IRB Authorization Agreements – Reliance Agreements

SINGLE Vs CENTRAL IRB

- **Single IRB (sIRB):** A single IRB is selected on a study-by-study basis; usually is an existing IRB that agrees to serve as the IRB of record for a particular study.

- **Central IRB:** A central IRB reviews for all sites participating in a program that usually includes more than one multi-site study. Often is established specifically for this purpose (e.g. NCI Central IRB).

(*Unless required by the FOA or contract solicitation, you not have to create a Central IR. For many studies, your institutional IRB can serve as the single IRB of record)*

NIH – POLICY on SINGLE IRB (sIRB)

- **Who does the policy apply to?**
  - U.S. NIH-funded studies that involve non-exempt research on human subjects at multiple sites?
    - **Included**: Generally, NIH grants and contracts
    - **Excluded**: Career/training/fellowship grants don't apply

- **Implementation**
  - **Study teams:** must include plans for single IRB review at the time of application (including communication plans, identification of the IRB of record, and confirmation from all sites that they will comply with the IRB of record's policies)
    - No page limit to sIRB plan
    - Do not include reliance agreement or communication plans
    - If study onset is delayed, include information regarding compliance with the NIH sIRB policy in the delayed onset study justification; a complete sIRB plan must be provided to IC prior to initiating study.

  - **If awarded:** NIH approval of the proposal for single IRB use will appear as a term and condition in the Notice of Award or Contract Award letter

- **Can I get an exception?**

  - **Yes, under the following circumstances**

    - **Policy-Based Exceptions**
      - When Federal, State, Tribal, Local law/regulations/policies require local review

        - Tribal regulations/policies given specific consideration in order to ensure that the importance of their role recognized
        - Does not require NIH Exceptions Review Committee approval

    - **Time Limited Exceptions:**
        - When ancillary studies are part of ongoing studies or parent studies
            - Do not require sIRB until the parent is expected to comply with the sIRB policy.
            - Must be documented in the sIRB plan

    - C**ompelling Justification or Other Exceptions**
        - When there is a compelling justification for local IRB review
        - sIRB budget should only include costs associated with single IRB review
            - **Requires** NIH Exceptions Review Committee approval.

- **sIRB Costs**

    - Policy allows, but does nor require sIRB costs to be **Direct Charge**
    - Cost may be charged as Direct if:
        - Institution can differentiate the costs that are charged direct Vs indirect
        - Cost incurred for the responsibility to determine if sIRB costs are appropriately classified as direct or indirect
        - Its HU's responsibility to determine if sIRB costs are appropriately classified as direct or indirect

- **Costs Associated with sIRB Review**

    - **Primary Activity:**
        - Activities associated with conducting the ethical review of the proposed research protocol and the review of the template informed consent document.
        - Such routine activities are included in F & A rate

    - **Secondary Activities:**
        - Activities associated with the review of site-specific considerations (unlike circumstances) for all of the participating sites.
        - Project-specific activities "above and beyond" IRB review of human subjects' research.

TYPES of IRB RELIANCE AGREEMENTS

- Working with external partners:
    - **MOU** – Memorandum of Understanding (e.g. Howard-Georgetown (CTSA IRB))
    - **MRA** - Master Reliance Agreements (e.g. SMART-IRB, Chesapeake)
    - **Institutional Authorization Agreement** (IAA - Institutional)
    - **Individual Authorization Agreement** (IAA – Individual)
    - When requesting a reliance agreement depends on:
        - Type of submission and
        - Request to (cede/rely) for the study

- **Considerations**
    - Several Factors are considered when determining whether a Reliance Agreement should be used or whether each institution should conduct their own review:
        - Study protocol
        - Risk Level
        - Involved intuitions and investigators
        - Funding

WHEN HU IRB will be the IRB of RECORD for ANOTHER INSTITUTION

The ORRC staff will work with the external IRB or (when the institution has no IRB) the compliance or regulatory office at the other institution, to complete the following:

- Confirm the institution's willingness to establish an IRB Authorization Agreement;
- Verify that the other institution has a current FWA;
- Determine whether the HU IRB needs to be listed ("designated") on the other institution's FWA
- Complete HU IRB template Authorization Agreement, unless the external IRB has a specific template;
- Negotiate the terms of the agreement, if different from the standard agreement.
    - Any non-standard clauses should be brought to the attention of AVP ORRC will provide direction on obtaining informal review of the agreement by other appropriate HU offices/departments as needed, including but not limited to:
        - Office of General Counsel (review of contract for legal sufficiency);
        - Research Administrative services (consistency with any funding contract).
        - Complete the execution of the agreement by ensuring that both institutions have signed the agreement and that all relevant parties have copies (Institutional Official and Signatory Authority).

