

Date: Wednesday, April 29, 2020 1:24:26 PM

Print Close

View: SF - Reliance Information

Title: Reliance: Children's Hospital Philadelphia -Sample New Research Activity

Reliance Information

1 * What Institution will rely on the Boston Children's IRB (the IRB ceding review to BCH)? Children's Hospital Philadelphia - FWA00000459

If Other:

- **1.1** Please enter the name of institution.
- 1.2 FWA Number
- 2 * Who is the Principal Investigator at the relying site? Ashley Kuniholm

If the person you need to add to your protocol cannot be found using the "Add" button above, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that an account be created for the NON-BCH Principal Investigator. CHeRP Support will need the following information:

- First Name
- Last Name
- Email Address

3 What type of reliance agreement is being requested? Please select one:

3.1 Smart IRB Master: Reliance agreement between BCH and another SMART IRB affiliated institution.

See link for more information: https://smartirb.org/

- 3.1.1 What is the SMART IRB reliance application ID? GG00007865
- 3.2 Master (consortium-based): Reliance agreement among a consortium/network of institutions (other than SMART IRB).
 - 3.2.1 Please specify consortium:
- 3.3 Other: Reliance agreement between BCH and another institution not affiliated with a master agreement
 - 3.3.1 Please specify:
- 4 Please only list researchers/staff engaged in the protocol at the relying site IF they have a conflict of interest(expect to have any financial interest, financial relationship, or position / advisory role with any other entity).BCH IRB considers 'engaged' to be interacting with subjects and/or obtaining individually identifiable data.

Last Name	First Name	Employee ID	Role
View Mitchell	Anna	99923	Research Coordinator/Assistant

If the person cannot be found using the "Add" button above, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that an account be created for the NON-BCH person to be added here. CHERP Support will need the following information:

- First Name
- Last Name
- Email Address
- 5 * Financial Disclosure: Do any of the NON-BCH researchers, or staff affiliated with the protocol have or expect to have any financial interest, financial relationship, or position or advisory role with any other entity that may be affected by the research to be conducted under the protocol relationship with any entity that is providing funds or other support in connection with the protocol?

🔿 Yes 🔵 No

If YES:

5.1 Please describe the conflict of interest and any pertinent management plan.

5.2	Please submit any pertinent documentation.			
	Name	Date Last Modified	Version	Owner
	There are no items to display			

6 Please upload any reliance request documentation that the relying site completed, (if applicable)

Name	Date Last Modified	Version	Owner
Site Specific Requirements.docx	4/29/2020 1:22 PM	0.01	PI Test

7 * Will consent/assent form(s) need to be individualized for the relying sites (include site specific information such as additional HIPAA language, conflict of interest disclosures, injury language, contact information, addition of site header/logo, etc. boiler plate signature section).

🔵 Yes 🔿 No

8 * Will recruitment documents need to be individualized for the relying sites?

🔵 Yes 🔘 No

9 * Please indicate all research activities being conducted at the relying site and/or conducted by the relying site researchers at BCH. Check all that apply:

Recruitment

Consenting

Medical Chart/Record Review

Identifiable Data Analysis

Data Collection

Other

If Other:

Please specify:

If Data Collection:

Please check all that apply:

- Conducting surveys/questionnaires
- Drug/Device intervention

Clinical exams and medical assessments (i.e. exams, x-rays, scans, EKG, ECHO, EEG, MRIs)

Specimen collection (for clinical testing or research)

\Box	Other

If Other:

Please specify:

9.1 * Please describe all research activities being conducted at the relying site and/or conducted by the relying site researchers at BCH (specify where research activities will be conducted).

Describe all research activities being conducted at the relying site and/or conducted by the relying site researchers at BCH.

10 * What is your plan for communicating IRB actions, revised protocols, consents, etc. with this relying site (if different than described on the Multi-Site Information page, #1.2 of the main protocol)? Plan for communicating IRB actions, revised protocols, consents, etc. with this relying site

Title: Reliance: Children's Hospital Philadelphia -Sample New Research Activity

Consents and Recruitment Materials

1 Please upload the site specific consent here. Please be sure that the title includes the name of the institution

Name	Date Last Modified	Version	Owner
Site Specific Consent.docx	4/29/2020 1:23 PM	0.01	PI Test

2 Please upload the recruitment documents here

Name	Date Last Modified	Version	Owner
Recruitment Poster.docx	4/29/2020 1:24 PM	0.01	PI Test

Owner

Title: Reliance: Children's Hospital Philadelphia -Sample New Research Activity

PI's Statement

1 Upload any additional documents you think may be pertinent to this reliance request.

Name	Date Last Modified	Version

There are no items to display

2 * I am aware of and support the reliance request that is being made for Boston Children's Hospital IRB to serve as the IRB for record for the above mentioned site. As the PI, I take full responsibility for submitting initial and ongoing information that requires IRB review from the other relying sites. I will also keep the relying site PIs informed about any associated IRB review activities and will make available to all sites the approved protocol, recruitment materials, consents, reports of actions, and any other documents and communications pertinent to IRB review. I assure that I have the appropriate resources to fulfill these additional responsibilities in order to assure all required human subject protection policies.

• Yes • No