Boston Children's Hospital

Date: Friday, March 21, 2025 12:34:18 PM Print Close

IRB-P00034143 General Information

Title: Sample Reliance on Another IRB

General Information

1 * **Protocol Title:**
Sample Reliance on Another IRB

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.**
Sample Reliance on Another IRB

3 * **Provide a brief summary (in lay terms) of the research protocol. This should be a short description of the study that is understandable to a lay person. If applicable please include the burden and epidemiology of the disease/condition along with any unmet needs of the population.**
Brief summary

4 * **Principal Investigator (PI):** Matthew Stafford

4.1 * **To serve as a PI you must qualify under one of the following eligibility requirements. (Residents, interns, fellows and postdoctoral candidates are not permitted to be PIs). Please select the appropriate category that applies to you.**
Physicians, Dentists and Psychologists credentialed through the hospital with the BCH medical staff registrar as an active medical staff member and having an appointment of Instructor or higher at Harvard Medical School.

If Other patient services professionals:

4.1.1 **Research is part of your scope of employment responsibility and not to meet a training or degree requirement. Please explain how this research falls within the scope of your responsibilities at the hospital.**

4.1.2 **You have training and experience and confirmed clinical research competencies. Please explain your training and experience in clinical research.**

4.1.3 **Are you employed at Children's as a nurse or do you have nursing credentials through Boston Children's Hospital?**
Please note if this is checked yes, in accordance with the policies of the Nursing Department your protocol will be sent to the Nursing department for both scientific review and departmental sign off.
◯ Yes ◯ No

5 * **Is the person who will be primarily responsible for conducting the study at BCH different from the PI?**
◯ Yes ● **No**

If YES:

5.1 **Please add the person(s) who will be primarily responsible for conducting the study.**

Name	Appointment with Children's Hospital?
There are no items to display	

6 * **Has the PI, or if question #5 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human participants at BCH?**
● **Yes** ◯ No

7 * **Type Of Submission:**

- ○ New Research Activity
- ○ **New Research Activity Limited to Secondary* Use of Biological Material and Data
- ○ 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
- ○ Individual Patient Expanded Access
- ○ Humanitarian Use Device (HUD)
- ● **Reliance on Another IRB**
- ○ Projects that lack immediate plans for involvement with human participants, their data and/or their specimens (i.e.training grants)

** *Use this form only if:*
1) specimens/data are not identifiable or
2) specimens/data are identifiable but recorded by PI in de-identified format or meet the waiver of HIPAA authorization criteria listed below All other uses of secondary specimens/data must be submitted on a new research activity form.

* *Secondary means the tissue or data will be or was collected for a primary or initial purpose other than the research (i.e data from medical records, tissue from pathology)*

Waiver of HIPAA authorization (all criteria must be met)
• The proposed use of this data/document/record/specimen presents no more than minimal risk to the privacy of individuals
•The research could not practicably be conducted without the waiver of HIPAA authorization
• The research could not practicably be conducted without access to and use of protected health information with identifiers
• Waiving HIPAA authorization will not adversely affect the participant's rights or welfare

This form may not be selected if the study involves interaction/intervention with participants in order to obtain tissue/data specifically for this research.

8 * **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

9 * **Is this protocol related to cancer (primarily concerning malignancies, oncology patients, or involving use of malignant tumors)?**

○ Yes ● **No**

Note: If YES, your protocol will require review by the Dana Farber IRB instead.
For details, see: IRB Policy 2.14, "Reliance Agreement with Dana-Farber Cancer Institute (DFCI)"

10 * **Are you planning to use the Institutional Centers for Clinical and Translational Research (ICCTR) Study Operations Support?**
NOTE: the ICCTR was formerly the Clinical Research Center

○ Yes ● **No**

ICCTR Study Operations Support includes some of the following services:

- *project management (including protocol development, trial operations, and close out activities)*
- *study coordinator support*
- *research nurse or nurse practitioner support*
- *regulatory support- IRB or FDA*
- *data management (including database builds)*
- *development of case report forms*
- *data entry*
- *recruitment and retention of research participants*
- *administration of surveys and interviews*
- *biospecimen collection and tracking*
- *medical record abstraction*
- *multi-institutional clinical trial support*
- *development of data safety monitoring plans and data safety monitoring boards or committees*

11 * **Does this protocol generate study related charges in Epic that will be billed to the patient or insurance, and/or study fund?**
This includes experimental imaging, DEXA, blood samples, investigational products or devices.
Examples: A minimal risk study where the participant will answer surveys and receives physical therapy that is paid for by the study, an industry sponsored study where investigational product is given to a participant and paid for/donated by the sponsor, a federally funded study where MRIs and DEXA scans are paid for by the grant and not by the participants.

◯ Yes ● **No**

Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

12 * **Does this protocol require the department/Clinical Research Finance to invoice a sponsor (industry, foundation, or federal cooperative agreements)?**
Includes protocols with automatic payments by the sponsor, and cooperative group agreements where the study team has to provide an invoice to the prime institution
Example: An industry sponsored study where the team must invoice for milestones and/or other invoiceable items, a subcontract from CHOP where BCH must send invoices to CHOP directly.

◯ Yes ● **No**

Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

13 * **Will your study require research orders built in Epic?**
Research orders are required for the following: All ETU supported studies, Research imaging, Medications dispensed by IDS, all Research Labs including custom lab panels or studies intending to use research collects for sample collection. Study teams must request order builds for any of the above. Using clinical orders and placing a note in Epic that the order is for research is not acceptable.

