SMART TALK

A Community Forum to Explore Issues Surrounding Single IRB Review

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, grant number 3UL1TR002541-04S2.

What Is SMART Talk?

An approximately monthly forum with:

- Presentations on topics relevant for single IRB review
- Q&A on topic presented as well as questions submitted when participants register

Open and free to anyone with interest

Upcoming sessions

October: No SMART Talk → SMART IRB Symposium instead

November: Impact of Single IRB on HRPPs

December: TBD

FYIs

Please provide feedback by completing the survey – a link will be posted in chat and emailed.

A recording of this talk will be posted on the SMART IRB website

A link to the talk will be sent to those who registered for the talk when it is posted

If you have any questions for the panelists, please use the chat function or Q&A function to submit them

What Is SMART IRB?

SMART IRB is…

A federally funded project to support institutions and researchers in the implementation of single IRB

SMART IRB provides…

A master IRB reliance agreement

An Online Reliance System to initiate and track reliance

Other resources free to institutions and researchers

SMART IRB is NOT…

An IRB

An electronic system for Reviewing IRBs to receive studies for review

If We Don’t Answer Your Questions Today…

Reach out to a SMART IRB Ambassador

https://smartirb.org/ambassadors/

Aaron Kirby
Harvard Catalyst

Ada Sue Selwitz
University of Kentucky

Carissa Minder
Washington University in St. Louis

Stacey Goretzka
Medical University of South Carolina

Kathy Lawry
AAHRPP

Lubabah Helwani
University of California, Los Angeles

Nichelle Cobb
AAHRPP

Polly Goodman
Harvard Catalyst

Key Resources

IF YOU ARE NEW TO SINGLE IRB:
2023 SMART IRB Boot Camp

This online session, held February 7 & 9, provided training for IRB and HRPP personnel on successful implementation of the sIRB review model and demonstrated how to leverage SMART IRB resources to achieve that success. Watch session recordings and download slides.

- Slides and videos available
- Day 1: https://smartirb.org/assets/files/Day1_FINAL_2023SMARTIRBBootcamp.pdf
- Day 2: https://smartirb.org/assets/files/Day2_FINAL_2023SMARTIRBBootcamp.pdf

Harmonization Steering Committee Recommendations

https://smartirb.org/harmonization/

- Ancillary Review
- Conflict of Interest
- Post-Approval Auditing for Studies Subject to Single IRB Review
- Single IRB Continuing Review Process
- Single IRB Review: Responsibilities Associated with the Review of Study Personnel
- Reportable Events
- Institutional Profile
- Protocol-specific Document
- Fees and Costing Models under NIH sIRB Policy
- Institution v. IRB Responsibilities Guidance

Local considerations recommendations posted for comment until **September 30, 2023**

NEW Working Group: SMART IRB Reliance for Exemptions

Prior SMART Talks

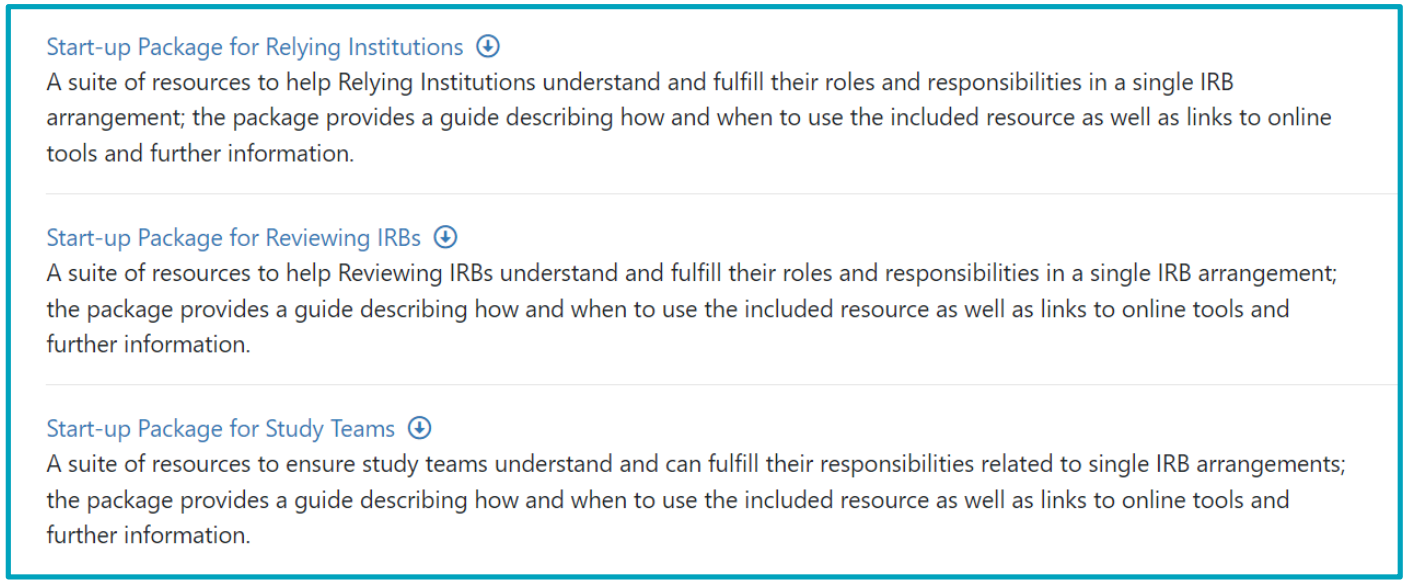
Start-Up Packages	Implementing the Agreement	Reviewing IRBs	Relying Institutions	Getting Started
Online Reliance System	Resources for IRB/HRPPs	**SMART Talk Forum**	sIRB Boot Camp	Training Study Teams

