

**BRANDMAN UNIVERSITY INSTITUTIONAL REVIEW BOARD
Continuing Review Request/Closure Report**

Instructions: Please complete all sections of this form and submit with attached documents, forms, and/or explanations to: BUIRB@brandman.edu.		
PRINCIPAL INVESTIGATOR (Last, First, M.I., Degree)	BUIRB PROJECT NUMBER	DATE
PROJECT TITLE		

1. a. Status of project Continuing Completed (Closure) Terminated
- b. Is subject enrollment continuing? Yes No
 If no, is the research permanently closed to the enrollment of new subjects? Yes No
 Have all subjects completed all research-related interventions? Yes No
 Does the research remain active only for long-term follow-up of subjects? Yes No
 Are the remaining research activities limited to data analysis? Yes No
- c. Are subjects being seen for follow-up? Yes No N/A
- d. Based on study results, has the risk/benefit ratio changed for this study? Yes No
 If yes, explain.

- e. Has there been a change in the PI, or the PI's role in the study?
 Yes No If yes, explain:

- f. Has there been a change in the PI's duties at Brandman University?
 Yes No If yes, explain:

- g. Have the physical or financial resources that are available to the study decreased since the last review? Yes No If yes, explain:

- h. Has there been any change in research staff since the last review? Yes No
- i. Do you wish to make any changes in research staff at this Continuing Review? Yes No
If yes, please indicate the type of change that you are requesting, the name of the individual(s) and the training and qualifications of the individual(s) as well as attach BUIRB Form "Request for Modification of Approved Project" with this submission.

NOTE: If an individual obtains informed consent independently of an investigator, they must have completed an approved training program, and documentation of this kept on file by the investigator.

2. Status of subjects

- a) Number of subjects enrolled in study since last report? Since project began?
- b) Number of female subjects since last report?
- c) Number of minority subjects since last report?
- d) Number of subjects who signed consents, but were dropped from study since last report? ("screen failures")
- e) Total number of patients who withdrew or were withdrawn from the study since last report?

Summarize the reasons for withdrawal:

- f) Number of subjects considered part of a vulnerable population since last report?
Indicate the reason subjects were considered part of a vulnerable population if a vulnerable population is being recruited:

How do you continue to protect the vulnerable population?

- g) Did all research subjects give written informed consent since last report? Yes No N/A
If no, provide explanation:

- h) If no subjects have been enrolled in this study, have any additional risks been identified?
 Yes No

3. Serious Adverse Events and Unexpected Adverse Events

- a) Have there been any complications, untoward side effects, serious adverse events, or unexpected adverse events at this site since the last report? Yes No
- b) If yes, have all events been reported? Yes No
- c) Summarize all events which occurred:

- d) Have any complications or untoward side effects been reported at other sites (SAE or IND Safety Reports) since last report? Yes No N/A
- e) If yes, have all non-local events been reported? Yes No

- 4.** a) Have any modifications to the protocol (including sponsor amendments) been approved since the last review? Yes No
- b) If yes, summarize the nature and purpose of all protocol modifications made since the time of last review:

- 5.** a) Are you submitting any modifications to the protocol (including sponsor amendments) with this Continuing Review? Yes No
- b) If yes, please summarize and include BUIRB Form "Request for Modification of Approved Project" with this submission

- 6.** Have unanticipated risks or significant new findings been discovered since the last review that might affect the subject's willingness to continue participation? Yes No.
- If yes, complete the following:

- a) Explain the risks or findings in detail:

- b) Do these risks or findings require modification of the informed consent form? Yes No.
If yes, have the modifications been submitted to the IRB? Yes No.
- c) Were subjects notified of these risks or findings? Yes No.
- d) Were subjects re-consented? Yes No

7. Did any unanticipated protocol deviations (including errors and accidents) occur since the last review? Yes No If yes, summarize all protocol deviations:

8. Advertising / Recruitment

- a) Were there any changes to the planned advertising or recruitment methods described in the original protocol since the last review? Yes No N/A
- b) If yes, summarize all changes that occurred:

9. Provide a summary description of study progress, number enrolled, subject experiences, research results obtained thus far, any complaints about research, summary of subject benefits, any new scientific findings (or relevant recent literature available), and any new information since the BUIRB's last review. (Please attach a separate page)

NOTE: This section must be completed.

10. Provide the original BUIRB approval date for this project:

11. Do you wish to change the protocol or informed consent at this time? Yes No
If yes, a BUIRB Form "Request for Modification of Approved Project", clearly delineating the change, must be attached, along with copies of the old and new informed consent or protocol with changes clearly highlighted.

12. Since last reported, has there been any change in the financial interests of the Principal Investigator, any Co-investigator or their spouse or dependent child(ren) with respect to the sponsor or other entity external to Brandman whose business interests are related to the data or results of this study? Yes No N/A (unfunded) If "yes", describe in detail the change in financial interest. Use the space here or attach a separate sheet.

13. Has the Principal Investigator been an author or co-author on any published or submitted articles since the last continuing review of this project? Yes No

14. Since last reported, has there been any change in the use of pharmacy, laboratory or radiology resources of the facility for procedures or tests that are not clinically indicated? Yes No
If yes, you must complete revised Impact Estimation Worksheets.

15. Since last report, have there been any changes to how information is stored? Yes No

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16. Have you had any external study monitor visits since the last review? Yes No

a) If yes, were there any serious findings or concerns identified by the monitor? Yes No
If so, please explain:

b) If yes, please attach all Study Monitor Reports and Follow-up Memos with this Continuing Review submission

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17. CERTIFICATION: By signing this document, I attest that all the information I have provided is accurate to the best of my knowledge. I certify that the rights and welfare of human subjects participating in this research project will be protected at all times and that the benefits to be gained from this study are commensurate with the risks involved. An approved informed consent will be properly executed in every case and documented in the medical record. I have reported all serious adverse events and unexpected adverse experiences as required. I will immediately report any complications arising from this study to the Brandman University Institutional Review Board (BUIRB). I certify that all investigators and all research staff who perform the informed consent procedure independently of an investigator have completed an approved educational program.

Principal Investigator	Date
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