◯ Yes ● **No**

If Yes:

13.1 Please select the category:

- ☐ ETU visits and/or lab processing
- ☐ Investigational Medication
- ☐ Research Collects
- ☐ Research Collects - will require processing or storage or shipment
- ☐ Research Imaging
- ☐ Standard of care medication administered as part of study protocol
- ☐ Other

If Other:

13.1.1 Please describe:

14 * **Will your study utilize the ETU?**

◯ Yes ● **No**

Note: If this study uses any ETU service, including laboratory processing, please submit a CROC Intake Form

15 * **Who is responsible for the protocol design?**

- ● **Sponsored Designed/Initiated**
- ◯ Investigator Designed/Initiated
- ◯ Collaboration/Jointly Designed

If Investigator Designed/Initiated:

15.1 Was the protocol peer-reviewed?

◯ Yes ◯ No

IRB-P00034143 Reliance on Another IRB

Title: Sample Reliance on Another IRB

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/by BCH investigators 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.

If YES:

1.1.1 Please indicate all research activities being conducted 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:

If Recruitment:

Will the BCH study staff contact patients to inform them about the study?

○ Yes ○ No

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.

If YES:

1.2.1 Please specify which BCH facilities or resources will be used and for which research assessments:

Text

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.

If YES:

1.3.1 Please indicate all research activities to be conducted by Children's staff/employees outside of 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 select 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:

1.4 * Children's staff or employees will solely be involved in data analysis* and/or recruitment limited to reviewing data for potential subjects.
Note: IRB submission may not be required if BCH involvement is limited ONLY to the review of de-identified data OR providing recruitment materials to patients. Please contact the IRB Reliance Specialist for assistance BEFORE completing this application if BCH's involvement is limited to these activities.

● **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.

1.5 * Funding is received through BCH (BCH is primary awardee) but all research activities conducted elsewhere. BCH staff not otherwise engaged in the research.

○ Yes ● **No**

Example:

- BCH is the prime awardee on a federal grant but all research activities will be conducted at other sub award sites.

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.

Justification for reliance agreement

IRB-P00034143 Research Team - Reliance

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)
BCH Department (if applicable)
Email Address

1 Research Staff - Children's Hospital Employees only:

	Last Name	First Name	BCH ID	Role	Editor	CC on Correspondence	Required Training Completed	Training Expiration	CHeRP Training	Date Modified	Date Created
View	Kuniholm	Ashley	123524	Admin Contact	yes	yes	yes	1/13/2028	yes	12/4/2019	12/4/2019
View	Ripton	Jessica	221454	Co-Investigator	yes	yes	yes	6/10/2024	no	3/17/2025	3/17/2025

2 PI: Matthew Stafford

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed	Date Created
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	2/2/2022	
Continuing Education	EQuIP: Talk/Meeting	8/4/2020	8/5/2020
Continuing Education	Rounds and Discussions with Research Nurses and Coordinators	7/1/2020	7/2/2020
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/22/2018	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	7/12/2018	
Continuing Education	Continuing Education/Department Meeting	5/2/2018	
Continuing Education	Continuing Education/Department Meeting	6/13/2016	
Training Received at Another Institution		11/15/2015	
Continuing Education	Continuing Education/Department Meeting	10/26/2015	
Continuing Education	Research Protocol Case Discussions	11/15/2012	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/9/2012	5/9/2012
Continuing Education	Continuing Education/Department Meeting	9/30/2011	
CHeRP Training		12/19/2010	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/15/2009	11/8/2010
Collaborative IRB Training Initiative (CITI Behavioral)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Biomedical)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Non-Interventional)		4/11/2006	11/8/2010
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	4/5/2006	11/8/2010

Title: Sample Reliance on Another IRB

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 IRB 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 Number	Owner

There are no items to display

IRB-P00034143 Reliance Information

Title: Sample Reliance on Another IRB

Reliance Information

1 * **A reliance agreement is needed for BCH to rely on external IRB. Please work with the Lead PI at the external site to determine what reliance agreement will be used for this study. Please note BCH strongly prefers to use the SMART IRB Master.**
Please select what reliance agreement is being requested:

- ☐ Single Reliance (Reliance agreement between BCH and another institution not affiliated with a master agreement)
- ☑ **SMART IRB Master**
- ☐ Master consortium/network Reliance (other than SMART IRB)

Please provide SMART IRB ID number.
555

Please upload a copy of the SMART IRB request here.
SMART IRB request.docx(0.01)

2 * **What Institution will be performing IRB review and serve as the IRB of record (the IRB providing review)?**
Columbia University Medical Center - FWA00002636

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**
Bob
* **Principal Investigator's Email**
Loblaw

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?
RASCAL00088981

4.2 Please upload a copy of the initial approval letter.
Initial Approval Letter.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
Name

5.2 Phone Number
Phone Number

5.3 Email
Email

IRB-P00034143 Multi Site Information - Reliance

Multi Site Information - Reliance

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**

1.2 Will data be shared between sites?

Yes

1.3 Please provide a description of the reviewing PI's oversight process to assure that relying institutions:
**** are provided timely access to approved and revised approved protocols, informed consents and recruitment materials**
**** are informed about the reviewing IRB's polices that pertain to this research**
**** provide (the reviewing PI) with any required COI management plans, required information pertaining to continuing reviews and any reportable events**

description of the reviewing PI's oversight process

IRB-P00034143 Subject Information - Reliance

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.
Number

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.
Larger number

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))
- [x] 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.*

Please describe the type and range of decisional impairment of the adult subjects to be included in the research.

Provide a rationale for why it is necessary to include adults with decisional impairment as participants in research, including information regarding the potential benefit to the individuals in relationship to potential risks.

Describe the criteria and procedures or measurements for evaluating the decisional status of the prospective participant to determine whether they are capable of consenting on their own behalf. This would include the use of standardized measurements, consults with another qualified professional, etc...

Describe how persons authorized to obtain legally valid consent will be identified in the event any individual is judged incapable of consenting on their own behalf. Please review the IRB policy to the right of this question that describes the requirements for determining a legally authorized representative for the subject. Briefly, these are court-appointed guardians, health care proxies, or durable power of attorney. Please note that family members are not automatically considered for this role and may only be permitted when there is documentation that neither of the previous exists. Please also explain how legal records regarding authority will be obtained, reviewed by the research team, and documented in the research record.

