

**Protocol Title:**

## **INSTRUCTIONS:**

- *You may use this document as a guide to write a protocol. You may use a different format, order, outline or template provided the necessary information is included.*
- *Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, delete them. For simple research, such as a retrospective chart review, less than a page may be necessary to address the relevant sections.*
- *For any items described in the sponsor's protocol, grant, contract, or other documents submitted with the application, you may reference the title and page numbers of these documents. If you reference page numbers, attach those pages to this protocol. Limit attached pages to those referenced in this protocol.*
- *When you write a protocol, keep an electronic copy so you can modify this copy when making changes.*

### **1. Protocol Title**

*Include the full protocol title as listed on the application form.*

### **2. Objectives**

*Describe the purpose, specific aims, or objectives.*

*State the hypotheses to be tested.*

### **3. Background**

*Describe the relevant prior experience and gaps in current knowledge.*

*Describe any relevant preliminary data.*

*Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.*

*Describe any procedures that are important to the research that will be performed regardless of whether the subject takes part in the research.*

### **4. Inclusion and Exclusion Criteria**

*Describe how individuals will be screened for eligibility.*

*Describe the criteria that define who will be included or excluded in your final study sample.*

*Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.)*

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- *Adults unable to consent*
- *Individuals who are not yet adults (infants, children, teenagers)*
- *Pregnant women*
- *Prisoners*
- *Individuals who do not understand English*

**5. Number of Subjects**

*Indicate the total number of subjects to be accrued across all sites.*

**6. Recruitment Methods**

*Describe when, where, and how potential subjects will be recruited.*

*Describe the methods that will be used to identify potential subjects.*

*Describe materials that will be used to recruit subjects. Attach copies of these documents with the application. For advertisements, attach the final copy of printed advertisements. When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape.*

*Describe the amount and timing of any payments to subjects.*

**7. Procedures Involved**

*Describe and explain the study design.*

*Provide a description of all procedures being performed because the subject is taking part in the research, including procedures being performed to monitor subjects for safety or minimize risks. Describe when these procedures are performed*

*Do not describe procedures that will be performed regardless of whether the subject takes part in the research. Describe these procedures in the Background section.*

*Describe:*

- *Procedures performed to lessen the probability or magnitude of risks.*
- *All drugs and devices used in the research and the purpose of their use, and their regulatory approval status.*
- *The source records that will be used to collect data about subjects. (Attach all surveys, scripts, and data collection forms.)*
- *What data will be collected including long-term follow-up.*

*Describe:*

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- *The duration of an individual subject's participation in the study.*
- *The duration anticipated to enroll all study subjects.*
- *The estimated date for the investigators to complete this study (complete primary analyses)*

**8. Data and Specimen Management**

*Describe the data analysis plan, including any statistical procedures.*

*When applicable, provide a power analysis.*

*Describe any procedures that will be used for quality control of collected data.*

*Describe how data and specimens will be handled study-wide:*

- *What information will be included in that data or associated with the specimens?*
- *Where and how data or specimens will be stored?*
- *How long the data or specimens will be stored?*
- *Who will have access to the data or specimens?*
- *Who is responsible for receipt or transmission of the data or specimens?*
- *How data and specimens will be transported?*

*If data or specimens will be banked for future use, describe the procedures to release data or specimens, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.*

**9. Provisions to Monitor the Data to Ensure the Safety of Subjects**

*This section is not required when research involves no more than Minimal Risk to subjects.*

*The plan might include establishing a data monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.*

*Describe:*

- *The plan to periodically evaluate the data collected regarding both harms and benefits to determine whether subjects remain safe.*
- *What data are reviewed, including safety data, untoward events, and efficacy data.*
- *How the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).*
- *The frequency of data collection, including when safety data collection starts.*
- *Who will review the data.*

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- *The frequency or periodicity of review of cumulative data.*
- *The statistical tests for analyzing the safety data to determine whether harm is occurring.*
- *Any conditions that trigger an immediate suspension of the research.*

**10. Withdrawal of Subjects**

*If applicable, describe anticipated circumstances under which subjects will be withdrawn from the research without their consent.*

