Boston Children's Hospital

Date: Monday, March 17, 2025 1:19:02 PM Print Close

IRB-P00034130 General Information

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

General Information

1 * **Protocol Title:**
Sample Establishment of Human Biological Specimen Repository/ Data Registry

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 Establishment of Human Biological Specimen Repository/ Data Registry

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

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

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

If Other patient services professionals:

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

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

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

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

If YES:

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

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

6 * **Has the PI, or if question #5 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human participants at BCH?**

● **Yes** ○ No

7 * **Type Of Submission:**

○ New Research Activity

○ **New Research Activity Limited to Secondary* Use of Biological Material and Data

● **Establishment of Human Biological Specimen Repository/ Data Registry (only) – repositories/registries are defined as a prospective collections of specimens or data that are processed, stored, distributed to multiple investigators for use in research.**

○ Request for Exemption

○ Individual Patient Expanded Access

○ Humanitarian Use Device (HUD)

○ Reliance on Another IRB

○ Projects that lack immediate plans for involvement with human participants, their data and/or their specimens (i.e.training grants)

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

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

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

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

8 * **Is this protocol related to child health (including perinatology, prenatal assessments, childhood antecedents of adult disease, and long-term follow up of pediatric disorders)?**

● **Yes** ○ No

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

○ Yes ● **No**

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

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

○ Yes ● **No**

ICCTR Study Operations Support includes some of the following services:

- *project management (including protocol development, trial operations, and close out activities)*
- *study coordinator support*
- *research nurse or nurse practitioner support*
- *regulatory support- IRB or FDA*
- *data management (including database builds)*

- *development of case report forms*
- *data entry*
- *recruitment and retention of research participants*
- *administration of surveys and interviews*
- *biospecimen collection and tracking*
- *medical record abstraction*
- *multi-institutional clinical trial support*
- *development of data safety monitoring plans and data safety monitoring boards or committees*

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

◯ Yes ● **No**

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

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

◯ Yes ● **No**

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

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

◯ Yes ● **No**

If Yes:

13.1 Please select the category:

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

If Other:

13.1.1 Please describe:

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

◯ Yes ● **No**

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

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

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

If Investigator Designed/Initiated:

15.1 Was the protocol peer-reviewed?

◯ Yes ◯ No

IRB-P00034130 Research Team

Research Team

If the person you need to add to your protocol cannot be found using the “Add” buttons below, please send an email to CHERP Support (cherp.support@childrens.harvard.edu) requesting that the person be added to the Research Staff. CHeRP Support will need the following information:

- First Name
- Last Name
- CHID# (if applicable)
- BCH Department (if applicable)
- Email Address

1 Research Staff - Children's Hospital Employees only:

	Last Name	First Name	BCH ID	Role	Editor	CC on Correspondence	Required Training Completed	Training Expiration	CHeRP Training	Date Modified	Date Created
View	Kuniholm	Ashley	123524	Admin Contact	yes	yes	yes	1/13/2028	yes	12/2/2019	12/2/2019
View	Ripton	Jessica	221454	Co-Investigator	yes	yes	yes	6/10/2024	no	3/17/2025	3/17/2025

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

Required Training Will Expire: 2/2/2025

Completed Training Courses:

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

Training Program	Continuing Education Description	Training Completed	Date Created
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

IRB-P00034130 Funding Sources

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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.

IRB-P00034130 Financial Disclosure

Financial Disclosure

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

◯ Yes ● **No**

If YES:

1.1 Please select the relationships as appropriate.

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

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

◯ Yes ● **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

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

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

◯ Yes ● **No**

If YES:

3.1 Please select as appropriate.

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

4 * **Do you or any person affiliated with the protocol have or expect to have any financial interest, financial relationship, or position or advisory role with any other entity that may be affected by the research to be conducted under the protocol (e.g. competitor, customer, collaborator or commercial sponsor affiliate)? Include any entity that may be benefited or harmed, directly or indirectly.**

