

# Frequently Asked Questions from Public Comments on SMART IRB Reliance Agreement Version 3.0

Public comments received on SMART IRB Reliance Agreement Version 3.0 included some questions and indicated some confusion regarding certain provisions in Version 3.0 and in Versions 1.0/2.0. This FAQ document addresses those questions and areas of confusion. In some cases, noted below, minor changes will also be made to the revised Version 3.0 to help clarify certain points.

One significant area of questions pertained to the plan for transitioning current Participating Institutions from Versions 1.0/2.0 to Version 3.0. **That transition plan has changed.** The first section of this FAQ document immediately below explains the new transition plan.

## Transition from Versions 1.0/2.0 to Version 3.0

### When Version 3.0 was initially posted for public comment, it included a notice on the top of the first page that all currently Participating Institutions would have to join Version 3.0 in order to continue participating in the Agreement. Is that still the case?

#### No, it will depend on the circumstances. In response to community feedback, the plan for transitioning to Version 3.0 has changed. As discussed in more detail below, in certain – but not all – instances, current Participating Institutions will need to join Version 3.0 in order to continue participating in the Agreement. However, Versions 2.0 and 1.0 will remain active for some current institutions.

Specifically:

##### All current Participating Institutions that are added to an ongoing instance of reliance or that participate in a new reliance request after the final Version 3.0 is issued (“goes live”) must join Version 3.0. In such cases, the Reviewing IRB Institution must also join Version 3.0.

##### Additionally, for ongoing instances of reliance or new reliance requests that will involve a federal agency that is new to SMART IRB (i.e., a federal agency other than NIH), all of the Participating Institutions involved in that reliance must join Version 3.0.

#### In all other cases, current Participating Institutions are *strongly encouraged* to join Version 3.0, but will not be required to do so. For example, a current Participating Institution already involved as a Relying Institution in an ongoing instance of reliance on the Version 3.0 go-live date may remain on the version that institution previously joined (Version 1.0 or 2.0) as long as no new federal agencies will be involved in the reliance, and does not need to join Version 3.0 unless/until that institution becomes involved in a new reliance request. Current Participating Institutions that nonetheless wish to transition to Version 3.0 in connection with ongoing reliance should contact their SMART IRB Ambassador for information about resources that may be available to assist with that transition.

#### Note that a current Participating Institution that either is required to or elects to transition to Version 3.0 in accordance with the above may, consequently, be under different versions of the Agreement with respect to different studies. A Reviewing IRB Institution may also, consequently, be under different versions of the Agreement with respect to different Relying Institutions in the same study. Participating Institutions will need to track which version of the Agreement applies to each study in which they are involved, and with respect to each reliance partner in that study. SMART IRB leadership will provide an overview of key operational differences between the terms of SMART IRB Agreement Versions 1.0/2.0 and the terms of the final Version 3.0 in order to assist Participating Institutions in identifying the differences between the versions that they will need to manage day-to-day. These complexities are the tradeoff for the flexibility that is permitted with the new transition plan.

### Can an institution that is new to the Agreement choose which version to join (Version 2.0 or 3.0)?

#### No. Once the final Version 3.0 is issued (“goes live:), Version 3.0 will be the only version of the Agreement available for new institutions to join.

### How does an institution (whether a current Participating Institution or a new institution) join Version 3.0?

#### An institution joins Version 3.0 by executing (signing) a Version 3.0 SMART IRB Joinder Agreement.

### Does executing a Version 3.0 SMART IRB Joinder Agreement mean that a current Participating Institution must demonstrate that it has had a quality assessment of its HRPP within the five years prior to the date of the Version 3.0 SMART IRB Joinder Agreement?

#### No. Current Participating Institutions do not need to demonstrate a quality assessment of their HRPP as long as their participation in the Agreement has been continuous since they initially joined Version 1.0/2.0.

## Joining the SMART IRB Reliance Agreement

### Is an institution required to have a human research protection program (“HRPP”) in order to join the Agreement?

#### An institution joining the Agreement is expected to have some way of ensuring human research protections in the human subjects research it conducts. As used in the Agreement, the term HRPP is intended to reference an institution’s way of ensuring these protections, however that may be accomplished. An institution need not have a formal accredited program or an IRB. Version 3.0 does not change anything in this regard. However, the revised Version 3.0 will include the following new substantive definition of HRPP to help clarify what is intended: “Human Research Protection Program or HRPP: An Institution’s policies, procedures, and oversight mechanisms for addressing human research protections.”

### Does the Agreement specify a minimum level of HRPP quality assessment that an institution with an IRB must perform to join the Agreement? If not, why not?

#### The Agreement requires any institution with an IRB to have undergone or at least initiated an assessment of the quality of its HRPP (which would include the IRB) before joining the Agreement. This is the case even if the institution does not plan on serving as a Reviewing IRB Institution. The assessment may be a third-party assessment or a self-assessment. The assessment does not need to involve or result in a formal certification or any other form of credential. With recognition that the scope and rigor of these assessments may vary considerably, the Agreement nonetheless intentionally does not mandate a particular type or form of assessment, in order to maximize opportunity for institutions to join the Agreement. However, if a Participating Institution has concerns about what quality assessment another institution performed, the Participating Institution can request that information from the other institution and make a decision about whether to participate in a reliance with that other institution. Version 3.0 does not change anything in this regard. Note that the HRPP quality assessment discussed here, which is a condition for a Reviewing IRB Institution to join the Agreement, is different from the obligation of a Relying Institution to have access to a compliance monitoring function or program for its specific Research, discussed under “*Compliance Monitoring by Relying Institutions*” below.

### If an institution has a different type of Assurance than an FWA, how can other Participating Institutions (particularly Reviewing IRB Institutions) become informed of any substantive differences in the terms or requirements of the Assurance from the terms/requirements of an FWA?