- All have been recorded since September 2019
- Available at https://smartirb.org/irb-admin/
- July 2023: Exploring the Financial Aspects of Single IRB, https://vimeo.com/848496007
- November 2022: A Conversation with the FDA and OHRP about Single IRB, https://player.vimeo.com/video/773359200
- February 2021: sIRB Issues Related to Planned Emergency Research, https://player.vimeo.com/video/513922852

Start Up Packages at smartirb.org/resources/

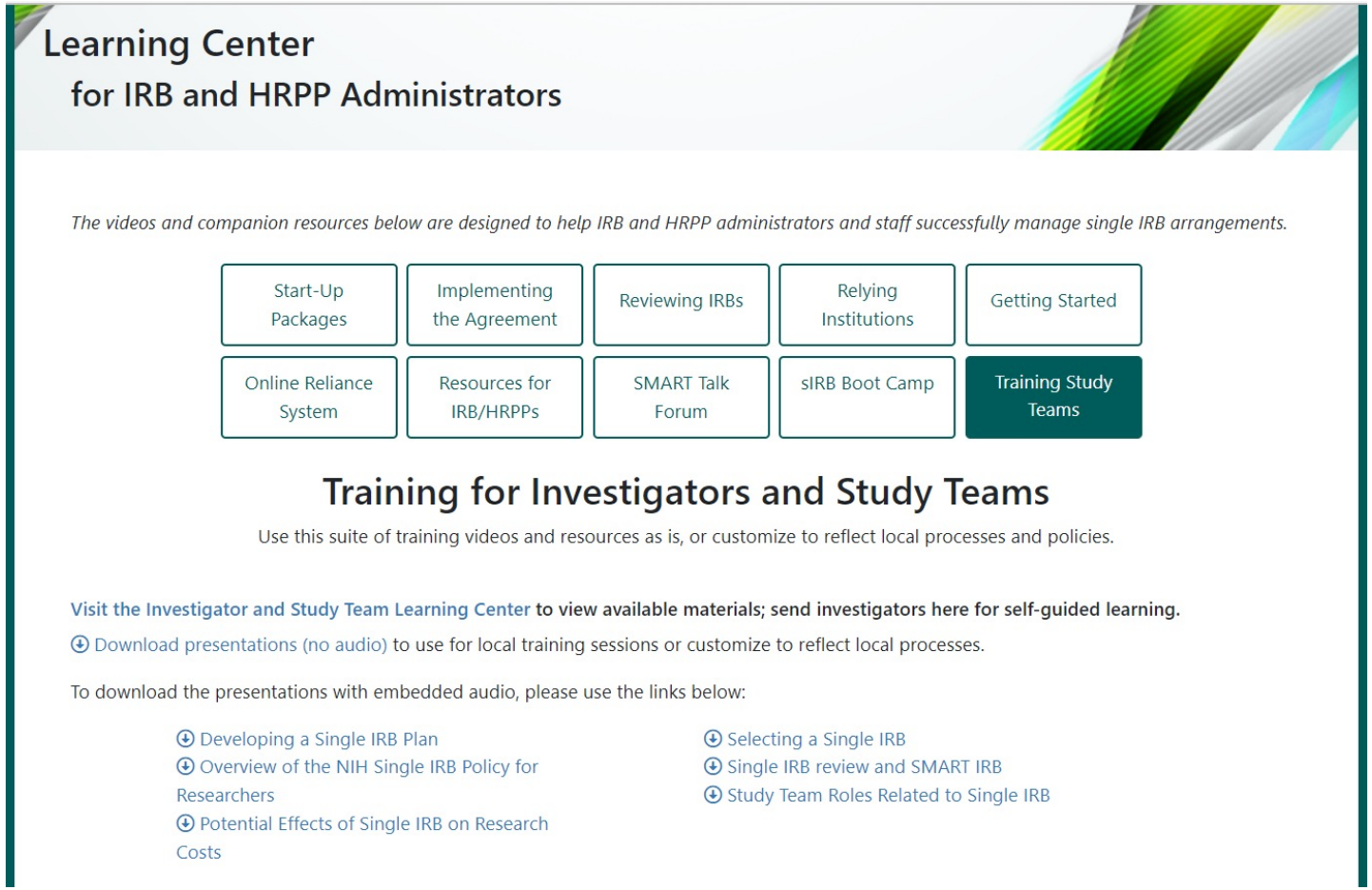
These packages contain a suite of resources based on role: Study Teams, Reviewing IRBs, and Relying Institutions. Also found in the SMART IRB Learning Center.

Each package provides a guide describing how and when to use the included resource as well as links to online tools and further information.



