

Reporting Protocol Deviations

The MVAHCS Institutional Review Board defines a protocol deviation as “a change or alteration in a procedure or procedures as outlined in the IRB-approved protocol, health care system or IRB policies and standard operating procedure.” [Note: The term “protocol violation” may also be used by study sponsors to indicate an extremely serious deviation, such as: events that impact ethical principles or undermine the scientific integrity of the data, or procedures not approved by the IRB that caused or had the potential to cause substantive harm to research volunteers.]

The VA Office of Research Oversight requires that “any research-related problems involving risks that are not anticipated in terms of nature, severity, or frequency of occurrence....must be reported promptly to the IRB.” These *unanticipated problems* include protocol deviations/violations.

Unanticipated problems involving risks to subjects or others must be reported to the MVAHCS IRB, using the [Unanticipated Problem Report](#) form. This form is used to report unanticipated problems (including protocol deviations) which have occurred during the conduct of a research study. **The Investigator is required to submit the signed, completed form to the IRB no later than 5 working days after the investigator first learns of the event.** This form can be found on the IRB SharePoint under FORMS and on the shared VA server.

On the form, the Investigator is asked to describe:

- the unanticipated problem (UP) which occurred
- provide an explanation of why the UP occurred
- characterize the impact of the UP on the research subject or others
- the potential effect on subject burden
- the impact on scientific validity of the study
- the steps which have been taken to resolve the UP
- the plan implemented to avoid or prevent future occurrences
- whether the current enrolled subjects need to be informed about this UP
- whether the UP has been reported to someone other than the IRB (e.g. sponsor, FDA, etc.)
- whether the UP requires modification of the currently approved protocol and/or consent form

Any supporting documentation should be attached to the form.

All investigators, IRB members and staff, R&D committee members and staff, and institutional officials are required to report these unanticipated problems involving risks to risks to subjects or others to the IRB, unless an exception has been previously granted by the IRB. An overview of the UP reporting and review process is provided [here](#).

References

1. MVAHCS IRB Standard Operating Procedures
2. ORO Memorandum, *Reporting Unanticipated Problems and Adverse Events to the IRB*, 12/6/2006