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 repository validation

3 * Provide a brief summary (in lay terms) of the research protocol.

werwer

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:

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Role</th>
<th>Editor</th>
<th>CC on Correspondence</th>
<th>Required Training Completed</th>
<th>CHeRP Training</th>
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2 Research Staff - Non Children's Hospital Employees only:

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<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Role</th>
<th>E-Mail</th>
<th>Required Training Completed</th>
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3 PI: Irine Breytburg

Completed Training Courses:

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<td>Collaborative IRB Training Initiative (CITI Continuing Education)</td>
<td>8/11/2011</td>
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<tr>
<td>Continuing Education</td>
<td>Good Clinical Practice (CITI)</td>
<td>5/11/2011</td>
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<tr>
<td>Continuing Education</td>
<td>Collaborative IRB Training Initiative (CITI Continuing Education)</td>
<td>2/11/2011</td>
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<tr>
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<tr>
<td>CHeRP Training</td>
<td></td>
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<tr>
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<tr>
<td>Continuing Education</td>
<td></td>
<td>6/15/2009</td>
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<tr>
<td>Collaborative IRB Training Initiative (CITI Behavioral)</td>
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<td>1/13/2009</td>
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</table>
Training Received at Another Institution
University of Rochester Training
University of Rochester Training
Continuing Education
Continuing Education Collaborative IRB Training Initiative (CITI Continuing Education)
Training Received at Another Institution
Continuing Education Introduction to Clinical Research Course

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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).
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

Specimens and/or Existing Data

1 * Does your research involve the use of:
   □ Excess human biological specimens
   □ Existing data, documents, or records

Specimen - Protocol Information

1 * Describe the purpose for specimen collection. What is the research question under study?

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

3 * What is the time period for the specimens that will be obtained (i.e. Brain tumor tissue collected from January 2006 to December 2006)?

4 * At the time of this submission, do all the specimens already exist (already stored or "on the shelf")?
   ○ Yes  ○ No
   If NO:
   4.1 Explain:

5 * Will the specimens be or have been collected for purposes other than for the currently proposed research?
   ○ Yes  ○ No
   If YES:
   5.1 Explain:

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

7 * 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
8 Provide the name of the individual who should be notified for specimen pick-up, if applicable.

Specimen - Details

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

<table>
<thead>
<tr>
<th>Specimen Category</th>
<th>Amount</th>
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There are no items to display

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 will be re-directed to the General Information form where you need to change type of submission to "New Research Activity" as the type of your research.*

Specimen - Storage

1 * Will specimens be released outside Children's Hospital?

☐ Yes  ☐ No

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

☐ Yes  ☐ No

*If YES:

2.1 Where will the specimens be stored?

2.2 What future types of research would you anticipate using the specimens for?

2.3 Who will be responsible for distributing the specimens?

Existing Data - Protocol Information

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

☐ Medical Record/Chart
☐ Films/X-rays
☐ Database
☐ Quality Improvement Records
☐ Hospital Administrative/Billing Records
☐ Other types of records

1.1 *If Other or Database were selected, please specify.*

2 * Select the individual(s) who will be responsible for querying medical records/charts and/or databases. This must be a Children's Hospital staff member or employee. All individuals must already be listed as a member of the research team.

<table>
<thead>
<tr>
<th>Last Name</th>
<th>First Name</th>
<th>Employee ID</th>
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*Please note only those individuals and departments who would normally have access to those records are permitted to review the record for research purposes.*

3 * Identify each individual who will be given access to the data (Name and precise role with
study/project).

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

5  * Describe the study population from whom medical record/chart and or database information will be obtained (i.e. diagnosis, age group, etc.).

6  * How many subject or database records will be reviewed?

7  * What is the time period for the records that will be reviewed (i.e. patient records from November 2000 to November 2001)?

8  * How long do you anticipate you will need to abstract/obtain existing records?

9  * How long do you anticipate it will take you to complete this research?

10 * At the time of this submission do all the records/data already exist?  This means at the time this form is submitted to the IRB all the records you need to access will already exist.
   ○ Yes  ○ No

11 * Will the data have been collected for purposes other than for the currently proposed research?
   ○ Yes  ○ No

If YES:
11.1 Please explain.

Existing Data - Data Types

1  If applicable, indicate which database(s) will be queried.
   □ Epic
   □ Powerchart
   □ Department of Radiology
   □ Departmental Databases/Registries
   □ Data Warehouse
   □ Financial/Billing Database
   □ Other
   
If Other:
   1.1 Specify:

2  If appropriate, indicate the record(s)/chart(s) that will be queried.
   □ Electronic Medical Records
   □ Hospital Records
   □ Departmental Records
   □ Other
   
If Other:
   2.1 Specify:

3  * Indicate what the data will be used for.
If Other:

3.1 Specify:

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

☐ Name
☐ Demographics (age, sex, address)
☐ 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:

4.1 Specify:

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.

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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/Subject Name or the names of relatives, employers, or household members
☐ Medical record numbers (or specimen #)
☐ Address street location
☐ Address town or city *
☐ Address state*
☐ Address zip code*
☐ 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
Follow-up HIPAA/Confidentiality

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

   Last Name      First Name      Employee ID

   There are no items to display

2 * 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:
   2.1 Which of the elements of PHI will you maintain links for?
   2.2 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.
   2.3 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.

3 * 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.

Risks/Benefits/Sharing Data and Specimens

1 * What are the risks or benefits to subjects whose information is used in this research? Specifically address risk to privacy. Explain why these risks are no more than minimal.
2 * Will data or specimens be sent outside of Children’s Hospital, Boston or shared with any individual who does not have a CHB employee ID#?
   - Yes  - No

   If YES:
   2.1 Please specify who will receive specimens or data and for what purpose.
   2.2 Will identifying information, as previously defined, be sent outside of CHB?
      - Yes  - No

      If YES:
      2.2.1 How will data be sent (describe actual methods and include plans for coding and/or encryption)?
      2.2.2 Why is it necessary to send data/specimens outside of Children's Hospital, Boston?

Consent/Authorization/Waivers

1 * Has 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 * Do you want to request a waiver of consent/authorization for the use of existing data, documents and records and/or retrospectively collected samples (all data and specimens must already exist at the time this protocol is submitted)?
   - Yes  - No

   If YES, please provide justification for all of the following conditions:
   2.1 The proposed use of this data/document/record/specimen presents no more than minimal risk to the privacy of individuals because:
   2.2 The research could not practicably be conducted without the waiver of informed consent and authorization because:
      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 The research could not practicably be conducted without access to and use of protected health information because:
   2.4 Waiving informed consent will not adversely affect the subject’s rights or welfare because:

3 * Do you plan to obtain informed consent?
   - Yes  - No

   If YES:
   3.1 Provide information about when and how consent will be obtained.
   3.2 Upload Consent.

   Name   Date   Last Modified   Version   Owner
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Title: irine test repository validation

Additional Documents

1 Please upload any additional documents if it is necessary.

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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 (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