Purpose of Form: This document clarifies common misunderstandings about the SMART IRB national reliance initiative. For additional information, you may watch the SMART Talk on this topic (https://smartirb.org/smart-talks/)

To Be Great Is to Be Misunderstood: Common Myths about SMART IRB Debunked

Myth about SMART IRB	The True Story
Myth: SMART IRB is an IRB.	SMART IRB is not an IRB; rather, it is a federally funded initiative designed to make multisite research work better for both IIRB/HRPP personnel and research teams. SMART IRB provides free resources in support of single IRB such as: • Reliance Agreement (SMART IRB Agreement): The legal framework that may be used to facilitate IRB reliance arrangements among Participating Institutions. The Agreement streamlines IRB review and oversight for multisite studies and eliminates the time and effort: of negotiating IRB authorization agreements for each study. • SMART IRB Ambassadors: Nationwide IRB/HRPP experts are available to assist institutions in joining and implementing the SMART IRB Agreement. • Reliance System: Allows institutions to join the Reliance Agreement and maintain their Institutional Profile. Provides a centralized system for investigators and institutions to request, track, and document reliance arrangements for their studies. • Resource Library: Browse, search, and sort SOPs, templates, checklists, tools, guidance, and more. These flexible resources are ready to use, easy to adapt, and designed to support IRB/HRPP staff, investigators, and study teams. • Education and Training: A range of free education and training materials to support IRB/HRPP professionals and researchers with single IRB, such as SMART Talks (conversations with experts about emerging issues, persistent challenges, lessons learned, and best practices), Boot Camp (expert-led sessions on what institutions need in place for single IRB review), and Symposia (advanced training on single IRB topics). • Harmonization: SMART IRB seeks to harmonize approaches by promoting the alignment of policies and processes and the adoption of common forms, practices, and workflows. Guidance, recommendations, and templates are collaboratively developed and informed by community feedback.
Myth: There is a fee to join SMART IRB.	Because SMART IRB is a federally funded program, there is NO COST to join the SMART IRB Agreement or to use any of SMART IRB's resources.

Version date: 07/26

Myth about SMART IRB	The True Story
Myth: SMART IRB means the reliance platform.	SMART IRB encompasses much more than the **Reliance System** (see above for a summary of some of the resources and tools that comprise SMART IRB). The Reliance System was developed to support adoption and use of the SMART IRB Agreement. The Reliance System is used for two purposes: 1) it allows institutions to join the Reliance Agreement and maintain their Institutional Profile; and 2) it provides a centralized system for investigators and institutions to request, track, and document reliance arrangements for their studies.
Myth: The SMART IRB Reliance System is required.	While institutions must use the **Reliance System** to join the SMART IRB Agreement and maintain institutional details relevant to their participation in the Agreement, it is optional for organizations to use the Reliance System to document reliance arrangements for their studies. The Reliance System is offered as a free, central option to assist with coordinating and documenting reliance, but institutions may choose to use other methods or systems.
Myth: NIH requires the use of SMART IRB.	Although NIH (specifically the National Center for Advancing Translational Sciences) funded the development of the SMART IRB platform, NIH does not require use of the SMART IRB Agreement (or any other SMART IRB resources) for NIH-funded research that must use a single IRB arrangement.
Myth: The SMART IRB Agreement can be used only for NIH-funded research.	The SMART IRB Agreement can be used for single IRB arrangements regardless of funding source. The research may be externally or internally funded; the Agreement does not limit the scope of what is covered based on funding source or status.
Myth: The language in the SMART IRB Agreement can be modified.	The language within the SMART IRB Agreement cannot be modified. Modifications will nullify and void the Agreement. This is distinct from documenting how **flexible terms** within the SMART IRB Agreement will be implemented.
Myth: Flexible terms were introduced with V3.0 of the SMART IRB Agreement and have made the agreement more difficult to use.	Flexibility has been part of the SMART IRB Agreement since its inception. SMART IRB recognized the need to harmonize single IRB processes while remaining flexible to cover a wide range of institutions. In the years following the initial development of the SMART IRB Agreement, institutions frequently used "flexible terms addenda" to outline items such as indemnification, insurance, etc. With the launch of SMART IRB Agreement Version 3.0, the SMART IRB team created optional resources (i.e., the **Implementation Checklist** and **Letter of Acknowledgement**) to help institutions efficiently document these items.

