Boston Children's Hospital

Date: Thursday, November 12, 2020 1:57:38 PM Print Close

Title: Sample New Research Activity

General Information

1 * **Protocol Title:**
Sample New Research Activity

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 New Research Activity

3 * **Provide a brief summary (in lay terms) of the research protocol.**
This should be a short description of the study.

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?
View	Matthew Stafford	yes

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 subjects at CHB?**
○ 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 subjects, 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 subject's rights or welfare

This form may not be selected if the study involves interaction/intervention with subjects 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 3.12, 'Reliance Agreements'

10 * **Will this protocol utilize any of the services of the ETU (Experimental Therapeutics 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 the ETU or research space at Waltham*
- *Nursing assistance at above sites*
- *Off-site nursing and/or research coordinator services provided through ETU*
- *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.)*
- *Use of specialist equipment located on the ETU (3DMD camera, DXA, pQCT, V-max, etc.)*

Note: If YES, your protocol will be routed for Harvard Catalyst CRC Protocol Review PRIOR to BCH IRB review.
For details, see: Institutional Centers for Clinical and Translational Research (ICCTR)

11 * **Does this protocol include COVID-related research with subjects diagnosed or suspected with COVID19 that meet any of the following criteria?**
• Use of discard clinical samples (nasal swabs, blood, etc.)
• Collection of clinical samples from patients (blood, nasal swabs, sputum, urine, stool etc.)
• Collection of demographic and clinical information at time of patient encounter
• Interaction or intervention with patients (therapies, extra testing , interviews) while in the hospital (inpatient, ambulatory, emergency department)
○ Yes ● **No**

Note: Do not check "Yes" for research limited to retrospective or prospective collection of data or surveys/interviews conducted with families and patients through non inperson encounters.

Note: If "Yes" - the scientific review will be automatically routed to a newly formed SRC committee established to conduct COVID19 research reviews. In addition you are required to obtain approval by institutional representatives who have been assigned responsibility by hospital location for prioritizing multiple requests, assuring protocols meet standards for infection control, and appropriate personnel are involved.
Please contact them early during your research planning so they can provide guidance.
Please note that the processes, capabilities, and requirements differ by site.

Investigators with proposals than span different locations should discuss their research plan with all site leads:
ED: Mark Neuman, MD
ICU and ORs: Adrienne Randolph, MD
In-patient: Benji Raby, MD
Laboratory Medicine: Orah Platt, MD and Nira Pollock, MD

If you would like to request ICCTR support please contact Andy Place, MD (Chief Medical Officer) and Cindy Williams, RN MS, NE-BC (nursing)

12 * **Does this protocol require follow-up research activities after a patient with COVID -19 leaves BCH?**

◯ Yes ◯ No

If YES:

12.1 Please select all that apply:

☐ Surveys, Questionnaires or Interviews

☐ Request for follow-up to acquire biological samples from a patient with COVID-19

☐ Other follow up activity that requires contacting the patient

If Other follow up activity:

12.1.1 Please explain:

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	Role	Editor	CC on Correspondence	Required Training Completed	CHeRP Training	Date Modified	Date Created
View	Dominguez Robleinscky		Co-Investigator	yes	yes	yes	no	10/9/2020	10/9/2020
View	Dufresne	Ami	Co-Investigator	yes	yes	yes	yes	10/15/2020	10/15/2020
View	Gawlowicz	Kennan	Co-Investigator	yes	yes	yes	yes	10/15/2020	10/15/2020
View	Kuniholm	Ashley	Admin Contact	yes	yes	yes	yes	11/22/2019	11/22/2019
View	Mitchell	Anna	Co-Investigator	yes	yes	yes	no	10/9/2020	10/9/2020

2 ***NOTE:*** **Accounts are no longer required for non-BCH researchers. These individuals remain under the jurisdiction of their home institution's IRB and should not be listed here. If you think there is a special circumstance, please contact your IRB Administrator.**

Research Staff - Non Children's Hospital Employees only:

Last Name	First Name	Role	Email	Required Training Completed
There are no items to display				

3 PI: Matthew Stafford

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed	Date Created
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	

Training Program	Continuing Education Description	Training Completed	Date Created
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 New Research Activity

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.

Funding Sources - Details

1 * **List of external sponsors for this protocol.**

Sponsor	Funding Category
View NATIONAL HEART, LUNG, AND BLOOD INSTITUT - 1049	Federal

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
- [x] **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.**

This should be a complete description of the other grants provided by the Sponsor, including dollar amounts.

9 **Upload any other pertinent documentation.**

Name	Date Last Modified	Version	Owner

There are no items to display

Multi Site Information

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.**

Use this to explain any communication methods, frequency of meetings/conference calls, etc.

2 * **Will other sites be asked to rely on BCH as the reviewing IRB?**

● **Yes** ○ No

If YES:

2.1 **Will data be shared between sites?**

Yes

2.2 **Please provide a description of your oversight process to assure that institutions that rely on the BCH IRB are:**
**** provided timely access to approved and revised approved protocols, informed consents and recruitment materials**
**** informed about the BCH IRB polices and pertain to this research**
**** provide you (the BCH investigator) with any required COI management plans, required information pertaining to continuing reviews and any reportable events**

Description of the oversight process.

3 **Please name the other sites if Question 1 or Question 2 is "Yes"**

Other site name.

Subject Information

1 **Enrollment Numbers**

1.1 * **Specify the number of subjects enrolled at Boston Children's Hospital, or at sites relying on BCH IRB review, 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, please indicate the total number of subjects to be recruited at BCH or at relying sites. If not applicable, please leave blank.**

125

1.3 **If this is a multi-center study, please specify the total number of subjects required to enrolled across all sites, including BCH and reliance sites, for data analysis.**

500

1.4 **If this is a multi-center study and a larger number of subjects must be enrolled across all sites to account for such things as screening failures, drop-outs, and lost to follow-up, please indicate the total number of subjects to be enrolled.**
If not applicable, please leave blank.

600

2 **Types of Subjects**

2.1 ***Gender**

☑ Males

- [x] Females

2.2 *Age

- [x] Neonates (up to 30 days)
- [x] Infants (between 30 days and 2 years)
- [x] Children (between 2-12 years)
- [ ] Adolescents (between 13-17 years)
- [ ] Adults, Ages 18-35
- [ ] Adults over 35

Specify entire age range.
0-12

2.3 Special Populations

- [x] Mentally Incapacitated
- [ ] Employees/Staff (Note: Employees/staff under the direct supervision of the PI may not be recruited.)
- [ ] Normal/Healthy Controls
- [ ] Students

Specify from where.

- [x] Pregnant Women/Fetuses
- [x] 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.
- [x] 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] Minorities

If NOT checked:

Provide scientific justification for excluding minorities.

- [ ] Non-English Speaking Subjects

If checked:

What plans do you have to provide the subject/family with a written translation of the consent form and other study materials and to ensure that all study interaction will be in a language understandable to the subject/family?

If NOT checked:

Please provide scientific justification for excluding non-English speaking subjects.
This must be a scientific justification. Simply citing cost of translation is not sufficient.

- [ ] Other populations potentially subject to special considerations not identified above (i.e. socially, educationally, economically disadvantaged, elderly, terminally ill or adults with questionable decision making capabilities)

Specify population.

Specify what additional safeguards will be taken to protect the rights and welfare of these subjects.

- [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.
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.
Rationale for why it is necessary to include adults with decisional impairment.

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...
Criteria and procedures or measurements for evaluating the decisional status of the prospective participant.

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 exist.Please also explain how legal records

regarding authority will be obtained, reviewed by the research team, and documented in the research record.

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.

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.

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's rights? This may include the use of an ombudsman, frequent cognitive status evaluations, etc...

Provide a description of how the participant will be protected if their capacity to consent is lost or fluctuates.

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Neonates

1 * **All research involving neonates must meet one or more of the following categories. Please check as appropriate.**
This research:

- [x] **Includes procedures do not substantially jeopardize the life or health of the neonate (this category is limited to minimal risk research only).**
- [ ] Presents diagnostic or remedial procedures to determine the life or health of the neonate involved.
- [ ] Presents diagnostic or remedial to preserve the life or health of the neonate involved.
- [ ] Compares or improves potential diagnostic or therapeutic neonatal interventions to improve the viability or quality of life of neonates and children.

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)
- [x] **Medical/Surgical ICU (7 South)**
- [ ] Medicine ICU (11 South)
- [x] **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
- [x] **OR/PreOp/PACU**
- [ ] Other Satellites (Lexington, Peabody, South Shore, etc.)
- [ ] Radiology

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 Remuneration

Recruitment

1 * **Describe plans for recruitment, including identification of potential participants, who is responsible for recruitment and how and when subjects will be recruited.**
This should explain how you will find and approach potential participants.

2 * **Will you need to search through BCH medical records or institutional databases such as i2b2 or BCH360 for the initial screening for potentially eligible subjects?**
● **Yes** ○ No

If YES:

2.1 **Will you be accessing records or contact information of patients not seen by your department, your service or your co-investigators?**
○ Yes ● **No**

In general, recruitment of patients from services outside of the investigators' area is not to be done without involvement of the departments in which the patients were seen.

If YES:

2.1.1 **Please describe how you will coordinate with other departments or care providers during the recruitment process.**

3 **If applicable, how will prospective subjects' healthcare providers (e.g., physician, dentist, etc.) be involved in the recruitment and/or be notified of their individual patients' participation in the study?**

4 * **Describe measures that will be implemented to avoid participant coercion or undue influence.**
For example, how will coercion be avoided in the PI is also the subject's treating clinician?

5 * **Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?**
● **Yes** ○ No

If YES:

5.1 **Please describe how frequently and in what manner individuals will be contacted.**
A phone call may be made two weeks after sending a letter.

6 Upload all recruitment materials, including letters, brochures, posters, phone interview scripts, newspaper ads, etc.

Name	Date Last Modified	Version	Owner
Recruitment Letter.docx	11/22/2019 2:37 PM	0.01	Ashley Kuniholm

7 Please describe how each document uploaded in question #6 will be used.

Recruitment letters will be sent to families of potential participants.

Remuneration

8 * Will subjects/families receive a form of payment, compensation or reimbursement?

(●) **Yes** ( ) No

Please answer the following information regading ClinicalTrials.gov registration.

9 * 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 subjects 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 subjects (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)**
- [ ] **(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.

9.1 Who will be responsible for registering the trial?

- [x] **Sponsor (if other than BCH PI/Sponsor-Investigator)**
- [ ] BCH PI or Sponsor-Investigator
- [ ] Investigator at another site
- [ ] Other

If Other:

9.1.1 Please specify who.

9.2 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:

9.2.1 Please insert "NCT" number for this trial

NOTE: A valid NCT number must be included before the IRB releases final approval for this protocol. If the NCT number is not included in the original submission you will need to register the trial and submit an amendment to include the NCT registration number before final approval is released.

Final approval for the protocol will not be issued until a valid NCT number is listed in the CHeRP smart form

Remuneration Details

Enter information about all forms of payment that will be used in this study and answer the corresponding questions.
Please note, any payment or gift should not be so large as to unduly influence the parent/child to participate.

1. ☑ **Reimbursement: payment for research-related expenses incurred. E.g. transportation, parking, meals, childcare.**

1.1 What form (check, cash) and total amount will be provided?
Clincard will be provided to reimburse for all travel expenses

1.2 Who will receive the reimbursement (subject, parent or both)?
Parent

1.3 When and how will the reimbursement be distributed?
Funds will be added after family provides receipts of travel expenses

1.4 How was this form and amount determined?
Clincard is standard payment for research subjects.

2 ☐ **Compensation: payment for time and inconvenience from participation. E.g. compensation for time-off work.**

2.1 What form (check, cash) and total amount will be provided?

2.2 Who will receive the compensation (subject, parent or both)?

2.3 When and how will the compensation be distributed?

2.4 How was this form and amount determined?

3 ☐ **Tokens of Appreciation: small payments or gifts for participation. E.g. toys, gift certificates, small payment.**

3.1 What form (gift, payment) and total amount will be provided?

3.2 Who will receive the token of appreciation (subject, parent or both)?

3.3 When and how will the token of appreciation be distributed?

3.4 How was this form and amount determined?

4 ☐ **Incentives: payments/gifts to encourage subject enrollment or continued participation. E.g. completion bonus.**

4.1 What form of incentive and total amount will be provided?

4.2 Who will receive the incentive (subject, parent or both)?

4.3 When and how will the incentive be distributed?

4.4 How was this form and amount determined?

Title: Sample New Research Activity

Screening for Recruitment

If you wish to query medical records in order to find potentially eligible subjects for recruitment, you will need to justify a waiver of informed consent.
Please answer the following questions:

1 * **This query of medical records presents no more than minimal risk to the subjects because:**
Need to justify waiver of consent to obtain PHI to send recruitment letter.

2 * **The waiver or alteration will not adversely affect the rights and welfare of the subjects because:**
Need to justify waiver of consent to obtain PHI to send recruitment letter.

3 * **Investigators are required to obtain only the minimum data necessary to achieve research goals. Justify why the data you are obtaining is the minimum necessary to achieve the recruitment goals.**
Need to justify waiver of consent to obtain PHI to send recruitment letter.

4 * **The recruitment could not be practicably carried out without the waiver of informed consent/assent and authorization because:**
Need to justify waiver of consent to obtain PHI to send recruitment letter.

5 * **The research could not practicably be conducted without access to and use of protected**

health information because:
Need to justify waiver of consent to obtain PHI to send recruitment letter.

Research Data, Documents, Subject Reports & Consent/Assent Forms: Storage

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

- [x] Children's Hospital Medical Record
- [ ] Departmental Medical Record
- [x] 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:

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

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

3 * **Explain the rationale for including or not including research data and the informed consent/assent forms in the BCH medical records.**
Consent for studies of investigational medical products need to be stored in BCH Medical record.

Please note: the confidentiality section of the consent form must specify whether research data and/or the informed consent/assent form(s) will or will not be included in the Children's Hospital or Departmental medical records. A sample statement is included on the Informed Consent Template.

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

Privacy and Confidentiality

Privacy

1 * **'Privacy' refers to a person's desire to control access of others to themselves. Describe the steps that will be taken to protect and assure the privacy of the subject.**
Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).
Description of how privacy will be protected.

Examples of issues:
• Potential subjects may not want to be approached for research purposes by someone they do not know.
• Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.
• Subjects may not want to be seen in areas that may stigmatize them (i.e. pregnancy counseling center).

Confidentiality

2 * **Investigators are required to obtain only the minimum data necessary to achieve the research goals. Please justify why the data you are obtaining is the minimum necessary.**
Explanation of why data to be collected is minimum necessary.

3 * **Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.**
Where and how will data be stored

4 * **Provide a plan to protect the identifiers from improper use and disclosure.**
How will identifiers be protected

5 * **Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers. For protocols that may be subject to future continuing and secondary data analysis, the IRB highly recommends providing justification for not destroying identifiers permanently.**
When will identifiers/links be destroyed.

6 * **Will a certificate of confidentiality be obtained for this research?**
○ Yes ● **No**

If YES:

6.1 Please upload certificate, if available.

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

6.2 ☐ **Check here if certificate is pending and will be submitted via an amendment at a later date.**

Title: Sample New Research Activity

Data Information

Investigators must complete this form when data is collected, transmitted, or stored electronically. The IRB may request a consultation from data security experts from Research Computing and ISD to ensure risks to research participants are minimized and appropriate safeguards are in place. It is important that all relevant questions are addressed to prevent a delay in review. If you have any questions, email us at IRB@childrens.harvard.edu. It is important to remember that all research data belongs to Boston Children's Hospital

1 * **Please select the appropriate category for the data that is collected for this research.**
☐ Anonymous Data Collection – at no time will any identifiers be recorded including IP addresses
☑ **Coded/Linked to Study ID, registered by the research team. (data is kept separate from identifiers and each subject has unique link or code)**
☑ **Identifiable data PHI/PII Data Collection – one or more personal identifiers will be collected**

2 * **Will you be collecting any whole genome/exome sequencing data?**
● **Yes** ○ No

3 * **Will you be collecting data for more than 500 participants?**
● **Yes** ○ No

Title: Sample New Research Activity

Type Of Data To Be Used For The Study

1 * **Please select the type of data to be used for the study:**

- [x] **Database**
- [ ] Genetic
- [x] **Genomic**
- [x] **Hospital Administrative/Billing Data**
- [x] **Imaging Data**
- [x] **Medical Data/charts**
- [ ] Quality Improvement Records
- [ ] Survey Data
- [ ] Other

1.1 **If Database: please specify**
Name and description of database.

1.2 **If Other: please specify**

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.**

- [x] **Patient/Subject Name or the names of relatives, employers, or household members**
- [x] **Medical record numbers (or specimen #)**
- [ ] Address street location
- [ ] Address town or city *
- [ ] Address state*
- [ ] Address zip code*
- [ ] Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures*
- [x] **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 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 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.

Title: Sample New Research Activity

IT Technologies

1 * **What technologies will be used to collect data? Please check all that apply:**

- ☑ **Mobile App**
- ☑ **Wearable Device**
- ☑ **Electronic Recording or Conferencing. Includes: audio recording, video recording, etc.**
- ☑ **Text Messaging**
- ☐ Not Applicable

Title: Sample New Research Activity

IT Technologies - Mobile App

1 * **Name of the mobile app**
Mobile app name.

2 * **Identify the mobile device platform(s) (IOS/Android/Windows) to be used.**
Name of platforms.

3 * **Identify who created the app.**
App creator name.

4 * **App creator entity**

- [x] **BCH**
- [x] **Academic**
- [ ] Non-profit
- [ ] For-profit

5 * **Whose device will be used?**

- [x] **Participant phone/tablet**
- [ ] Researcher/sponsor provides phone/tablet

6 * **Describe how the app is downloaded to the device.**
Download method.

7 * **Will data be stored on device for any period of time?**
● **Yes** ○ No

If YES:

7.1 Please describe (e.g. queue on device, stored on device indefinitely).
Description of device storage.

7.2 Are data encrypted on device?
● **Yes** ○ No

7.3 How are the data encrypted in transit?
Data encryption method.

8 * **How is the app secured on the device:**
How app is secured.

8.1 * **Is a password or PIN for app required?**
● **Yes** ○ No

8.2 * **Is a password or PIN for the device required?**
● **Yes** ○ No

9 * **Will the app be able to access other device functionality such as Location, Contacts, Notifications, etc.?**
● **Yes** ○ No

10 * **When data is transmitted from the device, please list all locations where it will reside (even temporarily).**
list of locations.

11 * **Does the application allow for a wipe of information and/or device?**
● **Yes** ○ No

12 **If applicable, describe how the data is coded (process used).**

12.1 Are phone numbers or mobile identification numbers stored with data?
● **Yes** ○ No

12.2 Are phone numbers or mobile identification numbers stored by the app server?
● **Yes** ○ No

13 * **Is there an executed Service Agreement?**
● **Yes** ○ No

If YES:

13.1 Please attach agreements or security affidavits if available.

Name	Date Last Modified	Version	Owner
Executed service agreement.docx	4/1/2020 10:11 AM	0.01	Matthew Stafford

14 * **Is there a "end user license agreement" (EULA)?**
● **Yes** ○ No

If YES:

14.1 Please attach agreement if available.

Name	Version	Owner
EULA.docx	0.01	Matthew Stafford

15 * **For PHI Data Collection, is there an executed BCH Business Associate Agreement?**

● **Yes** ○ No

If YES:

15.1 Please attach any agreements if available.

Name	Date Last Modified	Version	Owner
BAA.docx	4/1/2020 10:12 AM	0.01	Matthew Stafford

16 **Provide any additional information (e.g. is the app sponsor approved, will the app retain any participant information?).**

Title: Sample New Research Activity

IT Technologies - Wearable Device

******Also complete the mobile app form if a mobile app will be used with the wearable device***

1 * **Name of device:**
Name of device.

2 * **Who provides the wearable device?**

☑ **Manufacturer Provides Device**

☐ Researcher Provides Device

☐ Personal Device

3 * **Who registers the wearable device?**

☑ **Participant**

☐ Researcher

4 * **How is data encrypted in transit?**
How data is encrypted in transit.

5 * **How is data encrypted at rest?**
Data encryption details.

6 * **When data is transmitted from the device, please list all locations where it will stored (even temporarily).**
List of locations.

7 * **How is data coded:**
Data coding details.

7.1 * **Are phone numbers or mobile identification numbers stored with data?**

○ Yes ● **No**

7.2 * **Will GPS data be collected to identify locations?**

● **Yes** ○ No

8 * **URL with Vendor Data and Privacy Policies**
URLs

9 * **Is there an executed Service Agreement?**

○ Yes ● **No**

If YES:

9.1 Please attach agreements or security affidavits if available.

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

10 * **For PHI Data Collection, is the entity ready to endorse the BCH Business Associate Agreement?**

○ Yes ● **No**

If YES:

10.1 Please attach any agreements For PHI Data Collection if available.

Name	Date Last Modified	Version	Owner

There are no items to display

11 Provide any additional information.

Title: Sample New Research Activity

IT Technologies - Electronic Recording Of Data
Includes: audio and video recording.

1 * **Describe the method of capturing the image, video, and/or audio.**

☑ **BCH Zoom**

☐ Other

If Other:

1.1 Please describe.

2 * **Will the images, video, and/or audio be transmitted over the internet?**

● **Yes** ○ No

3 * **Where will the images, video or audio be stored?**

☑ **BCH RCFS**

☑ **Other**

If Other:

3.1 Please describe.
Encrypted collaborator drives.

4 * **How will the images, video and/or audio be secured to protect against unauthorized viewing or recording?**
Method of securing.

5 * **Once collection is complete, are the data going to be deleted from the server?**

● **Yes** ○ No

6 * **Will a 3rd party transcription service or app be used for any of the recordings?**

● **Yes** ○ No

If YES:

6.1 Please describe.
Names and descriptions of services or apps.

6.2 Is there an executed Service Agreement?

● **Yes**

○ No

○ NA

If YES:

6.2.1 Please attach agreements or security affidavits if applicable.

Name	Date Last Modified	Version	Owner
Service Agreement.docx	4/1/2020 10:15 AM	0.01	Matthew Stafford

6.3 For PHI Data Collection, is the entity ready to endorse the BCH Business Associate Agreement?

● **Yes** ○ No

If YES:

6.3.1 Please attach any agreements for Data Collection if applicable.

Name	Date Last Modified	Version	Owner

Name	Date Last Modified	Version	Owner
BAA.docx	4/1/2020 10:15 AM	0.01	Matthew Stafford

7 Provide any additional information.

Title: Sample New Research Activity

IT Technologies - Text Messaging

1 * Are you using the current text messaging available on the:

- [x] **Device**
- [ ] Separate Application

NOTE: If the latter, ensure mobile app section above is completed

2 * Whose device will be used?

