

# SMART IRB Reliance Agreement

- JHM IRB requires use of the **SMART IRB Reliance Agreement** as the basis of reliance.
- JHM IRB also requires execution of a **“Letter of Indemnification”** [LOI] as indemnification is not specified in the Agreement.
- With assistance from the JHM IRB reliance team, the lead study coordinator will send introduction emails to sites based on whether they have already executed the SMART Agreement and/or LOI with JHM IRB.

## Benefits:

- Eliminates the need for study-specific reliance agreement negotiation.
- Once you are a signatory to SMART, you may use SMART as your reliance agreement for any specific study that also involves institutions that are SMART signatories.
- JHM IRB has executed over 150 LOIs with sites.

700+  
signatories  
64  
CTSA Hubs



# How does this all work?

**Step 1:** JHM IRB will assist the lead study team with on-boarding sites to the required agreements [SMART and LOI]

- Sites that have already executed the required agreements will receive an email request to confirm willingness to rely
- Willingness to rely must be provided via email or letterhead from the site **IRB/HRPP point of contact**
- JHM IRB will execute a “*cede letter*”, documenting the reliance relationship
  - JHM IRB uses the SMART IRB Letter of Acknowledgment to document reliance.

# How does this all work?

**Step 2:** Study approval documents are released to relying sites to perform a required local context review

- Sites will complete a JHM Local Context Questionnaire [LCQ] which must be signed by the site PI and an IRB/HRPP signatory
- The LCQ collects information such as local investigator qualifications/training, local ancillary reviews, and identification of any specific local issues

**Step 3:** Sites return completed LCQ to lead study team and sites are reviewed/approved.

# Step 3: Site Review Process

- JHM Expedited Review Team includes three key players:
  - IRB Reliance Team Member: Ensures local context questionnaire is complete
  - Consent Form Specialist: *[not applicable for this project]* Ensures site-specific language has been provided for “editable” sections of the consent and builds the consent document
  - Compliance Team Member: Performs a “regulatory review” to identify whether there are areas of concern
- If issues are raised that impact the criteria for approval, the site application is assigned to the convened JHM IRB for review and site will be contacted.

# Step 3: Site Review Process

- Once a participating site (“pSite”) is approved, a site-specific approval letter will be issued.
  - *Note:* The participating IRB/institution may require receipt of the JHM IRB site-specific approval letter BEFORE the pSite can be activated locally
- pSites should check with their IRB/organization about the types of items that will require “local” review during the life of the study –
  - Examples:
    - Changes that affect local drug dispensation/dosing
    - Changes that may trigger a local ancillary review
    - Personnel changes/new conflicts

# How will sites talk to the JHM IRB ?

- Site documents are communicated through the lead PI/Point of Contact
- Sites are added as pSites
- Study-wide amendments controlled by overall PI
- Site-specific amendments/problem events/change in research can be submitted simultaneously
- pSites will submit annual enrollment data to the overall PI for inclusion in the continuing review application
  - Note: As this study is being conducted under a waiver of consent, the data JHM IRB would collect would differ than what would be sought if the study included a written consent process [e.g., how many participants were enrolled? Failed screening? Adverse events?]