When possible if legally valid consent cannot be obtained from the subject, assent should be obtained. Please describe if you plan to obtain assent and provide criteria used to evaluate the assent or dissent of the adult with decisional impairment.

If applicable to your population, provide a description of how the participant will be protected if their capacity to consent is lost or fluctuates. What provisions have been made to protect the subjects' rights? This may include the use of an ombudsman, frequent cognitive status evaluations, etc...

- [ ] Does this research protocol involve fetuses only?

If Yes:

Is this study purely observational?
◯ Yes ◯ No

Does this study involve fetal intervention/therapy?
◯ Yes ◯ No

IRB-P00034143 Study Location

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.

- [x] **Adolescent Medicine**
- [ ] Adolescent Surgery
- [ ] Cardiac Intensive Care Unit - 7 & 8 Hale
- [ ] Cardiac Surgery
- [ ] Infant Toddler Surgical
- [ ] Infant/Toddler Medical
- [ ] Intermediate Care Program (9 South)
- [ ] Medical Intensive Care Unit - 11 Berthiaume
- [x] **Medical-Surgical Intensive Care Unit - 7 & 8 Berthiaume**
- [ ] Neonatal Intensive Care Unit - 11 Hale
- [ ] Neurology
- [ ] Oncology/Hematology
- [ ] Psychiatry
- [ ] School Age Medical
- [ ] School Age Surgical
- [ ] Sleep Study
- [ ] Solid Organ Transplant
- [ ] Stem Cell Transplant

Other CH Locations

- [x] **Cardiac Cath Lab**
- [ ] Children's Hospital Primary Care Center (CHPCC)
- [ ] Emergency Department
- [ ] Experimental Therapeutics Unit (Boston)
- [ ] Experimental Therapeutics Unit (Waltham)
- [ ] Martha Elliot Health Center (MEHC)
- [ ] MRI
- [ ] Nuclear Medicine/PET
- [ ] OR/PreOp/PACU
- [ ] 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
- [ ] Participant'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:
Columbia

IRB-P00034143 Recruitment and Document Storage - Reliance

Recruitment and Document Storage

1 * **Describe plans for recruitment at BCH, including identification of /screening for potential participants, who will be responsible for recruitment, and how and when subjects will be recruited.**
Plans for recruitment at BCH

2 * **Describe informed consent/assent/authorization procedures to be followed at BCH, including who will obtain informed consent/assent/authorization, and when and where subjects will be consented/assented.**
Informed consent/assent/authorization procedures

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

- [x] Children's Hospital Medical Record
- [x] Departmental Medical Record
- [x] Separate Research Record
- [ ] Subject/family will receive results
- [ ] Sponsor, Collaborator and/or Coordinating Center
  Specify:
- [x] Medical Record at another institution, hospital, physician's office, etc.
  Specify:
  Explanation
- [x] 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.**

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

IRB-P00034143 Clinical Trials - Reliance

Clinical Trials.Gov

Please answer the following information regarding ClinicalTrials.gov registration.

1 * **Into which of the following category(s) does this protocol fall (check all that apply):**

- [x] **(a) A controlled clinical investigation other than phase 1 of a drug subject to FDA regulation (requires registration).** ***CONTROLLED*** **is defined as a design to permit comparison of a test intervention with a control to provide a quantitative assessment of the drug/ effect. This can include concurrent control groups as well as non-concurrent controls including historical controls or participants as their own controls (requires registration by FDA regulations)**
- [ ] **(b)** Protocol prospectively compares a device-based intervention subject to FDA regulation against a control in human participants (requires registration). An ***INTERVENTION*** broadly includes various techniques using the device such as, among other things device regimens and procedures, and use of prophylactic, diagnostic or therapeutic agents. This applies to studies other than a small clinical trial to determine feasibility of a device, or a clinical trial to test prototypes devices where the primary outcome measure relates to feasibility and not health outcome. **(Requires registration by FDA regulations)**
- [x] **(c) A device trial that is a pediatric post-market surveillance trial (requires registration by FDA regulation)**
- [ ] **(d)** Protocol prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes." Health-related interventions include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes). Health outcomes include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events. **(ICMJE requires registration)**
- [ ] **(e)** Protocol does not meet any of the criteria above (a-d) but research will be registered on clinicaltrials.gov (voluntary registration, statement optional)
- [ ] **(f)** Protocol does not meet any of the criteria above (a-d) and research will not be registered on clinicaltrials.gov

If (a), (b), (c), or (d) is checked, either FDA regulations or International Committee of Medical journal Editors (ICMJE) Guidelines *http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html* ***require that this trial be registered on a clinical trial registry. FDA requires registration on ClinicalTrials.gov site. ICMJE requires registration on one of a broader list of registries, including clinicaltrials.gov.***
For further information about required registrations you may go to:

• *http://clinicaltrials.gov/ct2/manage-recs* ***(FDA regulations)***
• *http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html* ***(ICMJE)***

Note if (a), (b) or (c) is checked, FDA regulations require that the consent form contains the following statement:

"A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, ***as required by U.S. Law. This web site will not include information that can identify you. At most, the web site will include a summary of results. You can search this web site at anytime."***

If (d) or (e) is checked you may voluntarily choose to include the statement above. Please make the appropriate updates to the consent form accordingly.

1.1 Who will be responsible for registering the trial?

- ☐ Sponsor (if other than BCH PI/Sponsor-Investigator)
- ☐ BCH PI or Sponsor-Investigator
- ☑ **Investigator at another site**
- ☐ Other

If Other:

1.1.1 Please specify who.

1.2 If you have selected BCH PI or Sponsor-Investigator do you have a Clinical Trial registration NCT number for this study at this time?

