

**Human Subjects Research - Initial Review Form**

**Guidelines for completing this research protocol:**

- All research protocols must be typed.
- Each individual on the research team that needs to be listed on the approval letter must be listed as an investigator or co-investigator on this form.
- If new personnel are added after IRB approval you must notify the IRB by submitting the Southeast Missouri State University (SEMO) Review and Monitoring Form.
- All items on the research protocol must be answered (\*see the exception for existing data protocols). If a particular item does not relate to your protocol, indicate “not applicable.”
- In order to ensure a timely review, research investigators are encouraged to be clear and concise, use lay language, and avoid the use of discipline specific language.

**Before you submit your research materials check the boxes below to ensure that you have the following documents prepared for IRB review:**

- Adequate training of research team (Training is required, but do not submit documents. CITI training results are automatically submitted to IRB)
- This Initial Review Form
- Informed consent/assent/parental permission document(s)
- Research materials (e.g., surveys, interview items, questionnaires for data collection, etc.)
- Recruitment materials
- Letter(s) of support (Usually only required if work is in collaboration with another institution)
- Request for Waiver of informed consent under 45 CFR§46.116 (c) and/or (d), (if applicable)

\*Guidelines for completing the IRB protocol and other research materials can be located at: <http://www.semo.edu/provost/irb>. *Allow 7-10 business days for the Initial Review. If the proposal must be considered by the full IRB, it will go to the first monthly meeting after that period.*

**All above materials should be submitted electronically to:**

Institutional Review Board -- [irb@semo.edu](mailto:irb@semo.edu)

**Section 1. Research Personnel**

*In the space provided, include all individuals who will interact or intervene with human subjects or their private, identifiable information. Additional personnel can be added under Section 9. If new members are added to your research team after IRB approval, the PI must submit the SEMO Review and Monitoring Form with the information below.*

Project Title:	
<b>Principal Investigator/ Faculty Advisor:</b> (Cannot be a student investigator.)	
Department:	
Address:	
Telephone Number:	
Email Address:	
Research with Human Subjects Training:	<input type="checkbox"/> NIH <input type="checkbox"/> CITI – Social and Behavioral Module
<b>Co-Investigator/Student Investigator:</b>	
Department/Non-SEMO Affiliation:	
Telephone Number:	
Email Address:	
Research with Human Subjects Training:	<input type="checkbox"/> NIH <input type="checkbox"/> CITI – Social and Behavioral Module <input type="checkbox"/> CITI – Student Class Projects Module
<b>Co-Investigator/Student Investigator:</b> (List additional investigators under section 9.)	
Department/Non-SEMO Affiliation:	
Telephone Number:	
Email Address:	
Research with Human Subjects Training:	<input type="checkbox"/> NIH <input type="checkbox"/> CITI – Social and Behavioral Module <input type="checkbox"/> CITI – Student Class Projects Module
<b>Is another institution engaged in the research?</b> (i.e., an agent of another institution/entity will interact or intervene with human subjects or their identifiable private information for research purposes, or obtain informed consent.) <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, list the institution(s):	
<b>Is another institution or review committee reviewing this research proposal?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes If yes, list the institution(s): If yes, has approval been obtained: <input type="checkbox"/> No <input type="checkbox"/> Yes (Submit all documentation from the external committee for IRB review, if applicable.)	

**Section 2. Funding or Anticipated Funding Source**

Not Applicable

Name of External Funding Agency:

Name of Internal Grant Program:

**Contract or Grant Title:**

**Contract or Grant Number:**

( N/A - funding is pending)

**Section 3: Participant Population and Recruitment**

**1. Targeted participant population, select all that apply:**

***1a. Note: if this research protocol calls for multiple samples, please attach and label a chart that describes each sample specifically.***

**Age:**

- Adults (>= 18 years old)
- Minors (< 18 years old)
- Specific age range:

**Gender:**

- No targeted gender population (i.e., both males and females will be recruited)
- Male
- Female
- Other (e.g., Transgender):

