



For Office Use Only

Received date - -

Protocol #

Meeting Date - -

PROTOCOL TITLE

PRINCIPAL INVESTIGATOR

Last Name First Name

Degree M.D. Ph.D. Other Faculty Rank

Department Section

Mail Code/Campus Mailing Address E-mail address

Campus Phone Number - - Fax Number - - Pager Unique ID# -

PRIMARY CONTACT

Investigators wishing to appoint a contact for IRB communications should complete all the information requested below.

Last Name First Name

Degree M.D. Ph.D. R.N. Other Title

Department E-mail address

Campus Phone Number - - Fax Number - - Pager Unique ID# -

CO-INVESTIGATORS/OTHER RESEARCH PERSONNEL

Please utilize supplemental forms A and B to list all participating co-investigators and other research personnel.

LEVEL OF REVIEW

FULL EXPEDITE - Attach Supplemental Form E to request expedited review

FUNDING

Internal Funding (Department Chair's signature required)

External Funding

Grant, Contract or Cooperative Group

Agency/Sponsor

TRACS ID#

Funded
(Y, N, Pending):

A copy of the entire grant application or sponsor protocol MUST be included with the submission.

Non-Cash Support from Manufacturer/Sponsor

Manufacturer/Sponsor

Type of support:

PERFORMANCE SITES

1. Identify each site other than the University of Chicago Hospital campus where research procedures will be performed (i.e., where recruitment or interaction with subjects, specimens, or data will take place).

LaRabida Children's Hospital

Friend Family Health Center *Approval from Friend Family Center will be required before initiating work at this site.*

Offsite U of C Clinic specify:

2. Is the University of Chicago the lead site for this study? **Yes *No N/A -single site (skip to pg 3)

* If no, and this is NOT a sponsored study, please attach a copy of the approval letter from the lead institution. You may then skip to page 3.

** If yes, please answer the following questions.

3. Identify below any sites other than the University of Chicago Hospitals where the research will be performed under the direction of the University of Chicago principal investigator or co-investigator.

A. Will research be performed at Weiss Memorial Hospital? * Yes No

**Approval from Weiss Hospital will be required before initiating work at this site. Please submit a copy of the approval from Weiss.*

B. Please list any additional sites where the research will be performed.

Provide certification or letter of IRB approval (non-cooperative group studies) or provide letters of cooperation or support (as appropriate). If not provided, please explain why a letter was not provided. Please attach additional pages as necessary.

1. Attached
 Letter to follow: _____
2. Attached
 Letter to follow: _____
3. Attached
 Letter to follow: _____

ADDITIONAL REVIEWS REQUIRED

Final approval by the IRB may depend upon review by other University of Chicago committees. Indicate if review and approval by these committees is necessary, and the date of approval, as applicable. Please provide documentation of review and approval. If review is required by a committee listed below and the study has not yet been submitted to that Committee, note that it should be submitted at this time.

	Review Required	Date of Approval	Protocol Number
General Clinical Research Center	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Clinical Trials Review Committee	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>
<i>Reviews research involving cancer patients, cancer treatments, or requiring support from the Cancer Research Center.</i> Note: if CTRC review is required, this review must be done prior to IRB submission.			
Pathology Sample Review Committee	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	
<i>Protocols in which the only objectives are to evaluate or study archival diagnostic specimens require review by the Pathology Biospecimen Utilization Committee. <u>Prospective</u> collection of cancer tissue for research purposes should be submitted to the CTRC. Contact Dr. Mark Lingen (mark.lingen@uchospitals.edu) for more information.</i>			
Institutional Biosafety Committee	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	<input type="text"/>
<i>Reviews the research use of biohazardous materials (biohazardous materials include recombinant DNA, agents infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi), and other genetically altered organisms and agents)</i>			
Radioactive Drug Research Advisory Committee	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<i>Reviews the use of radioactive drugs as well as the purchase and use of radioisotopes in humans (including research and routine)</i>			
Nursing Research Committee	<input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="text"/>	

PURPOSE OF STUDY

Is this a resubmission of previously-approved study? *Yes No

*If yes, complete and submit Supplemental Form R.

Please summarize the purpose of the study using non-technical language.

DESCRIPTION OF HUMAN SUBJECT POPULATION

As per 45 CFR 46, human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information (i.e., pathological specimens, medical records, etc.).

Please answer the questions below for the subject population to be enrolled at the University of Chicago site(s).

1. Number of evaluable subjects to be enrolled

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2. Estimated number of individuals to be taken through the consent process in order to obtain the desired number of evaluable subjects:

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Individuals who go through the consent process fall under the protection of the IRB even if they have no further participation in the study. Thus, please include leeway in this total number for any potential screen failures and any individuals who subsequently decline participation or otherwise drop out.

Note: *this is the number for which IRB approval will be granted, and any intention to enroll more than this number requires the approval of an amendment to the protocol prior to enrolling further subjects. Failure to submit an amendment in this instance is considered a protocol deviation.*

3. Age Range (check all that apply):

- A. 0-6 yrs. (submit parental consent form, if applicable, and Supplemental form C)
- 7-17 yrs. (submit parental consent form and child assent form, if applicable, and form C)
- 18 + yrs.

- B. Please specify the exact age range to be enrolled (i.e. 0-6 months, 18 and up, 18-24 yrs, etc.)

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4. Type of Subjects (check all that apply):

- inpatients
- outpatients
- healthy volunteers
- UC employees
- UC Undergraduate Students (Dean of Students approval is required)
- other (please specify) _____

5. Describe populations to be excluded from the research. Please describe procedures to assure equitable selection of subjects. Researchers should not select subjects on the basis of discriminatory criteria. Selection criteria that excludes one sex or racial or ethnic group requires a clear scientific rationale for the exclusion.

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6. A. Vulnerable populations to be targeted in the research (check all that apply):

- pregnant women - Supplemental form K must be included
- fetus/fetal tissue - Supplemental form K must be included
- nonviable neonates - Supplemental form N must be included
- minors under age 18, including viable neonates - Supplemental form C must be included
- wards of the State may be included
- prisoners - Supplemental form J must be included

Note: If a subject becomes a prisoner during the course of the research, this study must come back before the IRB, whether or not prisoners were previously identified as a study population.

B. Special populations to be targeted in the research (check all that apply):

- economically disadvantaged
- decisionally impaired - Supplemental form P must be included
- individuals with mental retardation
- illiterate
- Non-English speaking

A translated consent form should be prepared if written consent will be obtained.

7. Provide rationale for using special populations

Please provide a rationale for enrolling any of the groups listed in (6) above, as they require special consideration by federal regulatory agencies and/or the IRB.

SCREENING AND RECRUITMENT PROCEDURES

1. Will U of C research staff have any contact with the study subjects? **Yes *No

* If no, please attach Supplemental form W "Waiver of Consent/ Authorization" and **skip to the "Description of Study" section on page 8.**

** If yes, continue to question 2.

2. Describe how subjects will be identified for participation in this study.

3. Will advertisements be used to recruit subjects? Yes* No

*If yes, check the types of documents you will use in this process, label these documents with the type, and append these documents to the IRB application (check all that apply).

- Brochures Television
- Newspaper Internet
- Flyers or Posters Recruitment letter
- Radio Other _____

4. Do you wish to advertise this study on the University of Chicago Hospitals webpage?

Yes*

No

* If yes, please submit Supplemental form I.

5. Indicate the information that you will use or access when **pre-screening** or **recruiting** subjects for participation in a research study (check all that apply).