○ Yes ● **No**

5 * **Do you or any person affiliated with the protocol have or know of any arrangement or understanding, tentative or final, relating to any future financial interest, financial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?**

○ Yes ● **No**

6 * **The IRB prohibits special incentives in connection with clinical research, including, finder's fees, referral fees, recruitment bonuses, enrollment bonuses for reaching an accrual goal, or similar types of payments. Will you or anyone else in connection with the conduct of any research under the protocol receive money, gifts or anything of monetary value that is above and beyond the actual costs of enrollment, research conduct, and reporting of results, from the sponsor or any other entity?**

○ Yes ● **No**

7 * **Is there anything not disclosed above which you believe might constitute a conflict of interest or an appearance of a conflict of interest in connection with the protocol?**

○ Yes ● **No**

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

9 **Upload any other pertinent documentation.**

Name	Date Last Modified	Version Number	Owner

There are no items to display

IRB-P00034130 Multi Site Information

Multi Site Information

1 * **Is this a multi-center study?**

● **Yes** ○ No

NOTE: Please check Yes if all research activities are being conducted at multiple sites

If YES:

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

○ Yes ● **No**

If YES:

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

2 * **Will other sites be asked to rely on BCH as the reviewing or single IRB (sIRB)?**

○ Yes ● **No**

3 Other site names.
Please name the other sites if Question 1 or Question 2 is "Yes"
CHOP, MD Anderson

IRB-P00034130 Repository - Subject Information

Subject Information - Repository

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.
12

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.
12

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.
24

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.

2 Types of Subjects

2.1 *Gender

- [x] Males
- [x] Females

2.2 *Age

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

Specify entire age range.
2-17

2.3 Special Populations

- [ ] 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.

- [ ] Pregnant Women/Fetuses
- [ ] Prisoners/Incarcerated Youth (this would include children under the care of the Department of Youth Services). Consider if your target population will be or at higher risk of incarceration. If this category is chosen, you will be prompted to answer additional questions to meet federal regulations.
- [ ] Wards of the State (consider if your target population may contain wards of the state or children at risk of becoming a ward of the state (this includes foster children or any child that is in state custody))
- [ ] Minorities

If NOT checked:

Provide scientific justification for excluding minorities.
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.
Non English

☐ 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.

☐ Adults With Decisional Impairment

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

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

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

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

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

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

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

IRB-P00034130 Data Information

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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 participant 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**

IRB-P00034130

Type Of Data To Be Used For The Study

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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

1.1 If Database: please specify
N/A

1.2 If Other: please specify

IRB-P00034130

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 participant depression following review of a psychological measure that screens for risk of clinically significant depression. 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.

1.2 Outline the plan for addressing non-genetic incidental findings, (e.g., contacting the participant's primary care provider, referrals, timeline of how quickly results will be reviewed, etc.)

Dissemination of Non-Genetic Results

Research participants express the desire to receive information about study progress as well as aggregate or individual results. In addition, participants appreciate being acknowledged for their participation. As part of our ongoing efforts to recognize the efforts and partnership with research participants, investigators are asked to take whatever steps possible to acknowledge participants 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 participants with periodic updates or, in certain circumstances, to inform participants 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 participants' participation and, when appropriate, to provide results. We ask that investigators take steps beyond only providing results if a participant/family request 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?

2.2.2 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.

No return of results

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?
at study completion

3.2.1 What format will you use to provide aggregate results to families? (check all that apply)
Referring participants to published papers

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.
Thank you letter

IRB-P00034130 Repository Details

Repository Details

1 * **Data/Specimen Repository/Registry Name**
Data/Specimen Repository/Registry Name

2 * **This protocol involves the establishment of a:**

- [x] **Specimen repository**
- [x] **Data registry**

3 * **Specify where the repository/registry will be located. If it is at another site, provide information about the location, agency, etc.**
Location of repository/registry

4 * **Data for this repository/registry will be collected from the following types of subjects. Check all that apply:**

- [x] **Minors/children (age less than 18 years)**
- [x] **Adults (age 18 years or greater)**

5 * **Does this research involve neonates?**
● **Yes** ○ No

If YES:

5.1 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.

