**Western Michigan University**

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

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

### 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.

**Final Report**

**IRB Project Number:**

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

previously reported to the IRB? Yes No

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 and when it was first used.

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, when it was first used, and how many participants were consenting using the new consent/assent form.

***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:

**Remember to include the whole consent documents with your Final Report.**

**Signatures are not required for the Final Report.**

**Email the Final Report to the WMU IRB at ovpr-hsirb@wmich.edu.**