



Patient Advocacy Council

Institutional Review Board

Continuing Review Form

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Mobile, Alabama 36606
Phone: (251) 479-5472 • Fax: (251) 450-1253
Web Site: www.pacirb.com

| | |
|--------------------|---------------------|
| Sponsor: | Study Title: |
| Protocol #: | |
| PAC #: | |
| PI: | |
| PI #: | |
| City/State: | |

THE COMPLETION AND RETURN OF THIS REPORT IS NECESSARY TO COMPLY WITH FEDERAL REGULATIONS (21 CFR 56.108 & 56.109; 45 CFR 46.103 & 46.109)

You must terminate conduct of the study if IRB approval expires.

Please check the appropriate box and answer all questions

- INTERIM REPORT (study is NOT yet complete at your site)
 FINAL REPORT (study is completed at your site; i.e., all data have been collected and all participants have completed all study activities)

I. Recruitment and Enrollment

- Has this study started at your site (i.e., has subject recruitment begun and/or any consent discussions conducted)? Yes No If no, proceed to section III
- Total number of patients who were consented (signed the consent form): _____
Date the first participant was consented at your site (m/d/yyyy): _____
Date of the most recent consent or re-consent at your site (m/d/yyyy): _____
- Total number of consented patients who did not meet the enrollment criteria: _____
- Among the participants who met the enrollment criteria and were enrolled in the study:
 - Total number of patients still active in the study: _____
 - Total number of patients that dropped out or withdrew before completion: _____
 - Total number of patients who have completed the study: _____
 - Total number of patients who have been enrolled in the study: _____

The total number of patients still active, plus the number who dropped out or withdrew, plus the number of patients that have completed should equal the number of patients who have been enrolled (A + B + C = D).

5. Please provide the number of each gender of the subjects entered into the study:
- _____ Female _____ Male
6. Please provide the number of subjects enrolled in the study in each of the following groups:
- _____ Caucasian _____ African-American _____ Asian
- _____ Hispanic _____ Native-American _____ Other
7. Please provide the number of subjects enrolled in the study in each of the following groups:
- _____ Employees at the investigator's institution
 - _____ Students to be recruited in their educational setting
 - _____ Members of the armed forces to be recruited by another member
 - _____ Institutionalized persons
 - _____ Pregnant women
 - _____ Children/minors
 - _____ Economically or Educationally Disadvantaged
 - _____ Terminally Ill
 - _____ Nursing home residents
 - _____ Mentally Ill or Disabled
 - _____ Patients in emergency situations
 - _____ Prisoners
 - _____ Limited or non-readers
 - _____ Handicapped
 - _____ Others that may be vulnerable to coercion
 - _____ Those not from any of the above vulnerable populations
8. Have there been any patients who have dropped out or withdrawn consent since the last submitted Continuing Review report?
- Yes No
- If yes, list specific reasons for each patient who has dropped out or withdrawn consent since the last submitted report: _____
8. Is enrollment open or closed at this time? Open Closed
9. Has your site utilized advertising/recruitment materials during the current approval period?
- Yes No
- If yes, were these materials approved by PAC IRB? Yes No
10. Are there any non-English speaking patients enrolled in the study at your site?
- Yes No
- If yes, are you using a translated informed consent that has been approved by PAC IRB?
- Yes No

II. Conduct of the Study

1. Have there been any serious adverse events not previously reported to PAC?
- Yes No *(If yes, attach documentation)*
2. Have there been any unanticipated problems involving risks to subjects not previously reported to PAC?
- Yes No *(If yes, attach documentation)*
3. Have any protocol deviations occurred that have not been previously reported to PAC (i.e., deviations that were implemented to eliminate hazards to subjects, that increase risk to subjects, and/or that affect the conduct of the trial)?
- Yes No *(If yes, attach documentation of these deviations.)*
4. Has any participant sought compensation for an injury associated with the study?
- Yes No *(If yes, attach a letter of explanation.)*
5. Has any new risk or benefit information become available not previously reported to PAC?

Yes No (If yes, attach a copy of the new information.)

6. Are there any changes to the protocol or consent form not previously reported to PAC?
 Yes No (If yes, please attach a copy of the changes.)
7. Has there been any relevant literature or research findings not previously reported to PAC?
 Yes No (If yes, please attach)

III. Community and Site Information

1. Have there been any changes in state or local laws related to research or governing the rights of research participants at your site?
 Yes No (If yes, please attach a copies of the relevant statutes.)
2. Local public attitude toward research in your state, in your opinion is?
 Positive Negative If negative, please explain: _____
3. Has your site been audited for any study by the FDA since your last report? Yes No
If yes, was a Form 483 issued? Yes No
(If yes, attach Form FDA 483 and any letter of response.)
4. Are there any current investigations or charges involving the Principal Investigator or sub-investigator(s)? Yes No
(If yes, attach a letter of explanation.)
5. Have there been any changes in the status of board certification, licensure or hospital privileges of the Principal Investigator? Yes No
(If yes, attach a letter of explanation.)
6. If your medical license has been renewed during this reporting period, please attach a copy.
7. Name of contact person regarding this report: _____
Phone #: _____ Fax #: _____ Hours Available: _____

You must submit a signed copy of the consent form from the most recently consented/re-consented subject. If there is more than one consent form (including assent forms, addenda, etc.), please submit a copy of each form.

CHECK ONE OF THE FOLLOWING:

- A copy of the most recently signed consent form is enclosed/attached
 No patients have consented to participate in this study at this site

Federal regulations require IRB's to conduct continuing review of approved research and prohibit investigators from conducting research without IRB approval. Therefore, failure to submit the requested information on time will result in the board suspending or terminating approval of the study. Expiration, suspension, or termination of IRB approval means that all study activity must stop, including screening and enrollment, data collection, data submission to the sponsor, and all other study procedures except those necessary to protect patient rights, safety, and welfare. IRB's are also required by regulation to notify the sponsor, institutional officials, and the FDA (for FDA-regulated trials) of any suspension or termination of approval.

My signature indicates that I have reviewed the information provided in this report and that I will not continue conducting this study without IRB approval.

Signed: _____
Principal Investigator

Date: _____