So what is local context review and how do I "do" it?

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PRIM&R PUBLIC RESPONSIBILITY IN MEDICINE AND RESEARCH

2017 Advancing Ethical Research Conference
November 5-8 ★ San Antonio, TX

Agenda

- Responsibilities of Relying Organizations
- Understanding the two-part process
  - The Big Picture: Why have a 2 part process?
  - Institutional Profile
  - Study-Specific Local Context Questionnaire
- Key considerations for Relying Organizations
- Tools Available to Assist with the Process

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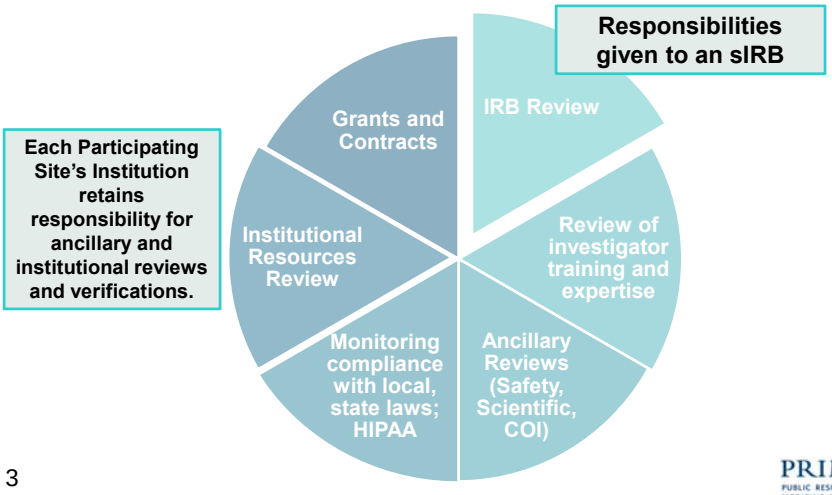
Single IRB Review ≠ Single Institutional Review



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What types of things do relying sites remain responsible for?

- **Education/Training/Qualifications**. Ensuring that its Research Personnel have adequate education, training, and qualifications to perform the research and safeguard the rights and welfare of participants. This includes ensuring personnel are credentialed to perform the research procedures.
- **Compliance**: Ensuring research personnel comply with determinations of the reviewing IRB and all applicable laws/institutional requirements
- **Institutional Reviews**: Ensuring all applicable institutional reviews required for the research to be conducted at that site are performed [e.g. radiation safety review, COI review, etc.]
- **Perform local context review**: Communicate to the reviewing IRB the requirements of any local laws, ancillary reviews, etc. and provide any required site-specific information for the consent form, where applicable.

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What is a Relying Organization's Responsibility?

A Relying Institution or Relying IRB shall identify, interpret, and communicate to the IRB of Record its Local Research Context, as are ***relevant to the given research study.*** *This information may be communicated via the Relying Institution's Institutional Profile and/or via direct submission to the IRB of Record, as applicable*. [IRBchoice]

Each Relying Institution will… 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. Such communication may be made through the Reviewing IRB's designee, as determined by the Participating Institutions* ***in connection with the specific Research***. [SMART IRB Agreement]

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Why a Two-Part Process?

- Organizations may have to make an initial determination about reliance EARLY [Will often occur at the time of grant preparation]
- Often no protocol exists at this time point
- Even at this early decision point organizations need SOME information to determine if they feel comfortable relying or in serving as the reviewing IRB for another organization
- This does NOT eliminate the need to provide study-specific information when the study materials ARE available

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Part 1: The Institutional Profile

- **General overview about the organization**
  - FWA number & legal components
  - Is the organization a HIPAA covered entity?
  - Is the organization accredited?
  - Are there any over-arching state laws/institutional policies that affect all research at the organization?
- **Organizational noncompliance**
  - Have there been any recent findings [OHRP/FDA] about your FDA?
- **How your site works**
  - Is your organization willing to serve as the privacy board?
  - Does your site permit the use of short forms?

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Part 2: Study Specific Local Context Questionnaire

- Completed by the Relying Organization on a study-specific basis
- Allows the Relying Organization to provide site-specific information with consideration for the specific study
  - Examples:
    - What are the institutional policies that are relevant for THIS study?
    - What ancillary reviews are required for THIS study?
- Completion can be concurrent with the process to ensure all other responsibilities have been addressed [training, COI, etc.]

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Part 2: Study-Specific Local Context Questionnaire

What's Included?

- Whether any FCOIs been identified specific to this study & provision of management plans
- Verification of appropriate training/credentials for site study personnel
- Study-specific consent requirements [general consent requirements may be collected up front]
- Identification of ancillary reviews that may impact the review of the sIRB
- Site specific requirements based on state law/institutional policy relevant to the study [data security, recruitment, community considerations]

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JHM sIRB Review Process:

Step 1: Initial Submission

- Convened Review Occurs per normal procedure
- Initial submission will include protocol, template consent, other study documents
- **Board can ask for specific items for local context review**

Step 2: Relying Site performs Local Context Review

- JH approved protocol and template consent are distributed to local sites along with a local context worksheet/survey
- Relying sites can communicate any site-specific concerns, locally required language for the consent, etc.

Step 3: Addition of sites via Change in Research

- Most changes in research will be processed expedited by our sIRB team [Operations & Compliance Staff]
- If warranted, site additions may be sent to the convened IRB for review [site-specific factors impact the criteria for approval]

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Local Context Review: Considerations for Relying Institutions

- How will "local context review" be operationalized at your institution?
  - Will you require a formal submission?
  - What study-specific documents will you require as part of that submission?
  - How will you coordinate local context review with any ancillary reviews required at your institution?
- Who has the authority at your institution to review and "sign-off" on the local context review?
  - Does the review occur within/outside your IRB?
  - Are those who are "approved" to provide sign-off clearly designated?
  - Is the signatory knowledgeable about local laws, institutional policies, etc.?
  - How do you ensure the information is accurate/of quality?

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Tools to Assist with this Process

- Reliance Request tool/application
- Harmonization of information collected via the "Institutional Profile" and "Study-specific questionnaire" [Harmonization Steering Committee- SMART Initiative]
- Trainings for Relying Sites about how to do this
- Sample "completed" Institutional Profiles and Study-Specific Local Context Questionnaires
- Online tools to collect this information & facilitate local review

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Using SMART IRB Exchange to Capture Local Context

Reviewing IRB	Relying Institution	Relying Site PIs	Coordinating Centers/Lead Study Teams
• Track • Export	• Confirm (not duplicate) site-specific local context • Provide study-specific local context	• Contact name & info • Site-specific differences (e.g., recruitment plan)	• Track/monitor site progress • Generate reminders

WHY DO IT THIS WAY?

1. Standard questions
2. Reduce the submission of duplicative information
3. Exportable information
4. Centralized tracking of local context submission
5. Facilitate notifications and reminders

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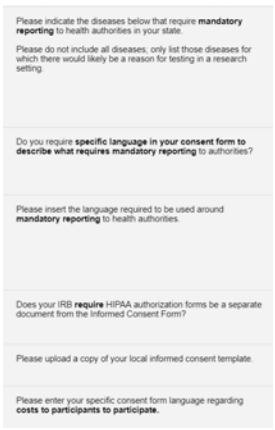
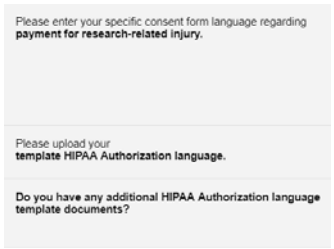
Reduce, Reuse and Recycle: Site-specific Information



Information is entered ONCE into Institutional Profile



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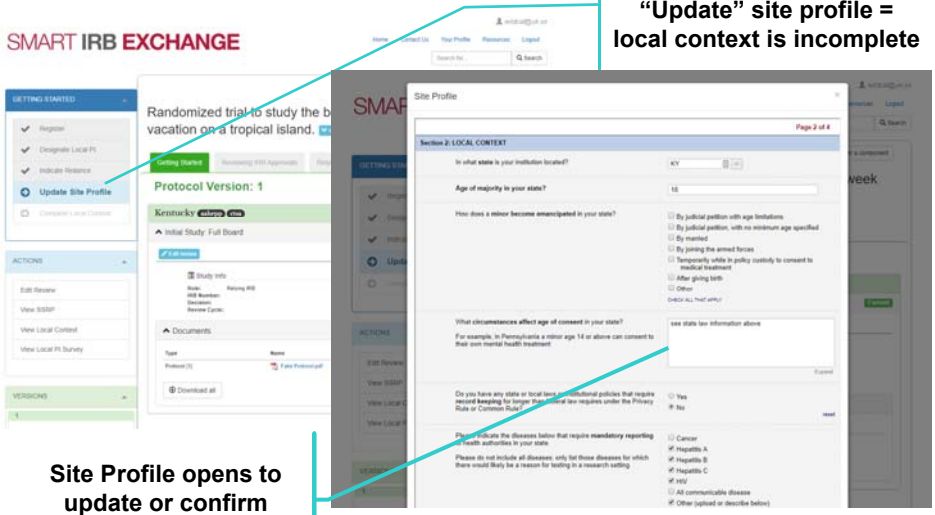
1. HRPPs update or confirm site-specific local context in Institutional Profile (IP)