- [x] **Personal Phone**
- [ ] Researcher Provides Phone

3 * What kind of information will be included in the text messages? For example: appointment reminders, instructions, links to other information

Information

NOTE: No PHI should be included in text messages

4 * Has consent from the subject been obtained to use text communications?

● **Yes** ○ No

5 * Is the communication:

- ○ One-Way
- ● **Two-Way**

6 * Is any other technology being used to collect data?

○ Yes ● **No**

If YES:

6.1 Please describe.

7 Provide any additional information.

IT Technologies - Data Storage

1 * Will PHI data be stored?

● **Yes** ○ No

If YES:

1.1 What server will be used to store the PHI data?

- [x] **BCH RC-FS**
- [ ] Other

If Other:

1.1.1 Please describe.

2 * Will NON PHI data be stored?

● **Yes** ○ No

If YES:

2.1 What server will be used to store the Non-PHI data?

- [x] **BCH AWS environment**
- [x] **BCH Dropbox**
- [x] **BCH Google Team Drive**
- [ ] BCH Department Managed Server
- [ ] BCH Study Team Managed Server
- [x] **Server/cloud not managed by BCH**
- [ ] Other

If Other:

2.1.1 Please describe.

3 * What type of workstation will be used for data use and storage?

- [x] **BCH owned desktop or laptop**
- [x] **Personal desktop or laptop**
- [x] **Sponsor provided desktop or laptop**

4 * Is encryption used to protect the data when stored on workstation?

- (●) **Yes**
- ( ) No
- ( ) NA

NOTE: Please be sure virus protection and operation systems are kept up to date.

5 * Will data be transmitted to a Third-party collaborator or sponsor?

(●) **Yes** ( ) No

If YES:

5.1 Please describe.
What will be transmitted, to whom, how and why.

5.2 Will BCH receive any data back?

(●) **Yes** ( ) No

If YES:

5.2.1 In what form and frequency (e.g. electronically/monthly, etc) ?
Form and frequency.

5.3 Will any materials be transferred with the data?

(●) **Yes** ( ) No

If YES:

5.3.1 Please list exact name of materials.
Exact name of materials.

6 * Do you have existing Service Agreement, or BAA agreements with collaborators and sponsors?

- (●) **Yes**
- ( ) No
- ( ) NA

If YES:

6.1 Please attach agreements or security affidavits

Name	Date Last Modified	Version	Owner
BAA.docx	4/1/2020 10:16 AM	0.01	Matthew Stafford

7 Please provide information on where the data will be stored at each phase of the protocol:

7.1 * During collection (i.e. redcap, video cameras, audio recordings on digital recorder)
Where the data will be stored in this phase of the protocol.

7.2 * During analysis/interrogation (i.e. E2, AWS, BCH workstation)
Where the data will be stored in this phase of the protocol.

7.3 * Storage after analysis (i.e. de-identified on G-Suite, file on RCFS)
Where the data will be stored in this phase of the protocol.

7.4 * Data sharing or publication (i.e. G-Suite drive, NIH repository)
Where the data will be stored in this phase of the protocol.

7.5 * Long term storage (i.e. retention for 6 years in G-Suite, file on RCFS)

Where the data will be stored in this phase of the protocol.

8 * **Please select names of all BCH individuals who will be given access to private health information.**

Last Name	First Name	ID
Kuniholm	Ashley	123524

9 * **Does anyone outside of BCH have access to the data?**

● **Yes** ○ No

If YES:

9.1 List anyone outside the study team who will have access to the data.

PIs at partner sites.

10 * **List the study team member responsible for maintaining the security of the data.**

Last Name	First Name	Employee ID
Stafford	Matthew	120216

11 * **Describe your reporting plan should your electronic data be intercepted, hacked, or breached (real or suspected).**

Reporting plan.

12 * **Is there any sponsor or agreement specific reporting policy?**

● **Yes**

○ No

○ NA

If YES:

12.1 Please describe.

Sponsor or agreement specific reporting policy.

13 * **Describe what will happen to the electronic data when the study is completed as BCH policies require that research records be maintained for at least 7 years after the study has ended.**

What will happen to the electronic data when the study is completed.

14 * **Will a publication arise from this study?**

● **Yes** ○ No

If YES:

14.1 Will the BCH PI publication be:

○ Published as a collaborator

● **Published as a academic co-authorship**

○ NA

If NA:

14.2 Please explain.

15 **Provide any additional information.**

16 *Please be sure your consent form discloses any risks of use of technology in the project. E.g. handling of data by third parties, Self-disclosure of identifiable information.*

* ☑ **I certify I have reviewed and am in compliance with the terms of service for all technologies to be used for research activities.**

Data and Safety Monitoring

All protocols that present greater than minimal risk require a data and safety monitoring plan(DSMP). Investigators may also choose to submit a plan for any protocol.

1 * **Please check one of the three categories.**

- (●) **This protocol is greater than minimal risk and therefore requires a DSMP (responses to all questions below are required).**
- ( ) This research is minimal risk but we have included a DSMP (respond to the questions below that apply to your DSMP).
- ( ) This protocol is minimal risk and we are not including a DSMP (do not respond to the questions below).

2 **Which individual or group will be responsible for monitoring the data and safety for this study?**

- [ ] Principal Investigator/Research Team
- [ ] Independent Monitor(s)
- [ ] Internal Committee at the Hospital
- [x] Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- [ ] Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- [ ] Other

Specify:

3 **Provide a description of the individuals who will be responsible for data safety monitoring, including the following details:**
(1) association with the research or study sponsor;
(2) nature of expertise and;
(3) whether they are independent of the commercial sponsor.
If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

Explanation of who will be on the DSMB.

Note: If this information is in the protocol, please specify where (by the section number) the relevant information can be located.

4 **What data will be reviewed?**

- [x] **Adverse events/Unanticipated problem**
- [ ] Aggregate data
- [x] **Enrollment numbers**
- [ ] Individual subject data/case report forms
- [x] **Protocol violations/deviations**
- [ ] Subject withdrawals/terminations
- [ ] Other

Specify:

5 **How often will data and safety monitoring be performed? Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.). If this information is in protocol, please specify where relevant information is located.**

Frequency of meetings

6 **Describe the responsibilities that have been given to the data and safety monitoring function. This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.**

Responsibilities of the DSMB

7 **If this protocol is for a multicenter trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.**

Reporting schedule

8 **If a DSM charter exists, please upload it.**

Data and Safety Monitoring Charter.docx	11/22/2019 2:44 PM	0.01	Ashley Kuniholm

Risks and Benefits

Risks

1 * **Provide a description of the foreseeable risks to subjects. Consider all types of risks, including physical, psychological, social/reputation, legal, financial, privacy and breach of a promise of confidentiality.**
Risks to subjects

2 * **What is the likelihood and seriousness of such risks?**
Likelihood and severity of risk

3 * **Describe provisions for minimizing risks to participants.**
How will risks be minimized

Potential Benefits

4 * **Are there potential direct benefits to the research participants?**
● **Yes** ○ No

If YES:

4.1 Describe the potential direct benefits to the research participants.
Direct benefit to the participants

5 * **Describe how the research may result in knowledge expected to benefit society.**
Benefits of the research

Pediatric Risk/Benefit Determination

All protocols that include children/adolescents must be classified into a risk/benefit category.

Does your study involve more than one risk/benefit category for different groups? If so, answer questions 1, 1.1, 1.2 and 1.3 to describe the least favorable risk/benefit scenario, and use the questions 2, 2.1, 2.2, 2.3, 2.4 to explain the risk/benefit assessment for the other groups of subjects in your study.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1 * **Check the category below that best represents the degree of risk and benefit which children in this study will be exposed to. If your study involves more than one group of subjects (eg. .experimental and placebo groups) consider whether the research presents a different risk/benefit assessment for each group. If this is the case select the least favorable risk/benefit ratio that might apply to any of the subjects.**
For example, a study may present greater than minimal risk with potential for direct benefit for an experimental group, but no potential for direct benefit for a placebo group. In this case you should select "Greater than Minimal Risk; No Potential for Direct Benefit" in this section and use section 2 below to describe the risks and benefits for the group for which there a potential for benefit.

○ No more than Minimal Risk; Potential for Direct Benefit

○ No more than Minimal Risk; No Potential for Direct Benefit

● **Greater than Minimal Risk; Potential for Direct Benefit**

○ Greater than Minimal Risk; No Potential for Direct Benefit, but likely to yield generalizable knowledge about the subject's condition

1.1 If Greater than Minimal Risk; Potential for Direct Benefit

1.1.1 How is the risk justified by the benefit?
justification of the risk

1.1.2 How is the benefit to risk assessment at least as favorable as presented by alternative approaches?
compare risk to alternative options

1.2 If Greater than Minimal Risk; No Potential for Direct Benefit

1.2.1 How is the risk of the protocol a minor increase over minimal risk?

1.2.2 How do the procedures present experiences to the subjects that are reasonably commensurate with those inherent in the subjects' actual or expected situations?

1.2.3 How is knowledge to be gained of vital importance for the understanding or amelioration of the condition?

1.2.4 Can the consent of both parents be obtained if reasonably available?

1.3 To which group of subjects does this risk/benefit assessment apply?

2 * **Does your protocol have more than one risk/benefit group?**
○ Yes ● **No**

If YES:

2.1 Check the category below that best represents the degree of risk and benefit which children in this study will be exposed to.

- ○ No more than Minimal Risk; Potential for Direct Benefit
- ○ No more than Minimal Risk; No Potential for Direct Benefit
- ○ Greater than Minimal Risk; Potential for Direct Benefit
- ○ Greater than Minimal Risk; No Potential for Direct Benefit, but likely to yield generalizable knowledge about the subject's condition

2.2 If Greater than Minimal Risk; Potential for Direct Benefit

2.2.1 How is the risk justified by the benefit?

2.2.2 How is the benefit to risk assessment at least as favorable as presented by alternative approaches?

2.3 If Greater than Minimal Risk; No Potential for Direct Benefit

2.3.1 How is the risk of the protocol a minor increase over minimal risk?

2.3.2 How do the procedures present experiences to the subjects that are reasonably commensurate with those inherent in the subjects' actual or expected situations?

2.3.3 How is knowledge to be gained of vital importance for the understanding or amelioration of the condition?

2.3.4 Can the consent of both parents be obtained if reasonably available?

2.4 To which group of subjects does this risk/benefit assessment apply?

Non-Genetic Incidental Findings and Dissemination of Research Results

Non-Genetic Incidental Findings

This section addresses incidental findings that are not genetic. Genetic incidental findings and return of genetic results are addressed in the "Genetic Research Results" section.

1 * **Is there a possibility of clinically significant non-genetic incidental findings being discovered during the research study? These may include the unexpected discovery of abnormal results following an MRI of a healthy control, or indications of subject depression following review of quality of life assessments etc. This should also be explained in the consent form.**

● **Yes** ○ No

IF YES:

1.1 Please describe any potential non-genetic incidental findings that may result from the study.

Describe any potential non-genetic incidental findings that may result from the study

1.2 Outline the plan for addressing non-genetic incidental findings (e.g., contacting the participant's primary care provider, referral, etc.).

Outline the plan for addressing non-genetic incidental findings.

Dissemination of Non-Genetic Results

Research subjects express the desire to receive information about study progress as well as aggregate or individual results. In addition, subjects appreciate being acknowledged for their participation. As part of our ongoing efforts to recognize the efforts and partnership with research subjects, investigators are asked to take whatever steps possible to acknowledge subjects for their participation and, when appropriate, to provide individual and aggregate results. Although it is not always possible to provide results within a defined period of time (sometimes for years), it may be possible to provide research subjects with periodic updates or, in certain circumstances, to inform subjects about the progress of the research in lieu of actual results. Please complete the following questions as they apply to your research. All investigators are expected to acknowledge subjects' participation and, when appropriate, to provide results. We ask that investigators take steps beyond only providing results if a subject/family requests it.