◯ Yes ◯ No

If YES:

1.2.1 Please insert "NCT" number for this trial

NOTE: A valid NCT number must be included before the IRB releases final acceptance of this reliance request. If the NCT number is not included in the original submission you will need to register the trial and update this form before final acceptance is released.

IRB-P00034143

Medical Expenses for Research Related Adverse Events

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?**

- [x] Corporate sponsor agreement
- [x] 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 Boston 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.**

- [x] **Patient/Participant name or the names of relatives, employers, or household members**
- [x] **Medical record numbers (or specimen #)**
- [ ] Address street location
- [x] **Address town or city ***
- [x] **Address state***
- [x] **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
- [x] **Electronic mail (email) address**
- [x] **Social security number**
- [x] **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 comparable image/video of the face
- [ ] Any unique identifying number, characteristic or video

Please explain in more detail.

- [ ] 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).*

PHI Disclosure

1 Please check all of the categories that indicate where a research participant'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 Boston Children's Hospital.

- [x] Internal at Boston Children's Hospital
- [x] Data Safety Monitoring Committee
- [ ] Food and Drug Administration (FDA)
- [x] Other health care providers of participant
- [x] Third Party Payers - if third parties are billed for procedures performed during research
- [x] Sponsor of Trial
- [x] Contract Research Organization (CRO): organizations contracted to perform portions of the study (i.e., screening, data collection)
  Specify the name/organization.
  CRO name
- [ ] Collaborator
  Specify who and the location.
- [ ] Cooperative Group/Network
  Specify the name of the network/group.
- [ ] Other
  Specify who and the location.

IRB-P00034143

Research Categories and Special Considerations - Reliance

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.

- [x] 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 part of the research protocol.
  This will include drugs administered as the object of the protocol, drugs relevant to aim of the research protocol or commercially available medications that are being used for research related procedures, testing or supportive care.
- [x] 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.
- [x] This protocol involves the collection and use of material for genetic studies or creation of IPS lines as part of this current study and/or for potential genetic studies in the future.
- [x] This protocol involves the use of a placebo.
- [x] This protocol includes an imaging exam or procedure performed in the Department of Radiology.Such procedures include MRI, Ultrasound, X-ray, CT, and PET and SPECT in the Division of Nuclear Medicine. Every study involving procedures in the Department of Radiology requires review and approval by Radiology. Studies are reviewed to determine whether or not the proposed imaging procedures can be accommodated in the Radiology schedule, have the appropriate resources available, and have been correctly identified and budgeted. Radiology must review and approve all budgets involving imaging studies prior to obtaining CTBO approval for the overall budget. All studies must be ordered through the Radiology Research Ordering system. Requests for research imaging for studies that have not been approved by Radiology, and orders placed in Power Chart, will be rejected. Contact Simon Warfield simon.warfield@childrens.harvard.edu and Kristina Pelkola kristina.pelkola@childrens.harvard.edu by email to initiate the review of your study.
- [x] 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).**
- [x] This protocol requires MRI equipment/scans for research purposes. This may include non-BCH equipment such as Hyperfine MRI or any other portable MR imaging system (Do not check this category if these procedures and assessments will be performed as part of clinical care). **
- [x] This protocol involves the establishment of a human biological specimen repository. Repositories are defined as prospective collections of specimens that are processed, stored and distributed to multiple investigators for use in research.
- [x] This protocol involves the collection of a tissue removed for clinical purposes that would routinely go to pathology.

- [x] This protocol acquires fetal biospecimens (This includes specimens taken from pregnant women or acquisition of fetal tissue obtained from terminations).
  If fetal tissue from terminations are proposed please be sure to include in your protocol document or SmartForm detailed information about where it is acquired from and how it will be used. In addition, submit copy of IRB approvals from sites where the tissue was actually obtained.
- [x] This protocol recruits or perform research assessments on pregnant women evaluated through the BCH Advanced Fetal Care Center (AFCC). Please note if this is checked, the AFCC will be notified and may contact you to discuss the research.
- [x] 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.
- [x] This protocol includes research that is conducted at a non US location.
  Please check this off if you are conducting international research but be aware that these questions do not apply to multi-site studies that are also multi-national.
- [x] This protocol involves collection of blood samples other than discarded specimens.
- [x] This protocol involves the use of a device that emits laser radiation.
- [ ] This protocol involves new equipment subject to review by Health Technology Management (formerly Biomedical Engineering). This includes devices used for the treatment, diagnosis, or monitoring of patients or research subjects. Devices requiring review at this time are those that are not already being managed by Health Technology Management. If you have any questions, call Health Technology Management at 617-355-6166.

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

3 * Is there any possibility that a referral to social work will be triggered or a social work assessment/consultation will be required as a result of your use of any quality of life measure or other survey/questionnaire?

(●) **Yes** ( ) No

If YES:

3.1 A responsible social worker must be identified before this protocol can be submitted.
Please check the following as appropriate:

3.1.1 [x] A BCH social worker has been identified to work on this project

3.1.2 [ ] A social worker from your own funding source will work with you on this project

3.2 Please address the following: What is their name? What is the expected time commitment (hours/wk)?
Name and expected time commitment.

3.3 Please upload a written agreement, signed by that social worker, stating that they are willing and available to make that time commitment.

Name	Date Last Modified	Version Number	Owner
Agreement.docx(0.01)	4/2/2020 10:58 AM	0.01	Matthew Stafford

*NOTE: If you have questions please email: socialworkadmin@childrens.harvard.edu with the following subject line: **Social Work Involvement in Research: IRB Protocol #XXXX** to schedule a 30 minute appointment to discuss the needs related to social work involvement in your study protocol.*

IRB-P00034143 Nursing/Biosafety/Gene and Cellular Therapy

Nursing/Biosafety/Gene and Cellular Therapy

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 participants
- ☐ 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.

Required services.

