

**ST. VINCENT HOSPITAL RESEARCH & REGULATORY AFFAIRS  
RESEARCH DESCRIPTION FORM**

THIS FORM MUST BE NEATLY TYPED. (DO NOT TYPE ON THE REVERSE SIDE OF ANY FORMS). **Note:**  
**To check a box on this form, double-click the box and select “Checked” under “Default Value.”**

RESEARCH PROPOSAL TITLE:  
IRB STUDY NUMBER:

**SECTION I: STUDY DESCRIPTION**

A. Succinctly describe the general purpose and nature of the research in lay terms.

**SECTION II: SUBJECT POPULATION**

A. State the number of subjects to be recruited both locally and nationally and number of research study sites (if a multi-center study). List total as a single number, rather than a range.

B. Check all that apply:

- Minors                       Pregnant Women                       Cognitively Impaired                       Prisoners  
 Economically/Educationally Disadvantaged                       Students/Residents/Fellows  
 None of the above (Go to section III)

If any of the above subject populations are being used, state the necessity for doing so:

If the study involves *minors*, indicate below in which category the research belongs and state the rationale for that category's selection:

**Category 1 (§46.404):** Research not involving greater than minimal risk to children. Explain how adequate provisions are made for soliciting the assent of the children and the permission (informed consent) of their parents or guardians.

**Category 2 (§46.405):** Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child. Explain why the anticipated benefit justifies the risk and why the relation of the anticipated benefit to the risk is at least as favorable as that of alternative approaches and explain how adequate provisions are made for soliciting the assent of the children and the permission (informed consent) of their parents or guardians.

**Category 3 (§46.406):** Research involving greater than minimal risk and no prospect of direct benefit to the individual child, but likely to yield generalizable knowledge about the child's disorder or condition. Explain why the risk represents only a minor increase over minimal risk, why the intervention or procedure presents experiences to the children that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations, and why the intervention or procedure is likely to yield generalizable knowledge about the children's disorder or condition which is a vital importance for understanding or amelioration of the disorder or condition, and explain how adequate

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provisions are made for soliciting the assent of the children and the permission (informed consent) of their parents or guardians.\*

**Category 4 (§46.407):** This category should be utilized in any instance where minors will be involved with research that does not fall under any of the above categories. Any research falling under this category will have to be reviewed separately under HHS prior to approval. This is per 45 CFR 46.407 which reads: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. In order to allow the IRB and HHS to evaluate the impact on children, please explain why the proposed research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and explain the risks involved.\*

\* NOTE. When research is covered by categories §46.406 and §46.407, the informed consent must be obtained from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

### SECTION III: RECRUITMENT & COMPENSATION

#### A. Recruitment

1. Describe how potential subjects will be initially identified:
  - Databases
  - Medical records
  - Advertisements
  - Newsletters
  - Self-referral
  - Physician referral
  - Clinics/office
  - Other – Describe:
  
2. Describe how potential subjects who are identified will be contacted:
  - Letter
  - Phone call
  - Face-to-Face
  - Other – Describe:
  
3. Who will be contacting them
  - Physician
  - Research Coordinator
  - Nurse
  - Other – Describe:
  
4. List and include a copy of all recruitment material to be shared with potential subjects

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## B. Compensation

1. Will subjects be compensated for participation in the study (e.g. payment, free services, gifts, course credit, including extra credit)?  
 No. Proceed to Section IV.  
 Yes. Complete items 2, 3, and 4 below.
2. Explain the compensation arrangements (e.g. amount and timing of compensation and the proposed method of disbursement), including reimbursement of expenses.
3. Justify the proposed compensation arrangements described in section 2. (e.g., how this proposed compensation arrangement is not considered to be coercive).
4. Explain if there will be any partial compensation if the subject withdraws prior to completion of the study.

### SECTION IV: STUDY PROCEDURES

Provide a brief description of all procedures being performed solely for research purposes. Examples would include an investigational drug, a blood draw that is taken purely for research (not treatment purposes) or a standardized survey that is being completed solely for the purposes of this research. This section will be similar to the corresponding section of the informed consent.

### SECTION V: POTENTIAL RISKS

State the potential risks – for example, physical, psychological, social, legal, loss of confidentiality or other – connected with the proposed procedures.

