

# **INSTITUTIONAL REVIEW BOARD POLICIES 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 Procedure 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*. HQ AF/SGRC audits a sample of minimal risk USAFA protocols and reviews all greater than minimal risk protocols. HQ AF/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 AFI 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 in 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 those in 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 HQ AF/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 Principal Investigator (PI). All communication between investigators and HQ AF/SGRC will flow through the IRB Chair. The IRB is informed of any changes requested by HQ AF/SGRC and the Chair's/PI's response at the next scheduled IRB meeting.
3. The Board will determine the continuing review of research at intervals appropriate to the degree of risk, but not less than once per year.

### **Institutional Review Board Responsibilities:**

1. 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).
2. The IRB shall provide for the indefinite maintenance of records relating to each specific research activity.
3. IRB records shall be accessible for inspection and copying by authorized representatives of HQ USAF/SGRC at reasonable times and in a reasonable manner, or shall be copied and forwarded to HQ USAF/SGRC when requested by authorized HQ USAF/SGRC representatives.

### **B. BOARD MEMBERS**

#### **IRB Members:**

Requirements for IRB membership are outlined in 32 CFR 219.107, AFI 40-402 USAFA Supplement 1 and the Multiple Project Assurance (MPA).

#### **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. At least annually, the chair or an appointed representative of the chair shall randomly select and spot check active research study records and consent processes in accordance with the procedures outlined in AFI 40-402, para. 2.6.12.
5. 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.
6. Reviews and approves all IRB minutes and letters from the IRB to investigators.
7. Handles all communication between investigators and HQ AF/SGRC.

**IRB Member Responsibilities:**

1. Must provide a current Curriculum Resume/Vitea 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 (principal investigator (PI), associate investigator (AI), 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 HQ AF/SGRC in a 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.

## **Administrator Responsibilities:**

The administrator shall receive from the research investigators through their department heads all research protocols which involve human subjects.

1. The chair will review all research studies that qualify for exemption from coverage under 32 CFR 219.101 approve/disapprove.
2. The administrator shall forward all nonexempt research protocols to board members for review 10 days prior to the monthly meeting.
3. All research protocols, except exempt, approved by the IRB will be forwarded to HQ AF/SGRC by the administrator. (The Surgeon General's Research Oversight Committee must approve all greater than minimal risk protocols prior to initiation and must concur with minimal risk protocols although they may be initiated upon local approval.) When an IRB approves a protocol on condition that the research investigator make modifications to the protocol, the administrator shall not forward the protocol to HQ AF/SGRC until determined that such modifications are made. As appropriate, the administrator and the chair may negotiate protocol modifications with the research investigator. Each protocol submitted to HQ AF/SGRC must include:

(a) Certification that the research was reviewed and approved by the IRB, established under this assurance (Note: The identification numbers of this assurance and the IRB must be included in the certification, see Form 310); or

(b) Certification that the research was reviewed and approved by an IRB established under another assurance (Note: The identification numbers of the approving IRB and the assurance under which it was established along with a copy of the signed agreement); or

(c) Notification that the research was determined to be exempt from coverage under 32 CFR 219 or that 32 CFR 219 is otherwise not applicable on Form 310.

(d) The administrator shall keep research investigators aware of decisions and administrative processing affecting their respective protocols.

(e) The administrator will prepare and maintain documentation of all IRB activities, to include the following:

(1) Copies of all research proposals reviewed, scientific evaluations (if any) that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.

(2) Minutes of IRB meetings which include the names of attendees at the meetings; members present and absent at the meeting as required by 32 CFR 219.103(b)(3); actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving research; a written summary of the discussion of controverted issues and their resolution; and dissenting reports and opinions. If a member in attendance has a

conflict of interest regarding any project, the minutes shall show that this member did not participate in the review, except to provide information requested by the IRB.

(3) Records of continuing review activities.

(4) Copies of all correspondence between the IRB and the research investigators.

(5) Statements of significant new findings provided to subjects as required by 32 CFR 219.116(b)(5).

(6) Written procedures for the IRB as required by 32 CFR 46.103(b)(4).

### **Orientation and Education of Members:**

1. New members to the Board are recommended from current members or department heads. For new cadet board members, a letter is sent out to all department heads asking them for recommendations for cadets to be on the board. The Department Heads will look for cadets with a unique learning and leadership experience and insight into the research process. Cadets from all academic majors are eligible to serve as members of the board.