Names

Medical Record Numbers

Addresses

Certificate Numbers (including device serial numbers for implants)

Employers' Names or Addresses

Health Plan Beneficiary Numbers

Relatives' Names or Addresses

Member or Account Number

Dates (except for years)

Vehicle Identifiers & Serial Numbers (e.g. VINS, License Plate #)

Ages (only if >89)

Voiceprints

Telephone and /or Fax Numbers

Fingerprints

E-mail Addresses

Full face photos and comparable images

Social Security Numbers

Any other unique identifying number, characteristic or code

Describe

6. Describe who will make initial contact with the potential subject. Please note: A patient may not be approached for participation in a research study without the assent and/or involvement of the patient's treating physician.

7. Describe the individuals or entities outside of the University of Chicago to whom screening data will be disclosed (sent to or shared with), as applicable. For example, if appropriate, indicate the study sponsor or clinical research organization to whom study screening logs are sent. If information is not being shared, please state "not applicable." NOTE: Disclosures **must** be tracked through the medical records database.

8. Describe your plan to protect the identifiers that are collected during the screening period.

9. Describe your plan to destroy the identifiers collected during screening at the earliest opportunity that is consistent with the goals of the study, unless there is a clinical or research justification for retaining them.

10. Check the following box to confirm that the statement is true for your research protocol.

I will not re-use Protected Health Information collected or used during the screening period.

The PI signature at the end of this form confirms that the PI will abide by the above statement. Note that "re-use" refers to any use for which the subject has NOT consented and does not refer to the use of screening data during the enrollment portion of the study.

11. Address why the research could not practicably be conducted without obtaining PHI prior to consenting of subjects. In addition, describe why the screening PHI is necessary for this research.

INFORMED CONSENT PROCESS

Simply giving a consent form or reading a consent script to a potential subject does not constitute informed consent. The following questions pertain to the process of informed consent.

1. How will informed consent be obtained from potential study participants?

Oral consent script

Complete and submit Supplemental form O, "Oral/Alteration of Consent/Authorization."

Written informed consent form

Attach the written consent form to be used in this study. Consent forms should be written in simple declarative sentences and be jargon free. Foreign language versions should be prepared for applicable research. The current consent form template is available on the IRB web site (<http://ors.bsd.uchicago.edu/IRB/>).

2. Will adult subjects have the capacity to give informed consent? Yes No*

*If not, describe the likely range of impairment and explain how, and by whom, capacity to consent will be determined. Individuals who lack the capacity to consent may participate in research only if a legally authorized representative gives consent on their behalf or the Illinois Surrogate Act is followed. Please submit Supplemental Form P if proxy consent will be sought.

3. How will you determine whether the subject understands the study? Throughout the course of the study, how will you continue to ensure the subject understands the study?

4. In relation to the actual data gathering, when, where, and by whom will consent be discussed and documentation obtained? (pre-operatively or several days before study procedures commence? by the PI or by the PI's nurse and certain members of the research team?) Please be specific.

DESCRIPTION OF STUDY

1. Does this research involve the use of any **DRUGS**? Yes* No

*If yes, complete and submit Supplemental Form D, the investigational brochure or package insert, and Supplemental Form Q.

2. Does this research involve the use of any **DEVICES**? Yes* No

*If yes, complete and submit Supplemental Form F and the investigator's brochure.

3. Does this research involve the use of **RADIOISOTOPES** or **RADIOACTIVE AGENTS**? Yes* No

*If yes, complete and submit Supplemental Form H.

4. Does the study involve blood drawing, marrow biopsy sampling, biopsy of other tissues, etc? Yes* No

*If yes, state how much and how often the samples are taken. In addition, clarify whether the samples would retain identification that could be linked to study subjects.

5. Will material be collected for **GENETIC ANALYSIS**? Yes* No

*If yes, complete and submit Supplemental Form G.

6. Describe the tasks/tests or procedures subjects will be asked to complete or undergo using non-technical language. (Suggestion: explain step by step what the subjects will be asked to do and distinguish those which are experimental from those which comprise routine clinical care.)

