**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:       N/A  (DD/MMM/YY) |
| This report pertains to a single study subject  Yes  No | This report pertains to more than one study subject  Yes  No | Study subject i.d number(s)   |  | | --- | |  | |  | |

|  |
| --- |
| 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?  Yes  No  If yes, explain and submit a serious internal adverse event reporting form. |
| 3. Were study subject(s) informed of the deviation?  Yes  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?  Yes  No |
| 6. Will a protocol amendment be submitted?  Yes  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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *Print Name Signature Date (DD/MMM/YY – 05-Jan-05)* |