

## CLINICAL INVESTIGATION ADVERSE EVENT REPORT

Reports must be received by the IRB within 5 working days of occurrence or reporting (1 working day for serious adverse events).

From: PI NAME (Last, First MI Rank) \_\_\_\_\_  
To: Chair, Institutional Review Board  
Via: Medical Monitor

**CIP #** \_\_\_\_\_ **Date:** \_\_\_\_\_

Study Title:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Patient ID# \_\_\_\_\_ Investigational Agent (if any) \_\_\_\_\_

Date of Event \_\_\_\_\_ Location of Event \_\_\_\_\_

Adverse Event \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Was the adverse event related to the Investigational Agent or study?

Unrelated \_\_\_\_\_ Related \_\_\_\_\_ Remote \_\_\_\_\_ Possible \_\_\_\_\_ Probable \_\_\_\_\_

What was the outcome of the adverse event? \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Has this event been reported to the maker of the Investigational Agent? \_\_\_\_\_

**Investigator Signature:** \_\_\_\_\_

More than minimal risk protocols must have a Medical Monitor who will review all adverse event reports and forward to the IRB with his/her own comments.

MEDICAL MONITOR NAME (Last, First MI Rank) \_\_\_\_\_

Medical Monitor Comment: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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**Medical Monitor Signature:** \_\_\_\_\_

\_\_\_\_\_