If subjects are not actively participating in the research (for example, this is a tissue collection protocol or a chart review), describe what will be done with tissues and/or data as well as how it will be obtained.

7. Does the research involve (Check all that apply):

- any surgical procedure
- administration of physical stimuli
- changes in diet or exercise
- possible invasion of privacy of subject or family
- deprivation of physiological requirements such as nutrition or sleep
- manipulation of psychological or social variables
- collection of personal or sensitive information in surveys or interviews
- use of a deceptive technique
- materials that subjects might consider offensive, threatening or degrading
- use of biohazardous materials *Note: IBC review is required on studies involving biohazardous materials*
- Other risks (specify):
- HIV/AIDS testing

Note that if your study involves testing for HIV status, either as part of screening procedures or during the study, all applicable federal, state, and local regulations concerning HIV/AIDS testing will apply. In addition, the consent form must include a statement describing the disclosure to the state of Illinois of positive HIV test results, which are linked with name, SSN#, and other PHI.

8. Indicate the Protected Health Information that will be collected about study subjects **DURING** participation in this study and/or information collected during screening that would **continue** to be used after screening.

- | | |
|--|---|
| <input type="checkbox"/> Names | <input type="checkbox"/> Medical Record Numbers |
| <input type="checkbox"/> Addresses | <input type="checkbox"/> Certificate Numbers (including device serial numbers for implants) |
| <input type="checkbox"/> Employers' Names or Addresses | <input type="checkbox"/> Health Plan Beneficiary Numbers |
| <input type="checkbox"/> Relatives' Names or Addresses | <input type="checkbox"/> Member or Account Number |
| <input type="checkbox"/> Dates (except for years) | <input type="checkbox"/> Vehicle Identifiers & Serial Numbers (e.g. VINS, License Plate #) |
| <input type="checkbox"/> Ages (only if >89) | <input type="checkbox"/> Voiceprints |
| <input type="checkbox"/> Telephone and /or Fax Numbers | <input type="checkbox"/> Fingerprints |
| <input type="checkbox"/> E-mail Addresses | <input type="checkbox"/> Full face photos and comparable images |
| <input type="checkbox"/> Social Security Numbers | <input type="checkbox"/> Any other unique identifying number, characteristic or code |

Describe

RISKS OF THE RESEARCH

- 1. Identify the risks (current and potential) and describe the expected frequency, degree of severity, and potential reversibility. Include any potential late effects. Also, include any non-physical risks (risks to employment, loss of confidentiality, etc.)**

2. Describe the precautions taken to minimize risk, including rescue provisions.

3. Why are the identified risks reasonable?

Please justify the risks in relation to the anticipated benefits to the subjects and in relation to the importance of the knowledge that may reasonably be expected to result from the research.

DATA AND SAFETY MONITORING PLAN

1. Is there a data safety monitoring board/committee to review this study for safety and adherence to the study protocol? Yes No

NOTE: Regardless to the response to this question, all subsequent questions in this section MUST be addressed.

2. Provide a general description of the data and safety monitoring plan which must include, at a minimum, a description of the reporting mechanism of serious/ unexpected adverse events to the IRB, the study sponsor (if applicable) and the FDA.

3. Describe plans for monitoring the progress of the study and the safety of study participants (e.g. timing of data and safety monitoring reviews and reports planned interim analysis, etc.).

CONFIDENTIALITY

1. Where will the data be kept and for how long? If audio or videotapes will be used, how will they be disposed of?

2. Describe provisions made to maintain confidentiality of data. Who will have access to raw data? Will raw data be made available to anyone other than the Principal Investigator and immediate study personnel? If yes, who, how, and why? Describe the procedures for sharing data. Describe how the subject will be informed that the data may be shared.

BENEFITS OF PARTICIPATION

List any anticipated direct benefits of participation in this research project. If none, state that fact here and in the consent form. Remuneration should not be described as a benefit.

