Children's Hospital Boston

Date: Tuesday, November 08, 2011 1:37:04 PM

Print Close

Title: irine test

General Information

1 * **Protocol Title:** Test

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.**
irine test

3 * **Provide a brief summary (in lay terms) of the research protocol.**
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4 * **Principal Investigator (PI):** Irine Breytburg

5 * **Type Of Submission:**

- ○ New Research Activity
- ○ New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients*
- ○ Request for Exemption
- ○ Single Patient Emergency
- ○ Humanitarian Use Device (HUD)
- ○ Projects that lack immediate plans for involvement with human subjects, their data and/or their specimens (i.e.training grants)
- ◉ **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.**
- ○ Existing Human Pluripotent Stem Cells obtained from fetal tissue and embryos for research procedures**

** Excess means the tissue is or was collected for reasons other than research purposes, or at least other than for the purposes of this research. Excess Human Biological Material is defined as any specimen obtained from patients (or human research subjects), e.g.: fixed, frozen or fresh pathology or autopsy specimens, any blood, urine, saliva, semen, breast milk or other biological material, any purified DNA, RNA, proteins, cell lines or clones.* ***This may not be selected if the study involves interaction/intervention with subjects in order to obtain tissue specifically for this research.***

*** If your research involves only laboratory studies with existing stem cells, this is the only application that needs to be completed. This option is not to be used to derive stem cells from embryos or fetal tissue. If there is any intervention with human subjects that involves either a) the derivation of stem cells from embryos or, b) the implantation of stem cells obtained from fetal tissue or embryos, please select "New Research Activity".*

6 * **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**

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

Note: If YES, please consult with your IRB analyst before proceeding. It is possible that your protocol will require review by the Dana Farber IRB instead.
For details, see: Catalyst and Dana Farber Cancer Center Reliance Agreements

8 * **Will this protocol utilize any of the services of the CTSU (Clinical and Translational Study 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 6 East, CAT/CR or research space at Waltham*
- *Nursing assistance at above sites*
- *Off-site nursing and/or research coordinator services provided through CTSU*

- *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.)*
- *Payment of any study-related research costs (patient care expenses, labs, other testing)*
- *Use of specialist equipment located on the CTSU (3DMD camera, DXA, pQCT, V-max, etc.)*

Research Team

1 Research Staff - Children's Hospital Employees only:

Last Name	First Name	Role	Editor	CC on Correspondence	Required Training Completed	CHeRP Training

There are no items to display

2 Research Staff - Non Children's Hospital Employees only:

Last Name	First Name	Role	E-Mail	Required Training Completed

There are no items to display

3 PI: Irine Breytburg

Completed Training Courses:

Training Program	Continuing Education Description	Training Completed
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	8/11/2011
Continuing Education	Good Clinical Practice (CITI)	5/11/2011
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	2/11/2011
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	1/11/2011
CHeRP Training		10/21/2010
CHeRP Training		10/21/2010
Collaborative IRB Training Initiative (CITI Biomedical)		5/12/2010
Continuing Education	Good Clinical Practice (CITI)	5/12/2010
Continuing Education	Good Clinical Practice (CITI)	8/14/2009
Continuing Education		6/15/2009
Collaborative IRB Training Initiative (CITI Behavioral)		1/13/2009
Training Received at Another Institution		1/13/2009
University of Rochester Training		1/13/2009
University of Rochester Training		1/13/2009
Continuing Education		2/20/2007
Continuing Education	Collaborative IRB Training Initiative (CITI Continuing Education)	2/20/2007
Training Received at Another Institution		2/16/2007
Continuing Education	Introduction to Clinical Research Course	7/16/2002

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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 CCI 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**
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2 * **This protocol involves the establishment of a:**
- [x] **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.**
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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)**
- [ ] 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

7 * **Does this protocol involve the collection of blood samples other than discarded specimens?**
(•) **Yes** ( ) No

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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.

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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)?**

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)?**

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

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.**

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.**

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.**

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.**
- 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.**
- 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.**
- 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.**

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.**

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.**

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

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

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

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

6 * **At the time of this submission will any "existing" (already collected) data/specimens be "grandfathered" into the repository/registry?**

○ Yes ○ No

If YES:

- 6.1 **Describe the consent status of the specimens/data. What kind, if any, of consent was obtained for collecting the specimens/data?**
- 6.2 **If applicable, include a copy of the consent form that was previously used.**

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There are no items to display			

7 * **Will the subjects receive any remuneration?**

○ Yes ○ No

If YES:

- 7.1 **Please describe the remuneration schedule.**

Operating Policies and Procedures of the Repository/Registry

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

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

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

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

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

3 **Distribution of de-identifiable specimens/data: Distribution of specimens/data that are coded, but not directly identifiable, when the recipient researcher will not seek to identify the individual from whom the specimens were obtained, is not considered human subjects research. However the recipient researcher must agree in writing to never attempt to access identifiable health/medical information or to attempt to identify the subject(s) who provided the specimen/data. Such coded specimens/data may be distributed without separate, independent IRB approval once the recipient researcher signs the agreement stating that s/he will not attempt to identify human subjects from whom the specimens/data were derived.**

Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such distributions. Also please include a copy of any letter or agreement recipient investigators will be asked to sign.
There are no items to display

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

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

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

- ☐ Children's researchers
- ☐ Non-Children's academic collaborators*
  Specify:
- ☐ 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.**

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.**

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.**

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.**

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

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

- ☐ Name
- ☐ Social Security Number
- ☐ Medical Record Number
- ☐ Address by street location
- ☐ Address by Town/City/Zip Code
- ☐ Dates(except year), e.g., date of birth; admission/discharge date; date of procedure; date of death
- ☐ Telephone Number
- ☐ Fax Number
- ☐ Electronic Email Address
- ☐ Web URLs
- ☐ Internet Protocol IP Address
- ☐ Health Plan Beneficiary Number
- ☐ Account Number
- ☐ Certificate/License Number
- ☐ Vehicle Identification Number and serial number, including license plate number
- ☐ Medical Device Identifiers and Serial Numbers
- ☐ Biometric Identifiers(finger and voice prints)
- ☐ Full Face Photographic Image
- ☐ Any Other Identifier or combination of identifiers likely to identify the subject

If Other:

2.1 Specify:

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).

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There are no items to display

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.

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.

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.

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.

☐ **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.

][]k

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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.

kl;jk;

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

sfasfg

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

hdfhd

*** *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.

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

2 **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.**

3 * **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.**

4 **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.**

5 * **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.**

6 * **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.**

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

8 * **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.**

9 * **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.**

10 **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.**

11 * **Please describe how and when the informed consent documents will be translated.**

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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 (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, 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**