

SOUTHEAST MISSOURI STATE UNIVERSITY
Institutional Review Board
Phone: (573) 651-2355

HUMAN SUBJECTS RESEARCH DETERMINATION WORKSHEET

Complete sections I and II of this worksheet to determine if your research requires submission to Southeast Missouri State University Institutional Review Board (SEMO-IRB).

This is a guide to help investigators determine if their project is considered human subjects research as defined by the Department of Health and Human Services (DHHS).

- Activities that **do** meet the definition of “human subject research” will require submission of an Initial Review Request form.
- Activities that **do not** meet this definition do not require IRB submission. Please note that you must still conduct all activities in an ethical manner.

Section I. DETERMINATION OF RESEARCH

“Research” is defined as a *systematic* investigation designed to develop or contribute to *generalizable* knowledge.

I.A. DOES THE PROPOSED ACTIVITY MEET ALL OF THE FOLLOWING CRITERIA TO BE DEFINED AS RESEARCH?

(1) Yes No Activities constitute a *systematic investigation*, (at least 4 subjects), that include research development, data collection and analysis, and evaluation.

(2) Yes No Conclusions will contribute to *generalizable knowledge* (i.e. intent to publish, present, or otherwise apply knowledge gained to a population outside of the local research context/entity).

*(CE, course/ internal program evaluations, many QA/QI programs, course requirements, or classroom exercises do not usually qualify as contributing to generalizable knowledge).

IF YOU ANSWERED “**NO**” TO (I.A.1) **OR** (I.A.2): **STOP HERE- DO NOT SUBMIT YOUR PROJECT TO THE IRB.**

IF YOU ANSWERED “**YES**” TO (I.A.1) **AND** (I.A.2): **CONTINUE TO SECTION II BELOW.**

Section II. DETERMINATION OF THE INVOLVEMENT OF HUMAN SUBJECTS “Human subject” means a living individual about *whom* an investigator conducting research obtains data through intervention or interaction with the individual, **or** the use of identifiable private information.

- *Data which describe organizational dynamics, external trends, environmental factors or other non-human factors, even if collected from humans, does not itself constitute human subjects research, unless primarily opinion-based.*
- *“About whom”= the information being elicited for the research is about the [living] individual (the “Whom”). The focus on the investigation is the opinions, characteristics, or behavior of the individual(s).*

II.A. DOES THE PROPOSED ACTIVITY INVOLVE HUMAN SUBJECTS?

(1) Yes No Collect data through *intervention*¹ or *interaction*² with an individual, including interviews, surveys, physical procedures manipulations of the subject's environment, and any other direct contact or communication with the subject (regardless of whether resulting data is identifiable or not).

1. Intervention: Includes both physical procedures by which data are gathered, and manipulations of the subject or subject’s environment performed for research purposes.
2. Interaction: Communication or interpersonal contact between investigator and subject.

(2) Yes No Obtain, view or otherwise handle any *private information*¹ which identifies individual subject(s) through the use of either *direct identifiers*² (name, address, etc.), or *indirect identifiers* in the form of a code that links back to the identity of subject through an existing key.

1. Private information includes (but is not limited to)
 - o Medical records and charts, specimens, data or tissue repositories
 - o Employment or educational records, and observations of behavior which the subject could reasonably expect no observation to be taking place.
 - o Personal thoughts, feelings, opinions, attitudes, beliefs, etc.
2. Direct identifiers include (but not limited to) name, street address, audio/ video-recordings, telephone, fax, email, SSN, medical record # (other potential identifiers evaluated on a case by case basis).
 - o If codes & key exist: check "N" here, and submit official correspondence from the holder of the key which states that researcher will *not* be given access to the key under any circumstances.

IF YOU ANSWERED "**NO**" TO (II.A.1) **AND** (II.A.2): **STOP HERE- DO NOT SUBMIT YOUR PROJECT TO THE IRB.**

IF YOU ANSWERED "**YES**" TO **EITHER** (II.A.1) **OR** (II.A.2.): **YOU ARE CONDUCTING HUMAN SUBJECTS RESEARCH- PLEASE SUBMIT YOUR STUDY FOR IRB REVIEW.**

IF YOU ARE STILL UNCERTAIN WHETHER OR NOT YOU ARE CONDUCTING HUMAN SUBJECTS RESEARCH AND WOULD LIKE VERIFICATION FROM THE IRB, PLEASE COMPLETE THE FOLLOWING SECTION IV.

SECTION III. RESEARCH DESCRIPTION

III.A. APPLICANT INFORMATION

Last Name:	First Name:	Title:
Department		
Phone:	E-mail:	

Please indicate *YOUR* primary research role (check all that apply):

- | | |
|---|---|
| <input checked="" type="checkbox"/> Principal Investigator (must be full-time SEMO faculty) | <input type="checkbox"/> SEMO Co-Investigator or Sub-Investigator |
| <input type="checkbox"/> Project/study coordinator | <input type="checkbox"/> Principal contact/administrator only |
| <input type="checkbox"/> Research Assistant/ Research team member | <input type="checkbox"/> SEMO Student |
| <input type="checkbox"/> Other _____ | |

Please indicate your type of research:

- | | |
|--|--|
| <input type="checkbox"/> SEMO Faculty/staff research | <input type="checkbox"/> SEMO Undergraduate student project |
| <input type="checkbox"/> SEMO Nursing Practicum/Clinical Residency requirement only | <input type="checkbox"/> SEMO Culminating Experience (CE)/CE |
| <input checked="" type="checkbox"/> Practicum SEMO Dissertation research requirement | <input type="checkbox"/> SEMO Class/Course/Curriculum |
| <input type="checkbox"/> SEMO Graduate Thesis/fieldwork | <input type="checkbox"/> Non-SEMO research |
| <input type="checkbox"/> Other _____ | |

This research involves: (check all that apply):

- All or some research activities are taking place at or through SEMO
- SEMO Collaborative research with another institution(s)
- No research activities will take place at or through SEMO
- Study has/will seek IRB approval at a non-SEMO institution

III. B. PROPOSED STUDY CHARACTERISTICS

(PLEASE COMPLETE THE FOLLOWING IN LAYPERSON TERMS).

1. Provide a 3-5 sentence, clear summary of the proposed research activity. Please include the purpose and aims of the research.

2. Briefly describe all research activities that will be performed by or conducted under the supervision of the SEMO faculty, staff, or students.

3. Briefly describe or list all study procedures to be conducted related to study participants (i.e., screening, recruitment, consenting, enrollment, procedures, etc.), types of data being collected, anonymous/identifiable information, and how you will be obtaining data from or about study subjects.

(Please be sure to attach any survey, interview, or focus group questions, if applicable.)