



# ASENTRAL™ IRB ANNUAL REVIEW REPORT

Investigator:  
Site:  
Address:

Date submitted:  
Asentral #:

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 Study closed     No subjects were enrolled     Investigator withdrawn     Study placed on hold     Other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 Asentral 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 Asentral 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 Asentral 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](mailto: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](mailto:cr@asentralirb.com). Please do not fax.***