Requests for the Partners IRB to Serve as a Central IRB (cIRB)

Points to consider

The request for cIRB review is increasing with the perceived benefit of streamlined review that will prove to be faster and more efficient. A cIRB may be considered for a single protocol being conducted at multiple sites or for a network or consortium that plans to conduct a number of protocols at network member sites.

If you are considering a request for the Partners IRB to be the cIRB, you must understand the responsibilities and costs involved in creating a cIRB.

Because the work of setting up and maintaining a cIRB requires significant effort on the part of the Human Research Office staff beyond that required for routine IRB review, it is necessary to be certain that a budget is developed to cover these additional costs. An estimate of costs will depend upon the number of sites; the number of protocols and the type of research. The Human Research Affairs Office also works closely with the Partners Office of the General Counsel and the Office for Interactions with Industry on these requests, and the budget will need to take into account the costs associated with the additional work for these offices (and in some cases, outside legal counsel costs) as well.

For the IRB to consider creation of a cIRB, the PI must complete the REQUEST FOR PHS IRB TO BE THE CENTRAL IRB (cIRB) form. This form should be returned to Maria Sundquist at *msundquist@partners.org.* The Human Research Affairs (HRA) Office can then best identify the resources required to provide a cIRB for your project. There are costs specific to setting up the cIRB as well as for the ongoing work of the cIRB.

Background information on central IRBs:

The oversight of a human research protocol includes both regulatory review (IRB review) and institutional compliance requirements. The cIRB performs only the regulatory IRB reviews, and each institution engaged in the research retains the responsibility for completing all other institutional requirements (such as compliance with the terms of its Federal Wide Assurance (FWA), oversight of its investigators and the conduct of the research, HIPAA compliance, compliance with state and local laws, etc.). Therefore it is critical to delineate the interface between and different responsibilities of the cIRB and the relying institutions.

Definitions:

Reviewing IRB: the IRB that conducts the regulatory review of a protocol. For the purpose sof this discussion, the reviewing IRB is the cIRB.

Relying institution: the institution that formally agrees to cede regulatory review to another IRB. Note that it is the institution- and not the IRB- that is the relying party.

Reliance Agreement: an agreement signed by institutional officials of both the relying institution as well as the institution of the designated cIRB or reviewing IRB. This agreement includes details of legal responsibility as well clear delineation of which institution is responsible for what in the review and oversight of a particular protocol.

Federal Wide Assurance (FWA): document an institution files with the Office of Human Research Protections (part of DHHS) that holds the institution to the federal standard of protection of human subjects in research.

Who does what in a basic cIRB model:

The cIRB (reviewing IRB) is responsible for:

- Conducting all regulatory review (usually including HIPAA Privacy Board determinations if any.)
- Fulfilling responsibilities delineated in the Reliance Agreement; e.g.,
    - Request and consider site-specific protocol feedback as appropriate
    - Communicate cIRB reviews with the PI and sites (usually through a cIRB liaison)
    - Report problems and events to institutional officials and regulatory agencies, e.g. unanticipated problems involving subjects or others, serious or continuing noncompliance, and suspension or termination of approved research

The relying institutions are responsible for:

- Complying with the Reliance Agreement
- Providing local site information as requested by the cIRB
- Notifying the cIRB of any state and/or local laws that may affect the protocol review
- Providing site-specific informed consent form language
- Completing all site sign-offs: e.g., division chief, any special site sign-off for research involving for example, Emergency Room, Operating Room or Labor and Delivery
- Completing all ancillary reviews; e.g., pharmacy, radiation safety, Conflict of Interest assessment.
- Ensuring researchers have fulfilled local credentialing requirements as needed
- Educating researchers and study staff
- Implementing HIPAA (e.g., tracking of disclosures made pursuant to a waiver of authorization)
- Ensuring compliance with the cIRB's requirements and determinations
- Investigating problems and events and reporting them to the cIRB

The PI is responsible for:

- Developing the protocol and submitting all required protocol documents through Insight/eIRB
- Coordinating communication between the cIRB and PI and all participating sites

Setting up the cIRB system requires a number of steps. The cIRB institution must:

- Understand the type of research that will be conducted
- Obtain information about central organization/governance of the research protocol and/or network/consortium with relevant SOPs
- Obtain information about the sites that will be involved in the research and FWAs
- Execute a reliance agreement with each of the relying institutions that have their own distinct FWA.