Training and Education for Investigators and Study Teams

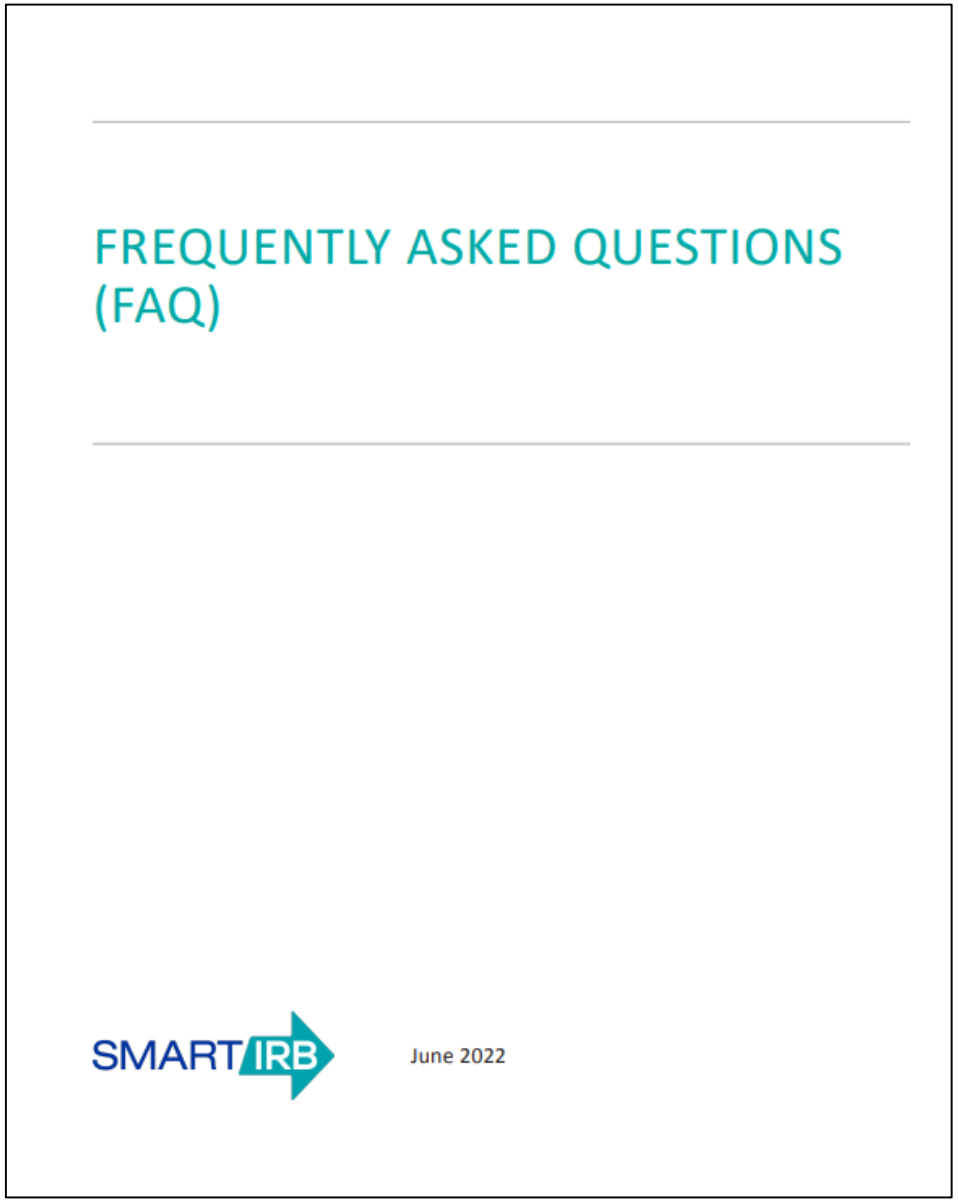
These can be helpful for IRB/HRPP administrators new to single IRB as well!



FAQs

Frequently asked questions covering eligibility, how to join, agreement provisions, and other important topics.

https://smartirb.org/assets/files/faq.pdf



SMART IRB SOP Manual

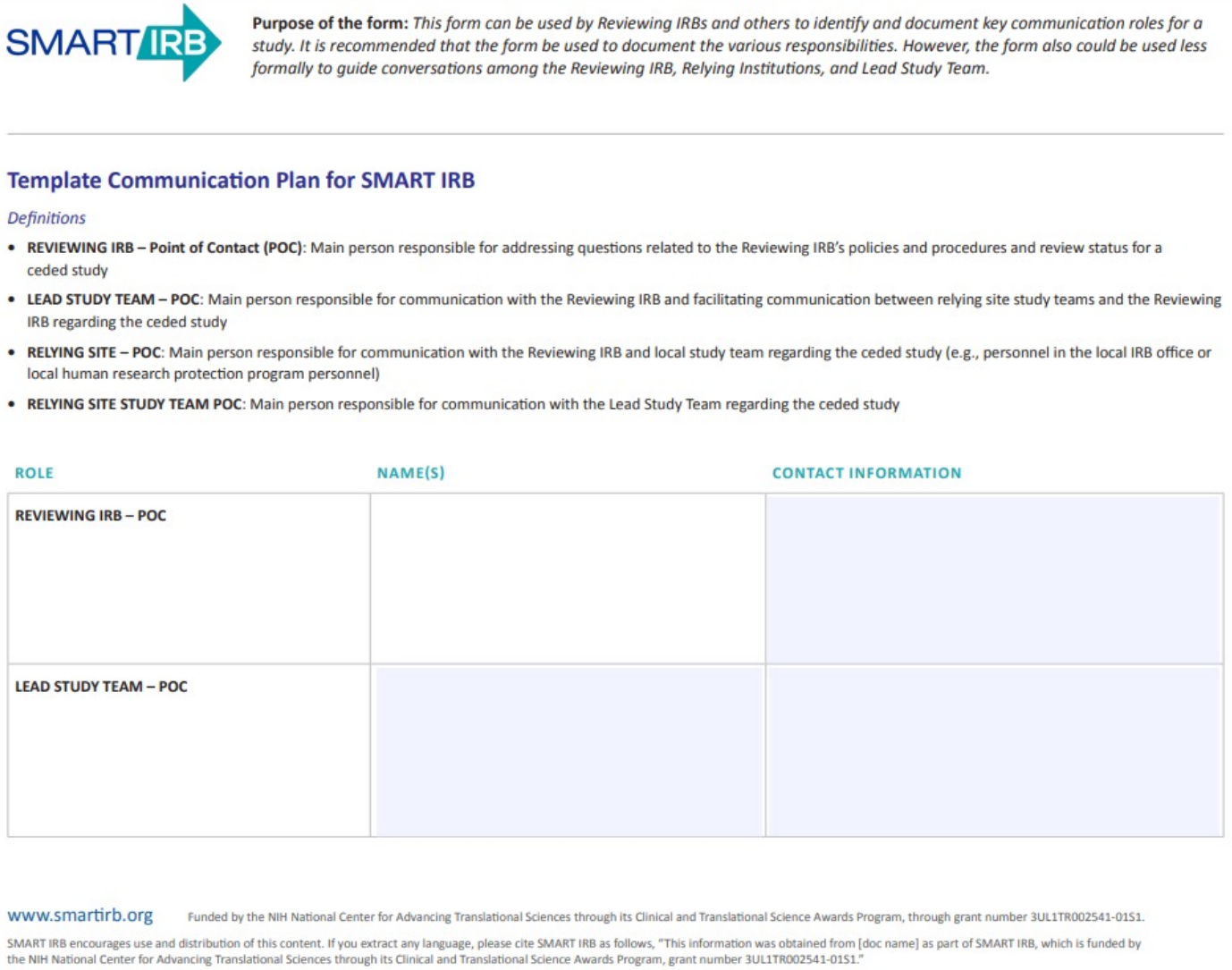
Standard operating procedures (SOPs) for establishing and implementing reliance provide clarity during the review and conduct of research using the SMART IRB Agreement.

