

Serious Adverse Event / Adverse Device Effect Notification Form

Reporting Instructions: Only events that are serious **and** unexpected **and** possibly related/related to the drug/device should be reported to Total IRB. If the event was classified as **not** related to the investigational drug or device, it does not need to be reported to Total IRB.

Serious and unexpected SAEs or ADEs are required to be submitted to Total IRB within 10 business days from the date the Investigator or designee becomes aware of the event. If the event resulted in death, the timeline shortens to notification within 5 business days.

I. STUDY INFORMATION	
Principal Investigator:	
Protocol Number:	
Sponsor name and/or Funding Agency:	

II. EVENT INFORMATION	
<p>1. Please check all the boxes that apply. Reporting to Total IRB is only required when all 3 boxes are checked.</p> <p><input type="checkbox"/> SERIOUS (an event that results in death, a life-threatening event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect)</p> <p><input type="checkbox"/> UNEXPECTED (an event that is not currently listed in the informed consent form or investigator brochure (or other drug information sheet used by study)</p> <p><input type="checkbox"/> Possibly related or related to study drug or device</p>	
2. Subject #:	
3. Start Date of Event:	Stop Date of Event:
4. Is subject still participating in trial? <input type="checkbox"/> Yes <input type="checkbox"/> No	

II. EVENT INFORMATION
5. Date the Investigator/designee became aware of event:
6. Report Type: <input type="checkbox"/> Initial <input type="checkbox"/> Follow Up
7. Event Resulted in (check all that apply): <input type="checkbox"/> Death <input type="checkbox"/> Life-threatening event <input type="checkbox"/> Inpatient hospitalization or prolongation of existing hospitalization <input type="checkbox"/> Persistent or significant disability/incapacity <input type="checkbox"/> Congenital anomaly/birth defect <input type="checkbox"/> Other:
8. Provide a summary of the event, treatment, outcome and circumstances of the event:
9. Will there be follow up information submitted regarding this event? <input type="checkbox"/> Yes <input type="checkbox"/> No
10. Does the investigator recommend changes to the protocol or informed consent form? <div style="text-align: center;"><input type="checkbox"/> Yes* <input type="checkbox"/> No</div> <p>*If Yes, specify recommended changes (or attach additional sheet with recommendations):</p>

III. PERSON COMPLETING FORM	
By submitting this form I certify that the information contained is complete and accurate and that no facts have been suppressed or misstated. The Principal Investigator (PI) is aware of all information in this form and I am authorized to submit to the IRB on the PI's behalf.	
Form Completed By _____	Date _____
Title, Company _____	
Phone: _____	Email: _____