

**BY ORDER OF THE
SUPERINTENDENT**



**HQ UNITED STATES AIR FORCE ACADEMY
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Medical Command

**HQ USAFA INSTITUTIONAL REVIEW BOARD
(IRB)**

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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(Dr. Kathleen A. O'Donnell)
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(Lt Col Daniel J. Zalewski)
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This instruction implements AFD40-1, *Health Promotion*, and references AFI40-402, *Protection of Human Subjects in Biomedical and Behavioral Research*. It provides guidance for the use of human subjects in research, development, test, and evaluation (RDT&E) conducted or funded by the Air Force. It applies to all United States Air Force Academy (USAFA) personnel conducting research with human participants.

SUMMARY OF REVISIONS

This document was updated to clarify changes in the requirements for expedited review requests and create a schedule for meetings of the Institutional Review Board. All acronyms throughout this publication were defined, and paragraphs were renumbered to ensure format consistency. An (I) indicates changes from the previous version, 21 February 2002.

1. The Institutional Review Board (IRB). The IRB provides compliance oversight concerning the policies and procedures governing the conduct of research involving human participants at the US Air Force Academy (USAFA). The Authorized Institutional Official (AIO) for the USAFA IRB and all matters related to the ethical treatment of human research participants is the USAFA Headquarters Director of Staff (HQ USAFA/DS). The Directorate of Plans and Programs, Institutional Research and Assessment Division (HQ USAFA/XPR) provides implementation and administration.

1.1. **Regulatory Basis.** Federal law requires that specific policies and procedures be followed in the use of human participants in research. These are found in Title 32 US Code of Federal Regulations, Part 219; *Protection of Human Subjects*, corollary is Title 45, US Code, Part 46 (Subpart A) and Title 21, US Code of Federal Regulations, Parts 50 and 56. These regulations are supplemented and interpreted for military institutions by AFI40-402. Collectively, these regulations provide the basis for the establishment and operation of the IRB at USAFA.

1.2. **IRB Oversight.** Federal regulation requires that any institution sponsoring research involving human participants apply to the Department of Health and Human Services for a *Project Assurance*. *Project Assurance* is a specific delegation of authority to the institution to conduct research involving human participants. The Air Force Biomedical Research Regulatory Division (USAF/SGXC) is responsible for implementing federal regulations governing human research in the Air Force. USAF/SGXC has officially delegated the authority to approve and monitor human research at USAFA to HQ USAFA/DS via the USAFA *Project Assurance*. USAF/SGXC reviews all USAFA IRB decisions and provides continuing oversight of local IRB operations. This oversight includes periodic inspections and assistance in interpreting and implementing applicable regulations.

1.3. **Organization of the IRB.** Federal law requires that an IRB have at least 5 members. The exact size and composition of the IRB is determined locally and is influenced by the nature of the research conducted at a particular institution. All IRB members are to come to every IRB meeting. When unable to attend, members are to notify the IRB Administrator no less than 3 days prior to the next IRB meeting. A quorum is required to conduct official IRB business. A quorum consists of a scientist, a nonscientist and at least 2 other members. HQ USAFA/DS appoints all IRB members with a letter to USAF/SGXC. Appointment terms are as follows: cadets are appointed for a 1-year term, 34th Training Wing (34 TRW) members are appointed for a 2-year term, and remaining members are appointed for a 3-year term. All terms are renewable by HQ USAFA/DS. Removal of an IRB member requires recommendation from the IRB Chair and a letter from HQ USAFA/DS. For each of the categories below, the HQ USAFA/DS may choose to appoint 1 or more individuals to the IRB at any time. The exact number of IRB members, therefore, may vary. At USAFA, the IRB is composed of the following:

1.3.1. **The Chairperson.** The Chairperson presides over the monthly IRB meeting. The Chairperson has the authority to assign IRB members as expedited reviewers. The Chairperson and Vice Chairperson are required to have prior experience as an IRB member or IRB Chairperson.

1.3.2. **Institutional Policy.** At least 1 member of the IRB must have the background and experience necessary to assist the IRB in understanding those aspects of USAFA organization, policies, procedures, and past practice essential to a full consideration of issues relevant to human research.

1.3.3. **Legal.** At least 1 IRB member must be an attorney. This member provides expert advice to the IRB in interpreting applicable legal standards.

1.3.4. **Professional Standards.** At least 1 IRB member must be a medical professional, preferably a physician. This member advises the IRB on clinical and medical practice issues and professional standards.