https://smartirb.org/assets/files/SMART_IRB_SOP-090816.pdf

Communication Plan for Single IRB Review

Institutions can use this template to document key communication roles, such as submitting initial and continuing reviews, amendments, and reportable events to the Reviewing IRB; providing conflict of interest management plans to the Reviewing IRB; and providing IRB-approved documents and communicating Reviewing IRB determinations to relying site study teams.

https://smartirb.org/assets/files/Communications_Plan_Form.pdf



SMART IRB

Purpose of the form: *This form can be used by Reviewing IRBs and others to identify and document key communication roles for a study. It is recommended that the form be used to document the various responsibilities. However, the form also could be used less formally to guide conversations among the Reviewing IRB, Relying Institutions, and Lead Study Team.*

Template Communication Plan for SMART IRB

Definitions

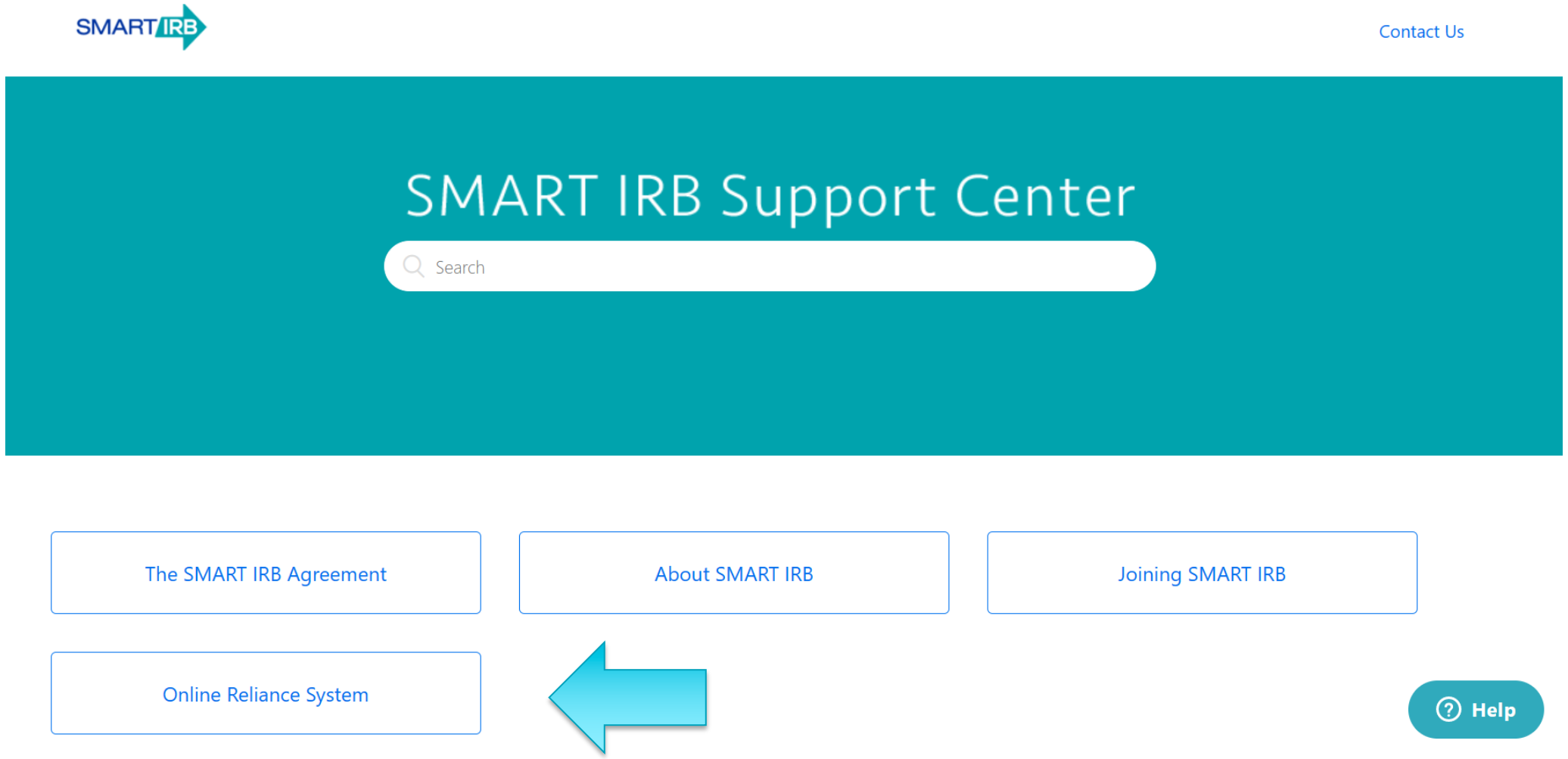
- **REVIEWING IRB – Point of Contact (POC)**: Main person responsible for addressing questions related to the Reviewing IRB's policies and procedures and review status for a ceded study
- **LEAD STUDY TEAM – POC**: Main person responsible for communication with the Reviewing IRB and facilitating communication between relying site study teams and the Reviewing IRB regarding the ceded study
- **RELYING SITE – POC**: Main person responsible for communication with the Reviewing IRB and local study team regarding the ceded study (e.g., personnel in the local IRB office or local human research protection program personnel)
- **RELYING SITE STUDY TEAM POC**: Main person responsible for communication with the Lead Study Team regarding the ceded study

