

HOW TO SUBMIT EXEMPT RESEARCH TO THE USAFA HUMAN RESEARCH PROTECTION PROGRAM (HRPP)

Hello Researcher,

Like any large bureaucracy, USAFA is required to comply with numerous regulations. However, the DoD has accepted federal regulations that reduce the red tape on some types of human subjects research. **32CFR 219.101** identifies six categories of human subjects research that are exempt from HRPP oversight. Here is what DoD requires of a Principal Investigator (PI): “Prior to start of an activity that is or may be research involving human subjects, obtain written determination from an appropriate [Exempt Determination Official] EDO or an Institutional Review Board (IRB) per paragraphs 6.a.(1)(a)1. and 10.d. of enclosure 2, and the PI’s [Institutional Official] IO/AIO [Authorized Institutional Official] per paragraph 6.a.(2). PIs are not authorized to make such determinations for their own activities (**DoDI3216.02_AFI40-402, Enclosure 2, 11.c.**)”

NOTE: The AF has PROHIBITED AF IRBs from reviewing research that has an IRB determination from another organization. If your study has been submitted to any HRPP or IRB for review, STOP, do not follow this instruction. 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 your study has NOT been submitted to any other IRB or HRPP, follow the steps below:

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*** or 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 secure the required signatures.
5. You submit your completed exemption request package to the HRPP Organizational Box, usafa.irb@usafa.edu by the ***monthly submission deadline*** . If you are submitting educationally exempt research submit your completed package to the Exemption Determination Officer (EDO). Please contact the EDO at 333-3277 for submission instructions. This package must include the completed HRPP Determination Request with all signatures, evidence of resource approval, and current training certificates for all researchers. Note: the IRB office does not keep these “on file.” Please submit a complete packet. If a complete packet is not submitted, the HRPP Support Personnel will return your submission.
6. Once a complete submission is received by the HRPP, it will be submitted to one IRB member for a

determination. If the IRB member requires clarification or additional information from the researcher, the IRB member will email you directly. Be sure to cc the HRPP Organizational Box, usafa.irb@usafa.edu, when corresponding directly with your reviewer.

7. There are three possible determinations your reviewer can make:
 - a. **NOT research involving human subjects.** The study does not meet the regulatory definition of research involving human subjects per [32CFR 219.102](#). In this case, the determination is sent to you and you are free to start your study.
 - b. **Human subject research eligible for exemption from the requirement for IRB review.** This study meets the definition of research involving human subjects and meets a least one of the six exemptions per section 219.101(b).
 - i. HRPP Support Personnel will inform you of the determination.
 - ii. Your study will be posted on the HRPP SharePoint site one week after the IRB submission deadline and will be available for two weeks to allow Mission Elements (ME) time to review and provide comments prior to the AIO signing the permission memo. This posting is required by your AIO and exists outside of the IRB review process.
 - iii. Once the two week comment time has elapsed, the IRB determination, resource approvals, and any ME comments that were posted on the HRPP SharePoint site, will be staffed to the AIO to obtain his/her decision to permit/not permit the research to be done at USAFA.
 - iv. Once the signed AIO permission memo is received, HRPP Support Personnel will send the determination and the AIO permission memo to you and you are free to start your study.
 - c. **Human subjects research ineligible for exemption from the requirements for IRB review.** This study meets the definition of research involving human subjects but does not meet any of the six exemptions per section 219.101(b). In this case, the research requires full IRB review. The determination is sent to you with instructions for submitting full protocol research.
8. 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, extending the time period.
9. No annual reports are required; the research is closed by HRPP Support Personnel.
10. Per [DoDI3216.02_AFI40-402, Enclosure 2, 11.f.](#), you must retain all your research records (e.g., protocol, 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.
11. The USAFA HRPP office maintains all administrative records for three years after closure and then destroys them appropriately.
12. Your files are subject to audit by USAFA HRPP and SGE-C.

13. You send any publications or presentations resulting from your study to the HRPP Organizational Box, usafa.irb@usafa.edu. Please reference your protocol number and title.

14. While every protocol is different, on average, the process from compliant submission on the **appropriate submission date** to approval takes approximately 4-6 weeks.