Creighton UNIVERSITY

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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 of the following sections. Protocols should include a version date and the Principal Investigator (PI) name in the footer of all pages (if possible), and pages are numbered.

For EdD/PhD students list yourself as the PI in the protocol and provide the name of your dissertation chair (listed as mentor in InfoEd).

*For **non** EdD/PhD students list yourself as Principal Investigator (PI) in the protocol and provide the name of your academic advisor (listed as mentor in InfoEd).*

A protocol record number is generated by InfoEd following the creation of a research submission account. If necessary correct any mistakes or errors in the InfoEd research submission account, do not create a new account for the proposed research.

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 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.

7) **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.

   If research is more 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 protocol.

8) **Benefits**: Include a discussion of known benefits to participating individuals and to society that may be cited in the literature. There are not always direct benefits to participating individuals (participant compensation is not a benefit), but there is the benefit of contributing to the advancement of science.

9) **Assessment of Potential Risks and Benefits**: Provide rationale for the necessity of exposing participants to risks. Summarize how risks to participants are minimized in the study design. Justify how the benefits or value of the information collected outweighs the risks to participants.

10) **Study Duration**: Estimated time in months from when the study is initiated to completion of data collection.

11) **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 a self administered survey or about how long for the researcher to interview a participant.

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

13) **Confidentiality and Privacy**: Describe procedures for protecting confidentiality of participant 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.

14) **Informed Consent Process**: Describe how the informed consent process is conducted. Not all research requires documenting informed consent or obtaining informed consent. Describe any proposed waivers or alterations to the informed consent process. Describe any special circumstances regarding informed consent (vulnerable populations such as children, prisoners, individuals with impaired decision making capacity; non-English speakers), or assent for minors who are participants (under age19 in Nebraska).

15) **HIPAA**: Indicate if access is needed to participants' Protected Health Information (PHI) for the proposed research. Describe whether participant authorization will be sought, or a HIPAA waiver will be requested from the IRB/Privacy Board. If relevant, describe the use of a Limited Data Set (LDS).

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