6 * **Does this protocol involve the collection of blood samples other than discarded specimens?**
● **Yes** ○ No

7 * **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

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:

7.1 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.
Decisional impairment

7.2 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 individual), 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.
Decisional impairment

7.3 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 subject with decisional impairment.

Decisional impairment

8 * **Will this protocol acquire fetal biospecimens? This includes fetal specimens taken from pregnant women or acquisition of fetal tissue obtained from terminations.**

◯ Yes ● **No**

NOTE: 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.

If YES:

8.1 Will you acquire samples or recruit pregnant women evaluated through the BCH advanced fetal care center? Please note if this is checked yes the Advanced Fetal Care Center, AFCC, will be notified and may contact you to discuss the research.

◯ Yes ◯ No

8.2 Will fetal biospecimens be obtained from terminated pregnancies?

◯ Yes ◯ No

NOTE: Be sure to include discussion of tissue acquisition in the specimen collection section and also upload copies of IRB approvals from sites where the tissue is actually acquired.

IRB-P00034130 Repository - Neonates

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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.

IRB-P00034130 Blood Collections

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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)?

One time

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

5mL

5 * Will research participants 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**

Purpose of Registry/Repository

1 * **Concisely state the objectives or purpose of this human specimen/data collection. State explicitly what diseases, conditions or processes will be studied.**
Objectives or purpose of this human specimen/data collection

2 * **Justify why collection of these specimens/data are warranted scientifically. Summarize briefly the knowledge to date about the disorders, or conditions under study. Describe the general directions for the research. If the purpose of the storage is for undefined or general uses, please describe the types of research expected, providing examples.**
Justify why collection of these specimens/data are warranted scientifically

IRB-P00034130 Specimen Details

Specimen Details

1 * **Human biological specimens for this repository will be obtained from the following Children's Hospital sources. Check all that apply.**

- [x] **Clinical Labs**
- [x] **Operating Room**
- [x] **Pathology**
- [x] **Inpatient areas**
- [ ] Outpatient clinics
- [ ] Other procedure areas (endoscopy, urodynamics, emergency department), please specify
- [ ] Other sources or collaborators at outside institutions, please specify

If Other:

1.1 Specify:

2 * **Will immortalized lymphoblastoid cell lines, fibroblast cell lines or tumor cell lines be created from the collected human biological specimens?**

○ Yes ● **No**

3 **Indicate if any of the following will be performed with the samples. Check all that apply.**

- [ ] Biological assays
- [x] **DNA single gene studies**
- [ ] SNP's
- [ ] GWAS
- [ ] Other

If Other:

3.1 Specify:

NOTE: Inexhaustible cell lines are considered of greater risk to confidentiality than finite samples that will eventually be entirely consumed by research

Specimen Collection

1 * **Briefly describe the type of human material/tissue to be collected for this repository, e.g., blood, urine, tumor tissue, etc.**
Describe the type of human material/tissue to be collected for this repository

2 **Human material/tissue collected for this repository will include the following. Check all that apply:**

2.1 ☑ **Excess human material/tissue 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).**

2.1.1 **Please explain where and how you will acquire the excess clinical specimens.**
explain where and how you will acquire the excess clinical specimen

2.2 ☑ **Prospectively collected human material/tissue obtained exclusively for research purposes during a clinically planned procedure, (e.g., cardiac biopsy at catheterization or open heart surgery, extra biopsies at andoscopy, additional intestine at gastric bypass, normal fat or skeletal muscle at surgery, extra CSF at LP, extra blood at phlebotomy).**

2.2.1 **Please explain where and how you will acquire the sample and how much extra will be obtained. Discuss any risks associated with specimen acquisition.**
explain where and how you will acquire the sample and how much extra will be obtained

2.3 ☑ **Prospectively collected human material/tissue obtained exclusively for research purposes during a procedure performed solely for research (e.g., blood, urine, skin, muscle, saliva, breast milk, semen or cells from cheek swabs).**

