

MICHIGAN TECH - INSTITUTIONAL REVIEW BOARD (IRB)
MODIFICATION / CONTINUATION / PROJECT COMPLETION FORM

This form must be signed by the responsible PI

Human Subject protocols are approved for a period of 364 days. Federal regulations require the IRB to review and approve all modifications or continuing, ongoing projects. You are required to provide information at the expiration date as indicated below. The IRB must approve any modifications prior to implementation.

THIS FORM AND ANY ATTACHMENTS MAY BE SUBMITTED ELECTRONICALLY TO IRB@MTU.EDU, FOLLOWED BY SENDING AN ORIGINAL SIGNATURE FOR OUR OFFICE FILE TO: Office of Research Integrity and Compliance

Principal Investigator _____ Dept. / email _____

Project Title: _____

Approval Number: M _____ Current Approval Expiration Date: _____

Funding Agency (if applicable): _____

THIS FORM IS BEING SUBMITTED FOR THE FOLLOWING PURPOSE:

- PROTOCOL MODIFICATION** (There HAVE BEEN changes in the protocol, investigators, consent or subject forms, etc.)

Protocol Modification Instructions

- The IRB must approve any modifications PRIOR to implementation.
- Use Appendix A for Procedural Modification/Addendum. Use the approved protocol documents including the consent form or any other information provided to the subjects, indicate all modifications by using a tracking tool and attach to this form.
- Use Appendix B for Personnel Modification/Addendum. Use page two (2) to indicate changes in investigators.

This WILL NOT extend the current expiration date if requested during the approval period.

- CONTINUATION REQUESTS** AT THE ANNUAL EXPIRATION DATE
(There HAVE been NO modifications to the protocol, investigators, consent, or subject forms, etc.)

- FINAL REPORT** - The Project is complete

YOU ARE REQUIRED TO PROVIDE THE FOLLOWING INFORMATION AT THIS TIME:

1. Indicate the number of subjects that participated in the study since last reporting period:
2. Describe any unanticipated problems involving risks to subjects or others (or N/A).
3. Identify numbers and reasons for withdrawal of subjects from the research (or N/A).
4. List any complaints about the research (or N/A).
5. Summarize any recent literature, findings, or other relevant information about risks associated with the research (or N/A).
6. If continuing, attach a current copy of the Consent Form and copies of any other information provided to the subjects.

List all co-investigators currently involved in this study.

| | | |
|------|-------|-------|
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |
| Name | Dept. | email |

PI Certification and Signature:

I assure that all faculty, staff, and students involved in the project are presently qualified or will be trained to conduct the project in a humane and scientific manner. I assure that the activities do not unnecessarily duplicate previous experiments.

INDICATE ATTACHMENTS SUBMITTED:

NO MODIFICATION, continuation requested

- Current Consent and subject forms, if applicable, are to be submitted when continuation is being requested. These forms will be stamped “approved” by our office and returned with your continuation memo.

MODIFICATION/ADDENDUM, Note: BOTH forms may need to be submitted.

- Appendix A – Procedural Modification/Addendum Request Form
Original protocol documents including consent and subject forms indicating modifications
- Appendix B – Personnel Modification/Addendum Request Form

Signature of Principal Investigator

Date

M_____

THIS FORM AND ANY ATTACHMENTS MAY BE SUBMITTED ELECTRONICALLY TO IRB@MTU.EDU, FOLLOWED BY SENDING AN ORIGINAL SIGNATURE FOR OUR OFFICE FILE TO:

For inquiry or further information, contact: Office of Research Integrity and Compliance
Cheryl Gherna, Coordinator (cagherna@mtu.edu)
Joanne Polzien, Director (jpolzien@mtu.edu)
906-487-2902 Fax: 906-487-2245

Procedural Modification/Addendum Request Form

You must receive written notification of approval from the IRB before implementing any changes (except when necessary to eliminate apparent immediate hazards to the subject.)

Note: This form may NOT be used for personnel changes. Please complete a Personnel Modification form, Appendix B, for personnel change requests.

Include this form along with your signed modification/continuation/project completion form. You must attach your current approved protocol and use a tracking tool to indicate ALL modifications. This will not extend your current expiration date if done during the approval period.

IRB # Principal Investigator:

Title:

- 1. Summarize/Itemize requested changes and justification for each.**

If you answer YES to any of the following questions, please explain on page 2 in the space provided.

- 2. Do changes require revisions to the assessment of risk of harm to the subjects?**

**YES – If yes, explain.
NO**

- 3. Do changes require revisions to the methods of ensuring anonymity or confidentiality?**

**YES – If yes, explain.
NO**

- 4. Are there new findings that may relate to a participant's willingness to continue taking part in the research study?**

**YES – If yes, explain whether these findings need to be provided to participants, and if so, how this will be accomplished.
NO**

- 5. Do changes require a revised consent statement or procedure?**

**YES – If yes, attach a revised consent form with the changes tracked, AND a clean copy for the IRB approval stamp.
NO**

For inquiry or further information, contact: Cheryl Gherna, Coordinator cagherna@mtu.edu or Joanne Polzien, Director jpolzien@mtu.edu phone 906-487-2902 fax 906-487-2245.

If you answered YES to questions 2-5, please explain below:

Appendix B

Personnel Modification/Addendum Request Form

Note: This form may NOT be used for procedural changes or continuation reviews. Please complete a Procedural Modification form, Appendix A, for procedural changes.

You must receive written notification of approval from the IRB before implementing any changes (except when necessary to eliminate apparent immediate hazards to the subject.)

Include this form along with your signed modification/continuation/project completion form.

IRB # Principal Investigator:

Title:

- 1. List each personnel change (name, contact information, whether being added or removed.) on page 2 of this form.**
- 2. For each individual being added, address each of the following on page 2 where space is provided:**
 - A. Will the Person be responsible for the design or conduct of the study, have access to human participants, or have access to identifying or confidential information?
 - B. Identify his/her role in the project.
 - C. Describe his/her level of experience with the procedures or techniques he/she will be performing.
 - D. Indicate where did each of the personnel listed receive training to perform the identified procedures and who supervised or provided the training. Also, when did the individual complete IRB training? Or completion of required CITI online training.
 - E. Explain how these skills/abilities will be periodically reviewed
- 3. For each individual being removed, address each of the following on a separate sheet:**
 - A. Has the individual's access to identifying or confidential information been removed?
 - B. Describe who on the research team will assume responsibilities previously assigned to the individual(s) being removed.
- 4. Do changes require a REVISED CONSENT statement or procedure?**

YES – If yes, attach a revised consent form with the changes tracked, AND a clean copy for the IRB approval stamp.

NO

For inquiry or further information, contact: Cheryl Gherna, Coordinator cagherna@mtu.edu or Joanne Polzien, Director jpolzien@mtu.edu phone 906-487-2902 fax 906-487-2245.

Changes in investigators:

Note: CITI online training must be completed by all new investigators added prior to engagement in the research study. Certification will be sent to the Research Integrity and Compliance Office once training is completed. If you need assistance, feel free to contact our office.

Add **delete**

CITI training completed **YES** **NO**

Name Dept. email

Add **delete**

CITI training completed **YES** **NO**

Name Dept. email

Add **delete**

CITI training completed **YES** **NO**

Name Dept. email