Institutional Review Board (IRB)
Arizona College of Nursing
2510 W Dunlap Ave, Suite 290
Phoenix, AZ 85021

Reportable Adverse Event Form

PI Name: Reviewer Name:

Protocol Number: Date:

Project Title:
Initial Review Level: ☐ Full ☐ Expedited ☐ Exempt

Form Submission
This form should be used to report the following types of adverse events in participants: 1. Unexpected events that are probably or definitely related to participation in the approved research protocol 2. Unexpected non-medical reportable events that are probably or definitely related to participation in the approved research protocol The IRB requires the Principal Investigator to report adverse events using this form immediately, but not more than 5 business days of notification from participant or research personnel. Reporting is required immediately, but not more than 3 calendar days in instances where the adverse event involved unforeseen death of a participant. **The following documents are required to be submitted with this form to irb@arizonacollege.edu:** i. All supplemental reports, documents, or communications related to the event, if applicable **Note: The IRB should not receive any identifiable participant information. Please ensure all supporting documentation is de-identified prior to submission.**

Contact Information	
Name:	Phone:
Email:	

Category of Report and Review Status	
Category of event reporting	☐ Medical Adverse Event ☐ Non-medical Adverse Event
Type of report	☐ Initial Report ☐ Follow-up Report
Resolution of adverse event	☐ Resolved ☐ Unresolved

Oversight entities (Federal Agency, Funding Agency, Other IRB, etc.) notified	☐ Yes ☐ No ☐ N/A

Summary of Adverse Event
Reporting of New Event
Provide a summary of the adverse event in the box below that includes the following: 1. Event Date 2. Date research personnel became aware of the event 3. A detailed description of the event, including number of participants involved and follow up actions taken by research personnel or other entities in response to the event 4. If the event is unresolved, provide a detailed plan of the additional actions that will be taken to resolve the event
Follow-up Report on Event
Provide a summary of participant and research outcomes since the initial report of the adverse event in the box below.

Response to the Adverse Event	
Does the proposed amendment(s) change the content of the consent form?	☐ Yes ☐ No
Does the adverse event require any changes to the approved protocol and/ or supporting documents?	☐ Yes ☐ No
If yes, submit an amendment to the IRB **If no,** provide an explanation of why amendments to the approved protocol and supporting documents is not warranted in the box below	
Do current and/ or past participants need to be notified of adverse event?	☐ Yes ☐ No
If yes, describe communication plan including timeline for notification **If no,** provide justification for not notifying participants in box below	

Risk/Benefit Analysis
Provide a summary in the box below of your risk/benefit analysis that includes: 1. If risks to participants remain reasonable in relation to potential benefits 2. If adverse event suggests that remaining participants are at increased risk than initial projection

Principal Investigator's Signature: _____ Date_____