**Race/Ethnicity:**

- No targeted race population (i.e., a variety of races will be recruited)
- African-American/Black  American Indian or Alaska Native  Asian  Hispanic/Latino  Indian (India)
- Middle Eastern  Native-American  Non-Hispanic White
- Other:

**Sexual orientation:**

- No targeted sexual orientation population
- Heterosexual
- Sexual minority (e.g., homosexual, bisexual), specify:

**College students:**

- No targeted college population
- SEMO general student body
- Targeted SEMO student population (provide the instructor or course information, name of the departmental subject pool, or specific characteristics):
- Students at institution(s) other than SEMO, specify:

**Other:**

- Illiterate  Inpatient participants  Institutionalized participants  Low income or economically disadvantaged persons  Non-English speaking  Mentally/Emotionally/Developmentally Disabled or impaired decision making capacity  Outpatient participants  Physically impaired
- Pregnant women  Prisoners  Other:

**2. Describe participant characteristics not included above, if applicable: ( Not applicable)**

**3. For each group of participants,**

**a. Describe inclusion criteria (if children, prisoners or other vulnerable participants will be recruited, explain why their inclusion is necessary):**

**b. Describe exclusion criteria:**

<p><b>4. For each group of participants,</b></p> <p>a. Provide an estimated population size:</p> <p>b. Provide an estimated sample size:</p>
<p><b>5. If participants are selected from records, (<input type="checkbox"/> Not applicable)</b></p> <p>a. Provide the name of the individual who has given the research team permission to use the records:</p> <p>b. Are the records private student or medical records? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><i>(Include the appropriate documentation to obtain these records, e.g., consent forms, FERPA/HIPAA release form, etc.)</i></p>
<p><b>6. Recruitment procedures, select all that apply:</b></p> <p><input type="checkbox"/> Student subject pool</p> <p><input type="checkbox"/> E-mail distribution via: <input type="checkbox"/> TeleSTARS <input type="checkbox"/> Personal email account <input type="checkbox"/> Survey software tool (e.g., SurveyMonkey, Qualtrics, etc.), specify:</p> <p><input type="checkbox"/> U.S. mail</p> <p><input type="checkbox"/> Handout/flyer</p> <p><input type="checkbox"/> Web site ad</p> <p><input type="checkbox"/> Newspaper ad</p> <p><input type="checkbox"/> Verbal announcement</p> <p><input type="checkbox"/> Other, specify:</p> <p><i>(Submit all recruitment materials, written materials as well as a sample of verbal recruitment announcements, for IRB review and approval, if applicable.)</i></p>
<p><b>7. For each group of participants, describe the details of the recruitment process</b> (e.g., how are you obtaining email/ mailing addresses, where are you distributing flyers, describe snowball sampling, etc.).</p>
<p><b>8. Describe how permission has been or will be obtained from outside institutions or entities to recruit, conduct research, or access records at their site.</b> (<input type="checkbox"/> Not applicable):</p> <p><i>(Append letters of support from outside entities, if applicable.)</i></p>
<p><b>9. What, if any, relationship exists between the researcher(s) and participants involved in the research or records?</b> (<input type="checkbox"/> Not applicable):</p>
<p><b>10. Describe any compensation, monetary inducements, or reimbursement for participation</b> (e.g., if participants are paid or offered extra credit, include the amount, how and when it will be coordinated). (<input type="checkbox"/> Not applicable):</p>

Section 4. Informed Consent Procedures	
<b>1. Will participants sign a written consent/assent/parental permission document? Check Yes/No below.</b>	
<input type="checkbox"/> Yes	<p><b>If yes,</b></p> <p>a. By whom will written consent be obtained (e.g., PI, student researcher, etc.):</p> <p>b. Describe the method that will be used to obtain voluntary informed consent/assent/parental permission (e.g., consent letter/form, script for phone interview, etc.) and in what setting will it be obtained (e.g., in-person, by phone, in a classroom, in the workplace).</p>