2.3.1 **Please describe the procedure you will perform for research purposes to obtaine the specimen. Include the size and quantity of the specimens and how often samples will be collected. Discuss any risks associated with specimen acquisition.**
describe the procedure you will perform for research purposes to obtain the specimen

2.4 ☐ **Other sources or collaborators at outside institutions.**

2.4.1 **Please describe how other sources will acquire the specimen and send them to you. Include whether the specimens are collected for your research only or whether the specimens exist for other purposes.**

IRB-P00034130 Registry/Data Repository

Registry/Data Repository

1 * **Health information/data for this repository will be obtained from the following source(s). Check all that apply:**

- [ ] Medical Record/Chart Review
- [x] **Electronic Medical Record**
- [ ] Films/X-rays
- [ ] Hospital Administrative/Billing Records
- [ ] Quality Improvement Records
- [ ] Other

If Other:

1.1 Specify:

2 **What is the time period for the records that will be reviewed and/or the specimens to be collected (i.e. patient records from November 2000 to November 2010, specimens from Dec 2010 to no set endpoint)?**

* **From:** January 2018 * **To:** ongoing

3 **Data to be collected. Check all that apply:**

- [ ] Personal data (name, address, PCP)
- [ ] Billing data
- [x] **Demographic data (age, gender, vital status)**
- [x] **Drug/device utilized**
- [ ] Diagnosis
- [ ] Reports, clinic/office notes
- [ ] Procedures/treatment
- [ ] Location of Service
- [ ] Laboratory data
- [ ] Provider of Service
- [ ] Radiology Images
- [ ] Other

If Other:

3.1 Specify:

4 * **Will your protocol include the collection of any of the following sensitive data?**

(●) **Yes** ( ) No

Human Subject Research Data is considered sensitive when the disclosure of information could have adverse consequences for subjects or others, place them at risk for criminal or civil liability, or damage their financial standing, employability, insurability, or reputation.

4.1 Check the categories as applicable.
Please note if any of these categories are selected there may be additional authorizations for release of the information following state and/or federal regulations.
You may contact irb@childrens.harvard.edu for guidance.

- [x] **Alcohol and substance use disorder tests and/or treatment**
- [ ] Mental health diagnosis and/or treatment

- ☐ Sexually transmitted disease testing and/or treatment
- ☐ Family planning consultation and/or treatments
- ☐ Assault and/or abuse records and treatment (e.g., domestic violence, sexual assault, child abuse and neglect)
- ☐ Genetic information (including tests performed, and/or results of the testing
- ☐ HIV/AIDS testing and/or treatment*
- ☐ Psychotherapy notes* (Defined as the actual notes taken and maintained by a clinician during a psychotherapy session that are not entered in the medical record)

**Please note these two categories require individual authorization from the patient (or the parent/guardian) for release of information for research purposes as required by state regulations. The New Research Activity Limited to Secondary Use of Biological Material and Data cannot be used for protocols which need to obtain consent or authorization from individuals, please contact the IRB office for guidance as needed.*

If any of the above categories are checked, please respond to the following questions:

4.1.1 Why is this sensitive data required for the aims of your study?
N/A

4.1.2 If requesting genetic information, will the data be used in epidemiological or clinical research conducted for the purpose of generating scientific knowledge about genes, learning about the genetic basis of disease, or developing pharmaceutical or other treatments of disease? Note if you answer no, then you will need to obtain the patient's (or their parent/guardian's) authorization to release their identifiable tests/analysis for research purposes
◯ Yes ◯ No

4.1.3 Explain how you are collecting the minimum necessary sensitive data to meet objectives of the study.
N/A

4.1.4 Who will have access to the sensitive data with protected health information identifiers or links to such identifiers?
N/A

4.1.5 What extra steps will be taken to assure the confidentiality of sensitive data when you plan to publish or present your research results?
N/A

5 Please attach the data collection form or list of data elements, including any personal or demographic information, which will be collected and recorded with or linked by code to the human biological specimens.

