



Date: Tuesday, November 08, 2011 11:59:33 AM  
 Title: irine test repository validation

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**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 repository validation

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 |                    |         |       |

#### Protocol Design

- 1 \* Is this a multi center study?  
 Yes  No
- If YES:
- 1.1 Is Children's Hospital, Boston the lead site or coordinating center?  
 Yes  No
- If YES:
- 1.2 Describe the plan to ensure communication among sites in terms of adverse events, unanticipated problems, protocol modifications, interim results, etc.
- 2 \* Is the person who will be primarily responsible for conducting the study different from the PI?  
 Yes  No
- 3 \* Has the PI, or if question #2 was YES has that person, previously served as a PI of a protocol involving interaction/intervention with human subjects at CHB?  
 Yes  No

#### Subject Information

- 1 Enrollment Numbers
- 1.1 \* Specify the number of subjects enrolled by, or under the auspices of Children's Hospital, that are required to complete data analysis.
- 1.2 If a larger number of subjects must be enrolled to account for such things as screening failures and drop-outs, provide an estimate of the larger number of subjects to be recruited through CHB. If not applicable, please leave blank.
- 1.3 If this is a multi center study, please specify the total number of subjects required by all sites for data analysis.
- 2 Types of Subjects
- 2.1 \*Gender
- Males  
 Females
- 2.2 \*Age
- Neonates (up to 30 days)  
 Infants (between 30 days and 2 years)  
 Children (between 2-12 years)  
 Adolescents (between 13-17 years)  
 Adults, Ages 18-35  
 Adults over 35
- Specify entire age range.
- 2.3 Special Populations
- Mentally Incapacitated  
 Employees/Staff (Note: Employees/staff under the direct supervision of the PI may not be recruited.)  
 Normal/Healthy Controls

- Students

**Specify from where.**

- Pregnant Women/Fetuses
- Prisoners/Incarcerated Youth (this would include children under the care of the Department of Youth Services). Consider if your target population will be or at higher risk of incarceration. If this category is chosen, you will be prompted to answer additional questions to meet federal regulations.
- Wards of the State (consider if your target population may contain wards of the state or children at risk of becoming a ward of the state (this includes foster children or any child that is in state custody))
- Minorities

*If NOT checked:*

**Provide scientific justification for excluding minorities.**

- Non-English Speaking Subjects

*If checked:*

**What plans do you have to provide the subject/family with a written translation of the consent form and other study materials and to ensure that all study interaction will be in a language understandable to the subject/family?**

*If NOT checked:*

**Please provide scientific justification for excluding non-English speaking subjects.**

- Other populations potentially subject to special considerations not identified above (i.e. socially, educationally, economically disadvantaged, elderly, terminally ill or adults with questionable decision making capabilities)

**Specify population.**

**Specify what additional safeguards will be taken to protect the rights and welfare of these subjects.**

### Study Location

1. **If your research is conducted in any of the following location(s) please check all that apply. If your research does not include any of these sites, please leave the questions blank.**

- Adolescent Medicine
- Adolescent Surgery
- Cardiac ICU
- Cardiac Surgery
- Infant Toddler Surgical
- Infant/Toddler Medical
- Intermediate Care Program (ICP, 11 South)
- Medical/Surgical ICU (7 South)
- Medicine ICU (11 South)
- Neonatal ICU
- Neurology
- Oncology/Hematology
- Psychiatry
- School Age Medical
- School Age Surgical
- Sleep Study
- Solid Organ Transplant
- Stem Cell Transplant

### Other CH Locations

- Cardiac Cath Lab
- Children's Hospital Primary Care Center (CHPCC)
- Clinical and Translational Study Unit (CTSU)
- Emergency Department
- Martha Elliot Health Center (MEHC)
- MRI
- Nuclear Medicine/PET
- Operating Rooms
- Other Satellites (Lexington, Peabody, South Shore, etc.)
- Radiology
- Waltham

### Off Premises e.g. Schools, other Hospitals, Home

- Beth Israel Deaconess
- Brigham and Women's Hospital
- Boston Medical Center
- Dana Farber Cancer Institute
- Harvard Medical School
- Harvard School of Public Health
- Subject's Homes
- Joslin Diabetes Center

- Mass Eye and Ear Infirmary
- Mass General Hospital
- MIT
- Other
- Physician Office
- School
- Tufts – New England Medical Center

1.1 *If Other:*  
Specify:

