Boston Children's Hospital

Date: Monday, March 17, 2025 12:11:57 PM Print Close

IRB-P00034129 General Information

Title: Sample New Research Activity Limited to Secondary* Use of Biological Material and Data

General Information

1 * **Protocol Title:**
Sample New Research Activity Limited to Secondary* Use of Biological Material and Data

Maximum of 230 characters may be entered.

2 **Full Title - If protocol title exceeds the 230 characters limited from field above, enter full title here. Otherwise, leave blank.**
Sample New Research Activity Limited to Secondary* Use of Biological Material and Data

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 of research protocol

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-P00034129 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

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	

Training Program	Continuing Education Description	Training Completed	Date Created
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/9/2012	5/9/2012
Continuing Education	Continuing Education/Department Meeting	9/30/2011	
CHeRP Training		12/19/2010	
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	5/15/2009	11/8/2010
Collaborative IRB Training Initiative (CITI Behavioral)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Biomedical)		8/2/2006	11/8/2010
Collaborative IRB Training Initiative (CITI Non-Interventional)		4/11/2006	11/8/2010
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	4/5/2006	11/8/2010

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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.

IRB-P00034129 Funding Sources - Details

Funding Sources - Details

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

	Sponsor	Funding Category
View	FOUNDATION FOR ANESTHESIA EDUC AND RES - 0558	External Foundation

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

Specimens and/or Existing Data

1 * **Does your research involve the use of:**

- [x] **Secondary use of human biological specimens/tissue**
- [x] **Secondary use of data, documents, or records**

2 * **Do you plan to contact patients in the future for follow-up information?**

○ Yes ● **No**

If YES, this is not the correct form - you are re-directed to the General Information page where you need to change type of submission to "New Research Activity" as the type of your research.

3 * **Equity, diversity and inclusivity considerations. Please specify:**

- ○ At least one study objective is related to EDI
- ○ At least one study objective is focused on racism or marginalization of under-resourced, under-represented, and/or diverse populations; or bias, discrimination, prejudice, or stigma based on dimensions of social marginalization (e.g., race, ethnicity, socioeconomic status gender identity, sexual orientation).
- ○ Not Applicable

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Secondary Specimen - Protocol Information

Secondary Specimen - Protocol Information

1 * **What was the primary purpose for which the specimens were collected ? (I.e samples were collected for clinical care and are left over after required clinical tests, samples are stored clinical pathology samples)**
Primary purpose of sample collection

2 * **What is the research question under study?**
Research question

3 * **Is any genetic research excluding WES, WGS proposed?**
● **Yes** ○ No

If YES:
NOTE: In general the IRB always requires that subjects consent to the use of their specimens for genetic research.This is a requirement for Whole Exome Sequencing (WES) and Whole Genome Sequencing (WGS) and for the creation of any sort of durable cell lines/organelles. If you are planning to perform WES, WGS, or creating any sort of durable cell lines/organelles consent is required and you should either submit a new research activity form with a consent form or submit the request as an amendment to the protocol that includes consent.
Other types of genetic research are considered on an individual basis and require strong justification as to why consent cannot be obtained. If you feel there is a reason to be able to perform genetic research with secondary samples (identified and non-identified) without consent or consent has been previously obtained please answer the following.

3.1 **Please check the category of genetic research to be performed:**
Multi-gene Sequencing (either individually or on a panel)

3.2 **Please describe the rationale of why you think informed consent is not required or specify when and how consent was previously obtained.**
(Please note the IRB may ask that you fill out a complete protocol application depending on these answers and justification).
Justification for not requiring additional consent.

4 * ☑ Secondary samples may not be used without consent for the creation of iPSC or organoids.
Please check here confirming that the samples will not be used for this purpose.

