COLORADO MESA UNIVERSITY

Sponsored Programs
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INCIDENT REPORT FORM

Instructions

All incidents of injury or other adverse effects experienced by participants must be reported by the principal investigator to the CMU Institutional Review Board, through the office of Sponsored Programs within 48 hours after the event.

SECTION A: General Information

OVERVIEW Answer Required

1. Protocol Number:
2. Title of Protocol:
3. Type of Review:
4. Study Status:
   - ◯ Enrollment open, participant(s) active in research intervention.
   - ◯ Enrollment open, no participant(s) currently active in research intervention.
   - ◯ Enrollment closed, participant(s) active in research intervention.
   - ◯ Enrollment closed, research limited to follow-up only.
   - ◯ Enrollment closed, research limited to data analysis only.
   - ◯ Other, please explain:

5. Other than this report, have any other reports been submitted to other offices/departments on or off the CMU campus regarding this event? **Answer Required**
   - ◯ No
   - ◯ Yes: If yes, please indicate where and when the reports were submitted.

INVESTIGATORS Answer Required

6. Principal Investigator (PI)

Name:	
Status:	
Telephone:	
Institutional Email:	
Department:	

SECTION B: Incident Information

INCIDENT

7. Severity of the incident: **Answer Required**
   - ◯ Mild
   - ◯ Moderate
   - ◯ Severe

   Date(s) of the Incident: From [ ] [ ] [ ] to [ ] [ ] [ ]

   Location(s) of the Incident:

8. Was the incident an anticipated risk described in the initial protocol application and informed consent?
   Answer Required
   - ◯ No
   - ◯ Yes: if yes, please explain:

9. In your judgment, was the event caused by procedures associated with the research protocol? **Answer Required**
   - ◯ Not enough information to make a determination
   - ◯ Not Related
   - ◯ Possibly Related: If related, to the research protocol, explain what procedures were already in place to minimize or reduce the risk of this event.

   - ◯ Related: If related, to the research protocol, explain what procedures were already in place to minimize or reduce the risk of this event.

10. Incident Involved: **Answer Required**
    - ◯ Data Breach
    - ◯ Drug(s)
    - ◯ Device(s)
    - ◯ Procedure(s)
    - ◯ Intervention
    - ◯ Treatment
    - ◯ Other, please explain:

11. 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. **Answer Required**

12. List the names of the individuals involved in the incident. Identify each individual according to their role in the study (e.g., participant, researcher, etc.). **Answer Required**

13. Did any of the individuals involved in the incident need treatment of any kind? **Answer Required**
    - ◯ No: if no, Skip SECTION C and complete SECTION D.
    - ◯ Yes: If yes, complete SECTION C and SECTION D.

SECTION C: Treatment Information

INFORMATION ABOUT THE TREATMENT(S)

14. Date(s) of the Treatment: From to
    ☐ Ongoing

15. Location of the treatment:

16. List the names of the individuals who received treatment. Identify each individual according to their role in the study (e.g., participant, researcher, etc.).

17. Describe, in detail, the treatment that each individual who experienced the incident received.

18. Describe the recovery of the individuals who experienced the incident.

- ◯ Not resolved at this time
- ◯ Minimal
- ◯ Moderate
- ◯ Complete
- ◯ Other, please explain:

19. List the names of the individuals who provided treatment.

SECTION D: Protocol Modification

MODIFICATION OF PROTOCOL

20. Are you going to inform the participants who are already enrolled in the study about this unexpected event? **Answer Required**

- ◯ No: If no, please explain why.

- ◯ Yes: If yes, Please explain why.

21. In your judgment, should the informed consent process and/or any other part of the protocol be modified as a result of this incident? **Answer Required**

- ◯ No
- ◯ Yes: If yes, submit a *Modification Form*.

Attach Modification Form **View Attachment(s)**

SECTION E: Investigator Assurance and Acknowledgement

PRINCIPAL INVESTIGATOR

I certify that the information I provided within this document correct and complete. **Answer Required**

Name / Signature of Principal Investigator

Date

All fields marked as 'Answer Required' must be completed before you can submit a protocol to the Colorado Mesa University IRB.

Attach Other Documents **View Attachment(s)**

Submit

OFFICIAL OFFICE USE ONLY

Date Received:

Protocol Number:

Reviewer:

Date Reviewed:

Notes:

Revised: October 2018