Boston Children's Hospital

Date: Monday, March 17, 2025 12:40:29 PM Print Close

IRB-P00034131 General Information

Title: Sample Request for Exemption

General Information

1 * **Protocol Title:**
Sample Request for Exemption

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 Request for Exemption

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

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

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

If Other patient services professionals:

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

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

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

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

If YES:

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

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

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

7 * **Type Of Submission:**
◯ New Research Activity
◯ **New Research Activity Limited to Secondary* Use of Biological Material and Data
◯ Establishment of Human Biological Specimen Repository/ Data Registry (only) – repositories/registries are defined as a prospective collections of specimens or data that are processed, stored, distributed to multiple investigators for use in research.
● **Request for Exemption**
◯ Individual Patient Expanded Access
◯ Humanitarian Use Device (HUD)
◯ Reliance on Another IRB

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

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

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

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

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

8 * **Is this protocol related to child health (including perinatology, prenatal assessments, childhood antecedents of adult disease, and long-term follow up of pediatric disorders)?**
● **Yes** ○ No

9 * **Is this protocol related to cancer (primarily concerning malignancies, oncology patients, or involving use of malignant tumors)?**
○ Yes ● **No**

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

10 * **Are you planning to use the Institutional Centers for Clinical and Translational Research (ICCTR) Study Operations Support?**
NOTE: the ICCTR was formerly the Clinical Research Center
○ Yes ● **No**

ICCTR Study Operations Support includes some of the following services:

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

11 * **Does this protocol generate study related charges in Epic that will be billed to the patient or insurance, and/or study fund?**
This includes experimental imaging, DEXA, blood samples, investigational products or devices.
Examples: A minimal risk study where the participant will answer surveys and receives physical therapy that is paid for by the study, an industry sponsored study where investigational product is given to a participant and paid for/donated by the sponsor, a federally funded study where MRIs and DEXA scans are paid for by the grant and not by the participants.
○ Yes ● **No**
Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

12 * **Does this protocol require the department/Clinical Research Finance to invoice a sponsor (industry, foundation, or federal cooperative agreements)?**
Includes protocols with automatic payments by the sponsor, and cooperative group agreements where the study team has to provide an invoice to the prime institution
Example: An industry sponsored study where the team must invoice for milestones and/or other invoiceable items, a subcontract from CHOP where BCH must send invoices to CHOP directly.
○ Yes ● **No**
Note: If you have questions about how to answer this, please contact OnCore.Support@childrens.harvard.edu

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

◯ Yes ● **No**

If Yes:

13.1 Please select the category:

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

If Other:

13.1.1 Please describe:

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

◯ Yes ● **No**

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

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

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

If Investigator Designed/Initiated:

15.1 Was the protocol peer-reviewed?

◯ Yes ◯ No

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Research Team

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

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

1 Research Staff - Children's Hospital Employees only:

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

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

Research Staff - Non Children's Hospital Employees only:

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

3 PI: Matthew Stafford

Required Training Will Expire: 2/2/2025

Completed Training Courses:

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

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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.

No funding needed

1.4 Please provide the name of the private donor.

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Financial Disclosure

Financial Disclosure

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

◯ Yes ● **No**

If YES:

1.1 Please select the relationships as appropriate.

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

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

◯ Yes ● **No**

If YES:

2.1 Please select the proprietary interest as appropriate.

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

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

◯ Yes ● **No**

If YES:

3.1 Please select as appropriate.

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

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

◯ Yes ● **No**

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

◯ Yes ● **No**

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

○ Yes ● **No**

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

○ Yes ● **No**

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

9 **Upload any other pertinent documentation.**

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

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Exemption Determination

Exemption Determination

A * **Are children involved in this research?**

○ Yes ● **No**

B * **Will prisoners be involved in this research?**

○ Yes ● **No**

If YES, please check the following:

B.1 ☐ **The research is aimed at involving a broader subject population that only incidentally included prisoners.**

Please note if your research only involves prisoners research subjects, it may not be considered exempt and you need to fill out a new research protocol application.

