



For adverse events occurring at the U of C Hospitals or a hospital affiliated with the University of Chicago

An adverse event is an undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention.

All fatal or life-threatening events that occur must be reported to the IRB within 48 hours of notification. If the initial contact is via telephone, a follow-up written report must be submitted to the IRB within five days.

Fatal: death

Life threatening: the subject is at substantial risk of dying at the time of the adverse event or it is suspected that the use or continued use of the procedure would result in the subject's death.

For drug/biologic studies, the death of a subject is considered a fatal adverse event if one of the following statements apply:

- (1) the death occurred within thirty days of last administration of the study drug or
(2) the death is considered possibly related to the study drug.

For device studies, the death of a subject who has an experimental device implanted at the time of death should be considered a fatal adverse event and thus reported accordingly, regardless of whether the subject is actively participating in the study at the time.

PROTOCOL NUMBER: [grid]

Principal Investigator - Last Name

First Name

[grid]

[grid]

Protocol Title

[grid]

EVENT INFORMATION

Adverse Event Date: [grid] - [grid] - [grid]

[ ] Initial Report [ ] Follow-up Report

Subject's I.D. [grid]

(i.d. number or initials)

Adverse Event (describe in 3-4 words) [grid]

The adverse event appears to be: [ ] Unexpected [ ] Expected

Research involved the use of a: [ ] Drug [ ] Device [ ] Procedure

Based on your review of the information, what is the relationship of the event to the research?

- [ ] Definite - clearly related to the research [ ] Unlikely - doubtfully related to the research
[ ] Probable - likely related to the research [ ] Unrelated - clearly not related to the research
[ ] Possible - may be related to the research

- In your opinion, do you expect this event to occur again?  Yes  No
- Is the event adequately described in the protocol and consent form?  Yes  \* No  
 \* If no, please consider whether an amendment should be submitted to add this risk.
- Should the protocol be modified to minimize this risk?  \* Yes  No  
 \* If yes, please submit an amendment to update the protocol.
- Will the consent form be modified as a result of this adverse event?  \* Yes  No  
 \* If yes, please submit an amendment to update the consent.
- Will subjects be re-consented as a result of this adverse event?  \* Yes  No  
 \* If yes, please submit an amendment to clarify how this will occur.

Please provide details of the adverse event. In this description, include the investigator's analysis of the event. Use additional pages as necessary.

**SIGNATURE OF INVESTIGATOR** (This form *must* bear the original signature of the principal investigator)

Principal Investigator

-

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Date

CHAIR OR DESIGNEE:

For IRB Use Only

- \* Doesn't meet reporting criteria - RETURN \*
- Request further information from PI
- Halt study enrollment immediately
- Send to Committee Meeting for Review
- Other (see comments)
- No additional action necessary

Comments:

\_\_\_\_\_  
Initials

\_\_\_\_\_  
Date