CAL POLY HUMBOLDT
Office of Research & Sponsored Programs Foundation

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Adverse Event Reporting Form

Federal regulations applying to human subjects research include the responsibility of the investigator(s) to report adverse events of any kind. As related to the study, these may be: an unexpected change (behavioral, clinical) in the subject; something that causes harm (e.g., physical or psychological injury, loss of confidentiality or anonymity); or something contrary to what is approved in the protocol.

This form is meant to guide the responsible faculty or staff member in reporting adverse events to the IRB. If the responsible faculty or staff member is not available, please contact the Institutional Officer at irb@humboldt.edu. Please use additional pages to provide more details.

Please return the completed form to the IRB by the next business day after the adverse event occurs or is discovered. For assistance, contact the IRB at irb@humboldt.edu or 707-826-5165.

Protocol title:
Protocol number:
Principal investigator(s):
Provide a brief summary of the approved activity per the protocol:
Describe the adverse event.
What was the immediate response/action?
When (date and time) did it happen? Where did it happen?
Who was there (names of PIs, research subjects, others)?
Has the event been reported to any other authority (e.g., academic department, police)? If yes, please describe.

What "follow-up" with the subjects or situation has been arranged? And when will it occur?
Why, in your judgment, did the event happen?
In your view, what could be done to prevent it the next time?
Do you plan to modify your protocol to address concerns? If Yes, please explain.
What else should the IRB know about this event?
IRB response to the event::

Please note: An Accident Report may need to be completed for this incident. Contact Cris Koczera, Director, Risk Management & Safety, 707-826-4635, cej32@humboldt.edu .