#### Version 3.0 permits institutions with any type of Assurance of compliance with the Federal Policy (not just an FWA) to join the Agreement. SMART IRB leadership is working with the federal agencies that grant other types of Assurances to provide guidance about the terms/requirements of their Assurances, or to direct where such guidance can be found. This effort is part of a broader discussion with the federal agencies about providing guidance to the SMART IRB community on agency-specific requirements in connection with initiation of reliance and determination of the Reviewing IRB (Mandated Processes), the conduct of reliance relationships once established (Mandated Policies), approval of research and consent forms, and conflict of interest processes, among other topics. More information on the development of this guidance will be forthcoming. In the meantime, Participating Institutions remain free to contact any federal agencies directly with questions.

### Why does Version 3.0 remove the requirement for institutions to provide institutional oversight of their exempt research as a condition for joining the Agreement?

#### Version 3.0 will no longer require institutions to provide institutional oversight of their exempt research as a condition of joining the Agreement because such requirement exceeds what is required by the Federal Policy and may present a barrier to entry to the Agreement or a burden for some institutions, particularly those that are not otherwise required by accreditation programs to provide such oversight. In practice, those Participating Institutions that elect to rely on other Participating Institutions for Exemption Determinations will have to have some mechanisms for their exempt research in order to be able to identify and communicate Local Considerations and Other Considerations relevant to the Federal Policy’s exemption criteria to the Reviewing IRB/Reviewing IRB Institution. Such Participating Institutions will also have to mechanisms in order to be able to meet the Agreement’s limited requirements for notification and reporting of noncompliance in connection with Exempt Research. (See the [**summary**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_SUMMARYOFCHANGES.docx) of the key changes made to Version 3.0 based on the public comments.) Given these requirements, there does not appear to be a benefit to requiring all Participating Institutions broadly to oversee their exempt research. In addition, a Participating Institution that is not comfortable working with another institution unless the latter has an oversight mechanism for its exempt research can inquire of the other institution what it has in place and can decline to enter reliance arrangements with the other institution in its discretion.

## Exemption Determinations and Exempt Research

### Why don’t the sections of the Agreement on conflicts of interest apply to Exemption Determinations?

#### The Federal Policy imposes only limited requirements for Exemption Determinations, including those determinations that are subject to Limited IRB Review. Conflict of interest information (such as information about an investigator’s conflicts of interest and any associated management plans) may be relevant to a Relying Institution’s decision whether or how to go forward with exempt research. However, such information is not relevant to the Federal Policy’s criteria for any of the exemptions. Nothing prevents a Relying Institution from applying its own conflict of interest policies to its exempt research locally, but the Agreement will not require the Relying Institution to provide conflict of interest information to the Reviewing IRB/Reviewing IRB Institution or require the Reviewing IRB/Reviewing IRB Institution to consider such information in performing an Exemption Determination. Version 3.0 does not change anything in this regard.

## Withdrawal of Reviewing IRB from Ceded Review

### What constitutes “significant cause” permitting a Reviewing IRB to withdraw from a Ceded Review?

#### Version 3.0 introduces a new right for Reviewing IRBs to withdraw from providing review and oversight of Research for a Relying Institution based on “significant cause.” An example of significant cause provided in the Agreement is a Relying Institution’s ongoing failure to comply with its obligations under the Agreement, when the Relying Institution is on notice of the failure and has not corrected it after a reasonable time. The Agreement intentionally does not contain an exhaustive list of what may constitute significant cause. However, as illustrated by the example, the primary intent of the provision is to address situations when the Reviewing IRB determines it cannot continue to serve in that role for a particular Relying Institution based on factors beyond the Reviewing IRB’s control, such as a breakdown in the relationship with the Relying Institution. In discussions with the community, the balance of views has been that a Reviewing IRB should not be able to withdraw from Ceded Review for a Relying Institution based on staffing or other resource changes or other factors occurring at the Reviewing IRB; rather, Relying Institutions have a reasonable expectation that a Reviewing IRB that agrees to oversee a study has the ability to serve in that role for the life of the study. A Reviewing IRB Institution that experiences a significant staffing or resource change or other issue affecting its ability to serve as a Reviewing IRB generally (for multiple Relying Institutions) can terminate its participation in the Agreement at any time (subject to obligations to work with its Relying Institutions to appropriately transition oversight of the Research it is overseeing). Version 3.0 also has a new “Force Majeure” provision underscoring that a Reviewing IRB is generally not excused from performing its obligations under the Agreement except in circumstances beyond its control. Public comments supported removing bankruptcy, insolvency, and dissolution of a Participating Institution as bases for excusal of performance under the Force Majeure provision.

### Is withdrawal of a Reviewing IRB from a Ceded Review for significant cause the same thing as a suspension or termination of IRB approval?

#### No. The withdrawal of a Reviewing IRB from a Ceded Review under the new withdrawal provision in Version 3.0 is distinct from and not by itself a suspension or termination of IRB approval for the Research within the meaning of the Federal Policy, FDA Clinical Investigation Regulations, or other potentially applicable regulations. The Agreement contemplates that such withdrawal could occur when a Relying Institution has failed to comply with the Relying Institution’s obligations under the Agreement. Such a failure does not necessarily mean that the Relying Institution has been noncompliant with the applicable regulations or with the Reviewing IRB’s determinations. For example, a Relying Institution may have repeatedly failed to provide conflict of interest information or information about Local Considerations/Other Considerations to the Reviewing IRB, which failure would constitute a breach of the Agreement but not necessarily noncompliance with the regulations. The Reviewing IRB may not identify any circumstances that warrant a suspension or termination of IRB approval but may still determine that it cannot continue to serve as a Reviewing IRB for the study for that Relying Institution and that it must withdraw from the Ceded Review. Of course, if the Reviewing IRB does identify circumstances that warrant a suspension or termination of IRB approval, the Reviewing IRB has the authority to take such action in addition to or in lieu of withdrawing from the Ceded Review.

### What is a “reasonable time” for the Relying Institution to correct its failure to comply with its obligations under the Agreement before a Reviewing IRB can withdraw from a Ceded Review?