1.3.5. **Scientist.** At least 1 IRB member must be a scientist. This member is normally an experienced principal investigator who advises the IRB on issues of scientific methodology and professional standards.

1.3.6. **34 TRW Representative.** At least 1 representative of 34 TRW will serve on the IRB to advise the IRB on Cadet Wing policies, procedures, and issues pertinent to cadet participation in human research.

1.3.7. **Nonaffiliated Representative.** At least 1 member of the IRB must have no official connection with USAFA. This member provides a disinterested perspective to the IRB and represents the community's interests.

1.3.8. Cadet Representative. At least 1 cadet will serve on the IRB to ensure that the interests of cadets, the primary source of participants in human research at USAFA, are represented.

1.4. Specific Responsibilities of the IRB:

1.4.1. The primary responsibility of the IRB is to review research protocols for all research involving human participants at USAFA. The review process is governed by the applicable Federal regulations, primarily 45 Code of Federal Regulations (CFR) 46 and 32 CFR 219. This review focuses on ensuring that the ethical principles embodied in Federal regulations are upheld. These principles are:

1.4.1.1. The Principle of Respect for Persons. Respect for persons incorporates at least 2 ethical convictions: (1) that individuals should be treated as autonomous agents, and (2), that persons with diminished autonomy are entitled to protection. At the Air Force Academy, we are especially mindful of cadets' vulnerability both as military members and as students.

1.4.1.2. The Principle of Beneficence. This principle states that persons are treated in an ethical manner, not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. The general rule of beneficent actions is maximize possible benefits, and minimize possible harms.

1.4.1.3. The principle of Justice. The question of justice is who ought to receive the benefits of research and bear its burdens? An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

1.4.2. As a final statement as to the purpose of any IRB, the Declaration of Helsinki provides a concise summary: *"Concern for the interests of the subject (participant) must always prevail over the interests of science and society."*

1.4.3. The IRB is responsible for providing continuing review (at least annually) on all protocols approved at USAFA.

1.4.4. The IRB is responsible for maintaining detailed records pertaining to the review process, including, copies of all protocols submitted; documentation of the review of each protocol and the issues discussed during the review; the disposition of the protocol; copies of all signed Informed Consent Documents (ICD) executed during the conduct of the protocol, and other relevant documents and correspondence. Requirements are outlined in AFI37-138, *Records Disposition-- Procedures and Responsibilities* and AFMAN37-139, *Records Disposition Schedule*.

1.4.5. The IRB advises the HQ USAFA/DS as required on the participation of humans in research activities.

2. The Scope of Activities Covered by the IRB. The IRB is responsible for all research activities involving human participants conducted at, or sponsored by, USAFA. Research is defined as a systematic investigation, including research, development, testing and evaluation, designed to develop or contribute to generalizable knowledge (**32 CFR 219**). A human subject or participant is a living individual about whom an investigator conducting research obtains (1) data through intervention with the individual or (2) identifiable private information. All such activities taking place at USAFA are subject to IRB oversight and must comply with the provisions of this instruction. Researchers outside USAFA wishing to use USAFA personnel as research subjects must obtain a USAFA sponsor and comply with all aspects of this instruction. Research investigators and Department Heads are responsible for making the determination

as to whether an activity is research involving human subjects. For the purposes of this instruction, the term "Department Heads" refers to the heads of the academic departments in DF, and to other officials at USAFA responsible for research oversight. When it is not clear whether the activity is research involving human subjects, research investigators should seek assistance from the IRB Administrator and the IRB in making this determination.

2.1. Exempt Research. Research involving human subjects may be exempted from IRB oversight if 1 of the following criteria is met, unless data is being obtained from 4th-class cadets by upper-class cadets.

2.1.1. 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.

2.1.2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, (see USAFAI36-2601, *USAFA Survey Program*, for Academy Survey guidance), interview procedures, or observation of public behavior unless:

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

2.1.2.2. 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, or the topic of the research includes ethical behaviors (e.g., honor-code related), sexual orientation or behaviors, or drug or alcohol use.

2.1.3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures (see USAFAI36-2601, *USAFA Survey Program*), interview procedures, or observation of public behavior that is not exempted elsewhere if:

2.1.3.1. The human subjects are elected or appointed officials or candidates for public office or,

2.1.3.2. Federal Statutes requires without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

2.1.4. 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.

