

# Getting Started: When the CHOP IRB provides Oversight for Outside Institutions

CHOP is willing to serve as the Reviewing IRB for one or more Relying Sites. This process requires each institution to accept this arrangement.

## 1. Start the Discussions

Contact the CHOP IRB to schedule a call to discuss your research and determine whether or not this arrangement is appropriate for your research. The IRB will need information about the research and the institutions that will be conducting the research. The IRB office will determine the applicable reliance agreement for each Relying Institution.

Contact the other site Principal Investigators to discuss the submission and IRB review process when CHOP is the Reviewing IRB. Encourage them to also speak to their local IRB about this process.

Additional information about the process can be found at the IRB website:  
<https://irb.research.chop.edu/irb-reliance-agreements>.

## 2. Submit Study for Review/Approval by CHOP IRB

Submit your study to the CHOP IRB in eIRB. Usually, the Reviewing IRB must grant approval of the protocol before another institution will agree to cede oversight.

## 3. Send Materials to Other Sites

When final IRB approval has been granted by CHOP\*, please provide a reliance packet to the other sites and ask that they rely on CHOP as the Reviewing IRB. This reliance packet should include the following:

- CHOP IRB Approval Letter addressed to the CHOP PI
- Customized Introduction Letter to outside institution (based on IRB template which explains the process of relying on the CHOP IRB)
- Relying Site Survey for completion by the local investigator in consultation with the local IRB (so that site-specific issues, such as state law or conflicts of interest by the local investigator(s), can be taken into account by the CHOP IRB)
- IRB Reliance Agreement (e. g. IRB Authorization Agreement or Determination Form) to be signed
- Protocol (*version date cited in the above CHOP IRB approval letter*)
- Consent Form Template(s) (*version date cited in the above CHOP IRB approval letter*)
- Other study materials required by that site for review (*e.g. recruitment materials specific for that site*)

The Relying Site may customize some sections of the consent form(s) to meet institutional requirements – injury compensation, HIPAA authorization language, investigator contact information. These edits will be reviewed as part of the final CHOP IRB review.

Many sites require that investigators submit a request to cede IRB oversight through their local IRB system. This submission is not an IRB review/approval (since the IRB review will be ceded to CHOP) but rather an administrative review to track research occurring at that site and to facilitate any required local ancillary reviews (safety committee reviews, clinical trials office reviews, etc.). Please ensure that other investigators follow their local IRB's process regarding these requests.

*\*Note: Many sites will want to see the approved protocol and consent document(s) to determine if they will rely on an external IRB. This is why it is suggested that study approval at CHOP take place first. However, it is possible in certain cases to start the submission process before final approval at CHOP.*

#### **4. Submit Materials to CHOP's IRB**

Once an outside Institution has agreed to rely on CHOP IRB oversight, the CHOP Principal Investigator must submit an amendment to the approved protocol in eIRB (see *Note* above for exceptions).

- An amendment must be submitted for each site. However, multiple requests can be grouped within a single amendment.
- Please do not submit any site documents until all the documents from that site are available and complete.

As part of the amendment, the study team must include the following in the eIRB study application:

- Applicable Reliance Agreement for the Relying Institution
- Relying Site Survey and related attachments
- Consent form and recruitment materials with site-specific edits, if applicable

#### **5. IRB Authorization Agreement Acknowledged by CHOP**

After submission in the eIRB system, the amendment will be reviewed by a member of the CHOP IRB. If approved, the CHOP IRB will provide an approval packet for each site Investigator. The packet will contain the CHOP IRB Approval Letter identifying the Relying Site, stamped Consent Form(s) and executed IRB Authorization Agreement/Determination Form. The CHOP Study Team must forward these documents to the Relying Site.

If the IRB Authorization Agreement/Determination Form was not previously signed by the CHOP Institutional Official (or designee), it will be signed at this time and provided to the CHOP Principal Investigator to share with the Relying Site.

## **6. Final Expectations**

The CHOP Study Team is responsible for all submissions to the CHOP IRB regarding initial IRB review, continuing review of the research and the activities at each site, and protocol amendments. The CHOP Study Team is also responsible for sharing IRB approval documentation to the Relying Sites.

Any reportable events that occur at CHOP or one of the Relying Sites must be submitted to the CHOP IRB, by the CHOP team, via the eIRB system. Reportable events include major protocol deviations, non-compliance that might be either serious or continuing, or unanticipated problems involving risks to subjects or others. See the CHOP IRB website page on Reportable Events for more information about what must be reported: <https://irb.research.chop.edu/reportable-events>.

At the time of continuing review, the CHOP team will collect each site's progress report (e.g. number of subjects enrolled) and submit it to the CHOP IRB.

## **7. Contact the CHOP IRB with questions:**

CHOP IRB Office  
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