



ASENTRAL™ IRB FINAL REVIEW REPORT

Investigator:
Site:

Date submitted:

Address:

Asestral #:

Sponsor:

Protocol Number:

1. Are any subjects still participating in this trial? Yes No If No, please check reason below.
 Study closed No subjects were enrolled Investigator withdrawn Study placed on hold Other
2. Is enrollment still open at your site? Yes No

Number of Subjects	Primary Trial	Trial Extension (if applicable)
Consented		
Enrolled in Study		
Dropped after Enrollment		
Completed		

3. **At your site**, have there been any deaths, hospitalizations, or other Serious Adverse Events (whether or not they are deemed drug related) not previously reported to Asestral IRB?
 Yes No
 (If yes, attach a copy of the SAE report).
4. List specific reasons for each randomized subject who has dropped from the study since the last annual review (use a separate sheet if additional space is required):
5. Has any new information involving risks or benefits to subjects become available from the sponsor that has not been previously reported to Asestral IRB? Yes No
 (If yes, attach a copy)
6. Have there been any changes to the protocol or informed consent form not previously reported to Asestral IRB? Yes No
 (If yes, attach a copy)
7. Have there been any changes in state or local laws related to research? Yes No
 (If yes, attach appropriate information)
(Massachusetts sites please attach an updated Mass. Dept. of Health Research License)

8. What is your community's attitude toward research? Positive Negative

If negative, please explain

9. Have you been audited by the FDA since your last report? Yes No

(If yes, date of audit [Click here to enter a date.](#) Please provide a copy of the report as soon as it becomes available)

10. Are there any current investigations or charges involving the Principal Investigator or Sub-Investigator?

Yes No

Signature: _____
Principal Investigator or Designee

Date: _____

IMPORTANT: Please attach copies of all updated medical and research licenses of all Investigators participating in this study as well as updated copies of CVs signed/dated within a year of the anniversary date of the study. In addition, please include a copy of the informed consent form(s) used to consent the most recently consented subject in the study (with the subject's name blackened out, but not the initials or any dates). Please submit the complete package via USPS, courier, or scan and email to cr@asentralirb.com.

PLEASE NOTE THAT ASENTRAL, INC. CAN NOT PROCESS FINAL REVIEW REPORTS WITHOUT THIS INFORMATION.

- Updated, signed (within one year of date of submission) CV from all Investigators in the study.
- Current medical and research licenses of all Investigators in the study.
- Signed copy (with subject's name and signature blackened out but all dates and initials left intact) of the informed consent form(s) used to consent the most recently consented subject in the study.

Please submit this information either by United States Postal Service or scan it and email it to cr@asentralirb.com. Please do not fax.