Creighton University Institutional Review Board
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Guidance/ Tool

Writing a Research Protocol

A protocol provides the scientific basis for the proposed research; it defines the study objectives, the population to be studied, the procedures to be followed, the evaluations to be performed, and the plan for analysis.

Please submit a protocol in InfoEd that includes all the following sections. Protocols should include a version date and the Principal Investigator (PI) name in the footer of all pages (if possible), as well as page numbers.

1) **Study Introduction**: Provide a short description of the proposed research and a brief statement of the study hypothesis or rationale. This should only take a few sentences.

2) **Background**: Discussion of existing data and published research relevant to the proposed study. Include justification for the research. This is typically several paragraphs.

3) **Objectives**: An objective is the purpose for performing the study in terms of the scientific question to be answered. The primary objective is to address the main research question. Secondary objectives are other constructs of the study that could clarify findings from the primary objective.

   Express each objective as a statement purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., feasibility, acceptability, engagement of the study target, identifying, mediation, moderation, efficacy, effectiveness, dissemination, implementation)

4) **Study Population**: Specify the sample size, gender, age, demographic group, general health status, and geographic location as applicable. Ensure the proposed sample size is adequate for analysis to support the study's objectives according to accepted quantitative or qualitative methodological standards.

5) **Inclusion/Exclusion Criteria**: Clearly define inclusion/exclusion criteria for participation in the proposed study.

6) **Subject Recruitment:** Describe the source of prospective subjects and your recruitment methods. If applicable describe any screening procedures for prospective subject eligibility. Include participant recruitment materials (e.g. ads, letters, recruitment invitation

letters/emails, social media postings or scripts, etc.) as separate attachments in InfoEd – do not include them in the protocol document itself.

7) **Methods:** Include a discussion of the data collection and analysis procedures for your research project including any measurement tools that will be used (i.e. questionnaires, focus groups, procedures, etc.) This should answer the question, "What will you do to carry out the research?". The method section is usually organized chronologically and should provide readers with enough detail to replicate the study. It should also give readers a sense of what it would be like to be a participant in the study.

8) **Risks**: Include a discussion of any potential risks already known or risks cited in the literature. Typically the risks in social/behavioral research are minimal that is the risks are no more than what is encountered in everyday life. Remember that research may pose non-physical risks such as emotional and social risks as well as risks to confidentiality and privacy. If your research is greater than minimal risk describe immediate risks and long-term risks. If the risk is directly related to study procedures describe alternative procedures that have been considered and explain why the alternative procedures are not included with study.

9) **Benefits**: Include a discussion of any known benefits to individuals participating in the study. Depending on the nature of the research, there may not be benefit to participants as a result of their participation. Include a separate discussion of how the research will or may benefit the community or contribute to the advancement of scientific knowledge. NOTE: Compensation to study subjects may not be identified as a study benefit.

10) **Assessment of Potential Risks and Benefits**: Provide an assessment of the risk/benefit ratio for the study overall. Include in your assessment a rationale for the necessity of exposing participants to the risks involved in the study. Summarize how risks to participants will be minimized in the study design. Justify how the benefits or value of the information collected outweighs the risks to participants.

11) **Study Duration**: Estimated time in days, weeks, or months from when the study is initiated to completion of data collection.

12) **Participant Duration**: The amount of time for an individual participant to complete all study related activities. For longitudinal studies describe frequency of interactions with each individual participant and duration of each interaction. Describe about how long will it take for a participant to complete any self-administered survey included in the study (if applicable) and/or a description of about how long it will take for the researcher to interview a participant.

13) **Compensation**: Describe any plans for providing incentives or compensation to participants.

Compensation to subjects must be prorated across the study and may not be contingent upon the participant completing the study.

14) **Confidentiality and Privacy**: Participation in research almost always poses a risk to participants privacy and confidentiality. Describe procedures for protecting the privacy of participants and the confidentiality of their data. Provide details about who will have access to the data. Describe whether identifiers will be attached to participant data or data is de-identified, or if data will be coded.

15) **Informed Consent Process**: Beginning with your plan for recruitment and the identification of potential subjects, describe how the informed consent process will be conducted. Where will the consent discussion take place? Who will be responsible for obtaining informed consent? Note that not all research requires obtaining or documenting informed consent. Describe any proposed waivers or alterations to the informed consent process that you are seeking. For example, will you be requesting a verbal consent process instead of having participants sign a consent form? Describe any special circumstances regarding informed consent in your study, including how you will obtain informed consent from members of vulnerable populations such as minors/children, prisoners, individuals with impaired decision making capacity, and/or non-English speakers.

16) **HIPAA**: Indicate if access is needed to participants' Protected Health Information (PHI) for the proposed research. Identify whether you will asks participants to sign a HIPAA Authorization form or whether you will request a HIPAA waiver from the IRB. If relevant, describe the use of any Limited Data Set (LDS) that you will be using to conduct your research.

17) **Data Analysis Plan**: Describe the data that will be selected for analysis and the statistical methods for qualitative or quantitative analysis.