2 * **Does your study involve the administration of any of the following to a human research participant?**

● **Yes** ○ No

If YES:

2.1 Please check all that apply.

- ☑ **Genetically-modified cells or seek to genetically modify patient tissues in vivo using recombinant or synthetic nucleic acid molecules (natural-derived or synthesized DNA or RNA)**
- ☐ A cellular or biologic product that involves complex manufacturing (e.g. cell culture or cell selection in a GLP/GMP facility, outside the operating room)
- ☐ Biological agents or material containing biological agents. Biological agents include bacteria, viruses, parasites, rickettsia, fungi, prions and toxins of biological origin regardless of pathogenicity to humans (e.g. fecal microbiota transplantations, oncolytic viruses)
- ☐ Xenotransplantation (cells, tissues or organs from a nonhuman animal source or have come into contact with nonhuman sources)

NOTE: Please note if the first or second option is checked, the protocol will be routed to a specialized institutional scientific review committee and will not be sent for your own departmental scientific reviewers.

If option *"Genetically-modified cells or seek to genetically modify patient tissues in vivo using recombinant or synthetic nucleic acid molecules (natural-derived or synthesized DNA or RNA)"* was selected, please check off as applicable for this research and answer the associated questions:

2.1.1 The protocol uses a new vector, genetic material, or delivery methodology that represents a first-in-human experience, thus presenting an unknown risk.

● **Yes** ○ No

2.1.1.1 If Yes, please describe vector, genetic material, and delivery method and what may be known about any associated risks.

Description of vector, genetic material, and delivery method and what may be known about any associated risks.

2.1.1.2 If No, please indicate the section or location in the protocol where the vector, genetic material or delivery methodologies risks are clearly described based on previous experience in human studies.

2.1.2 The protocol relies on preclinical safety data that were obtained using a new preclinical model system of unknown and unconfirmed value.

● **Yes** ○ No

2.1.2.1 If Yes, please describe the new preclinical model system of unknown and unconfirmed value.

New preclinical model system of unknown and unconfirmed value.

2.1.2.2 If No, please explain why this is not a preclinical model system of unknown and unconfirmed value.

2.1.3 The proposed vector, gene construct, or method of delivery is associated with possible toxicities that are not widely known and that may render it difficult for oversight bodies (IRB, IBC) to evaluate the protocol rigorously.

○ Yes ● **No**

2.1.3.1 If Yes, please describe why the possible toxicities are not widely known and may render it difficult for oversight bodies (IRB, IBC) to evaluate the protocol rigorously.

2.1.3.2 If No, please justify that the possible toxicities are widely known and oversight bodies (IRB, IBC) will be able to evaluate the protocol rigorously.

Justification.

IRB-P00034143

Drugs, Biologics or Other Products

Please provide information for the drug/product that will be used, administered, or applied to the participants as the object of the study or that is relevant to the objectives of the protocol. If there is more than one drug/product, please be sure to enter each drug/product. More than one drug/product may be entered under each category.

1 The drug/biologic/product being administered is an investigational product (not approved by the FDA)

Generic Name	Type of Product	Manufacturer
View generic name	Drug	manufacturer

2 The drug/biologic/product being administered is an FDA-approved agent but used outside of the FDA labeling in an unapproved dose, route of administration, population, disease, in concomitant medical use, etc.

Generic Name	Type of Product	Manufacturer
There are no items to display		

3 The drug/biologic/product being administered is FDA approved and being administered in accordance with approved labeling

Generic Name	Type of Product	Manufacturer
There are no items to display		

4 The drugs/biologics/products being administered does not fit into any of the above categories.

Generic Name	Type of Product	Manufacturer
There are no items to display		

5 The product being administered is a dietary supplement, herbal medicine, or medical food.

Product Name	Type Of Product
There are no items to display	

6 The research protocol requires the use of ancillary drugs. Ancillary drugs are medications that are used in an interventional study to manage events that may occur as a result of the use of the study drug that would otherwise not be administered to the research participant if they were not receiving the study drug. Ancillary medications are not the object of the study but are either
a) dictated by the protocol even if typically used in the standard of care, or
b) supplied by or reimbursed by the sponsor, or
c) must be dispensed as part of the protocol through the research pharmacy or a community pharmacy.

Generic Name	Type Of Product	Manufacturer
There are no items to display		

7 Select the individuals that can prescribe the drugs listed in this protocol. Only PIs and Co-Investigators should be added as prescribers.

Last Name	First Name	Employee ID
Ripton	Jessica	221454
Stafford	Matthew	120216

For your reference, please see the list of people who can be selected as a drug prescriber:

Matthew Stafford

Jessica Ripton

8 * If a drug trial, what phase?

- ○ 0
- ○ I
- ● **I/II**

- ○ II
- ○ II/III
- ○ III
- ○ IV
- ○ NA

9 **What is the drug schedule category for this drug? Please check all that apply.**

- ☑ **IND**
- ☐ Schedule I - drugs, substances, or chemicals are defined as drugs with no currently accepted medical use and a high potential for abuse.
- ☐ Schedule II - drugs, substances, or chemicals are defined as drugs with a high potential for abuse, with use potentially leading to severe psychological or physical dependence.
- ☐ Schedule III - drugs, substances, or chemicals are defined as drugs with a moderate to low potential for physical and psychological dependence.
- ☐ Schedule IV - drugs, substances, or chemicals are defined as drugs with a low potential for abuse and low risk of dependence.
- ☐ Schedule V - drugs, substances, or chemicals are defined as drugs with lower potential for abuse than Schedule IV and consist of preparations containing limited quantities of certain narcotics.
- ☐ Schedule VI - all prescription drugs that are not included in any other schedule

IRB-P00034143 Device

Special Considerations - Device

Provide information for the device that will be used, administered, implanted or applied to the participants as the object of the study or that is relevant to the objectives of the protocol. If there is more than one device, please be sure to enter each device under the appropriate category. More than one device may be entered under each category.

