HOWARD UNIVERSITY

Office of Regulatory Research Compliance
Institutional Review Board

Notification of Protocol Deviation/Violation Form

For the Principal Investigator:

IRB #:_____

Study Title:

1. Principal Investigator (PI): _____

Email: _____Phone:_____Fax:_____

Mail Box:_____Dept: _____Division: _____

2. Study Coordinator:_____

Email: _____Phone:_____Fax:_____

Mail Box:_____Dept: _____Division: _____

3. Co-PI or HU Sponsor: _____

Email: _____Phone:_____Fax:_____

Mail Box:_____Dept: _____Division: _____

I. Reporting Criteria:

This deviation/violation <u>adversely</u> 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: _____

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.

2. Please describe in detail the specific deviation/violation:

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:

4. Please explain how/why the deviation/violation occurred:

5. Please describe how the deviation/violation affected the:

(i) risk/benefit ratio for the subject(s):

(ii) integrity of the research data:

(iii) subject's willingness to continue study participation:

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

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

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.

_____ _____

Signature of PI **Date**

_____ _____

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***_____