

REPORT OF SERIOUS AND UNEXPECTED ADVERSE EVENT FORM

For any section in which additional space is needed, complete on plain bond paper.

Report Type: ____ Initial ____ Follow-up ____ Medical Monitor

IRB Log No: A-

Study Title:

Principal Investigator Name:

Study Drug/Device:

Reporting Individual (printed name, title/position, and phone number):

Total study enrollment to date: _____ participants _____ withdrawals _____ deaths

Subject Data: Subject ID _____ Age _____ Gender _____

Study Group/Arm _____ Enrollment Site _____

Event description (include admission/discharge dates, event resolution if known, subject status) and attach supporting documents (discharge summaries, lab reports, etc.):

Seriousness –check all that apply	Relationship to drug/device
<input type="checkbox"/> Fatal	<input type="checkbox"/> Not Related <input type="checkbox"/> Not Applicable
<input type="checkbox"/> Life Threatening	<input type="checkbox"/> Possibly <input type="checkbox"/> Probably
<input type="checkbox"/> Disability	<input type="checkbox"/> Definitely Related
<input type="checkbox"/> Hospitalization (initial or prolonged)	<input type="checkbox"/> Unclassifiable
Other (specify)	

Pertinent Medical History (to include medication use):

Actions Taken or Anticipated Actions in Response to this Event (Changes to consent form/protocol, blind broken, subject dropped from study):

Event reported to IRB of record: yes no n/a (circle one)

Date reported to IRB of record:

Other Serious and Unexpected Adverse Events Reported for this Study:

For Medical Monitor Reports Only - Assessment of Report from the PI (comments on concurrence/non-concurrence with diagnosis, treatment and relationship of event to participation in study):

Reporter printed name

Reported signature

Date