

**Mount Sinai Hospital Research Ethics Board
Protocol Deviation Report Form**

Do not leave any box blank. Submit typed, hard copy of this form with original signature to the REB office for review. See the Guidelines for Reporting Protocol Deviations for more information.

Principal Investigator:		MSH REB Number:		
Study Title:				
Sponsor:				
Date of Protocol Deviation: (DD/MMM/YY)	Date Deviation Reported to REB: (DD/MMM/YY)	Date Deviation Reported to Sponsor: (DD/MMM/YY) N/A <input type="checkbox"/>		
This report pertains to a single study subject <input type="checkbox"/> Yes <input type="checkbox"/> No	This report pertains to more than one study subject <input type="checkbox"/> Yes <input type="checkbox"/> No	Study subject i.d number(s) <table border="1" style="width: 100%;"><tr><td> </td></tr><tr><td> </td></tr></table>		
1. Provide description of the protocol deviation. If applicable, refer to the procedure from which the deviation occurred and indicate page number in protocol. Attach any relevant supporting documentation, including the report filed with the study sponsor.				
2. Were study subject(s) adversely affected by the deviation? <input type="checkbox"/> Yes <input type="checkbox"/> No If yes, explain and submit a serious internal adverse event reporting form.				
3. Were study subject(s) informed of the deviation? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, explain.				
4. a) In your opinion, how has this protocol deviation affected the safety/increased the risks to study subject(s) in the approved protocol?				
b) Describe any corrective actions that will be taken to ensure that similar deviations do not occur in the future.				
5. In your opinion, does the deviation affect the integrity of the study data? <input type="checkbox"/> Yes <input type="checkbox"/> No				
6. Will a protocol amendment be submitted? <input type="checkbox"/> Yes <input type="checkbox"/> No				
This signature attests that the PI is aware of the deviation and its safety implications and has assessed the impact of the deviation on the study procedures.				
Principal Investigator _____ <i>Print Name</i> <i>Signature</i> <i>Date (DD/MMM/YY – 05-Jan-05)</i>				