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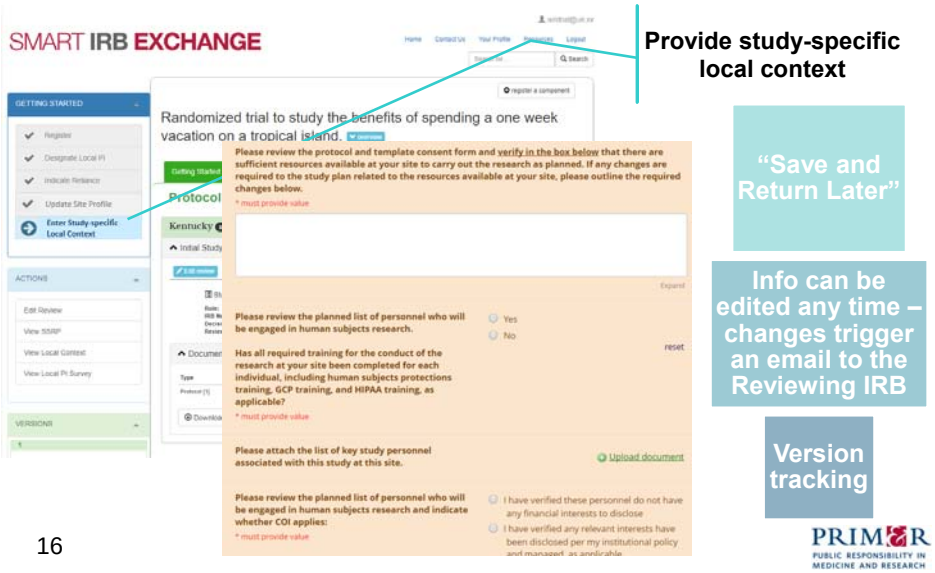
2. HRPPs enter study-specific local context



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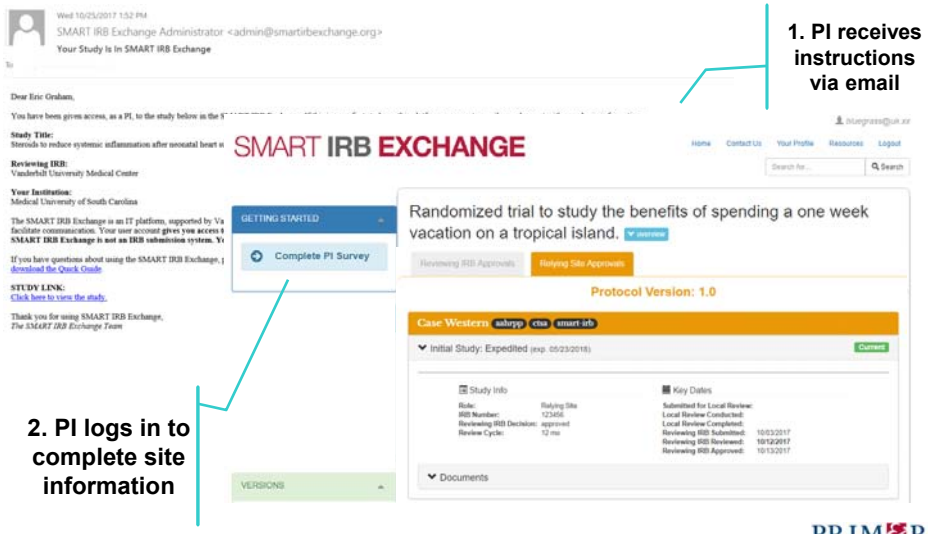
HRPP or PIs provide site information and contact information



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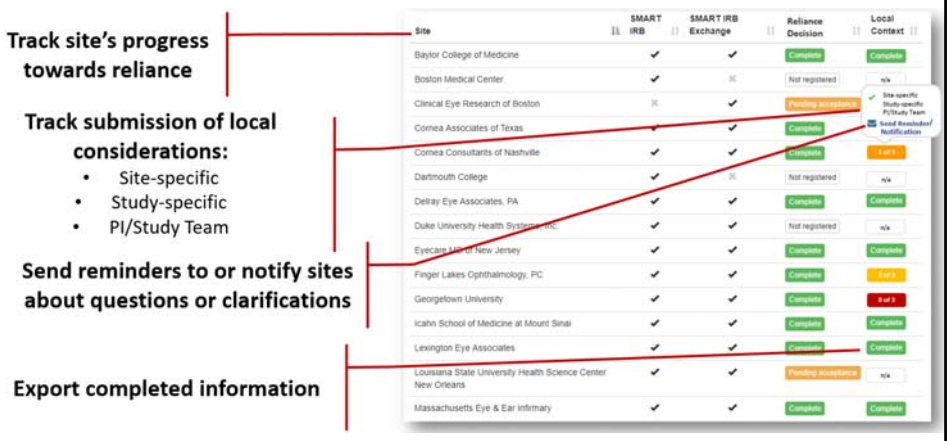
Reviewing IRBs/CCC/Lead Study Teams: Tracking Local Context Completion



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