Myth about SMART IRB	The True Story
Myth: If my institution signs onto the SMART IRB Agreement, we will be required to provide IRB review for other organizations.	Unless required by policy or as a condition of participation in a study or consortium, each **Participating Institution** elects on a case-by-case basis whether to cede or provide IRB review for any study or studies under the SMART IRB Agreement, as well as whether to participate in any ceded review agreed upon by other Participating Institutions.
Myth: Only one institution that is part of a group of affiliated institutions with separate FWAs needs to join SMART IRB (in other words, SMART IRB allows daisy chaining reliance).	To participate in the SMART IRB Agreement, each institution that has a separate FWA must join individually (i.e., must execute its own Joinder Agreement to the SMART IRB Agreement). This is required to clearly identify each FWA-holding institution that wishes to participate and document that each institution is directly agreeing to the terms of the SMART IRB Agreement. Use **this decision tree** to help you determine how an affiliate of another institution may join and participate in the SMART IRB Agreement.
Myth: The SMART IRB Agreement does not support social, behavioral, and education research.	The SMART IRB Agreement was developed to support a wide range of research, including social, behavioral, and education research (SBER). Many institutions use the SMART IRB Agreement for single IRB arrangements for all their research, including SBER.
Myth: To join the SMART IRB Agreement, organizations are also required to execute an indemnification agreement.	The SMART IRB Agreement does not require institutions to indemnify one another. The optional **SMART IRB Indemnification Addendum** was made available with SMART IRB Agreement V3.0, to offer a harmonized approach to indemnification for institutions that wish to sign it.

Myth about SMART IRB	The True Story
Myth: The SMART IRB Agreement must be re-executed if the institutional official has changed.	Once executed, an institution's Joinder Agreement to the SMART IRB does not need to be re-executed.
Myth: Organizations are required to use SMART IRB Standard Operating Procedures to govern the reliance arrangement.	While use of the **SMART IRB SOPs** is strongly encouraged, it is not required. SMART IRB acknowledges that: 1) some institutions have existing policies and procedures that they apply or that they prefer to apply to IRB reliance relationships and 2) in some cases, institutions are required, as part of funding conditions or participation in clinical trial networks or other programs, to use a particular set of policies and procedures to govern the reliance relationship. Institutions can still use the SMART IRB Agreement and other SMART IRB resources to support and document reliance in these situations. Participating Institutions may use their own policies and procedures for the reliance relationship if doing so would not render them in violation of any term of the SMART IRB Agreement, and they must agree that if a provision of their own policies and procedures conflicts with a term of the Agreement, then the SMART IRB Agreement will govern. For example, if a Participating Institution's policies and procedures prohibit disclosure of IRB minutes to an institutions, the SMART IRB Agreement's provision regarding access to minutes must apply. However, in the instance when a Participating Institution is required by funding conditions or participation in a network/program to use particular policies and procedures for reliance, those policies and procedures will override any conflicting requirements of the SMART IRB Agreement. In all cases, Participating Institutions involved in a research study under the SMART IRB Agreement must communicate with one another in writing regarding which policies and procedures will apply to such study(ies).
Myth: The SMART IRB Letter of Acknowledgement (LOA) must be signed.	SMART IRB does not require signature on the **SMART IRB Letter of Acknowledgment (LOA)**. However, some organizations do require signed LOAs. The SMART IRB LOA is one of the ways institutions execute SMART IRB reliance arrangements, particularly when not using the **SMART IRB Reliance System** or the **IRB Reliance Exchange (IREx)**.
Myth: My institution does not maintain an IRB so we can't join SMART IRB.	An institution that does not have an IRB can join the SMART IRB Agreement, provided they satisfy the other terms of eligibility; see section 1 of the Agreement (note: section 1.2 will not apply to the institution in this case). Participating in the SMART IRB Agreement will allow the institution to rely on the IRB of another Participating Institution for review of research in which the first institution is engaged. However, the institution may not review research for other Participating Institutions. Note: if your institution normally relies on the IRB of another institution for review, and you wish to use that IRB for the review of research covered under the SMART IRB Agreement, then that institution would also need to join the SMART IRB Agreement.

