Boston Children's Hospital

Date: Wednesday, April 29, 2020 12:00:40 PM Print Close

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.**
Brief summary (in lay terms)

4 * **Principal Investigator (PI):** PI Test

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 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)

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	Kuniholm	Ashley	Admin Contact	yes	yes	yes	yes	12/2/2019	12/2/2019

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:** PI Test

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed	Date Created

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

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Funding Sources

1 * **Select funding category.**

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

1.1 If internally sponsored - select as appropriate:

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

1.2 Enter any additional information if applicable:

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

1.4 Please provide the name of the private donor.

Financial Disclosure

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

○ Yes ● **No**

If YES:

1.1 Please select the relationships as appropriate.

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

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

○ Yes ● **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

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

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

○ Yes ● **No**

If YES:

3.1 Please select as appropriate.

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

☐ Other

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

○ Yes ● **No**

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

○ Yes ● **No**

6 * **The 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	Owner

There are no items to display

Repository Details

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

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

☑ **Specimen repository**

☑ **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 * **This protocol includes research that is conducted at a non US location.**

● **Yes** ○ No

6 * **Does this research involve neonates?**

● **Yes** ○ No

If YES:

6.1 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.

7 * **Does this protocol involve the collection of blood samples other than discarded specimens?**

● **Yes** ○ No

If YES:

7.1 Select the method(s) of blood collection.

- [ ] Venipuncture - At time of clinically indicated procedure
- [x] **Venipuncture - At time specifically for research**
- [ ] Heel/finger/ear sticks
- [ ] From catheter or heparin lock
- [ ] Other

If Other:

7.1.1 Please specify:

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

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:

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.

Decisional impairment

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 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

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 subject with decisional impairment.

Decisional impairment

9 * **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:

9.1 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

9.1 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.

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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:

- ☑ **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.

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 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**

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

Specimen Details

1 * **Human biological specimens for this repository will be obtained from the following Children's Hospital sources. Check all that apply.**
- ☑ **Clinical Labs**
- ☑ **Operating Room**
- ☑ **Pathology**
- ☑ **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
- ☑ **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.**

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
- ☑ **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 Indicate if any of the following health information/data be collected and stored in the repository/registry. Check all that apply:

- [ ] HIV status
- [x] **Substance abuse (drug or alcohol abuse)**
- [ ] Reproductive history (e.g., abortions)
- [ ] Sexual behavior/sexually transmitted disease
- [ ] Other potentially stigmatizing concerns (psychiatric diagnosis)

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	Owner
Data collection form.docx	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 populaiton

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	Date Last Modified	Version	Owner
Recruitment Letter.docx	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	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

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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:**
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 * **<u>Duration of storage, labeling/coding, security of specimens/data:</u> 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 <u>For electronic information</u>, 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 <u>For paper-based information</u>, 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 * **<u>Processes for distribution of specimens/data</u>: 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 **<u>Distribution of de-identifiable specimens/data:</u> 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	12/2/2019 4:50 PM	0.01	Ashley Kuniholm

4 * **<u>Re-contact of subjects providing specimens/data to a repository/registry</u>: 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.*

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

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

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

- [x] **Medical Record Number**
- [ ] Address by street location
- [x] **Address by Town/City/Zip Code**
- [x] **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:

Informed Consent and Authorization

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

(●) **Yes** ( ) No

If YES:

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

Name	Date Last Modified	Version	Owner
Consent Form.docx	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:

☑ **We will obtain consent when the child turns 18.**

Please specify how you plan to obtain consent when a subject turns 18.
Obtain consent

☐ **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.

☐ **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.*

Dissemination of 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.

1 * **Will this research produce individual results for research subjects?**

○ Yes ● **No**

If YES:

1.1 Will you be able to provide individual results to research subjects?

○ Yes ○ No

If YES:

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

If NO:

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

No return of results

2 * Will you be able to provide aggregate results to subjects?

● **Yes** ○ No

If NO:

2.1 Please explain why you will not provide aggregate results.

If YES:

2.2 When will you provide aggregate results?

at study completion

2.2.1 What format will you use to provide aggregate results to families? (check all that apply)

Referring participants to published papers

If Other:

2.2.1.1 Please describe.

3 If it is not possible to provide either individual or aggregate results (e.g., biorepository protocols), what steps will you take to thank subjects 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 subjects may learn about the progress of the research in general .

Thank you letter

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

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:

test

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.

International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

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.**
International research

12 * **Please describe how and when the informed consent documents will be translated.**
International research

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	12/2/2019 4:53 PM	0.01	Ashley Kuniholm

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 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 Establishment of Human Biological Specimen Repository/ Data Registry

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