2.1.5. 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:

2.1.5.1. Public benefit or service programs.

2.1.5.2. Procedures for obtaining benefits or services under those programs.

2.1.5.3. Possible changes in or alternatives to those programs or procedures or,

2.1.5.4. Possible changes in methods of levels of payment for benefits or services under those programs.

2.1.5.5. Taste and food quality evaluation and consumer acceptance studies if wholesome

foods without additives are consumed.

2.1.6. For educational research conducted within a single department, the determination of exempt status rests with the Department Head (head of a DF academic department, the Commander of the 34th Education Group (34 EDG/CC), the Director of Athletic Programs (34 TRW/AHP), and the Preparatory School Academic Dean (HQ USAFA/PLD). All Department Heads must attend an initial training briefing provided by the IRB and annual update briefings thereafter. In addition, Department Heads shall provide the IRB annually with a list of studies (including a brief description) that were determined exempt as educational research.

2.1.7. Final determination of exempt status for all research not covered under paragraph 2.1.6. may only be made by the IRB. A summary of the proposed research and justification for exemption should be submitted to the IRB Chairperson. The Chairperson will review the summary and consult with other IRB members as appropriate in making the determination as to exempt status. The summary and the determination will be presented to the full IRB for discussion and comment as soon as practicable.

2.2. Research Eligible For Expedited Review:

2.2.1. The policy of the USAFA IRB is to review all protocols at the monthly meetings. However, if circumstances require review prior to the next convened meeting, some research may be eligible for expedited review. Expedited review is a streamlined procedure whereby a research protocol involving no more than “minimal risk” may be reviewed by a subset of the IRB (as determined by the Chairperson or Vice Chairperson) outside of a convened IRB meeting. “Minimal risk” is defined as a level of risk not greater than that encountered in normal activities of daily living or work. Provisional approval of the protocol may be granted pending approval at the next convened meeting of the IRB. Protocols that are not recommended for approval under the expedited review process will be submitted to the full IRB for consideration.

2.2.1.1. The IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

2.2.1.2. The only other research for which the IRB may use an expedited review procedure is that which involves no more than minimal risk to the subjects and in which the only involvement of human subjects will be in 1 or more of the following categories:

2.2.1.2.1. Collection of hair and nail clippings, in a non-disfiguring manner, deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

2.2.1.2.2. Collection of excreta and external secretions including sweat, uncannulated saliva, placenta removed at delivery, and amniotic fluid at the time of rupture of the membrane prior to or during labor.

2.2.1.2.3. Recording of data from adult subjects using noninvasive procedures routinely employed in clinical practice. This includes the use of physical sensors that are applied either to the surface of the body or at a distance and do not involve input of matter or significant amounts of energy into the subject or an invasion of the subject's privacy. It also includes such procedures as weighing, testing sensory acuity, electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, diagnostic echography, and electroretinography. It does not include exposure to electromagnetic radiation outside the visible range (for example, x-rays, and microwaves).

2.2.1.2.4. Collection of blood samples by venipuncture, in amounts not exceeding 450 milliliters in an 8-week period and no more often than 2 times per week, from subjects 18 years of age or older and who are in good health and not pregnant.

2.2.1.2.5. Collection of both supra- and sub gingival dental plaque and calculus, provided the procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques.

2.2.1.2.6. Voice recordings made for research purposes such as investigations of speech defects.

2.2.1.2.7. Moderate exercise by healthy volunteers.

2.2.1.2.8. The study of existing data, documents, records, pathological specimens, or diagnostic specimens.

2.2.1.2.9. Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.

2.2.1.3. To obtain expedited review, a protocol package must be submitted to the IRB Administrator with a cover letter justifying the request for expedited review of the protocol. The protocol package must contain a hardcopy version of the protocol with original signatures, an electronic form of the protocol and 2 additional hardcopies of the protocol.

2.2.1.4. The research investigator will receive a letter from the IRB Administrator within 10 workdays stating the results of the expedited review.

2.2.1.5. All other research involving human subjects is subject to full review. When an investigator requests expedited review for a protocol that would normally be subject to full review, the request should include a justification for out-of-cycle review endorsed by the investigator's Department Head.

2.3. Procedures for Full Review of Research Protocols at USAFA:

2.3.1. The IRB will normally meet once each month. Meeting dates are announced on the IRB website <http://www.usafa.af.mil/irb> and posted 6 months in advance. IRB meetings are open to all interested parties, though the IRB may conduct certain business in Executive Session (without outside observers), as appropriate. IRB members can request review of any protocol by a special consultant(s). Principal investigators or their representatives should make every effort to attend the IRB meeting at which their protocol will be considered. Past practice has shown that delays in approval are minimized when the investigator is available to answer questions or make clarifications for IRB members.