#### The Agreement does not define “reasonable time,” as what is reasonable may vary depending on the particular circumstances, and the intent is to give flexibility for Participating Institutions to make this determination. The phrase “reasonable time” occurs in the Agreement in two other contexts as well: the time a Participating Institution has to share its findings of fact after an audit/investigation, and the time a Reviewing IRB must continue to oversee Research while oversight is being transitioned to another IRB. Each context in which the phrase is used is one in which there is no governing regulatory timeframe or requirement, and therefore flexibility has been prioritized.

## Consideration of Reliance Requests, Determination of Reviewing IRB, and Determination of Applicable Policies and Procedures

### What is the difference between a Mandated Process and a Mandated Policy?

#### Version 3.0 introduces two new defined terms, “Mandated Process” and “Mandated Policy,” to more efficiently reference certain federal department or agency requirements relevant to how reliance is initiated, how the Reviewing IRB is determined, and how a reliance relationship is conducted once established. These requirements are referenced in Versions 1.0/2.0 as well, but a goal of Version 3.0 is to streamline the references and to clarify and emphasize that when such requirements apply, they take precedence over the terms of the Agreement and govern in the event of any conflict with such terms. As used in Version 3.0, a “Mandated Process” is a federal department or agency process for initiating reliance or determining the Reviewing IRB. When a Mandated Process exists, it may dictate which Reviewing IRB is used for a study or group of studies. [NIH’s Single IRB Policy](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) is an example of a Mandated Process. Among other things, NIH’s Single IRB Review Policy describes how the Reviewing IRB is proposed and accepted for research that is subject to that policy. A “Mandated Policy” is a federal department or agency policy or procedure governing the conduct of a reliance relationship once it is established. For example, some agencies have policies or procedures requiring notification of certain events or information to their IRBs (when serving as Reviewing IRBs) within certain timeframes.

### Who determines, and how will Participating Institutions know, whether/when a Mandated Process or Mandated Policy applies?

#### Whether a Mandated Process or Mandated Policy applies will be determined by the terms of the process or policy itself. For example, NIH’s Single IRB Policy indicates that it applies to “non-exempt human subjects research protocols funded by the NIH that are carried out at more than one site in the United States.” Most Mandated Processes and Mandated Policies will attach based on the funding source of the Research. Participating Institutions can check with their grants/contracts offices as to whether any Mandated Processes apply to their Research, as such processes will typically be referenced as part of the terms of a funding award. With respect to Mandated Policies, Participating Institutions can check with human subjects officials at the relevant funding agency to find out whether any Mandated Policies apply. SMART IRB leadership is also discussing with the federal agencies how guidance could be provided to the SMART IRB community on agency-specific requirements in connection with both Mandated Processes and Mandated Policies, what to do if multiple agencies are involved in Research but their Mandated Processes or Mandated Policies conflict, and how Mandated Policies in particular could be made more visible to the community. Participating Institutions are also encouraged to communicate with one another through their POCs about whether and when any Mandated Processes or Mandated Policies apply.

### What if a Mandated Process applies but does not stipulate every aspect of how reliance is initiated or the Reviewing IRB is determined?

#### In the event a Mandated Process applies but only speaks to certain aspects of how reliance is initiated or the Reviewing IRB is determined, the relevant Participating Institutions should follow the processes laid out in the Section 3 of the Agreement (specifically Section 3.2 of Version 3.0). Note that based on public comments, Version 3.0 introduces greater flexibility in Section 3.2 by making the referenced processes suggestions rather than requirements.

### Why does the suggested process in the Agreement for initiating reliance limit the Overall PI to making a Reliance Request at the Overall PI’s institution of primary employment/affiliation?

#### The suggested process in the Agreement (Versions 1.0/2.0 as well as Version 3.0) for making a Reliance Request is for the Overall PI to make the request within the Participating Institution where the Overall PI is “primarily” employed or affiliated. The suggested process assumes that, in general, Research will take place at an Overall PI’s primary institution or that the primary institution will otherwise be engaged in the Research and therefore that the primary institution will want to be aware of and approve of the request. However, that assumption may not always be correct. Because Version 3.0 makes the process for Reliance Requests a suggestion rather than a requirement, Participating Institutions have flexibility to permit an Overall PI to make a Reliance Request within the Participating Institution where the Overall PI is secondarily or otherwise employed or affiliated, with the expectation that this would only be done when the secondary institution is engaged in the Research or there is some other reason for the Overall PI to direct the request to that secondary institution. Whether the Overall PI makes a Reliance Request to the Overall PI’s primary or secondary or other institution, the suggested process is for the institution to make the determination about the appropriateness of reliance and to determine how outreach to other involved institutions will occur.

### Under the suggested process in the Agreement for initiating reliance, can an Overall PI or a Participating Institution still use a designee to assist them with the process?

#### Yes. Version 3.0 removes the references in Section 3 of the Agreement to the Overall PI or a Participating Institution relying on the assistance of a designee to communicate about Reliance Requests, but the reason is only to streamline the Agreement, as prior feedback from the community on Section 3 generally had been to reduce the amount of process detail laid out in the Agreement. Nothing in Version 3.0 is intended to preclude the Overall PI or a Participating Institution from relying on a designee to assist with the Reliance Request process. Note also that Version 3.0 makes the process for Reliance Requests a suggestion rather than a requirement, so Participating Institutions have flexibility to alter the process they use as they see fit.

### Must a potential Relying Institution share its Assurance or information about its Assurance with all other Participating Institutions discussing a Reliance Request?

#### Nothing in the Agreement requires a potential Relying Institution to share a copy of its Assurance during the discussion of a Reliance Request (though other Participating Institutions could ask for a copy). Versions 1.0/2.0 do require a potential Relying Institution to disclose to the other Participating Institutions involved in discussion of a Reliance Request (including the Reviewing IRB Institution and the other Relying Institutions) whether the potential Relying Institution “checks the box” on its Assurance or otherwise extends its Assurance to all of its Research regardless of funding source. Version 3.0 narrows this requirement so that a potential Relying Institution only needs to disclose the scope of its Assurance to the Reviewing IRB Institution, and Version 3.0 moves this requirement from Section 1.1 (where it lives in Versions 1.0/2.0) to Section 3.2.1 (Version 3.0). This requirement to provide information about the scope of the institution’s Assurance to the Reviewing IRB Institution is the only part of the Reliance Request process as described in Version 3.0 that remains a requirement rather than a suggestion.

