Children's Hospital Boston

Date: Tuesday, November 08, 2011 1:35:29 PM

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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.

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There are no items to display

Single Patient Emergency

1 * Patient Name

2 * Patient Medical Record Number

3 * Please check one category.

- ○ The emergency use is being reported to the IRB prior to initiation (whenever possible the application must be submitted prior to the emergency treatment)
- ○ The emergency use is being reported to the IRB within 5 working days of initiation

3.1 * What is the estimated date to initiate the proposed therapy? If the emergency therapy already occured, please enter date therapy was administered.

4 * Provide a brief summary of the clinical history of the patient.

5 * Describe the therapy and provide the rationale for therapy.

6 * Provide a statement on the known risks and benefits.

7 * Please indicate which category is applicable. Please note in order to be eligible for an emergency exemption, at least one of the two following categories must be checked.

- ☐ Patient is in a life threatening situation.

Life threatening means diseases or conditions where the likelihood of death is high unless the course of the disease is interrupted and a disease or conditions with a potentially fatal outcomes, where the end-point of a clinical trial is survival. The criteria for life threatening do not require the condition to be immediately life threatening or to immediately result in death. Rather, the participants must be in a life threatening situation that requires intervention before review at a convened meeting of the IRB is feasible.

☐ Patient is in a situation which may be subject to severe debilitation by waiting for the next IRB scheduled meeting.
Severely debilitating meaning the disease or condition may cause major irreversible morbidity.
Examples of severely debilitating conditions include blindness, loss of arm, leg, hand, or foot, loss of hearing, paralysis or stroke. To see next IRB meeting date go to: www.childrenshospital.org/research/irb

7.1 * Please justify why the proposed treatment meets the criteria listed above, why there are no standard acceptable alternatives treatments and why there is not sufficient time to wait until the next IRB meeting.

8 * Have previous single patient emergency exemptions involving this same treatment been submitted for other Children's Hospital, Boston patients?
○ Yes ○ No

If YES:
8.1 How many single patient emergency exemption requests have been submitted?
8.2 What is the experience to date with previous emergency requests? How are the patients doing?

9 * Do you anticipate that more patients will require this treatment in the future?
○ Yes ○ No

If YES:
9.1 What plans are there for submission of a formal protocol for IRB review? If a protocol is already in place, please explain why this patient is not eligible for the active protocol.

Please note that the IRB can not provide multiple exemptions for emergency treatments. Concurrence of exemption from full IRB review will be acknowledged for one patient only. Subsequent requests for the same therapy must be submitted as a research protocol to the IRB at a convened meeting. The FDA does acknowledge that if a second patient were to require the same therapy, it would be inappropriate to deny clinically appropriate emergency treatment to the second individual if the only obstacle is a lack of sufficient time for the IRB to convene a meeting to review the issue.

10 * Is a drug being used?
○ Yes ○ No

11 * Is a device being used?
○ Yes ○ No

Single Patient Emergency - Financial Considerations

1 * Who will pay for the cost of the test article and intervention (drug or device)?
☐ Sponsor/Manufacturer
☐ Children's Hospital
☐ Patient's Insurance*
☐ Other

If Other:
1.1 Please describe:

2 * Who will pay for costs associated with use of the test article and intervention (surgical procedures, added tests, hospitalization, added time in hospital, etc)?
☐ Sponsor/Manufacturer
☐ Children's Hospital
☐ Patient's Insurance*
☐ Other

If Other:
2.1 Please describe:

** If the patient's insurance will be billed for the drug, device, or procedures related to this emergency treatment, please contact Patient Finance to confirm whether the insurance company will cover the costs.*

Single Patient Emergency - Informed Consent

1 * Please select one of the following:
1.1 ☐ Informed consent will be obtained from the subject, parent/guardian or legally authorized representative.

Upload a copy of the informed consent form with all the required elements.

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

1.2 ☐ Informed consent cannot be obtained.

If checked, choose one of the following options:

☐ **Option 1 - PI and a physician who is not otherwise participating in the clinical investigation have certified all of the following.**

Please check each box:

- ☐ The participant is confronted by a life-threatening situation necessitating the use of the test article.
- ☐ Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
- ☐ Time is not sufficient to obtain consent from the participant's legal representative.
- ☐ There is no available alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.

☐ **Option 2 - PI certifies that all of the following are true.**

Please check each box:

- ☐ Immediate use of the test article is, in PI's opinion, required to preserve the life of the participant.
- ☐ Time is not sufficient to obtain the independent determination a physician who is not otherwise participating in the clinical investigation.
- ☐ Before the use of the test article, PI certifies the following:

  - The participant is confronted by a life-threatening situation necessitating the use of the test article. Informed consent cannot be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
  - Time is not sufficient to obtain consent from the participant's legal representative.
  - There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the participant.

- ☐ After the use of the test article, PI will obtain from a physician who is not otherwise participating in the clinical investigation a certification in writing within 5 working days after the use of the article of all of the following:

  - The participant was confronted by a life-threatening situation necessitating the use of the test article.
  - Informed consent could not be obtained from the participant because of an inability to communicate with, or obtain legally effective consent from, the participant.
  - Time was not sufficient to obtain consent from the participant's legal representative.
  - There was available no alternative method of approved or generally recognized therapy that provided an equal or greater likelihood of saving the life of the participant

1.2.1 Upload certification from physician.

Name	Date Last Modified	Version	Owner

There are no items to display

3 If applicable, provide copies of any materials, protocols, investigational brochures provided by the sponsor or drug/device manufacturer or correspondence with FDA or any additional material.

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There are no items to display

OHRP's interpretation of DHHS regulations stipulates that data pertaining to a patient treated according to an emergency exemption without full IRB review are not to be used or included as prospective research.

Subsequent use of the same emergency treatment is subject to full board review. If subsequent use is anticipated, a full protocol should be submitted to the CCI as soon as possible.

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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