USA is a Participating Site - Rely on External IRB

Rely on External IRB

USA may be a participating site in a multi-site research study and rely on an external IRB. The external IRB may include an institutional IRB (e.g.; Clemson University) or an independent IRB (e.g. WIRB or Quorum). **This type of review is abbreviated at USA, but still requires you submit a research application via IRBNet. In addition to IRB Application Part A (Smart Form), the IRB Reliance Request/Registration form must be completed when an Investigator is submitting an initial request to rely on an outside IRB of multi-site research.**

When a USA PI requests an external IRB review his/her human subject's research, this is considered requesting a ceded review. A reliance agreement must be executed prior to the research being conducted. You may contact the USA IRB prior to submitting your application to discuss reliance agreements or if the external IRB has already agreed to be the IRB of record and has provided an authorization agreement, you may upload it into IRAP with your submission.

Application Instructions: Initial Review

USA investigators and/or their research staff must submit the following materials, as applicable, for initial review via IRBNet:

- USA IRB Application Part A (Smart Form)
- IRB Reliance Request/Registration Form
- Copy of protocol
- Consent/Assent forms approved by External IRB
    - If external IRB will incorporate USA IRB Consent Form Boilerplate Language, the external IRB-approved consent form or template consent form may be provided without the language incorporated
- IRB approval letter from external IRB

Submissions to USA IRB after External IRB Initial Approval

Change in PI

Investigator/Research staff must provide any change in USA PI by amendment via IRBNet.

Change in Funding

Changes in funding may include: new funding or additional funding received. The investigator/research staff must provide any changes in funding by updating IRB Application Part A (Smart Form).

Reportable Problems that Occur Locally

- Subject complaints
- Conflict of Interest updates
- Breaches of confidentiality
- HIPAA Privacy and/or Security violations
- Study suspensions/terminations from Reviewing IRB or Sponsor

Study Closure

The investigator/research staff must submit study closure information.

NOTE:

Monitoring of External IRB approved protocols: The USA 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 external IRB documents, e-mail notifications, and other correspondence must be stored / filed as previously maintained through normal USA IRB approval.