USAFA HRPP

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CHAPTER 1: HUMAN RESEARCH PROTECTIONS PROGRAM OVERVIEW AND AUTHORITY

1.1. PURPOSE.

Provide an overview of human subject research (HSR) at the United States Air Force Academy (USAFA).

1.2. HUMAN RESEARCH PROTECTIONS PROGRAM.

The USAFA Human Research Protections Program (HRPP) protects the rights and welfare of human subjects recruited to participate in HSR at USAFA or for other sites for which USAFA is the Institutional Review Board (IRB) of Record.

1.3. PRINCIPLES.

The HRPP uses the three basic ethical principles outlined in The Belmont Report as a basic justification for decision-making and judgments. The three principles are:

a. Respect for Persons (individuals are treated as autonomous agents and individuals with diminished autonomy are entitled to protection);

b. Beneficence (an obligation to do no harm and maximize possible benefits and minimize possible harms); and

c. Justice (answers the question: who ought to receive the benefits of research and bear its burdens?).

1.4. AUTHORITIES.

a. The HRPP/IRB is established and functions under the authorities outlined in 32 Code of Federal Regulations (CFR) 219, 45 CFR 46 Subparts B-D, 10 United States Code (U.S.C.) 980, DoDI 3216.02, and DoDI3216.02_DAFI40-402.

b. The Department of the Air Force (DAF)/Surgeon General (SG) delegated authority to oversee the DAF HRPP to the DAF Component Office of Human Research Protections (COHRP). DAF institutions are required to hold a DAF issued DoD assurance approved by the DAF COHRP to conduct HSR. USAFA maintains a DAF DoD assurance (see Table 1.1).

c. In addition to a DoD assurance, the HRPP/IRB maintains a Federal-wide Assurance (FWA) issued by the Office of Human Research Protections (OHRP). A FWA allows HSR supported by the Department of Health and Human Services (HHS; see Table 1.1).

Table 1.1. USAFA Assurances and IRB Registration.

Assurance Type	Assurance Number	Assurance Expiration	IORG	IRB Registration	IRB Expiration	Issuing Institution
DoD	F50046	2/27/2026	-	-	-	DAF COHRP
FWA	FWA00019017	10/3/2026	IORG0006125	IRB00007373	9/21/2024	HHS

1.5. RESEARCH AND HUMAN SUBJECTS DEFINITIONS.

A review determines whether a submission meets the definition of research and the definition of human subjects:

a. ***Research*** means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (32 CFR 219.102(l)).

b. ***Human subject*** means a living individual about whom an investigator (whether professional or student) conducting research:

(1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or

(2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

(3) ***Intervention*** includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

(4) ***Interaction*** includes communication or interpersonal contact between investigator and subject.

1.6. ENGAGEMENT.

a. An institution is engaged in HSR if its personnel:

(1) Obtain information or biospecimens through intervention or interaction with a living individual, and use, study, or analyze the information or biospecimens; or

(2) Obtain, use, study, analyze, or generate identifiable private information or biospecimens from a living individual.

(3) Actively recruit or obtain informed consent.

b. An institution is not engaged in HSR if its activities are limited to:

(1) Providing human subjects, facilities, or equipment.

(2) Providing information about HSR to potential subjects.

(3) Conducting HSR using de-identified data.

1.7. USAFA-PERMITTED RESEARCH.

Due to resource limitations and to ensure USAFA permanent party/cadets/cadet candidates are supported in HSR endeavors, USAFA only permits USAFA-conducted research. Exceptions must be approved by the USAFA Institutional Official (IO) through the USAFA Human Protections Director (HPD).

1.8. USAFA PERSONNEL.

USAFA permanent party, cadets, and cadet candidates are considered USAFA personnel and covered by the USAFA assurance. The following categories of individuals are not considered USAFA personnel and are not covered by USAFA assurances unless an Individual Investigator Agreement (IIA) is executed to provide such coverage:

a. USAFA contractors.

b. Personnel assigned to other institutions conducting HSR at USAFA.

1.9. USAFA-SUPPORTED RESEARCH.

USAFA-supported research involves human subjects for which USAFA provides any resources. Resources may include funding, facilities, equipment, research support personnel (not investigators), access to or information about USAFA personnel, or identifiable data or identifiable specimens from living individuals assigned to USAFA.

1.10. USAFA-COLLABORATIVE RESEARCH.

a. Collaborative research is considered USAFA-conducted research. For HSR to be considered USAFA-conducted, USAFA must be engaged.

b. If USAFA de-identified data is provided to non-USAFA personnel, the HRPP Determination Request shall include a detailed data de-identification plan in the procedures section, including:

(1) Non-USAFA personnel de-identified data recipient names and institutions.

(2) A statement indicating that obtaining de-identified data does not engage non-USAFA personnel nor their respective institution(s) in HSR.

1.11. USAFA-CONDUCTED RESEARCH.

Review of HSR involving USAFA and non-USAFA personnel where both USAFA and the institution are engaged is considered DoD-conducted research (DoDI 3216.02, para. 3.5.).

a. If the reviewing HRPP/IRB is a DoD HRPP/IRB, the DoD HRPP/IRB may serve as the HRPP/IRB of record.

(1) The PI emails documents submitted to the reviewing DoD HRPP/IRB and determination/approval to the HRPP (usafa.hrpp@afacademy.af.edu).

(2) The HRPP Administrator conducts an administrative review and the HPD conducts a compliance review to ensure USAFA requirements are met (DoDI 3216.02, para. 3.5.a.(8)(c)).

(3) The HRPP Administrator processes the institutional approval.

(4) HSR may start once institutional approval is granted.

(5) The reviewing DoD HRPP/IRB, PI, and HRPP will communicate throughout the HSR life cycle to ensure DAF and USAFA requirements continue to be met.

(6) The HRPP Administrator only maintains HSR records through closure because the USAFA HRPP/IRB is not the HRPP/IRB of record.

b. If the reviewing HRPP/IRB is non-DoD HRPP/IRB, the non-DoD HRPP/IRB may serve as the HRPP/IRB of record.

(1) The non-DoD HRPP/IRB shall have a FWA.

(2) The HRPP Administrator processes an Institutional Agreement for IRB Review (IAIR). The IAIR is signed before the non-DoD HRPP/IRB reviews the HSR or the HSR is amended to include USAFA. Once the reviewing non-DoD HRPP/IRB has a fully executed IAIR, it may conduct HSR review(s) on behalf of USAFA. The PI may obtain IAIR signatures from the reviewing non-DoD HRPP/IRB after receipt of an approved IAIR template from the HRPP.

(3) The PI obtains a Human Research Protections Official (HRPO) review.

(4) The PI emails documents submitted to the reviewing non-DoD HRPP/IRB, determination/approval, and HRPO review to the HRPP (usafa.hrpp@afacademy.af.edu).

(5) The HRPP Administrator conducts an administrative review and the HPD conducts a compliance review to ensure USAFA requirements are met (DoDI 3216.02, para. 3.5.a.(8)(c)).

(6) The HRPP Administrator processes the institutional approval.

(7) HSR may start once institutional approval is granted.

(8) The reviewing DoD HRPP/IRB, PI, and HRPP will communicate throughout the HSR life cycle to ensure DAF and USAFA requirements continue to be met.

(9) The HRPP Administrator only maintains HSR records through closure because the USAFA HRPP/IRB is not the HRPP/IRB of record.

c. Additional requirements for collaborative HSR with non-USAFA personnel for which the USAFA HRPP/IRB is the HRPP/IRB of record.

(1) The non-USAFA personnel shall be covered by an assurance.

(2) If the non-USAFA personnel are not covered by an assurance, USAFA may extend its DoD assurance through an IIA.

(a) The HRPP Administrator processes an IIA. Once the HRPP/IRB has a fully executed IIA, the non-USAFA personnel may be added to applicable HSR documentation at USAFA.

(b) The PI may obtain IIA signatures from the non-USAFA personnel and respective supervisor(s) after receipt of an approved IIA template from the HRPP.

(3) The HRPP Administrator conducts an administrative review and the HPD conducts a compliance review to ensure USAFA requirements are met (DoDI 3216.02, para. 3.5.a.(8)(c)).

(4) The HRPP Administrator processes the institutional approval.

(5) HSR may start once institutional approval is granted.

(6) The reviewing DoD HRPP/IRB, PI, and HRPP will communicate throughout the HSR life cycle to ensure DAF and USAFA requirements continue to be met.

1.12. USAFA-ONLY RESEARCH.

If only USAFA personnel are engaged in HSR at USAFA, the USAFA HRPP/IRB will review the HSR.

1.13. RESEARCH NOT REVIEWED.

a. Research involving biological or chemical warfare agents or weapons.

b. Classified research.

c. Research with prisoners or detainees.

d. Fetal research.

e. Research involving Food and Drug Administration (FDA) investigational drugs or devices.

1.14. RESEARCH REQUIRING ADDITIONAL PROTECTIONS.

If HSR includes populations identified below as subjects, see DoDI 3216.02, para. 3.9 for required safeguards.

a. Pregnant women, fetuses, and neonates.

b. Prisoners.

c. Children.

d. Detainees or prisoners of war.

e. DoD service members, reserve service members, National Guard members, DoD civilians, and DoD contractors.

1.15. INTERNET RESEARCH.

a. Internet data collection is rarely private, anonymous, or even confidential because the Internet is an insecure medium due to the vulnerability of data in transit. Information can be easily accessed, shared, hacked, and/or replicated; thus, PI responsibility for data stewardship and heightened awareness of subjects' privacy, confidentiality, and identity are critical. The risk is accentuated if research involves sensitive data. The potential risk of harm results from a confidentiality breach. Internet data collection may increase potential confidentiality risks because of third party sites, third party interception when transmitting data, and impossibility of ensuring data is destroyed once research is complete. Investigators should consider these risks when conducting risk-benefit analyses.

b. When information is sensitive or a confidentiality breach may involve risks to a human subject, data collection should be formatted to allow human subjects to skip questions or provide a response such as "I choose not to answer."

c. The security should be appropriate to the risk. For most research, standard security measures (encryption, secure socket layer (SSL)) suffices. This helps ensure data intercepted during transmission cannot be decoded and individual responses cannot be traced. However, greater than minimal risk studies involving transmission of sensitive information may warrant multiple-factor authentication such as passwords delivered by mail/phone or identity verification. It is recommended the highest level of data encryption be used, within given availability and feasibility. This may result in encouraging human subjects to use a specific browser or software.

d. Depending on risk level (e.g., collection of sensitive information) and specific HSR circumstances, it may be appropriate to utilize alternative means of collecting data. For example, allowing human subjects to complete a hard copy data collection instrument and mail it to the PI.

e. PIs are cautioned encryption standards vary from country to country and legal restrictions exist about export of certain encryption software outside US boundaries.

f. For sensitive information, if a server is used for data storage, PII should be kept separate from HSR data and HSR data should be stored encrypted. It is recommended data backups be stored in a safe location, such as an environmentally controlled and secure data room with limited access. Removing data identifiers, storing identifiers and data in separate files, and auditing data security directories should be routine procedures.

g. Virtual identities, personas. Online identities (personas, avatars) and corresponding character names in online communities should be treated like real persons. These personas and reputations can be traced back to real individuals. If a PI wishes to use names of internet personas or real names in publications, it is sufficient to consent the human controller or recognize consent from the avatar as a proxy for the controller. In some cases, consenting both the virtual persona and the human controller may be more appropriate.

1.16. FOREIGN RESEARCH.

a. A PI shall provide evidence to the HRPP that applicable national laws and requirements have been met.

b. The HRPP will document sources of information about foreign research context in writing. The OHRP created the International Compilation of Human Research Standards, which provides information about HSR requirements in many foreign countries.

c. General Data Protection Regulation (GDPR).

(1) The GDPR is the toughest privacy and security law it the world. Though it was drafted and passed by the European Union (EU), it imposes obligations onto organizations anywhere, so long as they target or collect data related to people in the EU. The regulation was put into effect on May 25, 2018. The GDPR will levy harsh fines against those who violate its privacy and security standards, with penalties reaching into the tens of millions of euros.

(2) With the GDPR, Europe is signaling its firm stance on data privacy and security at a time when more people are entrusting their personal data with cloud services and breaches are a daily occurrence. The regulation itself is large, far-reaching, and fairly light on specifics, making GDPR compliance a daunting prospect, particularly for small and medium-sized enterprises.

(3) For more information about the GDPR, visit: https://gdpr.eu/what-is-gdpr/

d. Following approval, the DAF COHRP will conduct an administrative review. The following two types of research conducted in a foreign country do not need DAF COHRP review and approval:

(1) Research conducted in the host country by an established DoD overseas research institution; or

(2) Research including only DoD-affiliated personnel who are U.S. citizens as human subjects.

1.17. RESOLUTION.

Requests for guidance regarding concerns, questions, or conflicts in the application of regulations, instructions, and HRPP shall be directed to the HPD.

CHAPTER 2: ROLES AND RESPONSIBILITIES

2.1. PURPOSE.

Describe HRPP, IRB, membership, appointment, and responsibilities of HSR stakeholders.

2.2. HUMAN RESEARCH PROTECTIONS PROGRAM VS. INSTITUTIONAL REVIEW BOARD.

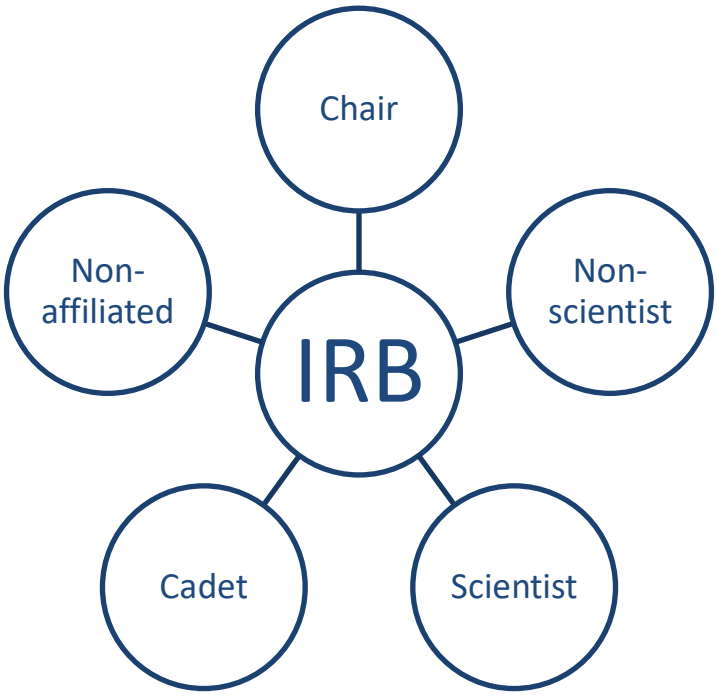
a. An HRPP is a collaborative effort among all who develop, review, approve, conduct, and facilitate HSR. It includes IOs, HPD, IRB, investigators, human subjects, and other stakeholders (see Figure 2.1). An HRPP is entrusted with protecting the rights and welfare of human subjects by supporting, guiding, and educating HSR that is ethically and scientifically sound. HRPPs vary in size and complexity, and are designed and resourced to meet the needs of its institution. Not all HRPPs have the same components nor functions; they vary from institution to institution. Nonetheless, HRPPs manage ethical and regulatory factors of HSR from cradle to grave.

Figure 2.1. HRPP Components.

b. An IRB, a component of the HRPP, is a board comprised of at least 5 people, charged with safeguarding rights and welfare of human subjects (see Figure 2.2). Some members fulfill specific roles. When the IRB meets, it reviews non-exempt protocols. However, its members (individually) may review HSR submissions without formally meeting to discuss HSR and requirements for approval. A fully constituted IRB is required for IRB members to conduct non-

exempt/expedited review and oversight actions on behalf of the board. As such, a fully constituted IRB will be maintained at all times to ensure compliance within the context of the HRPP.

Figure 2.2. IRB Membership.



2.3. HUMAN RESEARCH PROTECTIONS PROGRAM MEMBERSHIP.

The HRPP consists of an IO, one or more Alternate Institutional Officials (AIOs), Exemption Determination Officials (EDOs), HPD, HRPP Administrator, IRB members, and investigators with approved HSR protocols.

2.4. APPOINTMENTS AND RESPONSIBILITIES.

HRPP members are expected to be familiar with the HRPP to ensure reviews, approvals, and institutional approval are compliant with applicable requirements (see Appendix 1: Organizational Chart).

a. Commanders or Directors of DoD Institutions. Per DoDI 3216.02, if HSR involves DoD-affiliated personnel, a PI must receive approval from the DoD-affiliated personnel's command or DoD Component to conduct research. If the HSR takes place in a DoD facility, the PI must also receive approval from the command or DoD Component responsible for the facility. The USAFA Superintendent retains these authorities at USAFA and its personnel, and may delegate these authorities. The USAFA Superintendent is the IO and not a voting member of the IRB. The Vice Superintendent and Director A3/9, Operations and Strategic Analysis are AIOs and not

voting members of the IRB. The responsibilities of commanders or directors of DoD institutions outlined in DoDI 3216.02, para. 3.3, include:

(1) Establish, implement, and maintain an HRPP to ensure the institution's compliance with DoDI 3216.02.

(2) Provide experienced, well-qualified HRPP staff, appropriate resources, and periodically review the HRPP to ensure USAFA maintains resources necessary for compliance with DoDI 3216.02.

(3) Designate a HPD as the primary point of contact (POC) for the institution's HRPP.

(4) Evaluate and improve the institution's HRPP, its policies, and its standard operating procedures.

(5) Establish a program of post-approval compliance monitoring (PACM) of HSR conducted or supported by the institution.

b. HPD. The HPD is a voting member of the IRB and responsible for the overall administration of the HRPP. Additional responsibilities include:

(1) May serve as the IRB Chair. When the HPD serves as the IRB Chair, both roles will be documented separately in the DoD assurance.

(2) Serve as the primary POC for the HRPP.

(3) Review and coordinate official requests from DAF COHRP.

(4) Brief DAF COHRP requests and responses to the Director A3/9, Operations and Strategic Analysis as needed.

(5) Prepare briefings for the IO/AIO and other leaders/institutions as necessary.

(6) Train/educate HRPP stakeholders as needed, to include outreach activities (biannual email to USAFA [Appendix 8], ad hoc meetings, etc.).

(7) Ensure ongoing assessment and improvement of the HRPP.

