Southeast Missouri State University
Institutional Review Board
One University Plaza, Rhodes Hall 107, MS 6200
Cape Girardeau MO 63701
Phone: (573) 651-2355 Fax: (573) 651-2382
Website: http://www.semo.edu/provost/irb
E-mail: IRB@semo.edu

Human Subjects in Research

Review and Monitoring Form

I. Researcher Information			
Date of Most Recent IRB Approval Dates:			
Original IRB Protocol Number:			
IRB Review and Monitoring Protocol Number(s): (Enter NA if not applicable)			
What Type of Review Was the Original Protocol? (Check From the Options on the Right)	**Exempt** ☐	**Expedited** ☐	**Full Review** ☐
Project Title:			
Principal Investigator/Faculty Sponsor			
Department:			
Address:			
Telephone Number:			
Fax Number:			
E-mail Address:			

Policies regarding the protection of human subjects in research require a periodic review of all research protocols approved by the Southeast Missouri State University (SEMO) Institutional Review Board, unless the original IRB review found theresearch to fall under the exempt category.

Research protocols receiving either a full review or an expedited review must be renewed on a yearly basis. This Review and Monitoring Form must be received two weeks prior to the anniversary date (date originally approved). If the report is not received by this date, data collection for this study must stop.

If you have any questions, please contact:
Institutional Review Board
Email: IRB@semo.edu

II. Study Renewal

a. Will you be collecting data from human subjects during the upcoming renewal period?

☐ Yes ☐ No

a.1. *If yes, did the assessment of potential risks to subjects, as described in the approved study, change?*

☐ Yes* ☐ No

** If new risks have been identified, please modify the protocol as described in Section 3.*

b. Will the research covered by this renewal will be limited to the analysis of data you have already collected under this study?

☐ Yes ☐ No

c. Will the research covered by this renewal be limited to the secondary analysis of data collected by someone else?

☐ Yes ☐ No

c.1. *If yes, were there any deviations from the approved confidentiality procedure or was there unanticipated identification of subjects?*

☐ Yes* ☐ No

**If yes, explain without divulging private identifiable information:*

III. Study Modifications

a. Describe the proposed changes:

b. When submitting this form by e-mail, attach a copy of the most recently approved study using the Track Changes function in Microsoft Word. Label the document "Attachment III.b."

IV. Adverse Event

a. Date/Time of Incident:

b. Subject(s) ID or Initials:

c. In your opinion, is this a serious adverse event?
☐ Yes ☐ No Comments:

d. In your opinion, is this an unexpected adverse event?
☐ Yes ☐ No Comments:

e. In your opinion, was this incident related to participation in this study?
☐ Yes ☐ No Comments:

f. Was medical treatment provided for this event?
☐ Yes ☐ No Comments:

g. Does the subject require further medical treatment?
☐ Yes ☐ No Comments:

h. Will the subject remain in the study?
☐ Yes ☐ No Comments:

i. Are consent form changes required to better inform subjects of newly identified risks?
☐ Yes ☐ No Comments:

j. Include a detailed description of the event:

V. Study Completion

a. Indicate why you consider the study to be complete:

☐ All research/clinical investigation activities including data analysis and reporting are complete.

☐ The Lead Investigator never initiated the study.

☐ Subject accrual is finished, all data collection is complete and the only remaining activity is analysis of the data, the data are de-identified, and there are no identifying links or codes to the de-identified data.

☐ The Lead Investigator plans to leave the University and intends to continue the research activities at another institution.

☐ The study has been open for a period of three or more years and the Lead Investigator has enrolled no subjects in the study.

b. List any publications generated from the research project:

c. Date of completion:

Complete research protocols should be submitted electronically to:

Institutional Review Board
irb@semo.edu

Assurance and Submission
Your submission certifies that as a part of the research personnel you understand and accept the following obligations to protect the rights and welfare of research subjects in this research:

COMPLIANCE WITH FEDERAL AND UNIVERSITY REGULATIONS AND STANDARDS

- I recognize that as a member of the research team, it is my responsibility to ensure that this research and the actions of all research personnel involved in conducting the study will conform with the IRB approved protocol, IRB policies, and all applicable federal regulations including but not limited to HHS, FERPA, PPRA, and/or HIPAA regulations.
- I understand that failure to comply with all applicable HHS, FERPA, PPRA, and/or HIPAA regulations, IRB policies and procedures, and the provisions of the protocol as approved by the IRB may result in suspension or termination of my research project, notification of appropriate governmental agencies by the IRB, and/or suspension of my freedom to present or publish results.

IRB APPROVAL OF ALL PROTOCOLS

- I will not initiate any change in protocol without IRB approval except when it is necessary to reduce or eliminate a risk to the subject in which case the IRB will be notified as soon as possible.
- I understand that IRB approval is valid for no more than one year with continuing review by the IRB required at least annually in order to maintain approval status. I will not enter subjects in the study before IRB approval or if IRB approval expires. In the latter case, I will immediately contact the IRB to obtain permission to continue subjects in the research study.
- I recognize that it is my responsibility to ensure that the study has been reviewed for scientific merit and ethical content.
- I recognize that it is my responsibility to ensure that there is constant open dialogue between myself and the other research personnel to ensure that the research is conducted correctly, and the safety and protection of the subjects are ensured.
- I recognize that it is my responsibility to ensure that valid informed consent/assent/parental permission has been obtained from all research subjects or their legally authorized representatives. I will ensure that all project personnel involved in the process of consent are trained properly and are fully aware of their responsibilities relative to the obtainment of informed consent according to the IRB guidelines and applicable federal regulations. I will use only the currently approved, informed consent form or script for recruiting subjects.
- I understand that I am part of the collaborative effort to maintain the integrity of the human subjects' research approval process and procedures to ensure continuous quality improvement and academic excellence at SEMO.

COMMUNICATION WITH THE IRB

- I will promptly inform the IRB of any event that requires reporting in accordance with IRB policies and procedures on unanticipated events involving risks to subjects or others and adverse events (serious and/or unexpected).
- I will inform the IRB immediately of *any* significant negative change in the risk/benefit relationship of the research as originally presented in the protocol and approved by the IRB.
- I will inform the IRB immediately if I become aware of any violations of HHS regulations (45 CFR 46), FERPA regulations (34 CFR 99), PPRA regulations (34 CFR 98), HIPAA regulations (45 CFR 164.530), or IRB policies and procedures for the protection of human subjects.

IRB MONITORING OF STUDIES

- I will maintain all required research records and recognize that the IRB and federal government is authorized to inspect these records.
- I understand that, per OHRP/FDA guidelines, the IRB will be monitoring adherence to approved research protocols. The oversight process does not end with approval of a research protocol.

PRINCIPAL INVESTIGATOR/FACULTY ADVISOR ASSURANCE

- I certify, as a faculty sponsor, that the student investigator is knowledgeable about the IRB policies and applicable federal regulations governing research with human subjects and has sufficient training and experience to conduct this study in accord with the approved protocol. In addition, I will meet with the student investigator on a regular basis to monitor study progress. Should problems arise I agree to be available personally to supervise the student investigator in solving them. If I will be away, I will arrange for an alternate faculty sponsor to assume my responsibilities.
- **By submitting this request to irb@semo.edu from my SEMO email address**, the Principal Investigator (and responsible faculty member if this is a student research project) accepts responsibility for ensuring that all members of the research team: 1) complete the required training to fulfill their study responsibilities, 2) follow the study procedures as described in the IRB approved protocol and comply with Southeast Missouri State University's Policy and Procedure for Human Subjects and all IRB communication and 3) uphold the rights and welfare of all study participants.