To: Institutions Considering Relying on CHOP’s IRB

From: *insert CHOP PI/study coordinator*

Date: July 17, 2017

Protocol Title: *insert Protocol Title*

Thank you for your interest in relying on the Children’s Hospital of Philadelphia (CHOP) IRB for the above-referenced protocol. The CHOP IRB is willing to consider serving as the Reviewing IRB for one or more Relying Sites when the research will also be conducted at CHOP.

At this time, we are providing you with the associated information and documents so that you may review what is required to rely on the CHOP IRB for this research. Please contact your IRB and adhere to their process and requirements for relying on an external Reviewing IRB.

It is critical to clearly outline the responsibilities both for the Reviewing IRB and for the Relying Institution. The CHOP IRB’s document titled *Principal Investigator Responsibilities: CHOP and Relying Institutional Investigators* will help investigators understand the CHOP IRB’s expectations. In addition, the *IRB Authorization Agreement/Determination Form* that will be signed by both institutions outlines both the Reviewing IRB’s and the Relying Institution’s responsibilities.

A brief summary of the process and requirements for studies when CHOP is the Reviewing IRB for research conducted at outside institutions is outlined below:

1. Information about your site is required for the CHOP IRB to provide oversight and approval for your site’s participation in the referenced protocol. This documentation includes your site’s:
	1. Completed Relying Site Survey and any applicable documents referenced in the survey (this includes information that is specific to your institution, including state laws the CHOP IRB needs to consider and Conflict of Interest management plans);
	2. Signed IRB Authorization Agreement or Determination Form (if your institution has already entered into a Master Reliance Agreement with CHOP) - the reliance agreement needs to be signed by your site’s Institutional Official (this is a specific person who has been designated for this role at your site. Your IRB office should be contacted and facilitate this process); and
	3. Consent Form Template and recruitment material with site-specific edits (if applicable). Apart from the name and contact information of the site PI, only the following sections of the consent form may be edited - HIPAA language, financial COI disclosures, and local site-specific language regarding research-related injury. A final consent document will be approved that is specific for your institution, which incorporates the required language for these sections only. All other sections of your site-specific consent form must match the CHOP IRB-approved consent form.
2. Provide the applicable electronic documents to the CHOP PI for submission to the CHOP IRB.
3. The CHOP IRB will review your site information as an amendment to the previously approved protocol. If there are any clarifications required, the CHOP Principal Investigator will contact you for clarification.
4. Once your site has been approved by the CHOP IRB, the approval documents will be generated and released to your site. When applicable, you will be provided with the stamped site-specific consent form(s) that must be used to enroll subjects at your site. No human subjects research activities may begin at your site, for this study, until you have received CHOP IRB approval notice and complied with any additional requirements imposed by your local institution.

Please contact the CHOP Principal Investigator with questions about the research:

Please contact the CHOP IRB with questions about the IRB related documentation:

CHOP IRB Office

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