In order for a protocol to be exempt, all research procedures/interventions must fit into one or more of these categories. If there are procedures which are part of the research that are not listed below, the research is not exempt and a full application is required. Any research involving prisoners may not be determined to be exempt except for research aimed at involving a broader subject population that only incidentally includes prisoners. In addition there are some restrictions for research involving children; they are noted accordingly. Exempt categories 1-5 may not be used for research subject to FDA regulations.

Check the appropriate categories of your research and answer the specific questions. More then one category may be checked.

1 ☐ **Research, conducted in established or commonly accepted educational settings (for example: classrooms or other educational settings, education of residents in an academic medical center educational setting, online education) that specifically involves normal educational practices (for example research on instructional techniques) that are not likely to adversely impact a student's opportunity to learn required educational content or the assessment of educators who provide instruction.**
This includes most research on:

i. Regular and special education instructional strategies, and

ii. Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

1.1 Please describe why this research activity will not impact the student's opportunity to learn required content.

1.2 Please describe why this research activity will not impact the student's opportunity to learn required content.

1.3 Please explain why this research activity will not adversely impact the assessment of the educators who provide the instruction.

2 ☑ **Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior (including visual or auditory recording), if at least one of the following criteria is met:**

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and there are adequate plan to protect privacy of subjects and confidentiality of data

Note: When research involves children as subjects this exemption is limited to ONLY educational tests and observation of public behavior when investigators do not participate in the activities being observed and condition (i) or (ii) are met. Condition (iii) cannot be used for children if the research is of a sensitive nature. Research that involves surveys and interviews of children are NOT exempt.

2.1 Describe the types of educational tests (cognitive, diagnostic, aptitude, achievement), survey, interview procedures or observation of public behavior including visual or auditory recording.

Survey

2.2 <u>Please choose the appropriate option. At least one must be chosen to be exempt.</u>

2.2.1 ☐ **The information is recorded in such a manner that the identity of the human subject cannot readily be ascertained, directly or through identifiers linked to the subjects**

2.2.1.1 Please explain how the information is recorded to meet this criteria.

2.2.2 ☐ **Any disclosure of the responses outside the research will not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation.**

2.2.2.1 Please explain why or how this criteria is met.

2.2.3 ☑ **The information obtained will be recorded so that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects however provisions are made to protect the privacy of the subject and confidentiality of data.**

2.2.3.1 What identifying information will be collected?

What identifying information will be collected

2.2.3.2 Explain whether identifiers or links to identifiers will be recorded.

Explain whether identifiers or links to identifiers will be recorded.

2.2.3.3 Explain your plans for protecting the privacy of the subject and confidentiality of the data.

Explain your plans for protecting the privacy of the subject and confidentiality of the data.

3 ☐ **THIS EXEMPTION MAY ONLY BE USED FOR ADULT RESEARCH SUBJECTS AND DOES NOT APPLY TO CHILDREN**

Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. (Examples having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.) Any use of deception must be disclosed to the subject as part of a prospective agreement to participate in the research.
In addition at least one of the following criteria must be met:

i. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects; or

ii. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

iii. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and there are adequate plan to protect privacy of subject and confidentiality of data

3.1 Describe the benign behavioral intervention that is part of the research.

3.2 Describe why the intervention or methods used to collect data are harmless, painless, not physically invasive and not expected to cause physical or emotional harm or have a persistent or long term impact on the subject. In addition, explain how subjects will not find the interventions offensive or embarrassing.

3.3 Explain how the intervention is brief in duration? How long will the intervention take?

3.4 How is data collected?

- ○ Verbal responses
- ○ Written responses including data entry by the subject
- ○ Audiovisual recording

Note: Other methods of data collection would not be considered exempt

3.5 Is any deception involved?

○ Yes ○ No

If YES:

3.5.1 Please describe the deception.

3.5.2 Please explain how deception will be described to subjects as part of a prospective agreement to participate in the research.

