**Adverse Event Report**

Western Carolina University

Please complete and send the form with any attachments to [IRB@wcu.edu](mailto:IRB@wcu.edu)

Timelines for Reporting to the IRB

* 24 hours for an unanticipated study-related death
* 5 business days for an unanticipated problem that is a serious adverse event
* 10 days for an unanticipated problem that does not meet the criteria of serious adverse event

1. **ADMINISTRATIVE INFORMATION**

**Principal Investigator:**

**Department:**      

**WCU IRB #:**

**Study Title:**

Check all that apply to the problem/event being reported:

Unexpected

Related or possibly related (more likely related than unrelated) to the research

The research placed, or may have placed, subjects or others at a greater risk of physical, psychological, economic, or social harm than was previously known or recognized.

1. **STUDY INFORMATION**

What is the status of study and recruitment?

Open to recruitment

Closed to recruitment, but subjects are still receiving a required research intervention

Closed to recruitment, no subjects receiving a required research intervention but subjects are still undergoing follow-up

Closed to recruitment and no subjects receiving required research intervention or follow-up; data analysis is ongoing

Other, please explain:

1. **PROBLEM/EVENT INFORMATION**
2. Describe the nature and severity of the adverse event:
3. Date of problem/event:
4. Date the PI recognized/learned of the problem or event:
5. How many of the subjects were affected by the adverse event?
6. What is the status of the subject(s) participation in the study?
7. In the judgment of the PI, what is the likelihood that this problem/even was related to the research

More likely related than unrelated

More likely unrelated than related

1. **CORRECTIVE ACTIONS**
2. What actions were taken to address/correct/resolve the problem/event?
3. What actions are being implemented to minimize the likelihood of recurrence of the problem/event in the future?
4. Is the occurrence of the problem/event consistent with information included in the current, IRB-approved consent form and is the frequency and/or severity of the problem/even consistent with available published information (IRB-approved protocol, recruitment flyers, informed consent)?

Yes. If yes, please attach a copy of the current, IRB-approved consent form with all citations underlined.

No. If no, does this problem/even necessitate revision of the current consent form?

Yes. If yes, after submitting this form, please submit an Amendment and a revised consent form to the IRB

No. If no, please explain the rationale for not revising the form.

1. Does this problem/event necessitate revision of the protocol?

Yes. If yes, after submitting this form, please submit an Amendment and revised protocol to the IRB

No. If no, please explain the rationale.

1. Does this problem/event necessitate that currently enrolled subjects be notified or re-consented or that past participates be informed of this event?

Yes. If yes, please explain and describe the mechanism to be employed.

No. If no, please explain the rationale

*By submitting this request, the Principal Investigator (and responsible faculty member if the PI is a student) I declare that I have reviewed this report which provides a complete and accurate description of the event and that upon receipt of the IRB’s review, I will fully and immediately implement any corrective actions required by the IRB.*

*The parties (the IRB, the Principal Investigator, and responsible faculty member if the PI is a student) have agreed to conduct this application process by electronic means, and this application is signed electronically by the Principal Investigator and by the responsible faculty member if a student is the PI.*

*My name and email address together constitute the symbol and/or process I have adopted with the intent to sign this application, and my name and email address, set out below, thus constitute my electronic signature to this application.*

Date

     

PI Name PI Email Address

     

Responsible Faculty Name if PI is a Student Responsible Faculty Email Address if PI is a Student