1 Investigational Devices (devices not approved or cleared for marketing by the FDA)

	Generic Name	Trade Name	Manufacturer
View	generic name	trade name	manufacturer

2 FDA Approved Devices that are used for a non-approved indications or in a non-approved population or devices that have been modified /altered/ edited, reconfigured/changed/combined

Generic Name	Trade Name	Manufacturer
There are no items to display		

3 Devices that have been approved (PMA) or Cleared (510(k)) by FDA and used in accordance with labeling

Generic Name	Trade Name	Manufacturer
There are no items to display		

4 Other Devices

Generic Name	Trade Name	Manufacturer
There are no items to display		

5 * **If a device trial, what type?**

- (●) **Exploratory or Feasibility Study**
- ( ) Pivotal Study
- ( ) Post-Market Study

Imaging

1 * **Does your protocol involve any of the following radiological procedures that involve radiation exposure as part of the research protocol? (do NOT identify procedures that are part of the participant's required clinical care)**

● **Yes** ○ No

If YES:

1.1 Select all that apply:

- ☑ **X-rays**
- ☑ **Fluoroscopy / Cineradiography**
- ☑ **Computed Tomography (CT)**
- ☑ **Bone Density by X-Ray Absorptiometry (DEXA)**

If you checked any of the above:

1.1.1 Provide a description of the imaging protocol.
Imaging protocol.

1.1.2 Provide a detailed description of the radiation exposure involved in the study (i.e. how many additional x-rays, how much additional fluoroscopy time, etc.).
Detailed description of the radiation exposure involved.

1.1.3 Provide the whole-body radiation exposure per procedure anticipated from the research protocol expressed in units of milliRem (mRem) or milliSieverts (mSv). For a dose estimate please contact Radiation Safety at Radiation.Safety@childrens.harvard.edu**.**
Whole body radiation exposure per procedure.

2 * **Does your protocol involve any imaging studies that do not involve radiation exposure as part of the research protocol (do NOT identify procedures that are part of the participant's required clinical care)?**

○ Yes ● **No**

If YES:

2.1 Does it involve ultrasound?

○ Yes ○ No

3 **When do you expect to begin imaging?**
when

4 **If a radiologist/nuclear medicine specialist is collaborating on this research, please specify the individual.**
Ashley Kuniholm

5 * **Does your protocol involve Nuclear Medicine Studies as part of the research protocol? (do NOT identify procedures that are part of the participant's required clinical care)**

○ Yes ● **No**

Pathology Specimens

1 * **For those specimens that would routinely go to Pathology, please provide the following information for each category of specimen that will be collected.**

Tissue Type	Amount
View	3mm

IRB-P00034143 Protocol and Consent - Reliance

Protocol and Consent

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

Name	Category	Date Last Modified	Version Number	Owner
PROTOCOL.docx(0.01)		4/2/2020 5:01 PM	0.01	Matthew Stafford

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).Please ensure these are Word documents to allow for BCH IRB office edits.**

Name	Category	Date Last Modified	Version Number	Owner
Belgian Assent.docx(0.01)		4/2/2020 5:03 PM	0.01	Matthew Stafford
Belgian Consent.docx(0.01)		4/2/2020 5:03 PM	0.01	Matthew Stafford
English Consent.docx(0.01)		4/2/2020 5:03 PM	0.01	Matthew Stafford
Italian Assent.docx(0.01)		4/2/2020 5:03 PM	0.01	Matthew Stafford

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

Name	Date Last Modified	Version Number	Owner

There are no items to display

IRB-P00034143

PI's Statement

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, HIPAA and Boston Children's Hospital's regulations and policies relative to the protection of the rights and welfare of patients/participants participating in this study.**

● Yes ○ No

IRB-P00034143

Final Page

IRB-P00034143

Research Team Member For CHB Employees

Research Team Member For BCH Employees

1 **Choose Team Member and assign privileges.**

1.1 * **Person - Choose team member.**
Ashley Kuniholm

1.2 * **Editor - Indicate if this person should be allowed to edit the online forms, correspond with the IRB office, etc. It is recommended that one or two persons, other than the PI, are listed as Editors.**

● **Yes** ○ No

1.3 * **CC on Email Notifications - Indicate if this person should be CC'd on email notifications regarding this submission. Note: Editors receive all notifications.**

● **Yes** ○ No

2 * **Indicate the individual's role on the study. Please note that any prescribers must be listed as a either a principal investigator co-investigator and selected as a prescriber in the Drugs, Biologics or Other Products section question 7.**

○ Co-Investigator

○ Research Coordinator/Assistant

○ Research Nurse

● **Admin Contact**

○ Other Research Support

If Other:

Specify:

3 * **Will the individual intervene/interact with subjects?**

○ Yes ● **No**

4 * **Will the individual obtain consent from the subject?**

○ Yes ● **No**

5 * **Will the individual review identifiable data, databases, medical records, and/or handle identifiable biological specimens?**

● **Yes** ○ No

ID: VIEW46F5B54679400
Name: Research Team Member For CHB Employees

IRB-P00034143

Research Team Member For CHB Employees

Research Team Member For BCH Employees

1 **Choose Team Member and assign privileges.**

1.1 * **Person - Choose team member.**
Jessica Ripton

1.2 * **Editor - Indicate if this person should be allowed to edit the online forms, correspond with the IRB office, etc. It is recommended that one or two persons, other than the PI, are listed as Editors.**

(●) **Yes** ( ) No

1.3 * **CC on Email Notifications - Indicate if this person should be CC'd on email notifications regarding this submission. Note: Editors receive all notifications.**

(●) **Yes** ( ) No

2 * **Indicate the individual's role on the study. Please note that any prescribers must be listed as a either a principal investigator co-investigator and selected as a prescriber in the Drugs, Biologics or Other Products section question 7.**

(●) **Co-Investigator**

( ) Research Coordinator/Assistant

( ) Research Nurse

( ) Admin Contact

( ) Other Research Support

If Other:

Specify:

3 * **Will the individual intervene/interact with subjects?**

( ) Yes (●) **No**

4 * **Will the individual obtain consent from the subject?**

( ) Yes (●) **No**

5 * **Will the individual review identifiable data, databases, medical records, and/or handle identifiable biological specimens?**

( ) Yes (●) **No**

ID: VIEW46F5B54679400
Name: Research Team Member For CHB Employees

IRB-P00034143 Investigational Drug/Product

Investigational Drug/Product

1 * **Select the type of product that will be administered that is relevant to the aims of the research protocol. If there is more than one product which is relevant to the aims of the protocol, enter information about one product at this time. You will be able to enter additional products at a later time. Do not enter drugs that are administered for clinical care and not being evaluated as part of the research aims.**

- (●) **Drug**
- ( ) Biologic
- ( ) Combination
- ( ) Other

If Combination:
Please describe:

If Other:
Please describe:

2 * **What is the generic name or descriptor of the product?**
generic name

3 **What, if any, is the commercial/trade name of the product?**
commercial/trade name

4 * **Who is the manufacturer of the product?**
manufacturer

5 * **Who is the supplier of the product?**
supplier

6 * **Who holds the IND?**

- (●) **A company, organization, NIH, consortium or university.**
- ( ) Children's Investigator
- ( ) Other

6.1 **Specify the IND number if available (if it is not available, you will need to provide the IND number prior to final IRB approval).**
IND number

6.2 * **Please specify the name of the IND holder.**
name of the IND holder

6.3 **Upload a copy of FDA IND approval correspondence, if available.**

Name	Date Last Modified	Version Number	Owner
IND approval correspondence.docx(0.01)	4/2/2020 4:45 PM	0.01	Matthew Stafford

6.4 * **Is FDA IND approval pending?**
( ) Yes (●) **No**

7 * **What is the dosage, route of administration or application, and frequency and total duration of use of the product?**
dosage, route of administration or application, and frequency and total duration of use of the product

8 * **What is the proposed mechanism of action of the product? (Include any post-manufacturing modifications to the product expected to affect the proposed mechanism of action.)**

proposed mechanism of action of the product

9 **If there are any special issues regarding stability, please detail them here.**
any special issues regarding stability

10 **Please list any contraindications or potential drug interactions.**
any contraindications or potential drug interactions

11 **Are there any known antidotes? Please describe.**
any known antidotes

12 * **Will participants, or their insurance providers, be charged for the investigational drug/biologic?**
◯ Yes ● **No**

If YES:
Please upload written documentation from the FDA documenting a formal waiver for the sponsor of this research study to charge participant or their insurance providers for the investigational drug/biologic.

Name	Date Last Modified	Version Number	Owner

There are no items to display

13 * **Upload Investigator's Brochure and other pertinent documentation.**

Name	Date Last Modified	Version Number	Owner
Investigators Brochure.docx(0.01)	4/2/2020 4:46 PM	0.01	Matthew Stafford

14 * **Indicate who will administer the investigational product to the participant?**
MD
RN

If Other:
Explain:

ID: VIEW470B90F6B2400
Name: Investigational Drug/Product

IRB-P00034143 Investigational Devices

Investigational Devices

1 * **What is the generic name or descriptor of the device?**
generic name

2 **What is the trade name if applicable?**
trade name

3 * **Who is the manufacturer of the device?**
manufacturer

4 * **Who is the sponsor of the device trial (company, individual or entity that is responsible for conducting the study and complying with FDA sponsor responsibilities)? This may or may not be the manufacturer. Please note an investigator may hold sponsor responsibilities if it is an investigator initiated IDE (this applies to both significant and non-significant risk devices).**

- ○ A company, organization, NIH, consortium or university.
- ● **Children's Investigator**
- ○ Other

4.1 * **Please specify the Sponsor regardless of which of the above choices have been selected.**
Dr. Stafford

5 * **Who will pay for the device?**
Insurance

6 * **Is the device implanted or otherwise placed into the body?**
● **Yes** ○ No

If YES:

6.1 **Who will be responsible for the costs associated with the placement and removal of the device from the body?**
Insurance

7 * **Has the sponsor provided an investigational brochure or any other type of information about the device and previous animal or human studies?**
● **Yes** ○ No

If YES:

7.1 **Upload the information.**

Name	Date Last Modified	Version Number	Owner
Investigators Brochure.docx(0.01)	4/2/2020 4:47 PM	0.01	Matthew Stafford

8 * **What is sponsor's risk designation for the device according to FDA definitions?**

- ● **Significant Risk (SR)**
- ○ Non Significant Risk Device (NSR)
- ○ Exempted Investigations (e.g. in vitro diagnostics, consumer preference testing)
- ○ Other Classification

8.1 ***If Significant Risk (SR), please answer the following questions.***

8.1.1 **What is the IDE number?**
IDE number

8.1.2 **Who is the IDE Sponsor?**

- ◯ A company, organization, NIH, consortium or university.
- ● **Children's Investigator**
- ◯ Other

8.1.3 Please specify the name of the IDE holder.
Dr. Stafford

8.1.4 Please upload any FDA IDE approval correspondence.

Name	Date Last Modified	Version Number	Owner
IDE approval correspondence.docx(0.01)	4/2/2020 4:48 PM	0.01	Matthew Stafford

8.2 ***If Non-Significant Risk, please answer the following questions.***
In order to be considered a Non-Significant Risk Device (NSR) the IRB must agree with the sponsor's determination that the following conditions are applicable. Please justify how the following criteria are met.

8.2.1 The device is not intended as an implant (remaining 30 days or more in the human body) and presents a potential for serious risk to the health, safety, or welfare of a participant.

