

<b>SOP: 902</b>	<b>PROTOCOL DEVIATIONS</b>
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AAHRPP Element: I.3.J

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## **POLICY**

It is the policy of the University of Utah IRB to require Principal Investigators to report protocol deviations which are:

- Intended to eliminate apparent immediate hazard to a research participant or
- Harmful (caused harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm), or
- Possible serious or continued noncompliance

Any changes in the research protocol during the period, for which the IRB approval has already been given, may not be initiated without submission of an amendment for IRB review and approval.

Any report of a protocol deviation to the IRB should be made in a timely fashion but no later than within 10 working days of its occurrence or identification.

## **PROCEDURES**

1. The Principal Investigator reports protocol deviations by completing and electronically submitting a Report Form in the ERICA online system. Examples of reportable protocol deviations are posted on the IRB web site.
2. An IRB administrator performs a thorough review and evaluation of the deviation. Requests for clarifications, corrections or revisions to the report from the PI are made if further information is needed to evaluate the deviation.
3. The deviation is evaluated to determine if it had a significant effect on the participant's rights, safety, or welfare, or corrupted the integrity of the resultant scientific data. The IRB Chair may be consulted at any time during this process for assistance.
4. The Principal Investigator's proposed corrective action plan should describe an active process addressing the causal elements so the reviewer would conclude that the investigator has a serious, viable plan in place for assuring the safety of research participants and the oversight of data integrity.
5. After review and evaluation of the incident the following actions may be taken:
  - The protocol deviation is acknowledged as submitted.
  - The protocol deviation is returned to the PI to be submitted as an adverse event and/or unanticipated problem involving risks to participants or others. Please see SOP 901, Unanticipated Problems Involving Risks to Participants or Others.
  - If the IRB administrator determines that the protocol deviation meets the definition of non-compliance according to SOP 903, the protocol deviation is handled according to SOP 903, HRPP and Non-Compliance.