2 * **Will this research produce individual results for research participants?**

● **Yes** ○ No

If YES:

2.1 Will this research produce individual genetic results to research participants?

● **Yes** ○ No

IF YES: Please complete the Section on Genetic Research Results Return.

2.2 Will you be able to produce individual non-genetic results to research participants?

● **Yes** ○ No

If YES:

2.2.1 What types of results will you provide? How will you provide the results? When will you provide the result?

What types of results will you provide?

2.2.2 Will you give participants an option (opt-in or opt-out) to receive these results?

Will you give participants an option (opt-in or opt-out) to receive these results?

If NO:

2.3 Please explain why you will not provide individual results to families.

Dissemination of Aggregate Results

3 * **Will you be able to provide aggregate results to participants?**
● **Yes** ○ No

If NO:

3.1 Please explain why you will not provide aggregate results.

If YES:

3.2 When will you provide aggregate results and how will they be provided?
When will you provide aggregate results and how will they be provided?

3.2.1 What format will you use to provide aggregate results to families? (check all that apply)
Verbal communication with PI
Newsletters
Posting on websites
Dissemination through patient /community advocacy groups

If Other:

3.2.1.1 Please describe.

4 **If it is not possible to provide either individual or aggregate results (e.g., biorepository protocols), what steps will you take to thank participants and advise them about the progress of the study? For example, some investigators will provide a thank you letter and develop newsletters or website that participants may learn about the progress of the research in general .**

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.**
- ☑ 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.

- [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 to be done in Radiology or Nuclear Medicine for research purposes. Please contact Simon Warfield (Simon.Warfield@childrens.harvard.edu) and Kristina Pelkola (Kristina.Pelkola@childrens.harvard.edu). Simon and Kristina 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 Simon or Kristina immediately.
- [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 for research purposes MRI scans (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 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 involves collection of blood samples other than discarded specimens.
- [x] This protocol involves the use of a device that emits laser radiation.
- [x] This protocol includes research that is conducted at a non US location.

*** 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 ☑ 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 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	Owner
Service Agreement.docx	4/1/2020 10:19 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.*

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 subjects
- ☐ Monitoring requirement non invasive
- ☐ Monitoring requirement invasive

- [x] **Additional intravenous requirements**
- [x] **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.
Description of 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.

- [x] **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)**
- [x] **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)**
- [x] **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)**
- [x] **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.
Vector

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

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.
Possible toxicities are not widely known

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.

Protocol and Appendices

* **All investigators must submit an experimental design and protocol with the CHeRP submission. If there is a protocol from a corporate sponsor or cooperative group available and it contains the following necessary elements you may attach that. For investigator initiated research a link to a protocol outline that may be completed and attached may be found at:**
CHeRP Protocol Outline

If adding a document other than the Outline provided here make sure that all the headings in the Outline are included in your document. If this is a sponsor protocol you can upload as is.
Upload Protocol - please be sure the protocol includes the following sections.

- Specific Aims/Objectives
- Background and Significance
- Preliminary Studies
- Design and Methods
  - Study Design
  - Patient Selection and Inclusion/Exclusion Criteria
  - Description of Study Treatments or Exposures/Predictors
  - Definition of Primary and Secondary Outcomes/Endpoints
  - Data Collection Methods, Assessments, Interventions and Schedule (what assessments performed, how often)
  - Study Timeline (as applicable)
- Adverse Event Criteria and Reporting Procedures
- Data Management Methods
- Quality Control Method
- Data Analysis Plan
- Statistical Power and Sample Considerations
- Study Organization
- References

Upload protocol

Name	Date Last Modified	Version	Owner
Protocol.docx	11/22/2019 3:25 PM	0.01	Ashley Kuniholm

Appendix Materials:
Survey, questionnaires, assessments

Name	Date Last Modified	Version	Owner
Survey.docx	11/22/2019 3:25 PM	0.01	Ashley Kuniholm

Flow charts, schemas

Name	Date Last Modified	Version	Owner

There are no items to display

Other

Name	Date Last Modified	Version	Owner

There are no items to display

Method of Consent

1 * **Check all that apply:**
Please note that if a waiver of parental permission is requested, both "written informed consent/assent/authorization will be obtained from subjects" and "waiver of parental permission is requested" should be selected.

- [x] **Written informed consent/assent/authorization will be obtained from subjects.**
- [x] **Informed consent/assent/authorization will be obtained through a method other than a written document (i.e. verbal, survey completion).**
- [x] ***Waiver of informed consent and authorization are requested. No consent/authorization will be obtained.**
- [x] ***Waiver of parental permission is requested.**
- [ ] Other method.

Please explain any other method of consent or issue you want the IRB to review regarding consent and assent.

** Please note that this option cannot be applied to FDA regulated research.*

Written Consent

1 * **Who will obtain informed consent/assent/authorization?**
Principal investigator

2 * **When and where will informed consent/assent/authorization be obtained?**
Location of informed consent

3 * **Please indicate whether the children in this study are generally capable of providing assent. Take into account the ages, maturity and psychological state of the children involved.**

- ○ All are capable.

● **Some are capable.**

○ None are capable.

○ N/A - only adults will be enrolled

3.1 * **Explain your selection:**
Children ages 7 and older can provide assent

4 **If applicable, describe the process that will be used to obtain the child's assent.**
Assent signature will obtained on consent form.

5 * **How will you assure that the subject has adequate time to decide whether or not they want to participate?**
Sufficient time to decide

6 * **How will you determine that the parent and/or child understand the elements required in the informed consent/assent/authorization process?**
How do you know parents understand study?

7 * **Could children reach the age of majority while still actively involved in the protocol?**
● **Yes** ○ No

If YES, consent is required from the now adult, unless the committee grants a waiver of consent. Please answer one of the following two questions (7.1 or 7.2). You may also answer both if both apply.

7.1 **Please specify how you plan to obtain consent when a subject turns 18.**
Obtain consent at age 18

7.2 If you are requesting a waiver of consent when the child turns 18, address each of the following regulatory requirements to obtain a waiver of informed consent. All criteria need to be met in order for a waiver to be granted.

7.2.1 **Explain why the research could not practicably be conducted without access to and use of the identifiable health information/data.**

7.2.2 **Explain why the research involves no more than minimal risk to subjects.**

7.2.3 **Explain why the research could not practicably be conducted without the waiver of informed consent and authorization.**

7.2.4 **Explain why the waiver of consent/authorization will not adversely affect the rights and welfare of the individuals.**

8 * **Will any of the children originally enrolled in the study reach the age of majority and not have the ability to provide consent when they turn 18 because of decisional impairment?**
○ Yes ● **No**

Please Note once a child reaches the age of 18 they must consent for themselves. For children with decisional impairment once they reach 18, a parent must apply for and be granted the legal ability to continue to serve as a legally authorized representative. Otherwise the IRB must approve for others to be able to provide surrogate consent.

If YES, please respond to the following questions:

8.1 **Describe the criteria and /procedures or measurements for evaluating the decisional status of the now adult subject 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.**

8.2 **Describe how you will determine who is authorized to provide legally valid consent for the now adult subject. This could include use of durable power of attorney for healthcare, a legally appointed guardian (this must be a court-appointed induvidual), or the use of surrogate consent as approved in IRB. Please include whether and how legal records regarding authority will be obtained and reviewed by the research team.**

8.3 **When possible if legally effective consent cannot be obtained from the now adult 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 now adult sibject with decional impairment**

9 * **Regulations require that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, be provided to the subject. Describe how this requirement will be met.**
Provide additional information

10 * **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
	Consent Form.docx	11/22/2019 3:28 PM	0.01	Ashley Kuniholm

NOTE: Your consent must use the current required format.Click here to download the template

Informed Consent/Assent/Authorization Obtained via Another Method

1 ***To obtain consent via another method, at least one of the criteria listed below must be met. Please check the appropriate condition(s) and explain how this protocol meets the condition(s).**

1.1 ☐ The only record linking the subject and the research would be the consent document/authorization and the principal risk would be potential harm resulting from a breach of confidentiality. THIS CANNOT BE APPLIED TO FDA REGULATED RESEARCH. *(Please note in this situation the subject must be asked whether he/she wants written documentation and the subject's wishes should govern).*

Explain how the protocol meets this criterion.

1.2 ☑ The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Explain how the protocol meets this criterion.
Study is minimal risk

2 * **Is Protected Health Information (PHI) being obtained (as described in the 'Protected Health Information and HIPAA Authorization Information' section)?**

○ Yes ● **No**

If YES:

Provide the following justifications. All conditions must be met in order to grant an alteration of HIPAA authorization (method other than written):

2.1 **The use or disclosure of PHI involves no more than minimal risk to the privacy of subjects because :**

2.2 ******The research could not practicably be conducted without the alteration because:**

2.3 **The research could not practicably be conducted without access to and use of PHI because:**

****NOTE: You need to explain why the research could not be conducted if written HIPAA authorization is required. Common reasons include subjects are no longer or never seen at hospital (example: survey/interview conducted via telephone or online and consent is being obtained verbally), the only record linking the subject and the research would be the written authorization (example: PHI being obtained directly from subjects and medical record is not accessed), etc. If subjects are currently seeking care at the hospital making it possible to ask for their written authorization to obtain PHI for research purposes then it may not be possible to satisfy this criterion.*

3 * **Please indicate whether the children in this study are generally capable of providing assent via another method.**
Take into account the ages, maturity and psychological state of the children involved.

○ All are capable.

● **Some are capable.**

○ None are capable.

○ N/A - only adults will be enrolled

* **Explain your selection.**
Children ages 7 and older can provide assent

4 * **Explain how you propose to obtain consent/assent.**
An information sheet will be provided.

5 * **Will you provide the subject/subject's family with any written information/description about the study? If so, describe the written materials that will be given to potential subjects/family to inform them about the study (examples include an introductory letter, information sheet, etc).**
An information sheet will be provided.

6 * **When and how will potential subjects receive information about the research study?**
An information sheet will be provided.

7 * **Regulations require that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, be provided to the subject. Describe how this requirement will be met.**
Information will be provided

Waiver of Informed Consent and Authorization Requested

Please note this cannot apply to FDA regulated research.

