

**Institutional Review Board
for the Protection of Human Subjects in Research**

ADVERSE EVENT REPORT

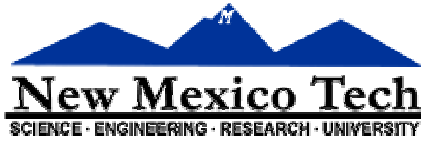
REV. 11 DEC 2003

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This form should be used to report single adverse events. Incident reports (i.e., reports of problems involving the conduct of the study or human participants, including problems with the recruitment and/or consent processes, and/or any deviations from the approved protocol) should be reported in a letter addressed to the IRB Administrator.

Return this form to the IRB Administrator, R&ED Office, Brown Hall.

Researcher Name:		Phone:
Department:		E-Mail:
Title of Project/Research:		
Original Period of Project / Research:	From:	To:
IRB Database Number:		IRB Initial Review Date:
Adverse Event (3-4 words):		
Date of Adverse Event:		Adverse Event appears to be: <input type="checkbox"/> Directly related to the research <input type="checkbox"/> Indirectly related to the research <input type="checkbox"/> NOT related to the research
Additional Details or Description of Adverse Event (a detailed report can be attached)		
Yes	No	Please answer the following questions to the best of your ability:
<input type="checkbox"/>	<input type="checkbox"/>	1. Was use of procedure intended to directly benefit the subject?
<input type="checkbox"/>	<input type="checkbox"/>	2. Has this type of adverse event been reported before?
<input type="checkbox"/>	<input type="checkbox"/>	3. Is this type of event likely to occur again?
<input type="checkbox"/>	<input type="checkbox"/>	4. Is the event adequately described in the protocol and consent form?
<input type="checkbox"/>	<input type="checkbox"/>	a. If NOT, are changes needed in the protocol and/or consent form? If you answer YES here, please complete a modification application (Form C) and attach it to this Report



YES	NO	
<input type="checkbox"/>	<input type="checkbox"/>	5. Have other agencies or sponsors been notified of this adverse event? If you answer YES, please list those agencies or sponsors:

Principal Investigator/Researcher Assurance:

As principal investigator/researcher, I hereby assure that the information I have provided on this form is correct and accurate, to the best of my knowledge.

Signature of Principal Investigator/Researcher

Date

Faculty Advisor Assurance:

As faculty advisor, I hereby assure that the information I have provided on this form is correct and accurate, to the best of my knowledge.

Signature of Faculty Advisor

Date

The fields below should be completed by the IRB Administrator

Date Received:

IRB Database Number:

IRB Administrator's Comments: