HUMAN RESEARCH PROTECTION PROGRAM POLICIES AND PROCEDURES
United States Air Force Academy (USAFA)
October 2016

Additional guidance located on the USAFA HRPP website:
http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx

1. OVERVIEW

1.1. Purpose:

1.1.1. The purpose of the USAFA Human Research Protection Program (HRPP) is to protect the rights and welfare of human research subjects recruited to participate in research conducted at USAFA or by USAFA personnel. The USAFA HRPP consists of an Institutional Official (IO), Authorized Institutional Official (AIO), two Exempt Determination Officials (EDO), HRPP Support Personnel, an Institutional Review Board (IRB), and multiple investigators. The purpose of these Policies and Procedures is to delineate the authority, principles, functions and operations of the USAFA HRPP.

1.1.2. This document will be reviewed annually. Any updates will be reviewed and approved by the AIO.

1.2. HRPP Authority:

1.2.1. The HRPP is established under the authority of DODI3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research and the USAF Academy Supplement. The HRPP functions under the authority outlined in the 32 CFR 219, 21 CFR 50 (Protection of Human Subjects), and 21 CFR 56 (Institutional Review Boards).

1.2.2. The Surgeon General's Research Oversight Committee (AFMSA/SGE-C) has officially delegated the authority to approve and monitor human research at USAFA to an Institutional Official (HQ USAFA/CC) via the USAFA *DoD Assurance of Compliance*. The USAFA/CC delegates the authority with a letter to a senior leader.

1.2.3. The HRPP will provide initial review for all research involving human subjects. The HRPP will provide continuing review on all non-exempt human subject research. Exempt research and studies determined not to be research involving human subjects do not require continuing review.

1.2.4. With the exception of the HRPP Support Personnel, HRPP personnel are not compensated by the institution for performing IRB duties. Since the IRB members are Federal Employees performing duties within the scope of their employment, liability coverage is provided by the Air Force.

1.2.5. AFMSA/SGE-C audits a sample of minimal risk USAFA protocols and reviews all greater than minimal risk protocols. AFMSA/SGE-C also provides continuing oversight of local HRPP

operations. HRPP records shall be accessible for inspection and copying by authorized representatives of AFMSA/SGE-C at reasonable times and in a reasonable manner, or shall be copied and forwarded to AFMSA/SGE-C when requested by authorized AFMSA/SGE-C representatives.

1.3. Principles Governing the HRPP:

1.3.1. The USAFA HRPP uses the three basic ethical principles outlined in the Belmont Report as a basis for decision-making and judgment. 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, maximize possible benefits, and minimize possible harms); and 3) *Justice* (Ensures that the benefits and burdens of the research are equitably distributed.)

1.3.2. These general ethical principles are applied to the conduct of research in the following requirements: selection of subjects for research, the risk/benefit assessment, and informed consent. A discussion of how subjects are selected for participation in research and an assessment of the risks and benefits of the research are required elements of the research protocol and are included in the USAFA HRPP submission template. The informed consent requirements for non-exempt human research are in the Informed Consent Document (ICD) template. The minutes of the IRB meetings document the extent to which each protocol has or has not satisfied all of these required elements.

1.4. RESPONSIBILITIES

1.4.1. The AIO's responsibilities are outlined in DODI3216.02_AFI40-402, Enclosure 2, Section 6. The AIO will:

1.4.1.1. Appoint EDOs and IRB members via a memorandum for a three year term, which can be renewed. All candidates must:

1.4.1.1.1. Be an appropriately qualified, experienced federal employee. Each member is provided a copy of the Amdur, R.J., Bankert, E.A. (2011) *Institutional Review Board Member Handbook* (3rd ed). Sudbury Mass: Jones and Bartlett Publishers for reference.

1.4.1.1.2. Successfully complete the online CITI Program human research protections training course for IRB Members and Support Staff, Affiliated with the U.S. Air Force Surgeon General's Office.

1.4.1.1.3. For EDOs, successfully complete AFMSA/SGE-C's EDO training course and 3-month internship. A USAFA IRB member will review all EDO determinations during the 3-month internship.

1.4.1.1.4. IRB members are recruited by the Chair with an email to all Research Directors or their equivalent requesting nominations. Nominee qualifications are reviewed and voted upon at a convened IRB meeting. Cadet member nominees are staffed to the Commandant for review and comment prior to review at the IRB meeting. HRPP Support Personnel staff the IRB recommended members to the AIO for approval.

1.4.1.2. Ensure policies and procedures for auditing the HRPP records.

1.4.1.2.1. The Chair designates IRB members to audit a sample of research activities and records annually.

1.4.1.2.2. The HRPP Support Personnel audit a sample of reviewed, exempt, and open protocol administrative files annually. HRPP Support Personnel audit a sample of EDO administrative files annually as well.

1.4.1.3. Establish procedures for review and approval of each study by the IO, AIO or other senior institutional official before the institution becomes engaged in research involving human subjects and prior to initiation of any substantive changes thereto. The AIO signs a memorandum either permitting or not permitting each human subjects research activity at USAFA, unless the AIO determines that permission should be obtained from the IO or other senior institutional official(s). Prior to signing the memorandum, the following will take place:

1.4.1.3.1. Institutional Leaders who have authority over the resources required to conduct the proposed research will approve the use of those resources.

1.4.1.3.2. Proposed research will be posted on the HRPP SharePoint site for two weeks to allow Institutional Leaders time to review and provide comments.

1.4.1.3.3. The drafted permission memo will be staffed for AIO signature with the protocol, IRB approval, resource approval, and any Institutional Leaders' comments.

1.4.1.4. Establish policies and procedures to suspend or terminate IRB approval, review of allegations of research misconduct, serious or continuing noncompliance, and Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO). The AIO requires the PI promptly report the following events using the *USAFA HRPP Deviations, Problems, and Safety Reporting Form.*

1.4.1.4.1. All research related deaths (whether anticipated or unanticipated).

1.4.1.4.2. Guidelines for reporting other events (anticipated or unanticipated deviations, problems and safety) that in the PI's judgment, warrants reporting or is in the best interest of the subject(s) (e.g., because it may affect the safety and/or welfare of subjects; it changes the risk level of the study; or the frequency of the same event significantly increases) are on the website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx) with definitions and timeline requirements. Any events reported by the PI or others (i.e. subjects, observers, etc.) are promptly investigated by the IRB Chair. The Chair determines if:

1.4.1.4.2.1. No further action is required. If the report is approved by the IRB Chair, HRPP Support Personnel will return the submitted form to the researcher with Page 3 (for Committee Use Only) completed. The researcher is free to continue her/his research. The report will be included in the next scheduled IRB meeting for information purposes.

1.4.1.4.2.2. Revisions and/or additional information are required. If the IRB Chair requires revisions/additional information s/he will contact the researcher directly. The IRB Chair may allow the research to continue or may suspend IRB approval until the required information is received and a course of action (COA) determined. The COA may include required corrective actions. The HRPP Support Personnel will send the researcher a letter with any required corrective actions in a change table. The researcher will return the completed change table to the HRPP Organizational Box, usafa.irb@usafa.edu. Upon receipt, the HRPP Support Personnel will forward the completed change table to the Chair. For additional information or clarifications, the Chair will contact the researcher directly and copy the HRPP Organizational Box.

1.4.1.4.2.3. The report requires full Board review. If the IRB Chair determines the report requires full Board review, it will be reviewed at the next IRB meeting. Any event that may warrant suspension of IRB approval, due to its nature or a pattern of non-compliance, will be reviewed by the full Board. The Board will determine if the event is anticipated or unanticipated, serious or minor, or continuing noncompliance (as appropriate) and will report it to AFMSA/SGE-C if required by DODI3216.02_AFI40-402, Enclosure 2, 6.h. and i. Disciplinary measures can be taken if the incident is determined sufficiently severe or there is a pattern of noncompliance.

1.4.1.4.3. Other unanticipated problems that impact the conduct or integrity of the study (e.g. FDA Clinical hold or recall, Published literature or data and safety monitoring board report impacting risk-benefit ratio, FDA Form 483 or warning letter, investigator medical license restriction or suspension, participant is incarcerated).

