Social Behavioral Application Instructions and Checklist

Regulations:
Title 45 Code of Federal Regulations Part 46 (45 CFR 46) Protection of Human Subjects specifies federal regulations for the conduct of research involving human subjects. All human subjects research at the University of Miami must be conducted in accordance with 45CFR46. The regulations are available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

Completing the Application:
Applications that require Full Board review must be submitted **at least 10 business days** prior to the next IRB meeting. The meeting schedule is available at: www.hsro.med.miami.edu

All applications should be entered in eProst and written in non-technical terms. It is the investigator's responsibility to provide information about research procedures so that the IRB has a clear understanding of what the research entails. Researchers should keep in mind that the individuals reviewing the application may be unfamiliar with the field of study involved.

Do not leave items blank in the application, or fail to provide to the IRB any poster, document, or other written communication to subjects. Such applications will be either tabled or disapproved.

In addition to submitting an IRB application, researchers should submit any supporting material that will assist the IRB's review.

Approval:
Data collection may not begin until researchers have received approval to conduct the research. At the same time, research shall not continue beyond the date stated on the approval letter. Research projects involving human subjects can be approved for up to one year at a time in accordance with Federal Regulations.

A study is considered complete when **data collection is** complete and there will be no further use of information identifying participants individually.

Application Checklist

This page is provided solely to assist you with completion of your application. Do not include this page with your application. This page is to be used as your guide. Be sure your completed application includes the following:

☐	**Title page** with the contact information for all investigators. This information will serve as the official roster of investigators for your protocol.
☐	**Complete application form.**
	☐ A brief description of the purpose, background, and methodological design of the study.
	☐ A description of the setting or location(s) of where the research will be conducted. (If applicable, attach letters of support or agreement showing you have permission to conduct research at this location.) This is particular pertinent to research being conducted within a school district, medical setting, or outside agency.
	☐ An estimate of how much time will be requested of each participant.
	☐ A description of any potential financial interest on the part of an industry funding source in the outcome of the research.
	☐ A description of any risks or potential benefits to participants for participating in this research.
	☐ A description of any compensation or incentives.
	☐ A description of inclusion and exclusion criteria in selecting participants.
	☐ A description of steps that will be taken should a participant become upset or distressed as a result of their participation in this study, if applicable. Provide a list of community agencies or counseling services that will be used as referral sources, if applicable.
	☐ A description of instances in which participant confidentiality would be broken (e.g., IRB audit, audit by federal authorities).
☐	**Grant proposal, research proposal, or prospectus.** The entire body of the proposal should be included as supporting document when you are seeking or have obtained funding from an external sponsor.
☐	**Copies of advertisements, recruitment letter(s), telephone scripts, instructions to participants. Recruitment cannot begin until the study has been reviewed and approved by the IRB.**
☐	**Forms that will be used to document informed consent and assent (e.g., written consent form, written assent, cover letter).** This is required unless a waiver of written consent is being requested.
☐	**Debriefing script** when applicable. Required when deception is used.
☐	**Copies of surveys, instruments or measures, questionnaires, interview schedules, focus group questions, screening instruments,** and/or other materials used to collect data.
☐	**Certification of back translation for any materials that were translated into a language other than English.**
☐	**CV/Biosketch for PI**
☐	**Statement of CITI** certification for all personnel involved with human subjects including data analysis