

APPENDIX E CONTINUING REVIEW

Investigator:

Protocol # :

Title:

ALL IRB APPROVED RESEARCH IS PARTICIPANT TO CONTINUING REVIEW

Please provide the following documents:

- A summary of your project experience.
- If you are currently recruiting participants, did you provide a copy of the informed consent form(s)?
- If you are currently recruiting participants, include the last signed copy of the Informed consent with the participants name blacked out.
- List any abstracts or new publications published within the last year that might be germane to this study.

1. Circle the status of this study:

Recruiting Participants	Following Participants	Data Analysis Only (If so, is data de-identified?)
Study Not Begun	Study on Hold	Completed/Discontinued

(Please explain if you have circled Study Not Begun, Study on Hold or Discontinued)

2. Are participants currently being recruited?

No _____ Yes _____

Please enclose a copy of the consent form(s) currently used in this study (even if unchanged from previous submission).

3. Number of participants enrolled since last year's review: _____

Female _____ **Male** _____

4. Total number of participants enrolled in the study to date: _____

5. Is this project funded: No _____ Yes _____

If yes, please provide current funding agency name(s) and grant number(s)

6. Is this research a clinical investigation of a new drug or medical device:

No _____ Yes _____ If yes, please provide IND/IDE# and expiration date.

7. Is ionizing radiation (e.g., x-rays, radioactive materials) used in this project:

No _____ Yes _____ If yes, has the portion of the study involving ionizing radiation been completed?

No _____ Yes _____ If no, list any changes in radiation dosimetry and radiation dose to the study population (show assumption and calculation)

8. Any changes in Principal or Co-Investigators:

No _____ Yes _____ If yes, please explain.

9. On a separate sheet, please provide a summary of the following as applicable:

- Preliminary information about any results and/or trends
- Adverse events and dates reported to the IRB.
- Do adverse event trends indicate that changes are needed in the consent form or in the study?
- Changes in protocol and dates approved by the IRB
- Difficulties in recruitment or retention of participants.
- The number of participants who withdrew from the study

10. Has the Principal Investigator received any direct compensation from the sponsoring company in the last year?

No _____ Yes _____ If yes, give details.

11. The PRINCIPAL INVESTIGATOR'S ORIGINAL signature is required. By signing below, the PI assures that the information contained on this form is true and accurate.

Original Signature of Principal Investigator

Date

Phone

Fax