**Grant Template Language regarding the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research**

**If the decision has been made to use CHOP as the IRB of record:**

The Children’s Hospital of Philadelphia (CHOP) IRB will serve as the reviewing IRB for this multi-center study. All participating sites will adhere to the sIRB Policy (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>). All identified sites have agreed to rely on CHOP as the sIRB. Any sites added after the award will rely on the sIRB.

The CHOP IRB will serve as a Privacy Board to fulfill the requirements of the HIPAA Privacy Rule (45 CFR 164.512(i)) for use or disclosure of protected health information for research purposes.

The CHOP IRB has extensive experience with providing IRB oversight for external institutions and complies with the registration requirements for both OHRP and the FDA (IRB00000316 and IRB00000317).

Unless already in place, prior to initiating the study, all participating sites will sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.

As of June 2017, CHOP has entered a Master Reliance Agreement with more than 20 institutions (the CHOP IRB’s website maintains a current list of institutions at <https://irb.research.chop.edu/irb-reliance-agreements>). For any of the participating sites, a determination form (available at <https://irb.research.chop.edu/irb-reliance-templates>) will be signed by both institutions to indicate that the reliance agreement is applied to a particular study.

CHOP has also signed the SMART IRB Authorization Agreement. The SMART IRB online system supports the documentation of reliance for a particular study. As of June 2017, more than 230 participating institutions have signed the SMART IRB Agreement (<https://smartirb.org/participating-institutions/>).

CHOP has a template IRB Authorization Agreement (IAA) for sites that are not signatories to either the Master Reliance Agreement or SMART IRB. This IAA will be used to negotiate a study-specific reliance agreement with the non-signatory sites.

The signed determination forms or IAAs will be maintained with the study documents in the CHOP IRB’s electronic IRB management system (eIRB). Entries to eIRB will document compliance with the IRB sIRB policy.

The CHOP IRB has developed a package for the principal investigator (PI) leading a multi-site research project where the CHOP IRB will serve as the reviewing IRB. This package includes the following:

a) A “Getting Started” document outlining the process for the CHOP PI to request that CHOP act as the reviewing IRB for other institutions,

b) An “Introduction Letter” to send to outside institutions who are considering relying on the CHOP IRB, and

c) A “PI Responsibilities” document outlining the responsibilities of the PI at CHOP and the responsibilities of the PIs at relying institutions, including information on how to communicate site information to the CHOP PI and the CHOP IRB. These documents are available on the CHOP IRB website at: <https://irb.research.chop.edu/single-irbs-and-irb-reliance-agreements>.

d) A “Relying Site Progress Report” which allows the collection of each site’s progress report (e.g. number of subjects enrolled) for submission to the CHOP IRB.

When the CHOP IRB serves as the Reviewing IRB (sIRB) for other sites, it will need information from each relying institution about local context, consent form requirements (e.g., injury compensation language), applicable state/local laws and any local conflict of interest determinations. The CHOP IRB will provide approval notices and approved informed consent documents customized with the local PI name, contact information and any other site-specific wording (e.g., injury compensation, HIPAA) for each relying institution.

The CHOP IRB, as the sIRB, will communicate with the CHOP PI through eIRB, which the CHOP investigators also use for all other IRB submissions at CHOP. Communication with relying sites and their PIs will occur through the same system. The CHOP IRB has developed a mechanism for the relying site PIs to communicate directly with the CHOP IRB through the eIRB system. This avoids the need to have the CHOP PI collect the information from all of the relying sites and submit them to the CHOP IRB. eIRB provides the ability for PIs from each relying institution, after a simple registration process, to log in and provide site-specific documents and information (e.g., annual reports, site-specific recruitment materials) to the CHOP IRB. The CHOP IRB, in turn, will post site-specific packages (approval letters, stamped consent forms, etc.) for the use of the relying site PIs.

**If, in delayed-onset research, a decision on which IRB will serve as the IRB of record has not yet been made:**

We will follow the *Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094)* and communicate plans to use a registered IRB of record to the funding NIH Institute/Center prior to initiating a multi-site study.