

Date: Tuesday, November 08, 2011 1:34:59 PM Title: irine test

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### **General Information**

1 \* Protocol Title: Test

Maximum of 230 characters may be entered.

- Full Title If protocol title exceeds the 230 characters limited from field above, enter full title here. Otherwise, leave blank.
- \* Provide a brief summary (in lay terms) of the research protocol.
- \* Principal Investigator (PI): Irine Breytburg
- \* 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
  - C Single Patient Emergency
  - C Humanitarian Use Device (HUD)
  - O 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

\* 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 Agree

- \* 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:

  - 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**

Research Staff - Children's Hospital Employees only:

CC on Correspondence Required Training Completed CHeRP Training

There are no items to display

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

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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If YES:

3.1 Please select as appropriate.

Fur	ing Sources	
1	Select funding category.  © Externally sponsored (federal, state, corporate, foundations)	
	O Internally sponsored	
	© Externally and internally sponsored	
	O No sponsor	
	O 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:	
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.	
Fin	ncial 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 O No	
	f 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 will be employed in the protocol? Include proprietary interests that you have assigned to any entity, including any institution you have been affiliated with.  C Yes O No	hat
	f 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 other support for the research to be conducted under the protocol?  Yes O No	or

	☐ 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 ntity that may be affected by the research to be conducted under the protocol (e.g. competitor, customer, collaborator or commercial sponsor affiliate)? Including entity that may be benefited or harmed, directly or indirectly.  Yes ONO			
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, nancial relationship, future grant, position, or advisory role either related to the protocol, or dependent on the outcome of the research under the protocol?  Yes C 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 mone 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?  C Yes  No			
7	* Is there anything not disclosed above which you believe might constitute a conflict of i protocol?  O Yes O No	nterest or an appearance of a confli	ct of interest in connection with the	
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			
Ex	xemption Determination			
	In order for a protocol to be exempt, all research procedures/interventions must fit into one or n resources that are not listed below, the research is not exempt and a full application is required addition there are some restrictions for research involving children; they are noted accordingly. regulations.	I. Any research involving prisoners may	y not be determined to be exempt. In	
	Check the appropriate category of your research and answer the specific questions. Moreover, the specific questions are supported by the specific questions and the specific questions are supported by the specific questions.	re then one category may be checke	d.	
1	Research conducted in established educational settings, involving normal education	onal practices,		
	<ul> <li>such as:         <ul> <li>i. Research on education instructional strategies, or</li> <li>ii. Research on the effectiveness of or the comparison among instructional techniques</li> </ul> </li> </ul>	ues. curricula.		
	or	•		
	<ul> <li>classroom management methods</li> <li>1.1 Please describe the educational setting in which the research will be conducte type of normal educational practices involved.</li> </ul>	d and the		
2	Research involving the use of educational tests (cognitive, diagnostic, aptitude, acl public behavior, only if:	hievement), survey procedures, inte	rview procedures or observation of	
	<ul> <li>i. Information is not recorded with identifiers linked to the subjects; and</li> <li>ii. Subjects' responses outside the research could not place the subjects at risk (e.g.)</li> </ul>	g. criminal or civil liability, financial stan	ding, employability, or reputation.	
	Note: When research involves children as subjects this exemption is limited to educationa in the activities being observed. Research that involves surveys and interviews of children		vior when investigators do not participate	
	2.1 Describe the types of educational tests, survey, interview procedures or obser public behavior.	vation of		
	2.2 Describe procedures to assure that information is not recorded with identifiers subjects.	s linked to		
	2.3 Describe why the information recorded does not place the subject at risk (crim financial, employment or reputation).	inal, civil,		

	Research involving the use of educational tests(cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under number 2 above if:  i. The human subjects are elected or appointed public officials or candidates for public office; or ii. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
	3.1 Describe the educational tests, surveys, interview or observations of public behavior and describe how the subjects meet the classification of elected appointed officials or candidates for public office.  3.2 Also describe how the confidentiality of the personally identifiable information will be
	maintained throughout the research and thereafter.
4	Research, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers. "Existing" means already on the shelf or in storage when the protocol is submitted.
	If your research falls under this category, please go to the "General Information" page from the Jump To menu and select "New Research Activity Limited to Excess Human Biological Material and/or Review of Health Information on Patients." as type of your research.
5	Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and designed to study or evaluate:  i. Public benefit or service programs;  ii. Procedures for obtaining benefits or services under those programs;  iii. Possible changes in or alternatives to those programs or procedures; or  iv. Possible changes in methods or levels of payment for benefits under those programs.
	The Office for Human Research Protections has determined that <u>all the following criteria must be satisfied</u> to invoke the exemption for research and demonstration projects examining "public benefit or service programs" as specified under Department of Health and Human Services (HHS) regulations at 45 CFR 46.101(b)(5).
	Please indicate that your project meets the following criteria:  The program under study must deliver a public benefit (e.g., financial or medical benefits as provided under the Social Security Act) or service (e.g., social, supportive, or nutrition services as provided under the Older Americans Act)
	☐ The research or demonstration project must be conducted pursuant to specific federal statutory authority.
	There must be no statutory requirement that the project be reviewed by an Institutional Review Board (IRB).
	☐ The funding agency must be contacted and provide approval to utilize this exemption category.
	5.1 If you feel your research fits this category, please submit proof of approval by a Department Agency Head.  Name Date Last Modified Version Owner  There are no items to display
6	<ul> <li>☐ Taste and food quality evaluation involving wholesome/safe foods.</li> <li>i. if wholesome foods without additives are consumed</li> </ul>
	OR  ii. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
	6.1 Please describe this activity in more detail.
7	* Does your research involve any other procedures, evaluations or interventions that are not listed in the categories above?  O Yes  No
	If YES, your protocol does not meet exemption criteria; you will be re-directed to the General Information form where you need to select another type of submission as the type of your research.
Exe	empt Protocol Information
1	* Give a brief synopsis of the research, including the background information and rationale.
2	* Describe the subject population to be studied. Include a description of how many subjects will be included and the inclusion and exclusion criteria.
3	Describe any recruitment process including advertisements to be used in the study.

- \* Describe the procedures to be used in the study.
- Describe any type of compensation/reimbursement that will be provided to subjects.
- \* Are there any ethical concerns about the research or the individuals participating in the research (invasion of privacy, undue influence to participate, reputation of groups of individuals based on research data)?

○ Yes ○ No

Please describe what extra protections will you take to address these concerns.

7 Upload any relevant documents.

Date Last Modified Version Owner

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## **Additional Documents**

Please upload any additional documents if it is necessary. Date Last Modified

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).

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- 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