In the course of working on a protocol, and most typically during Continuation Reviews or Post-Approval Monitoring, a researcher or reviewer might discover activities that were performed that were not in line with the expectations established under the approved protocol. It may also be the case that an activity was supposed to occur, per the approved protocol, and did not take place. In those cases, a reviewer has discovered a Reportable Event.

There are three kinds of Reportable Events. This guidance document is intended to guide staff and faculty in identifying, reporting, and processing each kind of Reportable Event.

I. Deviations

Deviations are the most common type of Reportable Event. A Deviation is a notable variance from the procedures, processes, and/or activities associated with an approved or exempted protocol which does not indicate the existence of previously unknown or unapproved risks to participants. An easy way to think about whether something is a Deviation is to consider whether it would have been approved as an amendment if it had been submitted before its occurrence. Examples of common deviations include:

- Adding CITI-trained research staff to the study team absent IRB approval for their addition
- Recruiting participants above the +15% threshold of the approved numbers of participants
- Utilizing recruitment materials that changed compensation from $5 (the approved materials’ amount) to $15 (unapproved, but used, materials’ amount) for study participation lasting no more than an hour

When a Deviation is identified by a member of the IRB, the IRB member should request a Deviation Report Form from the Principal Investigator of the study. When a member of the study staff discovers a Deviation, they should submit a Deviation Report Form to irb@usu.edu for processing.

Deviation Report Forms are processed by the first HRPP Coordinator to receive the Form. It is reviewed for accuracy, and sent to the HRPP Director, Chair, or to the Institutional Official (in that order of availability). If the report represents variances that are more than a Deviation (those categories are defined below), the report will be forwarded on to the IRB Chair for a determination regarding next steps. In general, when the Deviation Report Form reports a Deviation, the Report Form is simply made available to the IRB for notice & comment at the next scheduled meeting, due to their low-risk nature. Once the IRB has had an opportunity for notice and comment, the Deviation Report Form is filed to the appropriate protocol file. If any follow up is needed, the HRPP Office will reach out to the study team.

The IRB Chair has created a very helpful video that outlines the process for reporting of Deviations, which can be viewed here.

II. Unanticipated Adverse Events/Problems

Occasionally, an Unanticipated Adverse Event (UAE) or Unanticipated Adverse Problem (UAP) occurs during the conduct of research. These UAEs are identifiable by the following three criteria, all of which must be met:

1. The event was unanticipated, meaning that the nature, severity, or frequency of the event is not consistent with the determinations and approvals in place at the time that the IRB approved it;
2. The event was adverse, meaning that the event was an untoward or unfavorable occurrence for one of your participants, including abnormal signs, symptoms, or outcomes.
3. The event is related or possibly related to participation in the study.
Unanticipated Adverse Events need to be reported to the IRB as soon as is feasible. The first question the IRB Chair must address is whether the UAE constitutes a “serious” UAE. An Unanticipated Adverse Event is serious if it results in any of the following:

- Death
- Places participants at immediate risk of death
- Results in hospitalization;
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly or birth defect; or
- May jeopardize the participant’s health and require further intervention to prevent one of the other outcomes listed here, including potential dependency on drugs or the potential for drug abuse.

Serious UAEs require the Convened IRB to reconsider the protocol’s risks. If the IRB Chair determines that the UAE is not serious, they must next determine whether the UAE suggests that the risks of participation are greater than were previously known. Generally, the IRB Chair will consult with another IRB member or colleague with relevant scientific expertise in order to make that determination. It is not unusual for a study to be paused while the IRB Chair consults with the appropriate personnel to render this determination.

Finally, the IRB Chair may implement interim measures regarding the study, in order to minimize the occurrence of future Unanticipated Adverse Events. The study team should propose, in the Unanticipated Adverse Event/Problem Report Form, what measure or future corrective action should be taken, if any. The UAE/UAP, along with all of the steps implemented by the IRB Chair and consultants, will be reported to the Convened IRB for further consideration at its next available meeting.

III. Noncompliance

Noncompliance is a failure (whether intentional or unintentional) to comply with applicable federal, state, or local laws or regulations; requirements or determinations of the IRB; or university policy regarding research involving human subjects. Noncompliance can be an action or an omission.

Any type of reportable event could constitute Noncompliance, but in most cases, the reportable event is disposed of via the processes outlined above. If the reportable event cannot be processed via the Deviation or Unanticipated Adverse Event processes, it will be processed as Noncompliance.

There are two avenues for processing Noncompliance, and the process undertaken depends on whether the Noncompliance is considered to be serious or continuing.

Serious Noncompliance is any noncompliance which, in the judgment of the IRB, places human subjects at elevated or unreasonable risk; decreases potential benefits to participants; jeopardizes the safety, welfare, or rights of research participants or others; compromises a research participant’s ability to render informed consent; or compromises integrity of the human research protection program.

Continuing Noncompliance is any action or omission which, in the judgment of the IRB Chair or Convened IRB, demonstrates a pattern of noncompliance over time and/or across research projects. Such a pattern suggests that the likelihood of noncompliance will continue without intervention.
If the Noncompliance is minor (i.e. not serious or continuing), it is processed by the IRB Chair or the Institutional Official. An abbreviated investigation will take place, findings will be reported to the IRB Chair or IO, and that person will design a Corrective Action Plan.

If the Noncompliance is Serious or Continuing, an investigation will take place, and findings are submitted to the Convened IRB for consideration. The Convened IRB will render a final determination regarding the Serious or Continuing nature of the Noncompliance, and also designate a Corrective Action Plan. Serious or Continuing Noncompliance requires notification of the Noncompliance to institutional leaders, sponsors, and other parties as deemed relevant by the Convened IRB.