8.2.2 The device is not purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a participant.

8.2.3 The device is not of substantial importance in diagnosing, curing, mitigating, treating, or otherwise preventing impairment of human health and does not present a potential for serious risk to the health, safety, or welfare of a participant.

8.2.4 The device does not otherwise present a potential for serious risk to the health, safety, or welfare of a participant.

8.2.5 Who is the NSR Sponsor?

- ◯ A company, organization, NIH, consortium or university.
- ◯ Children's Investigator
- ◯ Other

8.2.6 Please specify the name of the NSR Sponsor.

8.2.7 Please upload any applicable FDA correspondence.

Name	Date Last Modified	Version Number	Owner

There are no items to display

8.3 ***If Exempted Investigations, please answer the following questions:***

8.3.1 Is this a diagnostic device?
◯ Yes ◯ No

If YES, please justify the following criteria:

8.3.1.1 Is noninvasive

8.3.1.2 Does not require an invasive sampling procedure that presents significant risk.

8.3.1.3 Does not by design or intention introduce energy into a participant.

8.3.1.4 Is not used as a diagnostic procedure without confirmation of the diagnosis by another, medically established diagnostic product or procedure.

8.3.2 Is this a device undergoing consumer preference testing, testing of a modification, or testing of a combination of two or more devices in commercial distribution?
◯ Yes ◯ No

If YES:

8.3.2.1 Please explain how this study is not for the purpose of determining safety or effectiveness and does not put participants at risk.

8.4 ***If Other Classification:***

8.4.1 Is the device being used to investigate a basic physiological principle?

8.4.2 Is your device still something else? Please explain:

9 Please complete the following information about device control and accountability.

9.1 * How and where will the device be received from the manufacturer?
How and where will the device be received

9.2 * Describe the location and manner in which the device will be stored?
Location and manner in which the device will be stored

9.3 * Who will have access to the device and how will access be controlled?
Device access and control.

9.4 * How will the device receipt, use and return be logged or otherwise documented?
device receipt, use and return documentation.

10 * How will extra devices be stored or returned to the manufacturer?
Storage and return plan.

11 Upload any correspondence or information available about the device risk determinations. Also attach information about the device and provide a picture if available.

Name	Date Last Modified	Version Number	Owner

There are no items to display

ID: VIEW470A74B3A2000
Name: Investigational Devices

IRB-P00034143 Pathology Specimen Data

Pathology Specimen Data

1 * **Specimen Category. Please note, you can only select one specimen category at a time. If you will be using multiple specimen types for this research, answer the questions on this page for the first specimen type, then click OK and Add Another to add more.**

- (●) **Blood**
- ( ) CSF
- ( ) Urine
- ( ) Sputum
- ( ) Saliva
- ( ) Tumor/Tissue
- ( ) Other

If Other:

1.1 Other:

If tumor/tissue is selected, please answer the following questions.

1.2 Specify type of tumor/tissue.

2 * **Specify type of tissue/material:**

- (●) **Fresh**
- ( ) Frozen
- ( ) Fixed
- ( ) Sterile
- ( ) Formalin- fixed paraffin embedded tissue (FFPE)
- ( ) Nucleic acid
- ( ) Scanned slides* (add disclaimer: this is not to be shared with a third party without special agreement, reach out to legal.. etc.)
- ( ) Other

If FFPE:

2.1 Please select all that apply

- [ ] Unstained slides
- [ ] Scrolls

If Scanned Slides selected:

2.2 How will you utilize digital images?

2.3 Do you plan on sharing digital images with third parties?

( ) Yes ( ) No

If Yes:

2.3.1 Is there a material transfer agreement in place?

( ) Yes ( ) No

If No:

Please contact the BCH legal department regarding material agreement.

If Other:

2.4 Specify:

3 * **Specify the amount required (if fresh/frozen tissue: specify in g mm in 3 dimensions, if unstained slides/scrolls: specify thickness, if fluid: specify in ml).**
3mm

4 * **Please justify why this amount is requested/required.**
Needed for fibroblasts.

5 * **Specify the number of samples requested.**
1

6 * **What period of time are the specimens requested from?**
Next 3 years

7 **Tissue collection specification:**
If FFPE tissue will be collected:

7.1 Is local pathology examination required?
◯ Yes ◯ No

7.2 Do you have a pathologist collaborator?
◯ Yes ◯ No

7.3 Specify workflow for block ID/specimen selection (e.g., if pathologist collaborator is on the protocol, the pathologist help in reviewing cases and selecting appropriate tissue/block for the study, or if no pathologist collaborator, study team will coordinate with pathology and submit TO form (pathology research request) and pay the charges requires for pulling archival slides and selecting appropriate tissue/block for the study)

If Fresh tissue will be collected:

7.4 Please specify location of collection

- ☐ IR(Interventional Radiology)
- ☑ **Pathology**
- ☐ Clinic
- ☑ **OR**
- ☐ Outside of BCH
- ☐ Left over from research protocol
- ☑ **Other BCH procedure areas**

7.4.1 If Other BCH Procedures areas, please explain:
test

7.4.2 If specimen will be obtained from outside of BCH, specify where the specimen will be obtained from.

8 * **Is local Pathology processing required (e.g., tissue fixation, processing into FFPE block?)**
● **Yes** ◯ No

If No:

8.1 Will tissue be sent directly to sponsor central lab?
◯ Yes ◯ No

9 * **Who will oversee tissue collection?**

- ☑ **Pathology collaborators**
- ☐ Study team
- ☐ Other

If Other:

9.1 Please specify:

9.2 If NO pathologist collaborator, please specify workflow for tissue collection (e.g. study team will coordinate with pathology department on the day of procedure with detailed plan

for tissue requirement and be present/available for tissue collection and pick up …. etc. be as detailed as possible).

10 **Budget**

*** Has the office managing the budget been advised and does the budget include the costs for Pathology services?**

● **Yes** ○ No

ID: VIEW470A26EED8000
Name: Pathology Specimen Data