

St. Luke's Health System  
Institutional Review Board Review (IRB)

PRINCIPAL INVESTIGATOR INTERVIEW INFORMATION:

Principal Investigators presenting protocols for review by the IRB should be prepared to answer the following questions at the IRB meeting:

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**PURPOSE & BACKGROUND:**

Provide background information and explain in lay language what research question(s) this activity is designed to answer.

Provide a complete description of the study design and sequence and timing of all study procedures that will be performed, e.g., volume of blood, size of biopsy, drug administration, questionnaire, name of physiological test etc.. Provide this information on each phase of the study.

Would subjects undergo these or similar procedures (medical, psychological, educational, etc.) if they were not taking part in this research? Describe how the study procedures differ from what subjects would otherwise undergo.

**DECEPTION:**

If any deception or withholding of complete information (e.g., placebo, double-blind) is required for this activity, explain why this is necessary and explain if, how, when, and by whom subjects will be debriefed. Does the consent form address this issue?

**SUBJECTS:**

How many subjects will you need to **complete** this study? (Study total) How many subjects do you anticipate to enroll? (At your site(s))

Explain how you will achieve equitable subject representation in the following categories: Age, Gender, Ethnic and racial minority populations. Explain any specific exclusions from these categories. (e.g., age > 18 < 70)

What are the specific inclusion and exclusion criteria for subjects in this study? (Answer for each subject group if different.)

Describe **all** the recruitment strategies you will use for each group of subjects. (Advertisements, Contact letters, telephone contact, web site, per capita payment of any kind associated with the enrollment of subjects etc.)

Explain who will approach subjects to take part in the study and how this will be done to protect subject's privacy.

Explain what steps you will take during the recruitment process to minimize potential coercion or the appearance of coercion.

Will you give subjects gifts, payments, services without charge, etc? If yes, explain.

Will any of the subjects or their third-party payers be charged for any study procedures? If yes, explain.

Where will the study procedures be carried out? Have you received approval from all institutions involved?

**RISKS & BENEFITS:**

Describe nature and degree of risk or possible injury, stress, discomfort, invasion of privacy, and other side effects from all study procedures, drugs, and devices (standard and experimental), interviews and questionnaires. Include psycho-social risks as well as physiological risks. Include risks of withholding standard care or procedures if this is the case.

Explain what steps you will take to minimize risks of harm and to protect subject's rights and welfare. (If you will include protected groups of subjects (minors, fetuses in utero, prisoners, pregnant women, decisionally impaired or economically or educationally disadvantaged subjects) please identify the group(s) and answer this question for each group.)

Is it possible you will discover a subject's previously unknown condition (disease, suicidal intentions, genetic predisposition, etc.) as a result of study procedures? If yes, explain how you will handle this situation.

Describe the anticipated benefits of this research for individual subjects in each subject group. (Note: there may be no individual benefit(s).)

Describe the anticipated benefits of this research for society, and explain how the benefits outweigh the risks.

**ADVERSE EVENTS OR EFFECTS:**

Explain who will handle notification to the Sponsor and the IRB of adverse events?

Explain who will handle notification to the Sponsor and the IRB of any deviation from protocol should it occur?

Are your facilities and equipment adequate to handle possible adverse events? If no, explain your plan.

Who will be financially responsible for treatment of physical injuries resulting from study procedures?

**CONFIDENTIALITY OF RESEARCH DATA:**

Will you retain any direct identifiers (names, Social Security numbers, patient, hospital, laboratory, or claim numbers, addresses, telephone numbers, locator information, etc.) If yes, explain why this is necessary.

Will you retain a link between study code numbers and direct identifiers? If yes, explain why this is necessary and for how long you will keep this link.

Describe how you will protect data against disclosure to the public or to other researchers or non-researchers. Explain who (other than team members of the research team ) will have access to data (e.g., sponsors, advisors, government agencies etc.).

Will you place a copy of the consent form or other study related material in the subject's medical or other personal record? If yes, explain why this is necessary.

Do you anticipate using any data (information, specimens etc.) from this study for other studies in the future? If yes, explain. Also, this information should be included in a separate addendum to the consent form.

Will you make audio-visual or tape recordings or photographs of subjects? If yes, explain what type of recordings you will make, how long you will keep them, and if anyone other than the members of the research team will be able to see or hear them.

**CONSENT PROCESS:**

Describe what will be said to the subjects to explain the research.

What questions will be asked to assess the Subject's understanding? (*Suggestion: the purpose of this question is to ask you to describe how you will assess subject's understanding of the consent process. Questions requiring "yes/no" answers do not do that very well. Please ask subjects to explain the purpose of the study as well as the risks and benefits to themselves as participants. Their answers to these questions should allow you to determine if they understand the study and their part in it. If they do not understand, informed consent has not been achieved even if the Subject signed the consent document.*)

In relation to actual data gathering, when will consent be discussed and documentation obtained?

Will the investigator(s) be securing all of the informed consent? If no, name the specific individuals who will obtain informed consent, include their job title and qualifications to obtain consent and answer subject's questions.

**PROJECT ADMINISTRATION:**

Has this project ever been denied approval by another IRB? If yes, explain why.