**Western Michigan University**

**I**nstitutional **R**eview **B**oard

WMU Mail Stop: 5456 Phone: (269) 387-8293

### Application for Continuing Review or Final Report Form

In compliance with Western Michigan University's policy that “the IRB's review of research will be conducted at appropriate intervals but not less than once per year,” the IRB requests the following information:

**Project Information**

**PROJECT TITLE:**

**IRB Project Number:** Date of Last Approval (Initial or Continuing Review):

Previous level of review:[ ]  Full Board Review [ ]  Expedited Review [ ]  Administrative (Exempt) Review

**Investigator Information**

**PRINCIPAL INVESTIGATOR OR ADVISOR**

Name:

Department:       Mail Stop:       Electronic Mail Address:

**CO-PRINCIPAL OR STUDENT INVESTIGATOR**

Name:

Department:       Mail Stop:       Electronic Mail Address:

**CO-PRINCIPAL OR STUDENT INVESTIGATOR**

Name:

Department:       Mail Stop:       Electronic Mail Address:

**Current Status of Research Project**

Please answer questions 1-5 to determine if this project requires continuing review by the IRB.

1. Has subject recruitment begun? If no, please provide an explanation [ ] Yes [ ]  No
2. Is the project closed to recruitment of new subjects?

 [ ] Yes (Date of last enrollment:     )  [ ] No (Project must be reviewed for renewal.)

1. Have all subjects completed research related interventions?

 [ ] Yes [ ]  Not Applicable [ ] No (Project must be reviewed for renewal.)

1. Has long-term follow-up of subjects been completed?

 [ ] Yes [ ]  Not Applicable [ ] No (Project must be reviewed for renewal.)

1. Has analysis of data been completed?

 [ ] Yes [ ] No (Project must be reviewed for renewal.)

* If you have answered **“No” to ANY** of the questions above, you must apply for **Continuing Review**.
* ***If you need to make changes in your protocol, please submit a separate memo detailing the changes that you are requesting.***
* If you have answered **“Yes” or “Not Applicable” to ALL** of the above questions, the project may be closed.

If the project is closed please use this form for the “Final Report.”

**[ ]  Application for Continuing Review [ ]  Final Report**

**IRB Project Number:**

1. Are there any changes in study personnel (add or remove investigators) not

previously reported to the IRB? [ ] Yes [ ] No

 If you need to add an investigator, provide details on an “Additional Investigator(s)

 Form” (available at <https://wmich.edu/research/forms>).

 To remove an investigator, submit a memo to the IRB detailing the change.

1. Since the last approval (initial or continuing review) has there been any modifications or additions

to the protocol, not previously reported to the IRB to with respect to the following?

* 1. Procedures [ ] Yes [ ] No
	2. Subjects [ ] Yes [ ] No
	3. Design  [ ] Yes [ ] No
	4. Data collection  [ ] Yes [ ] No
1. Has any instrumentation been modified or added to the protocol that has not already [ ] Yes [ ] No

been approved by the IRB?

 If **yes**, attach new instrumentation and a memo indicating the modifications made.

1. Are there changes to the consent/assent form not previously reported to the IRB? [ ] Yes [ ] No

 If **yes**, attach new consent/assent form and a memo indicating changes made.

***Verification of Consent Procedure:*** *Provide copies of the whole consent documents signed by the last two subjects enrolled in the project. Cover the signature in such a way that the name is not clear but there is evidence of signature. If subjects are not required to sign the consent document, provide a copy of the most current consent document being used.*

**SUMMARY OF THE RESEARCH**

1. Have there been any adverse events, unexpected or unanticipated study-related problems which have not previously been reported to IRB? If **yes**, provide details on an attached sheet. [ ] Yes [ ] No

1. Is there new risk or benefit information not previously reported to the IRB? [ ] Yes [ ] No

If **yes**, attach a memo indicating the risk or benefit information.

1. Summarize progress of the research using non-technical language that can be easily understood by a reviewer outside the discipline. Please use complete sentences to briefly summarize the research since the last review (initial or continuing).
2. List and describe any complaints about the research study since the last IRB review (initial or continuing review); include action taken to resolve the complaints (If not applicable, type NA).
3. List any voluntary withdrawals by participants from the study since the last IRB review (initial or continuing review); include action taken as a result of the withdrawals. (If not applicable, type NA).

**IRB Project Number:**

**SUBJECT RECRUITMENT**

1. Have research subjects been enrolled (or subject records, specimens, etc. obtained)? [ ] Yes [ ] No

**Provide a letter of explanation if no research subjects have been enrolled (or subject**

**records, specimens, etc. obtained).**

1. Total number of subjects approved in original protocol:
2. Total number of subjects enrolled so far:

 If applicable: Number of subjects in experimental group: Number in control group:

1. Estimated number of subjects yet to be enrolled:

**Email this completed, signed form to** **ovpr-hsirb@wmich.edu** **and include a clean consent documents as a WORD file to receive a renewed approval stamp.**

**INVESTIGATOR’S ASSURANCE**

I certify that the information contained in this IRB Application for Continuing Review and all attachments are true and correct. I certify that the research has been and will continue to be conducted according to the protocol as approved by Institutional Review Board.

I agree that I will not implement any changes in the protocol until such changes have been reviewed and approved by IRB. If, during the course of the research, unanticipated risks or harm to subjects are discovered, I will report them to IRB immediately. I agree to follow all applicable federal regulations, guidance, state and local laws, and university policies related to the protection of human subjects in research, as well as professional practice standards and generally accepted good research practices for investigators

**If this is a FINAL REPORT, you may return the form electronically (signature is not required).**

Principal Investigator/Faculty Advisor Signature Date

Co-Principal or Student Investigator Signature Date

Co-Principal or Student Investigator Signature Date

***Approved for a one-year extension by the IRB:***

IRB Chair Signature Date