1 **Provide the following justifications. All conditions must be met in order to grant a waiver.**

1.1 * **This research presents no more than minimal risk to the subjects because:**
Waiver of informed consent

1.2 * **The waiver or alteration will not adversely affect the rights and welfare of the subjects because:**
Waiver of informed consent

1.3 * **Investigators are required to obtain only the minimum data necessary to achieve research goals. Justify why the data you are obtaining is the minimum necessary to achieve the research goals.**
Waiver of informed consent

1.4 * **The research could not be practicably carried out without the waiver or alteration because:**
Waiver of informed consent
** Please note inconvenience, time and resources are not acceptable criteria.*

1.5 * **The research could not practicably be conducted without access to and use of protected health information because:**
Waiver of informed consent

2 * **If appropriate, how will subjects be provided with additional pertinent information after participation? If not appropriate, please specify why.**
Waiver of informed consent

Waiver of Parental Permission Requested

1 * **Specify why the research could not practicably be conducted without a waiver of parental permission and why parental permission is not a reasonable requirement.**
Waiver of parental permission

2 * **Specify why the risks associated with this protocol are minimal.**
Waiver of parental permission

3 * **Explain how the waiver of parental permission will not adversely affect the rights and welfare of the subjects.**
Waiver of parental permission

4 * **Investigators must encourage each adolescent to seek the support of a parent/guardian or another adult prior to participation.**
How will this be accomplished? The informed consent process and form must also address this issue./
Waiver of parental permission

5 **Investigators must establish procedures to allow adolescents to seek assistance on a confidential basis after completing surveys/questionnaires that may raise issues for which adolescents may desire further information or assistance.**
If applicable, please explain how this will be accomplished.
Waiver of parental permission

6 * **When, how and under what conditions will you obtain assent from the adolescent?**
Waiver of parental permission

Drugs, Biologics or Other Products

Please provide information for the drug/product that will be used, administered, or applied to the subjects 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
View	Generic name	Drug	Manufacture

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

	Generic Name	Type of Product	Manufacturer
View	Generic name	Drug	Manufacturer

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

	Generic Name	Type of Product	Manufacturer
View	Generic name	Drug	Manufacturer

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

	Product Name	Type Of Product
View	Name of product	Is the product being administered a dietary supplement or conventional food?

6 **Select the individuals that can prescribe the drugs listed in this protocol.**

Last Name	First Name	Employee ID
Breytburg	Irina	101589

Special Considerations - Device

Provide information for the device that will be used, administered, implanted or applied to the subjects 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
View	Generic name		Manufacturer

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

	Generic Name	Trade Name	Manufacturer
View	Generic name		Manufacturer

4 **Other Devices**

	Generic Name	Trade Name	Manufacturer
View	Generic name		Manufacturer

Genetic/IPS Lines Research Technology Classification

1 * **What type of genetic technology will be used in your research? You may select more than one.**

- [x] DNA Sequencing
  - [ ] Single Gene Sequencing
  - [ ] Multi-gene Sequencing (either individually or on a panel)*
  - [ ] Whole Exome Sequencing (WES)*
  - [x] Whole Genome Sequencing (WGS)*
- [ ] Genome-wide Association Study (GWAS)*
- [ ] Linkage Analysis*
- [ ] Microarray Analysis
  - [ ] Chromosomal Microarray Analysis (CMA)*
  - [ ] SNP Array
- [ ] Gene Expression/RNA Seq Analysis
- [ ] Other

If Other:
Please specify.

2 * **Will collected biological specimens (e.g. blood, tissue) be used to establish a DNA cell line?**

● **Yes** ○ No

If YES, please explain:

2.1 Why are you collecting the biological specimens to establish the DNA cell lines? Please describe.
Establishing a cell line

2.2 How do you plan on collecting these specimens?
Collection of speciments

2.3 How will the DNA cell lines be used?
Use of cell lines

Genetic Research - Page 2

1 * **Will family members be included in the study?**
● **Yes** ○ No

If YES:

1.1 What are the confidentiality issues that must be considered during the recruitment of family members (family members may not know an individual is sick or has a specific condition)?
Confidentiality issues

1.2 Describe the proposed strategy for recruiting subjects/family members. The plan should ensure that prospective subjects are sufficiently protected from coercion or undue influence.
Recruitment strategy

1.3 Describe how family members will be protected against the disclosure of medical or other personal information about themselves to other family members.
Protection against disclosure

Genetic Research - Page 3

1 * **RETURN OF RESULTS TO PARTICIPANTS: Will you return any genetic results from this study, either primary research results (i.e., those pertaining to the condition under study) AND/OR incidental/secondary findings (i.e. non-paternity OR genetic results that do not pertain to the condition under study but may be important for the participant to know, e.g., the identification of risk for disease or conditions other than the one under study) to the participant? The plan to return or not to return any genetic results has to be addressed in the consent form.**
● **Yes** ○ No

If YES:

1.1 Will you return primary research results (i.e. those pertaining to the condition under study in the participant) to participants?
● **Yes** ○ No

If NO:

1.1.1 Please explain why you will not provide primary research results to participants.

If YES:

1.1.2 Will you give participants an option (opt-in or opt-out) to receive these results?
Opt-in or opt-out

1.2 Is there the possibility that there may be incidental/secondary findings on participants? Please note that this must be answered yes if you are performing GWAS, multi-gene sequencing, WES, WGS, linkage analysis, or microarray analysis on family members. This should also be explained in the consent form.
● **Yes** ○ No

If YES:

1.2.1 Will you return incidental/secondary genetic results that do NOT pertain to the condition under study to participants?
● **Yes** ○ No

If YES:

1.2.1.1 Please describe the types of results you will return (e.g., use the ACMG recommended gene list or other criteria)?
ACMG recommended gene list

1.2.1.2 Will you give participants an option (opt-in or opt-out) to receive these results?
opt-in or opt-out

If NO:

1.2.1.3 Please explain why you will not provide incidental/secondary research results to participants.

2 * **RETURN OF RESULTS TO FAMILY MEMBERS: Will family members undergo genetic studies? This should also be explained in the consent form.**
● **Yes** ○ No

If YES:

2.1 Will you return primary research results (i.e. those pertaining to the condition under study in the participant) to family members?

● **Yes** ○ No

If NO:

2.1.1 Please explain why you will not provide primary research results to family members.

If YES:

2.1.2 Will you give family members an option (opt-in or opt-out) to receive these results?

opt-in or opt-out

2.2 Is there the possibility that there may be incidental/secondary findings on family members? Please note that this must be answered yes if you are performing GWAS, multi-gene sequencing, WES, WGS, linkage analysis, or microarray analysis on family members. This should also be explained in the consent form.

● **Yes** ○ No

If YES:

2.2.1 Will you return incidental/secondary genetic results that do NOT pertain to the condition under study to family members?

● **Yes** ○ No

If YES:

2.2.1.1 Please describe the types of results you will return (e.g., use the ACMG recommended gene list or other criteria)?

ACMG recommended gene list

2.2.1.2 Will you give family members an option (opt-in or opt-out) to receive these results?

opt-in or opt-out

If NO:

2.2.1.3 Please explain why you will not provide incidental/secondary research results to family members.

3 * In accordance with the Hospital's CLIA (Clinical Laboratory Improvement Amendment) license, research results of participant's laboratory tests not confirmed in a CLIA certified lab (including results of genetic testing), may not be released to the participant or to the participant's clinician for the purpose of diagnosis and/or treatment. Thus the research result/s must be confirmed in a CLIA-certified laboratory before communicating the results to the family/participant and return of results must be addressed in the consent form.
Will your genetic research be performed in a CLIA-certified lab?

○ Yes ● **No**

If NO:

3.1 Describe how you will arrange to have the test result confirmed in a CLIA-certified lab, the process for contacting the participant and/or family members, and what will be communicated to the participant and/or family members about the result and CLIA confirmation.

Confirmation in CLIA-certified lab

3.2 How will the costs of the testing in a CLIA-certified laboratory be covered? (If families are expected to cover the cost of the testing in a CLIA-certified laboratory this should be addressed in the consent document).

Cost coverage of testing

3.3 Specify how you will return the CLIA certified research results or incidental finding to participants and/or family members. Who will release the results? Who will be given the information (e.g. family, treating clinician)? What support will be available to the participant/family once the results are disseminated (i.e. genetic counseling)?

Results return plan

4 * Describe how the data will be protected from third parties, such as employers and insurance companies.

Data protection

5 * Are there psychological, economic and/or social risks associated with the genetic research and the results obtained?

● **Yes** ○ No

If YES:

5.1 What are the risks and what steps will be taken to minimize or eliminate these risks?

Discomfort

Placebo

1 * Briefly describe the placebo (drug, device, procedure, intervention, surgery, etc.) arm used in the study. Provide a justification for use of the placebo, including the length of subject participation in the placebo arm. Please justify why the study cannot be conducted without the use of the placebo. Your justification should address whether outcomes are subjective and how use of a placebo will address this issue, if applicable.

Placebo arm

2 * Describe any commonly used diagnostic/treatment approach(es) that will be withheld from subjects assigned to the placebo arm of this study. Will subjects be denied any type of

treatment or diagnostics that would be considered a current standard of care?
Any care that will be withheld from placebo group

3 * **Summarize any risks to subjects in the placebo arm consequent to not receiving active treatment for their disease or condition.**
Risks to placebo group

4 * **Summarize the potential benefits from participation in this protocol for subjects in the placebo arm.**
Benefits from participating

5 **If applicable, how will the condition or disease of subjects in the placebo arm of this study be monitored compared to the monitoring associated with standard care for this disease/condition?**

6 **If applicable, what criteria will be used to determine that the participation of a subject, who may be receiving a placebo treatment, should be discontinued due to his/her worsening disease or condition?**

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 subject'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.
X-rays

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.).
Radiation exposure

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). This information may be obtained by contacting Safety Officer Ryan Toolin at 617-355-7298 or ryan.toolin@childrens.harvard.edu**.**
Radiation exposure

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 subject's required clinical care)?**
● **Yes** ○ No

If YES:

2.1 Does it involve ultrasound?
● **Yes** ○ No

3 **When do you expect to begin imaging?**
Spring 2020

4 **If a radiologist/nuclear medicine specialist is collaborating on this research, please specify the individual.**
Specific radiologist's name

5 * **Does your protocol involve Nuclear Medicine Studies as part of the research protocol? (do NOT identify procedures that are part of the subject's required clinical care)**
● **Yes** ○ No

Nuclear Medicine Procedure

1 * **Will the nuclear medicine department at BCH be used?**
● **Yes** ○ No

If NO:

Detail where the nuclear medicine procedures will be conducted.

2 * **Radioisotope to be administered**
Radioisotope

3 * **Chemical form of the radioisotope**
Chemical form

4 * **Does the radiopharmaceutical have FDA approval?**
● **Yes** ○ No

5 * **Dose administered to a single patient (in millicuries per kg), minimum and maximum.**
Dose

6 * **Mode of administration**
mode of administration

7 * **Radiation exposure to the target organ and gonads (exposure data for other organs should be included, if available)**
radiation exposure

8 * **Will any complementary non-radioactive drugs be administered in conjunction with this study?**
● **Yes** ○ No

If YES:

8.1 Name of agent
Name of agent

8.2 Dosage
dosage

9 * **Will any other examination involving exposure to radiation be performed as part of this study?**
● **Yes** ○ No

If YES:

9.1 Provide exposure information.
Exposure to radiation

Human Biological Repository

Repositories are defined as collections of specimens that are processed, stored and distributed to multiple investigators for use in research. Answer these questions only if the establishment of a repository is part of the protocol. Storing remaining samples from the research is not considered a repository unless the purpose of storage is to make samples available to other investigators.

