



Incident/Adverse Event Report Form

Project Title: _____

Project # _____ **Date of Report:** _____

Principal Investigator: _____ **Subject ID/Initials:** _____

Date/Time of Incident: _____

Description of Event (*may attach additional pages*)

1. Is this a serious adverse event? _____Yes _____No

2. Is this an unexpected adverse event? _____Yes _____No

3. In your opinion, was this incident related to the test article?

_____ Related _____ Probable _____ Possible _____ Not Related

4. Was medical treatment provided for this event? _____Yes _____No

5. Does the subject require further medical treatment? _____Yes _____No

6. Will the subject remain in the study? _____Yes _____No

7. Are consent form changes required? _____Yes _____No