**INSTITUTIONAL REVIEW BOARD FOR THE**

**UNIVERSITY OF MARY WASHINGTON**

**Adverse Events Reporting Form**

**Use this form to immediately report** **any incidents occurring during or as an apparent result of research approved by the IRB in which an individual had an adverse experience (including physical, psychological, economic, or social harm), or if an event occurred during the research which suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.**

* This form should be completed by the Principal Investigator at UMW, or if student research, by the Faculty Supervisor
* Read and follow all INSTRUCTIONS available on the [IRB website](https://provost.umw.edu/irb/instructions-and-forms/)
* Do not alter or delete any questions or instructions on this form.
* **Attach the complete approved IRB application, including** the approval letter, attachments (consent form, data collection instruments, etc.), and any approved changes to and extensions of the IRB application.
* **Answer all questions on Parts A-D of this form and submit it to the** [**IRB Chair**](https://provost.umw.edu/irb/board-members/) **within five (5) calendar days of the event**. If any information for this form is unavailable or incomplete during this time frame, submit a subsequent revised form as soon as possible, but no later than three (3) weeks after the event date.

**A. Project Information**

1. Project Title

2. This form is to be completed by the Principal Investigator at UMW. If the research is conducted by students, the form should be completed by the Faculty Supervisor.

 Name

 Department

 UMW Email

 Phone

3. Data Collection Period (dates when data collection began and ended or is projected to end)

 From to

4. External Funding Agency (if not applicable, indicate N/A)

**B. Adverse Event or Unanticipated Problem**

Fill out a separate form for each adverse event or unanticipated problem occurring during or as an apparent result of the research. (See definitions in the Instructions at the end of this form.)

1. Date of Event (or your awareness of it)

2. Location of Event (e.g., Building and room no.)

3. Provide a detailed description of the adverse event or unanticipated problem that occurred. Include the following:

* The affected individual’s role in the research (e.g., participant, member of research team, or describe other role)
* The research procedures taking place at the time of the event and other conditions of the environment or the participant that may have contributed to the event
* The effects experienced by the participant
* The measures taken by researchers in response to the event and whether the individual was offered, and received or refused, medical treatment
* The outcome

If no individual was adversely affected, but the event indicates that participants may face risks not previously anticipated, explain these risks.

***Description of Event:***

4. Do you believe the incident was or should have been anticipated given the procedures, consent documents, and population characteristics contained in the approved IRB application?

 Yes No

***Explain:***

5. Do you believe the incident was related to, or possibly related to, participation in the study?

 Yes No

***Explain:***

6. Do you believe the event indicates that participants have been at greater risk than previously known?

 Yes No

***Explain:***

**C.** **Corrective Actions**

1. Describe the actions you are taking to correct the problem and prevent recurrence in this study. If appropriate, attach a revised IRB application form with any protocol changes and revised consent documents. If there are 1 or 2 minor changes to the research, you may attach a letter to the IRB Chair describing those changes in lieu of a revised IRB application. If you believe no corrective actions are needed, enter “None” in the space below.

***Description and Explanation of Corrective Actions:***

2. Do you plan to notify other participants in the research about this incident?

 Yes No

***Explain:***

3. Do you plan to submit a revised version of this reporting form? If so, it should be submitted within three (3) weeks of the event.

 Yes No

***Explain:***

**The IRB will evaluate the information provided on this form, and may require additional information or actions on the part of researchers. If necessary to protect the safety of participants, the IRB has the authority to monitor, suspend, or terminate the research. Notification of IRB actions will be provided in writing to the Principal Investigator/Faculty Supervisor who submits this form.**

**D. Signature**

This form is to be signed by the individual named in Part A.2 who completed this form, indicating the date the form was submitted to the IRB Chair. Your signature verifies that the information you provided on this form is complete and accurate to the best of your knowledge, as of the date given below.

**Signature of Principal Investigator/Faculty Supervisor Date**

 \*See INSTRUCTIONS at the end of this form for temporary use of electronic (typed) signature

**E. IRB Actions** (to be completed by IRB Chair within 25 days of the event; follow Instructions below)

1. Describe and explain actions taken by the IRB Chair and/or in a meeting of the IRB in response to this report.

2. Is a report to the Office for Human Research Protections required? If “Yes,” attach a copy.

 Yes No

***Explain:***

**Signature of IRB Chair Date**