutions.
  + Version 3.0:Documentation of self-funded liability coverage suffices for any institution (including private). All public institutions are exempt from coverage and documentation requirements.

## Performing Reviews

* Agreement Term/Section:Exemption Determinations (V3.0, Sections 2.1.2, 5.4.2, 6.3, 6.6)

#### Versions 1.0/2.0:

##### No explicit standards for performance of Exemption Determinations.

##### Agreement’s provisions on Local Considerations do not apply to Exemption Determinations.

#### Version 3.0:

##### Reviewing IRB/Reviewing IRB Institution must perform Exemption Determinations in accordance with the Common Rule. Reviewing IRB must perform Limited IRB Reviews and provide broad consent forms/scripts as required for certain exemptions. Reviewing IRB must review proposed changes to the Research to determine whether the Research remains eligible for exemption and whether new Limited IRB review is required.

##### Agreement’s provisions on Local Considerations apply (to a limited extent) to Exemption Determinations.

* Agreement Term/Section:IRB Review of Research Not Subject to Federal Requirements (Research That Is Not Federally Funded, FDA-Regulated, or Otherwise Subject to Federal Human Subjects Regulations) (V3.0, Section 5.4.1.2)
  + Versions 1.0/2.0:No explicit standards for performance of IRB review for such Research.
  + Version 3.0:Reviewing IRB must perform review of such Research in accordance with the Common Rule’s standards for review (e.g., Common Rule criteria for approval of the Research) unless the Reviewing IRB and Relying Institution agree on and document a different standard.
* Agreement Term/Section:Identification and Communication of Certain Federal Requirements Other Than Human Subjects Regulations (Other Considerations) (V3.0 Section 6.6)
  + Versions 1.0/2.0:No provision addressing responsibility to identify requirements of federal laws and regulations or of federal departments or agencies applicable to the Research (for example, federal confidentiality laws for certain types of records). Effectively the Reviewing IRB’s responsibility as a result.
  + Version 3.0:In addition to local factors, Relying Institution must identify and communicate to Reviewing IRB/Reviewing IRB Institution requirements of federal laws and regulations and of federal departments or agencies that are not readily apparent from the protocol or other documents submitted to the IRB or that are specific to that Relying Institution. Reviewing IRB expected to identify readily apparent requirements.
* Agreement Term/Section:Modifications to ICF (V3.0, Section 5.6)
  + Versions 1.0/2.0:Reviewing IRB controls what sections of ICF are customizable by Relying Institution.
  + Version 3.0:Reviewing IRB must consider Relying Institution requests for institution-specific modifications to ICFs/consent scripts necessary to address legal or regulatory issues, federal agency-specific requirements, or institutional requirements.
* Agreement Term/Section:HIPAA (V3.0, Section 4.4)
  + Versions 1.0/2.0:Reviewing IRB/Reviewing IRB Institution drives whose authorization form/language is used, whether authorization is merged with informed consent, who performs or obtains waiver/alteration determinations, and whether a waiver/alteration of authorization is ultimately approvable. Reviewing IRB/Reviewing IRB Institution is generally expected to provide authorization forms/language and perform waiver/alteration determinations.
  + Version 3.0:Relying Institution drives whose authorization form/language is used, whether authorization is merged with informed consent, who performs or obtains waiver/alteration determinations, and whether a waiver/alteration is ultimately approvable. Reviewing IRB/Reviewing IRB Institution not obligated to provide authorization forms/language or perform waiver/alteration determinations.

## Addressing Problems/Concerns

* Agreement Term/Section:Loss of Assurance or IRB Registration (V3.0, Section 7.2.1.3)
  + Versions 1.0/2.0:Relying Institution’s loss of Assurance or Reviewing IRB Institution’s loss of IRB registration results in immediate automatic termination of participation in the Agreement.
  + Version 3.0:Participation in Agreement for existing studies/activities may continue for grace period of 60 to 90 business days.
* Agreement Term/Section:Notification of Federal For-Cause Investigations (V3.0, Section 4.6.1)
  + Versions 1.0/2.0:No obligation to notify others in a reliance relationship of for-cause compliance investigations of the institution or its personnel by a federal research regulatory or funding agency.
  + Version 3.0:Reviewing IRB Institution and Relying Institution must notify one another of any for-cause compliance investigations of their institution or personnel by federal research regulatory or funding agencies related to the reviewed/exempted Research or potentially affecting the conduct or integrity of such Research, participant rights, or the Reviewing IRB/Reviewing IRB Institution’s authority or obligations.
* Agreement Term/Section:Withdrawal of Reviewing IRB from Ceded Review (V3.0, Section 2.5.2.2)
  + Versions 1.0/2.0:No mechanism for Reviewing IRB to withdraw from review.
  + Version 3.0:Reviewing IRB may withdraw from providing review/oversight for significant cause (e.g., ongoing and uncorrected failure by Relying Institution to comply with Agreement), with 60 business days’ prior written notice and explanation to Relying Institution.
* Agreement Term/Section:Reporting of Noncompliance in Connection with Exempt Research (V3.0, Sections 5.10, 6.13)
  + Versions 1.0/2.0:Agreement’s provisions on reporting of noncompliance do not apply to Exempt Research.
  + Version 3.0:Agreement’s provisions on reporting of noncompliance apply (to a limited extent) to Exempt Research.
* Agreement Term/Section:External Reporting of UAPs, Serious/Continuing Noncompliance, and Suspension/Termination of IRB Approval (V3.0, Sections 5.13.3, 6.16)
  + Versions 1.0/2.0:In addition to making any required reports to federal regulatory agencies (OHRP, FDA), Reviewing IRB/Reviewing IRB Institution makes any required reports to federal funding agencies (like NIH), state agencies, private sponsors, and other authorities.
  + Version 3.0:Reviewing IRB/Reviewing IRB Institution makes required reports to federal regulatory agencies (OHRP, FDA), but Relying Institution makes any required reports to federal funding agencies (like NIH), state agencies, private sponsors, and other authorities.
* Agreement Term/Section:Informal Dispute Resolution (V3.0, Section 4.6.2)
  + Versions 1.0/2.0:No obligation to try to resolve concerns about noncompliance with (breach of) the Agreement.
  + Version 3.0:Reviewing IRB Institution and Relying Institution must try to resolve such concerns. Sample informal dispute resolution options are provided. (No waiver or limitation of rights to sue or use other formal mechanisms.)