Name	Date Last Modified	Version Number	Owner
Data collection form.docx(0.01)	12/2/2019 4:49 PM	0.01	Ashley Kuniholm

Recruitment Details

1 * **Please describe patient population, (i.e., diagnosis, age group, surgical/medical, etc.) If applicable, provide an estimate on the number of subjects from whom data will be included in the repository/registry.**
Patient population

2 * **List the inclusion and exclusion criteria for subjects (bulleted lists are preferred). No group of persons (for example, men, women, minorities, non-English speaking) should be categorically excluded from the research without a good scientific or ethical reason to do so. Please provide the basis for concluding that the study population is representative of the population that stands to potentially benefit from this research.**
inclusion and exclusion criteria

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

Name	Category	Date Last Modified	Version Number	Owner
Recruitment Letter.docx(0.01)	Recruitment	12/2/2019 4:49 PM	0.01	Ashley Kuniholm

4 **Please describe how each document uploaded in question #3 will be used.**
Recruitment letter will be mailed

5 * **Explain in detail the specific methodology that will be used to recruit subjects who provide human biological specimens or data relating to medical history. Specify how potential subjects will initially learn about the possibility that they could provide samples or data to this repository. Specify how, when, where, and by whom, subjects will be approached about providing samples or data to this repository.**
Recruitment methods

6 * **Will you need to search through BCH medical records for the initial screening for potentially eligible subjects?**
● **Yes** ○ No

7 * **At the time of this submission will any "existing" (already collected) data/specimens be "grandfathered" into the repository/registry?**
○ Yes ● **No**

If YES:

7.1 **Describe the consent status of the specimens/data. What kind, if any, of consent was obtained for collecting the specimens/data?**

7.2 **If applicable, include a copy of the consent form that was previously used.**

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

8 * **Will the subjects receive any remuneration?**
● **Yes** ○ No

If YES:

8.1 **Please describe the remuneration schedule.**
Remuneration plans

IRB-P00034130 Screening For Recruitment

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

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 authorization /informed consent.

1 * **This query of medical records presents no more than minimal risk to the subjects because:**
Waiver justification

2 * **The waiver or alteration will not adversely affect the rights and welfare of the subjects because:**
Waiver justification

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.**
Waiver justification

4 * **The recruitment could not be practicably carried out without the waiver of informed consent/assent and authorization because:**
Waiver justification

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

Operating Policies and Procedures of the Repository/Registry

1 * **Duration of storage, labeling/coding, security of specimens/data: State how long you expect to maintain the repository/registry. Describe the acquisition, logging in, and tracking of specimens/data. Typically specimens/data are coded with a unique, random, identifying number in order to protect the confidentiality of research subjects. Explicitly state whether specimens/data will retain a key to the code linking the specimens/data to the individual from whom the specimen/data was obtained. Describe where the key to this code is kept and who has access to it. If, after obtaining specimens/data for a specific research goal, you plan to de-identify the remaining excess specimens/data for further research, clarify how and when this occurs.**

Duration of storage, labeling/coding, security of specimens/data

1.1 **For electronic information, describe how electronic security is maintained, including what password protections and virus software are enabled. Include whether you will follow the Children's Hospital security standards regarding laptops, encryption, web procedures, use of PDA's etc. Also describe how the system will be audited.**

Password protected database

1.2 **For paper-based information, describe where the identifiable information will be stored, who has access to the storage area, and how that access will be audited. If the information is stored off-site, describe how security at the facility is maintained and whether or not a business associate agreement has been or will be signed.**

2 * **Processes for distribution of specimens/data: Clarify the process by which other investigators may request specimens/data from the repository/registry, if proposed. Describe who oversees the requests (e.g., an individual, group of individuals, or board), provide their qualifications, and describe the process for determining the merits or acceptability of the request for specimens/data. Specify which members of the repository staff (include roles and responsibilities) will have access to the identifying information. Describe what data/specimens are provided to requesting researchers, and what health/medical information will be distributed by the repository/registry.**

Note that any release of *directly identifiable specimens or directly identifiable health information, or a key to the code linking the specimen/data directly to an individual* requires a separate, IRB-approved protocol. Clarify who at the repository will assess specimen/data requests and ensure that, where necessary, there is a current IRB-approved protocol covering the proposed research.

