**For the Principal Investigator:**

**IRB #:** Click here to enter text.

**Study Title:**

**1. Principal** **Investigator (PI)**: Click here to enter text.

Email: \_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone:\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_ Fax:\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_

Mail Box: Click here to enter text. \_\_\_Dept: Click here to enter text. \_\_\_Division: Click here to enter text. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. Study Coordinator**:Click here to enter text.

Email: \_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone:\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_ Fax:Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_

Mail Box: Click here to enter text. \_\_\_Dept: Click here to enter text. \_\_\_Division: Click here to enter text. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Co-PI or HU Sponsor:**  Click here to enter text.

Email: Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Phone:Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_ Fax:\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_

Mail Box: Click here to enter text. \_\_\_Dept: Click here to enter text. \_\_\_Division: Click here to enter text. \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**I. Reporting Criteria:**

**This deviation/violation adversely affects:** *(check all that apply)*

 **YES NO**

[ ] [ ]  **rights/welfare of subject(s)**

[ ] [ ]  **safety of subject(s)**

[ ] [ ]  **integrity of research data**

[ ] [ ]  **subject’s willingness to continue study participation**

***(Note: if you have checked "NO" to all of the above, please do not proceed with this report. This is not a reportable deviation/violation. However, if the IRB has specifically requested that you submit this report because of a lapse in approval or late submission, all sections of this form must be completed.)***

**II. Characterization:**

**The deviation/violation involves:**

[ ]  **Enrollment process** *(inclusion/exclusion criteria, ascertainment/recruitment, etc.)*

[ ]  **Consent process** *(oral or written)*

[ ]  **Drug/Device Administration** *(dosage, schedule, route of administration, formulation, etc.)*

[ ]  **Other Protocol Activities (***research activities, data analysis, reporting, etc.)*

[ ]  **Complaint from research subject**

[ ]  **Audit finding that requires corrective action**

[ ]  **Other:**

**III. Description:**

1. Date(s) of the deviation/violation: Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Note: If more than 10 business days prior to the date of submission to the IRB (or more than 24 hours for an unanticipated study-related death), please explain the delay in reporting.*

1. Please describe in detail the specific deviation/violation: Click here to enter text.

**3. If the purpose of this deviation report is a lapse in IRB approval, please describe all study activities, including enrollment, interventions, data analysis, that have occurred during the lapse:** Click here to enter text.

**4. Please explain how/why the deviation/violation occurred:** Click here to enter text.

**5. Please describe how the deviation/violation affected the:** Click here to enter text.

**(i) risk/benefit ratio for the subject(s):** Click here to enter text.

**(ii) integrity of the research data:** Click here to enter text.

**(iii) subject’s willingness to continue study participation:** Click here to enter text.

**6. Does this protocol deviation/violation require revision of the protocol and/or consent form?**

[ ]  **Yes** *(if yes, please submit a completed Amendment/Modification form and revised documents with changes marked)*

[ ]  **No**

**7. Please describe:**

 **(i) corrective actions, if applicable, for the deviation/violation; and**

Click here to enter text.

 **(ii) a plan for preventing the recurrence of the deviation/violation:**

Click here to enter text.

**By signing below, I declare that the above is an accurate and complete description of the protocol deviation/violation and that, upon receipt of the IRB’s review, I will fully and immediately implement any corrective actions required by the IRB.**

Click here to enter text.Click here to enter text.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of PI Date**

Click here to enter text.Click here to enter text.

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Signature of co-PI**

**For IRB Use Only:**

**I have reviewed this reported protocol deviation/violation and determined that:** *(check all that apply)*

**[ ] No further action is required.**

**[ ] The corrective action described in this form below is acceptable. PI must issue a statement to the IRB that he/she has implemented the corrective action plan as described.**

**[ ] PI must submit an interim report to the IRB on \_\_\_\_\_\_\_\_ describing his/her**

**progress in implementing the corrective action described below.**

**[ ] The attached corrective actions must be implemented.**

**[ ] The deviation/violation reported appears to represent serious or continuing**

**non-compliance. Review according to that policy is required.**

**[ ] Other: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Printed name/ title:* \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Signature*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *Date\_\_\_\_\_\_\_\_\_\_\_\_***

**Final IRB Clearance:**

***Printed name/title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_***

***Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date­­\_\_\_\_\_\_\_\_\_\_\_\_***