FOR IRB OFFICE USE ONLY:

IRB Protocol # _____

REQUEST FOR IRB REVIEW OF RESEARCH INVOLVING HUMAN SUBJECTS

Please complete this Request for Review as thoroughly as possible.

FORM MUST BE TYPED—HANDWRITTEN DOCUMENTS WILL NOT BE ACCEPTED.

Type of Review Requested:

☐ Exempt [Status (see RR 101) ☐ Expedited ☐ Full Board

For details regarding types of review, please see "Levels of Review" under FAQ at https://www.seu.edu/irb/faq/

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1. Research Project (This section to be completed for ALL types of reviews requested)

Protocol Title: _____

Date of Submission: _____ Research project start date*: _____

**The project start date cannot be earlier than the protocol's approval date. To start research as soon as the protocol is approved, please note "upon approval" for the project start date."*

Research project end date*: _____

**The project end date should be the date after which data collection ceases. This date should not exceed one year from the start date for expedited/full board review and no more than three years for exempt protocols, without an extension approval by the IRB.*

☐ Unfunded

☐ Internal Funding Source: _____

☐ External Funding (provide grant title and award # below) Grant Award #: _____

Grant Title: _____ Sponsor/Agency: _____

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2. Principal Investigator (PI) (This section to be completed for ALL types of reviews requested)

a. Faculty/Staff PI (Do not complete this section if you are a student.)

Name: _____ Email: _____

College/Department: _____

☐ Class Research Project ☐ Independent Research Project

Course Name and #: _____

Training must be completed before application can be reviewed. **Training completed:** ☐ **YES** ☐ **NO**

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3. Co-Investigators (This section to be completed for ALL types of reviews, if applicable.)

a. Name:_____

Institution (if not SEU): _____

Email:_____

Training must be completed before application can be reviewed. **Training completed:** ☐ **YES** ☐ **NO**

b. Name:_____

Institution (if not SEU): _____

Email:_____

Training must be completed before application can be reviewed. **Training completed:** ☐ **YES** ☐ **NO**

c. Name:_____

Institution (if not SEU): _____

Email:_____

Training must be completed before application can be reviewed. **Training completed:** ☐ **YES** ☐ **NO**

d. Name:_____

Institution (if not SEU): _____

Email:_____

Training must be completed before application can be reviewed. **Training completed:** ☐ **YES** ☐ **NO**

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4. Cooperating Institutions (This section to be completed for ALL types of reviews.)

a. Will the research be conducted on the SEU campus? ▣ **YES** ☐ **NO**

If "no," please indicate the location(s): _____

a. **Was permission granted to conduct the research at the off-campus location?**
☐ **YES** ☐ **NO** ▣ **N/A**

If "yes," please attach a copy of the documentation.

b. Is this research being done in cooperation with any institutions, individuals, or organizations not affiliated with SEU? ☐ **YES** ▣ **NO**

If "yes," please list: _____

a. **Has the other institution's IRB/ethics board approved this study?** ☐ **YES** ☐ **NO**
If "yes," please attach a copy of the approval

c. Are you directly or indirectly in a position of leadership over the participant pool? (Examples include but are not limited to: supervisor, manager, pastor, professor)
☐ **YES** ▣ **NO**

If "yes", please explain the relationship to the participants and what efforts have been put in place to mitigate coercion and harm:

5. **Research Project Description (This section to be completed for ALL types of reviews.)**

   a. **Rationale: Provide (in lay terms) a concise statement of the project's general aims in relation to the broader field of research.**

   b. **Specific Aims: Identify the variables to be manipulated and/or measured, and describe their expected relationships.**

   c. **Study Procedures: Describe the activities in which the participants will be engaged. Provide methods, procedures, interventions, and manipulations. Also, include the actual materials (including informed consent) participants will see and/or specific questions that will be asked, if possible. If this level of detail is not possible, provide an idea of the types of questions and the reason that greater specificity would not be possible at the point of submission. When using a methodology that might put the participants at risk, please reference previous research that used the same or similar methodology (use a separate page if more space is needed).**

   d. **Use of Deception: Describe in detail any deception used and explain why deception is critical to the research. When using a methodology that might put participants at risk, be sure to reference previous research that might use the same methodology.**

e. Training: Describe any supervision or training that will occur for research personnel involved in this study, including CITI training and any additional training. For student investigators, please include relevant research experience and/or coursework.

For protocols involving tests, surveys, questionnaires, or interviews: ☐ N/A

f. What type(s) of instruments/activities will be used (Check all that apply.)

☐ Test/Survey/Questionnaire

Type: ☐ published/standardized ☐ researcher-created ☐ other (please explain)

Format: ☐ paper ☐ telephone ☐ online ☐ other (please explain)

☐ Interviews

Type: ☐ published/standardized ☐ researcher-created ☐ other (please explain)

Format: ☐ face-to-face ☐ telephone ☐ online ☐ other (please explain)

Please attach a copy of any tests/surveys/questionnaires and/or interviews, etc.

g. Will the subjects encounter the possibility of stress or psychological, social, physical, and/or legal risks that are greater than those ordinarily encountered in daily life or during performance of routine physical or psychological examinations and/or tests?

☐ YES ☐ NO

If YES, please justify:

h. Will information be requested that subjects might consider personal and/or sensitive?