1 * **Enter information for each type of specimen that will be collected as part of the proposed repository and provide the pertinent information. Enter one at a time; please add additional specimens after completing the pertinent information for the selected specimen.**

	Specimen Category	Amount
View	Blood	10mL

Human Biological Repository - Identifiable Information

1 * **Will any identifiers or identifiable health information about the individual from whom the human material/tissue will be obtained be temporarily or permanently recorded with or linked to the material/tissue?**
○ Yes ● **No**

2 * **Will you retain a link to the subject's medical record in the repository so that the individual subject's health/medical information may be reviewed in the future?**
○ Yes ● **No**

3 * **Duration of storage, labeling of samples: State how long you expect to maintain the repository. Describe the acquisition, logging in, and tracking of samples. Explicitly state whether the repository will retain a key to the code linking the sample to the individual from whom the sample was obtained. Describe where the key to this code will be kept and who will have access to it. If, after obtaining identifiable tissue for a specific research goal, you plan to de-identify the remaining excess human material/tissue for further research, clarify how and when this will occur.**
Storage of samples

4 * **Process for Distribution of Tissue: Clarify the process by which other investigators may request tissue from the repository, if proposed. Describe who oversees tissue requests (e.g., an individual, group of individuals, or board), provide the process for**

determining the merits or acceptability of the request for tissue. Describe what materials are provided to requesting researchers. Clarify who at the repository will assess tissue requests and ensure that, where necessary, there is a current IRB-approved protocol covering the proposed research.
Distribution of samples

5 * **Will samples be distributed with a unique identifier?**
● **Yes** ○ No

If YES:

Distribution of tissue that is coded but not directly identifiable is not considered human subjects research if the recipient researcher will not seek to identify the individual from whom the tissue was obtained. However, there may be limitations as to how the samples can be used depending on the informed consent document that was signed. The recipient researcher must agree in writing to never attempt to access identifiable health/medical information or to attempt to identify the subject(s) who provided the sample(s). Such coded human material/tissue may be distributed without separate, independent IRB approval once the recipient researcher signs the agreement stating that s/he will not attempt to identify human subjects from whom the samples were derived.

Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such tissue distributions.

Name	Date Last Modified	Version	Owner
Tissue distribution letter.docx	11/25/2019 12:11 PM	0.01	Ashley Kuniholm

6 * **Will subjects potentially be re-contacted by representatives of the repository?**
● **Yes** ○ No

If YES:

6.1 Describe in detail:
(1) reasons for re-contact;
(2) how and when re-contact would occur, or might occur, if not obligatory;
(3) how subjects will provide updated contact information, if necessary;
(4) whether an option for "no re-contact" is possible and reasonable;
(5) what research information would be released to subjects or placed in medical records;
(6) what counseling would be provided, and what notification of subject's physicians would be undertaken, if any.
Recontact description

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	Tissue	10 grams

Pregnant Women or Fetuses

Federal regulations require that additional determinations be made for research that involves pregnant women or fetuses. Since you've indicated your research involves one or both, please complete the following form.

1 * **When appropriate, have studies been done on animals and non-pregnant individuals?**
● **Yes** ○ No

If YES:

1.1 Briefly explain the nature and findings of these previous studies.
Nature and findings of previous studies.

2 * **Choose the statement that best describes the anticipated risk to the fetus. Research that does not fall into one of these categories may not be conducted.**
● **The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman or the fetus.**
○ There is no prospect of direct benefit, the risk to the fetus are not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

2.1 * Provide a rationale for anticipated risk.
Rationale for anticipated risk.

3 * **Explain how the risk is the least possible for achieving the objectives of the research.**
How the risk is the least possible for achieving the objectives of the research.

4 * **Check one of the following benefit criteria and justify your selection.**
● **A. The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for the woman only.**
○ B. The risk to the fetus is caused solely by interventions/procedures that hold out the prospect of direct benefit for BOTH the woman and fetus.
○ C. There is no prospect of direct benefit, the risk to the fetus are not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

○ D. Research holds out the prospect of direct benefit solely to the fetus.

4.1 * **Justify the category selected above.**
Justification for the category selected above.

5 If the research falls into either:

- *Category A, B, C - consent is required only from the mother.*
- *Category D - consent must be obtained from the pregnant woman and the father if reasonably available*.*

**Consent from the father is required unless (a) he is unable to consent because of unavailability, incompetence, or temporary incapacity or (b) the pregnancy resulted from rape or incest.*

5.1 * **Please indicate who you plan to obtain consent from.**
Who you plan to obtain consent from.

5.2 * **Describe how you will ensure that individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus.**
How you will ensure that individuals providing consent are fully informed regarding the reasonably foreseeable impact of the research on the fetus.

6 * **Please check the following boxes in order to provide assurances that are required by federal regulation. All must be checked in order to conduct the study. If you cannot meet these requirements, please contact the IRB office at 617-355-7052.**

- ☑ **I assure that individuals engaged in the research will have no part in determining the viability of the neonate.**
- ☑ **I assure that no inducements, monetary or otherwise, will be offered to terminate the pregnancy.**
- ☑ **I assure that individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.**

7 * **All research involving fetuses must meet one or more of the following categories. Please check as appropriate.**
This research:

- ☑ **Includes procedures do not substantially jeopardize the life or health of the fetus (this category is limited to minimal risk research only).**
- ☐ Presents diagnostic or remedial procedures to determine the life or health of the fetus involved.
- ☐ Presents diagnostic or remedial to preserve the life or health of the fetus involved or the mother involved.
- ☐ Presents diagnostic or remedial procedures to improve the chances of a viable birth for a fetus with a congenital or other fetal conditions that would otherwise substantially impair or jeopardize the fetus's health or viability.
- ☐ Compares or improves potential diagnostic or therapeutic fetal interventions to improve the viability or quality of life of fetuses, neonates and children.

8 * **Will you recruit or perform research assessments on pregnant women evaluated through the BCH Advanced Fetal Care Center (AFCC)?**

● **Yes** ○ No

NOTE: If this is checked yes the AFCC will be notified and may contact you to discuss the research.

9 * ☑ I assure that at the time of recruitment the fetus is NOT the subject of a planned abortion.

Prisoners

Federal regulations define prisoner as ". . . any individual involuntarily confined or detained in a penal institution." The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing (45 CFR 46.303(c)).

The Federal regulations require additional duties for the IRB when prisoners are involved in a research activity. Please respond to the following questions.

1 * **Designate the category which describes the involvement of prisoners in this research protocol and justify your selection.**

- ● **Study of possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.**
- ○ Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- ○ Research on conditions particularly affecting prisoners as a class provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.

- ○ Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject and/or cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the Federal Register, of the intent to approve such research.
- ○ Proposed research does not fit into any of the above categories.

2 * **Justify the category selected above.**
Justification for the category selected above.

3 * **Is the research supported by DHHS (Department of Health and Human Services)?**
● **Yes** ○ No

4 * **Does the research present no more than minimal risk and no more than an inconvenience to the subjects?**
● **Yes** ○ No

4.1 * **Explain:**
Explanation.

5 * **Are there any possible advantages accruing to the prisoner through his or her participation in the research, (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) that are of such a magnitude that his or her ability to weigh the risk of the research against the value of such advantages in the limited choice environment of the prison is impaired?**
● **Yes** ○ No

5.1 Explain:
Any possible advantages.

Prisoners Page 2

1 * **Are the risks involved in the research commensurate with risks that would be accepted by non-prisoner volunteers?**
● **Yes** ○ No

1.1 * **Explain:**
Explanation.

2 * **Are the procedures for the selection of subjects within the prison fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?**
● **Yes** ○ No

If NO:

2.1 Explain (for example, randomization may not be applicable if prisoners are included incidentally rather than exclusively).

Note: Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for the particular research project.

3 * **Have you ensured that the research information is presented in a language understandable to the subject population?**
● **Yes** ○ No

3.1 Explain:
Explanation.

4 * **State how you will assure that parole boards will not take into account a prisoner's participation in the research when making decisions regarding parole?**
Explanation.

5 * **Explain how each prisoner will be informed in advance that participation in the research will have no effect on his or her parole?**
Explanation.

6 * **Does the research require follow-up beyond the period of incarceration?**
● **Yes** ○ No

If YES:

6.1 Discuss the provisions that have been made for locating the individual.
Explanation.

6.2 Explain how participants will be informed about how follow up will take place.
Explanation.

Wards of State

1 * **Explain why you anticipate that your target population may contain wards of the state or children at risk of becoming wards of the state (this includes foster children or any child that is in state custody).**
Explanation.

2 * **How will the consent of the legal guardian(s) of the ward(s) of the state be obtained? How will the investigator ensure that the appropriate person grants permission for each ward to participate in the research?**
Explanation.

3 * **How will the investigator determine whether there has been a change in guardianship status during the course of the research and permission should be obtained from the new guardian?**
Explanation.

4 * **Children who are wards of the state can be included in research that is greater than minimal risk and not likely to directly benefit the subject only if such research is related to their status as wards OR conducted in schools, camps, hospital, institutions, or similar settings in which the majority of children involved as subjects are not wards. Is this research greater than minimal risk with no prospect of direct benefit to the subjects?**
● **Yes** ○ No

5 **Provide any suggestions you may have for the appointment of an advocate.**

Please note that the IRB requires the appointment of an advocate for each ward who is a potential subject. An individual may serve as an advocate for more than one child; however, the advocate may not be associated in any way with the research or investigator(s) or be the potential subject's guardian and/or foster parent. In general, foster parents may not provide consent for foster children to participate in research. The advocate should be an individual who has the background and experience to act in the best interest of the child for the duration of the child's participation in the research. The IRB will work with the investigator to determine an appropriate advocate.

Title: Sample New Research Activity

International Research

Research conducted by Children's Hospital investigators falls under the hospital's purview and guidelines even when conducted elsewhere. If research is conducted internationally, the project must also have been approved by the local equivalent of an IRB before it can receive final approval from the Children's Hospital. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. In most situations, the IRB requires documentation of this "local approval" before it gives its approval.

1 * **Does this research involve any research activities in the European Union or the countries of Iceland, Liechtenstein or Norway?**
● **Yes** ○ No

If YES:

1.1 Please list the countries:
List of countries.

1.2 Does the study involve collection of information from or electronic monitoring of subjects in the European Union, Iceland, Liechtenstein or Norway?
● **Yes** ○ No

1.3 Is any data or information collected as part of the study going to be transferred or processed in the European Union Iceland, Liechtenstein or Norway?
● **Yes** ○ No

2 * **Describe qualifications the researcher has in relevant coursework, past experience, or training to verify his/her international/cross cultural research capabilities.**
Researcher qualifications

3 **If the investigator is working with local collaborators (Local Co-PI) please describe this arrangement. Please include information about the background and experience of the local collaborator as it pertains to this research protocol. Also describe the allocation of responsibility for the various research related activities.**

4 * **Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research, autonomy of individuals or groups, consent procedures, recruitment techniques, age of majority, requirements for parental consent, etc. Include an explanation of what cultural considerations will be required to conduct this study.**
Cultural norms

5 **If this research involves a population or community with limited resources, describe how the research is responsive to the health needs and the priorities of the population or community and**

how any intervention or product developed, or knowledge generated will be made reasonably available for the benefit of that population or community.

6 * **Explain the researcher's ability to speak, read, or write the language of the potential participants. Describe the primary language(s) spoken in the community. Explain provisions for culturally appropriate recruitment and consent accommodations such as translations or involvement of native language speakers.**
Researcher's language

7 * **Describe if the researcher has knowledge of or expertise in the local or state or national laws that may have an impact on this research. The researcher must understand cultural or community attitudes to appreciate laws, regulations, and norms and remain in compliance with U.S. regulations for the research as well as local requirements.**
Local laws

8 * **Have there been any specific issues that have been identified that may represent a difference in standard practices between the local IRB and the BCH IRB? If so please describe.**
Difference between local IRB and BCH IRB

9 * **Describe if the researcher was invited into the community. If yes, then provide documentation of the collaboration. If not, describe how the researcher will have culturally appropriate access to the community.**
Collaboration

10 * **Provide information about the ethics committee (IRB equivalent) or other regulatory entity conducting review of the research in the host country. Provide contact information for the local entity. If this research is US federally funded, additional documentation and inter-institutional agreements will be needed. Contact the Children's Hospital IRB office for guidance.**
Local ethics committee information

11 **Describe any aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants. Describe the steps you will take to minimize these risks.**
Increased risks

12 * **Please describe how and when the informed consent documents will be translated.**
Translation of informed consent

13 **Please upload documentation of the international IRB approvals or Ethics approvals here, if available.**

Name	Date Last Modified	Version	Owner
International IRB approval letter.docx	11/25/2019 12:14 PM	0.01	Ashley Kuniholm

Title: Sample New Research Activity

Blood Collections

1 **Select the method(s) of blood collection.**

- **1.1** ☑ Venipuncture
  - **1.1.1** ☐ At time of clinically indicated procedure
  - **1.1.2** ☑ At time specifically for research
- **1.2** ☑ Heel/finger/ear sticks
- **1.3** ☑ From catheter or heparin lock
- **1.4** ☐ Other

If Other:
1.4.1 Please specify.