ROLE	NAME(S)	CONTACT INFORMATION
REVIEWING IRB – POC		
LEAD STUDY TEAM – POC		

www.smartirb.org

Funded by the NIH National Center for Advancing Translational Sciences through its Clinical and Translational Science Awards Program, through grant number 3UL1TR002541-01S1.

https://support.smartirb.org/hc/en-us



Reconsidering Local Considerations: Recommendations for Harmonization

Today's panelists:

- **Nichelle Cobb**, Senior Advisor, SMART IRB; Senior Advisor for Strategic Initiatives, Association for the Accreditation of Human Research Protection Programs

- **Lubabah Helwani**, SMART IRB Ambassador; Principal Analyst, UCLA

SMARTIRB.org

Working Group on Local Considerations

SMART IRB Harmonization Efforts

- A major focus of the SMART IRB project is to harmonize the diverse approaches institutions apply to implementing single IRB review by promoting the alignment of policies and processes and the adoption of common forms and identification of common practices and workflows
- A Harmonization Steering Committee (HSC) provides leadership for the effort and includes membership from regulatory and government agencies, academia, independent IRBs, hospitals, and non-profits
- The HSC proposes and supports working groups that bring together experts across the community to propose recommendations on different topics

Local Context Harmonization Working Group Membership

Nichelle Cobb (AAHRPP) - Co-Lead	Lubabah Helwani (UCLA) - Co-Lead
John Baumann (Indiana U)	Kim Summers (UTSWHC)
Jenni Beadles (MGB)	Janelle Maddox-Regis (JHU)
David Forster (WCG IRB)	Eric Mah (UCSD)
Julie Moore (MGH)	Jessica Ripton (BCH)
Valery Gordon (NCATS)	Ada Sue Selwitz (U of KY)
Tiffany Gommel (NIH)	Emily Serdoz (Vanderbilt/IREx)
Stacey Goretzka (MUSC)	Shannon Sewards (Harvard)
Megan Kasimatis Singleton (JHU)	

Local Context Working Group

Charge: Evaluate and update currently available local context resources and provide best practices for the communication of and review of local context between relying institutions and the reviewing IRB for sites being reviewed under a reliance agreement.

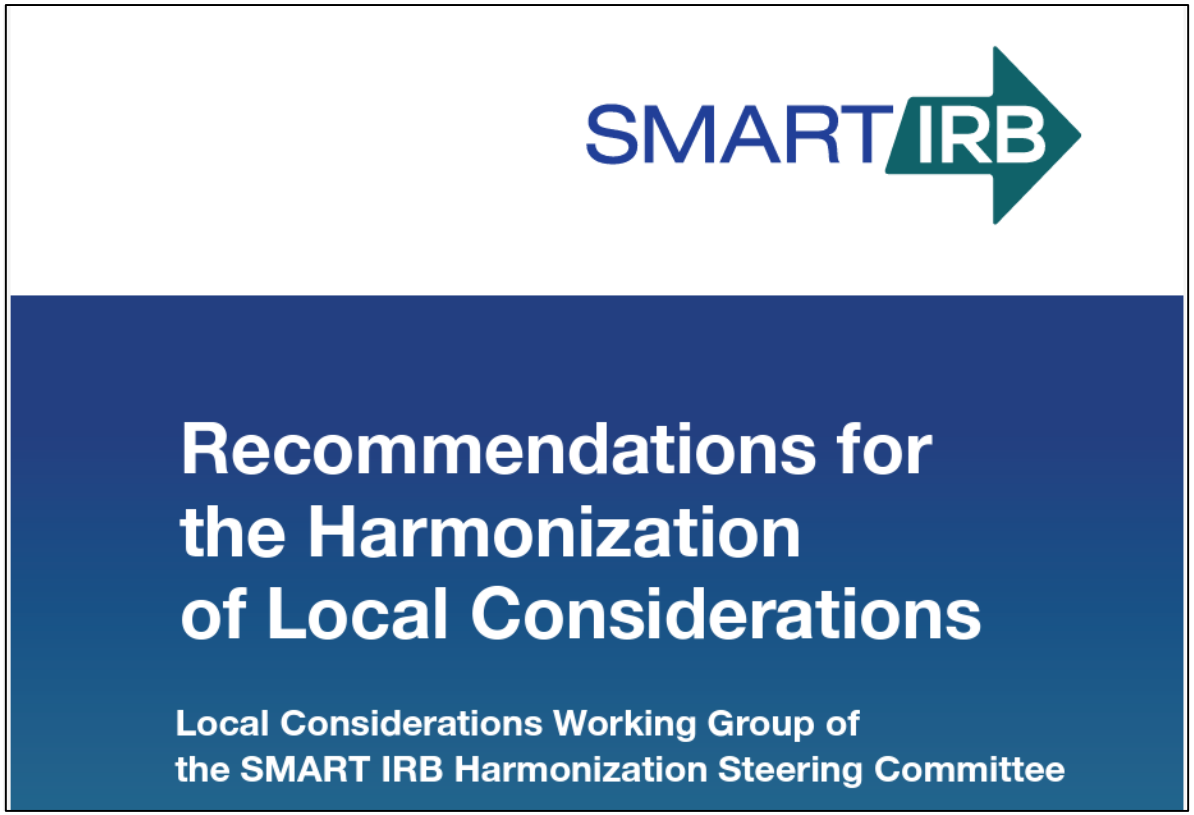
Local Context Working Group Considerations

- Evaluate and update current SMART IRB local context forms – Institutional Profile & Protocol Specific Document.
- Develop a potential workflow for how local context should be communicated between Relying Institutions and the Reviewing IRB.
- Define what variations between sites may be considered local context vs. those requiring an amendment such differences in standard of care (SOC) among sites, consent procedures, and sites open/closed to accrual.
- Consider how changes to local context should be communicated when the study is underway.