Myth about SMART IRB	The True Story
Myth: My institution cannot join SMART IRB because it is not yet AAHRPP accredited.	AAHRPP accreditation **is not required** to participate in the SMART IRB Agreement. If an institution has an IRB or is an independent IRB organization, then the institution must have undergone or initiated an assessment of the quality of its human research protection program (HRPP) within the 5 years prior to joining SMART IRB (section 1.2 of the SMART IRB Agreement). SMART IRB does not proscribe the nature of this assessment. There are many ways an institution might fulfill this criterion; examples include: • Third-party assessment • Self-assessment • Accreditation through an external organization • OHRP's QA Self-Assessment Tool • FDA's Self-Evaluation Checklist for IRBs • AAHRPP Evaluation Instrument for Accreditation with self-documentation of satisfaction of requirements • Another approach with a comparable, comprehensive scope of review of the HRPP, including assessment of the IRB • Depending on its scope, an audit of the institution's IRB by a federal agency, with no major issues identified and any minor issues corrected/resolved, may also be sufficient to satisfy this requirement. The SMART IRB Agreement provides that Participating Institutions may obtain information about how any other Participating Institution satisfied this HRPP quality assessment requirement prior to determining whether to participate in a ceded review with that institution. If you have questions about how to fulfill this eligibility criterion, please **connect with an ambassador** or **contact us**.
Myth: SMART IRB resources, like the Communication Plan, cannot be modified.	Unlike the language within the SMART IRB Agreement itself, institutions are welcome to modify many other resources that SMART IRB provides, including the **Communication Plan for Single IRB Review**. SMART IRB provides a variety of checklists, FAQs, templates and SOPs in its **Resource Library** for institutions to ADOPT and ADAPT to meet their needs.
Myth: The SMART IRB Agreement cannot be used to cover reliance arrangements for exempt human subjects research.	The SMART IRB Agreement was designed to cover all IRB determinations, including exempt, limited review, expedited, and full (convened) IRB review and is fully consistent with the 2018 Revised Common Rule.

Myth about SMART IRB	The True Story
Myth: The SMART IRB Agreement does not require Reviewing IRBs to consider any Local Considerations, Other Considerations, and other local information communicated to it by Relying Institutions.	The SMART IRB Agreement requires a Reviewing IRB to take into account any local requirements communicated to it by the Relying Institution in connection with the study. These may include applicable state and local laws and regulations; institutional policies, standards or other local factors (including local ancillary reviews and restrictions on use and disclosure of PHI); and applicable federal laws and regulations other than human subjects protection regulations that may affect the study. An example of other potentially applicable federal laws and regulations is 42 CFR Part 2, regarding the confidentiality of certain substance abuse treatment records. If a study involves use/disclosure of such records, the Relying Institution would be expected to communicate to the Reviewing IRB any requirements applicable to its site under these regulations. The SMART IRB Agreement also requires Relying Institutions to identify and communicate to the Reviewing IRB requirements of any applicable federal laws or regulations or of relevant federal departments or agencies that are not readily apparent from the IRB submission for the research or that are specific to the Relying Institution that would affect the conduct by or approval of the research on behalf of the Relying Institution.
Myth: The SMART IRB Agreement always requires the Reviewing IRB to be responsible for reporting events (e.g., serious or continuing noncompliance or unanticipated problems) to federal agencies.	The default position in the SMART IRB Agreement is that the Reviewing IRB, with support of its institution as applicable, will draft and make the report and will provide the Relying Institution with an opportunity to review and comment on the report prior to its submission to the external authority. The Agreement allows the Relying Institution to make its own additional report; in such case, the Relying Institution will provide a copy of that report to the Reviewing IRB. Alternatively, the Reviewing IRB and involved Participating Institutions may agree on an alternate arrangement, whereby the Relying Institution drafts and makes the report or the Reviewing IRB and Relying Institution jointly make the report.
Myth: The SMART IRB Agreement requires Reviewing IRBs to review the congruence of any federal grant application/proposal with the research protocol submitted to the IRB.	SMART IRB Agreement V3.0 includes a grant congruence review provision, because congruency review may be required by laws/regulations other than the Common Rule or other federal rules (such as state laws) or by any type of funding agencies or sponsor. The provision is only triggered if such laws or regulations or any funding agencies or sponsors require congruence review. However, at the request of federal agencies, SMART IRB Agreement V3.0 provides that federal agencies, when serving as the Reviewing IRB, are not required to and will not perform a grant congruence review and that in such reliance arrangements, the responsibility for that review (where required) will remain with the Relying Institution.