

HOW TO SUBMIT A PROTOCOL DEVIATION OR PROBLEM TO THE USAFA IRB

Hello Researcher,

Sometimes during research something unexpected happens. Perhaps you lost your laptop that you had stored data on, perhaps you enrolled more subjects than you were approved for, or maybe, a subject fainted during a fitness test...all of these are examples of incidents that must be reported to the USAFA IRB.

1. If you are unsure if your incident is reportable it is best to err on caution and report! Please refer to the [Deviations, Problems, and Safety Reporting Guideline](#) for definitions and timeline requirements.
2. Report the incident using the [Deviations, Problems, and Safety Reporting Form](#) in the required timeline. Submit the form to the HRPP Organizational Box, usafa.irb@usafa.edu. Please put "Deviation Submission" in the subject line of your email. Your report must include the full reporting form and required attachments.
3. Once a complete submission is received HRPP Support Personnel will forward it to the IRB Chair.
4. The IRB Chair will review the report and make one of the following determinations:
 1. No further action by the Primary Investigator is required.
 2. Revisions/additional information required.
 3. Report requires a full Board review.
5. If the report is approved by the IRB Chair, HRPP Support Personnel will send you back your form with Page 3 (for Committee Use Only) completed and you are free to continue your research.
6. If the report is approved by the IRB Chair, HRPP Support Personnel will include your report in the IRB read-ahead for the next scheduled meeting for information purposes.
7. If the IRB Chair requires revisions/additional information s/he will contact you directly. The IRB Chair may allow the research to continue or may suspend IRB approval until the required information is received and a course of action (COA) determined. The COA may include required corrective actions.
8. The HRPP Support Personnel will send you a letter with any required corrective actions in a change table.
9. You will return the completed change table to the HRPP Organizational Box, usafa.irb@usafa.edu. Upon receipt, the HRPP Support Personnel will forward the completed change table to the Chair. All additional information or clarifications required by the Chair will be coordinated directly with you with a copy to the HRPP Organizational Box.
10. If the IRB Chair determines the report requires full Board review it will be reviewed at the next IRB meeting.
11. Disciplinary measures can be taken if the incident is determined sufficiently severe or there is a pattern of non-compliance.
12. The Final determination will be sent to you by the HRPP Support Personnel.