THE LEADER IN GLOBAL EDUCATION

FAIRLEIGH DICKINSON UNIVERSITY

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Unanticipated Problems/Reportable Events Form

Date of this Application: | **School/Department:**

IRB#:

IRB Approval Expiration Date:

Project Title:

A. Administrative Information:

ROLE	Name & Degree	E-mail	Phone	Fax
Principal Investigator:				
Faculty Mentor:				

B. Study Funding

Funding is provided to support this project: ☐ No ☐ Yes

If yes, please complete the following:

Name of your funding source:	
Has the report been sent to the funder and/or funder notified of the event:	☐ No ☐ Yes, please append the information provided to the funder.

C. Reportable Events Definition and Procedure

Unanticipated problems are considered in general to include, even though the Office for Human Research Protection (OHRP) does not define an unanticipated problem, the following to be an unanticipated problem involving risk to a subject or others (eg. the sexual partners of subjects, individuals the subject may come into contact with, family members, research personnel, etc.) Events where a subject is directly harmed are defined as adverse events. Although adverse events occur most commonly in the context of biomedical research, adverse events can occur in the context of social and behavioral research. ONLY unanticipated adverse events that are related to the research need to be reported to the IRB. Unanticipated problems are considered in general, to include any incident, experience, or outcome that meets ALL of the following criteria as stated in guidance provided by OHRP:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;

2. Related (related means an event is related in the opinion of the investigator and/or/in conjunction with a faculty mentor, it was more likely than not to be caused by the research procedures or if it is more likely than not that the event affects the rights and welfare of the current participants) or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and

3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

4. Serious Adverse Event is defined as any adverse event that: (1) results in death; (2) is life-threatening (places the subject at immediate risk of death from the event as it occurred); (3) results in inpatient hospitalization or prolongation of hospitalization; (4) results in a persistent or significant disability/incapacity; (5) results in a congenital anomaly/birth defect; or (6) based upon appropriate medial judgement, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, suicidal thoughts/tendencies, development of drug dependency or drug abuse.)

D. Describe the Event: (include date of the event and date of the awareness of event)

Please provide a lay term description of the event that occurred with the date the event occurred and date of the first awareness of the event. Please include any information on risk to the participant and relation of the event to the study. Please also provide all procedures that were completed once the event was discovered. Provide a status of the event at the time of reporting.

E. Study and Event Information

The study is: (check one and provide additional information as requested)	☐ **Currently in progress (open to enrollment)** **Number of subjects enrolled:** **Number of subjects currently in active research procedures:** ☐ **Closed to enrollment (participants in follow up)** ☐ **Closed**
Was this an internal event (took place at FDU) or an external event (took place off campus, another site)	☐ **Internal** ☐ **External; location and relation to the study:**
Is this event a Serious Adverse Event or another Unanticipated Event: ☐ **Serious Adverse Event** ☐ **Unanticipated Event (see guidance here)**	**OHRP defines serious adverse event as any adverse event that:** **1. results in death;** **2. is life-threatening (places the subject at immediate risk of death from the event as it occurred);**

	3. results in inpatient hospitalization or prolongation of existing hospitalization; **4. results in a persistent or significant disability/incapacity;** **5. results in a congenital anomaly/birth defect; or** **6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (examples of such events include allergic bronchospasm requiring intensive treatment in the emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).**
Description of all steps and actions taken in response to the incident or to resolve the issue:	
Number of similar events experienced with this study:	
Was the event reported within policy time frames? (Human Research Compliance Manager must be notified of serious adverse events and unanticipated problems within 24 hours of awareness). ☐ **Yes** ☐ **No**	**If not, explain:**
What was subject's participation level after the event?	☐ **Subject stopped research participation** ☐ **Subject had already completed research Subject continued research participation** ☐ **Subject withdrew from further participation** ☐ **Subject continued participation/follow-up only Investigator withdrew subject from participation Other (describe):**

	☐ **PI/Faculty Mentor withdrew the participant from the study. Provide justification and information provided to the participant.:**
Effect on the Research: (please complete on right)	☐ **Continue as planned with no changes to the research protocol or consent process. Explain why:** ☐ **Continue with changes to the research protocol or consent process; Attach proposed changes for IRB review and approval using an amendment submission form.** ☐ **Suspend new subject enrollment until the event is further examined;** ☐ **Be terminated (stopped completely), with all subjects removed from research.** ☐ **Other:**
Investigator Assurance: **I have reviewed the contents of this form and hereby assure that the information provided is complete and accurate to the best of my knowledge.** **As the Faculty Mentor, I have assisted the student with this submission. I have reviewed the contents of this form and hereby assure that the information provided is complete and accurate the best of my knowledge:**	**Signature:** **Principal Investigator:** **Faculty Mentor(if applicable):**

For FDU IRB USE ONLY: Signature of Reviewer: Date:

Event to be included on agenda for Board Review. ☐ **Activity does not require notification to the IRB.** ☐

Submission Instructions (PLEASE DO NOT SUBMIT THE INSTRUCTION PAGES TO THE IRB)

This form must be submitted via email to Kim Diccianni, CIP at dicciann@fdu.edu.

This will allow for ease of dissemination and timely review of the submission. Supporting documentation should be scanned and sent electronically with your proposal.

E-mail requirements

1. Include a description of your submission type in the subject heading of your email to the IRB, i.e. · New Project; Continuing Review; Amendment; Final Report; Complaint of a Participant; Unanticipated Problem/Reportable Event; etc.
2. In the body of your e-mail provide:

    - The Project Title, Principal Investigator, Faculty Mentor (if applicable)
    - A list all of the documents that you will be attaching to your e-mail or sending via regular mail, e.g.. Unanticipated Problems/Reportable Events Form, Information about the event, Application, Consent Document(s), Methods and Procedures, Protocol Summary, Interview script, Questionnaire, Advertisement, TV/Radio Ad Script, PI Agreement, Faculty Agreement, Grant Application, Dissertation, Thesis, etc.
    - Provide a version date for each document.
    - Make sure all documents are attached before you send the e-mail.
    - Scan, whenever possible, and send any documents with signatures required
    - Documents are accepted in PDF, JPEG or Microsoft Word formats. *However, all Consent/Assent Forms are required to be submitted in Microsoft Word format.*

If you require any assistance, please contact Kim Diccianni, CIP, Human Research Compliance Manager at (201) 692-2219.