

**Eastern Michigan University**  
**University Human Subjects Review Committee (UHSRC)**  
**CONTINUING REVIEW**

*NOTE: This completed, signed report must be returned to the Graduate School no later than one year after date of official UHSRC approval. If not, the approval for this project will terminate and a new application must be approved before data collection may continue.*

The Office for Human Research Protections (OHRP) requires that “an IRB shall conduct continuing review ... at intervals appropriate to the degree of risk, but not less than once per year.”

Continuing review must be substantive and meaningful. Review by the IRB, is otherwise appropriate for expedited review under Section 46.110. Ordinarily, if your research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. It is also possible that research activities that were previously judged as exempt in accordance with Section 46.101(b), or were qualified for expedited review in accordance with Section 46.110, have changed or will change, such that full committee review is now required.

OHRP interprets “not less than once per year” review to mean on or before the one-year anniversary date of the previous IRB review required by Section 46, even if the research activity began some time after the IRB approval date.

To comply with federal policy, the EMU HSRC has prepared the following report form to facilitate your annual continuing review report. Please complete the Continuation Form (p. 2) and attach any information you think is needed to define any planned changes in your study, as these may affect the protection of human subjects. The EMU HSRC will review any proposed changes for your previously approved research in an expedited manner prior to the scheduled continuing review date in accordance with Section 46.110.

When you propose any change in your research study, the UHSRC must review and approve changes before they can be implemented. The only exception is the rare circumstance in which a change is necessary to eliminate apparent immediate hazards to the research subjects. If this happens to your research study, immediately inform the UHSRC of the change by completing the Adverse Event Reporting form. The UHSRC will review the change to determine that it is consistent with protection of human subjects. Unanticipated risks to subjects or new information that may affect the risk/benefit assessment you defined in your approved application must be promptly reported to, and reviewed by, the UHSRC via this form to ensure adequate protection of human subjects (see UHSRC Adverse Event Reporting Form).

The EMU HSRC wants to know if your information is still accurate and complete. You may confirm this by completing the information below and attaching any additional information that you think suitable to explain changes in your study. If this is your third Continuing Review Request please complete a new application. Please return this document with any attachments you may have to the Graduate School, 200 Boone Hall. If you have questions please call 487-0042 or email the document to: [human.subjects@emich.edu](mailto:human.subjects@emich.edu).

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

Date: \_\_\_\_\_

Title of Project: \_\_\_\_\_

Reference Number: \_\_\_\_\_

Principal Investigator: \_\_\_\_\_

Department/School: \_\_\_\_\_

Phone: \_\_\_\_\_

Address: \_\_\_\_\_

Email: \_\_\_\_\_

Fax: \_\_\_\_\_

Co-PI/Project Director(s): \_\_\_\_\_

If a **student project**, list faculty sponsor: \_\_\_\_\_

**Signature of faculty sponsor:** \_\_\_\_\_

Student number: \_\_\_\_\_

Program and status/year: \_\_\_\_\_

1) Has this project enrolled any participants yet?  Yes  No

If yes, how many? \_\_\_\_\_

How many more will be enrolled? \_\_\_\_\_

If no participants have been enrolled, please list the reason(s) why data collection has not commenced:

2) Was an adverse event report filed for this study during the past year?  Yes  No

If yes, were steps taken to effectively manage the event?  Yes  No

If yes, please explain how procedures have been changed to minimize the risk and manage any future event.

NOTE: An adverse event is defined as any experience that has taken place during the course of a research project, which, in the opinion of the investigators, was harmful to a subject participating in the research, increased the risks of harm in the research, or had an unfavorable impact on the risk/benefit ratio. The investigator does not necessarily have to feel that an adverse event was *caused by* research participation in order for it to merit reporting to the UHSRC. An *Adverse Event Report* form should be submitted within 24 hours of the PI learning of the event; see UHSRC Policies and Procedures.

- 3) Since the previous UHSRC approval date, have you made any change(s) to your protocol that has not already been submitted to the UHSRC (e.g., using the Minor Modification form)?  Yes  No

If yes, please explain in **section 5**, below.

- 4) Do you plan any change(s) to your protocol as data collection continues?  Yes  No

If yes, please explain in **section 5**, below.

- 5) Please indicate which types of changes you have made or intend to make to your protocol:

a) Addition or deletion of key personnel?  Yes  No

b) Changes to advertisements, notices, flyers, or other recruitment materials or procedures?  Yes  No

c) Changes to the study design?  Yes  No

d) Changes to enrollment criteria?  Yes  No

e) Changes in data collection methods?  Yes  No

f) Changes to the risk/benefit ratio?  Yes  No

g) Changes to the consent form, assent sheets, or any study information sheets? (Use attached consent checklist to ensure all required elements are included in consent agreement).  Yes  No

h) Any other changes that relate to how participants are treated?  Yes  No

If yes to any of the items listed above, please explain the nature of these changes and the rationale for making the changes:

**Regardless of whether or not your consent form has changed, please adjust the dates in this standard paragraph and submit a current version of the consent agreement with this Continuation Form (see next page for the checklist of required elements):**

*This research protocol and informed consent document has been reviewed and approved by the Eastern Michigan University Human Subjects Review Committee for use from \_\_\_\_\_ to \_\_\_\_\_ (date). If you have questions about the approval process, please contact Dr. Deb de Laski-Smith (734.487.0042, Interim Dean of the Graduate School and Administrative Co-chair of UHSRC, [human.subjects@emich.edu](mailto:human.subjects@emich.edu)).*

**Please sign below where indicated and return this form and updated consent document(s) to the Graduate School, 200 Boone Hall. Also, send this form to [human.subjects@emich.edu](mailto:human.subjects@emich.edu) as an email attachment to facilitate the review process.**

Principal Investigator:

\_\_\_\_\_  
(Sign, or type E-Signature, if submitting electronically)

Date:

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\_\_\_\_\_  
Signature of UHSRC Reviewer

\_\_\_\_\_  
Date

## Checklist of Required Elements of Informed Consent

- 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:**