CHAMBERLAIN UNIVERSITY

Frequently Asked Questions (FAQs):
IRB Reliance Agreements at Chamberlain University

A. THE NOTION OF A RELIANCE AGREEMENT

1. What is a reliance agreement?

   A reliance agreement (also called an IRB Authorization Agreement) is a document signed by two or more institutions engaged in human subjects research that permits one or more institutions to cede primary review and oversight to another IRB. Such an agreement allows a single IRB to review and oversee human subject research activities for more than one site.

2. What is the purpose of a reliance agreement?

   Use of a reliance agreement avoids duplicate IRB initial review and continued oversight when multiple IRBs have jurisdiction for the same multi-site research protocol. Once the agreement is executed, it can decrease the administrative burden and regulatory oversight of multiple institutions' IRBs.

3. Are reliance agreements accepted by all institutions?

   No. Institutions vary as to whether they will make use of reliance agreements, or they may use reliance agreements in certain contexts but not in others. Institutions usually decide if they will allow a reliance agreement based on the research protocol being reviewed. Some institutions have standing arrangements to utilize other IRBs for specific types of research. Current federal regulations allow for reliance agreements to be used for multi-site research.

4. Does Chamberlain University use reliance agreements?

   Yes. Chamberlain University has agreed to allow other institutions to cede review and oversight to the Chamberlain University IRB, and it has also agreed to relinquish review and oversight to IRBs at other organizations; however, Chamberlain's willingness to use agreements is study and context-specific.

5. How is a decision made whether a reliance agreement should be considered and used?

   Several factors (such as the study protocol, the risk level, the involvement of each institution and its investigators, funding, etc.) are considered when determining whether a reliance agreement should be used or whether each institution should conduct their own independent review. Chamberlain University investigators are encouraged to contact the IRB (irb@chamberlain.edu) to assist with such determinations.

B. THE PROCESS OF REQUESTING CHAMBERLAIN TO BE THE *RELYING* INSTITUTION

1. What does it mean for Chamberlain to be the "relying" institution?

   Becoming the relying institution allows Chamberlain to cede primary responsibility for reviewing and overseeing a study to another IRB. This, however, does not relieve Chamberlain of all accountability for the protection of study subjects. Chamberlain will still be responsible for ensuring that study activities carried out in Chamberlain facilities adhere to the study protocol and Federal requirements, ensure that Chamberlain researchers are appropriately qualified and comply with Chamberlain policies, and monitor any unanticipated problems or adverse events involving Chamberlain facilities or members of the Chamberlain community.

2. How does the Chamberlain University IRB decide to accept or decline a request to become a relying institution?

   Several factors (such as the study protocol, the risk level, the involvement and requirements of each institution and its investigators, funding, regulatory requirements, etc.) are considered in deciding whether a reliance agreement should be sought or whether each engaged institution should conduct their own IRB review. The decision to accept or decline the use of a reliance agreement is done on a protocol-by-protocol basis.

3. How do I submit a request for Chamberlain University to become a relying institution?

   The principal investigator (PI) of the study must submit an "IRB Reliance Agreement Request for Chamberlain University IRB to Serve as the *Relying* IRB" form to the Chamberlain IRB. The IRB will complete the necessary information on the form and return it to the PI. The PI will then take the form to the IRB who will assume primary oversight for completion. The PI must return a copy of the agreement form to the Chamberlain IRB signed by all parties. This process must be completed prior to the initiation of the study.

C. THE PROCESS OF REQUESTING CHAMBERLAIN TO BE THE *REVIEWING* INSTITUTION

1. What does it mean for Chamberlain to be the "reviewing" institution?

   Becoming the reviewing institution allows Chamberlain to assume primary responsibility for reviewing and overseeing a study. By doing so, all other IRBs involved in the study will become relying IRBs. The Chamberlain IRB will require a separate agreement with each IRB who will become a relying IRB.

2. How does the Chamberlain University IRB decide to accept or decline a request to become a reviewing institution?

   Several factors (such as the study protocol, the risk level, the involvement and requirements of each institution and its investigators, funding, regulatory requirements, etc.) are considered in deciding whether a reliance agreement should be sought or whether each engaged institution should conduct their own IRB review. The decision to accept or decline the use of a reliance agreement is done on a protocol-by-protocol basis.

3. How do I submit a request for Chamberlain University to become a reviewing institution?

   The principal investigator (PI) of the study must submit an "IRB Reliance Agreement Request for Chamberlain University IRB to Serve as the *Reviewing* IRB" form to each IRB who will serve as a relying IRB. After each IRB has completed the form, the PI will submit completed forms to the Chamberlain IRB. The Chamberlain IRB will then evaluate each agreement and the study protocol. Upon approval, the Chamberlain IRB will provide completed reviews and agreements to the relying IRBs. This process must be completed prior to the initiation of the study.

D. RESPONSIBILITIES ONCE AN AGREEMENT IS IN EFFECT

A. What are my responsibilities as the principal investigator (PI)?

The responsibilities of the PI are no different toward the reviewing IRB; all usual PI responsibilities still apply. Relative to the relying IRB, PI responsibilities include, but are not limited to, the following:

- Informing the relying IRB of all unanticipated problems and adverse events occurring in locations and contexts under the jurisdiction of the relying IRB;
- Ensuring that all study personnel at locations under the jurisdiction of the relying IRB are appropriately qualified and following approved protocols;
- And for ensuring that all study procedures occurring in locations under the jurisdiction of the relying IRB adhere to the approved study protocol and all policies and procedures of the relying institution.

E. ADDITIONAL INFORMATION

1. How can I receive additional information?

   Additional information and forms are located at the Chamberlain University IRB website (https://library.chamberlain.edu/IRB). You may also contact the IRB at irb@chamberlain.edu .

Reference: Boston Children's Hospital IRB
https://www.childrenshospital.org/~/media/research-and-innovation/office-of-clinical-investigation/reliance-agreement-faqs.ashx?la=en