Boston Children's Hospital

Date: 2/25/2015, 1:23:32 PM

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Title: Protocol to Rely on Institute XYZ

General Information

1 * **Protocol Title:** Protocol to Rely on Institute XYZ

Maximum of 230 characters may be entered.

2 **Full Title - If protocol title exceeds the 230 characters limited from field above, enter full title here. Otherwise, leave blank.**
Protocol to Rely on Institute XYZ

3 * **Provide a brief summary (in lay terms) of the research protocol.**
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4 * **Principal Investigator (PI):** Jane Smith

5 * **Type Of Submission:**

- ○ New Research Activity
- ○ New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients*
- ○ Establishment of Human Biological Specimen Repository/ Data Registry (only) – repositories/registries are defined as a prospective collections of specimens or data that are processed, stored, distributed to multiple investigators for use in research.
- ○ Request for Exemption
- ○ Single Patient Emergency
- ○ Humanitarian Use Device (HUD)
- ◉ **Reliance on Another IRB**
- ○ Projects that lack immediate plans for involvement with human subjects, their data and/or their specimens (i.e.training grants)

** Excess means the tissue is or was collected for reasons other than research purposes, or at least other than for the purposes of this research. Excess Human Biological Material is defined as any specimen obtained from patients (or human research subjects), e.g.: fixed, frozen or fresh pathology or autopsy specimens, any blood, urine, saliva, semen, breast milk or other biological material, any purified DNA, RNA, proteins, cell lines or clones.* ***This may not be selected if the study involves interaction/intervention with subjects in order to obtain tissue specifically for this research.***

*** If your research involves only laboratory studies with existing stem cells, this is the only application that needs to be completed. This option is not to be used to derive stem cells from embryos or fetal tissue. If there is any intervention with human subjects that involves either a) the derivation of stem cells from embryos or, b) the implantation of stem cells obtained from fetal tissue or embryos, please select "New Research Activity".*

6 * **Is this protocol related to child health (including perinatology, prenatal assessments, childhood antecedents of adult disease, and long-term follow up of pediatric disorders)?**
○ Yes ◉ **No**

7 * **Is this protocol related to cancer (primarily concerning malignancies, oncology patients, or involving use of malignant tumors)?**
○ Yes ◉ **No**

Note: If YES, please consult with your IRB analyst before proceeding. It is possible that your protocol will require review by the Dana Farber IRB instead.
For details, see: Catalyst and Dana Farber Cancer Center Reliance Agreements

8 * **Will this protocol utilize any of the services of the CTSU (Clinical and Translational Study Unit)? Please select "No" for the following types of submission:**
1. Request for Exemption
2. Projects that lack immediate plans for involvement with human subjects, their data and/or their specimens (i.e.training grants)
○ Yes ◉ **No**

These services include:

- *Use of space on 6 East, CAT/CR or research space at Waltham*
- *Nursing assistance at above sites*
- *Off-site nursing and/or research coordinator services provided through CTSU*
- *Specimen collection or processing, sample storage and preparation for shipping*
- *Assistance from nutritional Metabolic Phenotyping Core (preparation of research meals, analysis of food records, etc.)*
- *Potential coverage of study-related research costs (patient care expenses and labs); basic charges covered by Harvard Catalyst grant. Contact CTSU for more details.*
- *Use of specialist equipment located on the CTSU (3DMD camera, DXA, pQCT, V-max, etc.)*

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Reliance on Another IRB

This protocol should be completed when Boston Children's Hospital (BCH) IRB will rely on another institution's IRB. Although another institution will provide IRB review and approval, this protocol will go through administrative review to track all research occurring at BCH and to manage any applicable ancillary (non-IRB) reviews.

1 Please check all categories which are appropriate for your research and reliance agreement.

1.1 * BCH staff or employees will recruit, consent and/or perform research assessments at Boston Children's Hospital facilities but will rely on another IRB.

Yes **No**

Example:
- A research protocol is approved at another hospital but the Boston Children's Hospital PI will recruit and consent subjects at BCH.

1.2 * Subjects are enrolled in research protocols at other sites under the jurisdiction of another IRB but the facilities or resources of Boston Children's Hospital are used for one or more of the research assessments.

Yes **No**

Example:
- Research subjects recruited from another site are sent to BCH for a research procedure and the BCH staff member is a co–investigator.

1.3 * Children's staff or employees will recruit, consent and/or perform research assessments of research subjects outside of Children's Hospital and under the jurisdiction of another IRB.

Yes **No**

Example:
- A Children's investigators collaborate with a PI from another institution and agrees to travels to a community health center to conduct interviews as part of a larger study approved by another IRB.

