##### INDIANA UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB)

# SUMMARY SAFEGUARD STATEMENT

IRB STUDY NUMBER:

PRINCIPAL INVESTIGATOR:

DOCUMENT DATE:

[to be assigned by IRB]

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.”**

STUDY TITLE:

*Please type only in the gray boxes. To mark a box as checked, double-click the box, select “checked”, and click “OK”.*

## Section I: Study Description

A. Please describe (in lay terms) the general objective(s) of the proposed research, including research question(s), hypothesis, and a short summary of the main interactions/interventions. If appropriate, describe any usual methods, that were considered, but not chosen, and why.

## Section II: HIPAA

A. Are you part of a covered entity or are you involving a covered entity in your research? Please review the **Covered Entity Checklist** for guidance.

No. You are not subject to HIPAA. For additional information, please see the **Covered Entity Checklist** available on the IU Human Subjects Office website. Proceed to Section III.

Yes. Continue below:

B. Will protected health information (PHI) be utilized, accessed, collected, or generated as part of the study? For additional guidance on PHI, please refer to the definitions in the Standard Operating Procedures document.

No. Your research is not subject to HIPAA. However, will health information (that is not PHI) be used that is:

De-identified?

Part of a Limited Data Set?

Health information will be received from a separate covered entity from that of the investigator. You must establish a data use agreement with the entity providing the health information.

Health information will be obtained from within the investigator’s own covered entity. No data use agreement is required.

No health information will be utilized in any form.

Yes. Your research is subject to HIPAA. Complete the HIPAA & Recruitment Checklist.

## Section III: Test Articles

1. Does this research involve *the* *study of* any **DRUGS or BIOLOGICAL PRODUCTS**? (at least one objective of the study is related to obtaining data about the drug or biological product)

* **DRUG**: a substance manufactured via chemical process and intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease OR (other than food) intended to affect the structure or any function of the body of man.
* **BIOLOGICAL PRODUCT**: a substance manufactured via biological process and otherwise meets the above definition of a drug; includes a wide range of products such as vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins. (Hereafter, the use of the term ‘drug’ includes a biological product.)

**NOTE**: You should answer YES to this question regardless of the FDA approval status of the drug(s) (e.g. approved, commercially available, lawfully marketed, investigational, compassionate use, etc.). Also, answer YES for open label extension, treatment, or emergency use studies.

No.

Yes.

1. This study involves a drug(s) for which at least some aspect of the drug’s(s’) administration is dictated by the protocol. (e.g. randomization to determine the drug(s) administered; protocol dictates the route, dose, timing, etc.)

No.

Yes. Please list all drugs being studied **AND** complete a Drug or Biological Product Form for each drug listed:       (This study is considered FDA regulated.)

1. Does this research involve *the* *study of* any medical **DEVICES**? (at least one objective of the study is related to obtaining data about the medical device)

* **DEVICE**: an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, OR intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

**NOTE**: You should answer YES to this question regardless of the FDA approval status of the device(s) (e.g. approved, cleared, 510(k) clearance, commercially available, investigational, compassionate use, Humanitarian Use Device, in vitro, non-invasive diagnostic, custom, etc.).

No. **(**If this study involves the use of an HUD that is NOT part of a clinical investigation, a full IRB application is not

required. Please submit the Summary Safeguard Statement – HDE.)

Yes.

1. This study involves a device(s) for which at least some aspect of the device’s(s’) use is dictated by the protocol. (e.g. randomization to determine the device(s) to be used, method of use, timing, frequency, device settings, etc.)

No.

Yes. (This study is considered FDA regulated.)

* 1. Does this study involve an in vitro diagnostic device which is being studied using leftover human specimens that are not individually identifiable?

No. Complete item b.

Yes. Please complete the Request to Conduct Research without Consent: In Vitro Diagnostic Devices Using Leftover Human Specimens that are Not Individually Identifiable and continue to Section IV.

* 1. Please listall devices being studied **AND** complete a Medical Device Form for each device listed:      .

