Institutional Review Board External Adverse Event Report

If adverse consequences or unanticipated side effects are encountered in the course of a study, or new information becomes available that could change the perception of a favorable risk/benefit ratio, the principal investigator is responsible for informing the Committee PROMPTLY. The WSCU IRB will make the final determination regarding protocol changes required due to adverse event reports.

Protocol Number:	
Principal Investigator (PI):	
Protocol Title:	
Adverse Event Information	
Adverse event date:	
Adverse event (describe in 1 sentence):	
Nature of the Event (Submit this form ONLY if all three boxes are checked.)	
1. Unexpected	
2. Related or Possibly Related	
3. Serious	
PI's Signature and date:	
Do you expect this event to occur again?	
Is the event adequately described in the protocol and consent form?	
Should the protocol be modified to minimize this risk?	
Will the consent form be modified as a result of this adverse event? *If so, please submit an amendment to the consent form.*	
Will subjects be re-consented as a result of this adverse event?	
Describe the event, including the investigator's analysis of the event. Use additional pages, if necessary.	
Principal Investigator's Signature and date:	
For IRB Use Only	
IRB Chair's (or designee's) Signature and date	
Further action by IRB:	

Last updated 7/12/07