

**BRANDMAN UNIVERSITY 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 buirb@brandman.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) | BUIRB 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 BUIRB 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** _____

Use the Adobe signing function. Do not use DocuSign software to sign the is form.

Chair/Advisor Approval

Date _____

**BRANDMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD
REQUEST FOR MODIFICATION OF APPROVED PROJECT**

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 Brandman University Institutional Review Board.

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

COMMENTS:

Chair, Brandman University Institutional Review Board

Date