Adverse Events Reporting Form

Study Title:

Principal Investigator:

Study ID:

Date of Event Reporting:

1. Participant Information
2. Participant ID
3. Age
4. Gender
5. Adverse Event Details:

a. Date and Time of Adverse Event:

b. Nature of Adverse Event: Describe the adverse event in detail.

c. Severity of the Adverse Event (Mild/Moderate/Severe)

d. Relation to the Study Procedures: (Clearly specify if the adverse event is related to the study procedures.)

e. Action Taken (Describe the immediate actions taken in response to the adverse event):

1. Medical Intervention
   1. Was medical intervention required (Yes or no)
   2. Details of medical intervention (Describe the medical intervention provided, if applicable):
2. Outcome of Adverse Event:
3. Investigator’s Assessment:
   1. Investigator’s Assessment of Causality (Specify the investigator’s assessment of the relationship between the adverse event and the study procedures).
   2. Preventability (Could the adverse event have been prevented? Yes/No/Not Applicable)
4. Additional Information”
   1. Witnesses to the Adverse Event (List any witnesses)
   2. Relevant Documentation (Attach any relevant documents, such as medical records, incident reports, etc.)
5. Signature and Date:

Principal Investigator’s Signature:

Date: