

Institutional Review Board

***INSTRUCTIONS: How to Write a Human
Research Protocol***

- **If you believe your activity may not meet the definition of “Human Research” subject to IRB oversight, contact the IRB Office prior to developing your protocol**
- **These instructions accompany the “Human Research Protocol Template” document.**
- **The italicized bullet points below serve as general guidance to investigators on the kinds of information that may be applicable to include in each section. Do not include this italicized text in your protocol.**
- **Note that, depending on the nature of your research sections below will not be applicable. Indicate this as appropriate.**
- **For any items described in the sponsor’s protocol or other documents submitted with the application, investigators may simply reference the page numbers of these documents.**
- **When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes to the protocol.**

1) Protocol Title

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

2) Investigator

- *Include the investigator’s name as listed on the application form.*

3) Objectives

- *Describe the purpose, specific aims, or objectives of the Human Research.*
- *State the research question or hypotheses to be tested.*

4) Background

- *Provide the scientific or scholarly background and rationale for the Human Research based on the existing literature.*
- *Describe the relevant prior experience and gaps in current knowledge.*
- *Describe any relevant preliminary data.*
- *Explain the significance of the Human Research in terms of why this Human Research important and how will it add to existing knowledge.*

- *Describe the importance of the knowledge expected to result.*

5) Setting of the Human Research

- *Describe the setting and location in which the Human Research will be conducted. If applicable, describe:*
 - *Site-specific regulations or customs affecting the research.*
 - *Local scientific and ethical review structure.*
 - *Composition and involvement of any community advisory board.*
 - *Whether you have secured permission to use the site.*

6) Resources available to conduct the Human Research

- *Demonstrate (e.g., based on retrospective data) a potential for recruiting the required number of suitable subjects within the agreed recruitment period.*
- *Describe/estimate the time that you will devote to conducting and completing the research within the agreed time period.*
- *Describe the number and qualifications of your staff, their experience in conducting research, their knowledge of the local study sites, culture, and society.*
- *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the investigational product(s), and their research-related duties and functions.*
- *Describe the facilities in which your research will be conducted.*
- *Where applicable, describe the availability of medical or psychological resources that participants might need as a consequence of the Human Research.*

7) Study Design

NOTE: Researchers developing multi-faceted protocols (e.g., multiple phases, study groups, research components, etc.) may want to develop separate “Study Design” sections for each component of their research rather than trying to combine disparate components into a single section.

a) Recruitment Methods

- *Describe the following where applicable:*
 - *The source of participants, including when, where, and how potential participants will be recruited.*

- *The methods that will be used to identify potential participants.*
- *The expected number of participants needed to complete the Human Research.*
- *Any materials that will be used to recruit participants. Include copies of these documents with the application.*
- *The amount and timing of any payments to participants.*
- *For advertisements, submit the final copy of printed advertisements. When advertisements are taped for broadcast, provide 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.*
- *For research in which biological specimens or tissue samples will be used, describe the source of the materials (e.g. certified specimen banks, discarded specimens gathered for non-research purposes, prospectively collected samples, etc.).*
- *For research in which biological specimens or tissue samples will be used, describe whether any individually identifiable information will be associated with the samples.*

b) Inclusion and Exclusion Criteria

- *Describe how you will screen for eligibility. Describe the criteria that define who will be included or excluded in your final study sample.*

c) Study Endpoints

NOTE: This section is only required for biomedical research. It is generally not applicable to social or behavioral research.

- *Describe the primary and secondary study endpoints.(For example, studies may be conducted until a certain time point, until a re-occurrence of disease, or certain clinical condition is met.)*
- *Describe any primary or secondary safety endpoints.(Examples may include evidence of liver toxicity, an inability to tolerate further chemotherapy, or other side effects related to a drug or device.)*

d) Procedures involved in the Human Research.

- *Describe and explain the study design.*
- *Provide a timeline of all procedures being performed, including procedures being performed to monitor participants for safety or minimize risks.*
- *Provide the overall duration of the research.*
- *Describe procedures taken to lessen the probability or magnitude of risks.*

- *Identify which procedures are being done as part of the Human Research and which are being conducted anyway for other reasons.*
- *Describe the source records that will be used to collect data about participants.*
- *Describe what data will be collected including long-term follow-up*
- *If student/school records are to be used, include a list of specific data to be obtained from the school and note whether it is identifiable at the student level, in accordance with FRPA/PPRA requirements.*
- *Describe any plans to conduct audio or video recording of research participants during the conduct of the research.*

e) Data and specimen management

NOTE: Data confidentiality issues are a separate topic that is addressed in section 11 below.

- *As applicable, describe the following:*
 - *The data and specimens to be sent out or received.*
 - *What information will be included in that data or associated with the specimens.*
 - *Who is responsible for receipt or transmission of the data.*
 - *How specimens and data will be transported.*
 - *The plan to manage the data.*
 - *Any procedures that will be used for quality control of collected data.*
 - *The data analysis plan, including any statistical procedures. Provide a power analysis.*

f) Provisions to monitor the data for the safety of participants

NOTE: This section is only required when Human Research involves more than minimal risk to participants. It is not applicable to research that is not more than minimal risk.

