

## **INSTITUTIONAL REVIEW BOARD POLICY AND PROCEDURES**

### **A. OVERVIEW**

#### **Purpose:**

The purpose of this Policy and Procedure is to delineate the authority, purpose, principles, functions and operations of the Institutional Review Board (IRB). This Policy and Procedures pertains to research involving the use of human subjects **not exempt** from Institutional Review Board (IRB) review as described by 32CFR219, 21 CFR 56, and AFI 40-402.

#### **Institutional Authority:**

AF/SGRC has officially delegated the authority to approve and monitor human research at USAFA to HQ USAFA/CV via the USAFA *Multiple Project Assurance*. AF/SGRC audits a sample of minimal risk USAFA protocols and reviews all greater than minimal risk protocols. USAF/SGRC also provides continuing oversight of local IRB operations. The IRB is established under the authority of Air Force Instruction 40-402, Protection of Human Subjects in Biomedical and Behavioral Research and the USAF Academy Supplement 1 to USAFI 40-402. The IRB functions under the authority outlined in the Protection of Human Subjects, Code of Federal Regulation (CFR), Title 32, Part 219 and 21 CFR 56 Institutional Review Board (FDA).

#### **Purpose of the IRB:**

The purpose of the IRB is to protect the rights and welfare of human research subjects recruited to participate in research protocols at the USAF Academy.

#### **Principles Governing the IRB:**

1. The USAF Academy IRB uses the three basic ethical principles outlined with the Belmont Report to govern or use as a basic justification for decision-making and judgments. The three principles are: 1) *Respect for Persons* (individuals are treated as autonomous agents and individuals with diminished autonomy are entitled to protection); 2) *Beneficence* (an obligation to do no harm and maximize possible benefits and minimize possible harms); and 3) *Justice* (answers the question: who ought to receive the benefits of research and bear its burdens?)
2. These general ethical principles are applied to the conduct of research in the following requirements: informed consent, risk/benefit assessment and selection of subjects of research. The informed consent requirement of human use research (non-exempt) is documented in the USAF Academy's standardized Informed Consent Document (ICD). Risk/benefit assessment is documented in the USAF Academy Protocol format, the ICD and in the minutes of the IRB meetings. Finally, selection of subjects of research is documented in the USAF Academy protocol format and on occasion, in the minutes of the IRB meetings.

**Authority of the IRB:**

1. The Board will provide initial and continuing review for all investigations involving human subjects except for those protocols that meet the criteria for exemption from review listed in 32 CFR 219.101. The Board will recommend approved as written, conditionally approved (with modifications to secure final approval), tabled, or disapproved to the Vice Superintendent, in whom approval authority is vested (final approval authority for greater than minimal risk studies resides with the Surgeon General's Research Oversight Committee (SGRC)). The IRB has the authority to suspend or terminate approval of research consistent with 21 CFR 56.113 and 32 CFR 219.113. The IRB has the authority to place a restriction on any study, such as upper class cadets may not recruit from within their chain of command or may not recruit 4-degrees. The IRB has the authority to require progress reports from the investigator and to oversee the conduct of the study (AFI 40-402, para. 2.6, 32 CFR 219.109 (e), and 21 CFR 56.109 (f)).
2. In the event that USAF/SGRC requests modification/clarification of a new protocol an official request will be sent to the IRB Administrator and Chair. The Chair will review the request and provide a response, or, when necessary, the Chair will request a response from the Principle Investigator (PI). All communication between investigators and USAF/SGRC will flow through the IRB Chair and Administrator. The IRB is informed of any changes requested by USAF/SGRC and the Chair's/PI's response at the next scheduled IRB meeting.

**Institutional Review Board Responsibilities:**

The IRB's duties are outlined in 32 CFR 219.107 to 219.109, (21 CFR 56.107-109), AFI 40-402, para. 2.6, AFI 40-402 USAFA Supplement 1, and in the Multiple Project Assurance (MPA).

**B. BOARD MEMBERS****IRB Members:**

Requirements for IRB membership are outlined in 32 CFR 219.107 and AFI 40-402 USAFA Supplement 1.

**IRB Chairperson Duties and Responsibilities:**

1. The IRB Chairperson or designee will take steps so that the IRB represents diversity with respect to gender, ethnicity, and professional discipline.
2. Ensures the meetings are conducted in a professional manner, and that the views and concerns of all members are considered. The Chair is responsible for ensuring the basic ethical principles (respect for persons, beneficence, and justice) and the application of informed consent, risk/benefit assessment, and selection of subjects of research are followed.
3. Ensures the conduct of all members is appropriate and that the review and discussion of research topics considers the pertinent information.

4. For adverse event reporting, the Chair determines whether the event requires immediate action or is reported at the next regularly scheduled meeting, following the procedure outlined in AFI 40-402, para. 3.8.1.
5. Reviews and approves all IRB minutes.

**IRB Member Responsibilities:**

1. Must provide a current curriculum vita/resume to the Administrator updated as appropriate.
2. Attend board meetings or make provisions for an appointed alternate to attend.
3. Review all Board business prior to each meeting. All required reading is distributed to the primary board member. It is the primary member's responsibility to pass the packet on to an alternate if unable to attend.
4. Abstain from voting if they are a signatory (investigator, associate investigator, director of research, or department head) on any study under review. Members may also abstain for any other potential conflict of interest (such as a familial relationship with an investigator). Members who are signatories on studies may answer questions and clarify issues as needed.
5. Participate in Expedited Reviews as requested by the Chair.
6. Complete CITI training provided by USAF/SGRC in timely manner.
7. Are not compensated by the Institution for performing the duties as members or Chair. Since the IRB members are Federal Employees performing duties within the scope of their employment, liability coverage is provided by the Air Force.
8. Handles all communication between investigators and USAF/SGRC.