	<p>c. For assent/parental permission procedures, describe how you will ensure that only minors with parental permission forms will be included in the research. If applicable, describe how you will match or align minor assent forms with parental permission forms. <input type="checkbox"/> Not applicable</p> <p>d. Will participants receive a copy for their records? <input type="checkbox"/> Yes <input type="checkbox"/> No, explain:</p> <p><i>(Submit all informed consent documents for IRB review and approval.)</i></p>
<input type="checkbox"/> No	<p><b>If no,</b></p> <p>a. Will participants be asked to complete an online survey in which the research team will present them with a written statement including all of the required elements of consent and will they be asked to complete the survey, thereby ensuring their voluntary participation in the research?  <input type="checkbox"/> Yes (skip to part d. below) <input type="checkbox"/> No</p> <p>b. If participants will not sign a written consent/assent/parental permission document or be presented with a written statement, you must request a waiver of written documentation of consent.</p> <p>c. If participants will not sign a written consent/assent/parental permission document, will they receive an information sheet that provides them with what they need to know before deciding to participate? <input type="checkbox"/> Yes <input type="checkbox"/> No, explain:</p> <p>d. Will participants receive a copy for their records? <input type="checkbox"/> Yes <input type="checkbox"/> No, explain:</p> <p><i>(Submit all information sheets for IRB review and approval, if applicable.)</i></p>
<p><b>2. If potential participants or their legally authorized representatives are non-English speaking, please explain how the investigator will identify these participants and ensure their ability to understand information about the study to provide consent. <input type="checkbox"/> Not applicable</b></p>	

**3. Indicate factors that might interfere or influence consent procedures:**

- No known factors.
- Research will involve enrolled students in a course/program taught by a member of the research team.
- Participants are employees whose supervisor(s) is/are recruiting/requiring participation.
- Participants have a close relationship to research team.
- Research involving deception.
- Other, specify any relationship that exists between the research team and the participants:

**a. Describe the procedures to mitigate the above factors:**  Not applicable

**Section 5. Study Description**

**1. Provide a brief description of the purpose of the proposed research project, including research questions or hypotheses, and any relevant background information.** *Use language understood by a person unfamiliar with your area of research.*

**2. Type of research, select all that apply:**

- Faculty/independent research
- Student research
- Class project – course:
- Honors thesis or project/Master’s thesis/Dissertation
- Research conducted in established or commonly accepted educational settings, involving normal educational practices (e.g., effectiveness of or the comparison among instruction techniques, curricula, or classroom management methods).
- Other, specify:

**3. Do you plan to publish, present, or archive your results?**  Yes  No  Uncertain

**4. Provide an estimated data collection period:**

*(This timeframe must begin after the IRB approval date.)*

**Section 6. Study Procedures**

**1. Select all research methods that apply:**

- Paper surveys/questionnaires
- Online surveys/questionnaires, specify which survey software tool:
- Telephone surveys/questionnaires
- Standardized written/oral/visual tests
- Intervention (e.g., experimental manipulation)
- Interviews
- Focus groups
- Oral history
- Field work:  public observation  classroom observation  work site observation  Other:
- Ethnography:  participant  observer  participant-observer
- Voice, video, digital or image recordings made for research purposes
- Moderate exercise and muscular strength
- Materials (i.e., archived data, documents, records, or biological specimens) that have been collected or will be collected for non-research purposes.
- Materials (i.e., archived data, documents, records, or biological specimens) that have already been collected or that which currently exists.  
Provide the source of the existing or archived data:
- Collection or study of materials (i.e., archived data, documents, records, or biological specimens) that are

publicly available or if the information is recorded so that participants cannot be identified, directly or indirectly through identifiers

Materials (i.e., archived data, documents, records, or biological specimens) that have been collected for another research project

Other, specify:

**2. List and briefly describe the testing instruments, surveys, interview items, and/or additional research materials which will be used in the research** (*instruments included in this item must be labeled and submitted for review*):