**Recruitment and Remuneration**

**Recruitment**

- 1 \* Describe plans for recruitment, including identification of potential participants, who is responsible for recruitment and how and when subjects will be recruited.
- 2 If applicable, how will prospective subjects' healthcare providers (e.g., physician, dentist, etc.) be involved in the recruitment and/or be notified of their individual patients' participation in the study?
- 3 \* Describe measures that will be implemented to avoid participant coercion or undue influence.
- 4 \* Does the recruitment strategy involve contacting individuals multiple times in an effort to secure their enrollment into the study?  
 Yes  No

*If YES:*

4.1 Please describe how frequently and in what manner individuals will be contacted.

- 5 Upload all recruitment materials, including letters, brochures, posters, phone interview scripts, newspaper ads, etc.

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

- 6 Please describe how each document uploaded in question #5 will be used.
- 7 \* Will CHB-Connect (a volunteer registry for clinical research) be used to identify potential research subjects? The volunteer registry for clinical research is available on the Children's Hospital website.  
 Yes  No
- 8 Recruitment information about approved protocols can be automatically posted on the Children's Hospital external website " Find a Clinical Trial" once the research receives final approval.  
  
\* Do you want this protocol to be posted?  
 Yes  No  
  
*If YES:*  
8.1  I assure that there are no restrictions by any funding agency, sponsor, cooperative group or any other oversight authority on posting this research protocol on the Children's Hospital external website. (Please be sure to review any clinical trial agreements, confidentiality agreements or oversight documentation associated with this research before checking this box).

*You will be re-directed to another form to enter the information that will be posted on the site.*

**Remuneration**

- 9 \* Will subjects/families receive a form of payment, compensation or reimbursement?  
 Yes  No

**Research Data, Documents, Subject Reports & Consent/Assent Forms: Storage**

- 1 \*Where will research data, documents and subject reports be sent and stored? Check all that apply.
  - Children's Hospital Medical Record
  - Departmental Medical Record
  - Separate Research Record
  - Subject/family will receive results
  - Sponsor, Collaborator and/or Coordinating Center  
Specify:
  - Medical Record at another institution, hospital, physician's office, etc.  
Specify:
  - Research Registry  
Will data include patient identifiers (name, medical record, SS #)?  
 Yes  No
  - Other  
Specify:
- 2 \*Where will the signed informed consent and assent be stored? Check all that apply.
  - Children's Hospital Medical Record
  - Departmental Medical Record
  - Separate Research Record

- Sponsor, Collaborator and/or Coordinating Center
- Medical Record at another institution, hospital, physician's office, etc.
- Research Registry
- Not Applicable

**3 \* Explain the rationale for including or not including research data and the informed consent/assent forms in the CHB medical records.**

*Please note: the confidentiality section of the consent form must specify whether research data and/or the informed consent/assent form(s) will or will not be included in the Children's Hospital or Departmental medical records. A sample statement is included on the Informed Consent Template.*

**Medical Expenses for Research Related Adverse Events**

**1 \*How will the cost of reasonably foreseeable medical care in the event of a research related adverse event be covered?**

- Corporate sponsor agreement
- Likely to be covered by insurance
- Philanthropic or other grant
- Foundation or Departmental Funds
- Interdepartmental arrangements
- Other

**Explain:**

- Not applicable

**Privacy and Confidentiality**

**Privacy**

**1 \*'Privacy' refers to a person's desire to control access of others to themselves. Describe the steps that will be taken to protect and assure the privacy of the subject. Detail specific actions the Research Team will take to ensure that privacy is protected through each phase of the study (e.g. access to medical records for recruitment, mailings to subjects, phone calls with subjects, research visits).**

**Examples of issues:**

- Potential subjects may not want to be approached for research purposes by someone they do not know.
- Potential subjects may not want others to know they have a disease or were previously treated for a condition; therefore, you may want to avoid sending a recruitment letter in the mail that may be opened by others.
- Subjects may not want to be seen in areas that may stigmatize them (i.e. pregnancy counseling center).

