Approval Number:
Approval Date:
IRB Member:

# APPLICATION FOR HUMAN SUBJECTS PROTOCOL
## Institutional Review Board (IRB) for Research with Human Subjects

**NOTE: Training certificates and numbers are required for everyone included on this application.** Co-investigators from institutions not affiliated with Samford University must either complete SU's required on-line IRB training or provide documentation of similar training elsewhere.

| | | | | | |
|---|---|---|---|---|---|
| **Project Title** | | | | | |
| **Principal Investigator Information** | **Name** | | **E-mail** | | |
| | **School or Dept** | | **Status:** Select one: | ◯Student ◯Faculty/Staff *(If student, provide information for responsible faculty below)* | |
| | **Campus or Mailing Address** | | **Phone** | | **Certificate # and Completion Date** |
| **Faculty Advisor, if PI is a student** | **Name** | | **E-mail** | | **Certificate # and Completion Date** |
| | **School or Dept** | | **Phone** | | |

**List additional co-investigators, including those from other institutions. Attach contact information for additional researchers.**

| **Name** | **Degree(s)** | **Dept or School** (provide address if off-campus) | **Contact Information** | **Certificate # Cert Exp Date** |
|---|---|---|---|---|
| | | | **Phone:** | |
| | | | **E-mail:** | |
| | | | **Phone:** | |
| | | | **E-mail:** | |
| | | | **Phone:** | |
| | | | **E-mail:** | |

**Investigator's Agreement:**
I certify that I as well as all co-investigators have completed the required Samford University IRB online training and that certificate numbers for each investigator are included with this application. I agree to not begin data collection/analysis until I receive IRB approval. I agree to obtain approval before making any changes or additions to the project. I will provide progress reports at least annually, or as requested. I agree to report promptly to the IRB all unanticipated problems or serious adverse events involving risk to human subjects. A copy of the informed consent will be given to each subject if applicable and a signed original will be retained in my files.

**Faculty Advisor's Agreement:** (If the Principal Investigator is a student)
I certify that, as the student's faculty advisor, I have:

☐ read and approved the materials submitted; and
☐ completed the required Samford University IRB online training. My certificate number is

**This application and any additional documentation should be submitted electronically via your Samford e-mail account. NOTE: The electronic submission of this application from your Samford University e-mail account constitutes your signature. For student researchers, this application must be sent from faculty advisor's e-mail account.**

| **1. Current or Planned Funding Source (Internal or External)** | |
|---|---|
| Has project received approval for grant funding?<br>◯**Yes** ◯**No** | If Yes, funding source/agency is: |
| Grant/Contract No. (if available): | |

**2. Conflict of Interest.** Will members of the research team have financial interest in, receive personal compensation from, or hold a position in an industry sponsoring this study or otherwise have a potential conflict of interest regarding the conduct of this study?

◯**Yes** ◯**No** If **Yes**, provide explanation below.

**3. Student Investigators.** Check box below

☐ Undergraduate ☐ Master/EdS ☐ Doctoral

**4. Purpose of Project.** In the space below, provide a **brief summary (250 words)** of the purpose of the project in layman's terms including: (a) background information as necessary, (b) research question(s), and (c) explanation of why the study is needed.

| **5. Enrollment Information.** | |
|---|---|
| Expected number of participants: | |
| Expected gender representation: | **Males** **Females** |
| Expected age of participants: | |

| **6. Vulnerable Populations.** "YES" to any item A-E will necessitate an Expedited or Full Review and Written Informed Consent from Participant and/or Parent/Guardian. | **YES** | **NO** |
|---|---|---|
| A. Children: minors under 18 years of age | ◯ | ◯ |
| B. Non-English speaking | ◯ | ◯ |
| C. Decisionally impaired or mentally incompetent | ◯ | ◯ |
| D. Prisoners, parolees and or other convicted offenders | ◯ | ◯ |
| E. Pregnant women<br>Check "Yes" if study is about pregnancy, pregnant women and/or the fetus or neonate. | ◯ | ◯ |

**7. Summary Checklist – Are any of the following involved?**

The items listed below ARE NOT an all-inclusive list of methods or procedures but are intended to provide "triggers" or reminders for you to provide appropriate information in subsequent questions in the application or to provide supplemental materials necessary for the review process.

