Office of Human Research Ethics Training Tips
Protocol Deviations & Violations: OHRE SOP 23

23.2 Protocol Deviations

A deviation is defined as a variance from the approved study protocol that:

- Is generally noted or recognized after it occurs.
- Has no substantive effect on the risks to research participants.
- Has no substantive effect on the scientific integrity of the research plan or the value of the data collected.
- Did not result from willful or knowing misconduct on the part of the investigator(s).

Some examples of protocol deviations are:

- Performing a planned procedure on a different timetable than previously specified in the research protocol because of an unforeseen disruption such as a subject's vacation.
- A mechanical failure such as a recording device malfunction.

23.2.1 IRB notification and response in case of protocol deviations

- Deviations should be tracked by the investigator and reported to any sponsor or data and safety monitoring committee in accordance with their policies.
- **Deviations should be summarized and reported to the IRB at the time of continuing review.**
- **Primary Reviewer needs to review these deviations FROM THE PAST YEAR ONLY and assess if subject safety is being compromised. Were some incorrectly reported as deviations that were really violations?**

23.1 Protocol Violations (are reviewed by IRB F)

A violation is defined as a variance from the approved study protocol that:

- Has harmed or increased the risk of harm to one or more research participants.
- Has damaged the scientific integrity of the data collected for the study.
- Results from willful or knowing misconduct on the part of the investigator(s).
- Demonstrates serious or continuing noncompliance with federal regulations, State laws, or University policies.

Some examples of protocol violations are:

- Proceeding with the protocol before obtaining final IRB approval.
- Failing to follow the established criteria or procedures that were approved by the IRB.
- Adding, removing or modifying a research instrument (or adding to an existing instrument) in a survey study without prior IRB approval unless the changes are within a range of anticipated potential changes specified as acceptable within the IRB approval.
- Implementing any change in the protocol without IRB approval.

23.1.1 IRB notification and response in case of protocol violations

- Upon receipt of a protocol violation, it is reviewed by a Chair and may be referred to IRB F for review.
- If it is deemed a serious violation (e.g., one that affects subject safety) the Chair may suspend the study pending IRB review of the violation(s).
- Correspondence about serious violations should be copied to the OHRE Compliance Coordinator, Director of OHRE, the Institutional Official, and others as relevant.
- Violations should be reported within one (1) week of the investigator becoming aware of the event using the same online mechanism used to report Unanticipated Problems and Adverse Events (See 19.0)
- **Primary Reviewer: note requirements by IRB F for submission of modifications and check that those were done by the study team.**

23.3 Single patient/subject exceptions

When an investigator anticipates a one-time, intentional action that departs from an IRB approved protocol, he or she may request a one-time exception from the IRB. An example would include enrollment of a single subject who does not meet all eligibility criteria for a study, but the investigator and sponsor have agreed this subject should be enrolled.

Under these circumstances the investigator should request this exception by submitting a modification form; the IRB approval should note that this modification applies to one subject only and not to the study as a whole.

Renewal Submission Form Questions

7.
Have there been any deviations since the last renewal? No

8.
Have there been any unanticipated problems (including but not limited to adverse events and adverse subject outcomes) since the last renewal?

9.
Are you requesting any modifications to the study application, the consent documents, or any related documents at the time of this renewal? Yes

Any modifications requested as part of this renewal should be incorporated into the application at this time. This includes uploading any revised attachments. Consent forms should be revised within the 'Consent Forms' section of this application. Please provide a brief summary of your requested modifications in the box below. Clearly distinguish new and revised attachments and consent forms from those previously approved.

- *We have added two Research Assistants and have removed from our personnel.*
- *We have updated the consent form with a more current date.*
- *We propose no additional modifications to our protocol at this time.*

Do any of the proposed changes increase risk? No

10.
Have all modifications approved by the IRB since the study was initially approved or last renewed been implemented? Of particular importance are changes related to subject safety, such as re-consenting subjects to explain new study information/risks or the implementation of additional safety measures.