(a) Periodically audit and/or assign HRPP members to audit HSR.

(b) Investigate activities that might be HSR but were not submitted to the HRPP/IRB for a determination. Report findings to the Director A3/9, Operations and Strategic Analysis and/or at the next convened IRB. Recommend sanctions if action(s) are determined to be sufficiently severe or there is a pattern of noncompliance.

(8) Identify and contact subject matter experts or consultants as needed.

c. HRPP Administrator. The HRPP Administrator is not a voting member of the IRB; responsibilities of this position include:

(1) Maintain HRPP/IRB online resources.

(2) Conduct administrative review(s) of submission(s) to ensure requirements are met prior to tasking a reviewer.

(a) Ensure personnel listed on HSR are covered by a FWA and/or appropriate agreements are in place prior to issuing approvals.

(b) Send submissions to an EDO/IRB member for determination.

(c) Notify investigators on requirements resulting from HRPP/IRB determinations; may consult with the HPD as needed.

(3) Coordinate necessary administrative actions prior to and during convened IRB meeting. These include scheduling a location and enabling remote participation, developing and distributing agenda and readaheads to IRB members, tracking attendance, conflict of interest (CoI) disclosures, and drafting minutes.

(a) Submit convened IRB meeting draft minutes to attending IRB members for comments/edits prior to approval.

(b) Track IRB member attendance at convened IRB meeting.

(4) Prepare staff packages for HRPP members and others as required.

(5) Provide a monthly status of lapsed training and/or approval(s) to HRPP members, Research Directors, and Department Heads.

(6) Staff letter(s) of appointment for approval.

(7) Maintain HSR records from inception through closure and destroy no earlier than three years after closure.

(8) Maintain HSR database.

d. IRB Chair. The IRB Chair should have at least one year of HRPP/IRB experience; additional responsibilities include:

(1) Document and periodically update IRB members approved to issue determinations and conduct expedited reviews.

(2) Solicit IRB members, obtain USAFA/Cadet Wing (CW) approval for cadet nominations, and forward to HRPP Administrator for appointment by IO/AIO.

e. IRB Members. IRB membership is defined in 32 CFR 219.107. The IRB is comprised of at least the following primary positions: Chair, Scientist, Non-scientist, and Non-affiliated. The IRB will maintain a minimum of five members at all times. To ensure cadet representation, the IRB will attempt to appoint cadets to the IRB. Each position may have one or more alternates. The IRB Chair may promote an alternate to primary in writing when a primary departs to ensure

requirements in 32 CFR 219.107. Appointment by the IO/AIO of a replacement primary member will be made as soon as feasible. If IRB membership constitution is lost, the IRB ceases to operate until it regains constitution. No actions will take place on behalf of the IRB until constitution is re-established. Potential IRB members may be recruited through Department Heads or individuals with similar responsibility. Nominee qualifications are reviewed by the HPD and/or IRB Chair and appointed by the IO/AIO. IRB members are appointed for a renewable three-year term. Responsibilities of IRB members include:

(1) Provide a current Curriculum Vitae (CV) and Collaborative Institutional Training Initiative (CITI) training to the HRPP (usafa.hrpp@afacademy.af.edu) prior to being appointed as an IRB member.

(2) Maintain CITI training throughout appointment.

(3) Review submissions, issue determinations, and meet deadlines (or request extensions) as requested by the HRPP Administrator, HPD, or IRB Chair. Prior to reviewing submissions and issuing determinations, IRB members will be coached on how to conduct reviews and issue determinations by an experienced IRB member.

(4) Conduct HSR audits (as requested by the HPD or IRB Chair), document findings, and report results.

(5) Notify the HRPP Administrator, HPD, and/or IRB Chair if a CoI exists prior to completing assignments and convened IRB meeting.

(6) Attend convened IRB meetings. RSVP to the HRPP Administrator within one business day.

f. EDOs. Any USAFA permanent party can apply to become an EDO. EDOs must complete training and certification required by DAF COHRP. Once training and certification are complete, the HRPP Administrator staffs a letter of appointment to the AIO for approval. EDO responsibilities are outlined in DoDI3216.02_DAFI40-402 and additional responsibilities include:

(1) Mentor investigators as required.

(2) Ensure submissions are complete and assign a protocol number.

(3) Review submissions per Chapter 13: Exempt Research.

(4) Provide a summary of research reviewed, resulting determination(s), all communication, and associated documents to the HRPP (usafa.hrpp@afacademy.af.edu).

(5) Maintain all HSR records for at least three years after HSR closure.

g. Investigators. To serve as a PI, an individual must have prior HSR experience. Investigators become HRPP members when HSR is determined, approved, and permitted.

(1) PIs shall: (1) become familiar with relevant federal, DoD, DAF, and USAFA publications governing HSR; (2) execute HSR as approved and permitted; and (3) protect rights and welfare of human subjects.

(2) PIs are ultimately responsible for complete submission(s), conduct of research, breaches of human subjects protections, and research team member responsibilities listed in the protocol. The HRPP Administrator forwards administratively complete submissions for a determination or review. Additional requirements may be identified by the HPD, IRB reviewer, or other stakeholders based on HSR characteristics and resources sought. At a minimum, a complete submission includes:

(a) Current form(s).

(b) Meets current federal, DoD, DAF, and USAFA requirements.

(c) Mission Element (ME) letters of support (LoS) (as needed).

(d) CITI training that is up to date and commensurate with role for all research personnel.

(e) CVs for all research personnel (excluding cadets).

(f) Signatures for all research personnel.

(3) The status (USAFA permanent party, cadet, contractor, fellow, volunteer, etc.) and role (PI, research assistant, research coordinator, etc.) of personnel listed shall be clearly stated.

(a) Investigators (including cadets) with no prior HSR experience may serve as an associate investigator (AI) or another role under the purview of an experienced PI.

(b) A PI determines if non-USAFA personnel conducting HSR are covered by an assurance (DoD or FWA).

1. If non-USAFA personnel are covered by an assurance, the non-USAFA personnel institution of assignment must sign an IAIR to allow the USAFA HRPP/IRB to be the IRB of record.

2. If non-USAFA personnel are not covered by an assurance, the non-USAFA personnel and respective supervisor(s) sign an IIA to be covered by a USAFA assurance (DoD and FWA).

(4) Current CITI training commensurate with role shall be maintained for research personnel.

(5) Close/amend open HSR prior to departing USAFA.

(6) Maintain HSR records for a minimum of three years after closure.

h. Department Heads.

(1) Recommend EDOs, HRPOs, and primary/alternate IRB members.

(2) Ensure EDOs, HRPOs, and IRB members have time to complete required training.

(3) Ensure EDOs, HRPOs, and IRB members have time to complete assignments.

(4) Ensure IRB members have time to attend convened IRB meetings.

(5) Ensure department staff conducting HSR are mentored about HSR methodology and protocol development.

(6) Review HSR submissions, ensure PIs have adequate time and resources to conduct HSR, and indicate HSR support.

(7) Require PIs to get an official determination is there is a question regarding whether an activity is HSR.

CHAPTER 3: EDUCATION AND TRAINING

3.1. PURPOSE.

Describe education and training required of USAFA personnel involved in HSR (see Table 3.1).

Table 3.1. CITI Training Groups.

Group	Description
1	Senior AF Leadership, IOs, Advisors to the IO
2	AF Headquarters Oversight Personnel
3	IRB Members and Support Staff, Regulatory Oversight of Extramural Human Subjects Research
4	Investigators
5	Research Support Personnel, Research Monitors, Ombudspeople, Subject Advocates, DSMB Members
6	Research Coordinators, Clinical Coordinators, Study Coordinators, Research Administrators

3.2. HUMAN RESEARCH PROTECTIONS PROGRAM AND INSTITUTIONAL REVIEW BOARD.

The Office of the Assistant Secretary of Defense has established minimum education requirements for DoD personnel who are part of an HRPP, to include periodic training with required educational topics (Minimum Education Requirements Memo (MERF), 16 August 2012). To ensure compliance with the MERF, the DAF COHRP provides human subjects protection training through CITI. CITI training must be aligned with the individual's role in reviewing or executing HSR. Additionally, HRPP/IRB stakeholders are expected to be familiar with the HRPP to ensure approvals, institutional approval, reviews, and submissions comply with USAFA policies. Personnel whose CITI training has expired shall ceased conducting HRPP/IRB activities.

a. IO/AIO. Training for the Superintendent (IO), the Vice Superintendent (AIO), the Director A3/9, Operations and Strategic Analysis (AIO), and other individual(s) to whom the IO as the Commander of USAFA has delegated HSR institutional approval authority is coordinated through the HPD using DAF COHRP-provided and USAFA information slides. Subsequent training may be completed in-person or by reviewing slides provided by the HPD. Personnel whose CITI training has expired shall not sign institutional approvals.

b. EDOs. EDOs must successfully complete initial and refresher DAF COHRP EDO training. EDOs whose training has expired shall not conduct EDO activities.

c. IRB Members and HRPP Staff. IRB members and HRPP staff will complete and maintain CITI training commensurate with role, as determined by DAF COHRP and affiliated with the AF/SG's Office. Professional development for IRB members may be included in convened IRB meetings and relevant to issues discussed. If an IRB member is an investigator, s/he must

complete CITI training commensurate with both roles. Personnel whose CITI training has expired shall not conduct HRPP/IRB activities.

3.3. INVESTIGATORS.

Personnel who are responsible for developing/conducting HSR must complete CITI training for investigators affiliated with the AF/SG's Office. Current CITI training shall be included in each submission. The HRPP Administrator will review CITI training; missing CITI training for personnel listed will not be reviewed. Investigators whose CITI training has expired shall cease conducting HSR activities.

a. Periodic training is required for all investigators and associated personnel engaged in HSR.

b. PIs are responsible to ensure research personnel listed meet CITI training requirements commensurate with role and maintain CITI training documentation in HSR records throughout their tenure in HSR (even after removal) until records can be destroyed, typically three years after closure.

c. The HRPP/IRB may accept CITI training from other DoD affiliation(s) (e.g., AFRL, ARL, OUSD(P&R), etc.).

d. USAFA will not accept CITI training from civilian institutions (e.g. UCCS, KSU, etc.) because it does not address DoD requirements. Investigators from civilian institutions who are conducting HSR at USAFA must complete CITI training affiliated with the AF/SG's Office.

e. Investigators must review the HRPP to ensure compliance with USAFA guidance. The HRPP is posted in the USAFA HRPP/IRB Teams group.

3.4. RESEARCH SUPPORT PERSONNEL.

Personnel participating in a limited and/or defined part of HSR under the direct supervision or guidance of a PI shall complete CITI training commensurate with role affiliated with the AF/SG's Office. Current CITI training must be included in each submission. The HRPP Administrator will review CITI training; missing CITI training for personnel listed will not be reviewed. Research support personnel whose CITI training has expired shall cease conducting HSR activities.

3.5. RESEARCH MONITORS, OMBUDSPEOPLE, SUBJECT ADVOCATES, AND DATA SAFETY MONITORING BOARDS.

Personnel not part of the research team and appointed by the IRB or identified in the IRB-approved HSR to act on behalf of the IRB (e.g., research monitor or ombudsperson) or on behalf of the research subject (e.g., Subject Advocate) shall complete CITI training commensurate with role affiliated with the AF/SG's Office. CITI training must be included in each submission. The

HRPP Administrator will review CITI training; missing CITI training for personnel listed will not be reviewed. Research monitors, ombudspeople, subject advocates, and Data Sharing Monitoring Boards (DSMBs) whose CITI training has expired shall cease conducting HSR activities.

3.6. RESEARCH COORDINATORS, CLINICAL COORDINATORS, STUDY COORDINATORS, AND RESEARCH ADMINISTRATORS.

Personnel who are responsible for conducting HSR under the auspices of PIs or personnel involved in preparation/administration of HSR shall complete the Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators training affiliated with the AF/SG's Office. CITI training must be included in each submission. The HRPP Administrator will review CITI training; missing CITI training for personnel listed will not be reviewed. Research Coordinators, Clinical Coordinators, Study Coordinators, and Research Administrators whose CITI training has expired shall cease conducting HSR activities.

3.7. EXPIRED TRAINING.

The HRPP Administrator shall review the training status of all personnel listed above at the beginning of every month and email stakeholders to ensure training requirements do not lapse. The emails will emphasize the importance of maintaining CITI training and clearly state individuals must cease HSR activities commensurate with role once CITI training expires. This action supports PACM.

CHAPTER 4: RECORDKEEPING

4.1. PURPOSE.

Describe requirements for access and retention of HRPP and HSR records (see Appendix 4: Folder and Record Naming Convention).

4.2. RECORDS MANAGEMENT.

a. The HRPP maintains electronic files for guidance, forms, documents, and HRPP records.

b. EDOs maintain HSR records following the same procedures outlined below. EDOs shall forward all HSR records about a determination (to include emails between EDO and PI), amendment(s), or other action(s) related to HSR reviewed or as tasked by the HRPP to maintain a repository of HSR records in a centralized location. EDOs do not maintain records for HSR reviewed by another institution, EDO, or reviewer.

c. All HSR records for which a non-USAFA IRB is the IRB of record are maintained by the HRPP Administrator through closure.

d. PIs shall maintain HSR records per para. 4.6.

4.3. HUMAN RESEARCH PROTECTIONS PROGRAM RECORDS.

a. Records should not be corrected after they are finalized. If modification is necessary, the original must be legible, reason(s) for modification(s) shall be clear, and the modification must be signed, initialed, and/or dated as appropriate by the person making a correction.

b. Records are stored using Air Force Records Management practices.

c. Additional records include:

(1) DoD assurance and FWA.

(2) Communications to and from HRPP and DAF COHRP and/or other governing bodies.

(3) Training documentation for HRPP staff, IO, AIO, and IRB members.

d. HSR records for which USAFA is the HRPP/IRB of record include:

(1) The initially approved HSR submission.

(2) All information and materials provided to human subjects (e.g., recruitment materials, recruitment scripts, instructions, data collection instruments, debriefing materials).

(3) Amendments.

(4) Informed Consent Documents (ICDs).

(5) Continuing reviews and closure reports of non-exempt HSR.

(6) Reports of Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSOs).

(7) Significant correspondence and/or notifications between HRPP and PIs.

(8) Significant correspondence between HRPP and IO/AIO.

(9) Significant correspondence between HRPP and DAF COHRP.

(10) Deviations.

(11) Noncompliance reports.

(12) Complaints.

(13) Notices (e.g., training, report due) and approval letters (e.g., resources, HSR, amendments, continuing reviews, and closure reports).

(14) Convened IRB meeting minutes.

(15) CITI training.

(16) Health Insurance Portability and Accountability Act (HIPAA) authorization documents (if applicable) or waivers. The HRPP/IRB does not maintain HIPAA records because it is not a covered entity. PIs needing 10 Medical Group (MDG) resources are responsible for following 10 MDG HSR requirements (see Appendix 2: 10 MDG Relationship).

(17) IAIRs.

(18) IIAs.

(19) PACM.

e. HSR records for which the USAFA IRB is not the IRB of record include:

(1) Approved HSR, determination, and supporting documentation submitted to the non-USAFA HRPP/IRB.

(2) IAIR (if a non-DoD IRB).

(3) HRPO review.

(4) Relevant portion(s) of the convened IRB meeting minutes during which the IRB was notified.

(5) Institutional approval.

(6) Complaints.

(7) Relevant correspondence among the HRPP/IRB, PI, non-USAFA HRPP/IRB, and DAF COHRP.

f. Other records include:

(1) Convened IRB meeting minutes.

(2) IRB member rosters (including CVs and CITI training).

(3) Documentation of HRPP/IRB actions (e.g., IRB member appointment, program approval).

4.4. STORAGE.

The HRPP/IRB saves records in SharePoint, a cloud-based network accessed by authorized users. HRPP personnel have external hard drives where records may be backed up periodically.

4.5. ACCESS.

Access by the HRPP occurs through Office 365 credentials with multi-factor authentication.

a. The HRPP/IRB provides records to the IRB Chair, IRB members, IO/AIO, leadership, and officials of federal and state regulatory agencies on a need to know. HRPP/IRB records are accessible for inspection and copying by authorized representatives of federal agencies or departments.

b. PIs and authorized HSR personnel have access to records related to their HSR upon request. The HRPP/IRB limits access to HRPP/IRB records to individuals/institutions with a legitimate reason, as determined by the HPD.

4.6. HUMAN SUBJECTS RESEARCH RECORDS.

a. HSR records are maintained by PIs. PIs conducting HSR at USAFA under the approval of a non-USAFA IRB must maintain records in accordance with (IAW) this document.

(1) HSR records shall be maintained at least three years after closure (32 CFR 219.115(b) and DoDI 3216.02, para. 3.15(a)).

(2) HIPAA records shall be maintained at least six years in a HIPAA-compliant manner.

(3) PIs conducting HSR at USAFA understand HSR records are subject to inspection at any time by the USAFA HRPP/IRB, DAF COHRP, or DoD Office for Human Research Protections (DOHRP), regardless of IRB of record.

b. HSR records may include:

(1) HRPP Determination Request.

(2) Amendment(s).

(3) Approval(s).

(4) Institutional approval.

(5) Signed ICDs.

(6) CITI training for all research personnel commensurate with role.

(7) Approved data de-identification Plan.

(8) HIPAA authorization documents or waivers.

(9) Noncompliance reports.

(10) Audits.

(11) Complaints.

(12) IAIRs.

(13) IIAs.

c. If a PI departs USAFA before the three-year retention period:

(1) PI(s) must notify the HRPP of departure and provide contact information.

(2) Transfer HSR records to another PI(s) in the same department, Research Director, or Department Head.

(a) The HRPP must be notified of who shall retain HSR records at USAFA after departure.

(b) The departing PI may not keep copies of HSR records.

d. Records are subject to audit by DAF COHRP and HRPP/IRB to ensure required HSR documentation is maintained.

4.7. RETENTION.

The HRPP Administrator retains administrative records and deletes them no earlier than three years after HSR closure or rescinded institutional approval. Records are deleted periodically, as workload allows, but no less than monthly.

CHAPTER 5: RECRUITMENT, SELECTION, AND CADETS

5.1. PURPOSE.

Identify recruitment and selection of human subjects, with emphasis on cadet factors. Cadets include cadets at USAFA and cadet candidates at USAFA Preparatory School (PS).