1.4.1.4.4. An UPIRTSO includes any incident, experience, or outcome that meets all of the following criteria:

1.4.1.4.4.1. Unexpected (in terms of nature, severity, or frequency) given the procedures as described in the protocol documents (e.g., the IRB-approved research protocol and informed consent document) and the characteristics of the subject population being studied;

1.4.1.4.4.2. Related or possibly related to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by procedures involved in the research); and

1.4.1.4.4.3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, even if no harm has actually occurred.

1.4.1.5. The USAFA HRPP will not review ANY research that is submitted with a determination from another HRPP. The USAFA submission form expressly asks researchers if their study has been submitted to any other IRB/HRPP. Specific instructions are provided to researchers on the USAFA IRB website and/or by HRPP Support Personnel.

1.4.1.6. All financial, professional and/or personal conflicts of interest (COI) must be identified in the HRPP Determination Request form. Conflicts may be potential or actual, perceived or real, harmful or insignificant. Any reported conflict of interest will be reported to the IRB Chair or HRPP Support Personnel. The IRB Chair will review the report for potential harm and required disclosure to the research subjects and will attempt to identify a resolution with the PI. Significant financial interests must be disclosed to the IRB and institutional officials and any identified financial conflict of interest must be appropriately managed. A significant financial interest could directly and significantly affect the design, conduct, or reporting of research (42 CFR 50, Subpart F and 45 CFR 94). Financial COIs will be disclosed to subjects during the consent process. The Chair will report the results of the review and resolution at the next IRB meeting. In the event that a resolution cannot be attained, the Chair will engage the AIO into the process.

IRB members cannot participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest. Financial COI conditions or restrictions “might” be imposed to manage the COI.

1.4.2. The IRB Chair responsibilities are outlined in DODI3216_AFI40-402, Enclosure 2, Section 7. The Chair will:

1.4.2.1. Document IRB members approved to conduct expedited review. The document will be updated when the IRB member roster is updated.
1.4.2.2. Investigate activities that might be human subjects research, but were not submitted to the HRPP. The Chair will report findings at the next scheduled IRB meeting. Disciplinary measures can be taken if the incident is determined sufficiently severe or there is a pattern of noncompliance.
1.4.2.3. Assign IRB members to audit research activities at regular intervals throughout the year. The IRB member will document the audit findings and report the results at the next scheduled IRB meeting.

1.4.3. The HRPP Support Personnel responsibilities are outlined in DODI3216_AFI40-402, Enclosure 2, Section 8. HRPP Support Personnel will:

1.4.3.1. Maintain the HRPP website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx) that includes all submission deadlines, IRB meeting dates, the monthly review schedule, and other information that a researcher needs to properly submit to the USAFA HRPP.
1.4.3.2. Suspense PIs on all requirements that result from HRPP review and determinations.
1.4.3.3. Review all non-EDO submissions to the HRPP to ensure that the submission is the appropriate type and all required support materials are included. A complete submission includes different support materials based on the type of submission. See the website for the various submission types with accompanying instructions.
1.4.3.4. Post all research submissions on the HRPP SharePoint site no later than one week after the IRB monthly submission deadline for mission element comments.
1.4.3.5. Assemble the read-ahead for the IRB meeting and send it to members no later than the Friday before the meeting. The read-ahead will contain all documents for review at the monthly meeting, as well as a summary of all exempt, expedited, and/or non-human subjects research that has been reviewed since the previous meeting.
1.4.3.6. Maintain all administrative records for three years after the closure date and destroy them appropriately.
1.4.3.7. Prepare all briefings and staff packages for the IO and/or AIO. HRPP Support Personnel will staff a permission memo for research protocols approved by the EDO and IRB to obtain permission from the AIO that the research is appropriate for conduct at USAFA or by USAFA personnel. HRPP Support Personnel will brief the annual training slides to the IO and AIO.
1.4.3.8. Review and coordinate all official requests from AFMSA/SGE-C and provide a response, or, when necessary, will request a response from the Principal Investigator (PI). All communication between investigators and AFMSA/SGE-C will flow through the IRB Support Personnel (with the exception of Human Research Protection Official (HRPO) review). The IRB is informed of what AFMSA/SGE-C requested and what USAFA provided/responded at the next scheduled IRB meeting.
1.4.3.9. Immediately issue a letter to the PI and copy the PI's Research Director or equivalent and Department Head or equivalent when IRB approval has lapsed. Research activities will not resume without IRB approval.

1.4.3.10. Assign IRB members as expedited reviewers based on the document provided by the IRB Chair.
1.4.3.11. Determines whether each investigator is engaged in human subject's research and if the researchers are covered by Federal assurance and agreements, if applicable. Personnel assigned to a USAFA billet (such as Distinguished Visiting Professors or Researchers) are covered by the USAFA Assurance while assigned to the USAFA billet.
1.4.3.12. Ensures that all HRPP personnel (to include the IO, AIO, EDO, IRB Members, HRPP Support Personnel, Investigators, etc.) have the required training per the Minimum Education Training Requirements Memo, 16 August 2012. Training is tracked in the "Training Tracking File."

1.4.4. The HRPO responsibilities are outlined in DODI3216_AFI40-402, Enclosure 2, Section 9. USAFA does not have a HRPO; therefore, all researchers that require HRPO review must contact SGE-C directly. Contact information and instructions are provided on the USAFA HRPP website.

1.4.5. The IRB's duties are outlined in 32 CFR 219.107 to 219.109, (21 CFR 56.107-109). Requirements for IRB membership are outlined in 32 CFR 219.107. The USAFA IRB is comprised of the following members: Chair, IRB Administrator, Cadet Representative, Social Scientist, Legal Representative, Medical Standards (10MDG), and Non-Affiliated. Each position has at least one alternate member. Consultants may be brought in as appropriate. IRB members will:

1.4.5.1. Provide a current Resume or Curriculum Vitae to the IRB Support Personnel upon appointment to the IRB and prior to each time the appointment is renewed.
1.4.5.2. Attend board meetings or make provisions for an appointed alternate to attend. Members must respond to the HRPP Support Personnel at least 5 days prior to the scheduled meeting on who will and will not attend. Alternate members must attend a minimum of three meetings per year to ensure they are prepared to participate in lieu of the primary member if required.
1.4.5.3. Review all Board business and complete the USAFA IRB Review Template. Submit the completed review template to the IRB Administrator by noon the day prior to the meeting for each new submission and amendment being reviewed.
1.4.5.4. Abstain from voting if they are a signatory (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, however, they must exit the room during deliberation and voting by the Board.
1.4.5.5. Participate in expedited reviews and/or exemption determinations as approved by the Board Chair and requested by HRPP Support Personnel.
1.4.5.6. Execute required training prior to voting as an IRB member.

1.4.6. EDO responsibilities are outlined in DODI3216_AFI40-402, Enclosure 2, Section 10. EDOs will:

1.4.6.1. Assign a protocol number as follows: DF numbers will begin with 100 and CW numbers will begin with 200.
1.4.6.2. Post all reviewed research submissions on the HRPP SharePoint site no later than one week after the IRB monthly submission deadline with the EDO determination letter.
1.4.6.3. Maintain all administrative records for three years after the closure date and destroy them appropriately.

1.4.7. Principal Investigator (PI) responsibilities are outlined in DODI3216_AFI40-402, Enclosure 2, Section 11. Investigators who have prior experience conducting human subjects research may serve as a PI on a research protocol. Graduate students who are conducting human subjects research for the first time under the supervision of an experienced advisor may also serve as a PI on a research protocol. Investigators (including cadets) with no prior experience in human subjects research may serve as associate investigators (AI). The PI will:

1.4.7.1. Become familiar with all relevant rules and regulations (32 CFR 219; Title 10 USC Section 980; DOD Instruction 3216.02; DODI3216.02_AFI 40-402; DODI3216.02_AFI 40-402_USAFA Supplement 1 and USAFA Policy and Procedures) governing human subjects research in the DOD, Air Force and at USAFA. The information is available on the USAFA HRPP website.

1.4.7.2. Ensure all personnel involved in the research complete appropriate training annually as requested by HRPP Support Personnel.

1.4.7.3. Ensure that all submissions to the USAFA HRPP follow the instructions and use the forms provided on the USAFA HRPP website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx).