Not applicable

*(Submit all materials for IRB review and approval, if applicable. The titles or labels you use in this item must match your submitted materials. Do not submit copyrighted or print restricted materials. In the space above provide a description and indicate that there are copyright and/or print restrictions.)*

**3. Describe the research methods** (i.e., the methods selected in Item 1), **procedures to be used, and the tasks participants will be asked to complete** (i.e., the materials described in Item 2):

*(Your procedures should be presented in sequence and include details of any equipment or interventions to be used; clearly distinguish between activities that are research and activities that would occur regardless of whether the research was being conducted; describe what non-participants will do during this period, e.g., activities and supervision.)*

**4. Describe any other data or data collection tools not included in item 1, 2, or 3 above** (e.g., items included on the demographic sheet, data collection sheet, collection of unique identifiers or IP addresses):

Not applicable

*(Submit all materials for IRB review and approval, if applicable.)*

**5. Location of research, select all that apply:**

Southeast Missouri State University – main campus, specify the general characteristics of the location (e.g., reserved classroom, open computer lab, research lab, or Library, etc.) or if available the specific location (e.g., building and/or room number):

Southeast Missouri State University – regional campus, specify the general characteristics of the location (e.g., reserved classroom, open computer lab, etc.) or if available the specific location (e.g., building and/or room number):

Other off campus location(s), specify:

Internet research

Other, specify:

**6. Describe the duration** (how long will the participants be involved?) **and frequency of procedures** (how many times will the participants be asked to engage in the research activities?):

**7. If your study does not involve any of the procedures below skip to question 8. Otherwise, select all data collection activities that apply:**

- Blood samples by finger stick, heel stick, ear stick or venipuncture.
  - a. Indicate the type of participants:
    - Healthy, non-pregnant adults who weigh at least 110 pounds
    - Other adults or minors, describe:
  - b. How many times per week will blood be drawn?
  - c. How much blood will be drawn at one-time?
  - d. How much blood will be drawn in an 8-week period?
  - e. How often will collection occur?
  - f. Include blood borne pathogen training and procedures to dispose of needles:
- Noninvasive procedures to collect biological specimens for research purposes
- Sterile surgical/invasive procedures
- Banking of biological materials
- Noninvasive procedures to collect data such as use of physical sensors applied to the surface of the body and electrocardiography
- Procedures involving x-rays
- Ingestion of wholesome foods without additives
- Ingestion/application of substances other than wholesome foods without additives
- Clinical study of a drug/medical device
- Obtaining medical data from a health care provider, health plan or health care clearinghouse
- Genetic testing
- Other, specify:

**8. Is this research FDA-regulated** (i.e., It is an experiment that involves one or more of the following test articles: foods/dietary supplements that bear a nutrient content/health claim, infant formulas, food/color additives, drugs/medical devices/biological products for human use)?

- Not applicable
- No  Yes

**If yes, explain:**

**9. Will medical clearance be necessary for participants to be included in your research** (e.g., high risk physical exercise or conditioning, tissue or blood sampling, administration of substances such as food or drugs, etc.)?

- No  Yes

**If yes, explain how the clearance will be obtained:**

**10. Describe your debriefing procedures** (e.g., how and when will participants be debriefed about the research):

*(Be sure to attach your debriefing script.)*

### **Section 7. Data Privacy and Security**

**1. How are participant data, records, or specimens identified when they are made available or collected by your research team?**

- No identifiers (e.g., neither the researcher nor the source providing the data can identify a participant based upon information provided with the data).
- Direct identifiers (e.g., participant name, SSN, date of birth, email, street address, medical record number, or any other identifying variables listed under Section 6. Study Procedures, item 4).
  - a. Authorized personnel who will have access to identifiable information includes:**
- Indirect identifiers (e.g., an assigned code or pseudonym used to track participants)



a. **Does the research team have access to the code which links the data to the participants' identities?**  
 No  Yes

b. **Authorized personnel who will have access to identifiable information includes:**

Does this research involve protected health information?  
 No  Yes

a. **Authorized personnel who will have access to identifiable information includes:**

**2. How will the data, records, or specimens labeled when published or shared?** (Note: Sharing includes releasing, transmitting and providing access to any individual or entity outside of the research team). **Check all that apply:**

Data is not linked to identifying information.