5.2. EQUITABLE SELECTION.

a. Equitable selection of human subjects means selection criteria is fair and appropriate to the HSR question. Equitable selection of human subjects does not mean all groups are represented in proportion to the population.

(1) Human subjects are not excluded from HSR based on gender, gender orientation, race, national origin, religion, creed, education, or socio-economic status.

(2) Human subjects are not included in HSR because of their easy availability, compromised position, or because of gender, racial, economic, or cultural biases.

(3) One group of human subjects shall not be systematically selected to bear the burdens of HSR that could benefit another group.

(4) One group of human subjects shall not be systematically excluded from participation in HSR that could benefit that group.

(5) Safeguards should be in place and considered by HRPP stakeholders against:

(a) Coercion. Persuading someone to do something through force or threats.

(b) Undue influence. Persuading someone to do something based on a relationship.

(c) Perception of coercion or undue influence.

b. Selection of human subjects must be equitable and adequate provisions to protect privacy and confidentiality need to be maintained.

c. Selection of human subjects reflecting gender and minority participation in DoD-conducted or –supported shall comply with section 252 of PL 103-160. This criterion may be waived by DAF COHRP.

5.3. ADVERTISEMENT AND RECRUITMENT.

a. HSR advertisement. Any information given or presented to potential human subjects using radio, television, printed, electronic, World Wide Web, or other means with the intent to recruit human subjects into HSR.

b. The use of direct HSR advertisement to recruit potential human subjects is the beginning of the human subject selection and informed consent.

c. The text of direct advertisement (i.e. advertising that is intended to be seen or heard by prospective human subjects to solicit participation) is reviewed and approved by the HRPP (exempt) or IRB (non-exempt) prior to distribution, posting, publication, or broadcasting. Direct advertisements include:

(1) Written telephone scripts.

(2) Mailings.

(3) Printed flyers.

(4) Postings on bulletin boards.

(5) Newspaper advertisements.

(6) Press releases.

(7) Television and radio spots.

(8) Videotapes.

(9) Web pages.

(10) Emails.

(11) Any other media designed to impart information to potential human subjects for recruitment purposes (e.g., social media).

d. The content of advertisements includes:

(1) Name and contact information of PIs.

(2) A statement that the activity is HSR.

(3) Where the HSR will take place.

(4) HSR purpose.

(5) Brief description of eligibility criteria.

(6) A straightforward, truthful description of incentives or benefits to human subjects.

(7) Reimbursement or compensation (if any). Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited (DoDI 3216.02, para. 3.9.f.(7); see Chapter 6).

(a) The amount of payment may be stated but should not be stressed. Alternatively, the advertisement may state: "Payment for time and travel will be provided."

(b) Advertisements may state human subjects will be paid, but should not emphasize the payment nor the amount of pay (e.g., large or bold font).

(8) Time commitment or number of visits required of human subjects and the time period over which participation would occur.

(9) For printed advertisements, the HRPP should consider adequate font size, target sample, and HSR-appropriate illustrations.

e. The content of the advertisements shall not:

(1) Imply a waiver of human subjects' rights.

(2) Imply HSR procedures are safe or effective for the purposes of the HSR or that one intervention is in any way superior to any other intervention.

(3) Include statements that may be considered coercive.

(4) Promise "free medical treatment" when the intent is to say human subjects will not be charged for taking part in HSR.

(5) Include misleading statements about benefits arising from participation in HSR.

(6) Use the name of the commercial sponsor or product manufacturer.

(7) State or imply certainty of a favorable outcome or other benefit beyond what is outlined in the ICD or HSR.

(8) Overemphasize payment as an enticement to enroll (e.g., indicating payment amount in a larger or bold font than other text).

f. The wording of all advertisements must be exactly as approved the reviewer (EDO, IRB member, convened IRB).

(1) PIs are required to maintain the approved advertisement.

(2) Advertisements will indicate HRPP/IRB approval date.

g. The reviewer (EDO, IRB member, convened IRB) reviews:

(1) Information and language in the advertisement.

(2) Mode of communication or presentation of the advertisement to ensure:

(a) It does not appear coercive.

(b) It does not overstate or imply an outcome, degree of safety, or potential benefit described in consent documents and HSR.

h. PI(s) with an approved HSR from another institution wishing to advertise at USAFA must submit the advertisement, proof of HRPP/IRB approval from the originating institution, and relevant HSR documentation to the HRPP for an administrative review prior to requesting a LoS from the IO/AIO.

i. Advertisement placement.

(1) The HRPP/IRB only approves content (or content changes) of advertisements.

(2) The local authority only approves placement of advertisements.

(a) PI(s) are encouraged to contact appropriate local authorities where the advertisement is to be placed to obtain a LoS.

(b) PI(s) wishing to advertise in institutions outside USAFA must seek LoS from those institutions.

j. If the HRPP/IRB is contacted by a potential human subject about an advertisement, the HRPP assists in answering questions but will direct the potential human subject to the PI (if needed).

5.4. CADET VULNERABILITY.

a. Due to their position in the military, cadet rank hierarchies, and instructor-student relationships, cadets are vulnerable as human subjects. Recruitment procedures shall consider and minimize coercion based on these vulnerabilities.

b. Additional guidance on DoD-affiliated personnel as human subjects in DoDI 3216.02, para. 3.9.f (see below) applies to cadets:

(1) If the HSR involves DoD-affiliated personnel as subjects and if the HSR includes any risks to their fitness for duty (e.g. health, availability to perform job, data breach), the ICD must inform DoD-affiliated personnel about these risks and that they should seek command or Component guidance before participating.

(2) If the HSR involves DoD-affiliated personnel, the PI must receive command or Component approval to execute the research.

(3) Military and civilian supervisors, officers, and others in the chain of command are prohibited from influencing their subordinates to participate in HSR.

(4) Military and civilian supervisors, officers, and others in the chain of command must not be present at any recruitment session or during the HSR consent process for DoD-affiliated

personnel. Excluded supervisors or those in the chain of command may participate in separate HSR recruitment sessions, if applicable.

(5) Service members and all Reserve Component and National Guard members in a federal duty status are considered for purposes of this issuance, to be adults. If a Service member, Reserve Component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human subject.

(6) In order to approve research involving DoD-affiliated personnel as human subjects, the IRB or HRPO must determine whether the following requirements have been satisfied:

(a) The consent documentation must include, if applicable, potential risks for the revocation of clearance, credentials, or other privileged access or duty.

(b) For research involving recruitment of DoD-affiliated personnel in HSR determined greater than minimal risk, as defined by Part 219 of Title 32, CFR, and when HSR recruitment occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

1. Must not have a CoI with the research or be a part of the research team.

2. Must be present during the HSR recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.

3. Should be available to address DoD-affiliated personnel's concerns about participation.

(7) Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited IAW Title 5, U.S.C., with particular reference to Subparts G and H, with some exceptions for purposes consistent with Section 30 of Title 24, U.S.C.

c. USAFA allows cadets to participate in greater than minimal risk research. However, greater than minimal risk studies recruiting cadets shall be communicated to the IO and/or AIO when requesting institutional approval. The IO/AIO may decide it is not appropriate to recruit cadets and explicitly exclude cadets as a condition of institutional approval.

5.5. RESEARCH DURING BASIC CADET TRAINING.

Basic Cadet Training (BCT) is stressful and cadets are in a very vulnerable situation. For this reason, the Commandant of Cadets does not allow recruitment to occur during BCT unless approved by the Superintendent. PIs considering seeking approval to recruit cadets during BCT should consider incorporating the following safeguards into research planning, implementation, recruitment, and consent.

a. Emphasize the activity is HSR and voluntary; cadets can decline participation.

b. HSR during BCT requires coordination with and approval by the Commandant of Cadets. PIs should plan a minimum of 18 months for the coordination and approval process.

c. If logistically possible, provide incoming cadets with information about HSR before arriving at USAFA. This will give them an opportunity to understand the HSR and if they would like to participate in a non-coercive environment prior to arrival.

5.6. CADETS UNDER AGE 18.

a. All service members in a federal duty status, including Service Academy and PS cadets, are considered adults (DoDI 3216.02, para. 3.9.f.(5) or para. 5.2.b.(5)).

b. Rules governing research on minors, based on the jurisdiction in which they reside, apply to all who have applied to or were admitted to USAFA or USAFA PS, but have not yet arrived. The HRPP/IRB may restrict data collection to cadet candidates who have already reached the age of majority; however, parents can consent for cadet candidates or PS candidates under the age of 18.

CHAPTER 6: COMPENSATION AND BENEFITS

6.1. PURPOSE.

Describe differences between compensation and benefits of HSR reviewed by HRPP/IRB, HSR conducted by USAFA personnel, and HSR supported by but not conducted by USAFA.

6.2. COMPENSATION.

Compensation is something done or given in return for participation or make up for injury or damages occurred during participation. It may include money, material compensation (coupon, gift certificate), or non-monetary awards (extra credit). HSR shall comply with requirements for protecting human subjects from medical expenses (DoDI 3216.02, para. 3.12) and compensation to human subjects for participation. Compensation in and of itself is not coercive.

a. Cadets and PS cadet candidates are considered DoD-affiliated personnel and subject to restrictions defined in DoDI 3216.02, para. 3.9.f.(7), which states "Compensation to DoD-affiliated personnel for participation in research while on duty is prohibited IAW Title 5, U.S.C., with particular reference to Subparts G and H, with some exceptions for purposes consistent with Section 30 of Title 24, U.S.C."

(1) On-duty cadets may only be compensated for blood draws up to a maximum amount of $50 per blood draw (Section 30 of Title 24, U.S.C.). Cadets may not be otherwise materially compensated for general HSR participation while on-duty.

(2) Reasonable course or extra credit may be offered for HSR participation while cadets are on-duty. Such compensation shall be included in the HSR. If course or extra credit are offered for participation on-duty, a PI must identify and inform cadets about non-HSR participation alternatives involving comparable time and effort to obtain course or extra credit to minimize the potential of undue influence. These alternatives shall be included in the HSR.

(3) The USAFA Research Participation System (aka Participant/Cadet Pool or Sona) allows cadets to seek HSR they may want to participate for extra or course credit. An alternative activity is defined by instructor(s) and reviewed by the HRPP/IRB to ensure it entails comparable time, effort, and reward.

(4) Off-duty cadets may be materially compensated for HSR participation other than blood draws. Cadets are considered off-duty when on pass, on leave (or equivalent), or released after last military duty. Cadets receiving compensation for HSR participation off-duty shall have off-duty approval from their Air Officer Commanding (AOC).

b. USAFA permanent party are DoD members.

c. Compensation otherwise ordinarily acceptable in some populations may pose undue influence on vulnerable populations (children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons). At USAFA, cadets are

considered vulnerable population. PIs and the HRPP/IRB must minimize possibility of coercion and undue influence. Reasonable assessments can be made to minimize likelihood of undue influence or coercion.

d. Cadet and Service Member Participation Payment.

(1) Funds used to pay cadets and service members for HSR participation cannot be from a federal source. This includes funds used to provide in-kind compensation.

(2) If cadets are paid for HSR participation, they cannot concurrently receive extra credit.

6.3. BENEFITS.

a. Known benefits about HSR participation are stated accurately and not exaggerated in ICDs. Potential or uncertain benefits must be described as such, clearly indicating how much is known about uncertainty or likelihood of potential benefits. Indirect benefits, such as contributions to the general body of knowledge, may be included in ICDs.

b. IAW 32 CFR 219.116(b)(3), the ICD must include "A description of any benefits to the subject or to others that may reasonably be expected from the research."

CHAPTER 7: COMMAND SUPPORT AND INSTITUTIONAL APPROVAL

7.1. PURPOSE.

Describe procedures for obtaining LoS and institutional approval of HSR.

7.2. AUTHORITY.

Per DoDI 3216.02 para. 3.5.(a)(6), "If HSR involves DoD-affiliated personnel, the key investigator must receive approval from the DoD-affiliated personnel's command or DoD Component to conduct the research. If the HSR takes place on a DoD facility, the key investigator must also receive approval from the command or DoD Component responsible for the facility." As the Commander of USAFA and IO for HSR, the USAFA Superintendent retains the authority to permit HSR at USAFA and HSR involving USAFA-affiliated personnel. The Superintendent has delegated this authority to the Vice Superintendent and the Director A3/9, Operations and Strategic Analysis (see Table 7.1).

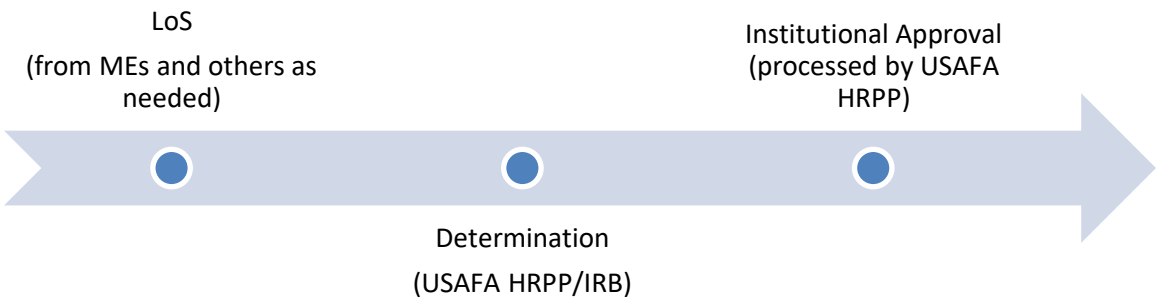
Table 7.1. Institutional Approval Authorities based on Determination.

Institutional Approval Authority	Determination
Superintendent	Non-exempt Expedited Exempt
Vice Superintendent	
A3/9 Director of Operation and Analysis	

7.3. REQUIRED ENDORSEMENTS.

USAFA requires LoS before processing submissions; the last approval is the institutional approval, which allows HSR to start. LoS' are required prior to HRPP/IRB review. Once the administrative review is satisfactory, the submission is forwarded to a reviewer or convened IRB meeting for determination/approval. Lastly, the institutional approval is processed contingent upon HRPP determination or IRB approval (see Figure 7.1).

Figure 7.1. Endorsement Process.



a. LoS. Commander approvals are required to use resources under his/her command. PI(s) must obtain LoS' and submit with HRPP Determination Request to the HRPP (usafa.hrpp@afacademy.af.edu). The HRPP will not forward submissions for review until all LoS' are obtained. The following are the most commonly sought LoS at USAFA:

(1) Surveys. HSR obtaining attitude, opinion, or intention data with a survey, interview, or focus group must have a Survey Control Number (SCN) issued by the USAFA Survey Control Officer or higher authority (usafa_surveys@afacademy.af.edu). The USAFA Survey Program has oversight of all surveys (to include polls, questionnaires, interviews, customer service polls, focus groups, or any other means of collecting attitude, opinion, preference or intention data and faculty research surveys) conducted on USAFA or involving USAFA personnel except:

(a) Surveys administered solely within a classroom or multiple sections of a common course by instructors or cadets within the classrooms for the purpose of demonstrating course-related concepts or course related opinions to enhance academic learning. Cadets and instructors should not administer course-developed surveys outside of the classroom without appropriate survey control approval.

(b) Post-experimental questionnaires that provide feedback about an experimental experience rather than being used as a data collection instrument related to the experimental hypothesis.

(c) Customer satisfaction surveys for products, service, or program if the sole purpose is to ask about the product, service, or program.

(d) Medical, nutritional, diagnostic, or counseling support assessment administered on an individual basis by medical personnel that does not ask for attitudes, opinions, or intentions.

(e) Diagnostic instruments administered and reported by USAFA agencies only on an individual basis for the purposes of education or careers assistance, or financial management awareness.

(f) Surveys directed and administered by higher headquarters, such as DoD, Office of Management and Budget (OMB), Defense Manpower Data Center (DMDC), or DAF Headquarters, while not overseen by the USAFA Survey Program, should be coordinated through the USAFA Survey Program and the USAFA OPR for the topic addressed.

(2) Data. HSR needing archival USAFA data (admissions, academic data) requires a data agreement signed by the institution owning the data. If the data will be shared with non-USAFA PIs (civilian university investigators), a USAFA PI must de-identify data prior to releasing it to ensure Privacy Act data are not released. USAFA's Office of Institutional Research (usafa_rfi@afacademy.af.edu) will review and approve a data de-identification plan as a part of the data request process. USAFA's Office of Institutional Research may release data after the HRPP/IRB issues a determination/approval and receives institutional approval.

(3) USAFA Research Participation System (aka Participant/Cadet Pool or Sona). If HSR recruits cadets through the USAFA Research Participation System, it must obtain approval from the Dean of Faculty Behavioral Sciences and Leadership (DFBL) Sona Director (anthony.ries@afacademy.af.edu).

(4) ME approval is required for (list not all-inclusive):

(a) CW. Cadets in the squadron (excluding academic time) or during training including BCT, CW personnel, resources, facilities, etc.

1. Aspects of cadet life that fall under the purview of the Commandant require CW Research Resource approval. This includes: (1) the use of any CW personnel assisting investigators from CW, other USAFA institutions, or external institutions; (2) cadets and/or CW permanent party as human subjects for HSR to be conducted outside of (a) USAFA Research Participation System, (b) Dedicated Survey and Administrative Time (DSAT), or (c) CW resources including, but not limited to, CW time, personnel, facilities, documents, data, etc.

2. Other than surveys approved by USAFA A9 during BCT and DSAT, HSR requests during BCT will not be approved unless directed by the Superintendent.

(b) Athletic Department (AD). Sports teams, AD personnel, resources, facilities, etc.

(c) Dean of Faculty (DF). DF personnel, resources, facilities, in-class HSR activities, or during academic time.

(d) DF Department Head in charge of classes targeted for recruitment. If recruitment occurs during academic time or in Fairchild Hall (e.g., coffee shop, posters in Fairchild, cadet store), the Department Head signature in the USAFA HRPP Determination Request Form is sufficient. If the PI's Department Head is not the same as the Department Head for the classes targeted for HSR, then a separate LoS is required to ascertain endorsement.

(e) USAFA PS. Students, personnel, resources, facilities, etc.

(f) 10 MDG. Medical/dental personnel, records, resources, facilities, etc. A PI must obtain 10 MDG endorsement and follow 10 MDG procedures to secure a LoS ((see Appendix 2: 10 MDG Relationship). The 10 MDG is part of the Defense Healthy Agency and not part of USAFA.