| | | YES | NO |
|---|---|---|---|
| A. Will research include use of existing data, research records, patient records, retroactive chart review, and/or human biological specimens *(submit data collection form)*? | | ○ | ○ |
| B. Will data collection include surveys, questionnaires or psychometric testing? *(submit copy of survey/questionnaire with protocol application)* | | ○ | ○ |
| C. Will data collection include interviews or focus groups? *(provide interview/focus group questions with protocol application)* | | ○ | ○ |
| D. Will research include deception or less than full disclosure? | | ○ | ○ |
| E. Will research include accessing student educational records? | | ○ | ○ |
| F. Will data collection include: | *Audio Recording? | ○ | ○ |
| | *Video Recording? | ○ | ○ |
| | *Photography? | ○ | ○ |

*If you answered "Yes" to any of the options in *Question 7*, this information must be disclosed in the informed consent document, if applicable. Also attach a copy of the questionnaire(s); inventories, or scales that will be completed by participants.

**NOTE:** Put your name and date in the file name on all files you attach separately when submitting your IRB application.

**8. Full description of the study design, methods and procedures including**:

- type of experimental design;
- study procedures, including sampling methods, permissions needed, timeline; location of study (e.g. name of school, hospital)
- sequential description (explained in steps) of involvement of participants (what they will do or what will be done to them);
- what kinds of data will be collected;
- details on the primary outcome measurements; and explain any follow-up procedures (if applicable).

**Enter the description of the study in the space below.**

**9. Duration of entire study and duration of an individual subject's participation, including follow-up evaluation if applicable, including:**

- number of required visits, tests, surveys to be completed, interventions.
- approximate duration of each intervention (i.e., how much time should the participant expect to spend).

This study will require how many visits/sessions:
Each session/visit will last how many minutes or days:
The duration of the entire study will be:

**10. Where will the participants be studied?** If off Samford University campus, list locations. (e.g. names of schools, school districts, clinics, hospitals, centers). Attach a copy of letter(s) of permission to conduct the research project from or any off-campus location (schools, etc.).

**11. Confidentiality.** Explain how you will protect the confidentiality of the data collected. Describe procedures for protecting against or minimizing any potential risks from breach of confidentiality or invasion of privacy. For example:

- Where will the data be stored? What security measures will be applied?
- Who will have access to the data? Provide explanation of why they need access.
- If applicable, specify your plans for de-identifying the material if audio/video recordings or photographs will be used.
- If applicable, describe procedures for sharing data with entities not affiliated with Samford University.
- Provide a timetable for destroying the data and identify how they will be destroyed or provide explanation for storage.

***NOTE:*** The IRB expects researchers to access the minimal amount of data to conduct the study and to comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements.

**12. Full description of risks and measures to minimize risks.** Give full descriptions and measures risk factors. For example:

- psychosocial harm (e.g. emotional distress, embarrassment, breach of confidentiality, etc.)
- economic harm (e.g. loss of insurability), and
- known side effects of study medication,
- risk of pain and physical injury.

**13. Benefits to subjects and/or society.** The possibility of benefits to society should be clearly distinguished from the possibility of benefit to the individual subject, if any. If there is no direct benefit to the individual subject, say so. Do not list monetary payment as a benefit.

**14. Incentives and Costs for participation.** If monetary, specify the amount and how this will be prorated if the subject withdraws (or is withdrawn) from the study prior to completion.

**15. Data analysis.** State how the data will be analyzed, indicate where and by whom data analysis will be performed.

**16. Methods of recruiting.** Tell how prospective subjects are contacted. Provide recruitment script (letters, email, flyers and advertising, telephone script, verbal, website, etc.).

**17. Waiver of Consent Documentation and/or Procedure.** The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if certain conditions are met and if sufficient justification is provided. If waiver is being requested, provide completed waiver form. See next section of application. Check box below indicating waiver request.

○ **Yes**, I would like to request a waiver of consent. Fill out the Request for Exempt Review Form
○ **No**, I do not request a waiver of consent. I have attached the Informed Consent form with this application.

**18. How will informed consent be obtained?** Give full descriptions and measures for all of the following applicable risk factors:

- Describe the process.
- All minors in a research study should have parent/guardian permission/consent. Obtain assent from children ages 7-18.
- When the consent of a legally authorized representative is substituted for consent of the adult subject, explain why this is necessary.
- If non-English-speaking subjects will be enrolled, a consent form should be prepared in their foreign language.
- Someone who is fluent in the subjects' language must be available to interpret.

**Attach a copy of the informed consent document(s) unless waiver is requested in question 17. Use Informed Consent form from IRB website.**

**19. Any Additional Information**