Processes for distribution of specimens/data

3 **Distribution of de-identifiable specimens/data: Distribution of specimens/data that are coded, but not directly identifiable, when the recipient researcher will not seek to identify the individual from whom the specimens were obtained, is not considered human subjects research. However 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 specimen/data. Such coded specimens/data 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 specimens/data were derived.**

Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such distributions. Also please include a copy of any letter or agreement recipient investigators will be asked to sign.

Data or Tissue distribution letter.docx(0.01) 12/2/2019 4:50 PM 0.01 Ashley Kuniholm

4 * **Re-contact of subjects providing specimens/data to a repository/registry: In general, investigators are advised to plan ahead carefully and describe potential uses and sharing of repository/registry materials, so that approved research that subjects have agreed to may proceed without the need to re-contact subjects. Re-contact of subjects to obtain consent for new types of research, collect additional samples, or provide clinically relevant information may be required in some situations and may require separate IRB approval if not fully defined at the time of repository inception. Research results may not be clinically useful or validated, and may not be ready for return to patients or physicians. If it is anticipated that subjects will be re-contacted by representatives of the repository/registry, please 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.**

Plan for re-contact

5 **Clarify with whom specimens /data will be shared. Check all that apply:**

- ☐ Children's researchers
- ☑ Non-Children's academic collaborators*

  Specify:
  Academic collaborators
- ☐ Academic and Commercial (for-profit) collaborators**

  Specify:
- ☐ Other

  Specify:

** The provision of human biological specimens to academic collaborators requires an academic Uniform Biological Materials Transfer Agreement (UBMTA), available from the Clinical Trials Office. Children's Hospital also recommends that you consider using a simple, faculty-approved collaboration agreement which is designed to fairly address publication, data access and similar issues. Some departments may also have department-specific applications or agreements to access or share specimens.*

*** The provision of human biological specimens to for-profit collaborators requires the existence of a bona fide intellectual collaboration between the Children's Hospital investigator and an individual or group at the for-profit site, and a Materials Transfer Agreement (MTA) executed by Children's Hospital. Please contact the Clinical Trials Office for assistance with these agreements.*

IRB-P00034130 Risks and Benefits

Risks/Benefits and Process to Address Unintended Consequences, Events, Risks

Benefits

1 * **It is not expected that subjects providing specimens for repositories will derive personal health benefits as a result of their contributions to specimen repositories. However, explain any specific future benefits that might be expected to accrue to individuals, families or groups of affected individuals. Indicate what medical, scientific, and societal benefits are likely to accrue as a result of research performed on specimens in this repository.**

Potential benefit

Risks

2 * **Risks to privacy and confidentiality should be discussed below. Clarify in this section any medical risks to subjects (e.g., risks of phlebotomy, or bleeding, infection, or scarring as a result of a biopsy performed solely for research purposes). Although uncommonly undertaken, if health/medical information from the research is returned to subjects or their physicians, discuss the potential risks, such as anxiety, or of false positive or false negative results.**

Risk of breach of confidentiliaty

Process to Address Unintended Consequences, Events, Risks

3 * **Describe who reviews and analyzes reports of any adverse events, breaches of confidentiality or complaints and forwards them to the IRB, and how and when these events are reported to the IRB. Describe how unanticipated problems involving risks to subjects or others (e.g., staff, families of subjects etc) will be reported to the IRB. Comment on whether any other regulatory bodies (e.g., FDA, NIH, or other IRBs) will also receive reports of such events, if this is relevant.**

