



UNANTICIPATED PROBLEM/EVENT REPORT FORM

Report of Protocol Waivers/Deviations/Violations or any other Problems, Injuries and Events that Require Prompt Reports to Asentral, Inc. IRB.

Submit to:
 Asentral, Inc. IRB
 15 Main Street, Suite 203
 Salisbury, MA 01952
 978-462-6416 (Fax) or
 cr@asentralirb.com

Principal Investigator:		Phone:
Email:		Printed name of person completing this form:
Sponsor:		
Sponsor Contact:		
Protocol Number:		IRB Number:

A. Complete the section below to describe the problem, event, or injury in the specific participant:

- Study specific participant(s) identifier(s):
- Date of problem/event:
- Briefly describe details of the event:

B. The PI must answer the following questions:

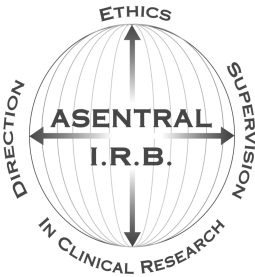
- Yes No Is it likely that this problem/event was related to the research procedures?
If yes, and the protocol involves a drug or device, check below the strength to which the drug or device was related.
 - Not related
 - Probably not related
 - Possibly related
 - Probably related
 - Definitely related
- Yes No Did the problem/event cause harm or place a participant(s) or non-participant(s) at increased risk of harm? **If yes**, explain.
- Yes No Will the participant(s) remain in the study?
- Yes No Has the Sponsor (either federal or private) been notified?
 Date Sponsor was notified:

 Signature of Principal Investigator

 Date of PI signature

For IRB Use Only

Asentral, Inc. IRB CHAIR/DESIGNEE REVIEW OF PROBLEM/EVENT REPORT:



The problem/event:

- Represents an unanticipated problem involving risks to participants or others
- Does not represent an unanticipated problem involving risks to participants or others

Yes No Is further action needed?
If yes, refer to convened IRB for review.

Yes No Did the problem/event result from serious or continuing noncompliance?
If yes, refer to convened IRB for review.

Signature (Asentral, Inc. IRB Chair/Designee)

Date