SOCIAL/BEHAVIORAL/EDUCATIONAL RESEARCH PROTOCOL

University of Missouri­­­–St. Louis

*Remove the light blue instructions before submitting and fix any formatting issues.*

Project Title:

IRB Number:

Version Number: 1

Version Date:

Principal Investigator:

Funding Source:

*Instructions: Use the section headings to write the protocol, inserting appropriate material in each. If a section is not applicable, leave heading and insert NA. If an Amendment is submitted to the IRB and those changes will require modifications to this protocol, the protocol will need to be re-uploaded with an Amendment. Upload two copies, a track changes and clean copy.*

1. **Research Objectives/Background**
2. Describe the purpose, specific aims, or objectives. State the hypothesis to be tested or the research questions that will guide the study.
3. Provide the scientific or scholarly background for, rationale for, and significance of the proposed research based on the existing literature and how it will add to existing knowledge.
4. **Recruitment Process**
5. Describe the recruitment process.
6. Describe how and where recruitment will take place.
7. **Consent Process**
8. Describe the consent process; including who will be asked to consent and what type of consent will be obtained from each subject population, if there is more than one.
9. **Inclusion/Exclusion Criteria**
10. List all inclusion and exclusion criteria.
11. List any restrictions on participation and appropriate screening procedures to ensure that the restrictions are maintained.
12. **Number of Subjects**
13. Include the anticipated enrollment number in this study. Include a break-down in numbers if there is more than one subject population.
14. Include the statistical analysis or other justification for the number of subjects enrolled.
15. **Study Procedures/Study Design**
16. Include a detailed description of the procedures and/or design to be followed (what will subjects be asked to do), and describe each intervention and/or interaction with the subjects and/or their data.
17. Describe the time commitment involved.
18. Include whether the procedure/item listed is research-only (occurring only because they are a participant in the research) or routine care/activity (it would occur regardless of the research and you are requesting to collect that data to include in your data analysis).
19. A table of events may be helpful in this section.
20. **Potential Risks**
21. Describe any reasonably foreseeable risks or discomforts to the subjects and the steps to minimize risks.
22. Include the plan for reporting unanticipated problems or deviations to the IRB. This plan must include a five-day reporting requirement to the IRB once becoming aware of an event.
23. **Anticipated Benefits**
24. Describe both direct and indirect benefits for either the individual or society.
25. **Compensation**
26. Describe the amount, method, and timing of disbursement. This includes checks, cash, gifts, extra/course credit, etc.
27. **Data Safety Monitoring Plan**

Describe the plan to monitor the data, if necessary. A plan is required for treatment and/or intervention studies, sensitive data are being collected, or there is a possibility for subjects to experience adverse events, etc.

1. The plan should include when something needs to be reported
2. The frequency of the monitoring, such as points in time or after a specific number of participants are enrolled
3. Who will conduct the monitoring, such as a data board, medical monitor, investigator, independent physician; the specific data to be monitored
4. Procedures for analysis and interpretation of the data
5. Actions to be taken upon specific events or end points (early stopping rules)
6. Procedures for communication from the data monitor to this site.
7. **Multiple Sites**
8. Specify who is the lead site and describe the roles of each site in the study.
9. Indicate whether all required approvals are already in place or will be in place at each site prior to project implementation. If the study will utilize a reliance agreement or a single IRB, please describe which institution(s) will be relying on another IRB for review, and which institution will be responsible for the IRB oversight of the relying IRB(s).
10. Describe the plan that is in place to manage information obtained from multiple sites that may be relevant to the protection of human subjects such as reporting unanticipated problems, protocol modifications, and interim results.
11. **References**
12. Findings from a literature search or pilot study must be outlined including appropriate detailed references to earlier studies and data.
13. If necessary, additional references to supporting data or additional information may be included in an appendix.