## Section IV: Performance Site

Indiana University

IUB Campus. Please state school/department/location(s):

IUPUI Campus. Please state school/department/location(s):

Bradford Woods

Center for Survey Research

Center for Evaluation & Education Policy (CEEP)

Indiana CTSI Clinical Research Center\*

Indiana Institute on Disability and Communication

IU Simon Cancer Center\*

Krannert Institute of Cardiology\*

Kinsey Institute

Oral Health Research Institute

Other:

Health & Hospital Corporation of Marion County

Bell Flower Clinic

Midtown Mental Health\*

Wishard Memorial Hospital\*

Community Health Clinics/Centers

Hospital/ER

Non-primary care

Wishard Specialty Clinics

OB/GYN Clinics

Indiana University Health Facilities

Bloomington Hospital

Beltway Centers

Central Indiana Cancer Centers

Methodist Hospital

Methodist-Affiliated Centers/Private Practices

Neuroscience Center

North Hospital

Riley Hospital for Children

Saxony Hospital

University Hospital

West Hospital

Other:

IU Health Clinics. Please list location:     .

IU Medical Group Specialty Clinic (IUMG-SC). Please list location:     .

Larue Carter Hospital

Monroe County Community School Corporation. Please list school:     .

Regenstrief Institute

Rehabilitation Hospital of Indiana

Richard L. Roudebush Veterans Affairs Medical Center\*. (Complete the Request Form for VA Research)

Other:

*\* Additional information and/or approvals may be required prior to submitting and/or initiating the research. Please see the IU Human Subjects Office website and check with the specific performance site for additional information.*

Please list other facilities not under the direct supervision of the investigator where research-related procedures will be performed (e.g. pathology, nursing, pharmacy, radiology, counseling). **\***

**You must ensure these persons/facilities are kept adequately informed about the study and their research-related duties and functions as they relate to the protection of human participants.**

## Section V: Subject Population

A. **Subject Population**. Check all subject population categories below for which there is a reasonable expectation of enrollment into this research study:

**Children** (Complete the Request Form for the Inclusion of Children in Research)

**Cognitively Impaired** (Complete the Request Form for the Inclusion of Cognitively Impaired Individuals in Research)

**Economically/Educationally Disadvantaged**

**Pregnant Women, Human Fetuses, or Fetal Material** (Complete the Request Form for the Inclusion of Pregnant Women, Human Fetuses, and Neonates in Research)

**Prisoners** (Complete the Request Form for the Inclusion of Prisoners in Research)

**Subjects Outside of U.S. Targeted for Enrollment** (Complete the Transnational Research Information Form)

**Veterans** or research funded by the VA, utilizing VA effort, property or resources, or enrolling VA patients. (Complete the Request Form for VA Research)

**Students**. When there is a teacher-student relationship dynamic, complete the following questions:

1. Clarify the necessity for involving students in the research:
2. Explain how the possibility of coercion or undue influence will be minimized when informed consent is being sought:
3. Explain what genuinely equivalent alternatives are available for students who wish not to participate:

B. **Inclusion/Exclusion**. List specific eligibility requirements for subjects, including those criteria which would exclude otherwise acceptable subjects (e.g. inclusion/exclusion criteria).

1. **Number of Subjects**. State the number of subjects to be involved in the research (i.e. number of subjects who will receive research intervention, or about/from whom information or specimens will be collected) both locally and nationally (if a multi-center study).

**NOTE:** The number provided will be the maximum number of subjects approved to participate in this research.

## Section VI: Recruitment

**NOTE:** Study information will be released to the Clinical and Translational Science Institute (CTSI) for the research study listing. To opt out of this listing requirement you will need to get opt-out approval from Dr. Anantha Shekhar, PhD, MD, Director of Indiana CTSI, prior to IRB submission. For additional information or to request opt-out approval, please contact Patrick McGuire at (317) 278-2176 or [pacmcgui@iupui.edu](mailto:pacmcgui@iupui.edu).

A. Is this research subject to HIPAA? (refer to Section II above)

Yes. Do not answer questions 1-3 below. Instead, complete the **HIPAA &** **Recruitment Checklist**.

No. Answer questions 1-3 below.

1. Describe how potential subjects will be initially identified (include specific source, e.g. databases, medical records, advertisements, newsletters, self-referral, physician referral, from clinics, etc.):

2. Describe how potential subjects who are identified will be contacted (e.g. letter, phone call, face-to-face) and who will be contacting them (e.g. their physician, research coordinator, nurse, etc.). Include a copy of all information to be shared with or intended to be seen by potential subjects.