**Confidentiality**

**2 \* Investigators are required to obtain only the minimum data necessary to achieve the research goals. Please justify why the data you are obtaining is the minimum necessary.**

**3 \* Describe where data will be kept, how it will be secured and who will have access to the data. If links to identifiers are used, please describe the coding mechanism, whether the code is derived from subject information, and how and where the mechanisms for re-identification will be protected and maintained.**

**4 \* Provide a plan to protect the identifiers from improper use and disclosure.**

**5 \* Provide a plan for destroying the identifiers at the earliest opportunity consistent with the conduct of the research or provide a health or research justification for retaining the identifiers. For protocols that may be subject to future continuing and secondary data analysis, the IRB highly recommends providing justification for not destroying identifiers permanently.**

**6 \* Will a certificate of confidentiality be obtained for this research?**

- Yes  No

*If YES:*

**6.1 Please upload certificate, if available.**

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

**6.2  Check here if certificate is pending and will be submitted via an amendment at a later date.**

**Protected Health Information and HIPAA Authorization Information**

**Protected Health Information (PHI)** is information acquired by Children's Hospital, including demographic information, that could reasonably identify an individual **AND**:

- Relate to the past, present, or future physical or mental health, condition or treatment of an individual; **OR**
- Describe the past, present, or future payment for the provision of healthcare to an individual.

There are some limited situations when research protocols will not use or create protected health information. For example, educational research conducted in a school setting.

**1 \*The following information is considered identifiable PHI under the Privacy Rules regulations. Indicate which of the following will be obtained.**

- Patient/Subject Name or the names of relatives, employers, or household members
- Medical record numbers (or specimen #)
- Address street location
- Address town or city \*
- Address state\*
- Address zip code\*

- Elements of Dates (except year) related to an individual. For example date of birth, admission or discharge dates, date of death, dates of procedures\*
- Telephone number
- Fax Number
- Electronic mail (email) address
- Social security number
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identification numbers and serial numbers including license plates
- Medical device identifiers and serial numbers
- Web URLs
- Internet protocol (IP) address
- Biometric identifiers (finger and voice prints)
- Full face photographic images
- Any unique identifying number, characteristic or code
- NONE OF THE ABOVE: this protocol will not use any identifiable PHI

\* These items may be included and considered a "limited data set". Use of data under the provisions of a "limited data set" require the signing of a data use agreement by the recipient (this includes researchers).

#### Protected Health Information and HIPAA Authorization Information - Continued

- 1 **Please check all of the categories that indicate where a research subject's PHI may be disclosed. For this purpose, "disclosure" means release, transfer, provision of access, or otherwise divulging protected health information outside the entity initially acquiring the information as specified in the protocol; most often that will be Children's Hospital Boston.**
- Internal at Children's Hospital
  - Data Safety Monitoring Committee
  - Food and Drug Administration (FDA)
  - Other health care providers of subject
  - Third Party Payers - if third parties are billed for procedures performed during research
  - Sponsor of Trial
  - Contract Research Organization (CRO): organizations contracted to perform portions of the study (i.e., screening, data collection)  
**Specify the name/organization.**
  - Collaborator  
**Specify who and the location.**
  - Cooperative Group/Network  
**Specify the name of the network/group.**
  - Other  
**Specify who and the location.**

#### Data and Safety Monitoring

All protocols that present greater than minimal risk require a data and safety monitoring plan(DSMP). Investigators may also choose to submit a plan for any protocol.

- 1 **\* Please check one of the three categories.**
- This protocol is greater than minimal risk and therefore requires a DSMP (responses to all questions below are required).
  - This research is minimal risk but we have included a DSMP (respond to the questions below that apply to your DSMP).
  - This protocol is minimal risk and we are not including a DSMP.

2 **Which individual or group will be responsible for monitoring the data and safety for this study?**

- Principal Investigator/Research Team
- Independent Monitor(s)
- Internal Committee at the Hospital
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Independent of PI and Sponsor
- Data and Safety Monitoring Board (DSMB) or Data Safety Committee (DSC) Not Independent of PI and Sponsor
- Other  
**Specify:**

3 **Provide a description of the individuals who will be responsible for data safety monitoring, including the following details:**

(1) association with the research or study sponsor;

(2) nature of expertise and;

(3) whether they are independent of the commercial sponsor.

If those monitoring the study are not independent of the sponsor, please describe how any potential conflicts of interest or biases will be avoided.

Note: If this information is in the protocol, please specify where (by the section number) the relevant information can be located.

