



Date: 2/25/2015, 1:21:08 PM
Title: Protocol to Rely on Institute ABC

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General Information

1 * Protocol Title: Protocol to Rely on Institute ABC

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 ABC

3 * Provide a brief summary (in lay terms) of the research protocol.
test

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.
test

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:

Table with columns: Last Name, First Name, Role, Editor, CC on Correspondence, Required Training Completed, CHERP Training. Note: There are no items to display.

2 PI: Jane Smith

Completed Training Courses:

Table with columns: Training Program, Continuing Education Description, Training Completed. Lists various continuing education and training courses with completion dates.

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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.

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 or 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?

- Single Reliance
- Harvard Catalyst
- Master consortium/network Reliance

If Harvard Catalyst:

1.1 Please provide Harvard Catalyst 'IRB Cede Review Request' ID.
5555

1.2 Please upload 'IRB Cede Review Request' application here.
Test document.pdf(0.01)

2 *What Institution will be performing IRB review and serve as the IRB of record (the IRB providing review)?
Institute ABC - 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@abc.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?

4.2 Please upload a copy of the initial approval letter.

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

Protocol Design

1 * Is this a multi center study?

Yes No

If YES:

1.1 Is Children's Hospital, Boston the lead site or coordinating center?

Yes No

If YES:

1.2 Describe the plan to ensure communication among sites in terms of adverse events, unanticipated problems, protocol modifications, interim results, etc.

2 * Is the person who will be primarily responsible for conducting the study at BCH different from the PI?

Yes No

3 * Has the PI, or if question #2 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human subjects at CHB?

Yes No

Subject Information

1 Enrollment Numbers

1.1 * Specify the number of subjects enrolled by, or under the auspices of Children's Hospital, that are required to complete data analysis.
100

1.2 If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through CHB. If not applicable, please leave blank.
100

2 Special Population

Prisoners/Incarcerated Youth (this would include children under the care of the Department of Youth Services). Consider if your target population will be or at higher risk of incarceration. If this category is chosen, you will be prompted to answer additional questions to meet federal regulations.

Wards of the State (consider if your target population may contain wards of the state or children at risk of becoming a ward of the state (this includes foster children or any child that is in state custody))

Adults With Decisional Impairment

*Decisional Impairment is defined as: persons who have impaired ability to make decisions as a result of intellectual or mental health challenges as well as individuals who have lost capacity to make decisions because of clinical situations such as unconsciousness.

Study Location

1. If your research is conducted in any of the following location(s) please check all that apply. If your research does not include any of these sites, please leave the questions blank.

- Adolescent Medicine
- Adolescent Surgery
- Cardiac ICU
- Cardiac Surgery
- Infant Toddler Surgical
- Infant/Toddler Medical
- Intermediate Care Program (ICP, 11 South)
- Medical/Surgical ICU (7 South)
- Medicine ICU (11 South)
- Neonatal ICU
- Neurology
- Oncology/Hematology
- Psychiatry
- School Age Medical
- School Age Surgical
- Sleep Study
- Solid Organ Transplant
- Stem Cell Transplant

Other CH Locations

- Cardiac Cath Lab
- Children's Hospital Primary Care Center (CHPCC)
- Clinical and Translational Study Unit (CTSU)
- Emergency Department
- Martha Elliot Health Center (MEHC)
- MRI
- Nuclear Medicine/PET
- Operating Rooms
- Other Satellites (Lexington, Peabody, South Shore, etc.)
- Radiology
- Waltham

Off Premises e.g. Schools, other Hospitals, Home

- Beth Israel Deaconess
- Brigham and Women's Hospital
- Boston Medical Center
- Dana Farber Cancer Institute
- Harvard Medical School
- Harvard School of Public Health
- Subject's Homes
- Joslin Diabetes Center
- Mass Eye and Ear Infirmary
- Mass General Hospital
- MIT
- Other
- Physician Office
- School
- Tufts – New England Medical Center

**1.1 If Other:
Specify:**

Recruitment and Document Storage

1 * Will CHB-Connect (a volunteer registry for clinical research) be used to identify potential research subjects? The volunteer registry for clinical research is available on the Children's Hospital website.

Yes No

2 Recruitment information about approved protocols can be automatically posted on the Children's Hospital external website " Find a Clinical Trial" once the research receives final approval.

*** Do you want this protocol to be posted?**

Yes No

If YES:

2.1 I assure that there are no restrictions by any funding agency, sponsor, cooperative group or any other oversight authority on posting this research protocol on the Children's Hospital external website. (Please be sure to review any clinical trial agreements, confidentiality agreements or oversight documentation associated with this research before checking this box).

You will be re-directed to another form to enter the information that will be posted on the site.

3 *Where will research data, documents and subject reports be sent and stored? Check all that apply.

- Children's Hospital Medical Record
 Departmental Medical Record
 Separate Research Record
 Subject/family will receive results
 Sponsor, Collaborator and/or Coordinating Center
Specify:
 Medical Record at another institution, hospital, physician's office, etc.
Specify:
 Research Registry
Will data include patient identifiers (name, medical record, SS #)?
 Yes No
 Other
Specify:

4 *Where will the signed informed consent and assent be stored? Check all that apply.