5 * **Describe the study population from whom human biological specimens will be obtained (i.e. diagnosis, age group, etc.).**
Study population

6 * **Will you obtain embryonic or fetal biospecimens? This includes human embryos, specimens taken from pregnant women, or acquisition of fetal tissue obtained from terminations.**
○ Yes ● **No**

NOTE: If embryonic tissue or fetal tissue from terminations are proposed please be sure to include in your protocol document or smart form detailed information about where it is acquired from and how it will be used. In addition, submit a copy of any IRB approval from sites where the tissue was actually obtained and documentation of what the consent included with regard to use of these specimens.

7 * **What is the time period for the specimens that will be obtained (i.e. Brain tumor tissue collected from January 2018 to ongoing)?**
January 2018 to ongoing

8 * **Are the specimens publically available?**

○ Yes ● **No**

If YES:

8.1 Provide information about the source that makes them publically available:

8 * **How long do you anticipate you will need to obtain specimens in order to complete this research?**

2 years

9 * **Will tissue/specimens be used to test the effectiveness of a medical device (including in vitro diagnostic devices) and will the information that is obtained be submitted for FDA approval of the device?**

○ Yes ● **No**

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Specimen - Details

Specimen - Details

1 Provide the following information for specimen(s) requested.

	Specimen Category	Amount
View	Tumor/Tissue	10g

Specimen - Storage

1 * **Will the specimens be stored/banked for future use?**

● **Yes** ○ No

If YES:

1.1 Where will the specimens be stored?
Storage location

1.2 What future types of research would you anticipate using the specimens for?
Future genetic research

1.3 Who will be responsible for distributing the specimens?
Study team

Secondary Data - Protocol Information

It is important to remember that all research data belongs to Boston Children's Hospital.

1 * **What was the primary purpose for which the data was collected ? (i.e clinical medical records, MRI's required for clinical care)**

Primary purpose for data collection

2 * **Please select the appropriate category for the data that is utilized for this research:**

- ☐ Anonymous Data – at no time are any identifiers recorded including IP addresses
- ☑ **Coded/Linked to Study ID, registered by the research team. (data is kept separate from identifiers and each subject has unique link or code)**
- ☑ **Identifiable data PHI/PII Data – one or more personal identifiers present in data**

3 * **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.

3.1 **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.**

- ☐ 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:

3.1.1 **Why is this sensitive data required for the aims of your study?**

3.1.2 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

3.1.3 Explain how you are collecting the minimum necessary sensitive data to meet objectives of the study.

3.1.4 Who will have access to the sensitive data with protected health information identifiers or links to such identifiers?

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

4 * Will you be using any whole genome/exome sequencing data?

● **Yes** ◯ No

5 * Will data include more than 500 participants?

◯ Yes ● **No**

6 * What type of data will be reviewed for research?

- ☑ **Medical Data/Chart**
- ☐ Imaging Data
- ☐ Database
- ☐ Quality Improvement Records
- ☐ Hospital Administrative/Billing Records
- ☐ Survey
- ☐ Genomic
- ☐ Genetic
- ☐ Other types of records

6.1 If Other or Database were selected, please specify.

7 * Please detail the process for obtaining data from for this study. Are any special permissions, contacts, agreements, etc. required?

Medical record abstraction

7.1 Please attach any agreements.

Name	Date Last Modified	Version Number	Owner

There are no items to display

8 * Briefly describe the purpose of the study. What is the research question under study?

Purpose of the study

9 * **Describe the study population from whom data will be obtained (i.e. diagnosis, age group, etc.).**
Study population

10 * **How many subject' data records will be reviewed?**
100

11 * **What is the time period for the data be reviewed (i.e. patient records from November 2018 to November 2019)?**
January 2018 to ongoing

12 * **How long do you anticipate you will need to abstract/obtain existing data?**
2 years

13 * **How long do you anticipate it will take you to complete this research?**
3 years

14 * **Are the records publically available?**
◯ Yes ● **No**

If YES:

14.1 Provide information about the source that makes the data publically available

15 * **Will any data that is collected be submitted for FDA in support of approval of any FDA regulated products (drugs, biologics, devices, mobile medical apps) device?**
◯ Yes ● **No**

