UNION UNIVERSITY
INSTITUTIONAL REVIEW BOARD

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