

Shawnee State University

_____ Date

_____ Application Number

ADVERSE EVENT REPORT REVIEW FORM

It is the responsibility of the Investigator to inform the IRB Chair and Administrator immediately of any unexpected event that occurs during the course of the research project that could affect the safety or welfare of the subjects. The Investigator must provide accurate documentation of the incident and work in conjunction with the IRB Chair or designee to investigate the incident to effect an appropriate resolution.

A. INVESTIGATOR INFORMATION			
<p>Please list all study personnel involved in the conduct of this study. All study personnel must complete required training in human subject research and provide to the IRB office certifying verifying completion of the requirement. The IRB will not review a study without such forms on file for all research personnel. Only SSU faculty, staff, students, or registered volunteers are considered SSU affiliated and thus covered by the SSU IRB review. All non-affiliated study personnel must have their participation reviewed by the appropriate IRB. (Attach a separate sheet if more space is needed.)</p>			
STUDY TITLE			SSU IRB Protocol Number
PRINCIPAL INVESTIGATOR OR FACULTY ADVISOR		Phone Extension	Email Address
DEPARTMENT			
CO-INVESTIGATOR OR STUDENT INVESTIGATOR		Phone Extension	Email Address
CO-INVESTIGATOR OR STUDENT INVESTIGATOR		Phone Extension	Email Address
CO-INVESTIGATOR OR STUDENT INVESTIGATOR		Phone Extension	Email Address

B. SPONSOR/FUNDING INFORMATION			
Is this project supported by an external funding agency?		<input type="checkbox"/> Yes	<input type="checkbox"/> No
If yes, please identify the source and contact information			
Agency:	Contact Person:	Phone:	Email:

C. LOCATION OF RESEARCH			
Where is the project taking place?		SSU	Other Facility
If not at SSU, attach a letter of cooperation on the letterhead of the facility and provide contact information. If there are multiple facilities, attach an additional page with the information for each.			
Facility Name:	Contact Person:	Phone:	Email:

D. DATE	
Date of the event	Date reported to IRB

E. ASSESSMENT OF THE EVENT
LOCATION OF EVENT
<input type="checkbox"/> Internal, on SSU Campus
<input type="checkbox"/> External, at site other than SSU. If External, list the location where the research was performed and the event occurred
DESCRIPTION OF THE EVENT
Describe the event in detail, attaching additional documents as necessary
DESCRIPTION OF INTERVENTIONS/MODIFICATIONS
Describe the interventions or modifications that will be instituted as a result of this event, if any

F. RISK ANALYSIS
<input type="checkbox"/> Event did not place subject or others at greater risk than was previously recognized.
<input type="checkbox"/> Event placed subject or others at greater risk than was previously recognized. Describe how and to what extent risk was increased.
Number of subjects exposed to the research intervention related to this event _____
Has this event occurred previously in this project or in other related research studies? <input type="checkbox"/> Yes <input type="checkbox"/> No
If Yes, summarize previous reports

G. RESEARCH STATUS
The research participant involved is <input type="checkbox"/> Still enrolled in the study <input type="checkbox"/> No longer enrolled in the study
Recruitment for this project is <input type="checkbox"/> Ongoing <input type="checkbox"/> Completed <input type="checkbox"/> Discontinued

Any external adverse event that places subjects or others at greater risk than was approved in the protocol submission must be reported to the IRB immediately upon occurrence. The IRB will review the report and advise the Investigator of their recommendations within 5 working days of receipt.

**Please complete and return form to:

**Institutional Review Board
Office of the Provost
Room 124 Massie Hall**