Youngstown State University

Institutional Review Board

Office of Research Services

Phone: 330-941-2377

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Protocol 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.

|  |
| --- |
| 1. INVESTIGATOR INFORMATION
 |
| **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 YSU faculty, staff, students, or registered volunteers are considered YSU affiliated and thus covered by the YSU 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.)** |
| STUDY TITLE | YSU 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 |

|  |
| --- |
| 1. SPONSOR/FUNDING INFORMATION
 |
| Is this project supported by an external funding agency? | [ ]  Yes | [ ]  No |
| If yes, please identify the source and contact information |
| Agency: | Contact Person: | Phone: | Email: |

|  |
| --- |
| 1. LOCATION OF RESEARCH
 |
| Where is the project taking place? | YSU | Other Facility |
| If not at YSU, 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: |

|  |
| --- |
| DATES OF THE EVENT |
| Date reported to the PI | Date of report |

|  |
| --- |
| ASSESSMENT OF THE EVENT |
| LOCATION OF EVENT  |
| [ ]  Internal, on YSU Campus |
| [ ]  External, at site other than YSU. 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  |
|  |

|  |
| --- |
| RISK ANALYSIS |
| [ ]  Event **did not** place subject or others at greater risk than was previously recognized. |
| [ ]  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? [ ]  Yes [ ]  No |
|  If Yes, summarize previous reports |

|  |
| --- |
| RESEARCH STATUS |
| The research participant involved is [ ]  Still enrolled in the study [ ]  No longer enrolled in the study |
| Recruitment for this project is [ ]  Ongoing [ ]  Completed [ ]  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.