**Orientation and Education of Members:**

1. New members to the Board will receive orientation to their duties from the IRB Administrator and training through the CITI Training provided by USAF/SGRC.
2. Each member receives continuing education information as part of the monthly IRB packets. Pertinent issues are discussed at meetings and documented in the minutes as appropriate.
3. All members have access to USAFA main library, containing journals and regulations pertaining to the conduct of research.

**Removal of IRB members:**

If an allegation of scientific misconduct is made against an IRB member, the investigation of this allegation shall be handled consistent with the guidelines outlined in AFI 40-402, para. 3.9.

## **C. BOARD MEETINGS AND IRB PROCEDURES**

### **Board Meeting Procedures:**

The IRB will meet monthly, usually on the fourth Thursday unless otherwise changed by the membership. Additional meetings may be convened at anytime upon the request of the Chairperson.

### **Rules of Order guiding board meetings:**

1. Requirements for a quorum and for approval of an agenda item are discussed in 32 CFR 219.108(b).
2. Voting: Voting will ordinarily be accomplished by a hand count, although the Chairperson may elect to employ other means of voting (e.g., written ballot of members present). The only valid votes will be from members or their representatives who are present at the meeting. No one present at the meeting shall have more than one vote. Board members must abstain from voting on protocols on which they are signatories (PI, Associate Investigator (AI), research director or department head) or where there is a potential for conflict of interest. The numerical results of the vote will be recorded in the minutes.
3. A period of discussion and the voting of Board members are conducted without the investigators (PI/AI's) in attendance. Investigators never participate in the voting process.

### **Appeals of IRB Decisions:**

1. Following each IRB meeting, the meeting minutes and all reviewed protocols are approved by the Authorized Institutional Official (AIO) and forwarded to USAF/SGRC.
2. Appeals must be received within 30 days of written notification of the IRB's decision. The appeal will be considered by the IRB at the next regularly scheduled board meeting. Investigators filing appeals are strongly encouraged to attend the board meeting at which their appeal will be heard.
3. All appeals should be addressed to the IRB Chairperson and sent to HQ USAFA/XPX. The appeal should address reasons for disapproval and provide substantive information (e.g. new information) for why the board should reconsider the decision.
4. No one has the authority to override IRB disapproval. Only the IRB can decide to reconsider a decision. If an appeal is considered by the IRB, the following actions are available: (1) affirm the decision; (2) reverse all or part of the previous decision; or (3) defer opinion until further information can be obtained.
5. The PI will be notified in writing of the results of the IRB meeting at which the response was considered.

**Compliance/Non-Compliance:**

1. **Continuing/Final Review:** A request for a continuing progress report or final report will be sent to the principal investigator one month prior to the report due date. If the report is not received by the due date, a second letter will be sent to the investigator with copies to the investigator's Research Director and department head and the research is immediately suspended. The research will remain in suspension until the investigator is in compliance with the IRB request.

2. **Research Conducted Without IRB Approval.** Investigators who conduct human subjects research without appropriate IRB approval place USAFA out of compliance with Federal requirements for human subjects' research. This can result in Federal or USAF actions that will prevent researchers, departments or USAFA from conducting human subjects' research and will jeopardize the USAFA human research certification from the Air Force Surgeon General. If the board becomes aware of research conducted without IRB approval, the chair will send a letter to the researcher instructing him/her to cease all data collection immediately. This letter will be copied to the Director of Research and Department Head of the researcher's department. The board will consider possible sanctions against the investigator at the next regularly scheduled board meeting. The investigator, Director of Research, and Department Head will be informed of the date, time, and location of that meeting and will be invited to attend. Sanctions may include (but may not be limited to) instructions to the researcher to destroy all improperly collected data and barring the investigator from conducting future human subjects' research at USAFA. The board will weigh the level of risk to which the subjects were exposed in deciding appropriate sanctions.

3. **Improperly Executed ICDs:** The board will ask researchers to remedy improperly executed consent documents in one or more of the following ways: obtain a proper signature from a subject if the subject's signature is missing; obtain proper witness or advising investigator's signatures if these signatures are missing; have the subject sign a new ICD if the signed ICD is missing. If the researcher is unable to obtain a proper signature from the subject, the board may elect to accept some other form of proof that the subject consented to participate in the study. Similarly, the board may elect to accept some other form of proof that the signature was properly witnessed if it is not possible to obtain a witness signature. If the researcher is unable to document that consent was obtained from one or more subjects, the board may instruct the researcher to destroy the data collected from these subjects.

**Survey Control Numbers (SCN) for Survey Research:**

The deadlines for investigators to submit surveys to HQ USAFA/XPX for protocols receiving full board review are listed on the IRB website. The IRB Chair automatically forwards surveys to HQ USAFA/XPX for survey approval for survey research eligible for exempt status or expedited review. Studies involving a post-experimental survey (such as a questionnaire about motion sickness symptoms after a flight simulator experiment) normally do not require a survey control number.

## **D. GUIDELINES FOR INVESTIGATORS**

### **Investigator Affiliations:**

1. Any USAFA permanent party may serve as a principal investigator on a research protocol.
2. Cadets may serve as associate investigators. Typically, the IRB requires that a member of USAFA permanent party serve as the principal investigator when one or more cadets are associate investigators.
3. AFIT and Air Officers Commanding (AOC) Masters Program graduate students may serve as associate investigators on USAFA protocols. A permanent party of the organization will be the PI on the study. These graduate students should have sponsorship through a USAFA organization, and should route the protocol through the chain of command of the organization prior to submitting it to the IRB.
4. Investigators who are not affiliated with USAFA must obtain sponsorship from a member of USAFA permanent party in order to conduct human subjects' research at USAFA.