1.4.7.4. Ensure that all AIs and research support personnel affiliated with the research are compliant with DOD, AF and USAFA requirements.

1.4.7.5. Maintain all research records for a minimum of three years including complete informed consent documents, not just the signature pages.

1.4.7.6. Close/Amend any open protocols prior to departing USAFA.

1.4.7.7. Obtain all other approvals that might be required and include them with the HRPP submission. The HRPP will not review submissions until all necessary approvals have been obtained. Incomplete submissions will be returned to the PI with the missing requirement identified.

1.4.7.7.1. Commander approval is required for the following:

1.4.7.7.1.1. Sport teams, AD personnel, resources or facilities – AD, 719.333.4008

1.4.7.7.1.2. Medical/dental personnel, records, resources or facilities – 10 MDG, 10 MSGS, 10 AMDS, 10 DS, 719.333.5866

1.4.7.7.1.3. Other 10 ABW personnel, resources or facilities – 10 ABW, 719.333.1015

1.4.7.7.1.4. Airfield personnel, resources or facilities – 306 FTG, 719.333.3330

1.4.7.7.1.5. Cadets in the squadron or during military training, CW personnel, resources or facilities – CW, 719.333.2263

1.4.7.7.1.6. Cadets in the classroom or during academic time – DF Department Head, 719.333.4508

1.4.7.7.1.7. DF personnel, resources or facilities – Dean of the Faculty, 719.333.4508

1.4.7.7.1.8. USAFA Preparatory School students, personnel, resources or facilities – PL, 719.333.2583

1.4.7.7.2. Research that involves obtaining attitude, opinion or intention data with a survey, interview or focus group must have a current USAFA Survey Control Number (SCN) issued by the USAFA Survey Control Officer, 719.333.6481.

1.4.7.7.3. Research that involves the Dean of the Faculty (DF) Subject Pool must be approved by the Director of the Subject Pool, currently in DFBL, 719.333.2514.

1.4.7.7.4. If a study requires archival USAFA data, such as admissions or academic data, contact A9O, xp.taskers@usafa.edu

1.5. TRAINING OF HRPP MEMBERS

1.5.1. The Office of the Assistant Secretary of Defense has established minimum education requirements for DoD personnel involved in human subjects research, to include an annual training with required educational topics (Minimum Education Requirements Memo, 16 August 2012). To ensure compliance with these requirements, the Air Force Surgeon General's Office (AF-SG) provides human subjects protection training through the Collaborative Institutional Training Initiative (CITI) and the United States Air Force Academy (USAFA) Human Research Protection Program (HRPP) provides human subjects protection training through the National Institute of Health (NIH) training. All investigators MUST have a CITI training certificate with an organizational affiliation of "U.S. Air Force Surgeon General's Office" that is no older than three years on file with the USAFA HRPP. Once an investigator has an AF-SG affiliated certificate, the CITI training requirement is complete for three years. On alternate years, investigators must complete NIH training or USAFA HRPP determined training. The cycle of training is as follows:

Year One AF-SG Affiliated CITI training
Year Two NIH or USAFA determined
Year Three NIH or USAFA determined
Year Four AF-SG Affiliated CITI training
And so on……

Investigators who wish to conduct human subjects research must complete the appropriate training. Upon completion of training, the certificates must be sent to usafa.irb@usafa.edu or included as separate supporting documents in a protocol submission. Protocols that include investigators who have not had the appropriate annual training will not be reviewed until the appropriate training certificates are received.

1.5.2. Training for the Superintendent (Institutional Official) and the Vice Superintendent (AIO) is done initially and every three years after with an in-depth briefing by the USAFA Chair and the HRPP Administrator using SGE-C provided slides and local information slides. On alternate years, an updated training brief might be given in person or staffed for review and signature.

1.5.3. Each IRB member also receives continuing education information as part of the monthly IRB packets. Pertinent issues are discussed at meetings and documented in the minutes as appropriate.

1.6. IRB MEETINGS AND MINUTES

1.6.1. The IRB meets monthly, usually on the third Thursday unless otherwise changed by the membership. Additional meetings may be convened at any time upon the request of the AIO or Chairperson. Submission deadlines are on the HRPP website.

1.6.2. **Rules of Order:**

1.6.2.1. Requirements for a quorum and for approval of an agenda item are in 32 CFR 219.108(b).

1.6.2.2. Research protocols scheduled for review are 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 made available to the consultants prior to the meeting.

1.6.2.3. Investigators are encouraged to attend the IRB meeting in which their protocol will be discussed to answer member questions or provide clarification when needed. Discussion and votes are conducted without the investigators or other visitors in attendance. Investigators never participate in the voting process.

1.6.2.4. Voting will 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 primary members present at a meeting, or their alternates who are present in their absence. 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 at any level 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 simple majority of members voting at the convened meeting.

1.6.2.5. Voting members will review the IRB checklist prior to the vote to ensure that (1) Risks to subjects are minimized, (2) Risks to subjects are reasonable in relation to anticipated benefits, (3) Selection of subjects is equitable, (4) Informed consent will be sought and documented from each prospective subject or the subject's legally authorized representative, (5) Informed consent will be appropriately documented, (6) when appropriate the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, (7) When appropriate the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects, and (8) When appropriate when reviewing a protocol with a device, does this meet the FDA regulations?

1.6.2.6. Voting members will determine the length of time for which the research is approved, but not greater than 365 days.

1.6.2.7. The draft meeting minutes are emailed to all board members for their review and changes. Once all changes are incorporated, members vote to approve the final meeting minutes using email voting buttons.

1.6.2.8. Approved meeting minutes are forwarded to the AIO for review and signature with a memo requesting permission to conduct the research. All signed and supporting documents are sent to AFMSA/SGE-C.

1.6.3. **Appeal of IRB or AIO Decisions**:

1.6.3.1. No one has the authority to override IRB disapproval. Only the IRB can decide to reconsider a disapproved protocol. 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 IRB meeting at which their appeal will be discussed.

1.6.3.2. All appeals should be addressed to the IRB Chairperson and sent to the HRPP Support Personnel. The appeal should address reasons for disapproval and provide substantive information (e.g. new information) for why the IRB should reconsider the decision.

1.6.3.3. An appeal considered by the IRB will result in one of the following actions: (1) affirm the decision; (2) reverse all or part of the previous decision; or (3) defer opinion

until further information can be obtained. If the appeal does not reverse the IRB disapproval, then the protocol will be closed.

1.6.3.4. If the IRB approved a study but the AIO disapproved it based on what is best for the institution, the appeal will be sent to the AIO for review. If the appeal does not result in a reversal of the AIO disapproval, then the research cannot be conducted and the protocol will be closed.

1.7. PROTOCOL VIOLATIONS AND ADVERSE EVENTS

1.7.1. All deviations from the approved research protocol, as well as problems or safety issues that arise during the research must be reported to HRPP Support Personnel. The HRPP website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx) contains guidelines, instructions, timelines and the *Deviations, Problems and Safety Reporting* form required to report to HRPP Support Personnel. The IRB Chair will review the report and make one of the following determinations:

1.7.1.1. No further action by the Primary Investigator is required.

1.7.1.2. Revisions/additional information are/is required.

1.7.1.3. The report requires a full Board review.

1.7.2. 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 or consent document is warranted. Additional details can be found in section B.1.d. above. Serious expected or unexpected adverse events must also be forwarded to the AIO. Serious, unexpected and related adverse events must be reported to AFMSA/SGE-C as soon as possible per DODI3216.02_AFI40-402, Enclosure 2, paragraph 6.i.

1.8. MISCONDUCT

1.8.1. Any serious, continuing, or suspected noncompliance with 32 CFR 219, DODI3216.02, DODI3216.02_AFI40-402, DODI3216.02_AFI40-402_USAFASUP or USAFA policies and procedures should be reported promptly to HRPP Support Personnel or any IRB member. The PI, Department Heads, and Research Directors are responsible for reporting any deviations from a research protocol or the determinations of the IRB.

1.8.2. An allegation of research or scientific misconduct should be brought to any IRB member. Allegations of scientific or research misconduct will be handled consistent with the guidelines outlined in DODI3210.07 and section B.1.d. above.

1.8.3. If an allegation of misconduct is made against an HRPP member, the investigation will be handled consistent with the guidelines outlined in DODI3210.07 as if it were research misconduct.