### Why does the Agreement make the SMART IRB SOPs applicable if Participating Institutions do not document what policies and procedures will apply to the conduct of their reliance relationship?

#### As under Versions 1.0/2.0, under Version 3.0 the SMART IRB SOPs are strongly encouraged to be followed but are not mandatory. In the absence of any applicable Mandated Policies, Participating Institutions may agree among themselves to follow different policies and procedures (called “Other Policies” in Version 3.0) for the conduct of their reliance relationships, with the understanding that the Agreement terms govern if there is a conflict between a provision of an Other Policy and the Agreement terms. However, Version 3.0 specifies that if Participating Institutions do not document their choice of policies and procedures, then they will be held to the SMART IRB SOPs. Version 3.0 introduces this additional provision in order to ensure that if Participating Institutions fail to communicate with one another about the policies and procedures they will follow in the conduct of their reliance relationship, they have a clear rule for what policies and procedures will apply.

## Qualifications of Personnel and IRB Members

### Does the Agreement require Participating Institutions to conduct background checks on their Personnel and IRB Members?

#### No. The Agreement only requires that Participating Institutions ensure that their Personnel and IRB Members (if applicable) have undergone any background checks that their institution requires. If a Participating Institution does not require such background checks of its Personnel or IRB Members, then it would not be necessary to conduct them. Version 3.0 does not change anything in this regard, but the revised Version 3.0 will make a minor language edit to help clarify what is intended.

## Notification of Compliance Investigations by Federal Agencies

### Are Participating Institutions required to notify one another of routine/not-for-cause compliance inspections by OHRP, FDA, and other federal agencies?

#### Version 3.0 introduces a new obligation for Participating Institutions to notify one another of any *for-cause* compliance investigation of their institution or IRB by OHRP, FDA, NIH, or another federal human subjects research regulatory or federal funding agency, when such investigation is related to Research under Ceded Review or for which an Exemption Determination was provided under the Agreement or when the conduct or integrity of the Research, the rights or welfare of Research participants, or the Reviewing IRB/Reviewing IRB Institution’s authority or ability to perform Covered Activities under the Agreement could be affected. This obligation does not extend to routine or other not-for-cause compliance investigations or inspections by these federal agencies. However, separate provisions of the Agreement discussed below (Versions 1.0/2.0 as well as Version 3.0) require Participating Institutions and their Personnel to notify one another of communications they have with such federal agencies regarding (among other things) unanticipated problems and regulatory compliance concerns regarding the Research. Therefore, to the extent a routine or other not-for-cause compliance investigation or inspection results in communicated findings or concerns about such matters, Participating Institutions will be informed of the matters and be able to ask further questions or take steps to ensure protection of Research participants. There is no obligation on Participating Institutions to notify one another of routine or other not-for-cause investigations or inspections outside of these circumstances.

## Notification of Communications with Federal Agencies

### What are Participating Institutions’ obligations to notify one another of communications they or their Personnel have with federal agencies?

#### The Agreement requires Participating Institutions to notify one another promptly of certain communications the institutions have with such federal agencies, namely communications regarding unanticipated problems, suspension or termination of IRB approval, serious and/or continuing noncompliance, and/or other regulatory compliance concerns regarding Research that is the subject of a Ceded Review or Exemption Determination under the Agreement. The obligation is to provide notification of communications to which the Participating Institution is a party (either sending or receiving), so an institution would not be in breach of the obligation with regard to communications of which it was not aware. In the case of Relying Institutions, however, they must also require their Personnel to notify the Reviewing IRB/Reviewing IRB Institution of such communications that the Personnel have with federal agencies on these matters. Version 3.0 does not change anything in regard to these obligations except to include such communications that a Participating Institution or Relying Institution Personnel send as well as such communications that they receive.

## Standard for IRB Review and Oversight

### Why does the Agreement make the Federal Policy the applicable standard for IRB review and oversight when Participating Institutions do not agree on a different standard of review?

#### Version 3.0 states that for Research that is not subject to the Federal Policy (directly or through an Assurance) or other federal human subjects regulations/policies or the FDA Clinical Investigation Regulations, the Reviewing IRB will review and oversee the Research in accordance with the standards of the Federal Policy unless the Reviewing IRB and Relying Institution(s) mutually agree on a different standard of review. (Note that this provision is intended only to address what criteria the Reviewing IRB will use for initial and continuing review and approval of the Research and for determinations about informed consent and assent. The provision expressly states that it does not require application of the Federal Policy’s requirements for reporting unanticipated problems, serious/continuing noncompliance, and suspension/termination of IRB approval to federal agencies.) Participating Institutions are free to elect a different standard for review of such Research. Version 3.0 introduces this provision in order to ensure that if Participating Institutions fail to communicate with one another about the standard of review, they have a clear rule for what standard will apply.

### If a Reviewing IRB Institution has “unchecked the box” on its Assurance, what standard of review applies to its review and oversight of Research on behalf of a Relying Institution?

#### From a regulatory perspective, a Reviewing IRB’s review and oversight of Research on behalf of a Relying Institution must meet the requirements of the *Relying Institution’s* Assurance, not the Assurance of the Reviewing IRB Institution. Therefore, whether a Reviewing IRB Institution has “unchecked the box” on its Federalwide Assurance, for example, is not relevant to the standard of review that the Reviewing IRB must follow in reviewing Research for a Relying Institution. If the Relying Institution checks the box on its Federalwide Assurance, the Reviewing IRB must apply the Federal Policy in conducting its review. Version 3.0 does not make any changes in this regard. Version 3.0 only adds language addressing what standard of review applies when the Research is not subject to any federal human subjects regulations/policies or the FDA Clinical Investigation Regulations. In other words, if a Relying Institution has “unchecked the box” on its Federalwide Assurance, and the Research is not subject to the FDA Clinical Investigation Regulations or any other federal human subjects regulations/policies, then the Reviewing IRB must follow the review and approval and informed consent and assent criteria in the Federal Policy unless it and the Relying Institution agree on a different standard of review.

