**IRB Project Modification Form**

This form is to be used when substantial changes are being made to the project/protocol. Federal regulations require "prompt reporting to the IRB of proposed changes in a Research activity" and "such changes in approved Research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject." (45 CFR 46 103(b)(4)(iii)).

The investigator must receive approval from the IRB before implementing any proposed substantial changes to the protocol that modify study activities. Changes that do not impact the procedure of the project/protocol (such as a change in investigator) may also be reported to the IRB using this form.

Modification forms may be submitted to the IRB at any time (send document to iboard@hamilton.edu; student PIs should copy their supervisor on the correspondence). Depending on the extent of and reason for the modification, it will undergo either expedited or full board review.

**Today’s Date:**

**IRB Approval #:**

**Project/Protocol Title:**

**Principal Investigator:**

**Faculty/Staff Advisor (if PI is not a faculty/staff member):**

**Type of Modifications**

☐ Procedures/Study activities

☐ Study population (ages, selection criteria, inclusion of vulnerable participants, change in number of participants)

☐ Consent form/consent process

☐ Instruments used or data collected

☐ Recruitment methods or advertising

☐ Administrative information only

☐ Change in researchers/principal investigator

☐ Change in contact information

☐ Change in title

☐ Change in funding sources

Describe in detail the proposed modification(s), including a rationale. List all modifications, if there is more than one. If a document (such as the consent form) is being modified, please describe where in the document the change occurs.

Does the proposed modification affect the risk to subjects (either increased or decreased)? If yes, explain.

Add to this document any materials affected by the modification, such as the consent form, recruitment tools, or instruments.

*By signing my name below, I certify that the answers provided on this form are complete and accurate. I assure that changes to the approved project will not take place without the approval of the Institutional Review Board, and that all protocol activities will take place in accordance with state, federal and college regulations.*

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 Signature of Principal Investigator Date