

IRB EXEMPTION REVIEW

Research activities in which the only involvement of human subject research participants will be in one or more of the following categories is exempt from further IRB review. Exemption applies to research that is of minimal risk and with adult subjects **except**:

Categories 1, 4, 5, 6, and 7 – which also apply to children as long as no identifiable information is collected

Category 2—which only applies to children in cases of observations of public behavior in which the researcher does not participate in the activities being observed. Survey and interview procedures involving children do not qualify for exempt review.

Prisoners –Incarcerated persons may be included as subjects of exempt research on a broader study population if their inclusion is incidental (rather than purposeful) and if the research does not seek to examine incarcerated persons as a subpopulations. Research subjects who incidentally become incarcerated during the research period may remain in an exempt research study.

Final determination as to whether a research project is exempt from further review rests with the IRB. If the project is determined to be exempt by the IRB, the principal investigator is still required to submit any project modifications to the IRB, as modification could change the status to non-exempt research.

Research categories exempt from further review:

1. **Research in established or commonly accepted educational settings about normal educational practices.** The research must be unlikely to have adverse impacts on students learning of required educational content or assessment of educators who provide instruction.
2. **Educational tests, surveys, interviews, and observations of public behavior** as long as one of the three criteria below are met:
 - a. Information obtained is not identifiable
 - b. Disclosure outside of the research would not put the subjects at risk of harm
 - c. Information obtained is identifiable, but adequate provisions are in place to protect privacy and maintain confidentiality
3. **Benign behavioral interventions in conjunction with the collection of information from adult subjects.** This exemption is not applicable to research with children. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, unlikely to be embarrassing or offensive to the research subject, and unlikely to have long-lasting or adverse impact on the research subject. Deceptive research is not eligible for exemption in this category unless the research subject consents to being unaware of or misled about the true nature and purpose of the research.
4. **Secondary research for which consent is not required.** Consent is not required for research using identifiable private information or identifiable biospecimens as long as one of the following criteria is met:
 - a. The identifiable private information or identifiable biospecimen is publicly available.
 - b. Information is recorded by the investigator in such a way that subjects cannot be readily identified.
 - c. Research use is regulated by HIPAA, insofar as *healthcare operations, research, or public health activities and purposes* are defined by HIPAA.
 - d. Analysis of data on behalf of a federal agency or department, if applicable federal laws are met.
5. **Research and demonstration projects conducted or supported by a Federal department or agency,** which are designed to study, evaluate, or otherwise examine:
 - a. Public benefit or service programs
 - b. Procedures for obtaining benefits or services under those programs

- c. Possible changes in or alternatives to those programs or procedures
 - d. Possible changes in methods or levels of payment for benefits or services under those programs
6. **Taste and food quality evaluation and consumer acceptance studies**, if:
- a. If wholesome foods without additives are consumed; or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.
7. **Storage or maintenance for secondary use for which broad consent is required**. Broad consent must be documented with an appropriate consent instrument containing all applicable elements of informed consent and also including elements specific to the secondary analysis, such as a general description of the data and the types of research that may be conducted.
8. **Secondary research for which broad consent is required provided that broad consent was secured and documented or waived**. The research must be within the scope of the broad consent and adequate provisions must be in place to protect the privacy of subjects and maintain confidentiality of the data. Under this exemption, the investigator may not return individual research results to subjects as part of the study unless required by law.

Office use only:

Date Received in Office: _____ IRB #: _____

Southeast Missouri State University IRB APPLICATION FOR EXEMPTION

The IRB retains final judgment as to whether a research study is exempt from further IRB review.

Note: Exempt status does not necessarily mean that the investigator is exempt from informed consent procedures. For any questions regarding this form or Exempt status, please contact the IRB at (573) 651-2298. Submit this completed application as a PDF along with PDF attachments if required to irb@semo.edu.

Date:

Principal Investigator Name(s):

Email:

Phone:

Student Investigators (if any) Name(s):

Email:

Phone:

Southeast Missouri State University Address of Principal Investigator:

Building:

Room #:

Department:

College:

Project Title:

Anticipated dates of project: Beginning: _____ Ending: _____

FUNDING: Anticipated source of funds, if any, including GRFC Funds. (If this project will be funded under a grant to another investigator, please give the title of the grant, name of agency or institution, and the investigator's name.)

Research activities in which the only involvement of human research participants will be in one or more of the following categories are usually exempt from further IRB review: (Check the category that applies to your study, and any that apply under that category.)

1. **Research in established or commonly accepted educational settings about normal educational practices.**

The research must be unlikely to have adverse impacts on students learning of required educational content or assessment of educators who provide instruction.

2. **Educational tests, surveys, interviews, and observations of public behavior** as long as one of the three criteria below are met:

Information obtained is not identifiable

Disclosure outside of the research would not put the subjects at risk of harm

Information obtained is identifiable, but adequate provisions are in place to protect privacy and maintain confidentiality

3. **Benign behavioral interventions in conjunction with the collection of information from adult subjects.**

This exemption is not applicable to research with children. Benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, unlikely to be embarrassing or offensive to the research subject, and unlikely to have long-lasting or adverse impact on the research subject. Deceptive research is not eligible for exemption in this category unless the research subject consents to being unaware of or misled about the true nature and purpose of the research.

