



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