(g) 10 Air Base Wing (ABW). 10 ABW personnel, resources, facilities, etc.

(h) 306 Flying Training Group (FTG). Airfield personnel, resources, facilities, etc.

(i) HQ USAFA.

(j) Center for Character and Leadership Development (CCLD). Personnel, resources, facilities, etc.

b. Institutional approval to conduct HSR at USAFA or use USAFA personnel as human subjects. Neither the Superintendent nor delegate will permit HSR until appropriate reviews, determinations, and approvals been obtained. The HRPP Administrator staffs institutional approvals.

(1) For exempt studies, the HRPP Administrator seeks institutional approval from an AIO. Institutional approvals are processed on a rolling basis and timelines may vary depending on workload. An institutional approval package includes approved HSR, exempt determination, and relevant ME comments. Other documents may be included as needed.

(2) For non-exempt studies, the HRPP Administrator seeks institutional approval from the IO or AIOs. Institutional approvals are staffed after convened IRB meetings and timelines may vary depending on workload. An institutional approval package includes HSR, IRB approval, LoS, and relevant ME comments (included in the "Views of Others" section of the staff summary sheet). Other documents may be included as needed.

(3) The IO/AIO may or may not permit HSR.

(a) If institutional approval is granted, the HRPP Administrator emails the institutional approval to the PI.

(b) If institutional approval is not granted, the HRPP Administrator emails the institutional approval memorandum to the PI, including reason for denial and appeal information. The PI may appeal by emailing the HRPP (usafa.hrpp@afacademy.af.edu), addressing reasons for denial, and providing new information or justification for IO/AIO reconsideration. As the Commander of USAFA, the IO as the authority on permitting or not permitting HSR at USAFA. The HRPP Administrator will forward the appeal to the IO/AIO and report the decision to the PI.

CHAPTER 8: CONFLICT OF INTEREST

8.1. PURPOSE.

Describe CoI requirements of USAFA personnel involved in HSR or other institutions for which the USAFA IRB is the IRB of record (32 CFR 219 and DoDI3216.02_DAFI 40-402).

8.2. BACKGROUND.

a. A CoI arises when an individual is or may be in a position to influence research or other decisions in ways that could lead to any form of personal gain for the individual or his/her immediate family or give improper advantage to others. CoIs may be potential or actual, perceived or real, harmful or insignificant. A real or perceived CoI may take various forms when an individual:

(1) Performs an action or decision that compromises the integrity of research.

(2) Has a personal relationship that may cause bias or create the appearance of bias.

(3) Holds a leadership position in a business entity or institution (e.g., service as an officer, member of the board of directors, or in any other position of trust, confidence, or responsibility whether or not the individual receives compensation for such service) that is engaged in HSR.

b. Types.

(1) Financial.

(a) A person has a significant financial interest or may benefit financially with respect to HSR when s/he and/or his/her immediate family receives any of the following:

1. Compensation of value that could be affected by HSR outcome.

2. A proprietary interest in the tested product (e.g., patent, trademark, copyright, licensing agreement, or right to receive royalties from product commercialization).

3. Any equity interest in the sponsor or product.

4. Significant payments or other sorts made directly by the sponsor as an unrestricted research or educational grant, equipment, consultation, or honoraria, or other payment (e.g., testing the effect of a software product for which the investigator may potentially benefit financially from the sale).

(b) Significant financial interest does not include salary, other remuneration from USAFA, mutual funds, or retirement accounts which the individual or his/her immediate family (i.e., spouse, domestic partner, dependent) does not exercise control.

(2) Professional. A person may benefit professionally if HSR is conducted or obtains a particular outcome (e.g., testing the effect of a software product is linked to a future job offer from a co-sponsor of the research).

(3) Rank or Authority. At USAFA, recruiting and enrolling cadets or other service members by investigators in position of authority could create a rank or authority CoI (e.g., cadets may feel pressured to participate in research conducted by a member of their service/academic/athletic chain of command).

8.3. HUMAN RESEARCH PROTECTIONS PROGRAM AND INSTITUTIONAL REVIEW BOARD.

It is essential HRPP stakeholders remain free from CoIs. No HRPP review authority, including regular or alternate IRB members, EDOs, and consultants may participate in review of HSR if a member has a CoI, except to provide information as requested. Such reviews include initial determinations, exemptions, expedited reviews, convened IRB meetings, continuing reviews, amendments, UPIRTSOs, noncompliance, and other ad hoc reviews.

a. An individual tasked with a review must disclose any potential CoI to the HRPP Administrator prior to conducting a review. For convened IRB meeting reviews, it is the responsibility of the IRB member or consultant to:

(1) Disclose a potential CoI to the HRPP Administrator as soon as possible but no later than 3 days after receipt of convened IRB meeting agenda and readaheads; and

(2) To contact his/her respective alternate IRB member to attend the convened IRB meeting, participate in the review, and vote.

b. At the beginning of convened IRB meetings, the IRB Chair asks if any IRB members have CoIs. If applicable, an IRB member will discuss his/her CoI and be recused from deliberations and voting. If quorum (quorum is satisfied when more than 50% of the primary members [or respective alternates] are present) is not met, the submission with a CoI will be postponed to the next convened IRB meeting or the IRB Chair may request an out-of-cycle convened IRB meeting.

c. HRPP review authorities (primary/alternate IRB members, EDOs) shall not review submissions if listed as research team member(s). However, research team members may answer questions as needed.

d. The HRPP Administrator documents all CoI disclosures in the convened IRB meeting minutes.

8.4. INVESTIGATORS.

Investigators must disclose any potential CoIs in initial, subsequent submissions. Or when discovered.

a. The CoI disclosure must include a list of all potential CoIs with the following:

(1) List significant financial interests with a research sponsor and other significant interests that may reasonably appear to affect or be affected by the research. The list must include the name of the institution in which the investigator has an interest, the nature of the interest (e.g., salary, equity, intellectual property rights, job offer), and a detailed description of the interest including an approximate dollar amount.

(2) List steps taken, if any, to minimize potential for harm to subject safety or research objectivity resulting from any of the disclosed CoIs.

(3) If there are no CoIs to disclose, the investigator must indicate this in the HRPP Determination Request.

(4) The CoI disclosure must be updated if the investigator acquires new significant financial interests with a sponsor or any other interest that might reasonably appear to affect or be affected by the research during its conduct, analysis of data, or reporting of HSR results (see 42 CFR 50.604 Responsibilities of Institutions regarding Investigator financial CoI).

b. Eliminating, Managing, or Reducing CoIs. If the HRPP determines there is a CoIs, the HRPP will determine how to satisfactorily resolve it.

(1) CoIs should be eliminated, if possible. Examples of possible actions to eliminate a CoI include divestiture of the interest, severance of the relationship that creates the interest, or disqualification of the investigator from participating in HSR.

(2) To ensure Rank or Authority CoIs are minimized, military rank must be removed from ICDs, service members must wear civilian clothing for in-person consenting processes, and uniforms or other "authority" items must be removed prior to interacting with human subjects.

(3) If an investigator cannot eliminate a CoI, the investigator should manage or reduce the scope of the CoI. Examples of possible actions to manage or reduce a CoI include:

(a) Modifications to the protocol.

(b) Objective, non-biased third-party oversight of HSR or consent process. The third party must be authorized for this role as indicated in the USAFA HRPP Determination Request.

(c) Disqualification from participation in the portion of HSR that could be affected (e.g. disqualification from HSR design, UPIRTSOs, analysis of data).

(4) The HRPP will not approve HSR until CoIs have been eliminated, managed, or reduced.

c. Disclosure to Subjects in the ICD. If a CoI cannot be eliminated, the HRPP may require documenting the existence and nature of the CoI and informing human subjects during the consent process. The consent process and document must state how the CoI is managed and

what additional protections are in place. If CoI disclosure is required, it must be accomplished according to the following:

(1) Human subjects must be informed in plain language.

(2) Investigators must disclose CoIs to human subjects - not other financial interests.

(3) The dollar amount of the CoI should not be disclosed to the research subject.

d. Confidentiality of Financial Disclosure Statements. To the extent allowed by law, the HRPP will maintain the confidentiality of all records of financial disclosure (42 CFR 50.606 Remedies). For example, if any such records are sought under the Freedom of Information Act (FOIA), the custodian of the records will work with the FOIA officer(s) to seek legal counsel and request the government assert all applicable exemptions to disclosure under FOIA. The HRPP will ensure financial disclosure statements are only accessible to personnel with a need to review.

e. Failure to Manage or Reduce CoIs. The HRPP may suspend research if it believes an existing CoI is:

(1) Not being reduced or managed IAW with HRPP requirements.

(2) A new CoI is deemed to threaten the safety of human subjects or the objectivity of the HSR; or

(3) Upon discovery, the investigator failed to disclose a CoI.

8.5. DOCUMENTATION.

In the event a CoI disclosure was not documented in the HRPP Determination Request, other CoI disclosure documentation may be accepted to ascertain CoIs were addressed for HSR.

CHAPTER 9: PRIVACY AND CONFIDENTIALITY

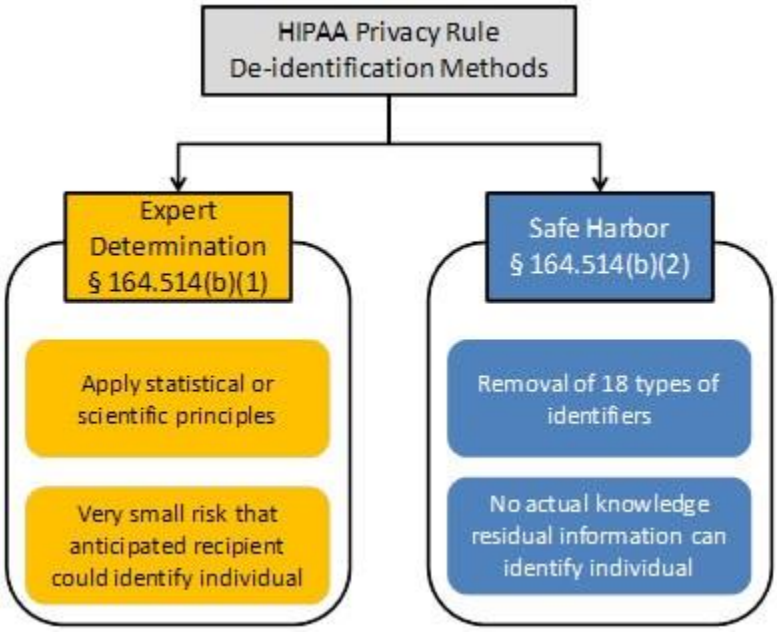
9.1. PURPOSE.

Describe the de-identified standard and Certificates of Confidentiality (CoCs).

9.2. THE DE-IDENTIFICATION STANDARD.

45 CFR 164.514(a) of the HIPAA Privacy Rule provides the standard for de-identification of protected health information. Under this standard, health information is not individually identifiable if it does not identify an individual and if the covered entity has no reasonable basis to believe it can be used to identify an individual. 45 CFR 164.514(b) and (c) of the Privacy Rule contain the implementation specifications that a covered entity must follow to meet the de-identification standard. As summarized in Figure 4.1., the Privacy Rule provides two methods by which health information can be designated as de-identified.

Figure 4.1. Privacy Rule De-identification Methods.



a. Expert determination method (implementation specifications: requirements for de-identification of protected health information). A covered entity may determine that health information is not individually identifiable health information only if a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

(1) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

(2) Documents the methods and results of the analysis that justify such determination.

b. Safe harbor method. The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(1) Names.

(2) All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:

(a) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and

(b) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000.

(3) All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

(4) Telephone numbers.

(5) Vehicle identifiers and serial numbers, including license plate numbers.

(6) Fax numbers.

(7) Device identifiers and serial numbers.

(8) Email addresses.

(9) Web Universal Resource Locators.

(10) Social security numbers.

(11) Internet Protocol addresses.

(12) Medical record numbers.

(13) Biometric identifiers, including finger and voice prints.

(14) Health plan beneficiary numbers.

(15) Full-face photographs and any comparable images.

(16) Account numbers.

(17) Any other unique identifying number, characteristic, or code, except as permitted by 45 CFR 164.514(c); and

(18) Certificate/license numbers.

c. Satisfying either method would demonstrate that a covered entity has met the standard in 45 CFR 164.514(a). De-identified health information created following these methods is no longer protected by the Privacy Rule because it does not fall within the definition of PHI. Of course, de-identification leads to information loss which may limit the usefulness of the resulting health information in certain circumstances. Covered entities may wish to select de-identification strategies that minimize such loss.

d. All HSR data, including audio or video recordings, must be de-identified or destroyed in a manner consistent with the data de-identification plan prior to closure.

e. PIs may retain de-identified data indefinitely after HSR closure.

9.3. CERTIFICATES OF CONFIDENTIALITY.

a. Synopsis of 2017 National Institutes of Health (NIH) policy changes. Effective October 1, 2017, NIH updated its policy for issuing CoCs for NIH-funded and conducted research. This update implemented Section 2012 pf the 21st Century Cures Act, P.L. 114-255, which states that the Secretary of HHS, shall issue CoCs to persons engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected. These CoCs protect the privacy of participants by limiting the disclosure of identifiable, sensitive information.

b. 21st Century Cures Act. Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, established new provisions governing the authority of the Secretary of HHS to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act. Specifically, the amended authority required the Secretary of HHS to issue to investigators or institutions engaged in biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is collected, a CoC to protect the privacy of individuals who are subjects of such research, if the research is funded wholly or in part by the federal government. The authority also specifies the prohibitions on disclosure of the names of participants or any information, documents, or biospecimens that contain identifiable, sensitive information collected or used in research by an investigator or institution with a CoC. If the research is not federally funded, the Secretary of HHS may issue a CoC to an investigator or institution engaged in such research, upon application.

c. Information Protected by a CoC.

(1) CoCs protect information, documents, and/or biospecimens that contain identifiable, sensitive information related to a participant. The CoC policy and Section 241 of Title 42 U.S.C. defines identifiable, sensitive information as information that is about an individual and that is gathered or using during the course of research where the following may occur:

(a) Through which an individual is identified; or

(b) For which there is at least a very small risk, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

(2) Note that the regulations focus only on the identifiability of the information and not on the sensitivity of the information.

(3) The CoC protections cover all copies of information, documents, or biospecimens gathered (i.e., collected) or used by the investigator during the research, including copies that are shared for other research activities.

(4) Once covered by CoC protections, these protections last in perpetuity.

d. Investigator and Institutional CoC Responsibilities. Investigators and institutions have several responsibilities associated with the CoC.

(1) Informing participants about the CoC.

(a) Investigators who are deemed issued or non-NIH funded investigators that are, after request, issued a CoC from NIH and will obtain informed consent need to inform the participants about the CoC protections and any exceptions to the CoC protections.

(b) Sample consent language regarding CoCs (use of this sample language is not required; investigators may use any language that satisfies the requirements for informing participants about CoC protections):

This research is covered by a Certificate of Confidentiality from the NIH. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evident unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state, or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal FDA. The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers, or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

(2) Not releasing participants identifiable, sensitive information except under limited circumstances.

(a) Identifiable, sensitive information covered by a CoC must not be disclosed or provided:

1. In any federal, state, or local civil, criminal, administrative, legislative, or other proceeding; or

2. To any other person not connected with the research.

(b) Limited circumstances when the investigator and institution may release participant's identifiable sensitive information:

1. If required by other federal, state, or local laws, such as for public health reporting of communicable diseases or child or elder abuse reporting (disclosure of identifiable, sensitive information [i.e., information, physical documents, or biospecimens] protected by a CoC must be done when such disclosure is required by other applicable federal, state, or local laws);

2. If the participant consents;

3. If necessary for the medical treatment of the participant and made with the consent of the participant; or

4. For the purposes of scientific research that is compliant with human subjects' regulations.

(3) Upholding the CoC protections. Institutions with a CoC agree to protect participant's identifiable, sensitive information from compelled disclosure and support and defend the authority of the CoC against legal challenges.

(4) Informing investigators and institutions receiving a copy of protected information about the CoC protections.

(a) CoC recipients are required to inform investigators or institutions who receive a copy of identifiable, sensitive information or obtain biospecimens that are protected by a CoC that they are also subject to the requirements of the CoC. These institutions and investigators are required to protect the identifiable, sensitive information or biospecimens from disclosure since the responsibilities apply to them equally.

(b) Investigators and institutions that are considering placing research data protected by a CoC in the participants medical records should discuss this with their institutional counsel.

(c) NIH funded investigators have additional CoC responsibilities.

e. A DoD institution conducting HSR or non-DoD institution conducting HSR with DoD support may request a CoC to Section 241 of Title 42, U.S.C. All studies involving LSGD collected on DoD-affiliated personnel will apply an HHS CoC.

(1) A CoC prohibits disclosing or providing, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding, or to any other person not connected with the research, the name of any individual or any such information, document, or biospecimen that contains identifiable information about the individual, created or compiled for purposes of research.

(2) Exceptions to the CoC must be listed in all informed consent documents, pursuant to DoDI3216.02_DAFI40-402 and as stated in Section 241 of Title 42, U.S.C. The CoC does not protect against disclosure in all cases. The following instances are considered reportable:

(a) Possible threat to self or others;

(b) Child abuse or neglect; and

(c) Communicable or infectious diseases requiring reporting to the Centers for Disease Control and Prevention or other public health entities.

(3) If any information regarding the HSR (e.g. participation or findings) will be included in subjects' medical records, the research review authority will take appropriate action to maximize protection of subjects (e.g., require omission of this information from the medical records, if appropriate, or disclose in the ICD this limit to the CoC's protection).

CHAPTER 10: AGREEMENTS

10.1. PURPOSE.

Describe agreement requirements of HSR.

10.2. INSTITUTIONAL AGREEMENTS FOR IRB REVIEW.

a. USAFA may designate non-DoD IRBs to review USAFA-engaged HSR as negotiated through an IAIR. USAFA will utilize an approved DoD IAIR template. If a non-DoD institution does not honor the approved DoD IAIR template, a similar agreement will be reviewed by applicable stakeholders (IRB Legal Representative, DAF COHRP, and others as required/requested by higher authorities).

b. Cooperative research involving more than one institution. In cooperative research, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 32 CFR 219. With IO/AIO approval, an institution participating in a cooperative activity may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort utilizing an IAIR.

c. IAIRs are required for exempt and non-exempt HSR.