Adverse event plan

IRB-P00034130

HIPAA/Privacy/Confidentiality

HIPAA/Privacy/Confidentiality

1 * **Describe methods used to protect the privacy of subjects and maintain confidentiality. Clarify whether special attention to confidentiality is necessary because of the nature of the research (i.e., the research involves collection of particularly sensitive personal information, for example, HIV status, reproductive history, data on illegal activities or drug use, or other potentially stigmatizing behaviors). Comment on whether a Certificate of Confidentiality has been obtained, if relevant. Specifically address where individually identifiable information will be stored and who will have access to such data. Explain how the potential for breaches of confidentiality and resultant risks to dignity, insurability and employment are minimized. Because genetic data may affect not only the individuals providing samples, but also their family members, or social groups, comment on potential psychosocial risks of genetic studies or DNA repositories to these extended groups also.**

Privacy and confidentiality protections

PLEASE NOTE: If this study is funded by the National Institutes of Health (NIH) or the Centers for Disease Control (CDC) then a Certificate of Confidentiality automatically applies.

If this study is funded by the National Institute of Justice (NIJ) then an NIJ Privacy Certificate will be required by the sponsor and automatically applies.

Certificates of Confidentiality can also be obtained from the NIH or the FDA regardless of sponsorship.

For more information, see Policy 9.6, "Certificates of Confidentiality"

1.1 * **Will a Certificate of Confidentiality or Privacy Certificate be obtained for this research?**

○ Yes ● **No**

If YES:

1.1.1 **Please upload the certificate, if available:**

Name	Date Last Modified	Version Number	Owner

There are no items to display

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

1.1.3 ☐ **Check here if this study is funded by the NIH, NIJ or CDC and the certificate is granted automatically and no document will be provided for upload**

2 **Data that are coded, where the key to the code is accessible to researchers, are considered protected health information (PHI) subject to HIPAA regulations.**

Select the following identifiers that will be recorded with or linked by code to the data.

- ☐ Name
- ☐ Social Security Number
- ☑ **Medical Record Number**
- ☐ Address by street location
- ☑ **Address by Town/City/Zip Code**
- ☑ **Dates(except year), e.g., date of birth; admission/discharge date; date of procedure; date of death**
- ☐ Telephone Number
- ☐ Fax Number
- ☐ Electronic Email Address
- ☐ Web URLs
- ☐ Internet Protocol IP Address
- ☐ Health Plan Beneficiary Number
- ☐ Account Number
- ☐ Certificate/License Number
- ☐ Vehicle Identification Number and serial number, including license plate number

- ☐ Medical Device Identifiers and Serial Numbers
- ☐ Biometric Identifiers(finger and voice prints)
- ☐ Full Face Photographic Image
- ☐ Any Other Identifier or combination of identifiers likely to identify the subject

If Other:

2.1 Specify:

IRB-P00034130

Research Categories and Special Considerations - Repositories

Registry/Repository Special Considerations

1 Please check all of the following that apply to the proposed research.

- ☐ This protocol involves the use of a non approved (investigational) device that will be used with or applied to the subjects to collect the data or specimens.
  Please note, you may use data or specimens for testing a device but you cannot use a device that will be implanted in or applied to subjects using this Registry/Repository IRB application Submission Type. Please contact the IRB Office with any questions.
- ☐ 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.
- ☐ This protocol involves the collection of a tissue removed for clinical purposes that would routinely go to pathology.
- ☐ This protocol includes research that is conducted at a non US location.
- ☐ This protocol involves new equipment subject to review by Health Technology Management (formerly Biomedical Engineering). This includes devices used for the treatment, diagnosis, or monitoring of patients or research subjects. Devices requiring review at this time are those that are not already being managed by Health Technology Management. If you have any questions, call Health Technology Management at 617-355-6166.
- ☐ Check here is any data or specimens collected in this protocol may be used at BCH or shared with other investigators, institutions or businesses to either support approval of an FDA regulated product (drugs, biologics, devices, mobile medical apps) or to test the effectiveness of a medical device (including in vitro diagnostic products).

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* participants*" and "waiver of parental permission is requested" should be selected.