When HU IRB will Rely Upon Another Institution

The ORRC staff works with the IRB office at the other institution, to complete the following:

- Confirm the institution's willingness to establish an IRB Authorization Agreement;
- Verify that the other institution has a current FWA and registered IRB;
- Request that the other institution use their specific template.
    - If the other institution does not have a specific template, modify and complete the HU IRB Authorization Agreement template.
- Negotiate the terms of the agreement, if different from the standard agreement.

- Any non-standard clauses should be brought to the attention of AVP ORRC to obtain guidance on obtaining informal review of the agreement by other appropriate HU offices as needed, including but not limited to:
  - Office of General Counsel (review of contract for legal sufficiency);
  - Research Administrative Services (review for consistency with any funding contract); and
  - Complete the execution of the agreement by ensuring that both institutions have signed the agreement and that all relevant parties have copies (Institutional Official and Signatory Authority).

Items to be Included in Application Submission:

- Cover letter requesting External IRB review
- Consent document with HIPAA Authorization (Reviewing IRB's consent template, with HU local context language and HU HIPAA Authorization inserted or as an appendix)
- HIPAA Authorization Form
- Protocol
- External IRB Approval
- Reliance agreement document or SMART IRB Acknowledgement
- Local Context Worksheet required by Reviewing IRB (if applicable). PI should fill out study specific information.
- Training Certifications

Factors Considered When Negotiating Ceded Review to Another IRB

Several Factors are considered when determining whether a Reliance Agreement should be used or whether each institution should conduct their own review:

- Study protocol
- Risk Level (Does HU want to get involve given risk level)
- Involved intuitions and investigators
- Funding
- Protocol
- ICF template
- Relevant study documentation
- Qualification of each investigator
- External IRB (registration with appropriate federal agency)
- Research procedures
- Study population

- Study site (suitability)

Assignment of Responsibilities

For example, who is responsible for the following?

- Compliance with HIPAA – **HU-IRB**
- Validation of investigator's ability to conduct the study (Credentials/Qualification) – **HU-IRB and Reviewing-IRB**
- Laboratory Safety review, if applicable – **HU-IRB**
- Institutional Biosafety Committee (IBC) review if applicable – **HU-IRB**
- Conflict of Interest Disclosure (COI) – **HU-IRB**
- Reporting of Adverse Events (AE) /Serious Adverse Events (SAE) – **Mostly Reviewing-IRB**
- Reporting of Serious Adverse Events to applicable Federal Agencies – **Most likely the Reviewing IRB**
- Consideration for the involvement of prisoners and report to Applicable Federal agencies - **Mostly Reviewing-IRB**
- Negligence - **HU-IRB**
- Scientific Misconduct **– HU-IRB**

HU Collaborative Agreement with Single/Central IRBs

- **SMART-IRB:** NCATS Central IRB (Trial Innovation Network)
- **IRB-SMART Exchange:** Electronic IRB/PI/Sponsor communication channel
    - Cosponsored by University of Utah/Hopkins/Vanderbilt
- **ADVARRA IRB:** A commonly used IRB
- **Others**: as determined by the NIH/Sponsor

Where to Submit Your Protocols:

Submit to the ORRC/HU-IRB:

- **All investigator initiated** single site studies
- **Multisite studies**, when HU IRB will serve as the reviewing IRB
- **All reliance agreement:** If HU must be in agreement that another IRB will have oversight of the study
- **If unsure:** Contact the ORRC

Submit to Central/Single IRB (NIH - sIRB Mandate)**:**

- **Multisite clinical trials** -- If another IRB will serve/has been selected as the central IRB
- Must go through HU-IRB first or Consult HU-IRB before engagement

Submit to GHUCCTS IRB:
ONLY GHUCCTS Funded studies – Especially, if implementing the study at more than one GHUCCTS institution