



Event Report Form

Western State Colorado University IRB / Human Research Protection Program

Instructions: **Complete and send the request form electronically to irb@western.edu.**

Note: checkboxes can be checked by putting an "x" in the box.

IRB #: Study Title:
Date of report:
Sponsor of study and OSP # if any:

The parties (i.e., IRB and PI and faculty advisor if PI is a student) have agreed to conduct this event report by electronic means, and this report is signed electronically by the Principal Investigator (PI) and by the faculty advisor 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 report, and my name and email address, set out below, thus constitute my electronic signature to this application.

Principal Investigator(s): Email:
Faculty advisor if student is the PI: Email:
Department(s):

- 1. Event Date: Date of Event Discovery by PI:
- 2. Research Site (where research activity was conducted and where the event occurred):
- 3. Detailed description of event including a) number of subjects affected by event, b) whether the event was related to the research, and c) whether the event was anticipated and described in the consent form or other information provided to subjects:
- 4. What corrective actions have been taken or are proposed in response to the event?
- 5. Are you aware if this event (or a related event) occurred previously in this study or other research studies involving the same research intervention/interaction?

No
 Yes, provide a summary of previous reports:

- 6. Status of subject(s) involved in the event:
 - Subject withdrew from research participation
 - Subject continued research participation
 - Subject has already completed the research
 - Investigator withdrew subject from further participation
 - Other:

7. How many subjects have been accrued to date?

- 7b. Study status:
 - Ongoing intervention/interaction without change in research protocol
 - Ongoing but all interventions/interactions have been completed for study
 - Research activities have been temporarily stopped for all subjects
 - Stopping all new subject enrollment

Stopping certain research activities for all subjects
 Other:

8. Do you propose a modification to the study protocol/consent form to address the event?

Yes, a modification request will be submitted
 No, explain why: