Franklin University Faculty and Staff Guidance

Research Protocol for Submission to IRB

NOTE: Doctoral candidates should NOT use this guidance to prepare the research proposal. This document is intended for faculty and staff projects that will be submitted to the IRB.

All submissions to the Franklin University IRB must include a complete research protocol or project summary that provides an overview of the proposed study. The research protocol should provide reviewers with the information needed to determine that federal, state, and institutional requirements have been met. Please ensure ALL this information is included with your IRB application in Cayuse IRB.

There is no required format or template. Different sections and formatting may be used, provided the necessary information is included in the submission.

Your research protocol should briefly describe the research design, procedures to be used, and importance of the knowledge that may reasonably be expected to result. Be sure to include the following:

Description of the Research

- **Study Background and Literature Review** - Provide a brief literature review, with citations, that focuses on the research question(s) and justifies the study. It is important to review the literature in a given field to determine what risk of harm, if any, the research topic or procedures might pose to participants and what additional protections may be necessary. Discuss the anticipated significance of the research.
- **Research Objectives** - List the specific aims of the study.
- **Research Questions/Hypotheses -** List the key question(s) you want your research to answer.

Design and Methodology

- **Description of Research Participants -** Include the number of research participants required for the study and the characteristics of those individuals. Discuss the sampling plan and sampling method for selecting your participants.
- **Participant Access** - Clearly state how you will gain access to potential participants and how you will recruit them to participate in your study.
- **Instruments -** Address the types of instruments to be used, equipment needed, and/or space required, as necessary.
- **Data Collection Plan and Procedures -** Describe your planned approach to collecting data using your selected instruments. Include a full description of what participants will be asked to do throughout the study. For example, if you are conducting focus group interviews, provide details about where the interviews will take place and whether you plan to audio or video record the interviews. Discuss your strategy if a participant does not agree to recording. Attach any

questionnaires, interview protocols, range of focus group topics with example questions/ prompts, and so on to your protocol.

Anticipated Risks and Potential Benefits to Participants

- **Risks** - Address all reasonable risks, including physical, emotional, legal, and potential threats to one's reputation. If the researcher has determined that the risk to participants is no greater than those risks associated with everyday life, the researcher should explain why that is the case.
- **Benefits** - Identify all potential benefits to individuals or groups participating in the proposed research. Note that compensation is not considered a benefit to participants.

Protecting Participants and Informed Consent

- **Data Security –** Discuss how data will be collected, transmitted, shared, and/or stored. Please refer to our data security guidance for more information.
- **Informed Consent** - Clearly state how participants will be reminded that their participation is completely voluntary. Include details about providing and collecting informed consent from participants.
- **Confidentiality or Anonymity** - Describe how you will maintain participant confidentiality or anonymity. These terms frequently are conflated. Please refer to the following definitions provided by the IRB:
    - ***Confidential***: Data will be available only to designated individuals, and any participant's data will not be available and identifiable to others.
        - Discuss how any identifiable information will be removed from the data (i.e., surveys, interviews, notes, etc.) and stored securely.
        - Consider how codes or pseudonyms may be used to replace names or other identifiers. If names will be replaced with pseudonyms or code numbers, explain how the master code list will be stored and who will have access to it.
        - Discuss what happens to any audio or video recordings after the study has closed.
    - ***Anonymous***: Most projects will not be entirely anonymous, even if questions or other research activities do not collect identifiers. To be truly anonymous, there must be no viable mechanism by which the identity of the respondent could be connected to the data. This includes email addresses and IP addresses that may be collected with online surveys or to correspond with interview participants.

Please contact the IRB at irb@franklin.edu with any questions.