**NON-COMPLIANCE/PROTOCOL DEVIATION REPORT FORM**

The HSC requires reporting of all non-compliance, deviations or policy violations within five (5) business days as per HSC Policy.

**1. Deviations generally do not have a major impact on subject welfare or data integrity. Examples of a protocol deviation may include:**

* Scheduling a required procedure outside of the time frame specified in the protocol
* Failure of subject to return study medication
* Implementation of unapproved recruitment procedure

**2. Violations affect a subjects rights, safety or well-being or integrity of the data being collected. It may also affect the primary safety or efficacy endpoints of the study. Examples are:**

* Enrolling subjects who did not meet entry criteria without prior permission
* Failing to obtain informed consent prior to any study-related procedures
* Failure to treat subjects according to protocol procedures that specifically relate to primary safety or efficacy endpoints.

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**Date:** Click here to enter a date. **Date of Event:** Click here to enter a date.

**PI Name:** Click here to enter text.

**Protocol Title:** Click here to enter text.

**Subject’s Initials:** Click here to enter text. **Subjects Study #:** Click here to enter text.

**Subjects Record #:**Click here to enter text.

**If externally funded, was the sponsor notified of the protocol deviation/violation?:**

 **Yes** [ ]  **Date Notified:** Click here to enter a date. **No** [ ]  **N/A** [ ]

**Provide a full description of the protocol deviation/violation as well as why the deviation/violation occurred (Attach as many pages as necessary):**

Click here to enter text.

**What will be done in the future to prevent recurrence of this protocol deviation/violation? (Attach as many pages as necessary)**

Click here to enter text.

**Submit to:** Office of Sponsored Programs, ATTN: Director