

Principal Investigator Responsibilities CHOP and Relying Institutional Investigators

Your institution has agreed to have the Children's Hospital of Philadelphia (CHOP)'s IRB provide IRB oversight for a multi-site study. It is important for Principal Investigators at both sites to understand their responsibilities under this agreement. Reliance agreements for particular studies outline responsibilities of each institution. This document is intended to review the responsibilities for both Principal Investigators to assure compliance with all applicable regulations and protocol responsibilities.

CHOP Principal Investigator Responsibilities:

1. Collect information from the Relying Site Principal Investigators required for the protocol application, including but not limited to the information listed below and information regarding any special local considerations that must be considered by the CHOP IRB, and provide this information to the CHOP IRB.
2. Include in the CHOP amendment application the following:
 - The name of the Relying Site Institution and Principal Investigator;
 - IRB Authorization Agreement or Determination Form for Master Reliance Agreement signatory institutions;
 - Completed Relying Site Survey, including any local context issues for inclusion in the CHOP IRB review of the Relying Site; and
 - Any management plans related to financial interest disclosures for Relying Site Principal Investigators and research personnel involved in the Study at the Relying Site, if applicable.
3. Promptly provide the Relying Site Principal Investigator with:
 - Current CHOP IRB approved protocol and consent documents;
 - Documentation of CHOP IRB approved modifications, amendments or changes to the protocol;
 - Documentation of CHOP IRB approval of continuing reviews, review and

- acknowledgement of unanticipated problems;
- Any other information required by the CHOP IRB to be provided to the Relying Site.
4. Notify the Relying Site Principal Investigator of the policies of the CHOP IRB for the reporting of any post-approval events, such as (i) proposed amendments or changes in Study activities, (ii) subject complaints or unanticipated problems involving risks to subjects or others, and (iii) protocol violations.
 5. Collect required information from the Relying Site Principal Investigator to complete the continuing review submissions.
 6. Collect reports from the Relying Site Principal Investigator of any unanticipated problems, deviations, suspensions and terminations, noncompliance, and/or subject complaints, and submit such reports to the CHOP IRB.
 7. Notify the Relying Site Principal Investigator about any lapses of CHOP IRB approval. If applicable, forward to the CHOP IRB any request from the Relying Site Principal Investigator for continuation of a specific patient on a research protocol during a lapsed period of approval.

Relying Site Principal Investigator Responsibilities:

1. Consult with your local Institution's IRB while completing the CHOP Relying Site Survey regarding questions related to state and local laws having impact on the research, FWA information, and preferred local Institution IRB contact information.
2. Comply with local Institutional requirements for human subjects training, conflict of interest disclosures and management plans, and ancillary approvals.
3. Follow local requirements for the submission of study team members, including personnel changes.
4. Do not initiate any human subjects research activities for this study at your site until you have received your CHOP IRB approval notice and have complied with all local institutional requirements. If CHOP IRB approval expires, all human subjects research activities for this study must stop.
5. Ensure that each individual to whom a task is delegated is qualified by virtue of education, training, and experience (e.g., hospital certification, human subjects

- research training, state license) to perform each of their delegated tasks.
6. Conduct the protocol and obtain informed consent as approved by the CHOP IRB.
 7. Provide the CHOP study team with the required continuing review information for submission to the CHOP IRB. This will include information regarding subject enrollment, minor protocol violations and adverse events.
 8. Promptly forward to the CHOP study team any reports of Unanticipated Problems Involving Risks to Subjects or Others and/or non-compliance with the applicable regulations, protocol, or CHOP IRB policies (<https://irb.research.chop.edu/policies>). The CHOP Principal Investigator will provide this information to the CHOP IRB for review.
 9. Personally conduct or supervise the research.
 10. Protect the rights, safety and welfare of the participants who will be under their care. To do this, the Principal Investigator agrees:
 - That the research is conducted in accordance with all federal regulatory requirements, state law and CHOP policies (including CHOP IRB SOPs);
 - That the research is conducted in accordance with the CHOP IRB approved plan; and
 - That they will ensure the accuracy, security and integrity of the research data and the subsequent analysis of that data.
 11. Maintain appropriate copies of all approvals, and other correspondence documenting the review and approval of the research as required by the regulations.