4 **What data will be reviewed?**

- Adverse events/Unanticipated problem
- Aggregate data

- Enrollment numbers
- Individual subject data/case report forms
- Protocol violations/deviations
- Subject withdrawals/terminations
- Other

Specify:

- 5 How often will data and safety monitoring be performed? Please specify if this is a specific number of times, at defined time points, after a certain number of subjects have been recruited or as needed (i.e. every 6 months, every SAE, every 5 subjects, etc.). If this information is in protocol, please specify where relevant information is located.
- 6 Describe the responsibilities that have been given to the data and safety monitoring function. This should include a discussion of whether the data and safety monitoring plan includes a charter, whether stopping rules will be developed, and if any interim analysis will be performed (if so, on what basis). If this information is in protocol, please specify where relevant information is located.
- 7 If this protocol is for a multicenter trial what mechanisms are in place to either receive or distribute results of the data and safety monitoring function in a prompt manner.
- 8 If a DSM charter exists, please upload it.  
There are no items to display

#### Risks and Benefits

##### Risks

- 1 \* Provide a description of the foreseeable risks to subjects. Consider all types of risks, including physical, psychological, social/reputation, legal, financial, privacy and breach of a promise of confidentiality.
- 2 \* What is the likelihood and seriousness of such risks?
- 3 \* Describe provisions for minimizing risks to participants.

##### Potential Benefits

- 4 \* Are there potential benefits to the participants?  
 Yes  No

If YES:

- 4.1 Describe the potential direct benefits to participants.
- 5 \* Describe how the research may result in knowledge expected to benefit society.

#### Incidental Findings and Dissemination of Results

##### Incidental Findings

- 1 \* Is there a possibility of clinically significant incidental findings being discovered during research procedure? Incidental findings may include discovery of unexpected genetic mutations, abnormal results following an MRI of a healthy control, or indications of subject depression following review of quality of life assessments.  
 Yes  No

If YES:

- 1.1 Please describe any of potential incidental findings that may result.
- 1.2 Outline the plan for addressing incidental findings (i.e. contacting the subjects primary care provider, referral, etc.).

##### Dissemination of Research Results

- 2 \* Research subjects have expressed the desire to receive information about the study progress and results after agreeing to participate. Although it is not always possible to provide results within a definitive period of time (sometimes for years), it may be possible to provide research subjects with periodic updates. In addition, acknowledging subjects for their participation is also appreciated. As part of our ongoing efforts to take into consideration research subject concerns, investigators are strongly encouraged to consider including some provisions for acknowledging subjects and providing results and follow-up information as applicable. Please explain whether you will be able to thank subjects and provide research results and, if so, how this will be accomplished. If you do not think this is feasible, appropriate or applicable to this research, please specify why.

#### Research Categories and Special Considerations

- 1 Please select the appropriate research category for your research. A primary category must be selected. A secondary category should be selected only if applicable.

##### \* Primary Research Categories:

- Intervention/Trial Therapeutic ( e.g. drugs, devices, comparison of therapeutic approaches, new procedures)
- Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)
- Behavioral/Psychosocial Interventions/Trials
- Establishment of Specimen Repository
- Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
- Quality Improvement
- Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
- Educational/Training – e.g. training of residents or other professional staff

##### Secondary Research Categories:

- Intervention/Trial Therapeutic ( e.g. drugs, devices, comparison of therapeutic approaches, new procedures)

- Intervention/Trial Non-Therapeutic (extra ECHO, MRI, physical exams for non-therapeutic purposes)**
- Behavioral/Psychosocial Interventions/Trials
- Establishment of Specimen Repository
- Epidemiology/Observational Study – e.g. survey, case/control/data registries, cohort studies
- Quality Improvement
- Lab Specimen Studies – e.g. blood, urine, extra tissue during biopsy, genetic research
- Educational/Training – e.g. training of residents or other professional staff