### SECTION VI: STUDY BENEFITS

- A. What, if any, benefit is to be gained by the SUBJECT?
- B. What information may accrue to SCIENCE or SOCIETY, in general, as a result of this work?

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**SECTION VII: CONFIDENTIALITY & SAFEGUARDS**

- A. Check the items below to explain how confidentiality and privacy of data collected for the purpose of the research study will be protected. Keep in mind that all members of the research team should only gather or share the minimum amount of PHI needed for the study.

**1. Data Source (Please check all that apply)**

- a.  Treatment or Test Results, Medical and/or Dental Records, etc.:
- Paper
  - Film
  - Electronic
- b.  Interviews (Phone or Face-to-Face)
- c.  Survey or Questionnaire
- Paper
  - Electronic
- d.  Video
- e.  Audio
- f.  Photographs
- g.  Other (Please describe): \_\_\_\_\_

**2. Data Recording / Collection Method (Please check all that apply)**

- a.  Computer:
- Laptop
  - Hard Drive
  - Local Shared Drive
  - Web-based
  - CDs, Floppy Disks, etc.
  - Other (Please describe): \_\_\_\_\_
- b.  PDA (Personal Digital Assistant)
- c.  Paper (e.g. Notes, Case Report Form, etc.)
- d.  Video
- e.  Audio
- f.  Other (Please describe): \_\_\_\_\_

**Please describe how you will safeguard data for all the Data Recording / Collection Methods described in VIII.A.2. by completing #3, #4 and #5 below. Please check all that apply.**

**3. Secure Storage**

- a. Who will have access to the individually identifiable information/data?
- |   |  |   |
|---|--|---|
| <input type="checkbox"/> Principal Investigator | <input type="checkbox"/> Research Coordinator                                    | <input type="checkbox"/> Co-Investigators |
| <input type="checkbox"/> Governmental Agencies  | <input type="checkbox"/> Research Sponsor, Monitor, Other Research Organizations |   |
- Other (Please describe – e.g. BioStats, outside multi-center collaborators, or other colleagues not listed as sub-investigators , etc.): \_\_\_\_\_
- b. Please describe the measures you are taking to safeguard the information/data:
- Locking cabinets and doors
  - Information is located in an area with limited public access
  - Computers and/or files will be password-protected
  - PDAs and removable media (such as CDs, diskettes, etc...) will kept in a secure location
  - Regular back-ups of electronic data. **NOTE: All electronic data should be backed up on a regular basis.**

Describe any other measures you are using to safeguard the data: \_\_\_\_\_

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#### 4. Secure Disposal

- a. How long will you retain the data before discarding?
- Minimum of 3 years for non-health data
  - Minimum of 7 years for health data, per Indiana State law
  - Per sponsor requirements
  - Indefinitely
  - Other (Please describe): \_\_\_\_\_
- b. How will you discard the data?
- Paper will be shredded  Delete files from or destroy diskettes and CDs\*
  - Permanently delete data from computers and PDAs\*  Other (Please describe)
- \_\_\_\_\_

#### 5. Sharing Data

For this purpose, sharing may include releasing, transmitting or providing access to research and health data within the research team, to research sponsors, etc. You must use reasonable safeguards when sharing any form of research data, health or non-health.

- a. Will you share data in any of the following formats?
- Non-Health Data only.
  - De-identified Data.
  - Identifiable Data (i.e. includes patient identifiers, names, initials, Subject ID numbers, etc. - Please answer items 1. and 2. below.)
1. Indicate which secure method(s) of transmission will be used? Check all that apply:
- Secured web site
  - Encrypted email
  - US Postal Service or other trackable courier services (not campus mail)
  - Fax in a secured area
  - Shared drive with password protection
  - Personal delivery by authorized research personnel
  - Private telephone conversation to authorized personnel
  - Other: (describe)
2. Will you share identifiable health data with anyone not listed as a sub investigator or sponsor?
1.  No – Proceed to Section IX.
  2.  Yes – Please list those individuals or entities: \_\_\_\_\_
- Data will not be shared – Please explain: \_\_\_\_\_

### SECTION VIII: FEDERAL FUNDING

- A. Has a proposal for funding been submitted to or is this study funded by a federal agency (e.g. NIH, CDC, etc.)?
- No. Proceed to Section XIV.
  - Yes. Provide one copy of the *entire funding proposal* or explain why one is not needed (e.g. the investigator is not the direct recipient of the grant money [federal pass-thru]):
- B. Is this study a National Institutes of Health (NIH) multi-center clinical trial that includes an NIH-approved sample informed consent?
- No.
  - Yes. Provide a copy of the NIH-approved sample consent document.

