

ADVERSE EVENT REPORT
NCI Institutional Review Board

Protocol Number:

Date Submitted:

Protocol Title:

Principal Investigator:

Institute:

Office/Branch:

Phone:

FAX:

E-mail:

Date of Adverse Event:

Location of Adverse Event:

NIH

Other (Specify)

Expected/Unexpected Adverse Event:

Expected

Unexpected

Is Toxicity Addressed in Consent?:

Yes

No (Justify)

Subject Description

MRN

SEX

DOB/AGE

Brief Description of the Nature of the Adverse Event: (use CTC terminology) (Use additional sheets if necessary)

Grade of Adverse Event:

Category (Outcome) of the Adverse Event:

Death	Disability/Incapacity	Life-Threatening	Congenital Anomaly/Birth Defect
Hospitalization – Initial or Prolonged		Required Intervention to Prevent Impairment	Other

Relationship of Adverse Event to Research:

Unrelated = (Clearly not related to the research)

Unlikely = (Doubtfully related to the research)

Possible = (May be related to the research)

Probable = (Likely related to the research)

Definite = (Clearly related to the research)

Have similar adverse events occurred on this protocol?

If "Yes", how many?

Please describe.

The Institutional Review Board has received and reviewed the adverse event listed above and concurs with the PI's assessment. The following action is required as a result:

No Action Required
Inform Current Subjects
Terminate or Suspend Protocol

Other
Amend Protocol
Amend Consent

IRB Chair

Date

Clinical Director, NCI

Date

PI Signature _____ Date _____

Reporter Signature _____ Date _____