

# So what is local context review and how do I “do” it?

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1:15pm

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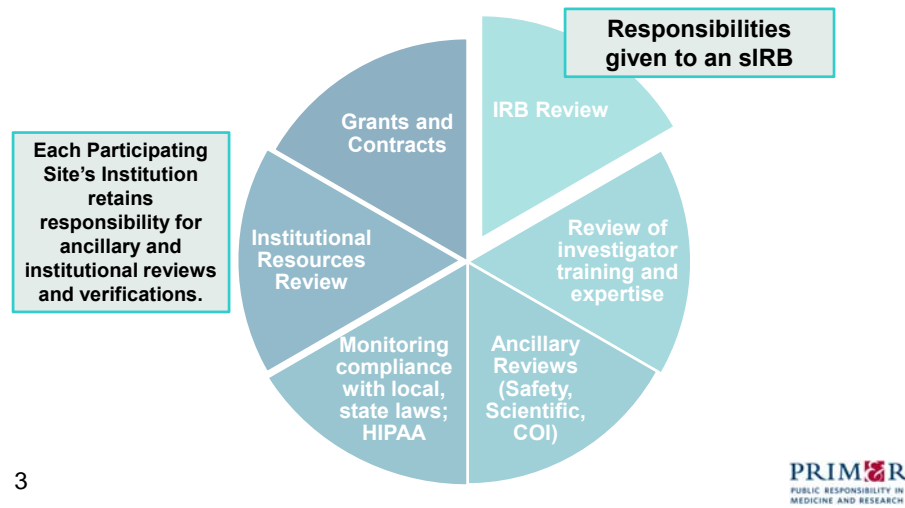


**2017 Advancing Ethical  
Research Conference**  
November 5-8 ★ San Antonio, TX

## 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

## Single IRB Review ≠ Single Institutional Review



## 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.?
- 11 ○ How do you ensure the information is accurate/of quality?



## 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
<ul style="list-style-type: none"> <li>Track</li> <li>Export</li> </ul>	<ul style="list-style-type: none"> <li>Confirm (not duplicate) site-specific local context</li> <li>Provide study-specific local context</li> </ul>	<ul style="list-style-type: none"> <li>Contact name &amp; info</li> <li>Site-specific differences (e.g., recruitment plan)</li> </ul>	<ul style="list-style-type: none"> <li>Track/monitor site progress</li> <li>Generate reminders</li> </ul>

### 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

**Section 2: LOCAL CONTEXT**

In what **state** is your institution located?

**Age of majority in your state?**

How does a **minor become emancipated** in your state?

Please describe how a minor becomes emancipated in your state.

What **circumstances affect age of consent** in your state?  
For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment.

Do you have any state or local laws or institutional policies that require **record keeping** for longer than federal law requires under the Privacy Rule or Common Rule?

Please indicate the diseases below that require **mandatory reporting** to health authorities in your state.  
Please do not include all diseases, only list those diseases for which there would likely be a reason for testing in a research setting.

Do you require **specific language in your consent form** to describe what requires **mandatory reporting** to authorities?

Please insert the language required to be used around **mandatory reporting** to health authorities.

Does your IRB **require** HIPAA authorization forms be a separate document from the Informed Consent Form?

Please upload a copy of your local informed consent template.

Please enter your specific consent form language regarding **costs to participants to participate**.

**Information is entered ONCE into Institutional Profile**

Please enter your specific consent form language regarding **payment for research-related injury**.

Please upload your **template HIPAA Authorization language**.

Do you have any **additional HIPAA Authorization language template documents**?

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

**SMART IRB EXCHANGE**

Home | Contact Us | Your Profile | Resources | Logout

SEARCH

SETTINGS STARTED

- Register
- Designate Local PI
- Indicate Reference
- Update Site Profile**
- Complete Local Context

ACTIONS

- Edit Review
- View SISP
- View Local Context
- View Local PI Survey

VERSIONS

1

Randomized trial to study the benefits of spending a one week vacation on a tropical island.

