

## **SOP 902: DEVIATIONS**

### **PURPOSE**

This SOP outlines the requirement for reporting of deviations at the University of Utah.

### **SCOPE**

This policy applies to human subject research conducted at the University of Utah.

### **DEFINITIONS**

- A. *Responsible Investigator (RI)*** is the individual who is the principal investigator and responsible for all ERICA tasks and requirements for the application they are listed on. This person holds the same responsibilities as a principal investigator (PI), but with the added understanding that they will be the primary contact for the study at the University of Utah. In this policy, both terms may be used interchangeably but are used to identify the principal investigator at the University of Utah site.

### **POLICY**

It is the policy of the University of Utah Institutional Review Board (IRB) to require responsible investigators to report deviations which meet one or more of the following criteria:

- Intended to eliminate apparent immediate hazard to a research participant; or
- Caused possible harm to participants or others, or placed them at increased risk of harm - including physical, psychological, economic, or social harm; or
- Represents possible serious or continued noncompliance

Any changes in the research protocol during the time 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 deviation made to the University of Utah IRB should be made in a timely fashion but no later than within ten working days of its occurrence or identification. For VA research, the report form must be submitted within five working days.

### **PROCEDURES**

1. The responsible investigator reports deviations by completing and electronically submitting a report form in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA). Examples of reportable 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 are made if further information is needed to evaluate the deviation.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



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. Any actions taken to correct issues should be clearly described. The responsible investigator should propose a preventive action plan that actively addresses the causal elements. This demonstrates to the reviewer that the investigator has a robust plan in place to ensure the safety of research participants and oversee data integrity.
5. After review and evaluation of the incident, the following actions may be taken:
  - The deviation is completed with the determination indicated.
  - The deviation is returned to the responsible investigator to be submitted as an adverse event and/or unanticipated problem involving risks to participants or others. Please see IRB SOP 901: Unanticipated Problems Involving Risks to Participants or Others.
  - If the IRB administrator determines that the deviation possibly meets the criteria for serious or continuing non-compliance as defined in IRB SOP 903: HRPP and Non-Compliance, it will be managed in accordance with IRB SOP 903: HRPP and Non-Compliance.

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