### **Investigator Responsibilities:**

1. Become familiar with all relevant rules and regulations (32 CFR 219; Title 10 USC Section 980; DOD Directive 3216.2; AFI 40-402; AFI 40-402 USAFA Supplement 1) governing human subjects' research in the Air Force and at USAFA. Utilize the information available on the USAFA IRB website.
2. Complete training modules on the CITI website provided by USAF/SGRC.
3. Comply with all IRB requests for reports and other information in a timely manner.
4. If working with non-USAFA affiliated researchers, provide appropriate assurance numbers to the USAFA IRB.
5. Report all adverse events to the IRB chair in a timely manner.
6. Properly safeguard all data collected from human subjects.
7. Properly safeguard and account for all informed consent documents collected from human subjects.
8. Ensure that all surveys administered as a part of survey-based research have been reviewed and received a survey control number (SCN) from HQ USAFA/XPX prior to their implementation.

**Adding or Deleting Investigators or Measurement Instruments to a Protocol:**

Investigators wishing to add/delete investigators or measurement instruments to/from a protocol must submit an amendment to the IRB requesting the addition/deletion of the investigators or measurement instruments. The amendment is normally in memorandum format describing the change in sufficient detail so that the board can assess whether the amendment results in a change in the risk/benefit ratio in the original protocol. Investigators wishing to add non-USAFA investigators to the protocol should submit the appropriate assurance numbers with the amendment. Investigators wishing to add a measurement instrument should provide the board a copy of the instrument with the amendment. Investigators should be forewarned that some instruments may require a survey control number from HQ USAFA/XPX.

**Investigator Presence during the Informed Consent Process:**

Generally speaking, investigators should be present and available to answer questions during the informed consent process. In the event that there is concern that the principal investigator may exert undue influence over the subject's decision to participate (such as an instructor-student or superior-subordinate relationship), then it may be appropriate to have an associate investigator (such as a cadet assistant) administer the informed consent. Because cadets are considered vulnerable subjects (due to their position in the military hierarchy at USAFA and their status as students), it is important that they have adequate time to consider participation in a non-coercive atmosphere. The board usually recommends the following safeguards: adequate time between the recruitment/information phase and enrollment/consent phase of the study, during which potential subjects have the opportunity to consider participation and pose questions; instructors refrain from recruiting their own students; and cadet investigators refrain from recruiting potential subjects within their squadron chains of command. Investigators are reminded to be mindful of the vulnerable status of cadets as subjects and to create a respectful and non-coercive environment in which cadets may choose whether or not to consent to participate in a given study.

**Most Frequent ICD Errors:**

1. Not addressing all questions in the ICD template.
2. Not deleting all italicized template information from the completed ICD.
3. Deleting non-italicized template information. Note: If items in the template are not italicized, they must be in the final ICD in the exact same form as in the template.
4. Not writing out all acronyms before using the abbreviate form (e.g. write out Department of Behavioral Sciences and Leadership before using the abbreviation DFBL).
5. Not removing investigators' ranks.
6. Not including the total number of subjects and total time required to participate in the Purpose of the Study section of the ICD.

7. Not writing out the procedures in layperson's terms.
8. Not including the DFBL subject pool language in the Benefits section when appropriate. Listing indirect benefits in the Benefits section. The Benefits section of the ICD should only contain direct benefits. If there are no direct benefits, then say, "There are no direct benefits from participation in this study."
9. Not including the time required to participate as a Risk/Inconvenience from the study.
10. Not deleting the statements about the Research Subjects' Bill of Rights or still photography/videotaping from the Decision to Participate portion of the ICD. Note: If investigators intend to tape or use still photography, or distribute the Research Subjects Bill of Rights (available for download from the IRB website), these statements should remain in the ICD.
11. Keeping information consistent in protocol and ICD.

#### **Most Frequent Protocol Errors:**

1. Not stating specifically why there is a need for human subjects (as opposed to using existing data or computer simulations).
2. Not specifically stating the hypotheses to be tested.
3. Not providing a power analysis or other rationale for the sample size requested.
4. Not stating procedures that will be in place to deal with the diminished autonomy of cadet subjects.
5. Not stating how the study will affect availability of cadets for their daily duties.
6. Not describing how the data will be stored and disposed of.
7. Not adequately summarizing what are the risks and benefits, and why the benefits outweigh the risks.
8. Not providing recruitment material.

#### **Safeguarding Information:**

Paper records and removable computer storage media (*e.g.*, CDs, tapes) that hold private information should be secured such that the data are available only to researchers involved in the specific project. Similarly, when private data are stored on non-removable computer storage media (*e.g.*, hard disks, servers), they should be protected with passwords or similar mechanisms such that the data are available only to researchers involved in the specific project.

## **E. USAFA-SPECIFIC INFORMATION**

### **Cadets as Subjects:**

Due to their position in the military hierarchy and the instructor-student relationship, cadets are doubly vulnerable as subjects. For this reason, it is the IRB's policy to not allow cadets to participate in research that is greater than minimal risk. The IRB would consider a modification of this policy in the event that a study has the potential to greatly benefit the cadets.

### **Cadets under Age 18:**

Every year, a few four-degrees enter USAFA who are not yet 18. AFI 33-332 defines a minor as "anyone under the age of majority according to local state law. If there is no applicable state law, a minor is anyone under age 18. Military members and married persons are not minors, no matter what their chronological age." (See also AFI 44-102, para 2.10; AFI 42-210, para 6.17.2.2.) Colorado statutes define the age of majority or emancipation differently in different contexts. A minor is emancipated by joining the military when it comes to parental responsibility for financial support, medical consent, and presence at an interrogation. (See Colorado statutes 9-1-103 and 12-34-103 and Colorado state bar advice on age of emancipation). Since cadets under age 18 do not require parental consent to receive medical treatment, it is the view of the board and its legal advisors that cadets under age 18 are not considered minors for the purposes of participation in research. As with all cadets, it is the policy of the USAFA IRB that cadets under age 18 may only participate in minimal risk research. The IRB may further limit their participation to social science research surveys that are (1) much less than minimal risk; (2) would cause little embarrassment/discomfiture during completion of the survey; and (3) would cause little embarrassment/discomfiture even if the survey were accidentally disclosed. Researchers who are considering collecting data from cadet candidates before they in-process to the Academy should be forewarned that the rules governing research on minors will apply for all cadet candidates under age 18. Normally, in these circumstances the board will restrict researchers to collecting data only from those cadet candidates who have already turned 18.