3. Is the investigator currently conducting competing studies? Competing studies refers to two or more studies which utilize overlapping or very similar eligibility criteria.

No.

Yes. Please describe the plan to ensure fair and unbiased recruitment:

**NOTE**: Allowing the Principal Investigator or the subject to choose one study over another is rarely acceptable. Consider randomization procedures or exclusive enrollment in one study at a time.

## Section VII: Study Procedures

List all methods by which information or data about or from subjects will be obtained, including any drugs or devices to be used on human subjects and all procedures/interventions that are being performed that would not otherwise be performed outside of the research study [e.g. 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]. Describe the frequency and duration of the procedures.

**NOTE:** Please include all surveys, instruments, survey/focus group questions, etc. that will be used for this research.

## Section VIII: Risk/Benefit Ratio

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

1. State the potential benefits to be gained by the **SUBJECT**.

1. State the potential benefits or information which may accrue to **SCIENCE** or **SOCIETY**, in general, as a result of this work.

1. Explain how the potential risks to subjects are reasonable in relation to anticipated benefits.

## Section IX: Protection Procedures

1. Describe procedures for protecting against, or minimizing, the potential risks described in Section VIII, including using procedures that are already being performed on subjects for diagnostic, treatment, or standard purposes, when appropriate.

1. Explain provisions to protect privacy interests of subjects. This refers to how access to subjects will be controlled (e.g. time, place, etc. of research procedures).

1. Is this a multi-center study?

No. Continue to the next section.

Yes. Is the PI the lead investigator?

No. Continue to the next section

Yes. Describe the plan for the management and communication of multi-site information that may be relevant to the protection of participants (e.g. unanticipated problems, adverse events, interim analysis, modifications, etc.).

## Section X: Data Safety Monitoring Plan

For all research that is **greater than minimal risk**, a Data Safety Monitoring Plan (DMSP) must be developed. This is a plan to assure the research includes a system for appropriate oversight and monitoring of the conduct of the study to ensure the safety of subjects and the validity and integrity of the data.

N/A. The research is minimal risk.

The DSMP is contained in the protocol. State where in the protocol the description is located:

NOTE: Ensure that all points outlined below are addressed in the description in the protocol. If any points are not addressed, within the protocol, they should be addressed below.

The DSMP is NOT contained in the protocol; however, this is a repository/database protocol and the primary risk is that of loss of confidentiality; thus, I do not need to complete this section.

The DSMP is NOT contained in the protocol. Complete the questions below.

|  |
| --- |
| 1. **Who will be responsible for the data and safety monitoring?** (Examples include: a DSMC or DSMB, medical monitor, investigator, independent physician) **Clarify if this individual or committee is independent from the sponsor and/or investigator.** |
|  |
|  |
| 1. **What will be monitored.** (Examples include: data quality, subject recruitment, accrual, and retention, outcome and adverse event data, assessment of scientific reports or therapeutic development, results of related studies that impact subject safety, procedures designed to protect the privacy of subjects) |
|  |
|  |
| 1. **What are the procedures for analysis and interpretation of data, the actions to be taken upon specific events or endpoints, the procedures for communication from the data monitor to the IRB and site, and other reporting mechanisms?** |
|  |
|  |
| 1. **What is the frequency of monitoring?** (The appropriate frequency of data and safety monitoring will be dependent on the nature and progress of the research; however, monitoring must be performed on a regular basis (e.g, at least annually). |
|  |
|  |
| 1. **What information will be reported to the IRB?** (Minimally, the IRB requires the following information at the time of continuing review: 1) frequency and date(s) of monitoring; 2) summary of cumulative adverse events; 3) assessment of external factors (i.e. scientific reports, therapeutic developments, results of related studies) that impacted the safety of subjects; 4) summary of subject privacy and research data confidentiality outcomes; and 5) any changes to the risk-benefit ratio. |
|  |

## Section XI: Payment for Participation

A. Will subjects be paid for participation in the study (e.g. monetary, free services, gifts, course credit, including extra credit)?

No. Proceed to next section.

Yes. Complete items 1-3 below.