10.3. INDIVIDUAL INVESTIGATOR AGREEMENTS.

a. USAFA may extend its assurance to external investigators through IIAs. USAFA will utilize an approved DoD IIA template.

b. IIAs are required for exempt and non-exempt HSR.

CHAPTER 11: HUMAN RESEARCH PROTECTION OFFICER AND COMPONENT-LEVEL ADMINISTRATIVE REVIEW

11.1. PURPOSE.

Describe submission and review procedures of HSR requiring HRPO review and/or Component-Level Administrative Review (CLAR).

11.2. HUMAN RESEARCH PROTECTION OFFICER REVIEW.

The following types of HSR require HRPO review:

a. USAFA-supported HSR:

(1) Funds or assistance for HSR provided by USAFA to non-DoD institutions through a grant, contract, or similar arrangement subject to Defense Federal Acquisition Regulation Supplement (DFARS) or other applicable DoD regulations, such as the DoD Grant and Agreement Regulations.

(2) USAFA assistance for HSR to non-DoD institutions, whether or not through collaboration between DoD and non-DoD institutions, such as facilities, equipment, personnel (investigators or other identified research team members), access to or information about USAFA-affiliated personnel for recruitment, data, or specimens.

b. If HSR is collaborative between USAFA and non-USAFA investigators with equal roles in leadership and conduct, HSR is DoD and non-DoD-conducted. If the IRB of record is non-DoD, a HRPO reviews HSR to ensure it addressed applicable DoD requirements. The HRPP ensures USAFA requirements are met. The PI emails a submission to the HRPP (usafa.hrpp@afacademy.af.edu) including:

(1) HSR protocol, ICDs, and supporting documents.

(2) Copies of substantive communication between PI and non-DoD IRB, including HSR determination/approval.

(3) Current CITI training and CVs for research team members.

(4) Contract, grant agreement, Cooperative Research and Development Agreement (CRADA), or other document describing nature of USAFA-supported HSR.

c. The HRPP Administrator coordinates with the DAF COHRP for HRPO review. The HRPO typically communicates directly with the PI about requirements.

d. After HRPO review, the PI follows DAF COHRP guidance on obtaining a CLAR, if necessary.

11.3. COMPONENT-LEVEL ADMINISTRATIVE REVIEW.

The DAF COHRP conducts a CLAR if any of these conditions apply (DoDI 3216.02, para. 3.5.b.):

a. Non-exempt HSR is conducted in a foreign country, unless it is conducted by a DoD overseas institution, or involves subjects who are DoD-affiliated personnel who are U.S. citizens.

(1) The PI provides evidence applicable national laws and requirements are met.

(2) The OHRP published the International Compilation of Human Research Standards providing HSR requirements in many foreign countries.

b. Non-exempt HSR requires a waiver of informed consent pursuant to Paragraph (b) of Section 980 of Title 10, U.S.C.

c. Non-exempt HSR is fetal research as described in Sections 289g–289g-2 of Title 42, U.S.C.

d. Large-Scale Genomic Data (LSGD) is collected from DoD-affiliated personnel.

e. Non-exempt HSR is classified.

f. Non-exempt HSR requires approval by the DOHRP.

11.4. INSTITUTIONAL APPROVAL.

Once applicable requirements are met (HRPO, CLAR), the HRPP Administrator staffs the institutional approval. If institutional approval is granted, HSR may commence. Future communication about HSR life cycle requirements are among the PI, IRB of record, and HRPP to ensure applicable requirements continue to be met.

CHAPTER 12: SCIENTIFIC REVIEW

12.1 PURPOSE.

Assure sound research design yields scientifically useful data, outlining criteria and processes for the conduct of scientific review. Applies to HSR conducted at USAFA, investigators, scientific reviewers, and other stakeholders (see Appendix 5: Scientific Review Evaluation).

12.2. BACKGROUND.

The approval criteria for HSR under 32 CFR 219.111 require proposed activities minimize risk to human subjects through use of "procedures that are consistent with sound research design." This charge includes minimizing risks to the proposed design and analysis methods to yield scientifically valid results and prevent human subjects from being needlessly exposed to any research risks. While an IRB is required to "have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution" and to "be sufficiently qualified through the experience and expertise of its members (professional competence)," it is generally recognized that such a board can rarely be comprised of subject matter experts in all areas of research reviewed. To this end, a scientific review, outside of an IRB, is recommended to vet proposed HSR and provide recommendations to an HRPP. A sound research design has:

a. Well defined goals, objectives, hypotheses, and/or research questions having scientific merit and social value.

b. Scientific validity consistent with the stated goals, objectives, hypotheses, and/or research question(s).

c. Feasible goals.

d. A PI capable of successfully conducting proposed research.

e. A plan providing sufficient evidence to ensure likelihood of meaningful results.

12.3. SELECTION OF SCIENTIFIC REVIEWERS.

a. Scientific reviewers will be experts qualified by knowledge, experience, and/or training to review HSR for scientific merit, design, feasibility, and methodology. Scientific reviewers should preferably have direct HSR experience with an established publication record. A scientific reviewer should be employed by USAFA. In the case that USAFA lacks an adequate scientific reviewer, a non-USAFA scientific reviewer may be considered exceptionally based on need.

b. USAFA permanent party that meet criteria described above are suggested, but not required, representative scientific reviewers.

12.4. INVESTIGATOR RESPONSIBILITIES.

a. Prepare a protocol in sufficient detail to allow for a meaningful review of its scientific characteristics. In the event that the HSR has previously received a scientific review from an external agency, the PI may submit that review in lieu of obtaining an additional scientific review.

b. Contact Department Head(s) to request identification of scientific reviewers with sufficient expertise to provide a meaningful review of HSR scientific merits and facilitate appointment orders signed by the IO/AIO. Reviewers may not be involved in the conduct of HSR, have any CoIs, and may be from or outside USAFA.

c. Respond to the scientific review in a timely manner by addressing all scientific reviewer comment(s).

d. Submit the scientific review and response along with revised HSR documents to the HRPP.

12.5. SCIENTIFIC REVIEWER RESPONSIBILITIES.

a. Review HSR in a timely manner and complete the Scientific Review Evaluation Form.

b. Review PI response(s) and HSR revision(s).

c. When the PI has responded adequately, sign and return the Scientific Review Evaluation Form to the PI.

12.6. HUMAN RESEARCH PROTECTIONS PROGRAM RESPONSIBILITIES.

a. Ensure receipt of scientific review documents.

b. Notify the HPD and IRB Chair (for non-exempt HSR) of any concerns.

c. Review proposed HSR IAW applicable regulatory requirements.

d. Receive the scientific review for inclusion in submission.

e. Determine if a scientific review is credible and meets requirements.

12.7. PROCEDURES.

a. Submission of scientific review.

(1) The PI creates a HSR package for initial review or significant HSR modification. The HSR defines rationale for the experimental design, type of data to be collected, method of

analysis, details of facility, equipment, data collection methods, references, and other relevant information.

(2) The PI submits the HSR package to usafa.hrpp@afacademy.af.edu.

b. The HRPP Administrator conducts an administrative review.

c. The HPD conducts a full administrative review of all HSR documents. This includes verifying required documents are submitted and acceptable and coordinates with the PI to ensure the HSR is ready for a scientific review.

d. Scientific review procedure.

(1) The scientific reviewer completes a Scientific Review Evaluation (Appendix 5). The scientific reviewer should focus on the scientific merit, design, feasibility, and methodology of the proposed protocol. The scientific reviewer will distinguish between suggestions for improvement and requirements. The scientific reviewer may address administrative concerns related to the protocol with the PI.

(2) The PI must address each scientific reviewer comment completely in writing and make appropriate changes in documents to address the scientific review concerns.

(3) The PI will update the HSR package to reflect updates.

(4) The scientific reviewer submits the completed scientific review package to the HRPP (usafa.hrpp@afacademy.af.edu). This package will include:

(a) Completed Scientific Review Evaluation.

(b) Electronic version of the HSR package with tracked changes, if used.

(c) Any other communication between the scientific reviewer and PI related to required or suggested changes and responses.

(5) The HRPP Administrator reviews the scientific review package for completeness.

(6) The PI may appeal to the scientific reviewer and HPD within 30 calendar days if s/he disagrees with the content of the scientific review.

(7) The HPD endorses the HSR package for applicable review. The HRPP reserves the right to request an additional scientific review for a variety of reasons including:

(a) If the review is considered not substantive (i.e., reviewer answers identically to all Scientific Review Evaluation criteria);

(b) From a potentially conflicted party (i.e., an AI or subordinate).

(c) Does not appear favorable.

(d) Does not appear to be from a scientific reviewer with sufficient expertise.

(e) Conflicting opinions arise from reviews regarding scientific merit.

CHAPTER 13: NOT HUMAN SUBJECTS RESEARCH

13.1. PURPOSE.

Describe process for determining whether an activity meets the regulatory definition of research and activities potentially involving HSR conducted by USAFA personnel (see Appendix 3: Generic Human Subjects Research Submission Process).

13.2. BACKGROUND.

The following activities are deemed not to be research (32 CFR 219.102(l)(1-4):

a. Scholarly and journalistic activities (*e.g.*, oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

d. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

13.3. SUBMISSION.

"Only designated federal DoD HRPP personnel are authorized to make determinations regarding whether or not an activity is HSR or is exempt HSR." (DoDI3216.02, para. 3.5.a.(7)) Any activity that may meet the definition of research (32 CFR 219.102(l)) and human subjects (32 CFR 219.102(e) must be submitted to the HRPP for determination.

a. Initial submission requirements are determined by:

(1) Personnel affiliation.

(2) HSR location.

(3) Whether another HRPP/IRB reviewed the HSR.

b. PIs submit a complete HRPP Determination Request to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate "Not Human Subjects Research (NHSR) Determination Submission."

13.4. REVIEW.

The HRPP Administrator responds to emails in the order received and determines whether to send the submission to an EDO, IRB member, or consults with the HPD based on the submission content.

a. If the submission is sent to an EDO, the EDO:

(1) Assigns a USAFA FAC number. This FAC number takes the format of FACYYYY01XXN, where YYYY is the AY, 1XX is a sequential number, and N stands for NHSR.

(2) Requests additional information from the PI as needed and cofacademy.af.edu).

(3) Conducts the determination.

(4) May approve or conditionally approve the submission.

(5) Emails the NHSR determination to the HRPP (usafa.hrpp@afacademy.af.edu).

(6) The HRPP Administrator:

(a) Adds the NHSR determination in the next convened IRB meeting agenda.

(b) Creates a closed folder to store records and emails for a minimum of three years.

(c) Updates the HSR database.

(d) Processes and emails an MFR to the PI.

b. If the submission is sent to the HRPP, the HRPP Administrator:

(1) Assigns a USAFA tracking number.

(2) Conducts an administrative review and requests additional information from the PI (as needed).

(3) Forwards the submission to an EDO or IRB member with a suspense date. The EDO or IRB member making the determination:

(a) Requests additional information (as needed) from the PI as needed and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(b) Conducts the determination.

(c) May approve or conditionally approve the submission.

(d) Emails the NHSR determination to the HRPP (usafa.hrpp@afacademy.af.edu).

(4) Upon receipt of the NSHR determination:

(a) Adds the NHSR determination to the next convened IRB meeting agenda, readaheads, and/or minutes.

(b) Processes and emails an MFR to the PI.

(c) Creates a closed folder and maintains for a minimum of three years.

13.5. OUTCOMES.

a. NSHR. The activity does not meet the definition of research. This activity does not need to be re-reviewed unless:

(1) Procedures change (e.g., PI is now using identifiable data) or

(2) Intent changes (e.g., investigators were only using the results to assess a program, but now they believe the results could contribute to generalizable knowledge).

b. HSR. The activity is HSR (exempt, exempt with limited IRB review, non-exempt).

(1) Exempt. The activity is HSR eligible for exemption from the requirement of IRB review. The activity meets the definition of research involving human subjects and falls into at least one of the 8 exemption categories in 32 CFR 219.104.

(2) Exempt with limited IRB review.

(a) Limited IRB reviews are done via expedited review.

(b) An EDO may determine limited IRB review is required, but may not conduct the limited IRB review unless dually appointed as an IRB member.

(c) Once PIs receives an exempt limited IRB review determination, and institutional approval, HSR may begin.

(3) Non-exempt. The activity is HSR ineligible for exemption from the requirements of IRB review. The activity meets the definition of research involving human subjects but does not meet any of the 8 exemption categories in 32 CFR 219.104.

CHAPTER 14: EXEMPT RESEARCH REVIEW

14.1. PURPOSE.

Describe procedures to determine exempt and potentially exempt HSR (see Appendix 3: Generic Human Subjects Research Submission Process).

14.2. BACKGROUND.

a. Section 101 of the pre-2018 version of 32 CFR 219 contains six exemption categories. Research activities submitted prior to 21 January 2019 that fall into one or more of these categories are exempt from the requirements of 32 CFR 219.

b. Section 104(d) of the post-2018 version of 32 CFR 219 contains 8 exemption categories. Research activities submitted after 21 January 2019 that fall into one or more of these categories are exempt from the requirements of 32 CFR 219.

c. HSR activities determined to be non-exempt under the pre-2018 version of 32 CFR 219 were reviewed for conversion eligibility to exempt status under the post-2018 version of 32 CFR 21 throughout 2019.

d. Exempt HSR is not exempt from requirements outlined in DoDI3216.02 DAFI40-402 or USAFA HRPP.

e. If HSR includes prisoners or minors (less than 18 years old– does not include cadets as per DoD they are not minors for research purposes) it will not be considered exempt even if it falls into an exemption category because it includes prisoners or minors unless prisoners are incidentally included.

f. Prior to starting exempt HSR, PIs receive an exempt determination and institutional approval from the HRPP.

(1) PIs are not authorized to determine their own activities (DoDI 3216.02, para. 3.5.a.(7)).

(2) PIs are not authorized to permit their own activities.

g. The four most commonly used exemption categories at USAFA are one through four.

(1) Category 1 (32 CFR 219.104(d)(1)). "Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods." At USAFA, established or commonly accepted educational settings include academic courses,

squadron training, CW training environments, AD courses, and similar educational settings. HSR categorized as Scholarship of Teaching and Learning (SoTL) normally falls into this exemption category.

(2) Category 2 (32 CFR 219.104(d)(2)). "Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 32 CFR 219.111(a)(7)."

(3) Category 3 (32 CFR 219.104(d)(3). "Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

(c) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 32 CFR 219.111(a)(7).

(d) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(e) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research."

(4) Category 4 (32 CFR 219.104(d)(4)). "Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(a) The identifiable private information or identifiable biospecimens are publicly available;

(b) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(c) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, Subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(d) The research is conducted by, or on behalf of, a federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.***"**

(5) Category 5 (32 CFR 219.104(d)(5)). "Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

(a) Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects."

(6) Category 6 (32 CFR 219.104(d)(6)). "Taste and food quality evaluation and consumer acceptance studies:

(a) If wholesome foods without additives are consumed, or

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

(7) Category 7 (32 CFR 219.104(d)(7)). "Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 32 CFR 219.111(a)(8)."

(8) Category 8 (32 CFR 219.104(d)(8)). "Secondary research for which broad consent is required: research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(a) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained IAW 32 CFR 219.116(a)(1) through (4), (a)(6), and (d);

(b) Documentation of informed consent or waiver of documentation of consent was obtained IAW 32 CFR 219.117;

(c) An IRB conducts a limited IRB review and makes the determination required by 32 CFR 219.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(d) The investigator does not include returning individual research results to subjects as part of the HSR plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results."

14.3. SUBMISSION.

"Only designated federal DoD HRPP personnel are authorized to make determinations regarding whether or not an activity is HSR or is exempt HSR." (DoDI3216.02, para. 3.5.a.(7)) Any activity that may meet the definition of research (32 CFR 219.102(l)) and human subjects (32 CFR 219.102(e) must be submitted to the HRPP for determination.

a. Initial submission requirements are determined by:

(1) Personnel affiliation.

(2) HSR location.

(3) Whether another HRPP/IRB reviewed the HSR.

b. PIs submit a HRPP Determination Request to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate "Exempt determination request." The following documents are required for exempt submissions:

(1) LoS (as needed).

(2) CITI training commensurate with role for all personnel listed.

(3) Current CVs for all personnel listed; CVs not needed for cadets.

(4) Surveys (as needed).

(5) SCNs (as needed).

(6) Agreements (as needed).

c. If exempt HSR involves collecting statistical information under a promise of confidentiality per the Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA), consistent with section 512 of Public Law 107-347, it requires for additional review by DAF COHRP and SAF/CIO A6 approval.

14.4. REVIEW.

The HRPP Administrator responds to emails in the order in which they are received and determines whether to send the submission to an EDO, IRB member, or consults with the HPD based on the submission content.

a. If the submission is sent to an EDO, the EDO:

(1) Assigns a USAFA FAC number. This FAC number takes the format of FACYYYY01XXE, where YYYY is the AY, 1XX is a sequential number, and E stands for exempt.

(2) Requests additional information from the PI as needed and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(3) Conduct the exemption determination.

(4) May approve or conditionally approve the submission.

(5) Emails the exempt determination to the HRPP (usafa.hrpp@afacademy.af.edu).

(6) The HRPP Administrator:

(a) Adds the exempt determination to the next convened IRB meeting agenda, readaheads, and/or minutes.

(b) Creates an active protocol folder.

(c) Seeks endorsement from the HPD prior to processing institutional approval.

(d) Processes an institutional approval.

(e) Updates the HSR database.

(f) Processes and emails an MFR, institutional approval, and approved documents to the PI.

b. If the submission is sent to the HRPP, the HRPP Administrator:

(1) Assigns a USAFA tracking number.

(2) Conduct an administrative review and requests additional information (as needed).

(3) Forwards the submission to an EDO or IRB member with a suspense date. The EDO or IRB member making the determination:

(a) Requests additional information from the PI as needed and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(b) Conducts the exemption determination.

(c) May approve or conditionally approve the submission.

(d) Emails the exempt determination to the HRPP (usafa.hrpp@afacademy.af.edu).

(4) Upon receipt of the exempt determination:

(a) Adds the exempt determination to the next convened IRB meeting agenda and readaheads.

(b) Creates an active protocol folder.

(c) Seeks endorsement from the HPD prior to processing an institutional approval.

