Non-Compliance Reporting Guide

A. Event Details *[Brief description or outline of the topic/process/problem being documented; can be formatted as a paragraph, numbered list, or bulleted items. Provide specific information including exact dates and citations of protocol requirements or regulation that was not followed.]*

1. What is the requirement that was not met?
2. What was the error and when did it occur?
3. Who is responsible? (Job titles only, no names)
4. When and how was the error discovered?
5. Was there an impact to subjects' rights or welfare?

Example: On November 6, the IRB approved a revised consent form with new risk information. All subjects consented after November 6 should receive the updated consent form. On November 20, a sub-investigator enrolled Subject XYZ using an outdated informed consent document initially approved on March 3. On November 26, a team member noted this error when conducting data entry. The subject has not yet received study drug, therefore the subject was not harmed as a result of this event.

B. Root cause analysis *[Process used to identify the underlying cause(s) of non-compliance. Once the root cause has been identified, a preventive action plan can be created to avoid future instances of non-compliance. Common practice is to ask "why?"5 times to uncover the underlying cause.]*

C. Corrective Actions *[Description of the actions taken or planned by the site personnel to correct the non-compliance. If the site was instructed to perform these corrective actions (i.e., by the sponsor or monitor), indicate by whom and as of what date. Indicate if this will result in a change to study documents.]*

D. Preventive Action Plan *[Description of the actions taken or planned by the site personnel to prevent future instances of non-compliance. If the site was instructed to perform these preventive actions, indicate by whom and as of what date. Preventive action plan should address the root cause of the non-compliance.]*

E. Study Information

a. Current study status
b. Number of subjects actively participating in research
c. Are subjects receiving interventions?