

**Eastern Michigan University
University Human Subjects Review Committee (UHSRC)
REVIEWER RESPONSE FORM**

Title of Proposal being reviewed: _____
Principal Investigator (s): _____
Date of Review: _____
HSRC Reviewer: _____

This proposal is:

Exempt Conditionally Exempt Not Exempt from Review

If Exempt, please specify exemption met by this protocol.

If Exempt, skip to Item 6 (if any other comments/concerns), complete item 7, sign (electronically) and return the form.

Complete Consent Checklist if PI will be using a consent form, or explain in Item 5 why a Consent form is not necessary.

If Conditionally Exempt (i.e., you feel the protocol is likely exempt, but there are some issues that would need to be clarified by the Co-Chairs before Exemption can be granted), please specify conditions or clarification necessary for exemption status, and **mark checklist for informed consent if consent is needed.**

If “conditionally exempt,” skip to Item 6 (if any other comments/concerns), complete item 7, and sign and return the form.

Please also complete items 1-5 if conditional status is tenuous, and your comments in those areas might clarify issues involved in determination of Exemption status.

If Not Exempt, complete items 1-7, Rationale for Expedited Review, and informed consent checklist.

1. What potential risks are there for subjects participating in this research?

Are procedures adequate to minimize any risks to subjects? No Yes

If no, explain what must be done to sufficiently minimize risks:

2. If there are potential risks, should the potential knowledge from the research be pursued in light of these risks? No Yes

Do the benefits of this research outweigh any potential risks to the subjects?
No Yes

3. Are procedures to be used by the researcher sufficient to ensure that there is informed consent on the part of subjects and that their participation is voluntary?
No Yes

If no, please make suggestions below, and fill out the attached checklist of Required Elements of Informed Consent.

4. Is the P.I. applying for a waiver of signed informed consent?
No Yes

If yes, check below to indicate the reason for the waiver.

- The only record linking the subject and the research would be the consent document AND the principal risk is potential harm resulting from a breach of confidentiality.
- The research presents no more than minimal risk of harm to subjects AND involves no procedures for which written consent is normally required outside of the research context.

5. Are procedures sufficient to allow for confidentiality of information for individual subjects, both in gathering and in the dissemination of information?
No Yes

If no, please make suggestions below:

6. Other comments or concerns:

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7. Please rate the proposal on the following scale and give reason(s) for your rating.

<input type="checkbox"/> Exempt	<input type="checkbox"/> Acceptable	<input type="checkbox"/> Acceptable with Provision	<input type="checkbox"/> Not Acceptable	<input type="checkbox"/> Recommend Full Board review	<input type="checkbox"/> Not Enough Information Provided
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Reason(s) for marked rating or identify provisions: _____

Please fill out the “Rationale for Expedited Review” and “Checklist of Required Elements of Informed Consent” form attached.

Thank you for noting items missing from consent document(s).

If there are provisions or document was conditionally exempt:

- Final review and approval may be granted by one of the UHSRC co-chairs
- I would like to see revised versions prior to final approval

Signature of Reviewer

Date

rev. 6/08

Rationale for Expedited Review

Applicability: Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories. If you have approved research as an expedited reviewer, please check the categories below that describe the proposal you have reviewed.

Clinical Studies

- Clinical studies on drugs only when an investigational new drug application (21 CFR Part 312) is not required.
- Clinical studies on medical devices only when an investigational device exemption application (21 CFR Part 812) is not required or the device is cleared/approved for marketing and the device is being used in accordance with its cleared/approved labeling.
- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (a) from healthy, nonpregnant adults who weigh at least 110 pounds from whom the amounts drawn do not exceed 550 ml in an eight-week period and collection may not occur more frequently than two times per week, or (b) from other adults and children, considering the age, weight, and health of the subjects, the amount drawn may not exceed the lesser of 50 mL or 3 mL per kg in an eight period and collection may not occur more frequently than two times per week.
- Prospective collection of biological specimens for research purposes by noninvasive means. Collection of data through noninvasive procedures routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
- Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Social Science Studies

- Collection of data from voice, video, digital, or image recordings made for research purposes.
- Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Continuing Review

- Continuing review of research approved by the convened IRB where (a) research is permanently closed to enrollment of new subjects, or (b) no subjects have been enrolled and no additional risks have been identified, or (c) the remaining research activities are limited to data analysis.
- Continuing review of research, not conducted under an investigational new drug application or investigational device exemption (see above), but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Checklist of Required Elements of Informed Consent
Check wherever applicable

- A statement that the study involves research
Comments: _____
- Purpose of the research
Comments: _____
- Duration of subject's participation
Comments: _____
- Description of the procedures followed
Comments: _____
- Means of public dissemination
Comments: _____
- Description of foreseeable risks or discomforts to subject
Comments: _____
- Description of benefits to subject or to others
Comments: _____
- Disclosure of appropriate alternative procedures or courses of treatment
Comments: _____
- Statement of extent to which confidentiality of records identifying subject is maintained
Comments: _____
- Statement of how participant confidentiality is maintained in public dissemination
Comments: _____
- For research of greater than minimal risk, information regarding medical treatments or counseling should personal injury or problems occur
Comments: _____
- List of contacts who can answer questions about the research and subject's rights, and respond to research-related injury to subject
Comments: _____
- Statement that participation is voluntary
Comments: _____
- Statement that refusal to participate will involve no penalty or loss of benefits
Comments: _____
- Statement that the subject may discontinue participation at any time
Comments: _____
- Statements of significant new findings developed during the course of research that may relate to subjects' willingness to continue participation
Comments: _____

Provide Rationale for Exclusion of a Required Element, or concerns about missing items, if not already explained above:

Exempt Activities

Investigators may not determine their own research to be exempt from HSRC review. Exemption decisions are made through the expedited review process.

Activities that are not research are exempt from HSRC review. Research is defined as: “A systematic investigation designed to develop or contribute to generalizable knowledge.”

Research that does not involve human subjects is also exempt from HSRC review. A human subject is defined as “a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be determined to be exempt from UHSRC review. Requests for exemption must cite the statutory basis for the requested exemption from the categories listed below:

Research

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - a. Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; AND
 - b. Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under Criterion 2, above, if:
 - a. The human subjects are elected or appointed public officials or candidates for public office; OR
 - b. Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and 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; or
 - 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. Wholesome foods without additives are consumed, or
 - b. 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 Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Exempt Activities: Program Review

1. **Federal Regulations Exemptions.** Research and demonstration projects that are conducted by or subject to the approval of department or agency heads, and that are designed to study, evaluate, or otherwise examine 1) public benefit or service programs; 2) procedures for obtaining benefits or services under those programs; 3) possible changes in or alternatives to those programs or procedures; or 4) possible changes in methods or levels of payment for benefits or services under those programs.
2. **EMU Program Review Data.** Data collected for the purpose of the evaluation, review, and improvement of EMU academic and extra-curricular programs is exempt from review under the Federal Regulations exemptions listed above *unless* these data are collected: 1) for use beyond program review, and/or 2) for publication beyond the review process for EMU programs administered by EMU, by its associated accrediting agencies, and by other related educational bodies. Program Review proposals that meet the criteria for exemption from review do not need to be sent to the EMU HSRC.

Note: The above exemptions do not apply to research involving prisoners as subjects.