**2 Please check all of the following that apply to the proposed research.**

- This protocol involves the use of a drug, biologic, nutritional supplement, herbal or homeopathic medicine, medical food, medical gas, inhalation therapy, topical cream, chemical or other compound that will be administered as the object of the protocol or because it is relevant to the aims of the research protocol.
- This protocol involves a device that will be used, administered, implanted, or applied to the subjects, as the object of the protocol or is relevant to the objectives of the protocol. This includes investigational devices classified as both significant risk and non significant risk as well as FDA approved/marketed devices.
- This protocol involves genetic testing.
- This protocol involves the use of a placebo.
- This protocol includes an imaging study to be done in Radiology or Nuclear Medicine. Please contact Stephen Whalen [stephen.whelen@childrens.harvard.edu](mailto:stephen.whelen@childrens.harvard.edu). Stephen will collect some additional information from you and coordinate the review of the information through Radiology to assure that the imaging protocol can be performed, the correct charges have been established and that Radiology will be able to accommodate the study in the imaging schedule. You will not be able to have imaging performed without this. It is imperative that you contact Stephen immediately.
- This protocol requires for research purposes 1) radiological assessments and procedures that involve radiation exposure ( X-ray, CT, PET scans) 2) nuclear medicine procedures (imaging or therapeutic) or 3) MRI scans. ( Do not check this category if these procedures and assessments will be performed as part of clinical care).\*
- This protocol involves the establishment of a human biological specimen repository. Repositories are defined as prospective collections of specimens that are processed, stored and distributed to multiple investigators for use in research.
- This protocol involves the collection of a tissue removed for clinical purposes that would routinely go to pathology.
- This protocol includes an 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.
- This protocol includes research that is conducted at a non US location.
- This protocol involves collection of blood samples other than discarded specimens.

*\*\* This must be selected if the protocol involves imaging, regardless of where the imaging may occur.*

**Nursing/Biosafety Resources**

**1 \* Will this protocol require any of the following nursing services for any research related direct care requirements?**

Yes  No

*If YES:*

**1.1 Check all that apply:**

- Assessment of physical/mental status of subjects
- Monitoring requirement non invasive
- Monitoring requirement invasive
- Additional intravenous requirements
- Collection of blood and specimens
- Frequent timed lab draws
- Accompany patients to test areas
- Patient/family education, including self and home care
- Administration of investigational drugs and other substances
- Use of new technology/equipment in study protocol
- Symptom management/intervention
- Constant supervision
- Requirements from other services that require nursing coordinator

**1.2 Specify required services.**

**2 \* Does your study involve recombinant DNA, human pathogens, biological toxins, gene transfer and/or the transplantation of animal tissues into humans?**

Yes  No

**Protocol and Appendices**

**\* All investigators must submit an experimental design and protocol with the CHERP submission. If there is a protocol from a corporate sponsor or cooperative group available and it contains the following necessary elements you may attach that. For investigator initiated research a link to a protocol outline that may be completed and attached may be found at: [CHERP Protocol Outline](#)**

**1 Upload Protocol - please be sure the protocol includes the following sections.**

- Specific Aims/Objectives
- Background and Significance

- Preliminary Studies
- Design and Methods
  - Study Design
  - Patient Selection and Inclusion/Exclusion Criteria
  - Description of Study Treatments or Exposures/Predictors
  - Definition of Primary and Secondary Outcomes/Endpoints
  - Data Collection Methods, Assessments, Interventions and Schedule (what assessments performed, how often)
  - Study Timeline (as applicable)
- Adverse Event Criteria and Reporting Procedures
- Data Management Methods
- Quality Control Method
- Data Analysis Plan
- Statistical Power and Sample Considerations
- Study Organization
- References

**Upload protocol**

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

**2 Appendix Materials:**

**2.1 Survey, questionnaires, assessments**

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

**2.2 Flow charts, schemas**

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

**2.3 Other**

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

**Method of Consent**

**1 \* Check all that apply:**

*Please note that if a waiver of parental permission is requested, both "written informed consent/assent/authorization will be obtained from subjects" and "waiver of parental permission is requested" should be selected.*

- Written informed consent/assent/authorization will be obtained from subjects.
- Informed consent/assent/authorization will be obtained through a method other than a written document (i.e. verbal).
- \*Waiver of informed consent and authorization are requested. No consent/authorization will be obtained.
- \*Waiver of parental permission is requested.
- Other method.

**Please explain any other method of consent or issue you want the IRB to review regarding consent and assent.**

*\* Please note that this option cannot be applied to FDA regulated research.*

**Drugs, Biologics or Other Products**

**Please provide information for the drug/product that will be used, administered, or applied to the subjects as the object of the study or that is relevant to the objectives of the protocol. If there is more than one drug/product, please be sure to enter each drug/product. More than one drug/product may be entered under each category.**

**1 The drug/biologic/product being administered is an investigational product (not approved by the FDA)**

Generic Name	Type of Product	Manufacturer
There are no items to display		

**2 The drug/biologic/product being administered is an FDA-approved agent but used outside of the FDA labeling in an unapproved dose, route of administration, population, disease, in concomitant medical use, etc.**

Generic Name	Type of Product	Manufacturer
There are no items to display		

**3 The drug/biologic/product being administered is FDA approved and being administered in accordance with approved labeling**

