



ASENTRAL™ IRB QUARTERLY CONTINUING REVIEW REPORT

Investigator:
Site:
Address:

Due Date:
Asestral #:

Sponsor:

Protocol Number:

1. Has the study begun at your site? Yes No (Go to #3 below)
- Study closed No subjects were enrolled Investigator withdrawn Study placed on hold Other

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

2. **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? (If yes, attach a copy of the SAE report)
- Yes No
3. Has any new information involving risks or benefits to subjects become available from the sponsor not previously reported to Asestral IRB? (If yes, attach a copy)
- Yes No
4. Have there been any changes to the protocol or informed consent form not previously reported to Asestral IRB? (If yes, attach specific information)
- Yes No
5. Have there been any changes in state or local laws related to research? (If yes, attach appropriate information)
- Yes No
6. What is your community's attitude toward research? Positive Negative
If negative, please explain:
7. Have you been audited by the FDA since your last report?
(If yes, date of audit Provide a copy of the report as soon as it becomes available)
- Yes No
8. Are there any current investigations or charges involving the Principal Investigator or Sub-Investigator?
- Yes No

If yes, please explain

Signature: _____
Principal Investigator or Designee

Date: _____