

Protocol Deviation Report Form

Only significant protocol deviations should be reported to Total IRB. Significant protocol deviations are required to be submitted within 10 business days from the date the Investigator or designee becomes aware of the event.

In general, violations are considered to be significant protocol deviations if they: increased the risk to the subjects or others, affected the rights, safety or welfare of the subjects, or affected the integrity of the study. If it is anticipated that this deviation will occur again, an amendment to the protocol should be considered.

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

II. PROTOCOL DEVIATION INFORMATION	
Subject #:	
Date of Violation:	
Date reported to Sponsor:	
1. Category of Deviation:	<input type="checkbox"/> increased the risk to the subjects or others <input type="checkbox"/> affected the rights, safety or welfare of the subjects <input type="checkbox"/> affected the integrity of the study <input type="checkbox"/> None of the above (then not required to be reported to Total IRB, as does not qualify as a major protocol deviation)
2. Did protocol deviation occur to eliminate an apparent immediate hazard to the subject? <input type="checkbox"/> Yes <input type="checkbox"/> No <i>FDA 21 CFR 56.108(a)(4) and ICH 3.3.7 state that planned deviations from the protocol require prior approval by the IRB except when necessary to eliminate an apparent immediate hazard to the subject.</i>	

II. PROTOCOL DEVIATION INFORMATION	
3. Description of Protocol Deviation:	
4. Reason for Deviation: <i>Note – If same/similar deviation has occurred in the past for this protocol be sure to detail that information and why deviation recurred.</i>	
5. Actions taken to prevent future occurrence:	

III. PERSON COMPLETING FORM	
<p>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.</p>	
<p>_____</p> Form Completed By	<p>_____</p> Date
<p>_____</p> Title, Company	
<p>_____</p> Phone:	<p>_____</p> Email: