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Date: Tuesday, November 08, 2011 1:36:14 PM

Title: irine test

# Print Close

#### **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.
- 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
  - C 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".
- \* 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)?

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

- \* 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)

		6	
( ·	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**

# Research Staff - Children's Hospital Employees only:

Last Name First Name Role Editor CC on Correspondence **CHeRP Training** Required Training Completed There are no items to display

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

First Name Required Training Completed Last Name

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

#### Title: irine test

# **Funding Sources**

1	* Select	fundina	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 Childre	n's fo	undation	funds
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Internal Children's Grant Award

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harmed, directly or indirectly.

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- 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?  Or Yes Or 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
	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?  Or Yes Or 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

Please upload any additional documents if it is necessary.

Date Last Modified Version Owner

There are no items to display