

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

Date _____

Title of Research: _____

IRB reference #: _____

Principal Investigator: _____

Department/School: _____

Phone: _____

Address: _____

Email: _____

Fax: _____

Co-PI/Project Director/Faculty Sponsor: _____

A protocol can be closed when data collection activities including participant recruitment, enrollment, interventions, interactions, and follow-up has been completed. PI may continue with data analysis and dissemination of findings.

- 1) Date of project closure at EMU: _____
- 2) Are any other study sites still open: Yes No Not applicable
- 3) Reason for closure: _____
- 4) Number of participants enrolled in the project: _____
- 5) Number of participants who withdrew from the project or who were withdrawn by the PI:

- 6) Reasons for removal of participant(s), if applicable: _____
- 7) Since the last review, have any adverse events taken place? Yes No
If yes, were the steps taken to manage the event effective? Yes No

If not, please explain:

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.

8) Provide a brief summary of the study including relevant findings.

9) Have results been disseminated in the form of any manuscripts, abstracts, presentations, etc.? Yes No

If yes, please list.

10) How will the data be stored and protected henceforth?

Please sign below where indicated and return this form to the Graduate School, 200 Boone Hall. Also send to human.subjects@emich.edu as an email attachment to facilitate processing.

Signature

Date

FOR UHSRC USE ONLY

Date of Original IRB Approval: _____

Date of Study Closure: _____

Level of Approval (check one): Exempt Expedited Full

Was the project approved at or above minimum risk? At Above

The UHSRC Chair may determine whether the PI needs to provide additional information after reviewing the information provided on this Closure Form.

UHSRC Approval:

Signature of Reviewer

Date