Data will be anonymized or de-identified (i.e., the participants' identity was once associated with the data but identifying information will be destroyed/removed before it is shared). **Indicate who is destroying the identifiers, when, and how:**

Coded and linked data (data is coded. With the code, the data may be linked back to identifiers, but the link back to identifiers will not be shared.).

Identifiable data (e.g., participant name, SSN, date of birth, email, street address, medical record number, or any other identifying variables listed under Section 6. Study Procedures, item 4).

Data will be shared in the aggregate **only**.

**3. Safeguarding and Storage of Research Materials, check all that apply and elaborate when necessary:**

Data is not linked to identifying information.

Consent/assent/parental permission forms will be stored in a separate location from data. **(You must provide a building and room number):**

Participant codes/ID numbers or pseudonyms will be used on all data and if there is a key linking the codes with the identifiable information it will be stored separate from the data.

All research materials will be maintained for a minimum period of three years in the following secure location on the SEMO campus **(You must provide a building and room number):**

Data will be kept on a password protected computer in the following secure location (e.g., **Your response must include a building and room number or a specific owner/user of the equipment**):

Mobile devices or removable media will be kept secure. Explain (e.g., password protected, encrypted, limited access, etc.):

Research data or materials transmitted or maintained in electronic format will be kept secure. **Explain** (e.g., encrypted when transferring or storing):

Provide additional information for any other technology or medium used to store and/or transmit information not addressed above which may apply to your specific research:

**Section 8. Risk-Benefit Analysis**

**1. Do the data or records to be collected relate to any illegal activities** (e.g., immigration status, drug use, abuse, assault)?  
 No  Yes  
**If yes, explain:**

**2. Will participants be asked to provide information or records that may be harmful to their reputation or employability, or to the company/entity that they are representing?**  
 No  Yes  
**If yes, explain how you will mitigate this harm:**

**3. Will information or records be requested that participants might consider to be personal or sensitive?**

<input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes, explain:</b>
<b>4. Will the participants be presented with materials that might be considered to be offensive?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes, explain:</b>
<b>5. Please answer both a. and b. below:</b> a. Identify any foreseeable stress or psychological, social, physical, criminal or legal risks for participants: b. Will the participants encounter the possibility of stress or psychological, social, physical, criminal or legal risks that are greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests? <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes, provide justification for the use of greater than minimal risk procedures:</b>
<b>6. Will the participants be deceived or misled in any way?</b> <input type="checkbox"/> No <input type="checkbox"/> Yes <b>If yes, explain:</b>  <i>(If yes, you must complete Section 6. Item 10.)</i>
<b>7. Describe specific measures used to minimize or protect participants from anticipated risks:</b>
<b>8. Describe any expected benefits for research participants or society as a whole:</b>
<b>9. If your research involves an invasive or high risk procedure, cite your experience with this kind of research and/or this population. List any co-investigators who will be working with you and cite their experience, if applicable. <input type="checkbox"/> Not applicable</b>

<b>Section 9. Miscellaneous</b>
<b>1. Include all other research personnel working with human subjects or their private, identifiable data not listed on page 1</b> (Information needed: Name, Affiliation, Telephone Number, Email Address, Research Training): <input type="checkbox"/> Not applicable
<b>2. Special considerations not otherwise included above:</b> <input type="checkbox"/> Not applicable

<b>Section 10. Assurance and Submission</b> <i>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:</i>
<b>COMPLIANCE WITH FEDERAL AND UNIVERSITY REGULATIONS AND STANDARDS</b> <ul style="list-style-type: none"> <li>◆ 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.</li> <li>◆ 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.</li> </ul>

#### 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](mailto: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.