Comment on the Recommendations!

How to Review and Comment

- Go to https://smartirb.org/harmonization/
- Download and review the recommendations
- Complete the survey to provide feedback **by September 30, 2023**



Background

Regulatory Considerations

- Federal single IRB (sIRB) requirements (e.g., Common Rule and NIH policy) highlight the need for Relying Institutions to communicate information to the reviewing IRB to ensure appropriate oversight for each institution, often referred to as local context
  - The phrase “local context” is frequently used but does not appear in regulations
- The need to collect local consideration information is based on the interpretation of the Common Rule [45 CFR 46.107(a)] and FDA regulations [21 CFR 56.107(a)], which require IRBs to be sufficiently qualified through the experience and expertise of its members (professional competence) and the diversity of its members to be sensitive to such issues as “community attitudes”.
  - Additionally, IRBs are required to be “able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice.”

The SMART IRB Agreement

- The SMART IRB Agreement requires:
  - Relying Institutions to communicate to the Reviewing IRB "the requirements of any applicable state or local laws, regulations, institutional policies, standards, or other local factors, including local ancillary reviews, relevant to the Research ("Local Considerations") that would affect the conduct or approval of the Research at the Relying Institution".
  - the Reviewing IRB to consider any local considerations communicated to it by Relying Institutions.
- The SMART IRB Working Group used the term *local consideration* rather than *local context* because the SMART IRB Agreement uses that phrase, but viewed *local considerations* and *local context* to be interchangeable

Single IRB Review and Local Considerations

- Many Reviewing IRBs have forms and processes to collect local considerations information from Relying Institutions
  - What information Reviewing IRBs collect, when they obtain the information, and how they assessed the information varies across IRBs
- Relying Institutions vary in whose responsibility it is to provide information and verify information provided to Reviewing IRBs

The Working Group identified 3 key challenge areas for local context

Definition of local considerations (aka local context).

The type and detail of information collected to address local considerations.

Assessing local considerations throughout the life of a study.

The Working Group updated documents and created new ones

Document updates and new support documents

- Institutional Profile (updated)
- Study-Specific Document (updated - formerly Protocol-Specific Document)
- Local Considerations Information Guidance Table **(new)**
- Local Considerations Throughout the Life of a Study **(new)**
- Considerations for Investigators Writing Multi-Site Protocols **(new)**
- Single IRB Review Case Study: Addressing Variation in Institutional Assent Policies **(new)**
- Template Checklists for Reviewing IRBs and Relying Institutions to Identify When to Address Local Considerations after Initial Approval of a Study **(new)**

The Working Group made recommendations for harmonization in 3 areas

Area #1: What local considerations are

- How local considerations are defined
- How to distinguish between what should be standard IRB review practice versus what constitutes a local consideration

Local Considerations and Standard IRB Review Practice

- The Working Group distinguished between standard IRB review practice and local considerations
- The standard IRB review practice requires IRBs to determine if a study meets the criteria for IRB approval as outlined under applicable regulations
- Local considerations are issues that are unique about, or specific to, a Relying Institution that the Reviewing IRB needs to be aware of in order to conduct an adequate review of that site as opposed to what a Reviewing IRB should take into account to assess the study as a whole (i.e., standard IRB review practice)

Example	Standard IRB Review Practice	Local Consideration
Research study includes experimental drugs that could adversely affect a pregnancy	Determining how to minimize reproductive risks from drugs that can affect pregnancy, such as what forms of contraception would be acceptable	Any limits a Relying Institution may impose on what contraception it would be willing to provide to research subjects enrolled at its site (e.g., because of religious beliefs or practices) and what language it requires to be included in the informed consent about contraception
Subject selection and enrollment	Ensuring subject selection is equitable and that informed consent documents and forms provide information in a language understandable to the subject or the legally authorized representative. Whether vulnerable subjects are likely to be enrolled in the study, and additional safeguards that may be needed to protect the rights and welfare of these subjects	Participants or populations who might not be identified explicitly in a research protocol or IRB application and who could be enrolled at a site or whose records or biospecimens might be used for the research, such as those who: • May have ethical, cultural, or religious standards, • May be vulnerable to coercion or undue influence, • Are from discrete and insular communities, or • May have unique legal status (e.g., American Indian/Native Alaskan tribes)

Area #2: Adoption of universal forms and questions

To collect local consideration information and identifying the level of detail Relying Institutions/Relying PI need to provide Reviewing IRBs, including what information can be provided to Reviewing IRBs as attestations.

Area #3: Clarifying roles & timing related to local considerations

- Responsibilities surrounding the collection and verification of local considerations provided to the Reviewing IRB at initial review and throughout the duration of the study.
- Developing a model workflow for sharing local considerations information.

The Working Group Recommendations for Harmonization

Adopt a Harmonized Definition of Local Considerations

- **Proposed definition:** A *local consideration* is as an aspect about the Relying Institution which could affect the Reviewing IRB's determinations, including the criteria for IRB approval. Local considerations may include:
  - State and local laws or Relying Institution policies relevant to the study or subject population.
  - Customs, beliefs, values, or practices of a distinct subject population(s) that a Relying Institution could expect to be enrolled or included (such as records or biospecimens used for the research) in a study and that may have an impact on IRB review.
  - Variations in how a study will be implemented across sites, including differences in standard of care (i.e., routine care).

Harmonize Details Collected to Address Local Considerations

- The **Institutional Profile** will now contain information that remains static, such as how to implement the HIPAA Privacy Rule, state laws, institutional policies, and implementation of the flexibility options regarding unregulated research.
- **Implementation Checklist** for Use of the SMART IRB Agreement documents flexible provisions of the SMART IRB agreement and some of this information is local consideration information. Such as who will serve as the HIPAA Privacy Board, can HIPAA language be included in the consent form, and researcher conflict of interests.
- **Study-Specific Information** (previously known as Protocol-Specific document) will now document local consideration information that is not captured in the other two documents and may vary study by study or by the research activities taking place.
- **Retire: Relying Site Survey** as the other materials include the information collected in this document.