- *Describe the plans to periodically evaluate the data collected regarding both harms and benefits to determine whether participants remain safe.*
- *Describe who will review the data (e.g. the investigator, a medical monitor, a data safety monitoring board, etc.).*
- *Describe what data are reviewed, including safety data, untoward events, and efficacy data.*
- *Describe when data are reviewed.*

g) Withdrawal of participants

- *Describe anticipated circumstances under which participants will be withdrawn from the research without their consent.*
- *Describe any procedures for orderly termination.*
- *Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection.*

8) Risks to participants

- *List the risks, discomforts, hazards or inconveniences to the participants. For each, indicate the probability, magnitude, and duration. Consider physical, psychological, social, legal and economic risks.*
- *If applicable, indicate which procedures may have risks to the participants that are currently unforeseeable.*
- *If applicable, indicate which procedures may have risks to an embryo or fetus should the participant be or become pregnant.*

9) Potential benefits to participants

- *Describe the benefits that individual participants may experience. For each indicate the probability, magnitude, and duration of the benefit. Indicate if there is no direct benefit.*

10) Provisions to protect the privacy interests of participants

- *Describe any applicable impact that the study or study procedures may have on participants' privacy interests. ("Privacy interest" refers to a person's desire to control access of others to themselves. It involves consideration of whether the participants will be comfortable with the Human Research situation. For example, persons may not want to be seen entering a place that might stigmatize them, such as a pregnancy counseling center that is clearly identified as such by signs on the front of the building.)*
- *Describe the steps that will be taken to protect participants' privacy interests, when applicable.*

11) Provisions to maintain the confidentiality of data

- *Describe the steps that will be taken to abide by promises made to the participant to limit dissemination of identifiable data.*

- *Describe where data will be stored, who will have access to the data, measures taken to secure the data, and how long data will be stored.*

12) Medical care and compensation for injury

Note that this section is not applicable for research that involves no more than minimal risk.

- *If the research involves more than minimal risk to subjects, describe the provisions for medical care and available compensation in the event of research related injury.*

13) Cost to participants

- *Describe any financial costs that participants may incur through participation in the research, if applicable.*

14) Consent process

Note that the process of obtaining informed consent is distinct from the informed consent document itself.

- *As appropriate, describe the following:*
 - *The setting of the consent process.*
 - *The role of the individuals listed in the application as being involved in the consent process.*
 - *The time that will be devoted to the consent discussion.*
 - *Any waiting period between informing the prospective participant and obtaining the consent.*
 - *Any steps that will be taken to minimize the possibility of coercion or undue influence.*
 - *Indicate what language(s) other than English are understood by prospective participants or representatives. If participants who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those participants will be in that language.*
- *If the Human Research involves a waiver or alteration of the consent process (consent will not be obtained, required information will not be disclosed, or the research involves deception) review the “CHECKLIST: Criteria for Waiver or Alteration of the Consent Process” and address each of the criteria for approval.*

- *If the Human Research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), describe the following:*
 - *Whether parental permission will 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.*
 - *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.*
 - *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.*
 - *Whether assent will be obtained from all, some, or none of the children, and if some children, which children will be required to assent.*
 - *When assent of children is obtained, describe whether and how it will be documented.*
- *If the Human Research involves adults who may be unable to consent, describe the process to determine whether an individual is capable of consent.*
- *If the Human Research involves adults who are unable to consent, describe the following:*
 - *If permission of a legally authorized representative will be obtained:*
 - *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.)*
 - *Submit a statement from legal counsel describing which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the procedure(s) involved in this Human Research.*
 - *To obtain this statement, have legal counsel review the definition of “legally authorized representative” in 45 CFR 46.102(c) or 21 CFR 50(l). The IRB can provide you a copy of these regulations. Also provide legal counsel with a copy of the protocol or other document describing the procedures involved in the Human Research.*
 - *Describe the process for assent of the participants. Indicate whether:*

- *Assent will be required of all, some, or none of the participants. If some, indicate which participants will be required to assent and which will not.*
- *If assent will not be obtained from some or all participants, an explanation of why not.*
- *Describe whether assent of the participants will be documented, and the process to document assent.*

15) Process to document consent in writing

- *Describe whether and how consent of the participant will be documented in writing.*
- *If the consent process will not be documented in writing (consent will be obtained but the participant or representative will not sign a consent document) review the “CHECKLIST: Criteria for Waiver of Written Documentation of Consent” and address each of the criteria for approval.*
- *Note that, depending on the populations under study, multiple versions of the informed consent document may be needed.*

16) Vulnerable populations

- *If the Human Research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*
- *If the Human Research involves adults unable to consent, review the “CHECKLIST: Criteria for Research Involving Adults Unable to Consent” and address each of the criteria for approval.*
- *If the Human Research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”):*
 - *Review the “CHECKLIST: Criteria for Research Involving Children” and address each of the criteria for approval.*
 - *Describe the criteria that will be used to determine whether a prospective participant has not attained the legal age for consent to treatments or procedures involved in the Human Research under the applicable law of the jurisdiction in which the Human Research will be conducted. (E.g., individuals under the age of 18 years.)*
 - *Submit a statement from legal counsel describing which persons have not attained the legal age for consent to treatments or procedures involved in this Human Research, under the applicable law of the jurisdiction in which this Human Research will be conducted.*

- *To obtain this statement, have legal counsel review the definition of “children” in 45 CFR 46.402(a) or 21 CFR 50(0). The IRB can provide you a copy of these regulations. Also provide legal counsel with a copy of the protocol or other document describing the procedures involved in the Human Research.*
- *If the Human Research involves pregnant women, review the “CHECKLIST: Criteria for Research Involving Pregnant Women” and address each of the criteria for approval.*

17) Drugs or Devices

- *If the Human Research involves drugs or device, describe your plans to control those drugs or devices so that they will be used only on participants and be used only by authorized investigators.*

18) Multi-site Human Research

- *If this is a multi-site study where you are the lead investigator, describe the management of information (e.g., results, new information, unanticipated problems involving risk to participants or others, or protocol modifications) among sites to protect participants.*

19) Sharing of results with participants

- *Describe any plans to share the results of the research with participants.*