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

IRB-P00034130 Consent Procedures/Waivers - Legacy Data

Informed Consent and Authorization - Legacy Information

1 Will informed consent be obtained for data/specimen collection and storage?
Yes

If YES:

1.1 Upload a copy of the proposed informed consent(s).

Name	Date Last Modified	Version Number	Owner
Consent Form.docx(0.01)	12/2/2019 4:52 PM	0.01	Ashley Kuniholm

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

1.2 Explain in detail how, where, and by whom informed consent will be obtained from the subject providing specimens/data. Describe timing of consent, including how long subjects will be given to consider participation. Describe the qualifications and experience of the individuals who will be obtaining consent (e.g., genetic counselor, licensed physician, nurse practitioner). Describe how the principal investigator will be available for consultation or questions, when informed consent is obtained by someone other than the principal investigator.
Consent plan

1.3 When applicable, explain how provision of specimens/data to more than one repository is discussed with subjects. Typically each repository has a specific consent form.
Consent plan

1.4 If Children's investigators will not be obtaining informed consent from all subjects, but others collaborators will obtain consent, (perhaps even from outside institutions) clarify how the collaborators will provide you with documentation of consent and IRB approval of the relevant protocol and consent forms.
Consent plan

1.5 What will happen when subjects turn 18? If this is a repository /registry that either.
1. continues to collect specimens or data from medical records on an ongoing basis or
2. continues to keep the already collected samples/data with identifiers after a child turns 18

Consent is required from the now adult unless the committee grants a waiver of consent.

Please select those categories that will apply in your protocol:
Yes**We will obtain consent when the child turns 18.**
Please specify how you plan to obtain consent when a subject turns 18.
Obtain consent
No **We 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 (each required).

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

Explain why the research involves no more than minimal risk to subjects.Specifically explain why the research involves no more than minimal risk to the privacy of the individuals.

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

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

No **Other**
Please explain:

If NO:

Address each of the following regulatory requirements to obtain a waiver of informed consent.

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

1.7 Explain why the research involves no more than minimal risk to subjects. Specifically explain why the research involves no more than minimal risk to the privacy of the

individuals.

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

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

**** Please note: you need to explain why the research could not be conducted if informed consent is required. It is not enough to explain that there are insufficient resources or time available. Common reasons include, patients are lost to follow-up, may have been seen years ago so there is not current contact information, patients may be deceased, etc. If all the subjects are currently seeking care at the hospital it would be possible to ask for their consent to review their record for research purposes and it may not be possible to satisfy this criterion.*

IRB-P00034130 Written Consent

Written Consent

1 * **Who will obtain informed consent/assent/authorization?**
N/A

2 * **When and where will informed consent/assent/authorization be obtained?**
N/A

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:**
Explain

4 **If applicable, describe the process that will be used to obtain the child's assent.**
N/A

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

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

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 participant turns 18.**
Yes

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.**
Yes

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

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

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

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 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.
Turn 18

8.2 Describe how you will determine who is authorized to provide legally valid consent for the now adult participant. This could include use of durable power of attorney for healthcare, a legally appointed guardian (this must be a court-appointed individual), 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.
Turn 18

8.3 When possible if legally effective consent cannot be obtained from the now adult participant, 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 participant with decisional impairment.
Turn 18

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

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	Category	Date Last Modified	Version Number	Owner
Consent Form.docx(0.01)	Consent and/or Assent	12/2/2019 4:52 PM	0.01	Ashley Kuniholm

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

IRB-P00034130 Additional Documents

Title: Sample Establishment of Human Biological Specimen Repository/ Data Registry

Additional Documents

1 Please upload any additional documents if it is necessary.

Name	Category	Date Last Modified	Version Number	Owner

There are no items to display

NOTE: Please do not upload any documents been previously uploaded in another smartform location. This section should be used for non-patient facing documents that a sponsor requires to be submitted to the IRB. Additional study manuals may be uploaded here as needed per protocol.

PI's Statement

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

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

● **Yes** ○ **No**

IRB-P00034130

Final Page