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Existing Data - Data Types

Existing Data - Data Types

1 Check all categories of data that will be obtained during the record/database review.

- [ ] Name
- [x] **Demographics (age, sex, address)**
- [x] **Diagnosis**
- [ ] Lab values
- [ ] Radiology testing/images
- [ ] Procedures/Treatment
- [ ] Billing/Charges
- [ ] Length of Stay
- [ ] Location of service (OR, ED, inpatient, outpatient)
- [ ] Clinic/Office Notes
- [ ] Provider of record (who saw pt, signed d/c note)
- [ ] Other

If Other:

1.1 Specify:

IRB-P00034129 HIPAA/Confidentiality

HIPAA/Confidentiality

Protected Health Information (PHI) is information acquired by Children's Hospital, including demographic information, that could reasonably identify an individual AND:

- **Relate to the past, present, or future physical or mental health, condition or treatment of an individual; OR**
- **Describe the past, present, or future payment for the provision of healthcare to an individual**

There are some limited situations when research protocols will not use or create protected health information. For example, educational research conducted in a school setting.

1 **The following information is considered identifiable under the Privacy Rule regulations. Please indicate which of the following will be obtained and recorded even if for temporary purposes.**

- [ ] Patient/Participant name or the names of relatives, employers, or household members
- [x] **Medical record numbers (or specimen #)**
- [ ] Address street location
- [ ] Address town or city *
- [x] **Address state***
- [ ] Address zip code*
- [x] **Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures***
- [ ] Telephone number
- [ ] Fax Number
- [ ] Electronic mail (email) address
- [ ] Social security number
- [ ] Health plan beneficiary numbers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identification numbers and serial numbers including license plates
- [ ] Medical device identifiers and serial numbers
- [ ] Web URLs
- [ ] Internet protocol (IP) address
- [ ] Biometric identifiers (finger and voice prints)
- [ ] Full face photographic images/any comparable image/video of the face
- [ ] Any unique identifying number, characteristic or video

Please explain in more details.

- [ ] NONE OF THE ABOVE: this protocol will not use any identifiable PHI

** These items may be included and considered a "limited data set". Use of data under the provisions of a "limited data set" require the signing of a data use agreement by the recipient (this includes researchers).*

Follow-up HIPAA/Confidentiality

1 * **Please select names of all BCH individuals who will be given access to private health information associated with the specimens/data.**

Last Name	First Name	Employee ID
Breytburg	Irina	101589
Stafford	Matthew	120216

2 * **Who is responsible for managing access and storage of data?**

Last Name	First Name	Employee ID
Stafford	Matthew	120216

3 * **How will the access be managed?**

Access management plan.

4 * **Will any identifiers or identifiable health information about the individual from whom the specimens/data were obtained be temporarily or permanently recorded with or linked to the specimens/data?**

● **Yes** ○ No

If YES:

4.1 Which of the elements of PHI will you maintain links for?

Elements of PHI

4.2 How will the linkage codes be derived, protected and maintained? Describe the steps taken to assure privacy and confidentiality of the data obtained with the specimens/data and to protect the identifiers from improper use or disclosure.

Linkage code description

4.3 You are required to destroy identifiers (or links) at the earliest possible time. Please describe your plans and specify when this will occur or provide justification for retaining the identifiers.

Destroy identifiers

5 * **Investigators are required to only obtain the minimum necessary data in order to achieve the goals of the research. Please justify why the data you are obtaining is the minimum necessary to achieve the goals of the research.**

Justification of minimum necessary

Data Transmission/Processing/Storage

Please see the Information Security Page on data storage standards

1 * **Will PHI data be stored?**

(●) **Yes** ( ) No

If YES:

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

- [ ] BCH Research Computing File Share
- [x] **BCH RC-FS**
- [ ] BCH Clinical Department File Share
- [ ] BCH REDCap
- [ ] BCH AWS environment
- [ ] BCH Google PHI drive
- [ ] Third party server or cloud
- [ ] Other

If Other:

1.1.1 Please describe.

2 * **Will NON PHI data be stored?**

(●) **Yes** ( ) No

If YES:

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

- [ ] BCH Research Computing File Share
- [ ] BCH Clinical Department File Share
- [ ] BCH REDCap
- [x] **BCH AWS environment**
- [x] **BCH Dropbox**
- [ ] BCH Google Team Drive
- [ ] BCH Department Managed Server
- [ ] BCH Study Team Managed Server
- [ ] Server/cloud not managed by BCH
- [ ] Other

If Other:

2.1.1 Please describe.

3 * **How will PHI be ACCESSED?**

- [x] **BCH owned desktop or laptop**
- [ ] Encrypted personal desktop or laptop

☑ **Sponsor provided desktop or laptop**

4 *NOTE: Per BCH policy, PHI may not be STORED on a personal laptop, regardless of encryption. Please be sure virus protection and operation systems are kept up to date.*

5 **Please attest that you will report any real or suspected electronic data interception, hack, or breach to the IRB and ISD security.**

* ☐ **Yes I will report to the IRB and ISD security**

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

○ Yes

● **No**

○ NA

If YES:

6.1 Please describe.

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

● **Yes** ○ No

If YES:

7.1 Will the BCH PI publication be:

○ Published as a collaborator

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

○ NA

If NA:

7.1.1 Please provide any additional information.

8 **Provide any additional information.**

Risks/Benefits/Sharing Data and Specimens

1 * What are the risks or benefits to subjects whose data/specimens is used in this research? Specifically address risk to privacy. Explain why these risks are no more than minimal.

Risk of breach of confidentiality

2 * Do you anticipate that data alone or specimens with data will be released outside Children's Hospital (sharing with any individual who does not have a BCH employee ID#)?

● **Yes** ○ No

If YES:

2.1 Please describe who you may release the data or specimens with data to.

Other academic medical center

2.2 Is the recipient a HIPAA covered entity?

● **Yes** ○ No

2.3 What is the purpose of releasing data or specimens with data outside of BCH (i.e academic research collaboration or commercial collaborators) ?

purpose of releasing data or specimens with data outside of BCH

2.4 Will BCH receive any data back?

○ Yes ● **No**

If YES:

2.4.1 In what form and frequency (e.g. electronic/monthly)?

2.5 If available, please upload the Case Report Form (CRF) or spreadsheet that will be used to send data.

Name	Date Last Modified	Version Number	Owner
Case Report Form.docx(0.01)	12/2/2019 4:42 PM	0.01	Ashley Kuniholm

2.6 Will any of the following identifiers be sent out of BCH? Please check all that apply.

- ☐ Patient/Subject Name or the names of relatives employers, or household members
- ☐ Medical record numbers (or specimen #)
- ☐ Address street location
- ☐ Telephone number
- ☐ Fax number
- ☐ Electronic mail (email) address
- ☐ Social security number
- ☐ Health plan beneficiary numbers
- ☐ Account numbers
- ☐ Certificate/license numbers
- ☐ Vehicle identification numbers and serial numbers, including license plates
- ☐ Medical device identifiers and serial numbers
- ☐ Web URLs
- ☐ Internet protocol (IP) address
- ☐ Biometric identifiers (finger and voice prints)
- ☐ Full case photographic images

- [x] **NONE OF THE ABOVE**

If you check any of these categories, unless you obtain permission from the subjects, this is considered a non-authorized HIPAA disclosure and is only permitted in limited circumstance. If permitted, you will need a data use agreement (you may contact THE CTBO office for further information) and may need to have this disclosure tracked on an individual patient basis in the Hospital' HIPAA disclosure database.

