Boston Children's Hospital

Date: Sunday, March 23, 2025 2:27:32 PM Print Close

IRB-RL00050051-1 Reliance Information

Title: Reliance: Massachusetts General Hospital (MGH) -Test removal of device question

Reliance Information

1 * **What Institution will rely on the Boston Children's IRB (the IRB ceding review to BCH)?**
Massachusetts General Hospital (MGH) - FWA00003136

If Other:

1.1 Please enter the name of institution.

1.2 FWA Number
FWA

2 * **Who is the Principal Investigator at the relying site?**
Russell Jenkins

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?
1234

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	E-Mail	Role
There are no items to display				

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 Number	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 Number	Owner
Reliance-on-Another-IRB-Final-24Jan2022 (11).pdf(0.01)	3/23/2025 2:25 PM	0.01	Lisa Prock

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 * **For protocols approved with a waiver of informed consent/documentation (method other consent), will the verbal consent or information sheets need to need to be individualized for the relying sites?**

● **Yes** ○ No

10 * **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)
- ☐ Other

If Other:

Please specify:

10.1 * **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).**

Test

11 * **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)?**

Commmunicaton

IRB-RL00050051-1 Consents and Recruitment Materials

Title: Reliance: Massachusetts General Hospital (MGH) -Test removal of device question

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	Category	Date Last Modified	Version Number	Owner
Reliance-on-Another-IRB-Final-24Jan2022 (11).pdf(0.01)	Relying Site Consent/Assent	3/23/2025 2:27 PM	0.01	Lisa Prock

2 Please upload the recruitment documents here

Name	Category	Date Last Modified	Version Number	Owner
SOP Grant Certification 2.0.pdf(0.01)	Recruitment	3/23/2025 2:27 PM	0.01	Lisa Prock

IRB-RL00050051-1 Method of Consent Other Than Written

Title: Reliance: Massachusetts General Hospital (MGH) -Test removal of device question

Method of Consent Other Than Written

1 * **Is this protocol approved to obtain consent in a method other written consent? This means the protocol is approved with a waiver of consent documentation and participants may provide verbal consent.**

◯ Yes ● **No**

If Yes:

1.1 Upload all consent and assent documents that will be used for verbal or implied consent, including consent scripts, information sheets, emails with links to surveys, etc. If there is more than one, list the titles or categories of each document submitted (e.g. experimental, control, sub-study)

Name	Date Last Modified	Version Number	Owner
There are no items to display			

IRB-RL00050051-1 PI's Statement

Title: Reliance: Massachusetts General Hospital (MGH) -Test removal of device question

PI's Statement

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

Name	Date Last Modified	Version Number	Owner

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