*If applicable, describe any procedures for orderly termination.*

*If applicable, describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

**11. Risks to Subjects**

*List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects' participation in the research. Include as may be useful for the IRB's consideration, describe the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks.*

*If applicable, describe any costs that subjects may be responsible for because of participation in the research.*

*If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*

*If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*

*If applicable, describe risks to others who are not subjects.*

**12. Potential Benefits to Subjects**

*Describe the potential benefits that individual subjects may experience from taking part in the research. Include as may be useful for the IRB's consideration, the probability, magnitude, and duration of the potential benefits.*

*Indicate if there is no direct benefit. Do not include benefits to society or others.*

**13. Confidentiality**

*Describe the procedures for maintenance of confidentiality.*

*Describe the steps that will be taken secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

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## **14. Provisions to Protect the Privacy Interests of Subjects**

*Describe the steps that will be taken to protect subjects' privacy interests. "Privacy interest" refers to a person's desire to place limits on whom they interact or whom they provide personal information.*

*Describe what steps you will take to make the subjects feel at ease with the research situation in terms of the questions being asked and the procedures being performed. "At ease" does not refer to physical discomfort, but the sense of intrusiveness a subject might experience in response to questions, examinations, and procedures.*

*Indicate how the research team is permitted to access any sources of information about the subjects.*

## **15. Consent Process**

*If you are obtaining consent of subjects describe whether you will be following "INVESTIGATOR GUIDANCE: Informed Consent (HRP-802)" If not, describe your consent process in similar detail.*

### ***Non-English Speaking Subjects***

- *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
- *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language.*
- *Indicate the language that will be used by those obtaining consent.*

### ***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

- *Review the following documents to ensure you have provided sufficient information for the IRB to waive or alter consent:*
  - *CHECKLIST: Waiver of Consent HHS (HRP-300)*
  - *CHECKLIST: Waiver of Consent Emergency Research (HRP-301)*

### ***Subjects who are not yet adults (infants, children, teenagers)***

- *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
- *Describe whether parental permission will be obtained from:*

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- *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.*
- *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
- *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.*
- *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent.*
- *When assent of children is obtained describe whether and how it will be documented.*

### ***Cognitively Impaired Adults***

- *Describe the process to determine whether an individual is capable of consent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require children to sign assent documents.*

### ***Adults Unable to Consent***

- *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
- *Describe the process for assent of the subjects. Indicate whether:*
  - *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
  - *If assent will not be obtained from some or all subjects, an explanation of why not.*
  - *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

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## **16. Setting**

*Describe the sites or locations where your research team will conduct the research.*

- *Identify where your research team will identify and recruit potential subjects.*
- *Identify where research procedures will be performed.*
- *Describe the composition and involvement of any community advisory board.*
- *For research conducted outside of the organization and its affiliates describe:*
  - *Site-specific regulations or customs affecting the research for research outside the organization.*
  - *Local scientific and ethical review structure outside the organization.*

## **17. Vulnerable Populations**

*If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*

- *Review the following documents as applicable to ensure you have provided sufficient information for the IRB allow inclusion of specific vulnerable populations:*
  - *CHECKLIST: Pregnant Women (HRP-305)*
  - *CHECKLIST: Neonates of Uncertain Viability (HRP-306)*
  - *CHECKLIST: Nonviable Neonates (HRP-307)*
  - *CHECKLIST: Prisoners (HRP-308)*
  - *CHECKLIST: Children (HRP-310)*
  - *CHECKLIST: Wards (HRP-311)*
  - *WORKSHEET: Adults Lacking Capacity (HRP-414)*

## **18. Process to Document Consent in Writing**

*If you are documenting consent of subjects in writing describe whether you will be following “INVESTIGATOR GUIDANCE: Documentation of Informed Consent (HRP-803)” If not, describe your process to document informed consent in writing in similar detail.*

*If your research presents no more than minimal risk of harm to subjects and involves no procedures for which written documentation of consent is normally required outside of the research context, the IRB will generally waive the requirement to obtain written documentation of consent.*