## Access to Policies of Reviewing IRB/Reviewing IRB Institution

### How do Relying Institutions obtain access to policies and procedures of Reviewing IRBs/Reviewing IRB Institutions?

#### Reviewing IRBs/Reviewing IRB Institutions are required to make their applicable policies and procedures for review and oversight of Research and for Exemption Determinations available to a Relying Institution upon request. The Agreement does not specify the mechanism by which the policies and procedures must be made available; Reviewing IRBs/Reviewing IRB Institutions have flexibility to share the policies and procedures by whatever means they choose. A best practice for many Reviewing IRBs/Reviewing IRB Institutions may be to proactively make their applicable policies and procedures available to relevant Relying Institutions rather than waiting for a request. However, as not all Reviewing IRBs/Reviewing IRB Institutions make their policies and procedures publicly available (such as on a public access website), the Agreement does not mandate doing so. Version 3.0 does not change anything in this regard. Note that Mandated Policies (of Reviewing IRBs/Reviewing IRB Institutions that are federal departments or agencies) will generally be publicly available through the relevant agency.

## Consent Forms/Consent Scripts

### What sections of consent forms/consent scripts may a Relying Institution request to customize?

#### In order to streamline the Agreement and optimize flexibility, Version 3.0 removes from the Agreement the list of specific consent sections that are expected to be customizable. It is still expected that these sections will generally include the sections on costs that will be incurred by Research participants (and the availability of payment or reimbursement for such costs), the availability of treatment and compensation for Research-related injuries, and local contact information. However, Reviewing IRBs can permit customization of other sections, and under Version 3.0 Relying Institutions can request customization of any sections necessary to address legal or regulatory issues, federal department- or agency-specific requirements, or institutional requirements. Any customizations requested by a Relying Institution remain subject to review and approval by the Reviewing IRB.

### What are a Relying Institution’s obligations with respect to the section(s) of a consent form addressing Research-related injuries?

#### The Agreement requires a Relying Institution to ensure consistency between the provisions of any applicable contract between the Relying Institution and a sponsor/funder of the Research that address financial coverage for Research-related injuries and the section(s) of the IRB-approved Research consent form addressing Research-related injuries. A Relying Institution can do this by comparing the contract with the consent form and working with the sponsor/funder of the Research as necessary to ensure they are consistent. In performing this comparison, the relevant version of the consent form that must be consistent with the sponsor/funder contract is the version of the consent form that is ultimately approved by the Reviewing IRB (as it is the IRB-approved version that will be provided to Research participants). For Relying Institutions that may not have processes in place to operationalize this obligation, or where negotiation of the contract with the sponsor/funder may happen in parallel with the Reviewing IRB’s review and approval of the Research and the consent form, the Agreement provides an alternative to performing the consistency review: the Relying Institution can include a provision in its contract with the sponsor/funder stating that in the event of any inconsistency between the contract and IRB-approved consent form, any injury coverage language in the consent form that is more protective of human subjects than the language in the contract will control. Although ideally a consent form does not promise a Research participant more in terms of injury coverage than what the sponsor/funder agrees contractually to cover, the noted contract provision places the risk of such disconnect on the sponsor/funder, effectively requiring the sponsor/funder to honor any greater commitment that was made in the consent form. Version 3.0 does not change anything regarding the Relying Institution’s obligations, but the revised Version 3.0 will make minor language edits to help clarify what is intended.

## Audits by Reviewing IRBs/Reviewing IRB Institutions

### May a Reviewing IRB/Reviewing IRB Institution conduct an audit of a Relying Institution without cause?

#### The Agreement contemplates that a Reviewing IRB/Reviewing IRB Institution may audit or investigate a Relying Institution with regard to an “allegation or matter” relating to covered Research. The language of the Agreement does not preclude a not-for-cause audit by a Reviewing IRB/Reviewing IRB Institution; however, the expectation is that such audits or investigations will generally occur when there is cause. Not-for-cause auditing is generally expected to be conducted by the Relying Institution itself, as Relying Institutions are required to have access to a compliance monitoring function or program or have some other means of monitoring and auditing their own compliance, including conducting not-for-cause audits as appropriate. Version 3.0 does not change anything in this regard.

## Compliance Monitoring by Relying Institutions

### What is a Relying Institution’s obligation under the Agreement to monitor its Research?

#### The Agreement requires a Relying Institution to maintain, implement, or otherwise have access to a compliance monitoring function, program, or service that can audit (on both a for-cause and not-for-cause basis) the Relying Institution’s and its Personnel’s compliance with human subjects protections and other applicable requirements in the conduct of Research. The program, function, or service could be either internal or external to the Relying Institution, such as an internal compliance program or an external auditing service. The purpose of this requirement is to help ensure that Relying Institutions have the ability to monitor and report to the Reviewing IRB on their own compliance in carrying out specific studies covered under the Agreement. Note that the Relying Institution’s obligation is not to monitor its Research but rather to have the *ability* to do so. The requirement is waivable with the agreement of the Reviewing IRB/Reviewing IRB Institution. A Reviewing IRB might consider waiving the requirement in connection with lower risk Research, or where the Reviewing IRB intends to conduct compliance audits itself, for example. Note also that the contemplated monitoring ability is for *compliance* monitoring, not medical monitoring, consent monitoring, or other types of monitoring that a Relying Institution or Reviewing IRB might propose or require for particular studies. There is also no requirement for a Relying Institution to assess or monitor the overall quality of its HRPP (only Reviewing IRB Institutions must assess their HRPP quality, as a condition of joining the Agreement, as described under “*Joining the SMART IRB Reliance Agreement*” above). Version 3.0 does not change anything regarding the Relying Institution’s obligation to have access to compliance monitoring, but the revised Version 3.0 will make minor language edits to help clarify what is intended, including to clarify that the requirement is not for a quality assessment of the Relying Institution’s HRPP.

