**Date:**

**Re:** Protocol No. \_\_\_\_\_\_\_\_\_, entitled, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Event:** *[Description of study related event or accounting of information requiring an organizational change to the protocol or needing clarification]*

**Response:** *[Description of the immediate response to the event referred above and/or what steps were taken to implement a change or to clarify a study issue]*

**Corrective Action Plan:** *[Description of the general systematic response to resolve the described event or to improve the overall quality of the study]*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Study Coordinator Signature**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator Signature**

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date**