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*Review “CHECKLIST: Waiver of Documentation of Consent (HRP-303)” to ensure that you have provided sufficient information to allow the IRB to waive written documentation of consent.*

*You may use the following documents as guides to create a consent document or script:*

- *TEMPLATE Consent (HRP-500)*
- *TEMPLATE Consent for Minimal Risk Research (HRP-501)*

**19. Compensation for Research-Related Injury**

*This section is not required when research involves no more than Minimal Risk to subjects.*

*Describe the available compensation in the event of research related injury.*

*Provide a copy of contract language, if any, relevant to compensation for research-related injury.*

**20. Resources Available**

*Describe the qualifications (e.g., training, experience, oversight) of you and your staff as required to perform their role. When applicable describe their knowledge of the local study sites, culture, and society. Provide enough information to convince the IRB that you have qualified staff for the proposed research.*

*If you specify a person by name, a change to that person will require prior approval by the IRB. If you specify people by role (e.g., coordinator, research assistant, co-investigator, or pharmacist), a change to that person will not require prior approval by the IRB, provided that person meets the qualifications described above to fulfill their roles.*

*Describe other resources available to conduct the research: For example, as appropriate:*

- *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
- *Describe the time that you will devote to conducting and completing the research.*
- *Describe your facilities.*
- *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequences of the human research.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*



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**21. Drugs or Devices**

*If the research involves drugs or devices and is investigator-initiated, indicate whether there is any possibility that the results will be reported to FDA.*

*If the research involves drugs or devices, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.*

*If the drug is investigational (has an IND) or the device has an IDE or a claim of abbreviated IDE (non-significant risk device), include the following information:*

- *Identify the holder of the IND/IDE/Abbreviated IDE.*
- *Explain procedures followed to comply with FDA sponsor requirements for the following:*

<b>FDA Regulation</b>	<b>Applicable to:</b>		
	<b>IND Studies</b>	<b>IDE studies</b>	<b>Abbreviated IDE studies</b>
<b>21 CFR 11</b>	X	X	
<b>21 CFR 54</b>	X	X	
<b>21 CFR 210</b>	X		
<b>21 CFR 211</b>	X		
<b>21 CFR 312</b>	X		
<b>21 CFR 812</b>		X	X
<b>21 CFR 820</b>		X	

**22. Multi-Site Research**

*If this is a multi-site study where you are the lead investigator, describe the processes to ensure communication among sites, such as:*

- *All sites have the most current version of the protocol, consent document, and if applicable, HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site’s IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site’s IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will reported in accordance with local policy.*

*Describe the method for communicating to engaged participating sites:*

- *Problems.*

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- *Interim results.*
- *The closure of a study*

**23. Research Conducted in a Foreign Country**

*Any project that will be conducted in whole, or in part, at a location outside the United States must include answers to the following questions:*

- *List the study location and the primary language/dialect spoken by the proposed subject population.*
- *If this project has been, or will be, reviewed by a local IRB or Ethics Committee, provide the name, address, and contact information for the local IRB or ethics review committee at the foreign research site.*
- *If applicable, provide the name and contact information for any foreign investigator, collaborator, or institution assisting the PI in the conduct of the project.*
- *Briefly describe your knowledge of the intended population including knowledge of local customs, practices, and religions as they relate to this project.*
- *Describe your proficiency with the local language, or how information and communication will be translated throughout the project.*
- *Describe how the community will be notified, and information disseminated, regarding the results of the research project.*
- *Address any cultural, regional, or unique risks the IRB should be aware of when evaluating this research project.*
- *State how will you communicate with the IRB if you need to report an unanticipated problem (associated with risk to subjects or others associated with the study) or an amendment to the study.*
- *For student investigators, explain how the faculty sponsor will provide oversight for the study while you (or representatives) are conducting the research in the foreign country.*

**24. Community-Based Participatory Research**

*Describe involvement of the community in the design and conduct of the research.*

*Note: “Community-based Participatory Research” is a collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. Community-based Participatory Research begins with a research topic of importance to the community, has the aim of combining knowledge with action and*

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*achieving social change to improve health outcomes and eliminate health disparities.*