☐ YES ▣ NO

If YES, please explain:

i. Will the subjects be presented with materials that might be considered offensive, threatening and/or degrading? ☐ **YES** ▣ **NO**

If YES, please explain (include measures planned for intervention if problems occur):

6. PARTICIPANTS

a. Participant Population

Research involving study participants who are likely to be vulnerable to coercion or undue influence (such as minors under the age of 18 (45 CFR 45 Subpart D), prisoners (45 CFR 47 Subpart C), pregnant women, human fetuses, neonates (45 CFR 45 Subpart B), persons with mental disabilities, or persons whose economic status would leave them susceptible to coercion) is not eligible for exempt status.

a. How many participants are needed for the study? _____

b. Target Populations Include:

☐ Athletes
☐ Children 0-6 (Parental consent required)
☐ Children 7-17 (Parental consent & child assent required)
☐ Developmentally disabled (Guardian consent & Participant assent required)
☐ Elderly
☐ Mentally ill
☐ Military personnel
☐ Persons convicted of a crime or on parole
☐ Persons over the age of 18 ONLY
☐ Persons with English as a second language
☐ Physically impaired
☐ Pregnant women
☐ Teachers
☐ SEU staff
☐ SEU students
☐ Non-SEU college students
☐ Victims of crime

b. Describe the subjects of this study:

a. Describe the sampling population:

b. Describe the subject selection methodology:

c. Describe the procedures used to recruit subjects. Include copies of scripts, flyers, advertisements, posters, web based solicitations and/or emails:

d. What is the expected duration of participation for each segment (e.g., gender, ethnicity) of the sampling population?

a. If there is more than one session, please specify the duration of each session:

c. Participant Compensation and Costs

a. Participants will receive: ☐ Compensation ☐ Required Course Credit ☐ Extra Credit ☐ N/A

a. If compensation/course credit/extra credit is offered, please complete the following:
Type (e.g., gift card, cash, extra credit):_____
Amount: _____
Source: _____

b. If required course credit is offered for participation, please describe what alternative assignment(s) students may complete to get an equal amount of credit should they choose not to participate in the study:

c. Are other inducements planned to recruit participants? ☐ **YES** ☐ **NO**

If yes, please describe:

d. Participant Risks and Benefits

1. What are the benefits to participants in this study?

2. What are the risks (physical, social, psychological, legal, economic) to participants in this study?

a. Indicate the degree of risk (physical, social, psychological, legal, economic) the research poses to human subjects (select the one which applies).

☐ **MINIMAL RISK**: a risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

☐ **GREATER THAN MINIMAL RISK**: Greater than minimal risk is where the probability and magnitude of harm or discomfort anticipated in the proposed research are greater than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests.

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7. *Confidentiality and Data Security* (This section to be completed for ALL types of reviews.)

a. Will personal identifiers be collected? ☐ YES ☐ NO

b. Will identifiers be translated to a code? ☐ YES ☐ NO ☐ N/A

c. Will recordings be made (audio, video)? ☐ YES ☐ NO

a. If "yes", please describe:

b. If any type of audio or video recordings will be made of participants (including photographs), please describe how the participants' consent for this recording will be obtained.

d. Who will have access to data (surveys, questionnaires, recordings, interview records, etc.)?

e. Describe how participant confidentiality will be protected and research records secured.

f. How long will the records be retained? (SEU retains records for 5 years)

g. How will the records be destroyed after this time? ·

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8. Consent

a. Informed consent

1. Will consent forms be utilized? ☐ **YES** ☐ **NO**

If "no," Section 8b must be completed.

a. Will the consent form be presented on paper or online? ☐ **Paper** ☐ **Online**
b. If the participants are minors, will assent forms be used? ☐ **YES** ☐ **NO** ☐ **N/A**

If "no," please explain.

***Please attach the consent and/or assent form(s) that the participants and/or parent/guardian will be required to sign.*

b. Waiver of written informed consent *(only to be completed if the answer to 8a1 is "no")*

1. Will the only record linking the participant to the research be the consent document *and* will the principal risk to the participant be a breach of confidentiality? ☐ **YES** ☐ **NO**

2. Is this a minimal risk study that involves procedures for which written consent is not normally required? ☐ **YES** ☐ **NO**

3. Explain how consent will be obtained.

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9. The Principal Investigator should initial all items below:

_____I confirm that I have reviewed the protocol and any attachments, and I approve them.

_____I confirm that all items required by the IRB checklist (below) are submitted with this protocol. (If applicable)

_____I confirm that the proposed consent form is, in my judgment, appropriate for this research.

_____I understand that as Principal Investigator, I have ultimate responsibility for the conduct of IRB-approved studies, the ethical performance of protocols, the protection of the rights and welfare of human participants, and strict adherence to the study's protocol and any stipulations imposed by the Southeastern University Institutional Review Board.

_____I understand that it is my responsibility to ensure that the human participants' involvement as described in the funding proposal(s) is consistent in principle, to that contained in the Request for IRB Review. I will submit modifications to the IRB as necessary.

_____I agree to comply with all Southeastern University policies and procedures, as well as with all applicable federal, state, and local laws, regarding the protection of human participants in research.

_____ _____

Principal Investigator Signature Date

SUBMISSION CHECKLIST:

For submission to be complete, all applicable documents must be sent as attachments to: lrb@seu.edu

Incomplete protocol submissions will not be sent out for review and will be returned to the investigator(s).

YES	N/A	
☐	☐	This Request for Review application, fully completed and signed by researcher.
☐	☐	#4b Documentation of permission to conduct research in a location other than SEU.
☐	☐	#4d IRB approval documentation from another institution
☐	☐	#5a Research project description (check N/A if typed on form).
☐	☐	#5f Tests, questionnaires, interview questions, surveys, scripts, etc.
☐	☐	#6b3 Recruiting materials (including scripts), text of email or web-based solicitation.
☐	☐	#8a Consent and/or assent form(s).
☐	☐	#8a If using oral consent, researcher must provide a copy of the consent document that will be read to research participants and, if required, the name and address of the individual who will witness the oral consent. The oral consent document should include a statement indicating that completion of the research exercise will confirm the participants' consent to participate.
☐	☐	CITI training certificate(s).