



ADVERSE EVENT/SERIOUS ADVERSE EVENT FORM (ver.4.0)

A. Study and PI Information	
IRB Project/Protocol Number	
Date	Click or tap to enter a date.
Principal Investigator (PI)	
Protocol Title	
Faculty Advisor (If PI is a student)	

B. Event Report	
Please list information about the Adverse Event (AE)/Serious Adverse Event (SAE) below.	
1. Start date / End date	
2. Severity of the event	<input type="checkbox"/> Mild <input type="checkbox"/> Moderate <input type="checkbox"/> Severe
3. Study Intervention Relationship	<input type="checkbox"/> Definitely Related <input type="checkbox"/> Possibly Related <input type="checkbox"/> Not Related
4. Action Taken Regarding Study Intervention	<input type="checkbox"/> None <input type="checkbox"/> Discontinued Permanently <input type="checkbox"/> Discontinued Temporarily <input type="checkbox"/> Procedure/Dose/Activity Reduced <input type="checkbox"/> Procedure/Dose/Activity Increased <input type="checkbox"/> Procedure/Dose/Activity Delayed
5. Outcome of AE/SAE	<input type="checkbox"/> Resolved, No Sequel <input type="checkbox"/> AE/SAE still present- No Treatment <input type="checkbox"/> AE/SAE still present- Being Treated <input type="checkbox"/> Residual Effects Present- Not Treated <input type="checkbox"/> Residual Effects Present- Treated <input type="checkbox"/> Death <input type="checkbox"/> Unknown
6. Is this event expected?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Please provide more details the IRB should know regarding this event.	

NOTE: If there have been multiple AEs and/or SAEs, copy and paste the above table and add information. To copy and paste, go to developer -> unlock "protect form" -> copy and paste -> relock "protect form."