2.7 Will any of the following identifiers be sent out of BCH? Please check all that apply.

- [ ] Address town or city
- [ ] Address state
- [ ] Address zip code
- [x] **Elements of Dates (except year)**
- [ ] NONE OF THE ABOVE

If so, this is permitted only if the researcher and the individual receiving the information sign a Limited Data Set/Date Use Agreement, prior to sending this data out of BCH. Please contact the Clinical Trials Business Office (CTBO) at ctbo@childrens.harvard.edu

Consent/Authorization/Waivers

1 * **Has an informed consent already been obtained that permits the current research?**

◯ Yes ● **No**

If YES:

1.1 What was the subject's understanding of how the data/specimens would be used?

2 **Select one category:**

2.1 ☐ **There is no identifying information recorded. This includes none of the 18 HIPAA identifiers will be recorded.**

2.2 ☐ **Information will be recorded by the investigator in such a manner that the human subject cannot readily be ascertained directly or through identifiers linked to the subject.**

2.2.1 Please explain how you will record information to meet the criteria that the identify if the subject cannot be readily obtained.

2.2.2 Please check this box:

☐ **You agree that you will not re-contact the subjects or attempt to identify them**

2.3 ☑ **Information is recorded with identifiers or with links (codes) so that identification is possible and may be used by the investigator in the future.**

Since you are keeping identifiers or links to identifiers a HIPAA waiver of authorization is still required.
Please justify the following conditions:

2.3.1 The proposed use of this data/document/record/specimen presents no more than minimal risk to the privacy of individuals because:
Waiver justification

2.3.2 The research could not practicably be conducted without the waiver of informed consent and authorization because:
Waiver justification

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 then it would be possible to ask for their consent to review their record for research purposes then it may not be possible to satisfy this criterion. Another way to answer this question is to explain why obtaining consent would prohibit you from scientifically answering the question being asked. For example the condition is so rare that if all samples were not tested, the aims of the study could not be answered.

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

2.3.4 Waiving informed consent will not adversely affect the subject's rights or welfare because:
Waiver justification

IRB-P00034129 Additional Documents

Title: Sample New Research Activity Limited to Secondary* Use of Biological Material and Data

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-P00034129

Final Page

IRB-P00034129 Detailed Sponsor Information

Detailed Sponsor Information

1 * **What is the sponsor's name?**
FOUNDATION FOR ANESTHESIA EDUC AND RES - 0558

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

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

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

- ○ Federal
- ○ State
- ○ Corporate/Industry
- ● **External Foundation**

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

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

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

4 * **What is sponsor's contact name, if applicable?**
Contact name

5 * **What is sponsor's contact phone number?**
Contact phone number

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

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

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

- ○ Completed/Signed
- ● **Pending**
- ○ Not Required

ID: VIEW46F5DA7D2D400
Name: Detailed Sponsor Information

IRB-P00034129 Specimen - Details

Pathology Specimen Data limited

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

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

If Other:

1.1 Other:

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

1.2 Specify type of tumor/tissue.
Tumor/tissue

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

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

If FFPE:

2.1 Please select all that apply

- ☐ Unstained slides
- ☐ Scrolls

If Scanned Slides selected:

2.2 How will you utilize digital images?

2.3 Do you plan on sharing digital images with third parties?
○ Yes ○ No

If Yes:

2.3.1 Is there a material transfer agreement in place?

◯ Yes ◯ No

If No:

Please contact the BCH legal department regarding material agreement.

If Other:

2.4 Specify:

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

10g

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

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

10

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

January 2018 to ongoing

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

7.1 Is local pathology examination required?
◯ Yes ◯ No

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

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

If Fresh tissue will be collected:

7.4 Please specify location of collection

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

7.4.1 If Other BCH Procedures areas, please explain:

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

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

If No:

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

9 * Who will oversee tissue collection?

- ☐ Pathology collaborators
- ☐ Study team
- ☐ Other

If Other:

9.1 Please specify:

9.2 If NO pathologist collaborator, please specify workflow for tissue collection (e.g. study team will coordinate with pathology department on the day of procedure with detailed plan for tissue requirement and be present/available for tissue collection and pick up …. etc. be as detailed as possible).

10 **Budget**

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

◯ Yes ◯ No

ID: VIEW46F813A8B5000
Name: Specimen - Details