### **Educational Research:**

Review of educational research is handled in the same manner as all other potentially exempt research. Researchers should use the exemption request template on the IRB website to request an exemption for educational research.

### **Payment of Cadets for Participation in Research:**

Cadets may receive money as a part of a research project as long as (1) the funds are not from a DoD source; and (2) the money is integral to the research and is not solely compensation for participation. Paragraph 3.3.1 of AFI 40-402 states, "Active duty personnel may receive financial compensation for participation as a subject of research, as long as DoD funds are not used for payment and off duty employment is authorized." Therefore, researchers may consider paying cadets in research studies as long as the funds are from a non-DoD source (such as the National Science Foundation). In addition, cadets must have approval for off duty employment.

Paragraph 1.4.8.2 of the Cadet Sight Picture prohibits cadets from participating in off duty employment except during their summer leave periods. In addition, cadets must have AOC approval for off duty employment. When the money is integral to the experimental design, as is the case in experimental economics studies in which the amount of money subjects make is a function of their decisions, then the research study is not considered employment and thus is not subject to the off duty employment rules in the Cadet Sight Picture. Researchers may not pay cadets solely for participation in a research study. These guidelines are limited to USAFA IRB-approved research. If a cadet volunteered to participate in a University of Colorado, Colorado Springs (UCCS) or other local research project that paid subjects, the participation would be considered off duty employment and would be subject to the rules of the Cadet Sight Picture.

**Pilot Studies:**

The module “What is research?” in the CITI Training module clearly states that pilot studies, such as giving a survey instrument to a few subjects in order to refine the questions, meets the definition of research in 32 CFR 219.102(d) and therefore is subject to IRB oversight. Researchers considering running pilot studies should submit a protocol for the study to the IRB for review, using the appropriate template for their study (e.g. exempt or full board review). Researchers should clearly state that the study is a pilot study in explaining the design of the research, particularly the sample size.

**ATTACHMENT 1**

**SAMPLE CORRESPONDENCE TO RESEARCHERS**

Approved Research:

- Conditionally Approved with changes
- Approved no changes
- Disapproved Research
- Tabled Research

Amendments for Research:

- Conditionally Approved with changes
- Approved no changes
- Disapproved Amendment
- Table Amendment

Exempt Status Approval:

- Conditionally Approved with changes
- Approved no changes
- Exempt Status Disapproved
- Exempt Status Tabled

Expedited Review Approval:

- Conditionally Approved with changes
- Approved no changes

Continuing Progress/Final Report Approved:

- Conditionally Approved with changes
- Approved no changes
- Continuing Progress/Final Report Disapproved
- Continuing Progress/Final Report Tabled
- Continuing Progress/Final Report Reminder

Protocol Closure

- Delinquent Required Changes
- Educational Research Exempt Final Determination
- Non-Educational Research Exempt Request Template

**SAMPLE CORRESPONDENCE TO USAF/SGRC**

USAF/SGRC Cover Letter  
OF-310



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2006033H Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your protocol, FAC2006033H, – *Research Title*, at its Meeting Date meeting. The study was conditionally approved as minimal risk pending resolution of the following:

a.

b.

c.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where the changes were made and email the changed documents to the IRB Administrator. The above required changes are due to the IRB by COB 2 October 2006. You cannot recruit subjects or begin data collection until the required changes have been completed and approved by our office. Failure to comply may result in closure of this research and suspension of further research here at USAFA.

3. Please use tracking number FAC2006033H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *name*

*date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol *FAC2006025H* Approved

1. The HQ USAFA Institutional Review Board considered your protocol *FAC2006025H*, *Title* at its *meeting date* meeting. The study and any required changes were approved as minimal risk for a maximum of 26 subjects. Please place the following statements at the bottom of your recruitment material: 'Approved: HQ USAFA IRB *FAC2006025H*.' 'Expiration date of this protocol is \_\_\_\_\_.' This will inform potential subjects that your research has been reviewed and approved. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
2. **Reminder:** The IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk but not less than once per year. **There is no grace period beyond one year from the last IRB approval date.** In order to avoid lapses in approval of your research, please submit your continuation report at least six weeks before the protocol's expiration date. **It is ultimately your responsibility to submit your research protocol in time to allow for continuing review and approval by the IRB before your protocol's expiration date.** Please keep this letter in your protocol file as proof of IRB approval and as a helpful reminder of your expiration date. Failure to comply with this requirement may result in closure of your protocol and suspension of further research here at USAFA.
3. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes should be submitted for IRB approval **before** they are implemented. You **must coordinate** all cadet-wide emails through Cadet Wing Director of Staff.
4. When you submit an annual report for this research, all original informed consent documents (ICDs) collected to date **must** accompany the report. If the ICDs are not properly executed you will not be allowed to use the data. When data collection and analysis are complete please submit your final report in a timely manner. As the principal investigator for this study, you must contact the IRB prior to departing or transferring from USAFA.
5. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2004008H Disapproved

1. The HQ USAFA Institutional Review Board considered your protocol, FAC2004008H *Research Title* at its *Meeting Date* meeting. The study was disapproved based on the following reasons:

a.

b.

2. You may appeal or respond to the Board's decision either in writing, or in person within the next 30 calendar days or at the next scheduled IRB meeting, whichever comes later. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.