(d) Processes an institutional approval.

(e) Processes and emails an MFR, institutional approval, and approved documents to the PI.

14.5. OUTCOMES.

a. NSHR. The activity does not meet the definition of research. This activity does not need not re-reviewed unless:

(1) Procedures change (e.g., PI is now using identifiable data); or

(2) Intent changes (e.g., investigators were only using the results to assess a program, but now they believe the results could contribute to generalizable knowledge).

b. HSR. The activity is HSR (exempt, exempt with limited IRB review, non-exempt).

(1) Exempt. The activity is HSR eligible for exemption from the requirement of IRB review. The activity meets the definition of research involving human subjects and falls into at least one of the 8 exemption categories in 32 CFR 219.104.

(2) Exempt with limited IRB review.

(a) Limited IRB reviews are done via expedited review.

(b) An EDO may determine limited IRB review is required, but may not conduct the limited IRB review unless dually appointed as an IRB member.

(c) Once PIs receives an exempt limited IRB review determination, and institutional approval, HSR may begin.

(3) Non-exempt. The activity is HSR ineligible for exemption from the requirements of IRB review. The activity meets the definition of research involving human subjects but does not meet any of the 8 exemption categories in 32 CFR 219.104.

14.6. CLOSURE.

a. Continuing reviews are not required for exempt studies. The HRPP Administrator emails the PI requesting a status update no less than annually. If the PI reports HSR is open, the HRPP Administrator annotates the update and sends an email to the PI NLT a year later.

b. When a PI reports the closure of exempt HSR, the PI and HRPP Administrator maintain records for three years after closure date. If an EDO issued a determination, then the EDO may also maintain records for three years after closure. The HRPP Administrator:

(1) Processes and emails the PI a closure MFR.

(2) Creates a closed folder and maintains for a minimum of three years.

CHAPTER 15: RESEARCH REVIEWED VIA EXPEDITED REVIEW

15.1. PURPOSE.

Describe authority and procedures of expedited review (32 CFR 219.110) (see Appendix 3: Generic Human Subjects Research Submission Process).

15.2. BACKGROUND.

a. Exempt HSR for which limited IRB review is a condition of exemption:

(1) Category 2 (32 CFR 219.110(d)(2)(iii)). "Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. (…)

(a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by 32 CFR 219.111(a)(7)."

(2) Category 3 (32 CFR 219.110(d)(3)(i)(C)). "Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met: (…)

(a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and

(b) An IRB conducts a limited IRB review to make the determination required by 32 CFR 219.111(a)(7)."

(3) Category 7 (32 CFR 219.110(d)(7)). "Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by 32 CFR 219.111(a)(8)." At present, USAFA does not apply this exemption category.

(4) Category 8 (32 CFR 219.110(d)(8)(iii)). "Secondary research for which broad consent is required: research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met (at present, USAFA does not apply this exemption category):

(a) An IRB conducts a limited IRB review and makes the determination required by 32 CFR 219.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph (d)(8)(i) of this section; and

(b) The investigator does not include returning individual research results to subjects as part of the HSR plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results."

b. The Secretary of HHS has established, and published as a Notice in the Federal Register, a list of categories of research that may be reviewed by the IRB through an expedited review procedure (32 CFR 219.110).

(1) Research activities that:

(a) Present no more than minimal risk to human subjects, and

(b) Involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

(2) The categories in this list apply regardless of the age of subjects, except as noted.

(3) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects (financial standing, employability, insurability, reputation, or be stigmatizing), unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

(4) The expedited review procedure may not be used for classified research involving human subjects.

(5) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened.

(6) Categories one (1) through nine (9) pertain to both initial and continuing IRB review.

c. Federal Register list of research categories eligible for expedited review:

(1) Category 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

(a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required (note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review).

(b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used IAW its cleared/approved labeling.

(2) Category 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) From healthy, non-pregnant adults who weight at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

(b) From other adults and children, considering their age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

(3) Category 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

(a) Hair and nail clippings in a non-disfiguring manner;

(b) Deciduous teeth at time of exfoliation or if routine patient care indicates need for extraction; permanent teeth if routine patient care indicates a need for extraction;

(c) Excreta and external secretions (including sweat);

(d) Uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying dilute citric solution to the tongue;

(e) Placenta removed at delivery

(f) Amniotic fluid obtained at the time or rupture of the membrane prior to or during labor;

(g) Supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished IAW accepted prophylactic techniques;

(h) Mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

(i) Sputum collected after saline mist nebulization.

(4) Category 4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing (studies intended to evaluate the safety and effectiveness of the

medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples:

(a) Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy to the subject or an invasion of the subject's privacy;

(b) Weighing or testing sensory acuity

(c) Magnetic resonance imaging;

(d) Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

(e) Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

(5) Category 5. Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

(a) Some research in this category may be exempt from the HHS regulations for the protection of human subjects (45 CFR 46.101(b)(4)). This category refers only to research that is not exempt.

(b) Note that Expedited Category 5 includes materials "that have previously been collected." Data "that have been collected" are defined as "existing data."

(6) Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Category 7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(8) Category 8. Continuing review of research previously approved by the convened IRB as follows:

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

(9) Category 9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

d. An IRB may use the expedited review procedure to review the following (32 CFR 219.110):

(1) Some or all of the research appearing on the list described in para. 15.2.(b) and 15.2.(c) of this Chapter, unless the reviewer determines that HSR involves more than minimal risk.

(2) Minor changes in previously approved research during the period for which approval is authorized; or

(3) Research for which limited IRB review is a condition of exemption under § 219.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7) and (8).

e. Under an expedited review procedure, the review may be carried out by the IRB Chair or by one or more experienced IRB members designated by the IRB Chair from among IRB members. In reviewing the research, the reviewers may exercise all authorities of the IRB except the reviewers may not disapprove the research. A research activity may be disapproved only after review IAW non-expedited procedure set forth in § 219.108(b).

f. Expedited reviews are presented at convened IRBs to advise IRB members of HSR approvals.

15.3. SUBMISSION.

a. Initial submission requirements are determined by:

(1) Personnel affiliation.

(2) HSR location.

(3) Whether another HRPP/IRB reviewed the HSR.

b. PIs submit a HRPP Determination Request to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate “Non-Exempt Expedited Determination Submission.”

c. The following documents are required for non-exempt expedited submissions:

(1) LoS (as needed).

(2) CITI training commensurate with role for all personnel listed.

(3) Current CVs for all personnel listed; CVs not needed for cadets.

(4) Surveys (as needed).

(5) SCNs (as needed).

(6) Agreements (as needed).

(7) ICD(s) or ICD(s) waiver.

15.4. REVIEW.

The HRPP Administrator responds to emails in the order in which they are received and determines whether to send the submission to an EDO, IRB member, or consults with the HPD based on the submission content.

a. The IRB does not generally support expedited review of initial submissions.

(1) The IRB Chair may direct expedited reviews of initial submissions.

(2) Expedited review of initial non-exempt HSR submissions will be performed by the IRB Chair or an IRB member designated by the IRB Chair in writing (32 CFR 219.110). ICD (or waiver or alteration) requirements and special considerations for vulnerable populations apply to HSR eligible for expedited review.

b. Expedited reviews of eligible submissions may be conducted by one IRB member.

c. The HRPP Administrator:

(1) Assigns a USAFA tracking number.

(2) Conducts an administrative review and requests additional information (as needed).

(3) Forwards the submission to IRB member(s) (as required) with a suspense date.

(a) ICD (or waiver or alteration) requirements and special considerations for vulnerable populations apply to HSR eligible for expedited review.

(b) Reviewing IRB member(s):

1. HSR submission(s) may be disapproved by a convened IRB meeting (32 CFR 219.108(b)).

2. Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

3. Completes review forms (as needed).

4. May approve or conditionally approve the submission.

5. Emails review forms to the HRPP (usafa.hrpp@afacademy.af.edu).

(4) Upon receipt of the determination:

(a) Adds the review to the next convened IRB meeting agenda, readaheads, and/or minutes.

(b) Seeks endorsement from the HPD prior to processing institutional approval (if applicable).

(c) Processes an institutional approval (if applicable).

(d) Updates the HSR database.

(e) Processes and emails an MFR, institutional approval (if applicable), and approved documents to the PI.

15.5. OUTCOMES.

a. NSHR. The activity does not meet the definition of research. This activity does not need to be re-reviewed unless:

(1) Procedures change (e.g., PI is now using identifiable data) or

(2) Intent changes (e.g., investigators were only using the results to assess a program, but now they believe the results could contribute to generalizable knowledge).

b. HSR. The activity is HSR (exempt, exempt with limited IRB review, non-exempt).

(a) Exempt. The activity is HSR eligible for exemption from the requirement of IRB review. The activity meets the definition of research involving human subjects and falls into at least one of the 8 exemption categories in 32 CFR 219.104.

(b) Exempt with limited IRB review.

1. Limited IRB reviews are done via expedited review.

2. An EDO may determine limited IRB review is required, but may not conduct the limited IRB review unless dually appointed as an IRB member.

3. Once PIs receives an exempt limited IRB review determination, and institutional approval, HSR may begin.

(c) Non-exempt. The activity is HSR ineligible for exemption from the requirements of IRB review. The activity meets the definition of research involving human subjects but does not meet any of the 8 exemption categories in 32 CFR 219.104. Non-exempt HSR may be:

1. Approved via expedited review. The activity is reviewed and meets 32 CFR 219.110, DoD, DAF, and USAFA requirements. Non-exempt HSR may begin after IO/AIO approval.

2. Conditionally approved via expedited review. The submission is reviewed and does not meet 32 CFR 219.110, DoD, DAF, and/or USAFA requirements.

3. If non-exempt HSR cannot be approved via expedited review, it is referred to a convened IRB (see Chapter 16).

15.6. CLOSURE.

The HRPP may administratively close expedited HSR provided the HSR presents no greater than minimal risk to human subjects and meets one or more expedited review categories.

a. When to close expedited HSR.

(1) HSR was approved and permitted but never initiated.

(2) A PI plans to leave USAFA and HSR will not be transferred to another USAFA PI.

(3) A PI may submit an amendment to assign a new PI in lieu of closure. The amendment must include an updated protocol, ICD (if applicable), and relevant documentation (CVs, CITI training, etc.).

(4) HSR may be closed if:

(a) All subjects were enrolled, data collection is complete, and the remaining activity is analysis of de-identified data or specimens.

(b) HSR data are de-identified; keys linking identities to numbers or other identifiers were destroyed.

(c) HSR including audio or video recordings; transcription is complete, transcripts are anonymous, and original recordings have been destroyed.

b. How to close expedited HSR. PI submits a Request to Continue or Close a Research Protocol to the HRPP (usafa.hrpp@afacademy.af.edu).

c. How to process expedited HSR closure. The HRPP Administrator:

(1) Conducts an administrative review and requests additional information (as needed).

(2) May seek endorsement from the HPD prior to processing closure review (as needed).

(3) Adds the submission to the next convened IRB meeting agenda and readaheads.

(4) Processes and emails the PI a closure MFR.

(5) Creates a closed folder and maintains for a minimum of three years.

CHAPTER 16: RESEARCH REVIEWED VIA CONVENED INSTITUTIONAL REVIEW BOARD

16.1. PURPOSE.

Describe submission and review procedures of non-exempt HSR (see Appendix 3: Generic Human Subjects Research Submission Process).

16.2. BACKGROUND.

Research that does not meet an exemption, limited IRB review, or expedited category must be reviewed by convened IRB.

16.3. SUBMISSION.

a. Initial submission requirements are determined by:

(1) personnel affiliation.

(2) HSR location.

(3) Whether another IRB reviewed the HSR.

b. PIs submit a HRPP Determination Request to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate "Non-Exempt Determination Submission."

c. The following documents are required for non-exempt submissions:

(1) LoS (as needed).

(2) CITI training commensurate with role for all personnel listed.

(3) Current CVs for all personnel listed; CVs not needed for cadets.

(4) Surveys (as needed).

(5) SCNs (as needed).

(6) Agreements (as needed).

(7) ICD(s) or ICD(s) waiver.

d. Non-exempt submissions ready for review by the first business day of the month when the convened IRB meeting takes place will be considered.

16.4. REVIEW.

The HRPP Administrator responds to emails in the order in which they are received and determines whether to send the submission to an EDO, IRB member, or consults with the HPD based on the submission content.

a. The HRPP Administrator:

(1) Assigns a USAFA tracking number.

(2) Creates an active protocol folder.

(3) Conducts an administrative review and requests additional information (as needed).

(4) Seeks endorsement from the HPD prior to forwarding to the IRB Chair.

(5) Adds the submission to the next convened IRB meeting agenda and readaheads.

(6) Forwards the submission to the IRB Chair.

b. The IRB Chair:

(1) Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(2) Completes required forms.

(3) Tasks an IRB member with completing required forms.

(4) Compiles forms responses for review at the convened IRB meeting.

(5) Chairs the convened IRB meeting.

(6) Confirms quorum (Chair or Vice Chair, primary or alternate non-scientist, and another primary or alternate IRB member whether scientist, non-affiliated, or cadet); quorum is satisfied when more than 50% of the primary members (or respective alternates) are present.

(7) Confirms voting IRB members do not have CoIs.

(8) The IRB may approve, conditionally approve, or disapprove the submission.

c. Upon convened IRB meeting, the IRB Administrator:

(1) Drafts minutes.

(2) Seeks endorsement from the IRB Chair and present IRB members prior to finalizing minutes.

(3) Seeks endorsement from the HPD prior to processing approvals, conditional approvals, and institutional approval.

(4) Processes approvals, conditional approvals, and institutional approval.

(5) Updates the HSR database.

(6) Emails an MFR, institutional approval, and approved documents to the PI.

16.5. OUTCOMES.

a. NSHR. The activity does not meet the definition of research. This activity does not need not re-reviewed unless:

(1) Procedures change (e.g., PI is now using identifiable data) or

(2) Intent changes (e.g., investigators were only using the results to assess a program, but now they believe the results could contribute to generalizable knowledge).

b. HSR. The activity is HSR (exempt, exempt with limited IRB review, non-exempt).

(1) Exempt. The activity is HSR eligible for exemption from the requirement of IRB review. The activity meets the definition of research involving human subjects and falls into at least one of the 8 exemption categories in 32 CFR 219.104.

(2) Exempt with limited IRB review.

(a) Limited IRB reviews are done via expedited review.

(b) An EDO may determine limited IRB review is required, but may not conduct the limited IRB review unless dually appointed as an IRB member.

(c) Once PIs receives an exempt limited IRB review determination, and institutional approval, HSR may begin.

(3) Non-exempt. The activity is HSR ineligible for exemption from the requirements of IRB review. The activity meets the definition of research involving human subjects but does not meet any of the 8 exemption categories in 32 CFR 219.104. Non-exempt HSR may be:

(a) Approved via convened IRB. The activity is reviewed and meets 32 CFR 219.110, DoD, DAF, and USAFA requirements. Non-exempt HSR via convened IRB may begin after IO/AIO approval.

(b) Conditionally approved via convened IRB. The submission is reviewed and does not meet 32 CFR 219.110, DoD, DAF, and/or USAFA requirements.

16.6. CLOSURE.

The HRPP may administratively close HSR reviewed via convened IRB provided the HSR presents no greater than minimal risk to human subjects.

a. When to close non-exempt HSR.

(1) HSR was approved and permitted but never initiated.

(2) A PI plans to leave USAFA and HSR will not be transferred to another USAFA PI.

(3) A PI may submit an amendment to assign a new PI in lieu of closure. The amendment must include an updated protocol (signed by the new PI), ICD (if applicable), and relevant documentation (CVs, CITI training, etc.).

(4) HSR may be closed only if:

(a) All subjects were enrolled, data collection is complete, and the remaining activity is analysis of de-identified data or specimens.

(b) HSR data are de-identified; keys linking identities to numbers or other identifiers were destroyed.

(c) HSR including audio or video recordings; transcription is complete, transcripts are anonymous, and original recordings have been destroyed.

b. How to close non-exempt HSR. PI submits a Request to Continue or Close a Research Protocol to the HRPP (usafa.hrpp@afacademy.af.edu).

c. How to process non-exempt HSR closure. The HRPP Administrator:

(1) Conducts an administrative review and requests additional information (as needed).

(2) May seek endorsement from the HPD prior to processing closure review (as needed).

(3) Adds the submission to the next convened IRB meeting agenda and readaheads.

(4) Processes and emails the PI a closure MFR.

(5) Creates a closed folder and maintains for a minimum of three years.

CHAPTER 17: INFORMED CONSENT

17.1. PURPOSE.

Describe procedures for obtaining informed consent from human subjects. The general requirements for informed consent, documentation of informed consent, and conditions under which some or all of the elements of informed consent or documentation of informed consent can be waived are in 32 CFR 219.116 and 32 CFR 219.117. Title 10 U.S.C., Section 980 places additional limitations on when informed consent may be waived in DoD-funded HSR.

17.2. BACKGROUND.

PIs demonstrate respect for human subjects by obtaining informed consent. Informed consent consists of three elements: (1) disclosing to potential human subjects information needed to make an informed decision; (2) facilitating the understanding of what was disclosed; and (3) promoting voluntariness of the decision about whether or not to participate in HSR.

a. Informed consent is an ongoing communication process between PI(s) and human subjects, beginning with an initial approach of a PI to a potential human subject (through a flyer, brochure, email, advertisement) and continuing until HSR is completed.

b. PIs facilitate understanding by using plain language (e.g., no jargon or medical terms, 8th grade Flesh-Kincaid reading-level) and ensuring sections of the informed consent are presented in a language understood by the human subject.

c. Voluntary consent is imperative. No administrative sanctions or loss of benefits will be taken against human subjects declining or withdrawing from participation in HSR.

d. During informed consent, PIs shall create a respectful environment minimizing possibility of coercion, perceived coercion, or undue influence.

(1) Coercion occurs when an overt or implicit threat of harm is intentionally presented to obtain compliance. For example, a PI may tell a prospective human subject s/he will lose access to needed health services if s/he does not participate in HSR.

(2) Perceived coercion occurs when a human subject believes there is a threat of harm when there is no intent to harm. For example, an instructor recruits his/her students for HSR. Cadets may believe grades will be influenced if they do not participate.

(3) Undue influence, by contrast, occurs through an offer of excessive or inappropriate reward or other overture to obtain compliance. For example, a PI may promise psychology cadets extra credit if they participate in HSR. If that is the only way a cadet can earn extra credit, then the PI is unduly influencing potential human subjects. If, however, an instructor offers comparable non-research alternatives for earning extra credit, the possibility of undue influence is minimized.

(4) To avoid creating a situation that is coercive, perceived to be coercive, or unduly influential, PIs shall design an informed consent process meeting the following requirements:

(a) PIs shall provide adequate time between recruitment/information phase of HSR and enrollment/consent phase.

(b) Instructors shall not recruit human subjects from their classes.

(c) Coaches shall not recruit human subjects from cadets they coach.

(d) Squadron leaders shall not recruit subjects from their squadron.

(e) Cadets shall not use or display rank while recruiting cadets nor directly recruit cadets below their rank.

(f) Service members shall not use or display rank while recruiting service members.

(g) PIs may be required to use an ombudsperson when obtaining informed consent and recruiting human subjects in group settings (e.g., athletic teams, squadrons).

(5) The consent process description in the protocol shall indicate how informed consent will be obtained and, if this does not include obtaining physical or electronic signatures, appropriate waivers must be requested for non-exempt research (i.e., waiver of the requirement to document informed consent via signature). The informed consent process must respect cognitive and language abilities of potential human subjects.

(a) When obtaining consent from non-English-speaking human subjects, the informed consent process must be in the native language of the human subjects and at a reading or speaking level appropriate to the language abilities of the potential human subjects.

(b) If potential human subjects are illiterate, the informed consent process shall use an alternative process using presentation formats (e.g. illustrations) understandable to potential human subjects. Use of a short form to document informed consent may be appropriate.

(c) If potential human subjects are cognitively impaired, the informed consent process should use presentation formats understandable to potential human subjects. Use of a short form to document informed consent may be appropriate.

(d) In cases in which a written and signed ICD may be inappropriate, a PI may request a waiver of some or all of the elements of informed consent or a waiver of documentation of informed consent.

(6) Limits to confidentiality for service members. There are numerous situations in which confidentiality of data cannot be guaranteed for service members. If any of these limits are likely to apply to HSR, the informed consent process should make potential human subjects aware of these limits and potential consequences of mandatory reporting. Potential human subjects should be informed about whether potentially damaging information from HSR will be

stored in their personnel or medical records where they could be accessed outside the HSR context. These limits include, but may not be limited to:

(a) Mandatory reporting of suicidality, harm to self or others, substance abuse or use of illicit substances.

(b) Legally mandated reporting of sexual assault harassment or spouse/child/elder abuse.

(c) Reporting of potential honor code violations by cadets.

(7) As part of the informed consent process, the PIs must be available to answer questions about the HSR prior to enrollment. The PI contact information and the HRPP/IRB contact information must be in the ICD so human subjects can contact either a PI or the HRPP/IRB with questions, comments, or complaints.

(8) A PI must provide a current (not expired) ICD to the human subject. For HSR approved under the pre-2018 Common Rule, PIs must provide a current (not expired) hard copy of the ICD to the human subject or legally authorized representative (LAR). Per 32 CFR 219.102(m), for HSR approved after 21 January 2019 or for which transition to the post-2018 Common Rule was approved by the IRB, PIs may provide either an electronic or hard copy of the ICD.

17.3. INFORMED CONSENT DOCUMENTATION.

a. PIs conducting non-exempt HSR at USAFA must conform to the documentation of informed consent requirements outlined in 32 CFR 219.117.

(1) The form may be either a written or electronic document containing all elements of consent outlined in 32 CFR 219.116 or a short form stating required elements of consent were presented orally to the human subject or LAR.

(2) The human subject may read or be read the consent document.

(3) Consent documents may be signed by the human subject or LAR.

(4) In the case of a short form documenting required elements of consent were presented orally to the human subject, additional requirements of 32 CFR 219.117(b)(2) must be met.

b. PIs conducting non-exempt HSR at USAFA must use approved (not expired) ICDs. The ICD does not replace the process of discussion between the PIs and human subjects.

c. For PIs conducting collaborative research, the HRPP/IRB may approve the use of an ICD approved for the HSR by another IRB if it conforms to applicable federal regulations (32 CFR 219.116 and 117, §50.25, §50.27; 45 CFR 46.116, and §46.117). Where appropriate, the ICD approved by the other IRB must include USAFA PI contact information. In certain cases,

documentation of informed consent may be waived or modified to include use of a short-form consent document.

d. For HSR approved under the pre-2018 Common Rule, informed consent must be documented with a wet signature unless the IRB waived this requirement. For HSR approved after 21 January 2019 or approved by the IRB to transition to the post-2018 Common Rule, informed consent may be documented with a wet or electronic signature. The HSR must clearly state the procedure for documenting informed consent and PIs may not deviate from approved procedures.

17.4. ELECTRONIC INFORMED CONSENT.

a. An electronic ICD includes elements of consent appropriate for the HSR. As the security of online transmissions may not be guaranteed, the following statement describing limits to confidentiality is typically required: "Your confidentiality will be maintained to the degree allowed by the technology used. Specifically, no guarantees can be made regarding the interception of data sent via the Internet by third parties." or "This research involves transmission of data over the Internet. Every reasonable effort has been taken to ensure effective use of available technology; however, confidentiality in online communication cannot be guaranteed."

b. Security of data and confidentiality. Internet data collection is rarely private, anonymous, or confidential because the Internet is an insecure medium and data in transit are vulnerable. The ease with which information can be accessed, shared, hacked, and/or replicated is unique to Internet research. For this reason, critical PI responsibilities for good data stewardship and heightened awareness of human subjects include privacy, confidentiality, and identities. This risk is accentuated if research involves sensitive data. The potential source of risk is harm resulting from a breach of confidentiality. Collecting data over the Internet can increase potential risks to confidentiality because of third party sites, risk of third-party interception when transmitting data across a network, and the impossibility of ensuring data is completely destroyed once HSR is complete. Human subjects should be informed of these potential risks in the ICD. For example:

(1) "Although every reasonable effort has been taken, confidentiality during actual Internet communication procedures cannot be guaranteed."

(2) "Your confidentiality will be kept to the degree allowed by the technology being used. No guarantees can be made regarding the interception of data sent via the Internet by third parties."

(3) "Data may exist on backups or server logs beyond the timeframe of this research."

17.5. WAIVER OF INFORMED CONSENT.

The IRB may approve a consent procedure which does not include or alters some or all elements of informed consent; or waives the requirement to obtain informed consent altogether provided conditions are clearly met.

a. If asking for a general waiver or alteration of informed consent, a PI must address elements required to approve a waiver in 32 CFR 219.116(d) (for studies reviewed under the pre-2018 Common Rule) or 32 CFR 219.116(f)(3) (for studies reviewed under the post-2018 Common Rule) in the HSR submission. In addition, a PI shall explain in the HSR submission why 10 CFR 980 does not apply.

b. If requesting a waiver of requirement to obtain a signed ICD from some or all of the human subjects, a PI must address elements required to approve a waiver of signed informed consent in 32 CFR 219.117(c) (for studies reviewed under the pre-2018 Common Rule) or 32 CFR 219.117(c)(1) (for studies reviewed under the post-2018 Common Rule).

c. A PI must clearly state the request for a waiver of informed consent or a waiver of documentation of informed consent and which elements s/he request be waived. The IRB shall document applicable waiver approval criteria have been satisfied. The IRB shall also document 10 U.S.C. 980 does not apply.

d. HSR involving deception/incomplete disclosure requires a PI to acknowledge deception in a subsequent debriefing process and, when possible, allow a human subject the opportunity to withdraw response(s).

e. The HRPP/IRB shall review instances of PIs deviating from waiver of informed consent as described in a protocol as potential noncompliance by the PIs.

17.6. BROAD CONSENT.

a. Broad consent permits PIs to conduct HSR with identifiable biospecimens and identifiable data without the requirement to obtain additional consent for future storage, maintenance, or HSR uses, so long as the future activities are within the scope of broad consent.

(1) Broad consent may be the most suitable pathway for HSR involving identifiable private information or identifiable specimens in cases in which a waiver of consent would not be available.

(2) PIs seeking broad consent are bound by the regulatory limitation that if a human subject "refuses to consent," the IRB cannot waive consent for the storage, maintenance, or secondary HSR use of the identifiable private information or identifiable biospecimens.

b. To implement a broad consent program, an institution would be required to install a system to track biospecimens and data for which human subjects provided broad consent and the terms of the board consent to determine which future HSR uses remain within scope.

(1) If a human subject is offered to provide broad consent but refuses, the limitation only proscribes secondary HSR uses of the identifiable materials, meaning that PIs could simply choose to de-identify the data and biospecimens of the human subject to conduct further HSR with them.

(2) A refusal from a human subject to give broad consent does not prevent the unconsented uses of his or her identifiable data and biospecimens for purposes that are not considered "research" under the revised Common Rule. If a person offered broad consent refuses to give that consent, institutions have three options:

(a) If allowed by other law, institutions may simply destroy the identifiable information and biospecimens of the human subject.

(b) Institutions may de-identify the information and biospecimens of the human subject and use them for future research without restraint.

(c) Institutions may decide to retain identifiable information and biospecimens, but allow their future use only for non-research purposes, such as quality improvement. In this third option, the institution must track the information and biospecimens of the human subject to ensure they are not used for future research purposes.

(3) Extensive and seamless IT system capacity will be necessary for any institution to implement fully a broad consent tracking system, as both broad consents and refusals to consent (unless the materials are destroyed) must be tracked over the lifetimes of human subjects who give broad consent and human subjects who refuse to give such consent.

(a) Due to these systems requirements for electronic tracking processes, institutions without interconnected, interfacing, and fully interoperable records systems will not be able to implement and benefit from the broad consent regimen established in the revised Common Rule.

(b) A "confederated," non-IT-unified system will simply not be able to, without significant error, track these consents and refusals to consent. These logistical barriers will greatly limit the utility of the broad consent option.

(4) DAF research review authorities seeking to permit DoD-conducted HSR using broad consent will submit to the DAF COHRP Director documentation that the broad consent is permissible in light of the requirements identified above. The DAF COHRP submits the notification to the DOHRP.

17.7. ASSENT.

Legally, people who have not reached the legal age of majority are unable to consent to participate in HSR and may not sign an ICD.

a. For HSR involving cadet candidates or individuals admitted to the USAFA PS who have not yet in-processed USAFA, consent must be obtained from the candidates' parents or parents' LAR. The ICD shall include assent for cadet candidates.

b. For HSR with children or individuals who have not reached the age of majority, consent shall be obtained from the parents or parent's LAR. Assent shall be obtained from the child. The structure and presentation format of the consent and assent process shall be appropriate to the age and cognitive level of the child.

CHAPTER 18: AMENDMENTS

18.1. PURPOSE.

Describe procedures to amend approved and permitted HSR (see Appendix 3: Generic Human Subjects Research Submission Process).

18.2. BACKGROUND.

a. Amendments after HRPP/IRB approval and institutional approval shall not be implemented by PIs without prior HRPP/IRB review and approval except when necessary to eliminate apparent immediate hazards to human subject(s).

b. Information related to amendments should be relayed to human subjects when the information might relate to the willingness of human subjects to continue to participate in HSR. How information will be relayed to human subjects (re-consent, informational email) should be included in the amendment submission. Amendment approvals may be issued by an EDO or IRB member unless the nature of proposed changes warrants review by a convened IRB. The convened IRB may determine an amendment relates to the willingness of human subjects to continue to participate in HSR and request the PI to relay pertinent information to human subjects.

c. Minor changes may be approved using expedited review procedures (32 CFR 219.110(b)(1)(ii)).

(1) Minor amendments make no substantial alteration in:

(a) Level of risk to subjects.

(b) HSR design or methodology.

(c) Population.

(d) Research team qualifications.

(e) Facilities supporting the safe conduct of HSR.

(f) Other factor(s) warranting review by convened IRB.

(g) Examples of minor changes include:

1. Research personnel changes if qualifications are greater than or equal to qualifications of currently listed research personnel.

2. Adding research sites, assuming they are similar to previously approved sites.

3. Deletion of question(s) in a survey; however, a new SCN must be requested through the A9.

4. Editing contact information in the ICD.

5. Editing dates and/or times.

6. Editing HSR title.

(2) Amendments are not required for exempt HSR that do not have the potential to affect the risk to subjects or exempt status. Examples of amendments that are not needed include:

(a) Adding a class to educationally exempt HSR.

(b) Increasing the total number of subjects.

(c) Extending HSR time period.

d. Major amendments to non-exempt HSR shall be reviewed by convened IRB. Single human subject exceptions require convened IRB review and approval. For example, when enrollment of a single human subject who does not meet eligibility criteria but the PI and/or sponsor agree this human subject should be enrolled.

e. Amendments to HSR that might affect the risk to subjects or exempt status such as collecting additional demographic information in a survey that might make data identifiable or changing procedures must be approved prior to implementation.

18.3. SUBMISSION.

a. PIs submit an Amendment Request to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate "Amendment Submission."

b. The following documents are required for amendment submissions:

(1) LoS (as needed).

(2) CITI training commensurate with role for all personnel added.

(3) Current CVs for all personnel added; CVs not needed for cadets.

(4) Surveys (as needed).

(5) SCNs (as needed).

(6) Agreements (as needed).

(7) ICD(s) or ICD(s) waiver.

18.4. REVIEW.

The HRPP Administrator responds to emails in the order in which they are received and determines whether to send the amendment to an EDO, IRB member, or consults with the HPD based on the amendment content.

a. If a minor amendment to exempt HSR (expedited review) is sent to an EDO, the EDO:

(1) Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(2) Conducts an amendment review.

(3) May approve or conditionally approve the amendment.

(4) Emails the amendment review to the HRPP (usafa.hrpp@afacademy.af.edu).

(5) The HRPP Administrator:

(a) Conducts an administrative review.

(b) Seeks endorsement from the HPD prior to processing amendment approval.

(c) Adds the amendment to the next convened IRB meeting agenda and readaheads.

(d) Adds records to the corresponding active protocol folder.

(e) Updates the HSR database.

(f) Processes an amendment approval.

(g) Processes and emails an MFR and approved documents to the PI.

b. If the submission is sent to the HRPP, the HRPP Administrator:

(1) Conducts an administrative review and requests additional information (as needed). Amended ICDs must be reviewed by an IRB member.

(2) For minor amendments, forwards the amendment to an EDO or IRB member with a suspense date.

(a) The EDO or IRB member reviewing the amendment:

1. Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

2. Conducts an amendment review and determines whether the amendment changes the exemption status. If the amendment changes the exemption status, the reviewer

contacts the PI to: (a) withdraw the amendment; (b) develop a plan to maintain exempt status; (c) or submit a non-exempt HSR determination request.

3. May approve or conditionally approve the amendment.

4. Emails the amendment review to the HRPP (usafa.hrpp@afacademy.af.edu).

(b) Upon receipt of the amendment review:

1. Seeks endorsement from the HPD prior to processing amendment approval.

2. Adds the amendment to the next convened IRB meeting agenda and readaheads.

3. Adds records to the corresponding active protocol folder.

4. Updates the HSR database.

5. Processes an amendment approval.

6. Processes and emails an MFR and approved documents to the PI.

(3) For major amendments (non-exempt research), the HRPP Administrator:

(a) Conducts an administrative review and requests additional information (as needed).

(b) Seeks endorsement from the HPD prior to forwarding to the IRB Chair.

(c) Adds the amendment to the next convened IRB meeting agenda and readaheads.

(d) Forwards the submission to the IRB Chair. The IRB Chair:

1. Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

2. Completes required forms.

3. Tasks an IRB member with completing required forms.

4. Compiles forms responses for review at the convened IRB meeting.

5. Chairs the convened IRB meeting.

6. The IRB may approve, conditionally approve, or disapprove the amendment.

(e) Upon convened IRB meeting:

1. Drafts minutes.

2. Seeks endorsement from the IRB Chair and present IRB members prior to finalizing minutes.

3. Seeks endorsement from the HPD prior to processing approval, conditional approval, or disapproval.

4. Add records to the corresponding active protocol folder.

5. Updates the HSR database.

6. Processes approval, conditional approval, or disapproval.

7. Emails an MFR and approved documents to the PI.

CHAPTER 19: CONTINUING REVIEW OF NON-EXEMPT RESEARCH

19.1. PURPOSE.

Describe procedures of continuing review of non-exempt HSR (see Appendix 3: Generic Human Subjects Research Submission Process).

19.2. BACKGROUND.

The purpose of continuing review is to determine whether all applicable regulatory criteria, including the approval criteria of 32 CFR 219.111 and the informed consent requirements of 32 CFR 219.116 and 117, are met.

a. A continuing review is not required when:

(1) Approved and permitted exempt and limited IRB review HSR.

(2) HSR eligible for expedited review under 32 CFR 219.110 or transitioned to post-2018 Common Rule.

(3) For HSR approved and permitted after 21 January 2019 or HSR with an IRB-approved transition to the post-2018 Common Rule, HSR progressed to one or both of the following:

(a) Data analysis, including analysis of identifiable private information or identifiable biospecimens; or

(b) Accessing follow-up clinical data from procedures that subjects would undergo as a part of clinical care.

b. A continuing review is required when:

(1) Non-exempt HSR approved and permitted prior to 21 January 2019 not approved for transition to exempt or eligible for expedited review under post-2018 Common Rule. Review shall be subject to approval criteria of pre-2018 Common Rule.

(2) Non-exempt HSR approved and permitted after 21 January 2019 not eligible for expedited review per 32 CFR 219.110. Review shall be subject to approval criteria of post-2018 Common Rule.

c. After initial IRB and institutional approval, the IRB retains responsibility for HSR oversight, including PACM. The IRB may approve, conditionally approve, or disapprove HSR to ensure criteria for approval are satisfied.

(1) An appropriate interval (not to exceed 364 days) for continuing review will be determined at initial IRB approval and at each subsequent continuing review.

(2) For non-exempt HSR not requiring continuing review (expedited), the IRB will maintain oversight by:

(a) Reviewing amendments.

(b) Inspecting HSR procedures and/or records.

(c) Reviewing closure reports.

d. If a continuing review meets an expedited review category, it is reviewed via expedited review.

(1) Expedited review category 8.

(a) Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

(b) Where no subjects have been enrolled and no additional risks have been identified; or

(c) Where the remaining research activities are limited to data analysis.

(2) Expedited review category 9.