2 * **How many individual samples will collected (not number of sticks)?**
1

Note: Multiple withdrawals of blood from an indwelling venous line are to be considered more than one collection.

3 * **What is the period of time the samples will be collected (please specify in weeks or if less than weeks in days)?**
single time point

4 * **Specify the total amount of blood collected in mls.**
10mL

5 * **Will research subjects be less than 16.5 kg?**
● **Yes** ○ No

If YES:

5.1 Will the total amount of blood to be drawn from children less than 16.5 kg be more than 3mL/kg?
○ Yes ● **No**

Title: Sample New Research Activity

Laser Device Categories

Please check the category(s) that apply to the laser devices used in this research protocols:

1
- ☑ Investigational laser device (devices not approved or cleared for marketing by the FDA)
- ☑ FDA approved laser device that has been modified/altered/reconfigured/ changed or combined or used for an unapproved indication
- ☑ Laser devices that have been approved (PMA) or Cleared 510(K) by FDA and used in accordance with labeling

Title: Sample New Research Activity

Investigational Laser Device (Devices Not Approved Or Cleared For Marketing By The FDA)

1 * **List laser wavelength(s).**
Lase wavelength

2 **Select the laser system classification.**
- ○ Class 1
- ○ Class 1M
- ○ Class 2
- ○ Class 2M
- ○ Class 3R (previously Class 3A)
- ● **Class 3B**
- ○ Class 4
- ○ N/A, laser system is a FDA approved IDE and has not been certified with FDA-CDRH

3 **For class 3B and 4 laser system classifications:**

3.1 List location(s) and department(s) where laser procedures will be performed.
Location

3.2 List BCH team members who will operate medical laser system.
Note: Clinical laser operators must be credentialed by BCH before operating medical laser class 3b and 4 laser systems.

Last Name	First Name	Employee ID
Stafford	Matthew	120216

3.3 List NON BCH team members who will operate medical laser system.
Note: Clinical laser operators must be credentialed by BCH before operating medical laser class 3b and 4 laser systems:

First Name	Last Name	E-Mail
There are no items to display		

4 * **Is the investigation medical laser device an approved IDE under 21 CFR 812.30 or considered approved under 21 CFR 812.2(b)?**
● **Yes** ○ No

If YES:

4.1 Provide a laser hazard evaluation. Evaluation should include laser beam parameters and calculations necessary to determine if the accessible laser emissions will exceed an applicable maximum permissible exposure (MPE's) listed in ANSI 136.1. If an MPE is exceeded the calculation should include the determination of Nominal Ocular Hazard Distance.

Name	Date Last Modified	Version Number	Owner

Name	Date Last Modified	Version Number	Owner
Laser evaluation.docx	11/25/2019 12:15 PM	0.01	Ashley Kuniholm

4.2 For laser systems with emission exceed that MPE, attach the standard operating procedure that list the safety and control measures necessary for the safe use of the laser system.

Name	Date Last Modified	Version Number	Owner
Laser SOP.docx	11/25/2019 12:15 PM	0.01	Ashley Kuniholm

Note: If device is not an approved FDA IDE compliance with 21 CFR 1040 is required.

5 * Does the investigation medical laser device comply with the Federal Laser Product Performance Standard (21 CFR 1040)?

● **Yes** ○ No

If YES:

5.1 Name of manufacturer or group providing certification.
Manufacturer

5.2 Attach operators manual.

Name	Date Last Modified	Version Number	Owner
Operators manual.docx	11/25/2019 12:16 PM	0.01	Ashley Kuniholm

Title: Sample New Research Activity

FDA Approved Laser Device That Has Been Modified/Altered/Reconfigured/Changed Or Combined Or Used For An Unapproved Indication

1 * List laser wavelength(s).
Laser wavelength

2 * Select the FDA-CDRH laser system classification.

- ○ Class 1
- ○ Class 1M
- ○ Class 2
- ○ Class 2M
- ● **Class 3B**
- ○ Class 3R (previously Class 3A)
- ○ Class 4

3 For class 3B and 4 laser system classifications:

3.1 List location(s) and department(s) where laser procedures will be performed.
Location

3.2 List team members who will operate medical laser system.
Note: Clinical laser operators must be credentialed by BCH before operating medical laser class 3b and 4 laser systems.

Last Name	First Name	Employee ID
Stafford	Matthew	120216

4 * Do the device modifications change the parameters of the emitted laser beam?

● **Yes** ○ No

If YES:

4.1 Provide a laser hazard evaluation. Evaluation should include laser beam parameters and calculations necessary to determine if the accessible laser emissions will exceed an applicable maximum permissible exposure (MPE's) listed in ANSI 136.1. If an MPE is exceeded the calculation should include the determination of Nominal Ocular Hazard Distance.

Name	Date Last Modified	Version Number	Owner
Laser evaluation.docx	11/25/2019 12:16 PM	0.01	Ashley Kuniholm

Title: Sample New Research Activity

Laser Devices That Have Been Approved (PMA) Or Cleared 510(K) By FDA And Used In Accordance With Labeling

1 * List laser wavelength(s)
Laser wavelength

2 * Select the FDA-CDRH laser system classification:

- ○ Class 1

- ○ Class 1M
- ○ Class 2
- ○ Class 2M
- ● **Class 3B**
- ○ Class 3R (previously Class 3A)
- ○ Class 4

3 For class 3B and 4 laser system classifications:

3.1 List location(s) and department(s) where laser procedures will be performed.
Location

3.2 List team members who will operate medical laser system.
Note: Clinical laser operators must be credentialed by BCH before operating medical laser class 3b and 4 laser systems.

Last Name	First Name	Employee ID
Stafford	Matthew	120216

Title: Sample New Research Activity

Additional Documents

1 Please upload any additional documents if it is necessary.

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, HIPAA 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**

Acting PI - Details

1. * Please list the person who will be primarily responsible for conducting the study.
Matthew Stafford

2. * Does this person have an affiliation or appointment with Children's Hospital?
● **Yes** ○ No

If YES:

2.1 Please describe appointment.
IRB Assistant Director

If NO:

2.2 Is the research protocol intended to support requirements for an educational degree?
○ Yes ○ No

If YES:

2.2.1 Describe type of degree.

2.2.2 What is the relationship between the person performing the study and the PI?

2.2.3 Please describe the actual research procedures the person will be performing.

2.2.4 How will this research protocol contribute to generalizable knowledge that will be of benefit to subjects and/or to the biomedical community?

2.2.5 Please describe how this research will contribute to, or support the general research interests of the principal investigator.

ID: VIEW46F8225B27000
Name: Acting PI

Detailed Sponsor Information

1 * **What is the sponsor's name?**
NATIONAL HEART, LUNG, AND BLOOD INSTITUT - 1049

1.1 If your sponsor is not in the list, please select "Other" from the list and specify your sponsor below.

Note: Use a '%' to conduct a wildcard search (e.g. a '%Pharm' search will return all options with 'pharma' at any place in the name).

2 * **Please select the appropriate category of funding.**

- (●) **Federal**
- ( ) State
- ( ) Corporate/Industry
- ( ) External Foundation

2.1 If the category of funding is "Federal", upload the grant(s) here. (Please include the scientific part. This is a requirement for federally supported research. You need not include biosketches or financial information here, just the description of the research.)

Name	Date Last Modified	Version	Owner
Federal grant application.docx	11/22/2019 2:32 PM	0.01	Ashley Kuniholm

3 * **What will the sponsor provide? Check all that apply:**
Research Funding - Committed

4 * **What is sponsor's contact name, if applicable?**
This person should be who OSP or CTBO needs to contact.

5 * **What is sponsor's contact phone number?**
123-456-7890

6 * **What is sponsor address?**
Mailing address

7 * **What is sponsor email address?**
contact@email.com

8 * **Is a Clinical Trial Agreement (CTA) required?**

- ( ) Completed/Signed
- (●) **Pending**
- ( ) Not Required

ID: VIEW46F5DA7D2D400
Name: Detailed Sponsor Information

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 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).**
123456

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

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

Name	Date Last Modified	Version	Owner
IND Study May Proceed.docx	11/25/2019 11:42 AM	0.01	Ashley Kuniholm

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

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.)**
Mechanism of action

9 **If there are any special issues regarding stability, please detail them here.**
Should the drug be refrigerated

10 **Please list any contraindications or potential drug interactions.**
Contraindications of the drug

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

12 * **Will subjects, 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 subject or their insurance providers for the investigational drug/biologic.

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

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

Name	Date Last Modified	Version	Owner
IB.docx	11/25/2019 11:43 AM	0.01	Ashley Kuniholm

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

If Other:
Explain:

ID: VIEW470B90F6B2400
Name: Investigational Drug/Product

Use of an Approved Drug/Product for an Unapproved Indication

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, enter information about one product at this time. You will be able to enter additional products at a later time.**

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

If Combination:
Please describe. Include whether it is regulated as a drug/device/biologic. What is the mode of action?

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 name

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

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

6 * **Briefly describe how the research use of the product departs from the FDA approved indication/labeling.**
How the use in the study is different from approved labeling

7 * **Describe the purpose of the evaluation (e.g. to support a new indication for the use of the drug, to support any other significant change in the labeling or advertising for the drug, etc.).**
Purpose the study

8 * **Is this research being conducted under an IND?**
( ) Yes (●) **No**

If YES:

8.1 Who holds the IND?
- ( ) A company, organization, NIH, consortium or university.
- ( ) Children's Investigator
- ( ) Other

8.2 Specify the IND number if available (if it is not available, you need to submit an amendment to update this information when obtained).

8.3 Specify the name of the IND holder.

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

Name	Date Last Modified	Version	Owner

There are no items to display

8.5 Is FDA IND approval pending?
( ) Yes ( ) No

If NO:

8.6 Is this research being conducted under a formal IND exemption request to FDA?
( ) Yes (●) **No**

If YES:

8.7 Upload a copy of the FDA letter granting the IND exemption.

Name	Date Last Modified	Version	Owner

There are no items to display

If NO:

8.8 Please confirm each statement or provide a justification for each criteria for IND exemption:

8.8.1 The drug product is lawfully marketed in the United States.
(●) **Yes** ( ) No

8.8.2 The investigation is not intended to be reported to FDA as a well-controlled study in support of a new indication and there is no intent to use it to support any other significant change in the labeling of the drug.
(●) **Yes** ( ) No

8.8.3 In the case of a prescription drug, the investigation is not intended to support a significant change in the advertising for the drug.
(●) **Yes** ( ) No

8.8.4 The investigation does not involve a route of administration, dose, patient population, or other factor that significantly increases the risk (or decreases the acceptability of the risk) associated with the use of the drug product.