2.3.1.1. A protocol package must be submitted to the IRB Administrator not less than 10 workdays prior to the date of the IRB meeting at which the protocol is to be considered. The package must contain a hardcopy version of the protocol with original signatures, an electronic form of the protocol, and enough hardcopies of the protocol for each IRB member to receive an individual copy. The list of current IRB members is posted on the IRB website stated in paragraph **3.1**.

2.3.1.2. Research investigators must use the protocol template and informed consent docu-

ment officially approved by USAF/SGXC. The most recent versions of these are posted on the IRB website. Any questions regarding format or content of protocols or Informed Consent Documents may be addressed to the IRB Administrator. Additional guidance to assist investigators in the preparation of materials for submission to the IRB may occasionally be posted on the IRB website, currently located at <http://www.usafa.af.mil/irb>. Since these documents are occasionally revised, the research investigator must use the current website version of these documents each time a new protocol is prepared.

2.3.2. IRB responsibilities focus on compliance with ethical standards established in Federal regulations. Scientific merit of proposed research is considered only insofar as risks inherent in proposed research must be evaluated against potential benefits. Department Heads, through appropriate procedures established within their respective departments, are responsible for reviewing research protocols for scientific merit prior to submission of the protocol to the IRB.

2.3.3. Protocols reviewed at IRB meetings will be evaluated as to the level of risk to which research subjects will be exposed. The IRB will determine whether the protocol is minimal risk or more than minimal risk. When a protocol is determined to involve more than minimal risk, specific additional elements of informed consent are required. In addition, more than minimal risk protocols will be subject to more frequent and more detailed continuing review and reporting requirements than minimal risk protocols. Ordinarily, the IRB will not approve greater than minimal risk research on cadet subjects. Only minimal risk protocols may be reviewed through the expedited review process.

2.3.4. All protocols, regardless of risk category, will be voted on by the IRB and may be approved, approved pending changes, or disapproved. All votes require a quorum of IRB members present at the meeting. A protocol must receive a majority of the votes for approval.

2.3.4.1. Official notification of unconditional approval of a research protocol by the IRB authorizes the investigator to execute the protocol.

2.3.4.2. When a protocol is approved pending changes, the Board will assign a minimum of 2 members to review the changes submitted by the investigator. The IRB administrator will forward a letter delineating the required changes to the assigned IRB reviewers and the Principal Investigator. The investigator may not execute the protocol until the conditions specified by the IRB have been satisfied and the IRB Administrator has notified the investigator that final approval has been granted.

2.3.4.3. When a protocol is disapproved, the protocol must not be executed.

2.3.5. Changes to an approved protocol must be submitted to the IRB Administrator for distribution to the IRB reviewers. The investigator must submit a cover letter delineating the changes to the protocol and informed consent document and a revised hard copy and electronic version of the protocol and informed consent document with the changes highlighted.

2.3.6. Each investigator submitting a protocol or changes to a protocol will be notified, in writing, by the IRB administrator of the decision by the IRB on his or her protocol. This notification will normally be provided within 10 workdays of the date of the meeting at which the protocol was considered.

2.3.7. Following each IRB meeting, the meeting minutes and all reviewed protocols are approved by the AIO and forwarded to USAF/SGXC. Allegations of IRB misconduct can be reported to

higher headquarters at USAF/SGXC, ATTN IRB Appeal, 5201 Leesburg Pike, Suite 1600, Falls Church, VA 22041, telephone (703) 998-0175. The investigator must include a copy of the protocol, USAFA IRB decision, and justification for appeal. The investigator also must provide a copy of the appeal request to the USAFA IRB Administrator.

2.3.8. The IRB is responsible for the approval, review, and oversight of any Human Subject Pools created at USAFA. Continuing review of the policies and procedures in practice with the pool should occur at least once per calendar year.

3. Investigator Requirements

3.1. **Responsibilities of the Investigator.** A protocol approved by the IRB becomes a document subject to review and inspection by the Air Force Surgeon General's Office, the U.S. Department of Health and Human Services, and the U.S. Food and Drug Administration. These inspections and reviews are conducted to ensure that the IRB has fulfilled its responsibilities in approving human subject research, and that investigators comply with the terms of approved research protocols. The records of investigators may also undergo inspection and review by these agencies. Failure to fulfill the outlined responsibilities may result in loss of the privilege to perform further research using human subjects and loss of the privilege to enroll new subjects in current research. Specific areas of interest for these inspections include the following:

3.1.1. Research must be conducted as stated in the protocol. Any changes to the protocol, informed consent document, or procedure must be submitted to the IRB for approval, according to paragraph 3.5, **before** the changes are implemented.