3.6 <u>Please choose the appropriate option. At least one must be chosen to be exempt.</u>

3.6.1 ☐ **The identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects**

3.6.1.1 Please explain how the information obtained is recorded to meet this criteria.

3.6.2 ☐ **Any disclosure of the responses outside the research will not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation**

3.6.2.1 Please explain how and why this criteria is met.

3.6.3 ☐ **The information obtained will be recorded in such a manner so that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects however provisions are made to protect the privacy of the subject and confidentiality of data.**

3.6.3.1 What identifying information will be collected?

3.6.3.2 Explain whether identifiers or links to identifiers will be recorded.

3.6.3.3 Explain your plans for protecting the privacy of the subject and confidentiality of the data.

3.7 Describe how you will obtain the prospective agreement from the subject to the specific research intervention and data collection.

Note: Prospective agreement does not need to meet all the elements of informed consent and documentation but needs to be a simple and meaningful way to assure prospective voluntary agreement.

4 Secondary research uses of identifiable private information or identifiable biospecimens (examples include data, documents, records, pathological specimens, or diagnostic specimens) when consent is not required and at least one of the following criteria are met:

i. The identifiable private information or identifiable biospecimens are publicly available

ii. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

iii. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is already covered under the HIPAA regulations for the purposes of "health care operations" or "research" or "public health activities and purposes"

iv. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non the research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

If your research falls under this category, please go to the "General Information" page from the 'Jump To Menu' and select "New Research Activity Limited to Secondary Use of Excess Human Biological Material and/or Review of Health Information on Patients." as type of your research. You will need to complete a different form.

5 ☐ **Research and demonstration projects that are conducted or funded by a Federal department or agency, or otherwise subject to the approval of department or agency heads (orthe approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study,evaluate, improve, or otherwise examine public benefit or service programs.**

i. Public benefit or service programs;
ii. Procedures for obtaining benefits or services under those programs;
iii. Possible changes in or alternatives to those programs or procedures; or
iv. Possible changes in methods or levels of payment for benefits under those programs.

5.1 Please describe this activity in more details.

6 ☐ **Taste and food quality evaluation involving wholesome/safe foods.**

i. if wholesome foods without additives are consumed

OR

ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

6.1 Please describe this activity in more detail.

7 * **Does your research involve any other procedures, evaluations or interventions that are not listed in the categories above?**

○ Yes ● **No**

If YES, your protocol does not meet exemption criteria; you will be re-directed to the General Information form where you need to select another type of submission as the type of your research.

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Exempt Protocol Information

Exempt Protocol Information

1 * **Describe the subject population to be studied. Include a description of how many subjects will be included and the inclusion and exclusion criteria.**
Subject population

2 * **Describe any recruitment process including advertisements to be used in the study. Please indicate 'N/A' if not applicable.**
Recruitment process

3 * **Describe the procedures/assessments to be used in the research.**
Research procedures

4 * **Describe any type of compensation/reimbursement that will be provided to subjects. Please indicate 'N/A' if not applicable.**
Reimbursement

5 * **Are there any ethical concerns about the research or the individuals participating in the research (invasion of privacy, undue influence to participate, reputation of groups of individuals based on research data)?**

◯ Yes ● **No**

If YES:

5.1 Please describe what extra protections will you take to address these concerns.

6 * **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

7 **Upload any relevant documents.**

Name	Date Last Modified	Version Number	Owner
Recruitment Letter.docx(0.01)	12/2/2019 4:59 PM	0.01	Ashley Kuniholm
Survey.docx(0.01)	12/2/2019 4:59 PM	0.01	Ashley Kuniholm

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Additional Documents

Title: Sample Request for Exemption

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.

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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**

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