Children's Hospital Boston

Date: Tuesday, November 08, 2011 1:35:52 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.**
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:

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			

Humanitarian Use Device

1 * **Name of Humanitarian Use Device (please include the generic and trade names as applicable)**

2 * **Source (supplier or manufacturer) of the device**

3 **Date of HUD designation, if known.**

4 * **FDA assigned HDE number**

5 * **What are the indications for the use of the device(disease or condition that the device is intended to treat or diagnose)?**

6 * **Provide a brief description of the device.**

7 * **What is the age range of the subjects?**

8 * **Describe the contraindications, warnings and precautions for use of the device.**

9 * **Are there any alternative practices, procedures or devices available to treat or diagnose the patient's disease or condition? If yes, please detail. Note: To be eligible for marketing approval under the HDE regulations, the sponsor must show that no comparable device, other than this device or a device being studied under an IDE, is available.**

10 * **Will data be collected on the patients?**

○ Yes ○ No

If YES:

10.1 **Will the collection of data be on safety and effectiveness and used to support a pre-marketing (PMA) application?**

○ 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.

10.2 **Will data be collected for any type of database or data repository?**

○ Yes ○ No

If YES:

10.2.1 **Please describe.**

10.2.2 **Describe how the data will be stored, confidentiality maintained and who will have access to the data.**

11 * **Who will cover the cost of the device and any procedures associated with using or implanting the device?**

12 **Attach the following Humanitarian Device Exemption (HDE) documentation as provided by the sponsor.**

12.1 **FDA Humanitarian Device Exemption (HDE) approval letter (or similar form from sponsor)**

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

12.2 **HUD manufacturer's information, including product labeling, clinical brochure and any other pertinent manufacture information materials.**

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

13 * **Explain who will obtain consent, when and how.**

13.1 Attach the Humanitarian Use Device consent form or information sheet to be provided to patients. Note if data is being collected in a database or repository to be used for future research or future additional marketing initiatives, please be sure the consent includes information regarding those uses.

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There are no items to display			

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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**