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.  

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:
   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:

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**Title:** irine test

### 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

Stem Cells

Before completing this section you must begin the stem cell registration process by filling out a stem cell registration form that must be signed by Leonard Zon, PhD. Once the registration form is completed you may apply for IRB approval by completing this application.

1 * Explain how the embryonic stem cells will be utilized:

2 * Are the embryonic stem cell lines on the existing NIH Human Embryonic Stem Cell Directory?

☐ Yes  ☐ No

If YES:

2.1 Please provide NIH Code. (You may use federal funds).

If NO:

Children’s Hospital requires that embryonic stem cells used for research purposes that are not on the NIH Embryonic Stem Cell Registry must have been collected and derived under the following principles:

- Informed consent must have been obtained for the donation any human material used during the derivation process.
- No financial incentives were provided for donation of human material
- In order to receive embryonic stem cells from sources other then NIH, a material transfer agreement (MTA) must be signed which includes assurance that these principles have been followed. (You may contact 617 355-7050 for information about the MTA).

Please check below:

2.2 I will not accept and use embryonic stem cells from sources other than NIH without a material transfer agreement that indicates the above referenced principles have been applied is signed by those providing the stem cells.

2.3 As Principal Investigator I assure that the above embryonic stem cells that are referenced above will only be used in accordance with the indications listed in this protocol and will not be transferred to any other individuals within or outside of Children’s without prior approval.

Title: irine test
Additional Documents

1 Please upload any additional documents if it is necessary.

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