



## **INSTRUCTIONS FOR THE IRB RESEARCH PROPOSAL FORMAT**

The IRB protocol is the formal design or plan for the proposed experiment or research activity. A protocol is a document that describes the parameters of a research experiment in specific detail. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data. The information provided must be descriptive enough to facilitate the understanding of a reviewer without leaving too many unanswered questions.

**Note:** A well-designed research study seeks to protect the rights of a human subject.

The following format is required for submission of an IRB proposal. Insert your title where indicated. Please replace the bulleted information provided under each heading with your research information.

**Please Delete All Information Above This Line.** This information should not appear on the proposal you are submitting for review.

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*Insert Your Research Proposal Title Here*

### **RESEARCH OBJECTIVES:**

- Provide background data that supports the objectives of the protocol.
- Provide a brief description of the theoretical and empirical goals of this research project.
- Describe the purpose of this research project. The research objectives should be directed toward the involvement and benefits towards the research subject(s) not the overall goals of the project.

### **SUBJECT RECRUITMENT:**

**Information:** Recruitment refers to the contact and the communication that takes place between the investigator and a potential participant. Recruitment occurs prior to the introduction of the consent process. Recruitment methods include but are not limited to verbal exchanges and advertisement. Recruitment processes should avoid the appearance of coercion or undue influence.

- Include estimated number and description of types of subjects (e.g., normal volunteers, pregnant women, students), age and sex.
- Describe the source of potential subjects (e.g., referral sources).
- Describe where and how potential subjects will be contacted, and what information they will be given about the study prior to obtaining consent.
- Provide eligibility criteria (inclusion and exclusion criteria). Exclusion of a population should be justified.

- If the subject information will be obtained from a database or archival data indicate how and from where the data will be obtained. These sources have no direct risk or benefit to subjects involved.

#### **METHOD AND PROCEDURES:**

- Explain the methods and procedures to be followed with an emphasis on implications for subjects' experiences, especially any risks that may be involved because of the study protocol.
- Identify all sites at which the research will be conducted. Collaboration letters should be included in the appendix for sites indicated.
- Include month/day/year of start and end dates of study.
- Explain tests/procedures/exams. Provide a table format if the research plan is complex.
- Indicate if there are any alternative procedures or treatments that the subject may be able to consider.
- Provide information about any standard treatment that will be withheld and rationale for doing so.
- Describe data to be collected and data analysis.
- Describe any costs or compensation. NOTE: compensation is NOT a benefit.
- If compensation is provided, specify what action will be taken if the subject discontinues participation before the experiment is completed. Note: subjects cannot be penalized for withdrawing from a research study.
- If the study uses database or archival data the methods and procedures provided should reflect ONLY the current study.

#### **BENEFITS:**

- Describe any benefits that subject(s) may reasonable expect to encounter. Examples of benefits are credit in a university course, medical treatment, counseling, understanding of a disease process, additional information about themselves or their condition, etc.
- If course credit is being given to students an alternative must be available for students who do not wish to participate to obtain equivalent course credit. This alternative treatment serves to decrease the possibility of coercive situation.
- If there are no known benefits to the subject, state that there are not direct benefits to the subject and describe the anticipated benefits to society and to knowledge development in the specific discipline.
- Do not state benefits that are unrelated to the research study. Compensation is NOT a benefit.
- Specify the level of risk in relation to anticipated benefits.
- If the study uses database or archival data there is no direct benefit to the subjects from which the data was obtained. The anticipated benefit to society needs to be stated.

#### **RISKS TO SUBJECTS:**

- Describe in detail any immediate or long-range risks, discomforts and/or inconveniences foreseeable to subjects associated with procedures used in the study.
- Detail the precautions you have taken to minimize these risks.
- Describe the level of medical, psychological or other care available through the study for research related risks.

- Justify the scientific necessity of the experimental aspects that lead to these risks. (Risks may be physical, psychological, social, economic, or legal.).
- If there are no known risks to the subject, describe the risk level in relation to the same procedure faced in normal life. Indicate whether these risks are greater than those faced in normal life while participating in a similar activity. For example, participating in an online survey may have no more risk to the participant than providing information online for other purposes based on the content of the survey. The comparison statement should be appropriately worded based on the specifics of the research.
- ***Do not state*** that risks are not reasonably foreseeable for the research being proposed.
- If the study uses database or archival data there are no direct risks to the subjects that provided the data.

#### **INFORMED CONSENT:**

- Describe the manner in which informed consent will be obtained.
- Indicate what kind of consent (e.g. parental, child, adult, etc) will be used.
- If the subjects are children/adolescents ages 7-18 years, an Assent Form must be included with the IRB application. The signed Assent Form along with the Parental/Guardian Consent Form must be retained on file for at least three years after completion of the research project.
- If prisoners, pregnant women, or fetuses are to be included in the research sample, it is likely that a full IRB review will be required and additional human subjects' protections will be expected.
- If the subjects do not read or comprehend English you must provide a consent form in their language as well as in English for IRB review and approval.
- If you are requesting a waiver of written consent (i.e. a signature on an informed consent form) from the subjects, you **MUST** justify this request by providing an explanation of why obtaining written consent would add additional risk to the subjects and your alternative provisions for informing them about the study.
- If consent documents from another site will be used indicate this and provide a copy of the authorized consent document and IRB approval with your application.
- Provide any other relevant information. Please be aware that the PI is legally required to retain all signed Informed Consent forms for at least three years after the project terminates
- The Informed Consent form must be written at a level that the subjects will understand. Use simple language. Avoid clinical jargon.
- Attach a copy of the written informed consent form (assent or parental consent where applicable). Consent documents **MUST** be in format requested. See examples on line.
- If the study uses database or archival data the use of informed consent is not applicable.

#### **CONFIDENTIALITY OF DATA:**

***Confidentiality of data MUST be address for all studies.***

- Indicate the extent to which confidentiality of records identifying subjects will be maintained.
- Describe the storage and disposal of information where applicable.

- Explain how data will be secured to safeguard confidentiality. Usually, this requires that the data be kept in a room or file cabinet that is customarily locked and that the PI is aware of all people who will have access to the data.
- If video or audiotapes will be used, provide storage and disposal information.
- Note that confidentiality is critical if information will be obtained about sensitive or illegal behavior. Indicate what level of confidentiality the subject will have in this situation or where there is a subpoena for information.

**APPENDIX:** *attach as applicable*

- Include one (1) copy of each instrument to be used in the study.
- Include tables or reference tools that would serve to enhance the knowledge of the individuals reviewing the research. You do not need to include a complete reference section with your proposal.
- Include a copy of the consent document or verbal statement to be read if a waiver is being requested.
- Include a copy of any recruitment documents