

Please complete and return form to the Office of the Registrar & Institutional Research (Bauer-North, 1st Floor)

Revised IRB Protocol Number (IRB Administrative Use Only)



Institutional Review Board (IRB) Addendum Form

Please see www.cmc.edu/IRB for a complete list of materials required for submission

Current IRB Protocol Number (if applicable)
Principal Investigator CMC ID # Faculty Staff Student
Department (& Institution if non-CMC) Phone Email
Campus Address
Title of Project
Beginning and completion dates of research to New beginning and completion dates of research to
Identify Current Status of Research: Ongoing Completed Discontinued
Identify the previous level of review of the research: Exempt Expedited Full Board

Please attach a BRIEF summary answering the following questions:

- 1) State what is being proposed and where in the protocol and/or consent what was changed (highlight changes).
2) Provide the rationale/justification for the change.
3) State what impact the change has on risks to participants. Please state the number of currently enrolled participants and if the change in risk will require re-consent. If the changes will not require re-consent, please state why.
4) State whether the change has an impact on the scientific integrity of the study, (i.e. decreases, increases, no impact).
5) List the documents included with the application that have been modified (consent forms, flyers, data collection forms, surveys). State what has been changed in each modified document (highlight changes).

The principal investigator assures the IRB that all procedures carried out under the project will be conducted by persons legally and responsibly entitled to do so, and that any deviation from the submitted project (change in principal investigator, participant recruitment procedures, research methodology, etc.) will be submitted to the IRB for approval prior to implementation.

Principal Investigator (signature) Date

I have verified that this research proposal is methodologically sound, that it minimizes risk to participants, and that the consent form is adequate.

Faculty/Director Sponsor (printed name) Department

Faculty/Director Sponsor (signature) Date

IRB Review Board Action:

- Certified by chair as exempt from review
Approved by chair under expedited review
Approved by full committee
Returned by full committee for additional details, clarifications, or adjustments

IRB Representative (signature) Date