Please explain how the use outside of the approved labeling does not put participants at increased risk due to participation in the study:
Description of how changes do not pose increased risk

8.8.5 **The investigation is conducted in compliance with the requirements for review by an IRB and with the requirements for informed consent.**
● **Yes** ○ No

8.8.6 **The investigation is conducted in compliance with the requirements of 21 CFR 312.7 (i.e. the investigation is not intended to promote or commercialize the drug product).**
● **Yes** ○ No

8.8.7 **Please provide any additional information if necessary.**

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

10 * **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.**
Mechanism of action

11 **List any contraindications or potential drug interactions.**
Contraindications

12 **Are there any known antidotes? Please describe.**
Antidotes

13 * **Will subjects, or their insurance providers, be charged for the investigational product?**
○ Yes ● **No**

14 **Please upload any additional documents, including the approved drug label or package insert.**

Name	Date Last Modified	Version	Owner
Package Insert.docx	11/25/2019 11:46 AM	0.01	Ashley Kuniholm

ID: VIEW470A4FA4F4400
Name: Use of an Approved Drug/Product for an Unapproved Indication

Drug/Product used under Approved Labeling

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.**
● **Drug**
○ Biologic
○ Combination
○ Other

If Combination:
Please describe. Include whether it is regulated as a drug/device/biologic. What is the mode of action?

If Other:
Please describe:

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

3 **If any, what is the commercial/trade name of the product?**
Commercial name

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

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

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

7 * **Will subjects, or their insurance providers, be charged for the investigational product?**
○ Yes ● **No**

8 **Please upload any additional, pertinent documents.**

Name	Date Last Modified	Version	Owner
Package Insert.docx	11/25/2019 11:47 AM	0.01	Ashley Kuniholm

ID: VIEW470A5B5BA5400
Name: Drug/Product Used Under Approved Labeling

Drugs/Products - Other

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.**

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

If Combination:
Please describe. Include whether it is regulated as a drug/device/biologic. What is the mode of action?

If Other:
Please describe:

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

3 **If any, what is the commercial/trade name of the product?**
Commercial name

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

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

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

7 * **Will subjects, or their insurance providers, be charged for the investigational product?**
( ) Yes (●) **No**

8 * **Please explain why this product does not fit into the previous three categories.**
Explanation of the use of this drug

9 **Please upload any pertinent documents.**

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

ID: VIEW470A5F4ADE800
Name: Drugs/Products - Other

The product being administered is a medical food, conventional food, or dietary supplement

1 * **What is the name of the product being administered?**
Name of product

2 * **Please select the product type:**
- ( ) Is the product being administered a medical food
- (●) **Is the product being administered a dietary supplement or conventional food?**

3 ***If the product was administered a medical food:***
Please upload the labeling.

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

4 ***If the product was administered a dietary supplement or conventional food:***

4.1 **What is the dosage of the product being administered?**
Dosage

4.2 **Is this study designed to evaluate whether a dietary supplement or conventional food may reduce the risk of a disease or intended to support a new or expanded health claim?**
( ) Yes (●) **No**

4.3 Will this study be conducted in any of the following populations:

- ☐ Individuals with altered immune systems
- ☐ Individuals less than 12 months old
- ☐ Individuals with serious or life-threatening medical conditions

Note: If any of the above populations are checked off, then an IND will be required in order to conduct this study.

4.4 Is this study designed to evaluate the dietary supplement or conventional food's ability to diagnose, cure, mitigate, treat, or prevent a disease?

○ Yes ● **No**

Note: If the answer to this question is yes, then an IND will be required in order to conduct this study.

4.5 As indicated in previous questions, is an IND required for this study?

○ Yes ● **No**

If Yes:

4.5.1 Who holds the IND?

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

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

4.5.3 Please specify the name of the IND holder.

4.5.4 Upload copy of the FDA IND approval correspondence, if available.

Name	Date Last Modified	Version Number	Owner

There are no items to display

4.5.5 Is FDA IND approval pending?

○ Yes ○ No

4.6 Please upload any investigator's brochure, approved labeling, if applicable.

Name	Date Last Modified	Version Number	Owner

There are no items to display

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.**
Sponsor

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

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?
Sponsor

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	Owner
IB.docx	11/25/2019 11:51 AM	0.01	Ashley Kuniholm

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?
G123456

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.
Sponsor

8.1.4 Please upload any FDA IDE approval correspondence.

Name	Date Last Modified	Version Number	Owner
IDE Approval.docx	11/25/2019 11:52 AM	0.01	Ashley Kuniholm

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 subject.

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 subject.

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 subject.

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

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 subject

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 subjects 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?
Device control information

9.2 * Describe the location and manner in which the device will be stored?
Device control information

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

9.4 * How will the device receipt, use and return be logged or otherwise documented?
Device control information

10 * How will extra devices be stored or returned to the manufacturer?
Devices will be returned

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	Owner

There are no items to display

ID: VIEW470A74B3A2000
Name: Investigational Devices

FDA Approved Devices Used Off-Label

1 * What is the generic name or descriptor of the device including, trade name, if applicable?
Generic name

2 * Who is the manufacturer of the device?
Manufacturer

3 * 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 also note the investigator may also hold sponsor responsibilities if it is determined the modification or use in a new population requires either an investigator initiated IDE or the investigator is designated a sponsor for a NSR device)

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

3.1 * Specify the Sponsors regardless of which of the above choices have been selected.
Children's Investigator

4 * Briefly describe how the research use departs from the FDA approved indication or how the device has been altered/ modified/ reconfigured/combined.
Description of off-label use

5 * Who will pay for the device?
Sponsor

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?

7 * What is sponsor's risk designation for the device according to FDA definitions? If you have questions about this, please contact the drug-device ancillary reviewer.

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

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

7.1.1 What is the IDE number?

7.1.2 Who is the IDE Sponsor?

- ○ A company, organization, NIH, consortium or university.

○ Children's Investigator

○ Other

7.1.3 Please specify the name of the IDE holder.

7.1.4 Please upload any FDA IDE approval correspondence

Name	Date Last Modified	Version	Owner

There are no items to display

7.2 ***If Non Significant Risk (NSR), 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:

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

7.2.2 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 subject.
Justification

7.2.3 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 subject.
Justification

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

7.2.5 Who is the NSR Sponsor?

○ A company, organization, NIH, consortium or university.

● **Children's Investigator**

○ Other

7.2.6 Please specify the name of the NSR Sponsor.
Children's Investigator

7.2.7 Please upload any applicable FDA correspondence.

Name	Date Last Modified	Version Number	Owner

There are no items to display

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

7.3.1 Is this a diagnostic device?

○ Yes ○ No

If YES, please justify the following criteria:

7.3.1.1 Is noninvasive

7.3.1.2 Does not require an invasive sampling procedure that presents significant risk

7.3.1.3 Does not by design or intention introduce energy into a subject

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

7.3.2 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:

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

7.4 ***If Other Classification:***

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

7.4.2 Is your device still something else? Please explain:

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

8.1 * **How and where will the device be received from the manufacturer?**
Device control

8.2 * **Describe the location and manner in which the device will be stored?**
Device control

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

8.4 * **How will the device receipt, use and return be logged or otherwise documented?**
Device control

9 * **How will extra devices be stored or returned to the manufacturer?**
Storage of devices

10 **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	Owner

There are no items to display

11 **Please attach a copy of the device label.**

Name	Date Last Modified	Version	Owner
Device label.docx	11/25/2019 11:55 AM	0.01	Ashley Kuniholm

OR

Provide a link to the website with the label information.

ID: VIEW4722BEE262800
Name: FDA Approved Devices Used Off-Label

PMA or Cleared (510(k)) Devices

1 * **What is the generic name or descriptor of the device including trade name, if available?**
Generic name

2 * **What is the 510K number?**
K123456

3 * **What is the source of the device? Include both supplier and manufacturer if different.**
Manufacturer

4 * **What is the purpose of the device and how will it be used in the study?**
Purpose

5 **Please complete the following information about device control and accountability.**

5.1 * **How and where will the device be received from the manufacturer?**
Device control

5.2 * **Describe the location and manner in which the device will be stored.**
Device control

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

5.4 * **How will the device receipt, use and return be logged or otherwise documented?**
Device control

6 * **How will extra devices be stored or returned to the manufacturer?**
Device storage

7 **Upload any correspondence or information available about the device classification determinations.**

Name	Date Last Modified	Version	Owner

There are no items to display

8 **Please attach a copy of the device label.**

Name	Date Last Modified	Version	Owner
Device label.docx	11/25/2019 11:56 AM	0.01	Ashley Kuniholm

OR

Provide a link to the website with the label information.

ID: VIEW470A7D6528000
Name: PMA or Cleared (510(k)) Devices

Other Devices

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

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

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

4 * **Explain why the device does not fall into any of the above classifications.**
Explanation

5 **Please complete the following information about device control and accountability.**

5.1 * **How and where will the device be received from the manufacturer?**
Device control

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

Device control

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

5.4 * **How will the device receipt, use and return be logged or otherwise documented?**
Device control

6 * **How will extra devices be stored or returned to the manufacturer?**
Device storage

7 **Upload any correspondence or information available about the device classification determinations.**

Name	Date Last Modified	Version	Owner

There are no items to display

ID: VIEW470A74C1CB000
Name: Other Devices

Editing Human Biological Specimen Data

1 * **Select the type of human biological specimens that will be collected as part of the protocol.**

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

If Other:
1.1 Specify:

2 * **Specify the amount (if tumor/tissue, specify in g mm in 3 dimensions; if blood, CSF or urine, specify in ml).**
10mL

If Tumor/Tissue is selected, please complete questions 3-6. For all other selections, please skip questions 3-5 and answer question 6.

3 **What are the specifications?**

- (●) **Fresh**
- ( ) Sterile
- ( ) Fixed
- ( ) Other

4 **Where will the tissue be obtained?**

- [x] **Pathology**
- [ ] OR
- [ ] Other BCH procedure areas
- [ ] Outside of BCH
- [ ] Left over from research protocol

If tissue will be obtained from Outside of BCH:
4.1 Specify from where.

5 **Specify the number of tissue samples to be collected.**
1

6 * **Check the appropriate category which accurately describes how and when the specimen will be obtained.**

- [ ] Prospectively collected human biological specimens obtained exclusively for research purposes during a procedure performed solely for research (muscle biopsy for research purposes).
- [x] **Prospectively collected human biological specimens obtained exclusively for research purposes during a clinically planned procedure, (e.g., extra biopsies at endoscopy, normal skeletal muscle at surgery).**

- [ ] Excess human biological specimens obtained for clinical care, and determined to be in excess of that needed for clinical and diagnostic purposes (e.g., tumor that is leftover after pathologist's sampling has been completed, extra blood).
- [ ] Human biological specimens that have been left over from previous research and are currently being stored.

ID: VIEW470A295C6E400
Name: Editing Human Biological Specimen Data

Pathology Specimen Data

1 * **Specify the type of tissue/tumor. Please complete this information separately for each type of tissue.**
Tissue

2 * **What are the specifications?**

- (●) **Fresh**
- ( ) Sterile
- ( ) Fixed
- ( ) Other

If Other:
2.1 Specify:

3 * **Specify the amount required (if tumor/tissue, specify in g mm in 3 dimensions).**
10 grams

4 * **Please justify why this amount is requested/required.**
Justification

5 * **Where will the specimen be obtained from?**

- [x] **Pathology**
- [ ] OR
- [ ] Other BCH procedure areas
- [ ] Outside of BCH
- [ ] Left over from research protocol

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

7 * **What period of time are the specimens requested from?**
10 years

ID: VIEW470A26EED8000
Name: Pathology Specimen Data