Protocol Version: 1

Kentucky

Initial Study Full Board

Documents

Name

Type

Download all

Site Profile

Section 2: LOCAL CONTEXT

In what state is your institution located? KY

Age of majority in your state? 18

How does a minor become emancipated in your state?

- By judicial petition with age limitations
- By judicial petition, with no minimum age specified
- By married
- By joining the armed forces
- Temporarily while in policy custody to consent to medical treatment
- After going birth
- Other
- (Check all that apply)

What circumstances affect age of consent in your state?

For example, in Pennsylvania a minor age 14 or above can consent to their own mental health treatment.

see state law information above

Do you have any state or local laws or institutional policies that require record keeping for longer than the federal law requires under the Privacy Rule or Common Rule?

Yes  No

Please indicate the diseases below that require mandatory reporting to health authorities in your state.

Please do not include all diseases, only list those diseases for which there would be a reason for testing in a research setting.

- Cancer
- Hepatitis A
- Hepatitis B
- Hepatitis C
- HIV
- All communicable disease
- Other (please list or describe below)

**“Update” site profile = local context is incomplete**

Site Profile opens to update or confirm

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# 2. HRPPs enter study-specific local context

**SMART IRB EXCHANGE**

Home | Contact Us | Your Profile | Resources | Logout

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SETTINGS STARTED

- Register
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- Update Site Profile
- Enter Study-specific Local Context**

ACTIONS

- Edit Review
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Protocol

Kentucky

Initial Study

Documents

Name

Type

Download

Please review the protocol and template consent form and verify in the box below that there are sufficient resources available at your site to carry out the research as planned. If any changes are required to the study plan related to the resources available at your site, please outline the required changes below.

\* must provide value

Please review the planned list of personnel who will be engaged in human subjects research.

Yes  No

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Has all required training for the conduct of the research at your site been completed for each individual, including human subjects protections training, GCP training, and HIPAA training, as applicable?

\* must provide value

Please attach the list of key study personnel associated with this study at this site.

Upload document

Please review the planned list of personnel who will be engaged in human subjects research and indicate whether COI applies:

- I have verified these personnel do not have any financial interests to disclose
- I have verified any relevant interests have been disclosed per my institutional policy and manuscript as applicable

**Provide study-specific local context**

**“Save and Return Later”**

**Info can be edited any time – changes trigger an email to the Reviewing IRB**

**Version tracking**

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# HRPP or PIs provide site information and contact information

**1. PI receives instructions via email**

**2. PI logs in to complete site information**

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

**Track site's progress towards reliance**

**Track submission of local considerations:**

- Site-specific
- Study-specific
- PI/Study Team

**Send reminders to or notify sites about questions or clarifications**

**Export completed information**

Site	SMART IRB	SMART IRB Exchange	Reliance Decision	Local Context
Baylor College of Medicine	✓	✓	Complete	Complete
Boston Medical Center	✓	✗	Not registered	n/a
Clinical Eye Research of Boston	✗	✓	Pending acceptance	Complete
Cornea Associates of Texas	✓	✓	Complete	Not
Cornea Consultants of Nashville	✓	✓	Complete	Not
Dartmouth College	✓	✗	Not registered	n/a
Delray Eye Associates, PA	✓	✓	Complete	Complete
Duke University Health System, LLC	✓	✓	Not registered	n/a
Eyecare MD of New Jersey	✓	✓	Complete	Complete
Finger Lakes Ophthalmology, PC	✓	✓	Complete	Not
Georgetown University	✓	✓	Complete	Not
Icahn School of Medicine at Mount Sinai	✓	✓	Complete	Complete
Lexington Eye Associates	✓	✓	Complete	Complete
Louisiana State University Health Science Center New Orleans	✓	✓	Pending acceptance	n/a
Massachusetts Eye & Ear Infirmary	✓	✓	Complete	Complete

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