

Adverse Consequences/Unintended Effects

Principal Researchers and Faculty Advisors (as applicable) are responsible for submitting this form to the IRB Secretary within 24 hours of any event that can be defined as an adverse consequence and/or unintended effect of the study. The study may not continue until the IRB has responded to the form submission. Adverse Consequences are defined as events causing physical and/or psychological harm. Unintended Effects are defined as unexpected events possibly related to the research procedures that could place subjects or others at greater risk of harm.

Principal Researcher(s)	Dates of Study
Faculty Advisor (as applicable)	Department
Title of Study	
Date of Incident	Involved Research Subject Identifier
Describe the research procedure involved and the exact timing, location, and nature of event(s) of the adverse consequences or unintended effects directly caused by the research. An additional statement and any related documentation may be attached to this form.	
Principal Researcher Signature	Phone Number and Email Address
Principal Researcher Printed Name	Date
Faculty Advisor Signature (if applicable)	Phone Number and Email Address
Faculty Advisor Printed Name	Date

Institutional Review Board will complete below.

May the study continue in its current form?	Yes	No
Does this event require revision to the approved research protocol?	Yes	No
Does this event require revision to the Informed Consent form?	Yes	No
If the answer is Yes to any of the above questions, inform Principal Research and Faculty Advisor (if applicable) that they must submit an expedited IRB Proposal form with changes detailed.		
Comments (an additional statement may be attached to this form):		
IRB Chair Signature	Date	

A decision regarding study continuance will typically occur within seven days of receipt of the form to the IRB Secretary, depending on the level of investigation required. Copies of this form with the IRB's decision will be disseminated to the Principal Researcher and Faculty Advisor (if applicable) by the IRB Secretary within two days of the IRB Chair's/Board's decision.