Generic Name	Type of Product	Manufacturer
There are no items to display		

**4 The drugs/biologics/products being administered does not fit into any of the above categories.**

Generic Name	Type of Product	Manufacturer
There are no items to display		

**5 Select the individuals that can prescribe the drugs listed in this protocol.**

Last Name	First Name	Employee ID
There are no items to display		

**Special Considerations - Device**

**Provide information for the device that will be used, administered, implanted or applied to the subjects as the object of the study or that is relevant to the objectives of the protocol. If there is more than one device, please be sure to enter each device under the appropriate category. More than one device may be entered under each category.**

**1 Investigational Devices (devices not approved or cleared for marketing by the FDA)**

Generic Name	Trade Name	Manufacturer
There are no items to display		

**2 FDA Approved Devices that are used for a non-approved indications or in a non-approved population or devices that have been modified /altered/ edited, reconfigured/changed/combined**

Generic Name	Trade Name	Manufacturer
There are no items to display		

There are no items to display

- 3 Devices that have been approved (PMA) or Cleared (510(k)) by FDA and used in accordance with labeling**
- | Generic Name                  | Trade Name | Manufacturer |
|-------------------------------|------------|--------------|
| There are no items to display |            |              |
- 4 Other Devices**
- | Generic Name                  | Trade Name | Manufacturer |
|-------------------------------|------------|--------------|
| There are no items to display |            |              |

#### Genetic Research Classification

- 1 \*How would you classify your genetic research? You may select more than one.**

- Gene Discovery
- Linkage Analysis
- Affected sib pair analysis
- Association Studies
- Candidate gene association studies
- Genome-wide association studies
- DNA Diagnostic Studies
- Gene Therapy Research
- Other

*If Other:*  
**Specify:**

#### Genetic Research - Page 2

- 1 \* In accordance with the Hospital's CLIA (Clinical Laboratory Improvement Amendment) license, research results of subject laboratory tests not confirmed in a CLIA approved lab (including results of genetic testing), may not be released to the subject or to the subject's physician. Will your genetic research be performed in a CLIA approved lab?**
- Yes  No

*If NO:*

- 1.1 Describe the procedures for assuring that genetic results will not be released for purposes of diagnosis or treatment.**

*If YES:*

- 1.2 Will the information be provided to subjects?**
- Yes  No

*If YES:*

- 1.2.1 Specify how this will occur. Who will release the results? Who will be given the information? What support will be available to the subject/family once the results are disseminated (i.e. genetic counseling)?**

- 2 \* Is there the possibility that incidental findings may be made (i.e. paternity, diseases, or conditions other than the one under study)?**
- Yes  No

*If YES:*

- 2.1 What will be done with this information?**

- 3 \* Describe how the data will be protected from third parties, such as employers and insurance companies?**

- 4 \* Are there psychological and/or social risks associated with the research and the results obtained?**
- Yes  No

*If YES:*

- 4.1 What are they and what steps will be taken to minimize or eliminate these risks?**

#### Genetic Research - Page 3

- 1 \* Will family members be included in the study?**
- Yes  No

*If YES:*

- 1.1 What are the confidentiality issues that must be considered during the recruitment of family members (family members may not know an individual is sick or has a specific condition)?**
- 1.2 Describe the proposed strategy for recruiting subjects/family members. The plan should ensure that prospective subjects are sufficiently protected from coercion or undue influence.**
- 1.3 Will family members be protected against the disclosure of medical or other personal information about themselves to other family members?**
- Yes  No
- 1.4 Will they be given the option to decide if they want to receive the information about themselves?**
- Yes  No

- 2 \* Will collected biological specimens (blood, tissue, DNA) be used to establish a DNA cell line?**
- Yes  No

If YES:

2.1 Please describe.

#### Placebo

- 1 \* Briefly describe the placebo (drug, device, procedure, intervention, surgery, etc.) arm used in the study. Provide a justification for use of the placebo, including the length of subject participation in the placebo arm. Please justify why the study cannot be conducted without the use of the placebo. Your justification should address whether outcomes are subjective and how use of a placebo will address this issue, if applicable.
- 2 \* Describe any commonly used diagnostic/treatment approach(es) that will be withheld from subjects assigned to the placebo arm of this study. Will subjects be denied any type of treatment or diagnostics that would be considered a current standard of care?
- 3 \* Summarize any risks to subjects in the placebo arm consequent to not receiving active treatment for their disease or condition.
- 4 \* Summarize the potential benefits from participation in this protocol for subjects in the placebo arm.
- 5 If applicable, how will the condition or disease of subjects in the placebo arm of this study be monitored compared to the monitoring associated with standard care for this disease/condition?
- 6 If applicable, what criteria will be used to determine that the participation of a subject, who may be receiving a placebo treatment, should be discontinued due to his/her worsening disease or condition?

#### Imaging

- 1 \* Does your protocol involve any of the following radiological procedures that involve radiation exposure as part of the research protocol (do NOT identify procedures that are part of the subject's required clinical care)?  
 Yes  No

If YES:

1.1 Select all that apply:

- X-rays
- Fluoroscopy / Cineradiography
- Computed Tomography (CT)
- Bone Density by X-Ray Absorptiometry (DEXA)

If you checked any of the above:

- 1.1.1 Provide a description of the imaging protocol.
- 1.1.2 Provide a detailed description of the radiation exposure involved in the study (i.e. how many additional x-rays, how much additional fluoroscopy time, etc.).
- 1.1.3 Provide a detailed breakdown as a function of age (newborn, 1y, 5y, 10y, 15y, adult) of the whole body of the radiation exposure per procedure anticipated from the research protocol expressed in units of millirem (mrem) or millisievert (msv). This may be obtained by contacting Mark Walsh, Rusty Lorenzen or Keith Strauss.

- 2 \* Does your protocol involve any imaging studies that do not involve radiation exposure as part of the research protocol (do NOT identify procedures that are part of the subject's required clinical care)?  
 Yes  No

If YES:

2.1 Select all that apply:

- MRI
- Ultrasound

- 3 \* When do you expect to begin imaging?
- 4 If a radiologist/nuclear medicine specialist is collaborating on this research, please specify the individual.
- 5 \* Does your protocol involve Nuclear Medicine Studies as part of the research protocol (do NOT identify procedures that are part of the subject's required clinical care)?  
 Yes  No

#### Human Biological Repository

Repositories are defined as collections of specimens that are processed, stored and distributed to multiple investigators for use in research. Answer these questions only if the establishment of a repository is part of the protocol. Storing remaining samples from the research is not considered a repository unless the purpose of storage is to make samples available to other investigators.

- 1 \* Enter information for each type of specimen that will be collected as part of the proposed repository and provide the pertinent information. Enter one at a time; please add additional specimens after completing the pertinent information for the selected specimen.

Specimen Category

Amount

There are no items to display

#### Human Biological Repository - Identifiable Information

- 1 \* Will any identifiers or identifiable health information about the individual from whom the human material/tissue will be obtained be temporarily or permanently recorded with or linked to the material/tissue?  
 Yes  No
- 2 \* Will you retain a link to the subject's medical record in the repository so that the individual subject's health/medical information may be reviewed in the future?  
 Yes  No
- 3 \* Duration of storage, labeling of samples: State how long you expect to maintain the repository. Describe the acquisition, logging in, and tracking of samples.

Explicitly state whether the repository will retain a key to the code linking the sample to the individual from whom the sample was obtained. Describe where the key to this code will be kept and who will have access to it. If, after obtaining identifiable tissue for a specific research goal, you plan to de-identify the remaining excess human material/tissue for further research, clarify how and when this will occur.

- 4 \* **Process for Distribution of Tissue:** Clarify the process by which other investigators may request tissue from the repository, if proposed. Describe who oversees tissue requests (e.g., an individual, group of individuals, or board), provide the process for determining the merits or acceptability of the request for tissue. Describe what materials are provided to requesting researchers. Clarify who at the repository will assess tissue requests and ensure that, where necessary, there is a current IRB-approved protocol covering the proposed research.
- 5 \* **Will samples be distributed with a unique identifier?**  
 Yes  No

If YES:

Distribution of tissue that is coded but not directly identifiable is not considered human subjects research if the recipient researcher will not seek to identify the individual from whom the tissue was obtained. However, there may be limitations as to how the samples can be used depending on the informed consent document that was signed. The recipient researcher must agree in writing to never attempt to access identifiable health/medical information or to attempt to identify the subject(s) who provided the sample(s). Such coded human material/tissue may be distributed without separate, independent IRB approval once the recipient researcher signs the agreement stating that s/he will not attempt to identify human subjects from whom the samples were derived.

Provide a copy of a formal letter or form that recipient investigators will be asked to sign for such tissue distributions.

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There are no items to display			

- 6 \* **Will subjects potentially be re-contacted by representatives of the repository?**  
 Yes  No

If YES:

- 6.1 Describe in detail:  
 (1) reasons for re-contact;  
 (2) how and when re-contact would occur, or might occur, if not obligatory;  
 (3) how subjects will provide updated contact information, if necessary;  
 (4) whether an option for "no re-contact" is possible and reasonable;  
 (5) what research information would be released to subjects or placed in medical records;  
 (6) what counseling would be provided, and what notification of subject's physicians would be undertaken, if any.

#### Pathology Specimens

- 1 \* **For those specimens that would routinely go to Pathology, please provide the following information for each category of specimen that will be collected.**
- | Tissue Type                   | Amount |
|-------------------------------|--------|
| There are no items to display |        |

[Title: irine test repository validation](#)

#### International Research

*Research conducted by Children's Hospital investigators falls under the hospital's purview and guidelines even when conducted elsewhere. If research is conducted internationally, the project must also have been approved by the local equivalent of an IRB before it can receive final approval from the Children's Hospital. When there is no equivalent board or group, investigators must rely on local experts or community leaders to provide approval. In most situations, the IRB requires documentation of this "local approval" before it gives its approval.*

- \* Describe qualifications the researcher has in relevant coursework, past experience, or training to verify his/her international/cross cultural research capabilities.
- If the investigator is working with local collaborators (Local Co-PI) please describe this arrangement. Please include information about the background and experience of the local collaborator as it pertains to this research protocol. Also describe the allocation of responsibility for the various research related activities.
- \* Provide a description of the context of cultural norms or local laws and differences with U.S. culture with respect to research, autonomy of individuals or groups, consent procedures, recruitment techniques, age of majority, requirements for parental consent, etc. Include an explanation of what cultural considerations will be required to conduct this study.
- If this research involves a population or community with limited resources, describe how the research is responsive to the health needs and the priorities of the population or community and how any intervention or product developed, or knowledge generated will be made reasonably available for the benefit of that population or community.
- \* Explain the researcher's ability to speak, read, or write the language of the potential participants. Describe the primary language(s) spoken in the community. Explain provisions for culturally appropriate recruitment and consent accommodations such as translations or involvement of native language speakers.
- \* Describe if the researcher has knowledge of or expertise in the local or state or national laws that may have an impact on this research. The researcher must understand cultural or community attitudes to appreciate laws, regulations, and norms and remain in compliance with U.S. regulations for the research as well as local requirements.
- \* Have there been any specific issues that have been identified that may represent a difference in standard practices between the local IRB and the CHB IRB? If so please describe.
- \* Describe if the researcher was invited into the community. If yes, then provide documentation of the collaboration. If not, describe how the researcher will have culturally appropriate access to the community.
- \* Provide information about the ethics committee (IRB equivalent) or other regulatory entity conducting review of the research in the host country. Provide contact information for the local entity. If this research is US federally funded, additional documentation and inter-institutional agreements will be needed. Contact the Children's Hospital IRB office for guidance.
- Describe any aspects of the cultural, political or economic climate in the country where the research will be conducted which might increase the risks for participants. Describe the steps you will take to minimize these risks.
- \* Please describe how and when the informed consent documents will be translated.

Title: irine test repository validation

**Blood Collections**

**1 Select the method(s) of blood collection.**

- 1.1  Venipuncture
  - 1.1.1  At time of clinically indicated procedure
  - 1.1.2  At time specifically for research
- 1.2  Heel/finger/ear sticks
- 1.3  From catheter or heparin lock
- 1.4  Other

If Other:

1.4.1 Please specify.

**2 \* How many individual samples will collected (not number of sticks)?**

Note: Multiple withdrawals of blood from an indwelling venous line are to be considered more than one collection.

**3 \* What is the period of time the samples will be collected (please specify in weeks or if less than weeks in days)?**

**4 \* Specify the total amount of blood collected in mls.**

**5 \* Will research subjects be less than 16.5 kg?**

Yes  No

If YES:

**5.1 Will the total amount of blood to be drawn from children less than 16.5 kg be more than 3mL/kg?**

Yes  No

Title: irine test repository validation

**Additional Documents**

**1 Please upload any additional documents if it is necessary.**

Name	Date Last Modified
There are no items to display	

Version

Owner

**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