2. New members to the Board will receive orientation to their duties from the IRB Administrator and training through the CITI Training provided by HQ AF/SGRC.

3. 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.

4. 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 third Friday unless otherwise changed by the membership. Additional meetings may be convened at any time upon the request of the Chairperson. The meeting minutes will be emailed to all board members for their concurrence prior to being forwarded to the AIO for his review and approval and then sent to HQ AF/SGRC. The minutes will be voted on at the next convened meeting.

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

1. Requirements for a quorum and for approval of an agenda item are discussed in accordance with 32 CFR 219.108(b).
2. Research protocols scheduled for review shall be distributed or otherwise made available to all members of the IRB prior to the meeting. When it is determined that consultants or experts will be required to advise the IRB in its review of a protocol, the research protocol shall also be distributed or otherwise made available to the consultants prior to the meeting.
3. 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 alternates who are present at the meeting. Members may not submit proxy votes if they are not present. 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, 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. For a research protocol to be approved it must receive the approval of a majority of those members present at the convened meeting.
4. 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.
5. When the minutes are forwarded to the AIO anything that the board determines as a concern to the institution will be flagged for the AIO's review. The AIO has requested that all minutes be sent to USAFA/JA prior to his review.
6. The board will provide a letter to investigators documenting the board's discussion and any decisions taken whenever a protocol is discussed at a meeting, even if a formal vote on the decision is not required.

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

1. 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.
2. All appeals should be addressed to the IRB Chairperson and sent to HQ USAFA/XPR. The appeal should address reasons for disapproval and provide substantive information (e.g. new information) for why the board should reconsider the decision.
3. 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.
4. If the AIO disapproves a study based on what is best for the institution, but the study was approved by the IRB for the protection of human subjects then the appeal will be sent to the AIO for review.

5. If the appeal is disapproved by the AIO and the board then the protocol will be closed. The PI can send in a new revised study using another protocol number.

### **Compliance/Non-Compliance:**

1. **Continuing/Final Review:** A request for a continuing review 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.

### **4. Reporting Changes in the Research:**

a. Research investigators are responsible for reporting promptly through their department heads to the IRB proposed changes in a research activity.

b. Changes in research during the period for which IRB approval has already been given, shall not be initiated by research investigators without IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subject.

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

The deadlines for investigators to submit surveys to XPA for protocols receiving full board review are listed on the IRB website. The IRB Chair automatically forwards surveys to XPA 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 AOC Masters Program graduate students may serve as investigators on USAFA protocols. 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 USCR 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 HQ AF/SGRC annually.
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. Reporting of Noncompliance: Research investigators and department heads are responsible for reporting promptly to the IRB any serious or continuing noncompliance with the requirements of this assurance or the determinations of the IRB.
6. Department heads, through appropriate procedures established within their respective departments, are responsible for reviewing research protocols for ethical considerations and scientific merit.

7. Report all adverse events (AE) to the IRB chair in a timely manner. Serious, expected or unexpected adverse events must also be forwarded to the AIO. Serious, unexpected and related adverse events must be sent to AF/SGRC as soon as possible, but within 15 working days of being notified of the adverse event. The IRB will review the incident to evaluate the effect of the adverse event on the risks of harm to other research subjects and determine if a change in procedures/consent document is warranted. The PI will report the AE using the FDA MedWatch Form 3500 or equivalent and submit the form to the IRB for review of the incident.
8. Properly safeguard all data collected from human subjects.
9. Ensure that informed consent is obtained from all subjects in accordance with 32 CFR 219.116.
10. Ensure that consent is obtained from the subject or the subject's legally authorized representative prior to the subject's participation in the research. No subject may participate in research prior to the obtaining of consent.
11. Ensure that the consent is in language that is understandable to the subject or the subject's representative, and that consent is obtained under circumstances that offer the subject or the subject's representative sufficient opportunity to consider whether the subject should or should not participate.
12. Properly safeguard and account for all informed consent documents collected from human subjects.
13. Ensure that all surveys administered as a part of survey-based research have been reviewed and received a survey control number (SCN) from USAFA/XPA 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 should 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 USAFA/XPA.

