Quick Guide: Requests for USA to Rely on External IRBs

***Reliance**—when one or more relying institutions choose to accept IRB review and oversight for a research project from another institution's reviewing IRB. In these situations, the reviewing IRB provides IRB review and oversight for conduct of the research at the relying institution(s).*

How Does It Work?

Step 1: What Studies are Eligible for External IRB Review?

NOTE: This does not apply to WIRB submissions or NCI CIRB submissions

- Federal agency requirement for single IRB review and approval (i.e., NIH sIRB policy)
- Sponsor requires the use of another independent/commercial IRB

Step 2: Submit a Request for External IRB Review

- To request review by an external IRB, the USA investigator/research site must submit the Request to Use an External IRB form via IRBNet. Create a *New Project in IRBNet*, Package 1 should include the following:
    - USA IRB Application Part A
    - IRB External Review Request form (located in IRBNet forms/templates)
    - Sponsor Protocol
    - Informed Consent with applicable USA Boilerplate included
- Investigator must electronically sign package 1 for USA IRB administrative review
- All key personnel listed on IRB Application Part A must have completed the required applicable human subject training.
- Submit Package 1 for USA IRB review and acknowledgment.
- An acknowledgement letter will be published in Package 1

Do NOT Submit to any external IRB without receipt of USA IRB acknowledgement letter

Step 3: Reliance / IRB Authorization Agreement

When reliance is accepted, federal regulations require the relationship to be documented by a written agreement called a Reliance Agreement / IRB Authorization Agreement.

NOTE: The Streamlined, Multisite, Accelerated Resources for Trials (SMART) IRB Reliance Platform was developed to assist institutions in implementing the NIH Single IRB Policy. SMART IRB developed a Master Common Reciprocal IRB Authorization Agreement, which many institutions are participating in, including USA. Institutions that have signed onto this master agreement are able to use it as a means of reliance, meaning that IRB Authorization Agreements would not need to be executed on a study-by-study basis.

USA may use the SMART IRB Master Common Reciprocal IRB Authorization Agreement as a means of reliance with other SMART IRB participating institutions.

If the reliance request involves an institution that is not signed onto the master agreement, the USA IRB will need to execute an individual IRB Authorization Agreement with the other institution(s).

For additional information about SMART IRB, visit https://smartirb.org/.

The Office of Research Compliance and Assurance can assist in facilitating completion of the Reliance Agreement.

Step 4: Post USA IRB Review (Post-reliance reporting)

Once the USA IRB has granted your request for reliance and the external IRB has approved your study, you are still required to continue to submit some items to the USA IRB. Investigators/research sites must notify the USA IRB of the following events:

- Protocol deviations that may represent a systematic problem requiring local evaluation by USA IRB to determine that sufficient local resources are available for safe conduct of the study
- Study holds or suspensions that are not built into the study design from the Sponsor (eg: interim analysis or enrollment complete need not be reported)
- Study Closure
- Study Terminations from sponsor
- Subject complaints
- Amendment to change PI or key personnel (NOTE: IRB Application Part A must be updated to reflect personnel changes)
- Conflict of Interest updates
- Breaches of confidentiality/HIPAA Privacy and/or Security violations
- Completion of annual check-in form (more information below)

Annual Check-In: This is not the same as a continuing review. Therefore, it may occur at a different time than the continuing review required by WIRB.

Project Personnel Updates: USA IRB application Part A should be updated, as needed, (i.e., study personnel, PI change and submitted to USA IRB)

Monitoring of protocols: The USA IRB/ Office of Research Compliance and Assurance may monitor any external IRB approved protocol as part of its quality assurance program.

Record keeping: Record keeping procedures for all files must be established, and IRB documents, e-mail notifications, and other correspondence must be stored / filed as previously maintained through normal USA IRB approval.