The Children's Hospital of Philadelphia®

Committees for the Protection of Human Subjects, Institutional Review Board

INVESTIGATOR RESPONSIBILITIES

IRB Website:
https://intranet.research.chop.edu/display/cmtirb/Home

Conditions of Approval
IRB approval does not include enrollment of pregnant women, the fetus or prisoners unless specifically included in the approval letter. If a participant becomes pregnant or incarcerated while on study, the IRB must be notified immediately. See **SOP 408** (Unanticipated Problems). For details see IRB **SOP 502** (Pregnant Women) and **503** (Prisoners).

Changes to Research Activities or Amendments: The investigator is responsible for ensuring that no changes are made to the research activity without the prior approval of the IRB. In multi-center studies, the sponsor or Study Chair must also prospectively agree to the change in writing. The sole exception to this requirement is when changes are needed to eliminate an immediate hazard to a subject. In this eventuality, a description of the event, the implemented deviation or change, the reasons for the change, and if appropriate, the proposed protocol amendment(s) should be submitted to the IRB promptly.

The IRB website should be consulted for more information including: IRB **SOP 403** and the IRB webpage on *Reportable Events*.

Continuing Review, Study Termination and Record Retention: Institutional policy and federal regulations require timely continuing review of ongoing research and reports of progress at least once per year unless the approval letter indicates a more frequent review. The expiration date for IRB approval is provided on the Approval Letter and in the eIRB study workspace. For details of the continuing review reporting requirements, consult IRB **SOPs 304/404** on the IRB website. Records must be retained for at least 3 years from study closure.

Granting Permission for Children to Participate in Research: When determining who is permitted to grant permission (consent) in the research setting, investigators must conform to CHOP policy for Consent (in treatment setting) RI-5-01. These definitions apply

1. Parent: means biologic or adoptive.
2. Guardian: means an individual authorized under state or local law to consent on behalf of the child.
3. Wards of the State/ Foster Children: Foster parents may NOT consent for treatment or research participation for minor children. Only when a legally authorized individual grants permission, may a foster child participate in research.

See IRB **SOPs 504**: Research involving Children and the webpages on *Children in Research*

Obligations for Obtaining Permission/Informed Consent (See **SOPs 504 and 702)**
In conformance with the additional protections for children (Subpart D), the IRB assigns a risk-benefit category to all research involving children as subjects. The risk category is listed in the approval letter and determines whether one or both parents/guardians must grant permission to allow their child to participate in research.

For research approved under §46.404/§50.51 or §46.405/§50.52, the permission and signature of one parent/guardian is usually sufficient.

1. For research approved under §46.406/§50.53 or §46.407/§50.54, the permission and signatures of both parents/guardians are required, unless one of the parents/guardians is not reasonably available. *Additional Requirements for Children who are Wards of the State (Foster Children)* (i) Wards cannot participate in research approved under these categories unless: the IRB determines that their participation is (a) related to their status as wards or (b) conducted in schools, camps, hospitals, institutions or similar settings where the majority of children involved are not wards of the state. The investigator must provide this information to the IRB to allow it to make this determination. (ii) An advocate is appointed for each child who is a ward. This is in addition any other individual acting on behalf of the child as guardian or in loco parentis.

Participants, Parents/Guardians Who Are Non-English Speaking: If the subject or their parents/guardians are non-English speaking, either the consent form must be translated into the native language or a Short Form consent process must be used. See the IRB webpage on *Short Form Consent*

Witnesses to the Consent Process
A witness (fluent in both languages) to the consent process is only required, when the subject's parent/guardian are illiterate or if a Short Form consent process is used.

Unanticipated Problems: CHOP policy requires prompt reporting of any unanticipated problem involving risks to subjects or others to the IRB within 1 week of identification. This includes (1) adverse events that are serious, not anticipated and related to the research activity (SAEs) and, (2) other unanticipated problems involving risks to subjects that are unexpected and related/possibly related to the research. Examples of reportable events include breaches of confidentiality and participant pregnancy or incarceration. AEs that are not serious can be summarized at the time of continuing review. The IRB website contains additional information including, IRB **SOPs 408** and the webpage on *Reportable Events.*