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**Institutional Review Board for the Protection of Human Subjects**

**Form G—Reportable New Information (RNI)**

**Instructions:**

* Please submit all proposal materials as one Word or PDF document.
* If student is principal investigator, form requires research advisor’s signature.

# SECTION ONE: SUMMARY INFORMATION

Provide information about the study.

|  |  |
| --- | --- |
| **Proposal Number:** |  |
| **Study Title:** |  |
| **Principal Investigator:** |  |
| **Faculty Research Advisor (if applicable):** |  |
| **Email:** |  |
| **Status:** | Undergraduate Student Graduate Student Faculty/Staff |
| **Research Category:** | Exempt Expedited Full Board Review |
| **Type of Report:** | Adverse Event or Injury  Participant Complaint  Problem or Finding  Protocol Deviation |

# SECTION TWO: REPORTING CRITERIA

Does the event being reported meet all of the following criteria? Check Yes or No.

|  |  |  |
| --- | --- | --- |
|  | **Y** | **N** |
| 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; and |  |  |
| Related—or possibly related—to the research; and |  |  |
| Suggests that the research places participants at a greater risk of harm (including physical, psychological, economic or social harm) than was previously known or recognized. |  |  |

If “Yes” to all, report the event by completing this form and forwarding with appropriate attachments to the Sponsored Programs Director/IRB Compliance Officer If “No,” do not forward to the IRB office.

# SECTION TWO: EVENT INFORMATION

1. **Date:** Provide the date of the event: Click or tap to enter a date.
2. **Assessment of the Event/Problem:** Indicate your assessment of the event or problem below (select all that apply):

Serious Event

Non-serious Event

Unexpected Event

Related to the Study

Unrelated to the Study

Unsure if Related to the Study

Not Applicable

1. **Description of the Event/Problem:** Describe in detail the event or problem being reported. If you are reporting a protocol deviation, explain the deviation and why/how the deviation occurred. Do not include participants’ personally identifiable information.
2. **Location of Event:** Indicate location where event occurred:
3. **Source of the Report:** Indicate whether the report relates to an internal local event (research site is under Whitworth University’s oversight) or an external non-local event (research site is under an external IRB’s oversight)

Internal (local event)

External (non-local event)

1. **Personnel:** Provide the names and positions of the project personnel that were involved in the event. If no project personnel were involved, put N/A.

|  |  |
| --- | --- |
| **Name** | **Position** |
|  |  |
|  |  |
|  |  |
|  |  |

1. **Status of Participants:** Indicate whether the participant(s) is/are still involved in the study.

Still in the study

No longer in the study

Not applicable

1. **Status of Research Recruitment:** Indicate whether participants are still being recruited into this study.

Ongoing

Completed (or stopped)

Not applicable

1. **Status of Interventions/Interactions:** Indicate whether participants are still participating in interventions or interactions for this study.

Ongoing

Completed (or stopped)

Not applicable

1. **Impact on Participants:** Indicate whether the event resulted in a violation of the participant’s rights, safety or welfare.

Yes

No

If yes, explain how the event resulted in a violation of the participant’s rights, safety or welfare.

|  |  |  |
| --- | --- | --- |
|  | **Y** | **N** |
| Is the risk of this event contained in the current consent form? |  |  |
| Should the consent form or any portion of the study be revised as a result of the event? |  |  |
| Will currently enrolled individuals be notified of this event? |  |  |
| If yes, describe method of notification: | | |

1. **Additional Comments:** Provide any additional comments and/or attachments that you would like to include in reference to this event/problem.

# SECTION THREE: AFFIRMATION OF INVESTIGATOR

As the Principal Investigator or research advisor (if Principal Investigator is a student), I am confirming that the information I have provided in this form is accurate and true.

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

Signature Date

# FOR IRB USE ONLY

The IRB Chair(s) and Compliance Officer have reviewed the event report. Based on the review, it has been determined that (check all that apply):

The reported event does not represent an unanticipated problem involving risks to participants or others.

The reported event should be recommended to the IRB as an unanticipated problem involving risks to participants or others.

Immediate action is needed to protect the rights and welfare of currently enrolled participants. The action being taken is:

For this event, which is being recommended to the IRB for consideration as an unanticipated problem involving risks to participants or others, describe a recommended management plan or a list of actions (check all that apply):

Modification to protocol/study procedures

Modification to level of risk

Modification to consent form

Provide additional information to current participants

Re-consent current participants

Re-train project staff to prevent future occurrences

Research will voluntarily be placed on hold

No action is planned

Other action planned:

**Note:** All IRB determinations of unanticipated problems involving risks to participants or others must be reported to agencies, organizational officials and participated as required in 45 CFR 46.103.b.

The IRB considered the above anticipated problem involving risks to participants or others and made the following determination:

Date:Click or tap to enter a date.

Following determination by the IRB, reporting to agencies and participants was completed on this date:Click or tap to enter a date. (Attach reports to agencies, participants and others)