4. **Secondary research for which consent is not required.** Consent is not required for research using identifiable private information or identifiable biospecimens as long as one of the following criteria is met:

The identifiable private information or identifiable biospecimen is publicly available.

Information is recorded by the investigator in such a way that subjects cannot be readily identified.

Research use is regulated by HIPAA, insofar as *healthcare operations, research, or public health activities*

and purposes are defined by HIPAA.

Analysis of data on behalf of a federal agency or department, if applicable federal laws are met.

5. **Research and demonstration projects conducted or supported by a Federal department or agency,** which are designed to study, evaluate, or otherwise examine:

Public benefit or service programs

Procedures for obtaining benefits or services under those programs

Possible changes in or alternatives to those programs or procedures

Possible changes in methods or levels of payment for benefits or services under those programs

6. **Taste and food quality evaluation and consumer acceptance studies**, if:

If wholesome foods without additives are consumed; or

If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. **Storage or maintenance for secondary use for which broad consent is required**. Broad consent must be documented with an appropriate consent instrument containing all applicable elements of informed consent and also including elements specific to the secondary analysis, such as a general description of the data and the types of research that may be conducted.

8. **Secondary research for which broad consent is required provided that broad consent was secured and documented or waived**. The research must be within the scope of the broad consent and adequate provisions must be in place to protect the privacy of subjects and maintain confidentiality of the data. Under this exemption, the investigator may not return individual research results to subjects as part of the study unless required by law.

ANSWER EACH QUESTION (1 – 9): (If you are using existing data, some questions may not apply: use N/A.)

1. Briefly, what is the purpose of your research (what do you want to learn from the project)?

2. What will be required of the research participant(s)?

3. From where will you recruit the participant(s)?

4. Total number of Participants and Controls: # of Males: # of Females:

5.

<p>Categories of Participants and Controls</p> <p><input type="checkbox"/> Adults</p> <p><input type="checkbox"/> Infants or Children (0-17 years of age)</p> <p><input type="checkbox"/> Pregnant Women</p> <p><input type="checkbox"/> Other (specify) _____</p> <p><input type="checkbox"/> Using existing data, no subjects recruited</p>	<p>Institutional Affiliation of Participants</p> <p><input type="checkbox"/> None</p> <p><input type="checkbox"/> Schools/College/University</p> <p><input type="checkbox"/> Prisons</p> <p><input type="checkbox"/> Hospitals/Clinics</p> <p><input type="checkbox"/> Other (specify) _____</p>
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6. Participants are:

- Mentally Competent Adults (able to give consent)
- Mentally Incompetent Adults (unable to give consent)

Note: Some categories of research participants are considered more vulnerable than others and are not eligible for participation in Exempt research.

7. Demographic Information collected (check all applicable items):

<input type="checkbox"/> Names	<input type="checkbox"/> Marital Status
<input type="checkbox"/> Social Security Numbers	<input type="checkbox"/> Income
<input type="checkbox"/> Addresses	<input type="checkbox"/> Job Title
<input type="checkbox"/> Phone Numbers	<input type="checkbox"/> Names of Employers
<input type="checkbox"/> Age/Date of Birth	<input type="checkbox"/> Types of Employers
<input type="checkbox"/> Sex	<input type="checkbox"/> Other (specify) _____
<input type="checkbox"/> Race/Ethnicity	

Please explain how any of the above demographic information will be used.

Describe the steps to be taken to protect the privacy and/or confidentiality of participants' responses or to maintain anonymity of the research records. (If privacy/confidentiality will not be maintained, state this.)

Note: If personal identifiers will be retained and used, you must explain this in the informed consent agreement and tell participants how you will use their identifiers.

8. How will you inform participants about the research project and procedures? Check one:

- Informed Consent Cover Letter
- Informed Consent Agreement
- Not Applicable

9. Where will the research be conducted (where will you interact with participants or obtain existing data)?

Note: If not at Southeast, in some circumstances you may need a signed permission letter. If so, attach a copy of the letter.

ATTACHMENTS (check all that apply and include with application):

- Questionnaire, survey, list of potential interview questions, etc. to be used with research participants
- Consent agreement, cover letter, telephone introductory script
- Permission to use existing data and/or permission from external institution (if applicable)
- Other

PRINCIPAL INVESTIGATOR'S ASSURANCE STATEMENT:

By submitting this form, I attest that I understand Southeast Missouri State University's policies concerning research involving human subject research participants and I agree:

- 1) to comply with all IRB policies, decisions, conditions, and requirements;
- 2) to accept responsibility for the scientific and ethical conduct of this research study;
- 3) to obtain prior approval from the IRB before amending or altering the research protocol or implementing changes in the approved consent/assent form, as it could change the exempt status of this research study;
- 4) to report to the IRB in accord with IRB policy any adverse event(s) and/or unanticipated problem(s) involving risks to participants;
- 5) to notify the IRB if external funding is received during the research study and comply with any additional regulatory requirements;
- 6) that each individual listed as an investigator in this application possesses the necessary training for conducting research activities in the role described for this research study.