1. Explain the payment arrangements (e.g. amount and timing of payment and the proposed method of disbursement), including reimbursement of expenses. **NOTE:** Payments must accrue and not be contingent upon completion of the study. However, a small payment (bonus) for completion of the study may be approved by the IRB if it is found to not be persuasive for the subjects to remain in the study.

1. Justify the proposed payment arrangements described in section B. (e.g., how this proposed payment arrangement is not considered to be coercive).

1. Explain if there will be any partial payment if the subject withdraws prior to completion of the study (e.g. prorated). Note: This payment may be paid at the end of the subject’s participation or at the end of the study.

## Section XII: Informed Consent Process

**Check here if this study will only enroll children and the parental/guardian permission (consent) process has already been explained on the Request Form for the Inclusion of Children in Research. You do not need to complete sections A-D below. Continue to Section XIII.**

**Check here if this study meets the criteria listed on the Request to Conduct Research without Consent: In Vitro Diagnostic Devices Using Leftover Human Specimens.** **You do not need to complete sections A-D below. Continue to Section XIII.**

**A. I WILL be obtaining informed consent from all subjects.**

1. **When (in what timeframe) and where (what setting) will consent take place?** Indicate any waiting period between informing the subject and obtaining consent. The timeframe and any waiting should ensure the prospective subjects or their legally authorized representatives are provided sufficient opportunity to consider whether or not to participate in the study.

2. **Who will be responsible for obtaining initial and ongoing consent?** **(check all that apply)**

Principal Investigator

Co-Investigator

Other (specify):

**NOTE:** Individuals who will be obtaining consent must be listed on the Investigator List.

a. **Explain how these individuals will be adequately trained to conduct the consent interview and answer subject’s questions (check all that apply):**

Passed the required Collaborative Institutional Training Initiative (CITI) modules

Attended the Research Coordinator Education Program (RCEP)

Attended the Research Coordinator Certification Program (RCCP)

Received study-specific training from study personnel

Other (specify):

**b. Indicate in what language(s) the consent interview will be conducted.**

English

Spanish

Other (specify):

**c. If the consent interview will be conducted in a language other than English, state how the interview will be conducted (e.g. use of an interpreter):**

**NOTE:** Ensure that language-appropriate consent documents are submitted with this application.

3. **Explain how subjects’ privacy will be protected during the consent process.** This refers to how access to subjects will be controlled (e.g. time, place, etc. of consent procedures).

1. **Indicate any factors that might result in the possibility of coercion or undue influence. (check all that apply)**

the research will involve students of the investigator(s)

the subjects will be recruited through institutions with which the PI has a close relationship

Other (please specify):

**Describe steps taken to mitigate the possible coercion**:

**B. I am requesting a waiver of the informed consent process for (check all that apply):**

**the entire study.**

**recruitment only (VA requirement: please see the sample language provided in VA Waivers for Recruitment located on the IU Human Subjects Office website).**

**a specific minimal risk research activity or procedure that is part of the study:**      **.**

**For the IRB to grant a waiver of informed consent, the below criteria must be satisfied. Please provide a response to each criterion.**

**NOTE:** Waivers of informed consent may not be granted for FDA regulated research (see Section III to determine if this study is FDA regulated).

1. The research involves no more than minimal risk to the subject. If you are requesting a waiver of informed consent for part of the study (e.g. recruitment or a specific minimal risk activity or procedure), please state to which activity/procedure the waiver request applies and explain how this criterion is satisfied.

2. Explain how the waiver will not adversely affect the rights and welfare of the subjects.

3. Explain how the research could not be practicably carried out without the waiver.

4. Explain how, if appropriate, subjects will be informed of pertinent results at the conclusion of the study.

5. **ONLY COMPLETE FOR RESEARCH AND DEMONSTRATION PROJECTS CONDUCTED BY OR SUBJECT TO THE APPROVAL OF STATE OR LOCAL GOVERNMENT OFFICIALS.** In order for the IRB to approve a waiver of informed consent for a research or demonstration project, conducted by or subject to the approval of state or local government officials, it must NOT be FDA regulated and be designed such that it studies, evaluates, or otherwise examines one of the following (check all that apply):

public benefit or service programs;

procedures for obtaining benefits or services under those programs;

possible changes in or alternatives to those programs or procedures; or

possible changes in methods or levels of payment for benefits or services under those programs.