Local Considerations Guidance Table

Local Considerations	HIPAA Privacy Rule Determinations and Authorization Language
Who is responsible for providing local consideration information to the Reviewing IRB at the time of initial review	Relying Institution
When should the local consideration information be provided to the Reviewing IRB?	Initial IRB review for the site
Specific language and details that the Reviewing IRB should request	HIPAA Authorization language will vary depending on the institution. Relying Institutions may include the HIPAA Authorization language or attach the specific form which cannot be altered, if requested by the Reviewing IRB and what is agreed upon in the SMART IRB Implementation Checklist.
Notes	• The Implementation Checklist for Use of the SMART IRB Agreement can be used to provide information on HIPAA determinations and actions; HIPAA authorization language and consent forms. • The Institutional Profile and Study-Specific Information document all capture different information on the HIPAA Privacy Rule.

Local Considerations Guidance Table

Local Considerations	Drug/device storage or management
Who is responsible for providing local consideration information to the Reviewing IRB at the time of initial review	Relying PI
When should the local consideration information be provided to the Reviewing IRB?	Initial IRB review for the site & after initial approval when amendments affect drug and/or device storage or management
Specific language and details that the Reviewing IRB should request	Attestation – "Relying PI/Relying Institution confirms that any drugs/devices used for this research study will be stored and managed as described in the study plan and in compliance with my institutions' policy."
Notes	SMART IRB Study-Specific Information Document can be used to document this information.

Timing and Responsibilities for the Collection of Local Considerations

Study Development	Initial Review	After IRB Approval
Broadly written protocol that encompasses the differences at each participating institution	Relying Site PIs/Relying Site Study Teams & Relying Institutions must work together to provide the Reviewing IRB with accurate local considerations information	Reviewing IRBs identify categories of changes that should trigger a review & Relying Institutions develop guidance for their study teams regarding what changes in research, events, and other information may impact local considerations and may require input from their institution's HRPP

Local Considerations Throughout the Life of a Study

Stage	Responsibilities	Key Local Considerations Information at this Stage
Study Development	• The investigator(s) developing a protocol or study plan should consider the compatibility of study procedures and planned participant population with potential participating sites • Investigators at potential participating sites should evaluate protocols or study plans to determine whether their site is a good candidate for the research and, if so, identify any differences that may need to be incorporated into study documents and communicate them to the overall principal investigator (and, if applicable, the Lead Study Team) • Institutions should provide protocol or study plan templates (similar to the protocol-specific addenda that some institutions have developed) and guidance for their research teams that take into account multisite research and single IRB review (e.g., how to address variations in recruitment approaches across institutions or study procedures)	• Protocols and study plans should be written to take into account variations across participating sites, including: institutional standards of care, available equipment and facilities, study population likely to be enrolled, recruitment process and materials; informed consent process, and data security. • When informed consent is required, template consent documents should accommodate language affected by institutional policy (e.g., compensation for injury, contraception permitted), differences in study costs, variations in study procedures across sites (e.g., differences in equipment, devices, or drugs used), and study team contact information.

Local Considerations Throughout the Life of a Study

Initial IRB Review of a Site

- The Reviewing IRB:
  - Must have a method to collect and consider information about how Relying Institutions will implement a study to make the required determinations for approval under applicable regulations, such as 45 CFR 46.111 or 21 CFR 56.111.
  - Must have a mechanism to integrate local considerations into its review, especially if a specialized position or team (e.g., a reliance team or reliance specialist) collects that information.
  - Should conduct reviews taking into account potential permissible variation across sites, such as in recruitment materials, informed consent and assent processes, and locally required informed consent language (e.g., compensation for injury, costs, contact information).
  - Must collect information about whether Relying Institutions are covered entities and, if so, how they implement the HIPAA Privacy Rule, if they have agreed to act as a Privacy Board for a study, and if the HIPAA Privacy Rule applies.
- Relying Institutions:
  - Must provide Reviewing IRBs with sufficiently detailed information about relevant institutional policies, state and local laws, and other local considerations that may affect the Reviewing IRB's assessment of that site.
  - Should ensure ancillary reviews, that could affect IRB review, (e.g., COI) are completed before IRB review of its site is conducted and communicate relevant information to the Reviewing IRB.
  - Should ensure their research teams are qualified and have adequate resources and facilities to conduct the study and provide such attestations to the Reviewing IRB.
  - Should ensure appropriate drug and device management and storage at sites under their purview.
- Relying Site PIs/Relying Site Study Teams must:
  - Provide Reviewing IRBs (working closely with the Relying Institutions POC) with information about implementation of the study at their site(s) that differs from what is described in the protocol.
  - Obtain sign off (e.g., by a reliance specialist or IRB personnel at their home institution) for any institutionally-required language that must be included in applicable consent documents.

- Relying Institutions may need to provide the following to the Reviewing IRB, such as through the SMART IRB Institutional Profile and SMART IRB Study-Specific Document:
  - State and local laws that may affect IRB review of a participating site(s).
  - Whether a Relying Institution requires the Common Rule to be applied to some or all of its human subjects research.
  - Institutional policies that may affect the informed consent process, content or other documentation.
  - Conflict of interest management plans relevant to the study put in place by the Relying Institution.
  - Attestations from the Relying Institution regarding the adequacy of study team qualifications and training as well as resources and facilities available to conduct the study.
  - Appropriate drug and device management and storage plans
  - Compliance with institutional data security requirements.
  - Completion of relevant ancillary reviews.
  - Information about any variations in study implementation at a Relying Site not captured in the protocol or study plan.

