

HOW TO SUBMIT AN AMENDMENT TO RESEARCH PREVIOUSLY APPROVED BY THE USAFA
HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

Hello Researcher,

There are three possible courses of action for obtaining approval to modify your approved research protocol that depend on the determination made in the initial review.

- a. If the determination was “Not research involving human subjects”, no amendments are required. However, if the intent of the activity has changed to a research focus (you would like to contribute to generalizable knowledge), a new submission is required.
- b. If the determination was “Exempt from IRB oversight”, amendments are required for modifications that might affect risk to subjects or the exemption category, such as, changes in procedures, data collection instruments, data plans, and investigators. Amendments are not required for modifications that will not affect risk to subjects or the exemption category, such as adding a class, increasing subject numbers or increasing the time period.
- c. If the determination was “Full protocol research”, any modification to the approved protocol requires an amendment.

If your research requires an amendment based on the information above, here is what you need to do:

1. Complete the [Amendment form](#).
2. Submit your completed form to the USAFA HRPP Organizational Box, usafa.irb@usafa.edu. A complete submission includes the amendment form completely filled out with signatures, the original protocol with changes highlighted using track changes, and the current submission date with the previous submission date crossed out.

Note: Make sure you amend your most recent, approved protocol. If your protocol has been previously amended, please “accept” the changes approved through previous amendments so that ONLY those changes related to the current amendment are highlighted.

3. Once a completed submission is received, HRPP Support Personnel add all submitted documents in the protocol file and decide if the amendment can be expedited or must be taken to full board review.
4. If the amendment can be expedited, HRPP Support Personnel send it to the IRB Chairperson or to an IRB member designated by the Chairperson to review. If modifications to the Informed Consent Document (ICD) are required, the IRB Legal Representative will also review the

amendment. Modifications to full protocol research can be expedited per 32 CFR 219.110(b)(2), “Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.” Modifications to exempt research can always be expedited.

5. If the amendment requires full board review (i.e., major changes), all submitted documents will be included in the read-ahead for the next IRB meeting.

6. The following three determinations can be made for amendments:

- a. Approved
- b. Require modifications
- c. Disapprove

7. If the amendment is approved, HRPP Support Personnel send you a letter and the amended research protocol can be implemented.

8. If modifications are required, HRPP Support Personnel send you a letter with a change table. 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 two IRB members to ensure all required modifications have been addressed appropriately. If modifications were required to the Informed Consent Document (ICD), one of the reviewing IRB members will be the Legal Representative. All additional information or clarifications required by the reviewers will be coordinated through the HRPP Support Personnel.

9. If the amendment is disapproved, HRPP Support Personnel send you a letter that includes the reason for the disapproval and information on how to appeal the decision.

10. The process from complete submission to implementation is approximately 2 weeks for expedited review to 4 weeks for full board review without modifications, if the submission is received by the **monthly submission deadline**.