1.8.4. Allegations of research or scientific misconduct will be reviewed at the next convened IRB meeting and reported to AFMSA/SGE-C in accordance with DODI3216.02_AFI40-402, Enclosure 2, paragraph 6.i. Disciplinary measures can be taken at the discretion of the IRB.

1.9. GUIDELINES FOR INVESTIGATORS

1.9.1. **Research Conducted Without IRB Approval**:

1.9.1.1. Investigators who conduct human subjects research without appropriate HRPP review and 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 may jeopardize the USAFA human research certification from the Air Force Surgeon General.

1.9.1.2. Some assessment projects, program evaluations, or other scholarly activities could be considered human subjects research based on definitions in the regulations. Only HRPP members can determine if one of these activities is 1) not human subjects research, 2) exempt human subjects research, or 3) non-exempt human subjects research. Contact the IRB Chair, Vice Chair, Administrator, or an EDO if you are not sure whether your activity is human subjects research.

1.9.1.3. If the HRPP becomes aware of research conducted without appropriate review and approval, the Chair will send a letter to the investigator, with copies to the Director of Research and Department Head or equivalent of the investigator's department, instructing him/her to cease all data collection immediately. The IRB will consider possible sanctions against the investigator at the next regularly scheduled 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. The IRB will weigh the level of risk to which the subjects were exposed in deciding appropriate sanctions.

1.9.2. **Research that Occurs in a Foreign Country:**

1.9.2.1. All research being conducted in a foreign country must be reviewed by the IRB. The PI must provide evidence that all applicable national laws and requirements of the foreign country have been met. The IRB is required to document the source of information about the foreign research context in writing. The Office of Human Research Protections (OHRP) created the International Compilation of Human Research Standards which provides information about human subjects research requirements in many foreign countries. Following IRB approval, SGE-C must conduct an administrative review and approve the research unless 1) the research will be conducted by an established DOD overseas research institution and the research will be conducted in the host country or 2) the research will be conducted by a DOD overseas institution and will include only DOD personnel or U.S. citizens as human subjects. USAFA HRPP Support Personnel will facilitate this review and approval.

1.9.3. **Research with an Existing Non-DOD IRB Determination:**

1.9.3.1. Per DODI3216.02_AFI40-402, Enclosure 2, 6.a.(6), SGE-C has prohibited an AF IRB from conducting a second HRPP review. The existing determination must be reviewed by a Human Research Protection Official (HRPO). SGE-C provides HRPO review for USAFA. The researcher must submit the non-DOD IRB determination with all supporting documents to usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil. Concurrent to HRPO review, the researcher must obtain resource support to conduct the research at USAFA. Section B.7.f.i. above and the USAFA HRPP website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx) provide information on how to obtain resource support from various organizations across USAFA. Once HRPO

approval has been obtained and resource support has been secured, send the approved protocol and supporting documents with HRPO approval and evidence of resource support to the USAFA.IRB@usafa.edu. USAFA HRPP Support Personnel will request permission from the AIO to allow the research at USAFA. If USAFA is engaged in the research, an Institutional Agreement for IRB Review (IAIR) will be accomplished with the non-DOD IRB that conducted the original review of the protocol, prior to the non-DOD IRB review of the amendment to add USAFA. More detailed instructions can be found on the USAFA HRPP website.

1.9.4. **Research with an Existing DOD IRB Determination:**

1.9.4.1. USAFA can accept an IRB determination from another DOD organization without additional review. The PI must provide HRPP Support Personnel with the IRB approved protocol and supporting documents, and the IRB approval documentation. However, resource support and permission from USAFA is required prior to initiating any research activities. The researcher must obtain resource support to conduct the research as USAFA. Section B.7.f.i. above and the USAFA HRPP website (http://www.usafa.af.mil/Leadership/InstitutionalReviewBoard.aspx) provide information on how to obtain resource support from various organizations across USAFA. Once HRPO approval has been obtained and resource support has been secured, send the approved protocol and supporting documents with HRPO approval and evidence of resource support and HRPP training to the USAFA.IRB@usafa.edu. USAFA HRPP Support Personnel will request permission from the AIO to allow the research at USAFA. If USAFA is engaged in the research, an Institutional Agreement for IRB Review (IAIR) will be accomplished with the DOD IRB that conducted the original review of the protocol, prior to the DOD IRB review of the amendment to add USAFA. More detailed instructions can be found on the USAFA HRPP website.

1.9.5. **Research that Requires IRB Review and/or SGE-C Review:**

1.9.5.1. As stated above, research that occurs in a foreign country must be reviewed by an IRB and might require SGE-C review as well. In addition, research that has an existing determination from a non-DOD IRB must be reviewed by SGE-C. Research with prisoners must receive IRB review from an IRB that has a member qualified to review research with prisoners. Research that includes surveys, interviews or focus groups with children as subjects must receive IRB review, unless the research only involves observation of public behavior when the investigator(s) do not participate in the activities being observed. SGE-C has determined research areas that require their review per DODI3216.02_AFI40-402, Enclosure 3, 3.b.(1). Please review DODI3216.02_AFI40-402, Enclosure 3, 3.b.(1) in detail to fully understand the items in the table below.

Requires IRB review	**Requires SGE-C review**
Research in a foreign country	Research in a foreign country unless excepted
Research with prisoners or a subject becomes a prisoner	
Research with children unless excepted	
	Research with an existing determination from a non-

	DOD IRB
	Research that permits waiver of informed consent under paragraph (b) of section 980 Title 10
	Research on a fetus
	Research that requires ASD(R&E) approval
	Research determined to be greater than minimal risk by an AF IRB unless excepted
	Research is National Clinical Trials Network and relied on the National Cancer Institute's CIRB
	Research that involves biological or chemical warfare agents or weapons
	Research that involves collecting statistical information under a promise of confidentiality per Confidential Information Protection and Statistical Efficiency Act
	Research that involves an FDA regulated investigational drug or device
	A proposed substantive change to approved research that makes it fall within a category that requires SGE-C review (e.g. greater than minimal risk)
	Clinical investigations seeking exemption of gender and minority participation

1.9.6. **Changes to the Research under IRB Oversight including Exempt:**

1.9.6.1. Changes in research during the period for which HRPP approval has already been given shall not be initiated by investigators without prior HRPP review and approval, except where necessary to eliminate apparent immediate hazards to the subject.
1.9.6.2. A PI wishing to change an approved protocol (e.g., add/delete investigators, measurement instruments, procedures) must request the change on the approved amendment form located on the HRPP website and submit it to HRPP Support Personnel. Minor changes (e.g., add/delete investigators) can be approved using expedited review. Significant changes that might affect risk to subjects (e.g., sensitive questions, invasive procedures) should be submitted prior to the IRB submission deadline and will be included in the full IRB review cycle.
1.9.6.3. For exempt research, amendments are not required for things that will not affect risk to subjects or the exemption category, such as adding a class, increasing subject numbers, or extending the time period of the study.

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

1.9.7.1. An investigator must be present and available to answer questions during the informed consent process.
1.9.7.2. 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 participate in a study. Because cadets are considered vulnerable subjects (due to their position in the cadet and 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. Researchers should consider using the SONA to recruit subjects at

USAFA. This online tool incorporates protection of subject participation anonymity and reduces coercion since the subjects review available research studies at their leisure and sign up for a study of their choosing when they wish. For information on using SONA, contact the Subject Pool Coordinator in DFBL. The following additional safeguards should be considered if SONA is not used:

1.9.7.2.1. Provide adequate time between the recruitment/information phase and enrollment/consent phase of the study.

1.9.7.2.2. Instructors must not recruit subjects from cadets currently in their classes.

1.9.7.2.3. Cadet investigators must not use or display their rank while recruiting subjects or not recruit cadet subjects below their cadet rank.

1.9.7.2.4. Military members must not use or display their rank while recruiting subjects.

1.9.8. **Improperly Executed Informed Consent Documents (ICD)s**:

If the IRB required documentation of informed consent for the research, there must be an appropriately signed ICD for each participant. The IRB will ask researchers to remedy improperly executed consent documents in one or more of the following ways:

1.9.8.1. Obtain a proper signature from a subject if the subject's signature is missing. If the researcher is unable to obtain a proper signature from the subject, the IRB may elect to accept some other form of proof that the subject consented to participate in the study.