## HIPAA

### How does Version 3.0 of the Agreement change the provisions of the Agreement related to HIPAA?

#### Version 3.0 does three things in regard to the Agreement’s HIPAA provisions: (1) it makes minor language edits to underscore that HIPAA compliance in connection with the Research is ultimately the legal/regulatory responsibility of the HIPAA Covered Entity Relying Institution; (2) it makes organizational edits to consolidate all provisions relating to HIPAA in one section of the Agreement; and (3) it shifts initial control of who provides HIPAA authorizations and who makes HIPAA waiver/alteration of authorization determinations from the Reviewing IRB/Reviewing IRB Institution to the Relying Institution. Item (1) was of particular importance to the federal agencies, and item (3) reflects feedback from both the federal agencies and the broader community that the Relying Institution as the ultimately responsible HIPAA Covered Entity should make the threshold decisions about which party will provide the authorizations and make the waiver/alteration determinations on which it will rely. Apart from these changes, Version 3.0 does not substantially change the HIPAA provisions from Versions 1.0/2.0.

### Does the shift in initial control of who provides HIPAA authorizations and who performs HIPAA waiver/alteration of authorization determinations to the Relying Institution remove any flexibility that is currently in the Agreement?

#### No. Version 3.0 provides a default, which is that a Relying Institution that is a HIPAA Covered Entity will provide its own HIPAA authorizations and perform or otherwise obtain its own HIPAA waiver/alteration of authorization determinations. However, if a Relying Institution does not or prefers not to do these things, then Version 3.0 provides that the Reviewing IRB/Reviewing IRB Institution (unless it is a Federal Institution) will do them. Participating Institutions should communicate with one another on these matters when a Research protocol is submitted to the Reviewing IRB/Reviewing IRB Institution or, at the latest, at the same time the Relying Institution provides its Local Considerations/Other Considerations to the Reviewing IRB/Reviewing IRB Institution.

### What if Research is being conducted through a consortium or other group that specifies particular rules about who provides HIPAA authorizations and who performs HIPAA waiver/alteration of authorization determinations for that Research?

#### There is sufficient flexibility in the Agreement for Participating Institutions to accommodate these external requirements. For example, if a consortium requires the Reviewing IRB to provide the authorization form or perform the waiver/alteration of authorization determination, and a Relying Institution wants to participate in that consortium, then the Relying Institution would simply not provide its own authorization form or perform the waiver/alteration of authorization determination, so that there is no tension with the consortium’s requirements.

### If a Relying Institution provides a stand-alone HIPAA authorization (to be provided to Research participants as a separate document from the informed consent document), who checks to see whether the content of the authorization is consistent with the content of the informed consent?

#### Although important, and a best practice, such a “consistency check” is not a regulatory responsibility. Therefore, as in the current Agreement, and in the interest of flexibility, Version 3.0 does not assign this task to either the Relying Institution or the Reviewing IRB/Reviewing IRB Institution. A Reviewing IRB/Reviewing IRB Institution may wish to read a stand-alone HIPAA authorization provided by the Relying Institution. Version 3.0 permits a Reviewing IRB/Reviewing IRB Institution to identify concerns about the content of the authorization from a human subjects perspective to the Relying Institution and requires the Relying Institution to work with the Reviewing IRB/Reviewing IRB Institution to address those concerns. Such concerns could include inconsistency with the content of the informed consent document and any resulting lack of clarity or understandability for the Research Participants. Reviewing IRBs/Reviewing IRB Institutions are encouraged to communicate their expectations for consistency of stand-alone HIPAA authorizations with informed consent documents to Relying Institutions and to work with Relying Institutions to discuss how such consistency may be assessed.

### Do the references to “waivers” of authorization in the HIPAA provisions of the Agreement include so-called “partial waivers” of authorization often granted in connection with Research participant recruitment and screening activities?

#### Yes. The references to waivers include any waivers of authorization that may be requested or granted for any stage of the Research.

### Why do the Agreement provisions on HIPAA focus on whether the involved Participating Institutions are HIPAA Covered Entities rather than on the particular Research in question?

#### HIPAA does not apply to Research, but rather to Covered Entities. Some Participating Institutions involved in an instance of Research may be HIPAA Covered Entities, and others may not. The Participating Institutions that are not HIPAA Covered Entities do not have or acquire any legal/regulatory obligations under HIPAA in connection with the Research. For example, Relying Institutions that are not HIPAA Covered Entities are not obligated to obtain HIPAA authorizations from their Research participants, even when other Relying Institutions that are HIPAA Covered Entities are obligated to do so. A Reviewing IRB/Reviewing IRB Institution will need to know which Relying Institutions are HIPAA Covered Entities and which are not so that it is clear on which Relying Institutions’ behalf the Reviewing IRB/Reviewing IRB Institution may be asked to provide HIPAA authorizations or perform HIPAA waiver/alteration of authorization determinations. Version 3.0 explicitly requires Relying Institutions that are HIPAA Covered Entities to so inform the Reviewing IRB/Reviewing IRB Institution. Relying Institutions should provide this information to the Reviewing IRB/Reviewing IRB Institution when a Research protocol is submitted to the Reviewing IRB/Reviewing IRB Institution or, at the latest, at the same time the Relying Institution provides its Local Considerations/Other Considerations to the Reviewing IRB/Reviewing IRB Institution.

