UMASS GLOBAL
A nonprofit affiliate of the University of Massachusetts

UMASS GLOBAL INSTITUTIONAL REVIEW BOARD
Request for Modification of Approved Project

Investigators must submit the Request for Modification when any document or procedure within the IRB approved protocol is revised. There is only one exception to this rule, specifically where the change is necessary to eliminate apparent immediate hazards to the subjects. In such cases, the investigator must submit a report to IRB explaining the protocol deviation. Amendments involving minor changes that pose no more than minimal risk to subjects will be reviewed on an expedited basis. Changes may not be implemented until final written IRB approval is received.

INSTRUCTIONS: The entire form must be completed. Upon completion you will need to sign and have your Chair sign. Then email the completed and signed form to irb@umassglobal.edu. Submit this application with the following:

- If the consent has been modified, submit a copy of the modified form with the changes marked, plus an unmarked copy
- A copy of the modified research protocol
- A summary of protocol modifications

PRINCIPAL INVESTIGATOR (Last, First, M.I., Degree)	**PROJECT NUMBER**	**DATE**
PROJECT TITLE		

1. BRIEF DESCRIPTION OF ORIGINAL PROTOCOL: (Attach additional sheets as necessary)

2. DESCRIBE THE MODIFICATION(S) REQUESTED. INCLUDE REASONS FOR THE CHANGE(S).

3. WILL THE MODIFICATION(S), IN YOUR OPINION, INCREASE OR DECREASE THE RISK OF HARM TO THE SUBJECTS? ☐ Increase ☐ Decrease ☐ No change

Explain (attach sheets as necessary):

4. WILL THE MODIFICATION(S) ALTER THE APPROVED CONSENT FORM? ☐ Yes ☐ No

If yes, attach original and one copy of a revised consent form, with additions and deletions clearly marked, to this form for review and approval.

5. DID ANY UNANTICIPATED PROTOCOL DEVIATIONS (INCLUDING ERRORS AND ACCIDENTS) OCCUR SINCE THE LAST REVIEW? ☐ Yes ☐ No

If yes, summarize all protocol deviations (attach sheets as necessary):

6. HAVE UNANTICIPATED RISKS OR SIGNIFICANT NEW FINDINGS BEEN DISCOVERED SINCE THE PREVIOUS IRB REVIEW THAT MIGHT AFFECT THE SUBJECTS' WILLINGNESS TO CONTINUE PARTICIPATION? ☐ Yes ☐ No

If yes, complete the following:

a) Explain the risks or findings in detail (Attached sheets as necessary):
b) Do these risks or finding require modification of the informed consent form?
☐ Yes ☐ No

c) Were subjects notified of these risks or findings? ☐ Yes ☐ No
d) Were subjects reconsented? ☐ Yes ☐ No

I certify that none of these changes have been made and that no changes will be implemented prior to IRB review and approval.

Principal Investigator: _____Date_____

_____

Chair/Advisor Approval

Date _____

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☐ The modification/amendment described on page 1 qualifies for and has been approved by expedited review.

☐ The modification/amendment described on page 1 has been reviewed and approved by the UMASS GLOBAL Institutional Review Board.

☐ The modification/amendment described on page requires additional changes to secure approval.

COMMENTS:

_____ _____

_ Chair, UMASS GLOBAL Institutional Review Board **Date**