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USAFA Human Research Protection Program (HRPP)

Submission Types

To jump to a review type, click on your choice below:

Not Human Subjects Research Review

Per DoDI3216.02_AFI40-402, Enclosure 2, 11.c., "Prior to start of an activity that is or may be research involving human subjects, obtain a 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 this enclosure, and the [Principal Investigator] PI's [Institutional Official] IO/AIO [Authorized Institutional Official] per paragraph 6.a.(2) of this Enclosure. PIs are not authorized to make such determinations for their own activities." **Any activity that may meet the definition of human subjects research** (32CFR219.102**) must be submitted** (excludes customer satisfaction and post program feedback directed solely at improving activities within the program). Course critiques, Chapel programs usage and satisfaction survey, and NCLS feedback forms are examples of excluded activities. Direct comparison of two different programs might be research and should be submitted for HRPP review.

NOTE: The AF has PROHIBTED AF IRBs from reviewing research that has an IRB determination from another organization; this includes a determination of not human subjects research. If your study has been submitted to any other HRPP or IRB for review, please use the appropriate instructions below.

Associated Instructions and Forms

- **Researcher Instructions for Not Human Subjects Research – Study has not been submitted to any other HRPP or Institutional Review Board (IRB)**
- **Researcher Instructions for Activities that Have Been Submitted to any DoD IRB or HRPP**
- **Researcher Instructions for Activities That Have Been Submitted to a Non-DoD IRB or HRPP**
- **2016-2017 Submission Dates**
- **Procedures to Obtain Resources and Survey Approval**
- **Form Access**
- **Not Research Involving Human Subjects: Most Frequent Errors**
- **Contact Information (Located top right of the IRB web page)**

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Exempt Review

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 PROHIBTED AF IRBs from reviewing research that has an IRB determination from another organization. If your study has been submitted to any other HRPP or IRB for review, please use the appropriate instructions below.

Associated Instructions and Forms

- **Guidelines for Applying the 6 Exempt Review Categories**
- **Researcher Instructions for Exempt Research – Study has not been submitted to any other HRPP or Institutional Review Board (IRB)**
- **Researcher Instructions for Activities that Have Been Submitted to any DoD IRB or HRPP**
- **Researcher Instructions for Activities That Have Been Submitted to any Non-DoD IRB or HRPP**
- **2016-2017 Submission Dates**
- **Form Access**
- **Mandatory Training Requirements**
- **Procedures to Obtain USAFA Resources and Survey Approval**
- **Exempt Research: Most Frequent Errors**
- **Contact Information (Located top right of the IRB web page)**

Initial Full Protocol Review

Research that cannot meet the criteria for exempt review must be submitted for full review.

NOTE: The AF has PROHIBTED AF IRBs from reviewing research that has an IRB determination from another organization. If your study has been submitted to any other HRPP or IRB for review, please use the appropriate instructions below.

Associated Instructions and Forms

- **Researcher Instructions for Initial Full Review Research – Study has not been submitted to any other IRB and there are no Non-USAFA investigator on the protocol**
- **Researcher Instructions for Initial Full Review Research – Study has not been submitted to any other IRB and there is a Non-USAFA investigator on the protocol**
- **Researcher Instructions for Activities that Have Been Submitted to any DoD IRB or HRPP**
- **Researcher Instructions for Activities That Have Been Submitted to any Non-DoD IRB or HRPP**
- **2016-2017 Submission Dates**
- **Form Access**
- **Mandatory Training Requirements**

- **Procedures to Obtain USAFA Resources and Survey Approval**
- **Initial Full Review Research: Most Frequent Errors**
- **Contact Information (Located top right of the IRB web page)**

Amendments

An amendment is required for any modifications to a full protocol from what was previously approved during the period for which approval was given. Changes in research procedures, the informed consent process, and/or the consent/assent document cannot be initiated by the investigator without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject. Should protocol changes be made without prior IRB approval, submit a memorandum immediately to the IRB addressing the nature of the change, why it was necessary, and the outcome.

An amendment is required to an exempt protocol 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.

Information relating to protocol modifications should be relayed to subjects when such information might relate to the subject's willingness to continue to take part in the research. How this information will be relayed to the subject (e.g., through a re-consent process using a modified consent form, or a letter sent to the subject) should be included in a modification request, and IRB approval obtained prior to implementation.

Approval of the submitted amendment is on the advice of the IRB chairperson or a designated representative unless the nature of the proposed changes warrants review by the full IRB. The IRB may determine the modification relates to subjects' willingness to continue to participate in the research, and request that the PI relay pertinent information to subjects. The investigator is notified in writing of the IRB's decision.

Associated Instructions and Forms

- **Researcher Instructions for Amending Previously Approved Research**
- **2016-2017 Submission Dates**
- **Form Access**
- **Amending Research: Most Frequent Errors**
- **Contact Information (Located top right of the IRB web page)**

Continuing/Final Reports

Federal regulations dictate that previously approved research protocols must be re-reviewed by the respective IRB at least once a year. Continuation/Final review by the USAFA HRPP requires the investigator to complete and return a continuing/final report form.

Associated Instructions and Forms

- **Researcher Instructions for Continuing/Final Reports**

- **2016-2017 Submission Dates**
- **Form Access**
- **Continuing/Final Reports: Most Frequent Errors**
- **Contact Information (Located top right of the IRB web page)**

Protocol Deviations, Problems and Adverse Events

Federal regulations dictate that HRPP's have in place written procedures for ensuring prompt reporting to the HRPP any protocol deviations, problems (anticipated and unanticipated), or safety concerns involving human subjects research.

Associated Instructions and Forms

- **Definitions and Reporting Requirements for Protocol Deviations and Problems**
- **Researchers Instructions for Submitting Protocol Deviations and Problems**
- **Form Access**
- **Contact Information (Located top right of the IRB web page)**