### Why doesn’t the Agreement discuss privacy boards?

#### Under HIPAA, a privacy board is an alternative body to an IRB that, like an IRB, is authorized to review and grant waivers/alterations of HIPAA authorizations. The Agreement does not discuss privacy boards because such boards would not be necessary where there is an IRB that is willing to perform HIPAA waiver/alteration of authorization determinations. Although some institutions may refer to their IRBs as “privacy boards” when the IRB is performing a HIPAA waiver/alteration of authorization determination, under HIPAA IRBs are permitted to perform such determinations by virtue of the fact that they are IRBs (assuming they meet IRB composition and related requirements for an IRB under the Federal Policy or the FDA Clinical Investigation Regulations). A Relying Institution that elects to perform or obtain its own HIPAA waiver/alteration of authorization determinations may do so through its own IRB or privacy board or through an external privacy board it engages for that purpose. If the Relying Institution does not perform or obtain its own such determinations, the Reviewing IRB (unless it is at a Federal Institution) performs them, in its capacity as an IRB. Note that privacy boards are not relevant in relation to HIPAA authorizations; the only function/authority of a privacy board under HIPAA is in relation to waiver/alteration of authorization determinations.

## Optional Indemnification Addendum

### Is a Participating Institution required to join the optional Indemnification Addendum or to enter any separate indemnification agreements with other Participating Institutions in connection with joining the Agreement?

#### No. The decisions whether to join the Indemnification Addendum and whether to enter any separate indemnification agreements with other Participating Institutions are up to each Participating Institution. As is currently the case, indemnification agreements are optional. The Indemnification Addendum is offered only to facilitate and streamline contracting for Participating Institutions who want to enter indemnification agreements in connection with Covered Activities.

### When can a Participating Institution join the optional Indemnification Addendum?

#### A Participating Institution can join the optional Indemnification Addendum at any time after the institution joins the Agreement. There is no time limit on when the institution can join the Indemnification Addendum.

### If a Participating Institution does not join the optional Indemnification Addendum, can it enter other, separate indemnification agreements with other Participating Institutions?

#### Yes. A Participating Institution is always free to enter separate indemnification agreements with other Participating Institutions. Version 3.0 does not change anything in this regard; it offers the Indemnification Addendum as an option but does not preclude institutions from entering their own indemnification agreements.

### If a Participating Institution wishes to join the optional Indemnification Addendum, is it required to join it with each new reliance arrangement or only once?

#### A Participating Institution only needs to join the Indemnification Addendum once, which indicates its willingness to apply the Indemnification Addendum to all reliance relationships under the Agreement that are initiated after that joinder (except to the extent the institution negotiates a more limited scope with any of the other Indemnification Participating Institutions it works with). A list of institutions that have joined the Indemnification Addendum will be posted on the SMART IRB website.

### If a Participating Institution joins the optional Indemnification Addendum but the other Participating Institutions with which that institution is involved in Covered Activities do not join the Indemnification Addendum, does the Indemnification Addendum apply to the Covered Activities?

#### No. The Indemnification Addendum will only apply with respect to Participating Institutions that join the Indemnification Addendum (called “Indemnification Participating Institutions”). An Indemnification Participating Institution that is considering entering a reliance relationship with another Participating Institution that will not join the Indemnification Addendum can seek to negotiate a separate indemnification agreement with that other Participating Institution, can decide to forego any indemnification agreement, or can decide not to enter the reliance relationship (just as currently a Participating Institution is free to refuse to enter a reliance relationship with other Participating Institutions who are not willing to sign any separate indemnification agreement).

### If Participating Institutions join the optional Indemnification Addendum, does the Indemnification Addendum apply to all of the Research in which those Participating Institutions subsequently become involved under the Agreement?

#### Yes, unless those Indemnification Participating Institutions agree among themselves that the Indemnification Addendum will only apply to specific such studies. Indemnification Participating Institutions can agree to limit the scope of studies to which the Indemnification Addendum will apply with respect to those institutions. Indemnification Participating Institutions might wish, for example, to only apply the Indemnification Addendum to interventional or other higher risk studies in which they are involved and not to apply it to relatively lower risk studies. In cases where a more limited scope is agreed by Indemnification Participating Institutions, such institutions remain free to enter any other separate agreement providing for indemnification or similar arrangements for allocation of financial liability or responsibility resulting from participation in the Covered Activities that they agree are outside the scope of the Indemnification Addendum.

### If Participating Institutions join the optional Indemnification Addendum, does the Indemnification Addendum supersede any separate indemnification agreements they may have previously entered?

#### As explained in the [**summary**](https://smartirb.org/assets/files/V3.0_2ndPUBLICCOMMENT_SUMMARYOFCHANGES.docx) of the key changes made to Version 3.0 based on the public comments, the Indemnification Addendum will not supersede any separate indemnification agreements entered by Indemnification Participating Institutions with respect to Covered Activities initiated prior to the Effective Date of the Indemnification Addendum. Such separate indemnification agreements will continue to apply to Covered Activities initiated under those separate agreements.

### Does the optional Indemnification Addendum exclude from an Indemnifying Party’s/Responsible Party’s obligations those Losses that are attributable to the Indemnified Party’s/Other Party’s own negligence, recklessness, willful misconduct, breach of the Agreement, or failure to comply with laws and regulations?

#### Yes. The Indemnification Addendum accomplishes this exclusion by specifying that an Indemnifying Party/Responsible Party is only obligated to indemnify/reimburse “to the extent” that Losses are attributable to the Indemnifying Party’s/Responsible Party’s or its IRB’s, trustees’, directors’, officers’, or Personnel’s negligence, recklessness, willful misconduct, breach of the Agreement, or failure to comply with laws and regulations. In other words, the Indemnifying Party/Responsible Party is only on the hook in the first instance to the extent a Loss is attributable to its or its IRB’s, trustees’, directors’, officers’, or Personnel’s specified acts or failures. To the extent a Loss is attributable to the Indemnified Party’s/Other Party’s own specified acts or failures (or those of its trustees, directors, officers, Personnel, and IRB members), the Indemnifying Party/Responsible Party has no obligations with respect to that portion of the Loss. This structure incorporates the concept of proportionality, in that a given Loss may be attributable to (caused by) more than one party, and is intended to limit a party’s indemnification/reimbursement obligations to the portion of the Loss it caused. Indemnification provisions may be drafted in various ways to accomplish this intent. The one in the Indemnification Addendum represents a consensus of the SMART IRB Harmonization Steering Committee Indemnification Working Group as to a streamlined approach that avoids the need to state carveouts.