3.1.2. Informed consent documents must be provided to research participants. In addition, investigators are required to maintain copies of ICDs that have been signed by the participants and to provide copies of all ICDs used during the execution of a research protocol to the IRB Administrator when the research has been completed.

3.1.3. A status report on the research must be submitted to the IRB by the date determined in the initial review by the IRB. This date shall not exceed 1 calendar year from the date of approval. Investigators must use the format approved by USAF/SGXC and must attach a copy of the ICD currently in use for the protocol. A current version of this format can be found on the IRB web site.

3.1.4. When a research protocol is completed, a Final Report and all original, signed ICDs must be submitted to the IRB Administrator for review and storage. Investigators must use the format for Final Reports approved by USAF/SGXC. A current version of this format can be found on the IRB website.

3.1.5. Any adverse events (injuries or unanticipated events related to risks to subjects) involving research participants enrolled in a protocol approved by the IRB must be reported to the IRB Chair or Administrator within 24 hours of its occurrence. Adverse events will be reported to the Board immediately.

3.1.6. Noncompliance with the terms of an approved protocol may result in the termination of the protocol approval by the IRB and loss of the privilege to enroll new subjects. Continued protocol noncompliance may result in the loss of the privilege to conduct research using human subjects at USAFA.

3.2. Guidelines for Investigators at USAFA . Certain aspects of the unique environment existing at the US Air Force Academy call for special concern and attention on the part of the investigator wishing to use human subjects as part of a research protocol. This is particularly true when researchers use cadets as subjects. Cadets are considered a doubly vulnerable population. The vulnerability at issue is vulnerability to coercion. Research participants may volunteer to participate in research only after they have been afforded the opportunity to consent or decline to participate. Cadets are potentially vulnerable to coercion in their role as students and as military members. Researchers must take special care to ensure that cadets are aware that their decision to consent or decline to participate in any research project will result in neither adverse nor favorable consideration by instructors in their classes or by others in their military chain of command.

3.2.1. Investigators can help assure swift and favorable outcomes if they make maximum use of the resources available to them on the IRB web site. The most common reason to delay approval of a protocol is the inability of the IRB to determine the answer to a relatively simple question about the proposed research when the researcher is not present at the IRB meeting. Investigators should attempt to provide as much detail as possible.

3.3. Common Problems That Delay Approval of a Protocol :

3.3.1. Potential problems in assuring the security or privacy of identifiable information about research subjects. This is an important element of risk assessment sometimes overlooked by investigators.

3.3.2. Potential problems in recruitment methods that may lead to undue influence on our doubly vulnerable population.

3.3.3. Incomplete documentation of informed consent. Potential subjects must be completely informed of every risk to which they might conceivably be exposed as a result of their participation in the study.

3.3.4. Incomplete documentation of procedures. IRB members must have a clear understanding of how the research participants will be recruited and treated in order to assess risk potential.

3.3.5. The most common area in which investigators have failed to comply with IRB requirements is in record keeping. ICDs are important legal documents and must be treated as such – they are the only real evidence that investigators have complied with ethical standards governing the conduct of human research. Failure to retain and provide copies of ICDs to the IRB with the Final Report is a serious breach of the investigator's responsibilities and obligations.

3.4. Cadet Investigators. Projects conducted by cadets to satisfy course requirements that involve collecting data from humans do not ordinarily meet the definition of research as a systematic investigation intended to contribute to generalizable knowledge, and so need not be submitted for IRB review. Activities that do fit this definition of research, as is often the case in a USAFA 499 class or other cadet research projects, are subject to the same IRB oversight as other research. It is the responsibility of instructors and Department Heads to ensure that appropriate consideration is given to ethical issues in the conduct of these projects. The IRB is available for consultation or advice regarding these issues.

3.4.1. Research conducted in combination with or as part of class projects is not exempt from IRB oversight automatically; the criteria in paragraph 2.1. must be met for exemption. If these criteria are not met, then a protocol must be submitted to the IRB.

JAMES W. SPENCER, Col, USAF
Director, Plans and Programs