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**SECTION IX: GENE THERAPY**

A. Does this study involve the use of gene therapy or recombinant DNA?

- No.  
 Yes.

B. If the study involves the use of gene therapy or recombinant DNA please provide a description of biomedical materials involved and the need for pharmacy support: \_\_\_\_\_

**SECTION X: FINANCIAL CONFLICT OF INTEREST**

A. Do any of the investigators listed under Section XII. of this document have a significant financial interest associated with the conduct of this study? (A significant financial interest is defined as either (1) an equity interest that exceeds \$10,000 or represents more than a 5% ownership interest in any one enterprise or entity, when aggregated for the Faculty or Staff Member and his or her Family Members; or (2) salary, royalties, or other payments expected to exceed \$10,000, when aggregated for the Faculty or Staff Members and his or her Family Members over the twelve months following the date of disclosure)

- No  
 Yes. List names of individuals with such financial interest: \_\_\_\_\_

**SECTION XI: INVESTIGATIONAL DRUGS/DEVICES**

N/A

A. Drugs

Name of Drug Sponsor: \_\_\_\_\_

Name of Drug: \_\_\_\_\_

IND Number: \_\_\_\_\_

Study Phase:  I  II  III  IV  Registry  Other – Describe: \_\_\_\_\_

If this study involves the investigational use of a marketed drug or biologic, and in the opinion of the investigator does not require submission of an IND, six conditions must be met (e.g. responses to conditions listed below must be “yes” for an IND to not be required). Please respond to the following conditions:

- |  | No                       | Yes                      |
|--|--------------------------|--------------------------|
| ▪ The study is not intended to be reported to FDA in support of a new indication for use or to support any other significant change in the labeling for the drug.  | <input type="checkbox"/> | <input type="checkbox"/> |
| ▪ The study is not intended to support a significant change in the advertising for the product.  | <input type="checkbox"/> | <input type="checkbox"/> |
| ▪ The study does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the drug product. | <input type="checkbox"/> | <input type="checkbox"/> |
| ▪ The study is conducted in compliance with the requirements for IRB review ( <a href="#">21 CFR 56</a> ) and informed consent ( <a href="#">21 CFR 50</a> ).  | <input type="checkbox"/> | <input type="checkbox"/> |
| ▪ The study is conducted in compliance with the requirement concerning the promotion and sale of drugs ( <a href="#">21 CFR 312.7</a> ).   | <input type="checkbox"/> | <input type="checkbox"/> |
| ▪ The study does not intend to invoke <a href="#">21 CFR 50.24</a> (Exception from informed consent for emergency research).   | <input type="checkbox"/> | <input type="checkbox"/> |

B. Device

Name of Device Manufacturer: \_\_\_\_\_

Name of Device: \_\_\_\_\_

IDE Number: \_\_\_\_\_

Type: \_\_\_\_\_

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The IRB is required to determine whether or not the device is significant risk. To help in this determination, please provide the sponsor's documentation on the risk assessment and the rationale used in making the risk determination. ***Please provide the investigator's assessment of the device risk below:***

Significant Risk

Non-significant Risk

Risk assessment and rationale for above risk determination:

<b>SECTION XII: INVESTIGATORS</b>
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List the principal investigator and any co-investigators and their respective departments. (If there are multiple investigators, please indicate only one person as the principal investigator; others should be designated as co-investigators).

A. Principal Investigator: Department

B. Co-investigators: (Please include the respective department)

List those directly interacting or intervening with subjects (including persons obtaining consent):

Name

Department

C. List other co-investigators who are not directly interacting or intervening with subjects:

D. If this study is a collaboration with investigators at unaffiliated institutions, and our IRB is providing the review and approval for their role in the study, list all such co-investigators,\* their respective institutions, and specify their role and what procedures they will be performing:

Name of Co-investigator

Institution

Role

Procedures performed