### As used in the optional Indemnification Addendum, does “negligence” include negligent use or disclosure of information?

#### “Negligence” could include any act or omission that constitutes negligence under underlying law, including underlying case law. The Indemnification Addendum is deliberately general in this regard and does not attempt to describe or single out particular potential forms of negligence, just as it does not enumerate examples of breaches of the Agreement or failure to comply with laws/regulations that could give rise to an indemnification/reimbursement obligation. Use or disclosure of Confidential Information, for example, could constitute negligence and/or a breach of the Agreement’s provisions on Confidential Information, but that determination would depend on underlying law and on the particular facts.

### Why does the optional Indemnification Addendum include indemnification/reimbursement for failure to comply with applicable law or regulation in the performance of the Indemnifying Party’s/Responsible Party’s obligations under the Agreement?

#### The purpose of including failure to comply with applicable law or regulation as a distinct basis for indemnification/reimbursement apart from breach of the Agreement is to enable the Indemnified Party/Other Party to require indemnification/reimbursement directly for the failure without having to also claim / show a specific breach of the Agreement. This ability may be of particular significance to Relying Institutions in situations when the Reviewing IRB fails to adhere to applicable regulations in its review or to apply the regulations in its approval of a consent, for example.

### Does the optional Indemnification Addendum provide for indemnification/reimbursement of regulatory or administrative fines and penalties?

#### No. The Indemnification Addendum defines covered “Losses” that are eligible for indemnification/reimbursement as damages, judgments, liabilities, costs, and expenses resulting from (private) third-party claims, suits, and demands. These types of losses are more commonly the focus of indemnification provisions and more likely to be acceptable to a broad range of institutions. Moreover, regulatory or administrative actions in the context of human subjects research are relatively less likely to be directly financial in nature (e.g., fines) than in other contexts and more likely to involve restrictions on participation of institutions or individuals in research activities or restrictions on funding opportunities, an indirect financial loss). Therefore, the consensus of the SMART IRB Harmonization Steering Committee Indemnification Working Group was to focus the Indemnification Addendum on Losses resulting from third-party claims.

### Under the optional Indemnification Addendum, which individuals are protected as Indemnified Parties/Other Parties?

#### The revised Version 3.0 clarifies that Indemnified Parties/Other Parties include individuals who are trustees, directors, officers, Personnel, and IRB members. The term “Personnel” includes any member of an institution’s team who is involved in conducting an instance of Research, and is intentionally broad (it can include employees, agents, faculty, medical/professional staff, students, volunteers, and others). Using the term Personnel in lieu of listing specific categories of individuals who may be involved in Research avoids inadvertently leaving out any categories of individuals, as different institutions may have different categories or descriptions.

### Under the optional Indemnification Addendum, can an Indemnifying Party settle a claim without the consent of the Indemnified Party?

#### Under the Indemnification Addendum, an Indemnifying Party has the right to agree to *financial* terms of settlements of a claim or other Loss without needing the consent of the Indemnified Party. Because the Indemnifying Party will have to pay financial settlements, the Indemnifying Party is given full control over the financial terms. However, an Indemnifying Party must obtain the consent of the Indemnified Party prior to agreeing to any *non-financial* settlement or to any *non-financial* term of settlement (including but not limited to any acknowledgement of liability or responsibility).

### The Agreement and the optional Indemnification Addendum make clear that Federal Institutions will not indemnify/reimburse other Participating Institutions. Given this, can Federal Institutions still join the Indemnification Addendum and be indemnified/reimbursed by other Participating Institutions?

#### As drafted, the Indemnification Addendum allows Federal Institutions to join it and receive indemnification/reimbursement (i.e., to be Indemnified Parties/Other Parties). SMART IRB leadership is discussing with federal agency representatives whether any Federal Institutions would agree to be ineligible from the Indemnification Addendum’s protections.

### Do indemnification/reimbursement obligations that arise under the optional Indemnification Addendum continue after an Indemnification Participating Institution’s participation in the Indemnification Addendum terminates?

#### Yes. An Indemnification Participating Institution’s obligations under the Indemnification Addendum to indemnify or reimburse for Losses survive any termination of the institution’s participation in the Indemnification Addendum or the Agreement. Survival of these obligations is addressed in the Survival provision of the Agreement itself (see revised Version 3.0, Section 8.14). There is no time limit on how long the indemnification/reimbursement obligations survive; the survival period is intentionally not limited to the underlying statute(s) of limitations applicable to third-party claims, as a third party may bring a claim outside the statute of limitations and an Indemnified Party/Other Party may incur costs in connection with such claim (such as defense costs to assert the applicable statute(s) of limitations) that should still be covered under the Indemnification Addendum.

### How does the optional Indemnification Addendum relate to indemnification agreements or provisions that a Relying Institution may have negotiated with a sponsor/funder in connection with the Research (such as in a clinical trial agreement)?

#### The optional Indemnification Addendum does not replace, preclude, or otherwise interfere with indemnification agreements or provisions that a Relying Institution may negotiate with a Research sponsor/funder. The Indemnification Addendum applies only to the Indemnification Participating Institutions (not to the Research sponsor/funder) and covers only Losses arising out of the reliance relationship. Indemnification agreements or provisions negotiated with a Research sponsor/funder, such as in a clinical trial agreement, would apply only to the parties to that agreement and to claims or losses arising out of that agreement, which would generally not include the Reviewing IRB Institution or the IRB’s review or determinations. A Relying Institution that elects to join the Indemnification Addendum could have indemnification obligations and rights both under the Indemnification Addendum and under its clinical trial agreement with a Research sponsor/funder, each covering different losses/claims or covering similar losses/claims but in regard to different parties. For example, such a Relying Institution that failed to comply with applicable law in its conduct of Research could have indemnification obligations both to the Reviewing IRB Institution under the Indemnification Addendum and to the Research sponsor/funder under the clinical trial agreement.