#### **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.

### **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.

### **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 at 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
- Amendment Tabled

#### Exempt Status Approval:

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

#### Expedited Review Approval

- Conditionally Approved with changes
- Approved no changes
- Expedited Review Disapproval

#### Continuing Progress Report Approved

- Conditionally Approved with changes
- Approved no changes
- Continuing Progress Report Tabled
- Continuing Progress Report Reminder

### SAMPLE CORRESPONDENCE TO HQ AF/SGRC

HQ AF/SGRC Cover Letter

OF-310



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *PI Name*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your protocol, **FAC9999999H**, – *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 **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. Wilbur Scott at 333-6740.

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/XPN

SUBJECT: Protocol **FAC999999H** Approved

1. The HQ USAFA Institutional Review Board considered your protocol *Protocol number, Research title* at its *meeting date* meeting. The study and any required changes were approved as minimal risk for a maximum of *100* subjects. Please place the following statements at the bottom of your recruitment material and informed consent document (ICD): 'Approved: HQ USAFA IRB FAC999999H.' 'Expiration date of this protocol is *1 July 2008*.' 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 Research Oversight and Compliance Division, 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 Director of Staff for the Cadet Wing.

4. When you submit an annual report for this research, all original 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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Disapproved

1. The HQ USAFA Institutional Review Board considered your protocol, **FAC9999999H 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 **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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol FAC9999999H Tabled

1. The HQ USAFA Institutional Review Board considered your protocol, FAC9999999H *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 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. Wilbur Scott at 333-6740.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

FROM: HQ USAFA/XPN

SUBJECT: Protocol *FAC999999H* Amendment Conditionally Approved

1. The HQ USAFA Institutional Review Board considered the amendment request for *FAC999999H*, *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 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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Amendment Approval

1. The HQ USAFA Institutional Review Board (IRB) considered your amendment request for **FAC99999999H, 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 Research Oversight & Compliance Division, 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 Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

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. Wilbur Scott at 333-6740.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR **Name**

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Exempt Status

1. The HQ USAFA Institutional Review Board considered your request for exempt status for **FAC99999999H, Title of Research**. Your request was 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 **FAC99999999H** 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. Wilbur Scott at 333-6740.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR **Name**

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Exempt Status

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 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 Research Oversight and Compliance Division, 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 XPN 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.
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. Wilbur Scott at 333-6740.

GAIL B. ROSADO  
HQ USAFA IRB Administrator



## DEPARTMENT OF THE AIR FORCE

HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

USAF ACADEMY COLORADO

MEMORANDUM FOR *Name*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Exempt Status Disapproved

1. The HQ USAFA Institutional Review Board considered your request for exempt status for **FAC99999999H, 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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPNR

SUBJECT: Protocol **FAC9999999H** 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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** 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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol **FAC9999999H** Expedited Review Disapproved

1. The HQ USAFA Institutional Review Board considered your protocol, **FAC9999999H Research Title** via expedited review. 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 **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. Wilbur Scott at 333-6740.

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/XPN

SUBJECT: Protocol **FAC9999999H** Continuing Progress Report Conditionally Approved

1. The HQ USAFA Institutional Review Board considered your continuing progress report for **FAC9999999H**, *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 **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. Wilbur Scott at 333-6740.

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/XPN

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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

SUBJECT: Protocol *FAC9999999H* 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 *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. Wilbur Scott at 333-6740.

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*

FROM: HQ USAFA/XPN

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  
HQ USAFA IRB Administrator



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

MEMORANDUM FOR AF/SGRC

Date

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

SUBJECT: USAFA Institutional Review Board (IRB) Action

1. USAFA protocol FAC9999999H, "*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.

WILBUR SCOTT, PhD  
HQ USAFA Institutional Review Board  
Chair

2. USAFA protocol FAC9999999H (*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  
HQ USAFA Institutional Review Board  
Administrator

3. I have reviewed the informed consent document to protocol FAC9999999H and determined it to be legally sufficient.

PAUL E. PIROG, Colonel, USAF  
HQ 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 type="checkbox"/> OTHER:	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
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/XPN	
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.EDU	2304 Cadet Drive, Suite 3800 USAF Academy, CO 80840-5002	
14. Name of Official: Gail Rosado	15. Title: Institutional Review Board Administrator	
16. Signature	17. Date	

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