3. Please use tracking number FAC2004008H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2006022H Tabled

1. The HQ USAFA Institutional Review Board considered your protocol, FAC2006022H *Research Title* at its Meeting Date meeting. The study was tabled pending resolution of the following items:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes were made and email the changed documents to the IRB Administrator. **The above required changes are due to the IRB by COB 9 February 2006.** Failure to comply may result in disapproval of this research.

3. Your protocol and the required changes will go before the Board at the next scheduled IRB meeting for re-review.

4. Please use tracking number FAC2006022H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC999999H Amendment Conditionally Approved

1. The HQ USAFA Institutional Review Board considered the amendment request for FAC9999999H, *Research Title* at its *Meeting Date* meeting. The request was conditionally approved pending resolution of the following:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes are made and email the changes to the IRB Secretary or Administrator. These requirements are due to the IRB by COB 24 November 2003. You may not be executing the terms of your amendment until the required changes have been completed and approved by our office. Failure to comply may result in disapproval of this request and closure of this research.

3. Please use the tracking number *FAC999999H* in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Amendment Approval

1. The HQ USAFA Institutional Review Board (IRB) considered your amendment request for FAC2002001H, *Title* for the inclusion of data from additional subjects. The amendment and any required changes were approved. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
2. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Amendment Disapproved

1. The HQ USAFA Institutional Review Board considered your amendment request for *FAC9999999H Title*, at its *Meeting Date* meeting. The request was disapproved based on the following reasons:

a.

b.

2. You may appeal or respond to the Board's decision either in writing, or in person within the next 30 calendar days or at the next scheduled IRB meeting, whichever comes later. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.

3. Please use tracking number FAC9999999H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Amendment Tabled

1. The HQ USAFA Institutional Review Board considered your amendment request for *FAC9999999H Title*, at its *Meeting Date* meeting. The request was tabled pending resolution of the following items:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes were made and email the changed documents to the IRB Administrator. **The above required changes are due to the IRB by COB 17 March 2004.** Failure to comply may result in disapproval of this research.

3. Your amendment request and the required changes will go before the Board for re-review at the next scheduled IRB meeting.

4. Please use tracking number FAC9999999H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Exempt Status Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your request for exempt status for FAC9999999H, *Title of Research*. Your request was conditionally approved and your study deemed exempt from IRB oversight in accordance with *32 CFR 219.101, paragraph (b)(1)(ii)*, pending resolution of the following:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where the changes were made and email the changed documents to the IRB Administrator. The above required changes are due to the IRB by COB 20 October 2003. You cannot recruit subjects or begin data collection until the required changes have been completed and approved by our office. Failure to comply may result in disapproval of this request.

3. Please use tracking number FAC9999999H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Exempt Status Approved

1. The HQ USAFA Institutional Review Board considered your request for exempt status for FAC9999999H, *Title of Research*. Your request and any required changes were approved and your study deemed exempt from IRB oversight in accordance with 32 CFR 219.101, paragraph (b)(1)(ii). The board agreed that sufficient safeguards were in place to protect research participants. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
2. The protocol will be considered closed, but will be retained in XPX for 5 years then sent to permanent storage for 25 years. As the principal investigator on the study, the Biomedical Research and Compliance Office of the Surgeon General's Office requires that you retain your data, reports, etc. for 3 years following completion of the study.
3. If the conditions under which you have been granted exempt status change, you must notify the IRB Chair or IRB Administrator immediately. We will advise you on whether additional IRB review is required. Participants must be 18 years old to participate in research.
4. Please use tracking number FAC9999999H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC1999003 Exempt Status Disapproved

1. The HQ USAFA Institutional Review Board considered your request for exempt status for FAC9999999H, *Title of Research*. Your request was disapproved as the Board determined that the protocol does not meet the requirements for exempt status in accordance with *32 CFR 219.101*.
2. The appropriate review status is: Full IRB review. Please submit a full protocol utilizing the template available on the IRB website at [www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm](http://www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm) at least 10 days prior to a scheduled meeting. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
3. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *NAME*

*DATE*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC199999H Exempt Status Request Tabled

1. The HQ USAFA Institutional Review Board considered your request for exempt status for *Title and number of research*, at its *meeting date* meeting. The request was tabled pending resolution of the following items:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes were made and email the changed documents to the IRB Administrator. **The above required changes are due to the IRB by COB 17 March 2004.** Failure to comply may result in disapproval of this research.

3. Your exempt status request and the required changes will go before the Board for re-review at the next scheduled IRB meeting.

4. Please use tracking number FAC2004008H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2001028 Expedited Review Approved

1. The HQ USAFA Institutional Review Board considered your protocol, FAC9999999H, *Title of Research*, under expedited review conditions. The protocol and any required changes were reviewed by two IRB members and approved as minimal risk for a maximum of 20 subjects, allowing you to begin your research. Please bear in mind, however, that concurrent review by the full Board at the next regularly scheduled IRB meeting is still required. Additionally, please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.

**2. Reminder:** The IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk but not less than once per year. **There is no grace period beyond one year from the last IRB approval date.** In order to avoid lapses in approval of your research and the possible suspension of subject enrollment, please submit your continuation report at least six weeks before the protocol's expiration date. **It is ultimately your responsibility to submit your research protocol in time to allow for continuing review and approval by the IRB before your protocol's expiration date.** Please keep this letter in your protocol file as proof of IRB approval and as a helpful reminder of your expiration date. Failure to comply with this requirement may result in closure of your protocol and suspension of further research here at USAFA.

3. Any problems of a serious nature should be brought to the immediate attention of the IRB, and any proposed changes should be submitted for IRB approval **before** they are implemented. You **must coordinate** all cadet-wide emails through the Cadet Wing Director of Staff.