1.9.8.2. Obtain proper witness or advising investigator's signatures if these signatures are missing. The IRB 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.

1.9.8.3. Have the subject sign a new ICD if the signed ICD is missing. If the researcher is unable to document that consent was obtained from one or more subjects, the IRB may instruct the researcher to destroy the data collected from these subjects.

1.9.9. **Safeguarding Information:**

1.9.9.1. 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.

1.9.9.2. 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.

1.9.10. **Continuing/Final Review**:

1.9.10.1. Per 32 CFR 219.109, all non-exempt research must be reviewed for continuation by a date designated by the IRB that is consistent with the research risk, but not longer than once per year. Non-exempt, minimal risk research is approved for 365 days UNLESS otherwise noted at the meeting.

1.9.10.2. HRPP Support Personnel will send a reminder to the PI, but it is the responsibility of the PI to provide a final or continuing report within 365 days of IRB approval. If a report is not received by the due date, a letter signed by either the Chair or the AIO will be sent to the PI with copies to the PI's Research Director and Department Head stating that IRB approval has expired and research activities must cease. The research activities cannot resume until the investigator receives IRB approval. Conduct of human subjects research

without IRB approval may jeopardize USAFA's eligibility for certain Federal research grants as well as USAFA's assurance from SGE-C.

1.10. USAFA-SPECIFIC INFORMATION

1.10.1. **Cadets as Subjects:**

1.10.1.1. Due to their position in the military and cadet rank hierarchies, as well as the instructor-student relationships, cadets are doubly vulnerable as subjects. Recruitment procedures must consider and minimize coercion based on these vulnerabilities.
1.10.1.2. Additional guidance on Military Personnel as Subjects can be found in DODI3216.02, Enclosure 3, paragraph 7.e.(1) and apply to cadets as well.
1.10.1.3. Greater than minimal risk studies will not be approved for cadet participation.

1.10.2. **Research during Basic Cadet Training (BCT)**:

Basic Cadet Training is stressful for cadets; this puts the cadets in a very vulnerable position. For this reason the board mandates the following additional steps to protect them:

1.10.2.1. Provide the cadets with the announcement of a research project before they arrive at the Academy. This will give them the opportunity to understand what the research entails and if they would like to participate prior to arriving at USAFA.
1.10.2.2. Emphasize that the activity is research and voluntary; they can decide not to participate.
1.10.2.3. All research during Basic Cadet Training requires Commandant's approval. Researchers should plan a minimum of 18 months for the approval process.

1.10.3. **Cadets under Age 18:**

1.10.3.1. Every year, a few four-degrees enter USAFA who are not yet 18. Since cadets are considered active duty personnel when they take the oath of office at the beginning of their cadet career, cadets are considered emancipated minors and are allowed to be treated as adults in all Academy activities, to include human subjects research. Colorado law supports this conclusion as well.
1.10.3.2. Researchers who are considering collecting data from cadet candidates before they in-process to the Academy, are forewarned that the rules governing research on minors will apply for all cadet candidates who are under the age of majority in the jurisdiction in which they reside. Normally, in these circumstances, the IRB will restrict researchers to collecting data only from those cadet candidates who have already reached the age of majority. However, parents can consent for Cadet Candidates under the age of 18.

1.10.4. **Educational Research**:

Researchers should use the HRPP Determination Request form on the IRB website to request an exemption for educational research. The form should be submitted to the DF EDO. Contact the DF EDO at 333-3277 for submission instructions.

1.10.5. **Payment of Cadets for Participation in Research:**

1.10.5.1. Cadets are considered Federal personnel and are subject to the restrictions defined in DoDI3216.02, Enclosure 3, Section 11. The funds cannot be from a DoD source (such as the National Science Foundation); and (2) the cadet subjects cannot receive course credit for their participation.
1.10.5.2. Off-duty for cadets includes when they are on passes, on leave, or equivalent, or released after their "last military duty (LMD)."

1.10.6. **Pilot Studies:**

Most pilot studies meet the definition of human subjects research in 32CFR219.102(d) and, therefore, are subject to HRPP review. Researchers considering running pilot studies should submit an HRPP Determination Form to the HRPP for review. Researchers should clearly state that the study is a pilot study in explaining the design of the research, particularly the sample size.

1.10.7. **Oral Histories:**

AFI 84-101 requires AF Historians to conduct oral history program interviews. These interviews are conducted with commanders and others by virtue of their position in the AF. Transcripts are made and the data is sent to the Air Force Oral History collection, and in some cases, to the USAFA Library. No analysis is conducted with the data. These Oral Histories are not considered human subjects research. However, if a researcher accesses the oral history data to conduct research, the researcher must submit a HRPP Determination Form to the HRPP. In addition, AFI 84-101 identifies Research Interviews which are interviews with people who have firsthand knowledge of organizational activities because of their involvement. As long as an Oral Historian's activities are confined to transcribing recorded interviews, it is not considered human subjects research. However, if activities include drawing conclusions or generalizing findings, an HRPP Determination Form must be submitted to the HRPP.

1.11. HRPP PROCEDURES (See Appendix 1 for a flow chart)

1.11.1. **General:**

Submissions for HRPP review must be on the USAFA HRPP Determination Request form from the HRPP website, sent to the HRPP Organization Box or EDO, and include all required signatures, training, and resource approvals per paragraph B.7.f.i. above. This constitutes a compliant package. If the submission is not compliant, the submitted package will be returned to the PI stating what is needed.

1.11.2. **Exemption and Not Human Subjects Research Review by an EDO:**

1.11.2.1. A PI submits a USAFA HRPP Determination Request form to the EDO.
1.11.2.2. EDO checks the following:
1.11.2.2.1. Has the research been submitted to any other IRB?
1.11.2.2.2. Is the research being conducted in a foreign country?
1.11.2.2.3. Are the subjects prisoners?
1.11.2.2.4. Are the subjects children?
1.11.2.2.5. Is training compliant?
1.11.2.2.6. Does the submission have all the appropriate signatures?

If any of a. through d. is “yes”, EDO forwards the request and supporting documents to the HRPP Organizational Box; otherwise, EDO ensures compliance.

1.11.2.3. EDO assigns a protocol number and creates an electronic file. File includes: submission form and supporting documents, training certificate for all investigators, vita for all investigators, excluding cadets, exemption determination form, any amendments and the determination for the amendment, all email communications regarding the research. The protocol number will be provided a letter at the end that reflects the determination: N - if the research is not human subjects research, E - if the research is exempt, or will send the research to the HRPP org box if it requires IRB review

1.11.2.4. Using the EDO Worksheet, the EDO determines if the project is

1.11.2.4.1. Research not involving human subjects per section 219.102 of Reference (c),
1.11.2.4.2. Human subject research eligible for exemption from the requirement for IRB review per section 219.101(b) of Reference (c), or
1.11.2.4.3. Research involving human subjects that requires Institutional Review Board (IRB) approval prior to start per part 219 of Reference (c).
1.11.2.4.4. If the determination is “not human subjects research”, the EDO will advise the PI of the determination by sending the EDO Worksheet to the PI.

1.11.2.5. If the determination is that the research is exempt per CFR 219.101(b), the EDO posts the submission on the USAFA HRPP SharePoint site one week after the IRB submission deadline and will be available for two weeks to allow Mission Elements (ME) time to review and provide comments prior to the AIO signing the permission memo. This posting is required by the AIO and exists outside of the IRB review process. Once the two week comment time has elapsed, the IRB determination, resource approvals, and any ME comments that were posted on the HRPP SharePoint site, will be staffed to the AIO to obtain his/her decision to permit/not permit the research to be done at USAFA. Once the signed AIO permission memo is received, HRPP Support Personnel will send the determination and the AIO permission memo to the EDO. The EDO will send the PI an approval to start the study.

1.11.2.6. If the activity requires IRB approval prior to start, the EDO will refer it to the IRB Organizational Box.

1.11.2.7. Each month a summary of EDO determinations will be included in the IRB meeting read-ahead for IRB awareness. This summary will include the protocol number, protocol title, investigator names, short summary of the research, exemption category with justification, date submitted, and date approved.

