



Opus Institutional Review Board

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Adverse Event or Unanticipated Device Effect Report Form

AE or Unanticipated Device Effect	
	Date of Report
	Date of Event
	Date Investigator / Study staff learned of event
	Date Reported to Sponsor
	Date Reported to FDA (if applicable)
	Opus IRB #

Principle Investigator	
	Principle Investigator
Yes <input type="checkbox"/> No <input type="checkbox"/>	Protocol
	Subject Initials or Identifier
Initial Report <input type="checkbox"/> Follow-up Report <input type="checkbox"/>	<i>(Select One)</i>

Resources	
Yes <input type="checkbox"/> No <input type="checkbox"/>	Are there adequate resources necessary to manage the adverse event and protect participants?
<input type="checkbox"/> Adequate time for the investigators to conduct and complete the research <input type="checkbox"/> Adequate number of qualified staff <input type="checkbox"/> Adequate facilities <input type="checkbox"/> Access to a population that will allow recruitment of the necessary number of participants <input type="checkbox"/> Availability of medical or psychosocial resources that participants may need as a consequence of the research	

Research Protocol

The purposes of the research:

The scientific rationale:

The procedures to be performed:

A Description of the procedures being performed already for diagnostic or treatment purposes:

The risks and potential benefits of the research to participants:

Event Details

If Serious Criteria (*check all that apply*)

- Life threatening
- Resulted in an in-patient hospitalization
- Prolonged an in-patient hospitalization
- Resulted in a persistent or significant disability / incapacity
- Resulted in a congenital anomaly / birth defect
- Death (date of death:)
- Other:

If Unanticipated / Unexpected Event: Any adverse experience, the specificity or severity of which is not contained in the current protocol

Investigator's Opinion of the relationship of the event to the study drug/device

No Relationship Possibly Related Probably Related Definitely Related

Describe Event (attach additional pages and supporting documentation):

Attach a copy of the current Informed Consent risk section.

Status of Event

Ongoing Resolved If Resolved provide date of resolution:

Yes No Is this event listed in the current IRB approved Informed Consent Form?

Yes No In the opinion of the Principle Investigator should this event be added to the Informed Consent Form?

Name of person completing this form

Date form completed

Email address

Phone Number

Fax Number

Signature of Principal Investigator

**Sub-Investigator may sign in PI's absence*

Date