Protocol Violation/Deviation Reporting Form

Protocol violations are considered to be any change or departure (i.e. "deviation") from the IRB-approved study design or study procedures of a research protocol. Once a protocol violation has been identified, it must be reported to the NTR IRB within **10 working days** of discovery. Researchers should complete this form and submit it in a new package within the IRBNet electronic system. Please note that the following information pertains to *ALL* studies, regardless as to whether the project is funded or unfunded. ***Submission of this completed document does not preclude additional investigation or inquiry by IRB staff or the IRB.***

NTR IRB Project #: Project Title:

Principal Investigator (PI): Phone Number:

Contact Person/Study Coordinator and Phone # (if different from P.I.):

Institution: Department/Institute:

Sponsor Protocol Number (or Funding Agency Award Number):

CIRCUMSTANCES OF THE PROTOCOL VIOLATION(S):

Date(s) that the violation(s) occurred:

Date(s) that the study staff identified the event(s)/violation(s):

Subject IDs of impacted participants (if applicable):

Provide a detailed description of the circumstances of the protocol violation(s) in the box below.

Describe the circumstances of the violation here including the cause of the event and how the event deviated from the IRB-approved protocol (*add additional lines as needed*).

INVESTIGATOR'S RISK ASSESSMENT OF THE VIOLATION(S):

Provide the PI's assessment regarding any impact on risks to study participants resulting from the violation(s), as well as the PI's justification for this risk assessment, in the box below. *If applicable, include a description of any additional treatment the participant(s) required due to the violation*.

Provide the PI's risk assessment here, i.e. "the violation did not increase risks to subjects because…." Or, "the violation did increase risks to subjects because…" Be sure to consider whether the violation(s) may have had an impact on subjects' rights, safety, or well-being, and/or the completeness, accuracy, or reliability of the study data (*add additional lines as needed*).

INVESTIGATOR'S PROPOSED CORRECTIVE ACTION PLAN(S):

Describe the proposed corrective action plan(s) that will be implemented to address the current violation(s) and to prevent similar violations from occurring in the future in the box below.

Provide the PI's proposed corrective action plan(s) here including any plans to address the current violation as well as any plans that will be implemented to avoid future recurrences of this violation (*add additional lines as needed*).

INVESTIGATOR'S ATTESTATION:

The Principal Investigator asserts that the information provided in this document is accurate to the best of his/her knowledge. The Principal Investigator also assures that any corrective action plans that are approved by the IRB will be implemented as stated. Failure to implement the corrective actions approved by the IRB will be considered additional protocol violations requiring further IRB review and consideration. **Recurring non-compliance is reportable to federal agencies and/or sponsors as required by regulations and sponsor policies and procedures.**

_____ _____

Principal Investigator's Signature Date

_____ _____

Contact Person/Study Coordinator's Signature (if applicable) Date

*****If applicable, please submit any relevant supporting documentation as separate attachments in the IRBNet system for IRB consideration. This could include, but is not limited to, reports to the study sponsor regarding the violation(s); examples of unapproved documents used by the study team; lists of unapproved data variables that were collected by the study team; and more.**

Do NOT upload any documents containing subjects' identifiable information [except for the subject ID(s)]. Please redact any subject information that is embedded within a supporting document.