1.11.2.8. The EDO must ensure and document that all exempt researchers complete annual training requirements while engaged in human subjects research.

1.11.2.9. EDO reviews and documents all amendments; determines if exemption still applies, notifies PI of exempt determination; if EDO determines it needs IRB review, forwards amendment and all supporting documentation to HRPP org box. Amendments are required for things that might affect risk to subjects or the exemption category, such as

changes in procedures, data collection instruments, data plans, and investigators. Amendments are not required for things that will not affect risk to subjects or the exemption category, such as adding a class, increasing subject numbers, extending the time period.

1.11.2.10. EDO maintains all records for three years and then destroys them appropriately.

1.11.2.11. Files are subject to audit by SGE-C and the USAFA HRPP.

1.11.3. **Exemption and Not Human Subjects Research Review by an IRB Member:**

1.11.3.1. A PI submits a USAFA HRPP Determination Request form to the HRPP Organizational Box, usafa.irb@usafa.edu.

1.11.3.2. Once the submission is received, HRPP Support Personnel check the following:

1.11.3.2.1. Has the research been submitted to any other HRPP?
1.11.3.2.2. Is the research being conducted in a foreign country?
1.11.3.2.3. Are the subjects prisoners?
1.11.3.2.4. Are the subjects children?
1.11.3.2.5. Are the resource permissions in place?
1.11.3.2.6. Is training compliant?
1.11.3.2.7. Does the submission have all the appropriate signatures?

If the answers to 2.a-d is "no", HRPP Support Personnel ensure compliance with 2.e. through 2.h. If the submission is not compliant, the HRPP Support Personnel return the submission to the PI with the appropriate direction to complete the submission.

1.11.3.3. Once a compliant submission is received, HRPP Support Personnel assign a protocol number and create a paper and electronic file. File includes: submission form and supporting documents, training certificate for all investigators, resumes for all investigators (excluding cadets), exemption determination form, and all communications regarding the research. The protocol number will be provided a letter at the end that reflects the determination: N - if the research is not human subjects research, E - if the research is exempt, or H – if it is determined to not be exempt. HRPP Support Personnel forward the HRPP Determination Request and supporting documents to one IRB member for review.

1.11.3.4. The IRB member makes a determination using the Research and Human Subjects Determination Form. If the IRB member requires clarification or additional information from the researcher, the IRB member interacts directly with the researcher and copies the HRPP Organizational Box.

1.11.3.5. There are three possible determinations, each with a separate action:

1.11.3.5.1. **Research not involving human subjects.** The study does not meet the regulatory definition of research involving human subjects per 32CFR 219.102. In this case the determination is sent to the PI and the PI is free to start his/her study.

1.11.3.5.2. **Human subject research eligible for exemption from the requirement for IRB review**. This study meets the definition of research involving human subjects and meets a least one of the six exemptions per section 219.101(b).

1.11.3.5.2.1. The study will be posted on the HRPP SharePoint site one week after the IRB submission deadline for two weeks to allow Mission Elements (ME) time to review and provide comments prior to the Authorized Institutional Official (AIO) signing the permission memo. DODI3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research, dated 10 September 2014, states in paragraph 6.a.(2) that Institutional Officials (IO) of DoD organizations shall "Establish procedures for review and approval of each study by the IO, AIO, or other senior institutional official before the institution becomes engaged in research involving human subjects and prior to initiation of any substantive changes thereto. The purpose of this review is to determine, on behalf of the institution and in light of local mission considerations, whether to permit the research. This review can be done before or after [Institutional Review Board] IRB approval, and is not part of the IRB review process."

1.11.3.5.2.2. Once the two week comment time has elapsed, the IRB determination, resource approvals, and any ME comments that were posted on the HRPP SharePoint site, will be staffed to the AIO to obtain his/her decision to permit/not permit the research to be done at USAFA.

1.11.3.5.2.3. Once the signed AIO permission memo is received by the IRB Administrative Office, the IRB will send both the IRB determination and the AIO permission memo to the PI.

1.11.3.5.3. **Human subjects research ineligible for exemption from the requirements for IRB review.** This study meets the definition of research involving human subjects but does not meet any of the six exemptions per section 219.101(b). This determination is sent to the PI by the HRPP Support Personnel and they are informed that the study will require full IRB review at the next scheduled IRB meeting.

1.11.3.6. The HRPP Support Personnel include a monthly report of all the research that has been exempted or determined to not be research involving human subjects in the monthly IRB meeting agenda. The monthly report will include protocol number, protocol title, reviewer name, investigator names, short summary of the research, exemption category with justification, date submitted, and date approved.

1.11.3.7. Per DoDI3216.02_AFI40-402, Enclosure 2, 11.f., the PI must retain all records (e.g., protocol, signed informed consent documents, IRB correspondence, and data) for at least three years after the research ends or for the length of time specified in applicable regulations, or institutional or sponsor requirements, whichever is longer.

1.11.3.8. The USAFA HRPP office maintains all records for three years after closure and then destroys them appropriately.

1.11.3.9. Files are subject to audit by SGE-C.

1.11.3.10. While every protocol is different, on average, the process from compliant submission on the appropriate submission date to approval takes 4-6 weeks.

1.11.4. **IRB Review:**

1.11.4.1. The PI submits a USAFA HRPP Determination Request to the HRPP Organizational Box, usafa.irb@usafa.edu.

1.11.4.2. Once the submission is received, HRPP Support Personnel check the following:

1.11.4.2.1. Has the research been submitted to any other IRB?
1.11.4.2.2. Is there a non-USAFA investigator?
1.11.4.2.3. Are the resource permissions in place?
1.11.4.2.4. Is training compliant?
1.11.4.2.5. Does the submission have all the appropriate signatures?
1.11.4.2.6. Does the submission have a separate and complete informed consent document or does it request a waiver of documented informed consent in the protocol?

If the answers to 2.a. and b. are "no", HRPP Support Personnel ensure compliance with 2.c. through 2.g. If the submission is not compliant, the HRPP Support Personnel return the submission to the PI with the appropriate direction to complete the submission.

1.11.4.3. Once a compliant submission is received, HRPP Support Personnel assign a protocol number and create a paper and electronic file. File includes: submission form and supporting documents (e.g., recruitment documents), training certificate for all investigators, resumes for all investigators (excluding cadets), and all communications regarding the research. The protocol number will be provided a letter at the end that reflects the determination: N – if the research is not human subjects research, E – if the research is exempt, or H – if it is determined to not be exempt.

1.11.4.4. The HRPP Support Personnel ensure a complete submission and supporting documents are included in the read-ahead for the monthly meeting. The Friday prior to the IRB meeting date, the read-ahead is provided to IRB members and all protocols are posted on the HRPP SharePoint site for two weeks to allow Mission Elements (ME) time to review and provide comments prior to the AIO signing the permission memo.

1.11.4.5. DODI3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research, dated 10 September 2014, states in paragraph 6.a.(2) that Institutional Officials (IO) of DoD organizations shall "Establish procedures for review and approval of each study by the IO, AIO, or other senior institutional official before the institution becomes engaged in research involving human subjects and prior to initiation of any substantive changes thereto. The purpose of this review is to determine, on behalf of the institution and in light of local mission considerations, whether to permit the research. This review can be done before or after IRB approval, and is not part of the IRB review process."

1.11.4.6. HRPP Support Personnel facilitate researcher presence at the meeting by providing them the meeting date, time and location.

1.11.4.7. At the IRB meeting, the Board can make any of the following determinations, per section 32 CFR 219.109.

1.11.4.7.1. Approve the research.
1.11.4.7.2. Require modifications to the research.
1.11.4.7.3. Disapprove all research activities.

1.11.4.8. Within two weeks of the IRB meeting, HRPP Support Personnel will accomplish the following:

1.11.4.8.1. Draft and finalize the meeting minutes
1.11.4.8.2. If modifications are required per the meeting minutes, send letter with change table to PI
1.11.4.8.3. Staff permission memo for approved or conditionally approved research with ME comments to AIO

1.11.4.9. If modifications to the research are required, the PI will return the completed change table to the HRPP Organizational Box, usafa.irb@usafa.edu. Upon receipt, the HRPP Support Personnel will forward the completed change table to two IRB members to ensure all required modifications have been addressed appropriately. If modifications were required to the Informed Consent Document (ICD), one of the reviewing IRB members will be the Legal Representative. If the reviewers require additional information or clarifications, the reviewers will contact the PI directly and copy the HRPP Organizational Box on all communication.