4. When you submit an annual report for this research, all original informed consent documents collected to date **must** accompany the report. When data collection and analysis are complete please submit your final report in a timely manner. As the principal investigator for this study, you must contact the IRB prior to departing or transferring from USAFA.

5. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2001028 Expedited Review Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your protocol, FAC9999999H, *Title of Research*, under expedited review conditions. The protocol was reviewed by two IRB members and was conditionally approved as minimal risk pending resolution of the following:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where the changes were made and email the changed documents to the IRB Administrator. The above required changes are due to the IRB by COB 20 October 2003. You cannot recruit subjects or begin data collection until the required changes have been completed and approved by our office. Failure to comply may result in closure of this research and suspension of further research here at USAFA.

3. Please use tracking number FAC9999999H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC999999H Continuing Progress Report Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your continuing progress report for FAC999999H, *Research Title* at its *Meeting Date* meeting. The report was conditionally approved pending resolution of the following:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes are made and email the changes to the IRB Administrator. These requirements are due to the IRB by COB 24 November 2003. Failure to comply could result in closure of this research and suspension of further research here at USAFA.

3. Please use the tracking number *FAC999999H* in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

*Date*

FROM: HQ USAFA/IRB

SUBJECT: Protocol FAC9999999H Continuing Progress Report Approval

1. The HQ USAFA Institutional Review Board considered your continuing progress report for FAC9999999H, *Research Title* at its *Meeting Date* meeting. The report and any required changes were approved. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
2. Your next continuing progress report (continuing progress report or final report) for this protocol is due no later than 1 October 2004. **Reminder:** The IRB must review and approve all human subjects research protocols at intervals appropriate to the degree of risk but not less than once per year. **There is no grace period beyond one year from the last IRB approval date.** In order to avoid lapses in approval of your research, please submit your continuation report at least six weeks before the protocol's expiration date. **It is ultimately your responsibility to submit your research protocol in time to allow for continuing review and approval by the IRB before your protocol's expiration date.** Please keep this letter in your protocol file as proof of IRB approval and as a helpful reminder of your expiration date. Failure to comply with this requirement may result in closure of your protocol and suspension of further research here at USAFA.
3. Any adverse reactions must be brought to the immediate attention of the IRB Chair or Administrator within 24 hours, and any proposed changes should be submitted for IRB approval **before** they are implemented.
4. All original informed consent documents collected to date **must** accompany the report. When data collection and analysis are complete please submit your final report in a timely manner. As the principal investigator for this study, you must contact the IRB prior to departing or transferring from USAFA.
5. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2004008H Continuing Progress Report Tabled

1. The HQ USAFA Institutional Review Board considered your continuing progress report for *Title* at its *Meeting Date* meeting. The report was tabled pending resolution of the following items:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes were made and email the changed documents to the IRB Administrator. **The above required changes are due to the IRB by COB 17 March 2004.** Failure to comply may result in disapproval of this research.

3. Your annual report and the required changes will go before the Board for re-review at the next scheduled IRB meeting.

4. Please use tracking number FAC2004008H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2004008H Continuing Review Disapproved

1. The HQ USAFA Institutional Review Board considered your continuing/final report for *FAC2004008H Title*, at its *Meeting Date* meeting. The report was disapproved based on the following reasons:

a.

b.

2. Please address the above issues, making any required changes in the electronic version of your submissions. **HIGHLIGHT** the places where changes are made and email the changes to the IRB Secretary or Administrator. These requirements are due to the IRB by COB 24 November 2003. Failure to comply could result in closure of this research and suspension of further research here at USAFA.

3. Your updated continuing/final report will go before the Board for re-review at the next scheduled IRB meeting.

4. You may appeal or respond to the Board's decision either in writing, or in person within the next 30 calendar days or at the next scheduled IRB meeting, whichever comes later. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.

5. Please use tracking number FAC2004008H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Continuing Progress Report Reminder for FAC9999999H

1. Our records show that we have not received a final/annual report for your research protocol *FAC9999999H Title*. If the research has been completed, please send us a final report before COB 20 March 2004, with the original, signed informed consent documents. Otherwise, a continuing progress report must be submitted by the aforementioned date.
2. The report is only **one page** in length and a sample format is located on our web page: <http://www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm>
3. If you have any questions or I can be of further assistance, please don't hesitate to contact me at 333-6593.

GAIL B. ROSADO  
Institutional Review Board Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI NAME*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2002009H Delinquent Continuing Review

1. Our records show that we have not received a signed original continuing/final report and corresponding Informed Consent Documents (ICDs) for the following research protocols due between *dates*:
2. You are currently in non-compliance of IRB directives. You must suspend subject recruitment and data collection, and are not authorized to utilize any data collected until your reports and ICDs have been received and verified by our office.
3. You must forward a signed original continuing/final report with any original informed consent documents collected to date by COB 10 May 2004 for each of the protocols listed above. The reports are only **one page** in length and samples are located on our web page [www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm](http://www.usafa.af.mil/superintendent/xp/xpx/irb/index.cfm).
4. Additional notices will be sent to your Department Head. Failure to comply with this letter will result in termination of the above research, mandatory destruction of all data collected, and suspension of further research here at USAFA.
5. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2357.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR PI Name

Date

FROM: HQ USAFA/IRB

SUBJECT: Protocol FAC2004013H Final Report Approval

1. The HQ USAFA Institutional Review Board considered the final report *for FAC999999, Research Title* at its *Meeting Date* meeting. The report and any required changes were approved. Please note that the USAFA Authorized Institutional Official, HQ USAFA/CV and the Surgeon General's Human and Animal Research Panel, AF/SGRC review all USAFA IRB actions and may amend this decision or identify additional requirements.
2. The protocol will be closed but will be retained in XPX for 5 years and then sent to permanent storage for 25 years. As the Principal Investigator on this study, the Air Force Medical Services Agency requires that you retain your data, reports, etc. for 3 years following the completion of the study.
3. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR Name

Date

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC9999999H Final Report Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your final report for FAC9999999H, *Research Title* at its 30 October 2003 meeting. The report was conditionally approved pending resolution of the following:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes are made and email the changes to the IRB Administrator. These requirements are due to the IRB by COB 24 November 2003. Failure to comply may result in suspension of further research here at USAFA.