1.4 * Children's staff or employees will solely be involved in data analysis* and/or recruitment limited to reviewing data for potential subjects.

Yes No

Example:
- BCH researchers are conducting a retrospective chart review, adding BCH patient data to another site's dataset.
- BCH researchers are involved in identifiable data analysis of BCH or another site's data.
- BCH researchers review data for potential subjects to be referred to another site's researchers.

** Please note that IRB oversight is required for identifiable data analysis. Analysis with de-identified data may not require IRB oversight.*

2 * Please indicate (provide rationale) why a reliance agreement is being requested. In other words, please describe why BCH IRB should cede review and oversight to another institution's IRB.

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Research Team

If the person you need to add to your protocol cannot be found using the "Add" buttons below, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that the person be added to the Research Staff. CHeRP Support will need the following information:
- First Name
- Last Name
- CHID# (if applicable)
- CHB Department (if applicable)
- Email Address

1 Research Staff - Children's Hospital Employees only:

Last Name	First Name	Role	Editor	CC on Correspondence	Required Training Completed	CHeRP Training
There are no items to display						

2 PI: Jane Smith

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	8/2/2012
CHeRP Training		2/9/2011
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	8/31/2009
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	8/22/2006
Continuing Education	EQuIP: Study Reviews	3/26/2004
Continuing Education	Continuing Education/Department Meeting	1/9/2004
Collaborative IRB Training Initiative(CITI original)		9/22/2001

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Funding Sources

1 * **Select funding category.**

- ○ Externally sponsored (federal, state, corporate, foundations)
- ○ Internally sponsored
- ○ Externally and internally sponsored
- ◉ **No sponsor**
- ○ Private Donor

1.1 If internally sponsored - select as appropriate:

- ☐ Department/ Division or Children's foundation funds
- ☐ Internal Children's Grant Award

1.2 Enter any additional information if applicable:

1.3 If the protocol does not have a sponsor, please detail how the study will be conducted without funding.

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1.4 Please provide the name of the private donor.

Financial Disclosure

1 * **Do you or any person affiliated with the protocol have or expect to have any investment or financial relationship (examples below) with any entity that is providing funds or other support in connection with the protocol?**

○ Yes ◉ **No**

If YES:

1.1 Please select the relationships as appropriate.

- ☐ Consulting
- ☐ Payments for protocol/study design
- ☐ Protocol-related payments not included in the research agreement budget
- ☐ Stock or Options
- ☐ Honoraria
- ☐ Scientific Advisory Board Membership
- ☐ Royalties or license fees related to the protocol, or to any test article or device which will be employed in the conduct of the research under the protocol (including any royalties or license fees received through an academic institution, including Children's Hospital).
- ☐ Equipment or other laboratory support
- ☐ Other support for research unrelated to the protocol
- ☐ Support for educational or other academic or medical efforts
- ☐ Other Grants
- ☐ Other

2 * **Do you or any person affiliated with the protocol have or expect to have any proprietary interest related to the protocol, or related to any test article or device that will be employed in the protocol? Include proprietary interests that you have assigned to any entity, including any institution you have been affiliated with.**

○ Yes ◉ **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

- ☐ Patent-licensed, in whole or part, to an entity providing funds for the research
- ☐ Patent-licensed, in whole or part, to another entity
- ☐ Other

3 * **Do you or any person affiliated with the protocol have or expect to have any advisory role, appointment, or employment with any entity that is providing funds or other support for the research to be conducted under the protocol?**

○ Yes ◉ **No**

If YES:

3.1 Please select as appropriate.

- ☐ Scientific Advisory Board Membership
- ☐ Other Advisory Role
- ☐ Officer
- ☐ Director
- ☐ Employment
- ☐ Other

4 * **Do you or any person 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 (e.g. competitor, customer, collaborator or commercial sponsor affiliate)? Include any entity that may be benefited or harmed, directly or indirectly.**
Yes **No**

5 * **Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?**
Yes **No**

6 * **The CCI prohibits special incentives in connection with clinical research, including, finder's fees, referral fees, recruitment bonuses, enrollment bonuses for reaching an accrual goal, or similar types of payments. Will you or anyone else in connection with the conduct of any research under the protocol receive money, gifts or anything of monetary value that is above and beyond the actual costs of enrollment, research conduct, and reporting of results, from the sponsor or any other entity?**
Yes **No**

7 * **Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?**
Yes **No**

8 **If any of the questions above are checked "Yes", please provide the name of the individual for whom the disclosure is made and describe in further details the disclosure. This section must include a full description of the financial relationship, including but not limited to, a detailed description, as applicable, of any test article of device involved; the advisory role or appointment; the competitor, customer, collaborator; any arrangement related to the research; and so on. Please also include actual amounts of any consulting or other monies received and the time period for which it was received. This section will not be reviewed without a full disclosure.**