ALTERNATIVES TO PARTICIPATION

List appropriate alternative clinical procedures or courses of treatment available to subjects. If there is a standard of care alternative, please describe this in detail. If there are no clinical alternatives, please state that participation is voluntary.

COMPENSATION FOR PARTICIPATION

1. Will subjects be paid or otherwise compensated for participation?

Yes*

No**

** If yes, please continue to answer questions 2, 3, and 4 of this section.*

***If no, please skip to the "Costs" section.*

2. What gifts, compensation, travel money or other reimbursement will be given to the subjects?

Please provide a dollar amount if applicable.

3. When will subjects receive compensation?

4. Please either describe a plan for prorating payments if a subject withdraws from the study early or provide a justification as to why prorated payment is not being offered.

COSTS

1. Will the subjects be charged for research-related procedures? *Yes No

For example, will subjects be charged for extra tests related to the research, i.e., implantation of a Humanitarian Use Device? *Note that in general, subjects should NOT be charged for procedures that are specific to the research and are not part of their standard of care. Please contact the Office of Clinical Research for questions about research billing.*

*If yes, please explain the charges.

2. Will any routine costs be billed to the subject or third party payor? *Yes No

* If yes, please specify below by checking all that apply.

- Items or services that are typically provided absent a clinical trial (e.g. conventional care)
- Items or services required solely for the provision of the investigational item or service (e.g. administration of a noncovered chemotherapeutic agent)
- Clinically appropriate monitoring of the effects of the item or service, or the prevention of complications
- Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service: in particular, for the diagnosis or treatment of complications, not including research-related injuries

3. Are there any costs indicated above that are considered experimental by the Centers for Medicare & Medicaid Services and therefore not likely to be covered or reimbursable by the subject's health insurance? *Yes No

Note that the consent form must disclose to subjects that there may be charges which, because of their experimental nature, cannot be billed to or be reimbursed by their insurance.

*If yes, please specify these costs below.

4. Will any costs (research items or services) be billed to the study account? *Yes No

*If yes, please specify these costs below.

CONFLICT OF INTEREST

Is there a potential conflict of interest of any member of the investigative staff associated with this protocol? Yes* No

* Please explain in a separate letter to the Committee the conflict associated with the P.I. or any other participant.

If you have questions about what constitutes a conflict of interest, please contact University Research Administration (URA) or see the "Financial Conflict of Interest" section on the URA website (<http://researchadmin.uchicago.edu>).

If yes, has this been disclosed to University Research Administration (URA)? Yes **No

** If no, please note that any conflict of interest **must** be disclosed to URA. If it has not previously been disclosed, contact URA.

LITERATURE REVIEW

Please include your protocol bibliography or attach the results of a literature search which justifies the involvement of human subjects in this research project.

OTHER MATERIALS

Please ensure all corresponding materials are enclosed in your protocol submission, including a separate protocol document. See the "Protocol Application Contents" section of the IRB Policy and Procedure Manual for a complete description (available on the IRB web site).

INVESTIGATOR'S ASSURANCE

I certify that the information provided in this application is complete and correct.

As Principal Investigator, I have ultimate responsibility for the protection of the rights and welfare of human subjects, conduct of the study, and the ethical performance of the project.

I agree to comply with all University of Chicago policies and procedures, as well as with applicable federal, state and local laws regarding the protection of human subjects in research, including but not limited to, the following:

- * The protocol will be performed by qualified personnel according to the University of Chicago IRB approved protocol,
- * No changes will be made in the protocol or consent form until approved by the University of Chicago IRB,
- * Legally effective informed consent will be obtained from human subjects if applicable, and
- * Adverse events will be reported to the IRB per the IRB Adverse event reporting policy.

I further certify that the proposed research is not currently being conducted and will not begin until IRB approval has been obtained.

Principal Investigator

- -

Date

DEPARTMENT CHAIR SIGNATURE

The signature of the Department Chair is required when the study is not externally funded.

Department Chair

- -

Date