- Reviewing IRBs and Relying Institutions can use the SMART IRB Implementation Checklist and Documentation Tool to capture whether a Reviewing IRB plans to serve as a HIPAA Privacy Board. and, if so, how the Relying Institution implements the HIPAA Privacy Rule (e.g., interpretation of the preparatory to research provision, requirement for a separate authorization form).

Local Considerations Throughout the Life of a Study

After Initial IRB Approval	• Reviewing IRBs should consider whether an amendment may require, prior to the review and approval of the amendment, a) re-review of each Relying Institutions local considerations information; or b) communication with the Relying Institution POC and/or the Relying Site Study Team to obtain additional local considerations information.
	• Relying Institutions and Study Teams should monitor changes in research, personnel updates, or new information that may require the provision of new or updated local considerations information to the Reviewing IRB.
	• Relying Institutions should provide guidance to their Study Teams regarding changes of protocol that may trigger local context considerations.
		• Updates to or new conflict of interest management plans relevant to the ceded research
		• Types of amendments that could affect local considerations, such as:
		  ○ The addition of new populations, sub-studies, unique recruitment strategies, pregnancy testing in minors, or new drugs or devices.
		  ○ Changes to types of contraception permitted.
		• See Appendix 7 for additional considerations

Assent example

- **What can research teams be encouraged to include in their multisite studies about assent to assist Reviewing IRBs in making assent determinations that may be responsive to differences in Relying Institution policies and practices?**
  - From which children assent will be obtained?
  - What information will be communicated to the child and how?
  - Will written assent be documented and, if so, what is the process to document assent?
  - Whether and how parental permission will be obtained?
  - The process used to determine these individual's authority to consent to each child's general medical care, as applicable.
  - Re-consent processes for children who become adults or emancipated minors.

Assent example

- **Challenge:** Varied assent policies and practices
- **Local considerations for assent:** State law, local law, institutional policy, and population
- **Reviewing IRB's responsibilities related to assent:** Are the children able to provide assent? Should assent be waived? Collect Relying Institutions local consideration information
- **How can IRBs proactively address a range of institutional policies and practices?** When assent is required:
  - Identify a default position regarding whether written assent is required, but allowing research teams to obtain written documentation of assent.
  - Approving assent scripts and/or forms for different ages and providing recommendations for study teams regarding which children they would suit

Resources Developed: Template Checklists to Identify When to Address Local Considerations after Initial Approval of a Study

Template Checklist to Identify When to Address Local Considerations after Initial Approval of a Study: For Reviewing IRBs

	Amendment Content
☐	Addition of a new subject population, especially children, pregnant women, prisoners, individuals with impaired decision-making capacity, LGBTQIA, other potentially vulnerable subject populations
☐	Addition of non-English speakers
☐	Significant change in recruitment method
☐	Addition of genetic testing
☐	Addition of testing for an infectious disease
☐	Addition of pregnancy testing or collection of information about pregnancy status
☐	Providing research results to participants
☐	Addition of or change in contraception used in the study
☐	Change in study drug or device storage or distribution
☐	Addition of a new drug or device that could affect billing
☐	Change in informed consent language that is commonly affected by institutional policy, such as compensation for injury language and study costs
☐	Addition of a new consent process

Template Checklist to Identify When to Address Local Considerations after Initial Approval of a Study: For Relying Institutions

	Event
☐	Change in State or local law or institutional policy that could affect a ceded research study
☐	Change in study personnel, including the site Principal Investigator (PI)
☐	New or additional ancillary review required that could affect IRB review
☐	New or changes in Conflict of Interest
☐	New or changes in funding
☐	If the Relying Institution is serving as the HIPAA Privacy Board, changes that could affect HIPAA authorization language that are not consistent with any IRB-approved informed consent language
☐	Changes in research activities taking place at the Relying Institution

Considerations for Investigators Writing Multi-Site Protocols

Potential Variation	Examples of questions to capture differences between sites
Recruitment procedures	• How will subjects be identified? • Who will approach potential subjects? • How will potential subjects be approached? • Are there any restrictions on who can be recruited for this study? • Are there any restrictions about who can approach some or all research participants? • Are there any restrictions on language that is permitted in recruitment materials?
Informed consent and assent processes	• Are there any languages other than English that potential subjects enrolled might read and speak that could influence translations of informed consent documents that may be required? • Are there any restrictions or requirements regarding who can obtain informed consent? • Are there any specific requirements or restrictions regarding electronic informed consent platforms that can be used?
When adults with impaired decision-making capacity are subjects	• What are the specific requirements regarding who assesses capacity to provide informed consent? • Is there any specific requirements regarding the methods are used to assess capacity to provide informed consent?

Considerations for Investigators Writing Multi-Site Protocols

Potential Variation	Examples of questions to capture differences between sites
Study procedures	• Are the procedures described in the protocol as standard of care (or routine care) NOT considered standard of care (or routine care)? • Would there be any differences in supportive, rescue or prophylactic therapies used from what is described in the protocol? • What are the locally available resources or equipment for ensuring necessary medical or professional intervention or equipment will be provided in the event of adverse events or unanticipated problems involving subjects? • Are there any differences in how biospecimens would need to be collected from what is described in the protocol? • Are there any differences in how data or biospecimens would need to be stored from what is described in the protocol?
Where study procedures occur	• Are there any differences where study procedures will occur (e.g., in clinics, in homes or in the community) from what is described in the protocol?
Drugs	• Are there any differences in the drugs available (e.g., brands, formulations used, route administered) from what is described in the protocol? • Are there any differences in how drugs would be dispensed from what is described in the protocol?

Questions and Discussion

Reminder: Comment on the Recommendations

How to Review and Comment

- Go to https://smartirb.org/harmonization/
- Download and review the recommendations
- Complete the survey to provide feedback **by September 30, 2023**

Save the date for the next SMART Talk

The Impact of Single IRB on HRPPs

November 15, 2023
2:00-3:30 pm ET

Questions?
Contact
help@smartirb.org

Register at smartirb.org

Sign up for our mailing list to be notified of future offerings