9 **Upload any other pertinent documentation.**

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

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Reliance Information

1 * **What type of reliance agreement is being requested?**
- [x] **Single Reliance**
- [ ] Harvard Catalyst
- [ ] Master consortium/network Reliance

If Harvard Catalyst:

1.1 Please provide Harvard Catalyst 'IRB Cede Review Request' ID.

1.2 Please upload 'IRB Cede Review Request' application here.

2 * **What Institution will be performing IRB review and serve as the IRB of record (the IRB providing review)?**
Institute XYZ - FWA00000000 *If Other:*

2.1 Please enter the institution name.

3 **Who is Principal Investigator at site for IRB of record (the IRB providing review)?**

* **Principal Investigator's Name**
Joe Schmoe
* **Principal Investigator's Email**
joeschmoe@xyz.edu

4 * **Has this protocol already been reviewed by the IRB of record (the IRB providing review)?**
Yes No

If YES:

4.1 What is protocol number?
1234

4.2 Please upload a copy of the initial approval letter.
Institute XYZ's IRB approval document.docx(0.01)

4.3 Please upload a copy of the latest approval letter (if continuing review has occurred).

5 **IRB CONTACT AT INSTITUTION TO REVIEW PROTOCOL (IRB of record)**

5.1 Name

5.2 Title

5.3 Phone Number

5.4 Address

5.5 Email

Protected Health Information and HIPAA Authorization Information

Protected Health Information (PHI) is information acquired by Children's Hospital, including demographic information, that could reasonably identify an individual **AND**:

- Relate to the past, present, or future physical or mental health, condition or treatment of an individual; **OR**
- Describe the past, present, or future payment for the provision of healthcare to an individual.

There are some limited situations when research protocols will not use or create protected health information. For example, educational research conducted in a school setting.

1 ***The following information is considered identifiable PHI under the Privacy Rules regulations. Indicate which of the following will be obtained.**

- [ ] Patient/Subject Name or the names of relatives, employers, or household members
- [x] **Medical record numbers (or specimen #)**
- [ ] Address street location
- [ ] Address town or city *
- [ ] Address state*
- [ ] Address zip code*
- [x] **Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures***
- [ ] Telephone number
- [ ] Fax Number
- [ ] Electronic mail (email) address
- [ ] Social security number
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identification numbers and serial numbers including license plates
- [ ] Medical device identifiers and serial numbers
- [ ] Web URLs
- [ ] Internet protocol (IP) address
- [ ] Biometric identifiers (finger and voice prints)
- [ ] Full face photographic images
- [ ] Any unique identifying number, characteristic or code
- [ ] NONE OF THE ABOVE: this protocol will not use any identifiable PHI

** These items may be included and considered a "limited data set". Use of data under the provisions of a "limited data set" require the signing of a data use agreement by the recipient (this includes researchers).*

Protected Health Information and HIPAA Authorization Information - Continued

1 * **Please check all of the categories that indicate how a research subject's data may be disclosed to other sites.**
De-identified data will be disclosed. Any codes to identifiers will be maintained at BCH.

If 'Identifiable data will be disclosed':

1.1 Specify what identifiers will be disclosed and provide justification why identifiers must be disclosed to other site(s).

Protocol and Consent

1 * **Upload a copy of the protocol that is submitted to/approved by the IRB of record.**

Name	Date Last Modified	Version	Owner
Institute XYZ's protocol.docx	2/19/2015 11:13 AM	0.01	Jane Smith

2 **Upload all consent and assent forms. If there is more than one, list the titles or categories of each form submitted (e.g. experimental, control, sub-study)**

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

3 **Upload any additional documents you think may be pertinent to this protocol at Boston, Children's Hospital.**

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

PI's Statement

- **I assure the information I obtain as part of this research (including protected health information) will not be reused or disclosed to any other person or entity other than those listed on this form, except as required by law or for authorized oversight of the research project. If at any time I want to reuse this information for other purposes or disclose the information to other individuals or entity, I will seek approval by the Institutional Review Board (IRB).**
- **I assure the IRB that there are appropriate resources (funding, equipment, space, support services) to conduct this research safely and in accordance with all required human subject protection policies.**

* **The PI accepts responsibility for assuming adherence to DHHS, FDA, and Children's Hospital's regulations and policies relative to the protection of the rights and welfare of patients/subjects participating in this study.**

(•) **Yes** ( ) **No**