

HOW TO SUBMIT A FULL PROTOCOL RESEARCH STUDY

THAT HAS NOT BEEN SUBMITTED TO ANY OTHER INSTITUTIONAL REVIEW BOARD (IRB)

AND A NON-USAFA INVESTIGATOR IS INVOLVED

Hello Researcher,

Let's check to be sure you have the correct instructions to follow.

- a. Has the research been submitted to any other IRB?
- b. Is there a non-USAFA investigator?

If a. is "yes", these instructions are NOT for you. Please follow [Researcher Instructions for Activities that Have Been Submitted to any DoD IRB or HRPP](#) or [Researcher Instructions for Activities That Have Been Submitted to a Non-DoD IRB or HRPP](#) as appropriate.

If b. is "no", these instructions are NOT for you. Please follow [Researcher Instructions for Initial Full Review Research – Study Has Not Been Submitted to any Other IRB and There is No External Investigator](#).

If a. is "no" and b. is "yes", you have the correct instructions so keep reading.

There are two courses of action that can happen based on the activities of the non-USAFA investigator. Will the non-USAFA investigator(s) receive identifiable data, interact with subjects, or obtain informed consent?

If the answer is "no", the non-USAFA investigator(s) is not engaged in human subjects research (per *HHS Guidance on Engagement of Institutions in Human Subjects Research*, <http://www.hhs.gov/ohrp/policy/engage08.html>) so click on the following instructions: [Researcher Instructions for Initial Full Review Research – Study Has Not Been Submitted to any Other IRB and There is No External Investigator](#).

- a. If the answer is "yes", again, there are two courses of action based on whether the non-USAFA investigator is from an organization that has an IRB. Does the non-USAFA investigator(s)'s organization have an IRB? (Note: you might need multiple forms if you have multiple non-USAFA investigators)
 - 1) If the answer is "yes", an [Institutional Agreement for IRB Review \(IAIR\)](#) is required that allows USAFA to be the reviewing IRB. Have the non-USAFA investigator obtain the required signatures and return the signed form to the USAFA Human Research Protection Program (HRPP) Organizational Box, usafa.irb@usafa.edu.
 - 2) If the answer is "no", the non-USAFA investigator will need to be covered by USAFA's Federalwide Assurance (FWA) with an [Individual Investigator Agreement\(s\) \(IIA\)](#). Have the non-USAFA investigator obtain the required signatures.

You can accomplish the next four steps while your non-USAFA researchers are obtaining signatures:

1. You ensure USAFA will support your study by providing the resources necessary for you to execute it. Refer to [Procedures to Obtain Resources and Survey Approval](#) for detailed instructions on how to secure appropriate approvals.
2. You ensure ALL investigators are current in their annual human subjects protection training. Refer to [USAFA IRB Training Instructions](#) for step-by-step instructions.
3. You review your experience and resume and ask yourself whether you have appropriate human subjects research experience to lead this study. Also, review the resumes of your investigators to ensure they have the appropriate experience to execute the study in compliance with HRPP requirements. As PI, you are responsible for any breaches in human subjects protection that occur.
4. You complete the [USAFA HRPP Determination Request](#) and the [USAFA Informed Consent Document \(ICD\)](#) AND secure the required signatures.
5. You submit your completed protocol package to the HRPP Organizational Box by the [monthly submission deadline](#). This package must include
 - 1) the completed HRPP Determination Request with all signatures
 - 2) a separate informed consent document or a request for waiver of documented informed consent in the protocol
 - 3) evidence of resource approval
 - 4) current training certificates for all researchers
 - 5) resumes for all researchers
 - 6) signed IAIR and/or IIA for all non-USAFA researchers

Note: the IRB office does not keep these “on file.” Please submit a complete package. If a complete package is not submitted, the HRPP Support Personnel will return your submission.
6. Once a complete submission is received, your protocol will be included in the read-ahead for the monthly meeting. The Friday prior to the IRB meeting date, the read-ahead is provided to IRB members and all protocols are posted on the HRPP SharePoint site for two weeks to allow Mission Elements (ME) time to review and provide comments prior to the Authorized Institutional Official (AIO) signing the permission memo. This posting is required by your AIO and exists outside of the IRB review process.
7. You attend the IRB meeting in which your research is reviewed either in person or by telephone.
8. At the IRB meeting, the Board can make any of the following determinations, per section 32 CFR 219.109.
 - a. Approve the research.
 - b. Require modifications to the research.
 - c. Disapprove all research activities.
9. Within two weeks of the IRB meeting, HRPP Support Personnel will accomplish the following:
 - a. Draft and finalize the meeting minutes
 - b. If modifications are required per the meeting minutes, send a letter with a change table to you

- c. Staff permission memo for approved or conditionally approved research with ME comments and IAIR and/or IIA to AIO

10. If modifications to the research are required, 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 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.

11. If the research is disapproved by the IRB, you will receive a letter that includes the reason for the disapproval and information on how to appeal the decision.

12. If the AIO permits the research, you will receive the IRB approval letter and the AIO Permission Memo for each permitted research protocol and the research can commence.

13. You are required to submit amendments for any modifications to the approved protocol prior to initiating those modifications.

14. You are required to submit an annual report to the USAFA IRB within 364 days every year to continue the research until you close the research with a final report.

15. If the AIO does not permit the research, you will receive a letter that includes the reason for the disapproval and information on how to appeal the decision.

16. Per [DoDI3216.02_AFI40-402, Enclosure 2, 11.f.](#), you must retain all research records (e.g., protocol, signed informed consent documents, IRB correspondence, and data) for at least three years after the research ends or for the length of time specified in applicable regulations, or institutional or sponsor requirements, whichever is longer. You must transfer research records to another PI or keep them with you and provide new contact information if you leave USAFA before the 3 years is over. In either case, you must inform the HRPP office that you are leaving USAFA.

17. The USAFA HRPP office maintains all administrative records for three years after closure and then destroys them appropriately.

18. Files are subject to audit by SGE-C and USAFA HRPP.

19. You must send any publications or presentations that result from the research to the HRPP Organizational Box. Please reference your protocol number and title.

20. While every protocol is different, on average, the process from compliant submission on the appropriate submission date to approval takes approximately 6-8 weeks.