UMASS GLOBAL
A nonprofit affiliate of the University of Massachusetts

UMASS GLOBAL 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: IRB@umassglobal.edu.		
PRINCIPAL INVESTIGATOR (Last, First, M.I., Degree)	IRB 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 IRB 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e) Total number of patients who withdrew or were withdrawn from the study since last report?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 reconsented? ☐ 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 IRB's last review. (Please attach a separate page)

NOTE: This section must be completed.

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

11. Do you wish to change the protocol or informed consent at this time? ☐ Yes ☐ No
If yes, a IRB 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

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

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 UMASS GLOBAL Institutional Review Board (IRB). 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**