

HUMAN RESEARCH PROTECTION PROGRAM (HRPP) DETERMINATION REQUEST

Date:

DON'T BE AFRAID! The instructions are at the back and are based on feedback from investigators that have gone before you and have had unanswered questions. PLEASE TAKE THE FEW MINUTES NECESSARY TO READ THEM. IT WILL SAVE YOU IN THE LONG RUN.

Has this study been reviewed by an IRB already? Yes No

If YES, STOP HERE and contact the IRB Administrator at 333-6593 or usafa.irb@usafa.edu.

Check one: Medical Non-medical

Title of Protocol (if applicable use the exact title listed in the grant/contract):

Protocol # (filled out by IRB Administrator):

Principal Investigator (PI) Information (A cadet cannot be a PI. If there is a 2nd PI; add their information at the end of this form)

Name & Rank:

Organization & Position:

Telephone number:

Email Address:

FWA or DoD Assurance Number (if not USAFA personnel):

Associate Investigator (AI) Information (no limit, please add additional AI information at the end of this form)

Name & Rank:

Organization & Position:

Telephone number:

Email Address:

FWA or DoD Assurance Number (if not USAFA personnel):

SUBMISSION

Not RESEARCH involving
human subjects

Exempt study
See 32CFR219.101

Full IRB Review

Please answer the following questions regarding your activity or study:

Will you be collecting or analyzing information?

Yes No

Does your study have organized processes or procedures?

Yes No

Does your study test a hypothesis?

Yes No

Can the information or outcomes you obtain be applied beyond the context of the activity?

Yes No

Do you intend to expand understanding of a condition or population, or add to a body of knowledge?

Yes No

Do you intend to provide results only to improve a program?

Yes No

Does your study involve the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens?

Yes No

Will you use an existing dataset and there is no way to identify any individual in the dataset directly or indirectly?

Yes No

Will you use an existing dataset such that a link exists that could allow the source of the data to be re-identified?

Yes No

Will you use an existing dataset but a trusted agent has stripped the identifiers before providing it to the investigators?

Yes No

Will your study be conducted in an educational setting, researching normal educational practices (e.g. curriculum)?

Yes No

Does your study involve educational tests, surveys, interviews, focus groups, or observation of public behavior?

Yes No

Does your study involve a taste and food quality evaluation or consumer acceptance studies?

Yes No

Do you have adequate experience with human subjects research to conduct this study as the PI?

Yes No

STUDY DESCRIPTION

1. **Total Maximum Number of Participants Required:**

2. **Is there external funding?** Yes No

3. **Do you have a financial interest in the outcome of this research? (Example: You are testing the effect of a software on learning and you benefit financially from the sale of this software)**

Yes No

If Yes, please describe:

4. Do you have a professional interest in the outcome of this research? (Example: The outcome of this research may be linked to future job offers from a co-sponsor if this research)

Yes No

If Yes, please describe:

5. Do you have a personal interest in the outcome of this research? (Example: The outcome of this research may benefit the financial or professional circumstances of a family member or close friend)

Yes No

If Yes, please describe:

6. Timeframe of Study:

7. Background:

8. Objectives:

9. Study Methods:

10. Subject Recruitment Methods:

11. Potential Risks/Inconveniences:

12. Direct and Indirect Benefits:

13. Risk/Benefit Analysis:

14. Compensation:

15. Confidentiality:

16. **Informed Consent Process (if full IRB review submission):**

17. **Relevant References from Literature:**

18. **Additional Information (include any information that did not fit above; reference the related page number and topic)**

Please obtain wet signatures, scan and email to usafa.irb@usafa.edu

Principal and Associate Investigators' Assurance Statement:

I read and understand the USAFA policies concerning study involving human subjects and I agree:

1. to comply with all IRB policies, decisions, conditions, and requirements;
2. to accept responsibility for the scientific and ethical conduct of this study;
3. to obtain prior approval from the Institutional Review Board before amending or altering the study protocol;
4. that each individual listed as an investigator in this application has received the mandatory human study protections education;
5. to submit documentation of any publications or presentations that result from this study;
6. to transfer all full protocol study documents to a USAFA colleague prior to departing the Academy or close the protocol.

Name, Rank, USAF (if military)

Title

Department

Principal Investigator

Name, Rank, USAF (if military)

Title

Department

Associate Investigator

Name, Rank, USAF (if military)

Title

Department

Associate Investigator

Endorsement by the Department Research Director or an individual with similar responsibility and authority:

This is to certify that I have reviewed this protocol and determined that it is scientifically valid, emphasizes good experimental design, and minimizes the use of and risks to human subjects.

Name, Rank, USAF (if military)

Title

Department

Director of Research

Endorsement by the Department Chair or an individual with similar responsibility and authority
(Note: If the Principal Investigator is also the Department Chair, the Vice Chairperson or equivalent should sign this section).

This is to certify that I have reviewed this study protocol. The proposed principal investigator is scientifically qualified to conduct the proposed study. This study is scientifically valid, emphasizes good experimental design, and minimizes the use of and risks to human subjects. I will ensure that the study records and data for this protocol will be maintained for a minimum of 3 years.

Name, Rank, USAF (if military)

Title

Department

Professor and Head or Director

Attachments:

See #7 of the instructions on page 5

INSTRUCTIONS FOR COMPLETING THE HRPP DETERMINATION REQUEST FORM

1. Questions may be directed to the IRB Office at 719-333-6593 or DSN 333-6593.
2. The Determination Request Form should be reviewed and signed by all investigators, as well as the Director of Study (if you are a DF member) and the Department Head or equivalent of the PI's department.
3. If the study includes survey, focus group, or interview procedures, the questions or assessment scales must be included with the application.
4. Depending on the type of study you are proposing, **additional approvals** may be required. **The HRPP will not review a Determination Request Form without copies of required approvals as stated below.**
 - a) Mission element commander approval is required for access to the following:
 - (1) Sport teams, AD personnel, resources or facilities – AD, 719.333.4008
 - (2) Medical/dental personnel, records, resources or facilities – 10 MDG, 10 MSGS, 10 AMDS, 10 DS, 719.333.5866
 - (3) Other 10 ABW personnel, resources or facilities – 10 ABW, 719.333.1015
 - (4) Airfield personnel, resources or facilities – 306 FTG, 719.333.3330
 - (5) Cadets in the squadron or during military training, CW personnel, resources or facilities – CW, 719.333.2263
 - (6) Cadets in the classroom or during academic time – DF Department Head, 719.333.4508
 - (7) DF personnel, resources or facilities – Dean of the Faculty, 719.333.4508
 - (8) USAFA Preparatory School students, personnel, resources or facilities – PL, 719.333.2583
 - b) If you are obtaining attitude, opinion or intention data, you must obtain a Survey Control Number from the Survey Control Officer at 719-333-6481.
 - c) If your study requires use of the Dean of the Faculty (DF) Subject Pool, you must obtain approval through DFBL at 719-333-2514 or DSN 333-2514.
 - d) If your study requires archival USAFA data, please send your request to A589.taskers@usafa.edu.
5. The study may be regulated by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule even if the study is exempt from the federal regulations for the protection of human subjects. If that is the case, please review the HIPAA regulations at: <http://www.hipaasurvivalguide.com/hipaa-survival-guide-toc.php>. HIPAA compliance is not the IRB's responsibility, but IS the investigator's responsibility.
6. Every investigator associated with the study is required to have annual human subject study training. You may access training through the National Institute of Health site at:
<https://phrp.nihtraining.com/users/login.php?l=3>.
7. Once the Determination Request Form is complete, please attach appropriate documentation and
 - a) If applicable, appropriate approvals (see item 4.a through d. above)
 - b) If applicable, instruments to be used for data collection (see item 3 above)
 - c) If applicable, an approved Data Collection and De-Identification Plan (see item 4.d above)
 - d) If applicable, copies of any material which will be used to recruit subjects (i.e. advertisements, flyers, telephone scripts, verbal recruitment scripts, cover letters, etc.)
 - e) If applicable, the informed consent document
 - f) Human Subjects Training certificates for all investigators dated within the past year (see item 6 above)
 - g) Investigator Vita/Resume (not needed for cadet investigators)
8. Submit the Determination Request Form and all attachments to the HRPP Organization Box usafa.irb@usafa.edu.

be done to the subjects, (i.e., tasks and information to be gathered from or about the participants). Indicate whether subjects will be randomized for the study and describe the control and experimental groups. Include descriptions of the facilities, equipment, and safety precautions, if applicable, the time for each task and total time for participation. Attach the data collection instruments or data items (e.g. interview script, survey tool, data collection form for existing data).

After the Determination Request Form is submitted:

1. The Determination Request is reviewed by the IRB Administrator and either sent out for immediate review (if not human subjects study or exempt) or scheduled for the next convened IRB meeting.
2. All study requests are forwarded to the Vice Superintendent for permission to conduct the study at USAFA. This permission does not guarantee the resources will be provided for the study (see item 4.a through d.)
3. The IRB Administrator will notify the investigator of the outcome of the review. Approval time can vary due to the volume of submissions and other issues.

SUBMISSION

According to DoDI 3216.02_AFI 40-402, Enclosure 2, 11.c.prior to starting any activity that is or may be study involving human subjects, all Principal Investigators (PIs) must obtain a written determination from an Exempt Determination Official (EDO) or an Institutional Review Board (IRB). PIs are not authorized to make such a determination. EDOs or IRBs determine whether possible study activities are:

- not study involving human subjects
- exempt study involving human subjects per 32 CFR 219.101(b)
- study involving human subjects that requires approval by an IRB

EDO's and IRB members receive extensive training from the AF on how to interpret the definitions of study and human subjects provided in 32 CFR 219.102. The USAFA EDO or IRB determines that a study is either not study involving human subjects or exempt from the federal regulations governing human subject study. This judgment is made with care and must be fully compliant with 32 CFR 219.101(b) and 102. Therefore, they are the only people designated with the authority to make the aforementioned determinations.

Also, it is the PI's responsibility to notify the HRPP if any changes or modifications are made in the study's design, procedures, etc. **BEFORE** executing those changes to ensure the changes do not change the determination of the study.

STUDY DESCRIPTION

1. **Number of Participants Required:** If you are sampling a population, provide a reason the sample size is adequate (e.g., power analysis) and increase the required number to account for subject attrition and missing data. If you are excluding subjects from the population or only recruiting certain types of people (e.g., only pilots), provide a reason for the exclusions or narrow recruiting. If relevant, address why you need human subjects rather than use existing data (e.g. medical record review), animals or simulation/modeling.
2. **Is there external funding?** If yes, provide the type and amount of funding.
3. **Time Frame of Study:** When it will start and duration.
4. **Background:** Provide an introduction, background information. Answer the question: Why are you doing this study?
5. **Objectives:** List your objectives or hypotheses.
6. **Study Methods:** Describe chronologically and in detail all procedures the subjects will do and what will

be done to the subjects, (i.e., tasks and information to be gathered from or about the participants). Indicate whether subjects will be randomized for the study and describe the control and experimental groups. Include descriptions of the facilities, equipment, and safety precautions, if applicable, the time for each task and total time for participation. Attach the data collection instruments or data items (e.g. interview script, survey tool, data collection form for existing data).

7. **Subject Recruitment Methods:** Describe how the prospective subjects will be identified for recruitment and describe the recruitment procedures, particularly address the diminished autonomy of cadets (especially 4th class cadets) and how the investigator will ensure that participation is voluntary. List or attach the recruitment flyers, emails, scripts, etc.
8. **Potential Risks/Inconveniences:** Describe any potential risks--physical, psychological, social, legal or other. Include total time required of subjects for participation and, if appropriate, how participation may affect availability for duty. Include an assessment or example of the severity and likelihood of the risk.
9. **Direct/Indirect Benefits:** Describe as direct benefits where the participant will personally gain something from the study itself (e.g., a free body fat test). If there are no benefits, input the statement, "There are no direct benefits." Include any Indirect Benefits such as value to the scientific body of knowledge, information to improve a program, etc.
10. **Risk/Benefit Analysis:** Please make an argument as to why the benefits outweigh the risks.
11. **Compensation:** Describe what subjects will receive for taking part in the study. For example, if using the DFBL Subject Pool, state, "Subjects will receive extra-credit points in their BS 110/310 course as it is stated in their course syllabus for participation in this study".
12. **Confidentiality:** Specify where the data or specimens will be stored and how the investigator will protect the data and/or specimens with respect to privacy and confidentiality. Provide a time table for destroying the data/specimens and identify how they will be destroyed, or provide rationale for perpetual maintenance. Also specify who will access the identified data/specimens, and why they need access. If applicable, discuss when and how the identifiers in a dataset or on specimens will be removed.
13. **Informed Consent Process (if full IRB review submission):** Describe the consent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing (whether there will be a waiting period), and steps taken to minimize the possibility of coercion or undue influence. Attach the Informed Consent Document (ICD) or request a waiver of documented informed consent. If requesting a waiver of informed consent please state that "32 CFR 219.116(d) permits the IRB to waive informed consent provided the following conditions exist: 1) The study involves no more than minimal risk to the subjects; 2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; 3) The study could not practicably be carried out without the waiver or alteration; and 4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation. Although it is up to the IRB to make this determination, I believe this study meets these four conditions because....."
The ICD must be in language that a lay person can understand and have no typographical or grammatical errors.
14. **Relevant References from Literature:** Provide full citations of references used above.