**C. I am requesting a waiver of *written documentation* of informed consent (i.e. a consent process will occur, but no signature will be obtained from the subject).**

Written statement regarding the research has been attached. Statement will be provided to subjects upon their request. Please explain:

     .

**For the IRB to grant a waiver of written documentation of informed consent, EITHER of the following criteria must be met. Please indicate which criterion is met and provide an appropriate response below.**

1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality, and the research is not FDA regulated. Each subject will be asked whether the subject wants documentation linking the subject with the research and the subject’s wishes will govern. Please explain:

**OR**

2. The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. Please explain:

**D. I am requesting modification to the required elements for informed consent document for:**

**the entire study**

**a specific minimal risk research activity or procedure that is part of the study**

**NOTE:** Modifications to the required elements for informed consent may not be granted for FDA regulated research (see Section III to determine if this study is FDA regulated).

Check all of the required elements below that you are requesting to modify or omit from the informed consent document:

Statement that the study involves research

Explanation of the purposes of the research

Expected duration of subject participation

Description of procedures to be followed

Identification of any procedures that are experimental

Description of any reasonably foreseeable risks or discomforts to subjects

Description of benefits (to subjects or others) that may reasonably be expected from the research

Disclosure of appropriate alternative procedures or courses of treatment

Statement describing the extent to which confidentiality of records identifying subjects will be maintained

Explanation regarding any compensation

Explanation of available medical treatments if injury occurs

Contact information for questions about the research, research-related injury, or subject rights

Statement that participation is voluntary

**For the IRB to grant a modification to the required elements of informed consent, the below criteria must be satisfied. Please provide a response to each criterion.**

1. The research involves no more than minimal risk to the subject. If you are requesting a waiver of informed consent for part of the study (e.g. a specific minimal risk activity or procedure), please state to which activity/procedure the waiver request applies and explain how this criterion is satisfied

2. Explain how the modification will not adversely affect the rights and welfare of the subjects.

3. Explain how the research could not be practically carried out without modification of informed consent.

4. Explain how, if appropriate, subjects will be informed of pertinent results at the conclusion of the study.

## Section XIII: Additional Reviews

N/A. This research does not require any additional institutional reviews. Proceed to next section.

A. Will this study specifically enroll cancer patients (e.g. is the study focused on cancer treatment or care or does the study include a control group of cancer patients) or involve cancer-related gene therapy?

No.

Yes. You must first obtain approval from the Scientific Review Committee (SRC) prior to submitting to the IRB. Please include that approval with your IRB study submission. Please contact the SRC at (317) 274-0930 or [crosrc@iupui.edu](mailto:crosrc@iupui.edu) for additional information.

Check here if this study is a retrospective chart review involving cancer patients; SRC approval is NOT necessary.

B. Does the study involve recombinant DNA (e.g. gene therapy)?

No.

Yes. IBC or BHC protocol number:

C. Does the study involve radiation / radioactivity (e.g. x-rays, nuclear medical scans) in addition to what is used for standard clinical treatment?

No

Yes. Radiation Safety approval must be obtained if radiation beyond standard of care is involved. Concurrent IRB and radiation safety review is permissible; however, final IRB approval will not granted until documentation of radiation safety approval is provided.

1. Does this study involve the use of *non-cancer-related* gene therapy?

No.

Yes. Has the proposal been submitted to the Indiana CTSI Clinical Research Center (CRC) Advisory Committee? (**NOTE**: It is a requirement of the School of Medicine for all non-cancer related gene therapy studies to be reviewed by the CRC Advisory Committee. Additionally, it is the CRC’s requirement that approval be granted from them prior to IRB submission.)

No. You must submit to the CRC Advisory Committee *before* you can submit to the IRB. Please call (317) 278-3446 for more information.

Yes. Include a copy of that approval with this study submission.

## Section XIV: Federal Funding

A. Is this research funded by a federal agency (e.g. DHHS, NIH, VA, CDC, ICTSI, etc.), or has it been submitted to a federal agency for funding?

No. Proceed to the next section.

Yes. Please ensure copies of the entire funding proposal and DHHS-approved sample informed consent (if applicable) are available to the IRB.

**NOTE:** If this is a federally-funded study, you will be required to track the race and ethnicity of subjects enrolled. This is reported to the IRB at the time of continuing review.