- Children's Hospital Medical Record
 Departmental Medical Record
 Separate Research Record
 Sponsor, Collaborator and/or Coordinating Center
 Medical Record at another institution, hospital, physician's office, etc.
 Research Registry
 Not Applicable

Medical Expenses for Research Related Adverse Events

1 *How will the cost of reasonably foreseeable medical care in the event of a research related adverse event be covered?

- Corporate sponsor agreement
 Likely to be covered by insurance
 Philanthropic or other grant
 Foundation or Departmental Funds
 Interdepartmental arrangements
 Other
Explain:
 Not applicable

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
 Medical record numbers (or specimen #)
 Address street location
 Address town or city *
 Address state*
 Address zip code*
 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 where a research subject's PHI may be disclosed. For this purpose, "disclosure" means release, transfer, provision of access, or otherwise divulging protected health information outside the entity initially acquiring the information as specified in the protocol; most often that will be Children's Hospital Boston.**
- Internal at Children's Hospital
 - Data Safety Monitoring Committee
 - Food and Drug Administration (FDA)
 - Other health care providers of subject
 - Third Party Payers - if third parties are billed for procedures performed during research
 - Sponsor of Trial
 - Contract Research Organization (CRO): organizations contracted to perform portions of the study (i.e., screening, data collection)
Specify the name/organization.
 - Collaborator
Specify who and the location.
 - Cooperative Group/Network
Specify the name of the network/group.
 - Other
Specify who and the location.

Research Categories and Special Considerations

- 1 **Please select the appropriate research category for your research. A primary category must be selected. A secondary category should be selected only if applicable.**
- * **Primary Research Categories:**
- Intervention/Trial Therapeutic (e.g. drugs, devices, comparison of therapeutic approaches, new procedures)
 - Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)
 - Behavioral/Psychosocial Interventions/Trials
 - Establishment of Specimen Repository
 - Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
 - Quality Improvement
 - Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
 - Educational/Training – e.g. training of residents or other professional staff
- Secondary Research Categories:**
- Intervention/Trial Therapeutic (e.g. drugs, devices, comparison of therapeutic approaches, new procedures)
 - Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)
 - Behavioral/Psychosocial Interventions/Trials
 - Establishment of Specimen Repository
 - Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
 - Quality Improvement
 - Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
 - Educational/Training – e.g. training of residents or other professional staff

- 2 **Please check all of the following that apply to the proposed research AND WILL BE PERFORMED at BCH facilities.**
- This protocol involves the use of a drug, biologic, nutritional supplement, herbal or homeopathic medicine, medical food, medical gas, inhalation therapy, topical cream, chemical or other compound that will be administered as the object of the protocol or because it is relevant to the aims of the research protocol.
 - This protocol involves a device that will be used, administered, implanted, or applied to the subjects, as the object of the protocol or is relevant to the objectives of the protocol. This includes investigational devices classified as both significant risk and non significant risk as well as FDA approved/marketed devices.
 - This protocol includes an imaging study to be done in Radiology or Nuclear Medicine. Please contact Stephen Whalen stephen.whelen@childrens.harvard.edu. Stephen will collect some additional information from you and coordinate the review of the information through Radiology to assure that the imaging protocol can be performed, the correct charges have been established and that Radiology will be able to accommodate the study in the imaging schedule. You will not be able to have imaging performed without this. It is imperative that you contact Stephen immediately.
 - This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure (X-ray, CT, PET scans) or 2) nuclear medicine procedures (imaging or

therapeutic). (Do not check this category if these procedures and assessments will be performed as part of clinical care).**

- This protocol requires for research purposes MRI scans (Do not check this category if these procedures and assessments will be performed as part of clinical care).**
- This protocol involves the collection of a tissue removed for clinical purposes that would routinely go to pathology.
- This protocol includes an 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.
- This protocol involves the use of a device that emits laser radiation.

** This must be selected if the protocol involves imaging, regardless of where the imaging may occur.

Nursing/Biosafety Resources

- 1 * Will this protocol require any of the following nursing services for any research related direct care requirements?

Yes No

If YES:

1.1 Check all that apply:

- Assessment of physical/mental status of subjects
- Monitoring requirement non invasive
- Monitoring requirement invasive
- Additional intravenous requirements
- Collection of blood and specimens
- Frequent timed lab draws
- Accompany patients to test areas
- Patient/family education, including self and home care
- Administration of investigational drugs and other substances
- Use of new technology/equipment in study protocol
- Symptom management/intervention
- Constant supervision
- Requirements from other services that require nursing coordinator

1.2 Specify required services.

- 2 * Does your study involve the use of recombinant DNA molecules (natural or synthetic DNA segments), biological agents (bacteria, viruses, parasites, rickettsia, fungi, microbial toxins and prions etc.), gene transfer or the transplantation of animal tissues into humans?

Yes No

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 ABC's protocol.docx	2/19/2015 11:24 AM	0.01	

- 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
Institute ABC's Consent form.docx	2/19/2015 11:24 AM	0.01	

- 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