1.11.4.10. If the research is disapproved, HRPP Support Personnel send a letter to the PI that includes the reason for the disapproval and information on how to appeal the decision.

1.11.4.11. Upon receipt of the signed AIO permission memo, HRPP Support Personnel send the IRB approval letter and the AIO Permission Memo to the PI for each permitted research protocol and the research can commence.

1.11.4.12. If the AIO does not permit the research, the HRPP Support Personnel send a letter to the PI that includes the reason for the disapproval and information on how to appeal the decision.

1.11.4.13. HRPP Support Personnel obtain signatures on the required approval memo from the legal representative and the Chair. HRPP Support Personnel send required documents to SGE-C.

1.11.4.14. PIs are required to submit amendments for any modifications to the approved protocol.

1.11.4.15. PIs are required to submit an annual report to the USAFA IRB within 364 days every year to continue the research until the research is closed with a final report.

1.11.4.16. Per DoDI3216.02_AFI40-402, Enclosure 2, 11.f., the PI must retain all research records (e.g., protocol, signed informed consent documents, HRPP correspondence, and data) for at least three years after the research ends or for the length of time specified in applicable regulations, or institutional or sponsor requirements, whichever is longer.

1.11.4.17. The USAFA HRPP office maintains all administrative records for three years after closure and then destroys them appropriately.

1.11.4.18. Files are subject to audit by SGE-C and USAFA HRPP.

1.11.4.19. Any publications or presentations that result from the research must be sent to the HRPP Organizational Box.

1.11.4.20. While every protocol is different, on average, the process from compliant submission on the appropriate submission date to approval takes approximately 6-8 weeks.

1.11.5. **Expedited Review:**

1.11.5.1. Expedited reviews are only performed if the PI provides a letter from the Department Head to the HRPP Organizational Box, usafa.irb@usafa.edu, providing justification for the expedited review.

1.11.5.2. HRPP Support Personnel send the protocol and request to an IRB member(s) for review with a protocol number. If the submission includes an Informed Consent Document (ICD) one of the reviewers must be the legal representative.

1.11.5.3. The IRB member(s) determine if the research qualifies for expedited review. If it does not qualify, the IRB member(s) return the protocol to the HRPP Support Personnel with a reason that it does not qualify and copies the PI. HRPP Support Personnel prepare it for IRB review.

1.11.5.4. If the research qualifies for expedited review and clarifications are required, the reviewer(s) ensure that the HRPP Support Personnel are copied on all remaining correspondence.

1.11.5.5. All required changes are sent to the HRPP Support Personnel who create a table of required changes (change table), as needed, from the review and includes all requirements from the legal review.

1.11.5.6. The HRPP Support Personnel send the change table to the PI.

1.11.5.7. The PI submits the revised protocol and ICD to the HRPP Support Personnel with changes tracked and highlighted.

1.11.5.8. The HRPP sends the revised protocol and ICD to the reviewer(s) for approval and they review the submitted changes.

1.11.5.9. When the protocol meets the reviewer(s) criteria (including the Legal Representative approving the ICD, the HRPP personnel draft an approval email to the HRPP Organizational Box.

1.11.5.10. NOTE: Expedited review does NOT eliminate the need for ME review through the SharePoint site unless the Investigator receives AIO approval for this exception.

1.11.5.11. Once AIO approval is obtained, HRPP Support Personnel notify the PI of the approval.

1.11.5.12. HRPP Support Personnel send required documents to SGE-C.

1.11.6. **Continuing/Final Review**:

1.11.6.1. Per 32 CFR 219.109, all non-exempt research must be reviewed for continuation by a date designated by the IRB that is consistent with the research risk, but not more than once per year.

1.11.6.2. About two months before the IRB approval for an approved research protocol expires, HRPP Support Personnel will send an email to the PI with the IRB approval expiration date that requests a Continuing or Final Report.

1.11.6.3. If HRPP Support Personnel do not receive a Continuing or Final Report in the next month, HRPP Support Personnel will send the PI a second email with the research approval expiration date that includes a link to the Continuing or Final Report template. Per 32 CFR 219.109(e), PIs are required to submit an annual report to the USAFA HRPP within 364 days every year to continue the research until the research is closed with a final report. It is the responsibility of the PI to provide a final or continuing report within 365 days of IRB approval. Reminders are a courtesy that HRPP Support Personnel will make every effort to ensure. However, an annual report within 364 days is the regulatory responsibility of the PI and NOT receiving a reminder will NOT result in an "extension" of the research beyond 364 days.

1.11.6.4. If all research-related interventions or interactions with human subjects have been completed and all data collection and analysis of identifiable private information described in the IRB approved research plan have been finished, then for the purposes of human subjects research oversight, the study has been completed. When the research has been completed, the PI submits a final report. In addition, the PI must submit any publications that have resulted from this research. Researchers should submit publications resulting from a research protocol as soon as the final version is accepted for publication, even if this occurs several years after the protocol has been closed.

1.11.6.5. If a report is not received by the due date, HRPP Support Personnel will notify the PI that IRB approval has lapsed and all research activities must cease until IRB approval is obtained. The PI's Department Head and Research Director will be copied on this email. The research activities cannot resume until the investigator receives IRB approval.

1.11.6.6. Continuing or Final Reports are submitted to the HRPP Organizational Box, **usafa.irb@usafa.edu**. A complete submission means all items have been completed, Informed Consent Documents (ICDs) have been appropriately accounted for (total # and the # properly/improperly executed), a copy of the current ICD is attached as a separate document, a copy of any presentations/publications that have resulted from this study are attached as a separate document, and the form is signed by the PI.

1.11.6.7. Once a complete submission is received, HRPP Support Personnel ensure the report and most current protocol are included in the read-ahead for the next monthly IRB meeting.

1.11.6.8. At the IRB meeting, the Board can make any of the following determinations:

1.11.6.8.1. Approve the report.
1.11.6.8.2. Table the report pending additional information.
1.11.6.8.3. Require modifications to the report.

1.11.6.8.4. Disapprove the report.

1.11.6.9. If the report is approved, HRPP Support Personnel send the PI a letter that includes the determination and the next IRB approval expiration date (one year from the IRB meeting date).

1.11.7. **Amendment Review:**

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

1.11.7.2. An amendment is required to an exempt protocol for modifications that might affect risk to subjects or the exemption category, such as changes in procedures, data collection instruments, data plans, and investigators. Amendments are not required for modifications that will not affect risk to subjects or the exemption category, such as adding a class, increasing subject numbers, extending the time period.

1.11.7.3. Information relating to protocol modifications should be relayed to subjects when such information might relate to the subject's willingness to continue to take part in the research. How this information will be relayed to the subject (e.g., through a re-consent process using a modified consent form, or a letter sent to the subject) should be included in a modification request, and IRB approval obtained prior to implementation. Approval of the submitted amendment is on the advice of the IRB Chair or a designated representative unless the nature of the proposed changes warrants review by the full IRB. The IRB may determine the modification relates to subjects' willingness to continue to participate in the research, and request that the PI relay pertinent information to subjects. The investigator is notified in writing of the IRB's decision.

1.11.7.3.1. A PI submits an Amendment Request Form to the HRPP Organizational Box.

1.11.7.3.2. The HRPP Support Personnel check the determination of the activity.

1.11.7.3.2.1. If the determination was "Not research involving human subjects", no amendments are required. However, if the intent of the activity has changed to a research focus, a new submission is required.

1.11.7.3.2.2. If the determination was "Exempt from IRB oversight", amendments are required for modifications that might affect risk to subjects or the exemption category, such as, changes in procedures, data collection instruments, data plans, and investigators. Amendments are not required for modifications that will not affect risk to subjects or the exemption category, such as adding a class, increasing subject numbers or increasing the time period

1.11.7.3.2.3. If the determination was “Full protocol research”, any modification to the approved protocol requires an amendment.

1.11.7.3.3. HRPP support Personnel check for a complete submission. A complete submission includes the amendment form completely filled out with signatures, the original protocol with changes highlighted using track changes, and the current submission date with the previous submission date crossed out.

1.11.7.3.4. Once a complete submission is received, HRPP Support Personnel include all submitted documents in the protocol file and decide if the amendment can be expedited or must be taken to full board review.

1.11.7.3.4.1. Non-substantive changes to either exempt or non-exempt research (i.e., increasing the number of subjects, changing an associate investigator) can be reviewed using expedited procedures.

1.11.7.3.4.1.1. A non-substantive or minor change is one which, in the judgment of the IRB reviewer, makes no substantial alteration in: a) The level of risk to subjects; b) The research design or methodology; c) The subject population; d) The qualifications of the research team; e) The facilities available to support the safe conduct of the research; f) Any other factor which would warrant review of the proposed changes by the convened IRB.

1.11.7.3.4.1.2. Examples of minor changes include but are not limited to: a) Changes in study research personnel; b) Adding research sites to a research study (assuming they are of a similar nature to those previously approved by the IRB); c) Extending the time period of the study to include follow-up with the research participants (with no additional invasive measures such as blood withdrawals); d) Changing the principal investigator (assuming the proposed PI has similar credentials to the previously approved PI); e) Deletion of questions in a questionnaire; f) Changing telephone numbers or contact persons on the consent form; g) Changing the dates or time for initiating a study; h) Changes in project title.

1.11.7.3.4.2. Substantive changes to exempt research (i.e., significant changes to procedures) must be reviewed by an EDO or using expedited procedures.

1.11.7.3.4.3. Substantive changes to non-exempt research must be reviewed by the IRB.

1.11.7.3.5. If the amendment can be expedited, HRPP Support Personnel send it to the IRB Chair or to an IRB member designated by the Chair to review. If modifications to the Informed Consent Document (ICD) are requested, the IRB Legal Representative will also review the amendment. Modifications to full protocol research can be expedited per 32 CFR 219.110(b)(2), “Minor changes in previously approved research during the period (of one year or less) for which approval is authorized.” Modifications to exempt research can always be expedited.

1.11.7.3.6. If the amendment requires full board review (i.e., major changes), all submitted documents will be included in the read-ahead for the next IRB meeting.

1.11.7.3.7. The following three determinations can be made for amendments:

1.11.7.3.7.1. Approved

1.11.7.3.7.2. Require modifications
1.11.7.3.7.3. Disapprove

1.11.7.3.8. If the amendment is approved, HRPP Support Personnel send a letter to the PI and the amended research protocol can be implemented.

1.11.7.3.9. If modifications are required, HRPP Support Personnel send a letter with a change table to PI. The PI will return the completed change table to the HRPP Organizational Box, usafa.irb@usafa.edu. Upon receipt, HRPP Support Personnel will forward the completed change table to two IRB members to ensure all required modifications have been addressed appropriately. If modifications were required to the Informed Consent Document (ICD), one of the reviewing IRB members will be the Legal Representative. If the reviewers require additional information or clarifications, the reviewers will contact the PI directly and copy the HRPP Organizational Box on all communication.

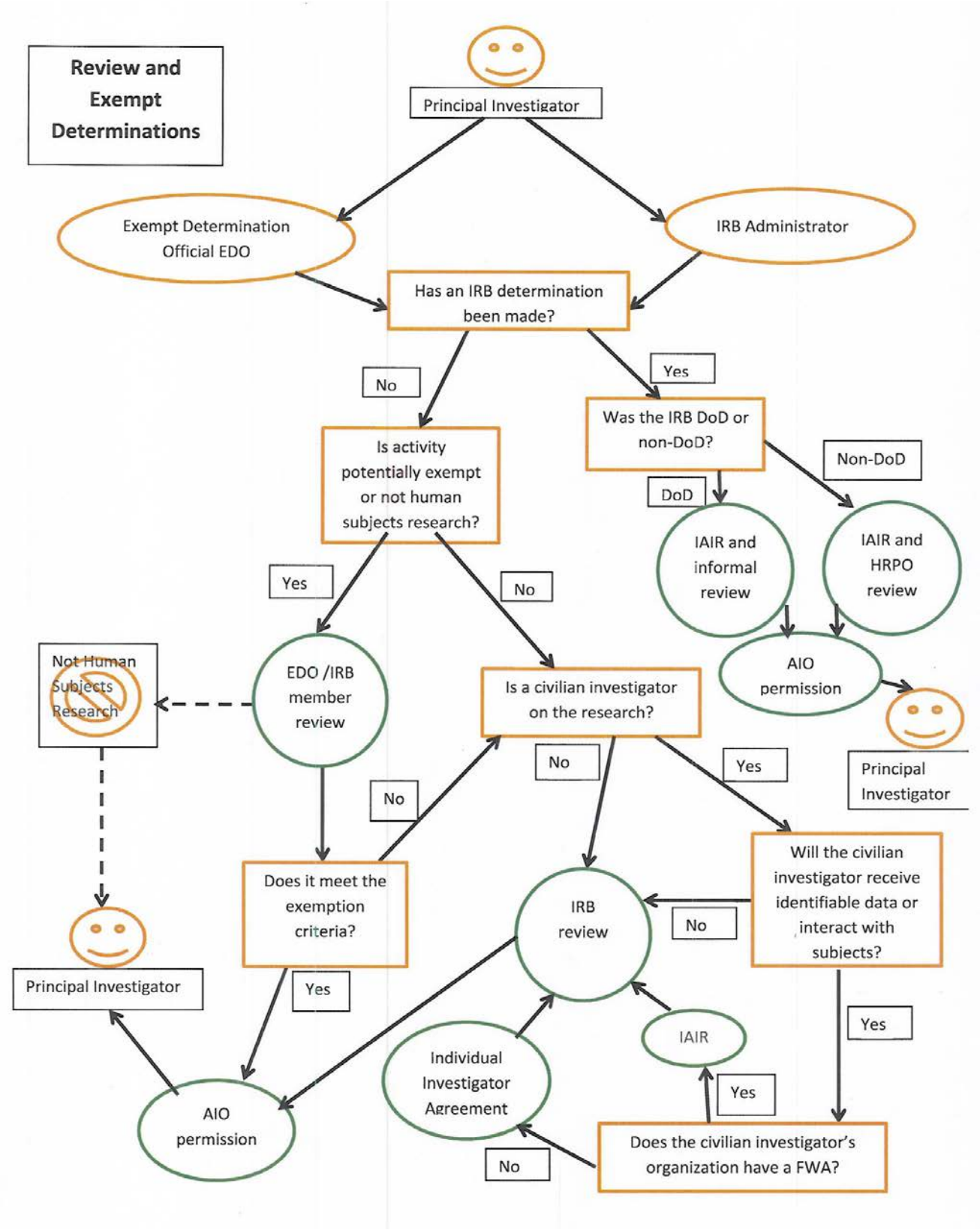
1.11.7.3.10. If the amendment is disapproved, HRPP Support Personnel send a letter to the PI that includes the reason for the disapproval and information on how to appeal the decision.

1.11.7.3.11. The process from complete submission to implementation is approximately 2 weeks for expedited review to 4 weeks for full board review without modifications, if the submission is received by the monthly submission deadline.

1.11.7.4. **Scientific Review:**

The Research Director and Department Head must review each protocol before submission and verify with their signature that the researcher is qualified to conduct human subjects research and the research design is sound. In addition, a scientific review by IRB members is conducted at each IRB meeting. The Research Director signing on the protocol is copied when the IRB requests changes from a PI.

Appendix 1


Review and Exempt Determinations
Principal Investigator
Exempt Determination Official EDO
IRB Administrator
Has an IRB determination been made?
No
Yes
Was the IRB DoD or non-DoD?
Non-DoD
DoD
IAIR and informal review
IAIR and HRPO review
AIO permission
Principal Investigator
Is activity potentially exempt or not human subjects research?
Yes
No
Not Human Subjects Research
EDO /IRB member review
Is a civilian investigator on the research?
No
Yes
No
Does it meet the exemption criteria?
Will the civilian investigator receive identifiable data or interact with subjects?
IRB review
No
Principal Investigator
Yes
IAIR
Yes
Individual Investigator Agreement
AIO permission
Yes
Does the civilian investigator's organization have a FWA?
No