

Appendix 4

Fort Lewis College Institutional Review Board

Unexpected Problem Report Form

1. Protocol title

2. IRB Protocol number

3. Contact Information

a. Principal Investigator (PI)

Name

Email address

Phone number

b. Co-PI

Name

Email address

Phone number

4. Date report was submitted to the IRB

Part 2: Information on Unexpected Problem

1. Please describe the unexpected event(s). Include all details such as the number of events, the dates of occurrences, number of participants involved, known or potential impact on participants, and any other relevant information.

2. Please describe the known or possible cause(s) for the event(s).

3. Please describe the actions, if any, that you, members of your research team, and/or others took in response to the event. Include the dates of those actions as well as who took them.

Part 3: Follow up

1. **Have you submitted or do you plan to submit for IRB review, an amendment as a result of the expected event? If yes, please describe the amendment briefly. If no, please explain why you believe that an amendment is not required.**

2. **Will you inform the participants who are already enrolled in your study about this unexpected event or any safety or procedure related information as a result of this unexpected event? If yes, describe what will be communicated, and when and how it will be communicated. If the communication will be in writing, please provide the text of the communication to the IRB.**

If no, please explain.

Part 4: Attestation

PI Signature

I certify that the information provided in this unexpected event report is correct and complete.

Signature

Date

Faculty Supervisor (if the PI is a student)

I have reviewed this unexpected event report and discussed the event, the causes and the corrective action plan with the PI.

Signature

Date

Please complete this form, obtain all relevant signatures and email it to the IRB office at irb@fortlewis.edu.