

- 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

- -

Date

CHAIR OR DESIGNEE: For IRB Use Only

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

Initials

Date