3. Please use the tracking number *FAC9999999H* in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2004008H Final Report Tabled

1. The HQ USAFA Institutional Review Board considered your final report for FAC2004008H Research Title, at its *Meeting Date* meeting. The report was tabled pending resolution of the following items:

a.

b.

2. Please make the above changes in the electronic version of your submissions, **HIGHLIGHT** the places where changes were made and email the changed documents to the IRB Administrator. **The above required changes are due to the IRB by COB 17 March 2004.** Failure to comply may result in disapproval of this research.

3. Your final report and the required changes will go before the Board for re-review at the next scheduled IRB meeting.

4. Please use tracking number FAC2004008H in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR PI Name

Date

FROM: HQ USAFA/XPX

SUBJECT: Protocol Closure

1. The HQ USAFA Institutional Review Board considered the final report for your protocol FAC2001022H Title of Study at its Meeting Date meeting. The report was accepted and the protocol was closed.
2. The protocol will be retained in XPX for 5 years from the date of closure and then sent to permanent storage for 25 years.
3. As the primary investigator on the study, the AF/SGRC requires that you retain your data, reports, etc. for 3 years following completion of the study.
4. If you have any questions or I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI NAME*

*Date*

FROM: HQ USAFA/XPX

SUBJECT: Protocol FAC2003002 Delinquent Required Changes

1. Our records show that we have not received the changes required by the IRB for your (*protocol, annual report, final report, amendment, exemption request, expedited review request*) for FAC2002002, *Title*. You cannot recruit subjects or begin data collection until the required changes have been completed and approved by our office.
2. You must forward the required changes by COB 20 October 2003. Additional notices will be sent to your Department Head. Failure to comply with this letter may result in (*closure, disapproval*) of this research and suspension of further research here at USAFA.
3. Please use the tracking number *FAC999999H* in any correspondence regarding this protocol. If you have any questions or if I can be of further assistance, please don't hesitate to contact me at 333-6593 or the IRB Chair, Dr. Kate Carson at 333-2597.

GAIL B. ROSADO  
HQ USAFA IRB Administrator

\_\_\_\_\_ (date) \_\_\_\_\_

MEMORANDUM FOR HQ USAFA IRB (Dr. Silz Carson)

FROM: \_\_\_\_\_ (Department Head) \_\_\_\_\_

SUBJECT: Request for Educational Research Exemption Final Determination

1. Under the authority of AFI 40-402, *Protection of Human Subjects in Biomedical and Behavioral Research*, USAFA Supplement 1, paragraph 2.6.4, and 32 Code of Federal Regulations (CFR), Part 219.101, the following information is provided:

a. \_\_\_\_\_ (name & rank) \_\_\_\_\_, DF \_\_\_\_\_, is conducting research within the Department of \_\_\_\_\_ involving human subjects.

b. The research \_\_\_\_\_ (title) \_\_\_\_\_ involves \_\_\_\_\_ (provide general description) \_\_\_\_\_

c. The type of funding mechanism for this research is \_\_\_\_\_ (indicate grant, contract, fellowship, cooperative agreement, or other – specify) \_\_\_\_\_

2. **I request a final determination that the above educational research is exempt from IRB oversight.** In my opinion, the only involvement of human subjects in this educational research activity is in one or more of the following categories: (check all that apply)

a.  Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as research on regular and special education instructional strategies, or research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods.

b.  Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement). I further find that information obtained is recorded in such a manner that human subjects cannot be identified directly or through identifiers linked to the subjects; or that any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

c.  Research involving the collection or study of existing educational data, documents, or records which are publicly available or the information is recorded by the investigator is in such a manner that subjects cannot be identified directly or through identifiers linked to the subjects.

| \_\_\_\_\_  
<Signature Block of Dept Head/Appropriate Authority>

\*\*The information above must be provided to the USAFA IRB, via the IRB Chair, Dr. Katherine Silz Carson (333-2597) no later than 7 days after exempt status has been preliminarily determined.

***Non-Educational Research Exemption Request Template***

*July 2006*

- *Format the protocol as a memorandum, on letterhead, addressed to the USAFA IRB (Dr. Silz Carson).*
- *Address all issues, below, using the paragraph structure shown. Use boldface for headings, as shown. Enter information for all headings, even if it is just "NA."*
- *Replace the italicized comments with your text and **do not remove any non-italicized words or statements unless told to do so in the template text.***
- *The IRB Chair (Dr. Silz Carson, 3-2597) will reply with a decision on whether or not the exemption request is granted.*

---

*Date*  
Exemption Request Template

**MEMORANDUM FOR:** USAFA IRB (Dr. Silz Carson)

**FROM:** *Principal Investigator (Must be USAFA personnel)*

**SUBJECT:** Request for Non-Educational Research Exemption Final Determination

**1. Administrative Information**

**Title of protocol:** *Title*

**Principal investigator:** *Name, Rank (Must be USAFA personnel)*  
*Position*  
*Telephone number*  
*E-mail address*

**Associate investigator(s):** *Name(s), Rank(s); or NA*  
*Position(s)*  
*Telephone number(s)*  
*E-mail address(es)*

**Organization:** *Name (usually a Department)*  
*Telephone number*  
*Organization's protocol identifier, if used*

**Note to researcher:** *If your research is "educational research," then your department head may make a recommendation directly to the IRB about whether or not your research is exempt. See the department head exemption form template on the IRB website (<http://www.usafa.af.mil/superintendent/xp/xpx/irb/links.cfm>) for categories that are eligible for department head exemption. If you think your research qualifies as educational research, **DO NOT** complete **THIS** template.*

*Educational research is generally research conducted in established or commonly accepted educational settings involving normal educational practices; research involving the use of*

*educational tests (cognitive, diagnostic, aptitude, achievement); or research involving the collection or study of existing educational data, documents, or records.*

**Category for exemption:**

*32 CFR 219.101(b) allows for research in the following categories to be exempt.*

**Choose the category below that is most appropriate for your research, change it from italic to standard font, and delete the other categories.**

*32 CFR 219.101(b):*

*(2) Research involving the use of survey procedures, interview procedures or observation of public behavior, unless:*

*(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and*

*(ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.*

*(3) Research involving the use of survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section if:*

*(i) The human subjects are elected or appointed public officials or candidates for public office; or*

*(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.*

*(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.*

*(5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:*

*(i) Public benefit or service programs;*

*(ii) Procedures for obtaining benefits or services under those programs;*

*(iii) Possible changes in or alternatives to those programs or procedures; or*

*(iv) Possible changes in methods or levels of payment for benefits or services under those programs.*

*(6) Taste and food quality evaluation and consumer acceptance studies,*

*(i) If wholesome foods without additives are consumed or*

*(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.*

**2. Summary of Research**

*Summarize the research in enough detail that the Chair can make a determination as to the project's exempt status. Researchers should briefly address:*

- *Background, rationale, and objectives*
- *Specific hypotheses*
- *Type of research and the study design*
- *Experimental and recruitment procedures, particularly addressing the diminished autonomy of cadets and how the researcher will ensure that participation is voluntary*
- *How the data are de-identified, if applicable*
- *If the data are identifiable, how the researcher will maintain confidentiality, and why disclosure of the data would not put the subjects at any risk*
- *Total time required of subjects for participation*
- *Total number of subjects with a rationale for the sample size*
- *How participation will affect availability for duty of military personnel*
- *Cite any relevant references from the literature*

### **3. Attachments**

- *Supporting documents (if applicable). These must include recruiting materials, questionnaires, rating scales, documents from other IRBs, etc.*
  - *Note: Exempt protocols employing questionnaires and surveys are still subject to review by XPX for quality and acceptability. Upon approval, XPX will issue a survey control number (SCN) for the questionnaires and surveys. The SCN must be shown on all surveys, questionnaires and informed consent documents used in the project. Researchers should refer to the IRB website (<http://www.usafa.af.mil/superintendent/xp/xpx/irb/relatedlinks.cfm>) and USAFAI 36-2601 for information on submitting survey materials for approval. The chair will not grant any exemption requests without a survey approval from XPX.*

*//Signed//*

*RESEARCHER'S SIGNATURE BLOCK*



DEPARTMENT OF THE AIR FORCE  
HEADQUARTERS UNITED STATES AIR FORCE ACADEMY  
USAF ACADEMY COLORADO

MEMORANDUM FOR AF/SGRC

29 April 2003

FROM: HQ USAFA/XPX  
2304 Cadet Drive, Suite 3800  
USAF Academy CO 80840-5002

SUBJECT: USAFA Institutional Review Board (IRB) Action

1. USAFA protocol FAC2003014H, "*Research Title*" is being forwarded for your information. The USAFA Institutional Review Board approved the protocol on 24 April 2003. Excerpts of meeting minutes are included with the attached protocol package.

KATHERINE SILZ CARSON, PhD  
Chair, Institutional Review Board

2. USAFA protocol FAC2003011H (*did/did not*) require modifications by the USAFA Institutional Review Board. If modifications were required, changes were verified and are highlighted in the protocol and ICD. The commander's approval was obtained on 12 May 2003. The researcher was notified of final approval on the same date.

GAIL B. ROSADO  
USAFA Institutional Review Board  
Administrator

3. I have reviewed the informed consent document to protocol FAC2003009H and determined it to be legally sufficient.

PAUL E. PIROG, Colonel, USAF  
USAFA Institutional Review Board  
Legal Representative

Attachment:  
Protocol Package

## Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption (Common Rule)

*Policy:* Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type <input type="checkbox"/> ORIGINAL <input type="checkbox"/> CONTINUATION <input type="checkbox"/> EXEMPTION	2. Type of Mechanism <input type="checkbox"/> GRANT <input type="checkbox"/> CONTRACT <input type="checkbox"/> FELLOWSHIP <input type="checkbox"/> COOPERATIVE AGREEMENT <input checked="" type="checkbox"/> OTHER:	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No. HQ USAFA/XPX FAC2002001H
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project (*Respond to one of the following*)

- This Assurance, on file with Department of Health and Human Services, covers this activity:  
 Assurance Identification No. \_\_\_\_\_, the expiration date \_\_\_\_\_ IRB Registration No. \_\_\_\_\_
- This Assurance, on file with (*agency/dept*) AF/SGRC, covers this activity. Assurance No. 50046, IRB Registration/Identification No. \_\_\_\_\_
- No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.
- Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph (2)

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

- This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.  
 by:  Full IRB Review on \_\_\_\_\_ or  Expedited Review on \_\_\_\_\_  
 If less than one year approval, provide expiration date \_\_\_\_\_
- This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution DEPARTMENT OF THE AIR FORCE HQ USAFA/XPX 2304 Cadet Drive, Suite 3800 USAF Academy, CO 80840-5002
11. Phone No. ( <i>with area code</i> )      719-333-6593 12. Fax No. ( <i>with area code</i> )        719-333-4309 13. Email: Gail.rosado@USAFA.AF.MIL	15. Title Institutional Review Board Administrator
14. Name of Official Gail Rosado	17. Date
16. Signature	

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