OHSP Policy and Process for Multi-Site Studies Using a Single IRB

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One IRB to rule them all!

Single IRB Requirement

- Federal Funding
  - OHRP (as of January 2020)
  - NIH (grant submissions as of May 2017)
- Multi-site (Cooperative Research)
  - More than one site
- NOT Exempt
  - Research receiving expedited or convened board review
  - *THE RULE DOES **NOT APPLY** TO EXEMPT OR NOT HUMAN SUBJECT RESEARCH*

What is a Reliance Agreement/IRB Authorization Agreement?

- A formal, written document that outlines the roles and responsibilities of each institution when an institution engaged in research decides to delegate IRB review to another IRB.
- Institutions must agree to the terms of the Reliance Agreement before research can begin.
- UR executes agreements via:
  - SMART IRB Online Portal
  - IRB Authorization Agreement (IAA)
- Portions of the agreements are flexible.
  - Examples:
    - HIPAA Determinations and actions
    - Indemnification

Reviewing vs Relying-What's the Difference?

- UR will be the Reviewing Institution
  - UR faculty “lead investigator” on a multi-site study
  - The RSRB is the Institutional Review Board (IRB) designated to review and approve the research.
- UR will be the Relying Institution
  - UR faculty participating site on a multi-site study
  - UR delegates the responsibility of IRB review and approval to another IRB.

Considerations-UR Reviewing Institution

- Costs
  - There are costs associated with review of non-UR sites (with exceptions)
  - RSRB's fee structure is available online!
  - Study-specific budgets must be created and reviewed with OHSP
    - This should happen ***before*** the grant is submitted.
- Study Team Effort
  - The IRB's responsibility is the IRB review of documents
  - The study team's role includes everything else
    - Providing approved templates and required forms, following up with sites to obtain documents, budgets, contracts, etc.
  - Study Coordinator  Study Manager

UR to act as the Reviewing Institution

1. Complete the eReliance Request form
2. Create Click IRB submission
    - New study or modification to an existing study
    - Submission must include a PI oversight plan
3. Reliance determination with each Relying site
4. Non-UR site (pSite) approval
    - The review level of the sites is determined by the board or board chair at the time of initial study approval.
    - After approval, the study team provides the approved documents to the site(s).

Tools to assist with Reliance

- Smart IRB Online Portal
  - It's *not* an IRB
  - It's a tool to request, track, and document reliance arrangements on a study-by-study basis
- IREx
  - A free web-based portal supporting single IRB review documentation and coordination for multi-center trials

Considerations-UR Relying Institution

- Even though we are deferring oversight, the University is still responsible for making sure that we are complying with institutional policy.
- This includes, but is not limited to:
  - Making sure all applicable UR institutional language is in the consent form(s)
  - Ensuring all required ancillary reviews have been completed
  - Verifying local procedures for recruitment and consent

Considerations-UR Relying Institution Continued

- You still have to communicate with the RSRB
  - Examples:
    - Provide initial approval and continuing review approval
    - Submit modifications that may impact institutional review
    - Submit Reports of New Information (RNIs) that resulted in the Reviewing IRB making a determination of serious non-compliance, continuing non-compliance, UPIRTSO, or suspending or terminating the research.

UR to act as the Relying Institution

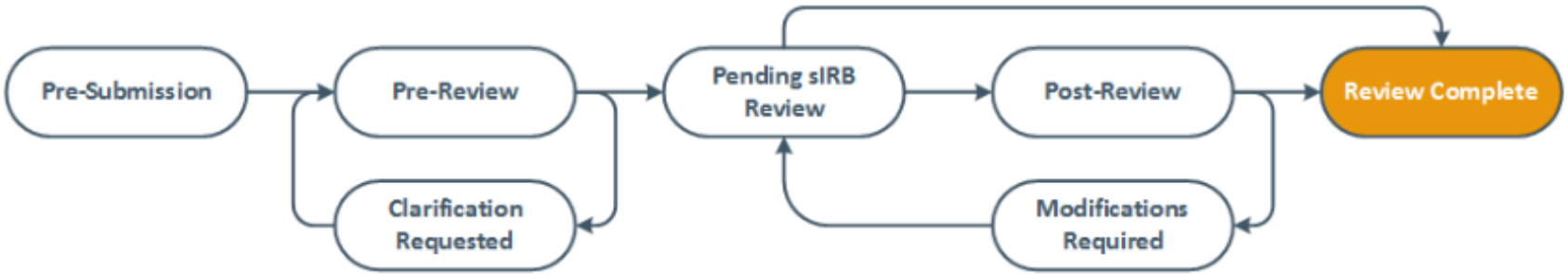
1. Fill out the eReliance Request Form
2. Create the submission in Click and work with IRB Coordinator to fulfill UR requirements
3. Execute Reliance Agreement with Reviewing Institution
4. Once the local context review is complete, the submission moves to “Pending sIRB Review.” UR study team submits to Reviewing IRB.

UR to act as the Relying Institution continued

5. Study team provides approval letter and approved documents via a comment in Click IRB. Be sure to select that you want to notify the IRB Coordinator that a comment has been left!

6. IRB Coordinator reviews approval letter and documents.

7. Submission moves to “Review Complete.” The study is not active at the UR until the status moves to this state



Policy and Guidance

- Policy 504 IRB Reliance and Collaborative Research
- Guideline 504a UR as Relying IRB
- Guideline 504b UR Reviewing IRB
- Guideline 504c PI Oversight Plan for Multi-Site Research
- Click IRB Study Staff Manual