(a) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

e. If a PI does not submit a continuing report prior to the IRB approval expiration, the HRPP Administrator emails the PI about IRB approval lapse and indicates HSR activities must cease until IRB approval is obtained. The Department Head and Research Director are copied

19.3. SUBMISSION.

a. PIs submit a continuing report to the HRPP (usafa.hrpp@afacademy.af.edu) and indicate "Continuing Review Submission."

b. Continuing report submissions ready for review by the first business day of the month when the convened IRB meeting takes place will be considered.

19.4. REVIEW.

The HRPP Administrator responds to emails in the order in which they are received and determines whether to send the submission to an IRB member (expedited review) or consults with the HPD based on the continuing report content. The HRPP Administrator:

a. Conducts an administrative review and requests additional information (as needed).

b. Seeks endorsement from the HPD prior to forwarding to the IRB Chair.

c. Adds the continuing report to the next convened IRB meeting agenda and readaheads.

d. Forwards the continuing report to the IRB Chair. The IRB Chair:

(1) Requests additional information from the PI (as needed) and copies the HRPP (usafa.hrpp@afacademy.af.edu).

(2) Completes required forms.

(3) If the continuing review is eligible for expedited review, tasks an IRB member with completing required forms. The process continues with para. 18.4.a.(5)(c).

(4) If the continuing review is not eligible for expedited review, tasks an IRB member with completing required forms.

(5) Compiles forms responses for review at the convened IRB meeting.

(6) Chairs the convened IRB meeting.

(7) The IRB may approve, conditionally approve, or disapprove the continuing report.

e. Upon convened IRB meeting:

(1) Drafts minutes.

(2) Seeks endorsement from the IRB Chair and present IRB members prior to finalizing minutes.

(3) Seeks endorsement from the HPD prior to processing approval, conditional approval, or disapproval.

(4) Processes approval, conditional approval, or disapproval.

(5) Updates the HSR database.

(6) Emails an MFR to the PI.

19.5. OUTCOMES.

a. An IRB member may:

(1) Approve continuation for an interval appropriate to the risk (not greater than 364 days).

(2) Conditionally approve continuation. The IRB member may require modifications if specific elements must be addressed to satisfy approval criteria of 32 CFR 219.111, 32 CFR 219.116, and 32 CFR 219.117. Changes are addressed via expedited review.

b. The IRB may:

(1) Approve continuation for an interval appropriate to the risk (not greater than 364 days).

(2) Conditionally approve continuation. The IRB may require modifications if specific elements must be addressed to satisfy approval criteria of 32 CFR 219.111, 32 CFR 219.116, and 32 CFR 219.117. Changes are addressed via expedited review or at the next convened IRB meeting.

(3) Disapprove continuation.

CHAPTER 20: POST-APPROVAL COMPLIANCE MONITORING

20.1. PURPOSE.

Describe how USAFA conducts risk assessments (RAs) and periodic audits of ongoing HSR assuring compliance with 32 CFR 219 and DoDI 3216.02 para. 3.3.f. PACM ensures HSR is executed according to approved procedures and the PI maintains HSR records appropriately (see Appendix 6: Risk Assessment Tool).

20.2. BACKGROUND.

a. Each regulatory agency, as well as funding sponsors, have a responsibility to ensure HSR is compliant with federal regulations, state laws, and when applicable, contractual obligations. An effective method to accomplish this responsibility is to conduct PACM of HSR procedures and records.

b. Regulatory entities. Several regulatory entities may audit protocols determined to be HSR, NHSR, and not research determinations at USAFA including:

(1) IRBs.

(2) DAF COHRP.

(3) Sponsors.

(4) HHS OHRP.

c. Intent. Audits are conducted to:

(1) Evaluate if HSR data is organized, complete, and legible.

(2) Verify informed consent was obtained prior to the conduct of HSR-related procedures.

(3) Verify human subjects met inclusion and exclusion criteria.

(4) Ascertain whether pertinent HSR safety information (UPIRTSOs and HSR procedures) were followed (or not) as permitted.

(5) Verify approved and permitted HSR was, and continues to be, followed appropriately.

(a) Evaluate if HSR procedures performed on human subject(s) were outlined in the approved and permitted HSR; and

(b) Amendments were implemented prior to approval.

(6) Verify information contained in HSR documents were, or are, accurate and verifiable.

(7) Verify HSR items are accounted for and maintained (if applicable).

(8) Other information as applicable.

d. Categories and criteria.

(1) Not for cause.

(a) Based on risk level.

(b) At PI(s) request.

(c) Identified by the convened IRB as requiring continuing review more frequently than annually.

(2) For cause:

(a) At the request of the HPD or IRB of record.

(b) Problems identified by human subject(s), individual(s), or entities not affiliated with the HRPP having witnessed HSR activities.

(c) Problems identified by a regulatory entity or sponsor.

e. The HRPP provides education, training, RAs, and PACM of approved and permitted HSR.

f. PACM begins with an institutional approval and ends with HSR closure.

g. Maintenance of HSR records post-HSR closure is part of PACM.

20.3. PROCEDURES.

a. RA Tool. HSR is evaluated and scored using the RA Tool (Appendix 6) by the HPD after institutional approval. The RA Tool may be used to re-evaluate HSR at continuing review.

b. Selection. HSR is audited based on the following criteria:

(1) Not for cause.

(a) Level of risk greater than or equal to seven are automatically scheduled for audit.

(b) Level of risk between six and seven are evaluated for additional needs and scheduled for audit if the HPD, IRB Chair (as needed), and PI(s) are in agreement of need.

(c) Level of risk equal to or below five are reserved for audit if meeting 19.3.b(2), 19.3.b(3), and 19.3.b(4) below.

(d) At PI(s) request to identify potential issues, best practices, or upon HSR transfer from departing PI(s).

(e) Identified by the convened IRB as requiring continuing review more frequently than annually.

(2) For cause:

(a) At the request of the HPD or IRB of record. Identification of significant problems during HSR and/or continuing review.

(b) Problems identified by human subject(s), individual(s), or institution(s) not affiliated with the HRPP having witnessed HSR activities.

1. Absence of reporting or large number of unexpected AEs.

2. Human subject(s) comment(s), concern(s), or complaint(s).

3. Whistleblowers.

(c) Problems identified by a regulatory oversight entity or sponsor.

c. Auditor(s). HSR is audited based on the following criteria:

(1) Not for cause. The HRPP Administrator reviews records and conducts the audit if level of risk is below than or equal to five.

(2) For cause. The HPD and/or IRB Chair (as needed) review records, conduct the audit, and may be accompanied by another HRPP member or a representative from institutions listed in para. 19.2.b.

(3) HSR conducted at a non-USAFA site may require travel by the auditor. If travel is not feasible, a person at the non-USAFA site, who is not affiliated with the HSR and who has sufficient understanding of HSR compliance, may conduct an audit and provide findings to the HRPP.

d. Coordination.

(1) Unanswered audit requests are referred to the HPD, IRB Chair, and Director A3/9, Operations and Strategic Analysis for further action.

(2) Not for cause and level risk equal to or below five:

(a) The HRPP Administrator emails the PI(s) to schedule a date, time, and location (as needed). If the original request is not feasible, an audit is rescheduled for a later date. The goal is to schedule the audit within three weeks to ensure a convenient time for the PI(s) and

auditor given other responsibilities. If the original request date is not feasible, an audit may be rescheduled for a later date. Every effort will be made to ensure the audit is scheduled within a month of the original request.

(b) The HRPP Administrator emails notification (copying the A3/9 Director of Operations) confirming date, time, location (as needed), and documents to prepare PI(s) for the audit. HSR staff is copied and invited to attend (as applicable).

(c) The HRPP Administrator conducts the audit. Records are selected by the HRPP Administrator but will always include the first subject and the last subject enrolled.

(d) Audits identifying deviations increasing the risk to benefit ratio and/or constitute risk to the human subjects are immediately referred to the HPD for consideration of a temporary HSR hold and referral to the IRB (if needed) to address risk issues.

(e) If audit results suggest noncompliance, the auditor reports it to the HPD and/or IRB Chair (if applicable) within two business days. Otherwise, results are provided to the HPD and IRB Chair (if applicable) within five business days.

(f) The HRPP Administrator adds the audit report to the next convened IRB meeting agenda and readaheads.

(g) The HRPP Administrator adds records to the corresponding active protocol folder.

(3) Not for cause and level risk equal to or above six:

(a) The HPD and/or IRB Chair email the PI(s) (copying the HRPP) to schedule a date, time, and location (as needed). If the original request is not feasible, an audit is rescheduled for a later date. The goal is to schedule the audit within three weeks to ensure a convenient time for the PI(s) and auditor(s) given other responsibilities. If the original request date is not feasible, an audit may be rescheduled for a later date. Every effort will be made to ensure the audit is scheduled within a month of the original request.

(b) The HPD and/or IRB Chair email (copying the HRPP and the A3/9 Director of Operations) notification confirming date, time, location (as needed), and documents to prepare PI(s) for the audit. HSR staff is copied and invited to attend (as applicable).

(c) The HPD and/or IRB Chair conduct the audit. Records are selected by the HPD and/or IRB Chair but will always include the first subject and the last subject enrolled.

(d) Audits identifying deviations increasing the risk to benefit ratio and/or constitute risk to the human subjects are immediately referred to the HPD for consideration of a temporary HSR hold and referral to the IRB (if needed) to address risk issues.

(e) If audit results suggest noncompliance, the auditor reports it to the HRPP Administrator and IRB Chair (if applicable) within two business days. Otherwise, results are provided to the HRPP Administrator and IRB Chair (if applicable) within five business days.

(f) The HRPP Administrator adds the audit report to the next convened IRB meeting agenda and readaheads.

(g) The HRPP Administrator adds records to the corresponding active protocol folder.

(4) For cause:

(a) The HPD and/or IRB Chair email the PI(s) (copying the HRPP) to schedule a date, time, and location (as needed). If the original request is not feasible, an audit is rescheduled for a later date. For cause audits are scheduled IAW request requirements (i.e., prior to the next convened IRB meeting).

(b) The HPD and/or IRB Chair email (copying the HRPP and the A3/9 Director of Operations) notification confirming date, time, location (as needed), and documents to prepare PI(s) for the audit. HSR staff is copied and invited to attend (as applicable).

(c) The HPD and/or IRB Chair conduct the audit. Records are selected by the HPD and/or IRB Chair but will always include the first subject and the last subject enrolled.

(d) Audits identifying deviations increasing the risk to benefit ratio and/or constitute risk to the human subjects are immediately referred to the HPD for consideration of a temporary HSR hold and referral to the IRB (if needed) to address risk issues.

(e) If audit results suggest noncompliance, the auditor reports it to the HRPP Administrator, HPD, and/or IRB Chair (if applicable) within two business days. Otherwise, results are provided to the HRPP Administrator, HPD, and IRB Chair (if applicable) within five business days.

(f) The HRPP Administrator adds the audit report to the next convened IRB meeting agenda and readaheads.

(g) The HRPP Administrator adds records to the corresponding active protocol folder.

(5) IRB requested:

(a) The HPD and/or IRB Chair email the PI(s) (copying the HRPP) to schedule a date, time, and location (as needed). If the original request is not feasible, an audit is rescheduled for a later date. IRB requested audits are scheduled IAW request requirements (i.e., prior to the next convened IRB meeting).

(b) The HPD and/or IRB Chair email (copying the HRPP and the A3/9 Director of Operations) notification confirming date, time, location (as needed), and documents to prepare PI(s) for the audit. HSR staff is copied and invited to attend (as applicable).

(c) The HPD and/or IRB Chair conduct the audit. Records are selected by the HPD and IRB Chair but will always include the first subject and the last subject enrolled.

(d) If audit results suggest noncompliance, the auditor reports it to the HRPP Administrator, HPD, and/or IRB Chair within two business days. Otherwise, results are provided to the HRPP Administrator, HPD, and/or IRB Chair within five business days.

(e) The HRPP Administrator adds the audit report to the next convened IRB meeting agenda and readaheads.

(f) The HRPP Administrator adds records to the corresponding active protocol folder.

e. Exit Interview. The auditor conducts an exit interview with the PI(s) after the audit report is complete. The interview includes discussing findings, recommendations, and issues during the audit. If there were no deviations, exit interviews are not necessary.

f. Responsibilities.

(1) IO/AIOs. Establish a program of PACM of HSR conducted or supported by USAFA.

(2) The HPD:

(a) Completes the RA Tool for approved and permitted HSR.

(b) Ensures PI(s) and HSR staff have appropriate education and training.

(c) Reviews preliminary findings that may change the risk-to-benefit ratio as originally approved and permitted, may represent an UPIRTSO, or may represent serious and/or continuing noncompliance and take appropriate action.

(d) Notifies the Director A3/9, Operations and Strategic Analysis of audits and identifies areas of concern.

(e) Ensures a requestor has access to relevant materials for a complete review.

(f) Conducts audits.

(g) Reviews audit findings and determines if IRB or IO/AIO action is necessary.

(3) The HRPP Administrator:

(a) Ensures PI(s) and HSR staff have appropriate education and training.

(b) Notifies the HPD of audits and identifies specific areas of concern.

(c) Conducts audits.

(4) The IRB Chair:

(a) Reviews preliminary findings that may change the risk-to-benefit ratio as originally approved and permitted, may represent an UPIRTSO, or may represent serious and/or continuing noncompliance and take appropriate action.

(b) Notifies the HPD of audit requests and identifies areas of concern.

(c) Conducts audits.

(d) Reviews audit findings and determines if IRB or IO/AIO action is necessary.

(5) PI(s):

(a) Schedule a PACM meeting with the HPD after approval, institutional approval, and before HSR initiation. This meeting serves to provide guidance to the PI(s), specifically about roles and responsibilities.

1. If the HSR has a coordinator and/or monitor, the PI ensures the coordinator and/or monitor are present. HSR staff are encouraged to attend.

2. Ideally, the meeting is scheduled near the location where HSR will be conducted to allow an initial audit that may include examining location(s) where consenting and HSR activities will occur, demonstration of equipment to be used, reviewing location(s) where HSR records will be stored, and other related activities.

3. This meeting is recorded by the HPD; a copy of this document is kept in the HRPP and a copy is provided to the PI.

(b) Coordinate with the HRPP Administrator, HPD, and/or IRB Chair to facilitate audit(s). This includes scheduling a date, time, and location to review records and meet with HSR staff (as applicable). Be available for and/or ensure HSR staff, who is/are sufficiently knowledgeable to discuss HSR, documents, and activities, are available during audit(s).

(c) Emails the HRPP (usafa.hrpp@afacademy.af.edu) of any pending audits (to include sponsor, federal, regulatory entities, etc.) and provides the report for inclusion in HSR records. The HPD reviews these reports as part of PACM.

(d) Remain compliant with approved and permitted HSR to include:

1. Ensure HSR staff understand and conduct HSR activities IAW federal, DoD, DAF, USAFA, and other applicable authorities.

2. Maintain HSR documents and records, both historical and current.

3. Ensure HSR staff maintain HSR training.

4. Follow USAFA guidance for publication clearance.

(6) The coordinator and/or monitor (if applicable):

(a) Attends the initial PACM meeting with the PI(s) and HPD to review specific HSR duties.

(b) Provides review(s), report(s), and/or input of UPIRTSOs and AE/SAEs as outlined in the HRPP.

20.4. OUTCOMES.

a. Audit outcomes.

(1) No deviations. No further action necessary, auditor may share best practices.

(2) Minor deviations. Deviations do not affect human subject safety or HSR outcomes (i.e., data interpretation).

(3) Major deviations. Deviations could potentially affect human subject safety, HSR outcomes, or a significant number of minor deviations suggest HSR staff are not carefully adhering to approved and permitted procedures.

(4) Insufficient information. Unable to render result(s).

20.5. NON-USAFA REGULATORY INSTITUTIONS.

a. Federal, state, or foreign governments may conduct for cause audits for noncompliance.

b. The HRPP makes every effort to cooperate with such audits by furnishing documents and making personnel available for interviews. PI(s), Research Directors, and Department Heads are expected to do the same.

c. The HRPP, through the IO/AIO, reports federal, state, or foreign government for-cause audits of noncompliance to the DAF COHRP within five business days of notification.

CHAPTER 21: DEVIATIONS, UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS, NONCOMPLIANCE, UNDUE INFLUENCE, AND COERCION

21.1. PURPOSE.

Describe responsibilities and procedures of reporting and reviewing alleged deviations, UPIRTSOs, and noncompliance. This policy applies to any activity that may be HSR, including activities not previously reviewed by the HRPP/IRB and activities that may have become HSR after a NHSR determination.

21.2. BACKGROUND.

a. If the HRPP/IRB becomes aware of potential HSR conducted without appropriate determination, approval, and/or institutional approval, it will investigate allegations.

b. Reporting requirements, investigating, and processing potential deviations and noncompliance are in DoDI 3216.02, para. 3.16:

(1) DoD institutions must promptly respond to allegations of noncompliance.

(2) For allegations involving a non-DoD institution, the non-DoD institution must investigate IAW the applicable support agreement, to be furnished to the supporting DoD institution via the HRPO. The DoD institution supporting the HSR must ensure in its agreements with the non-DoD institution that allegations are promptly and properly investigated. The DoD institution will then promptly report substantiated serious and/or continuing non-compliance findings to the COHRP.

c. PI(s) conducting HSR without HRPP determination, IRB approval, and/or institutional approval are noncompliant with federal, DoD, DAF, and USAFA requirements. This may result in federal, DoD, DAF, or USAFA actions preventing PI(s) from engaging in HSR and potentially jeopardizing the USAFA assurance. Assessment activities, program evaluations, or other scholarly activities could be HSR based on definitions in 32 CFR 219. Only EDOs and IRB members can determine if an activity is NHSR, exempt HSR, non-exempt expedited HSR, or non-exempt HSR.

d. Definitions.

(1) Deviation. A departure from HSR approved procedures, including obtaining and documenting informed consent that occurs without prior HRPP/IRB approval. HSR deviations may be emergency, major, or minor, and may or may not constitute noncompliance.

(a) Emergency deviation. An emergency deviation is always considered a UPIRTSO.

(b) Major deviation. A significant change to any part of the HRPP/IRB approved HSR, including changes to human subject population, recruitment, informed consent, HSR, data collection, and security procedures. Implementing (or failing to promptly report) a major deviation without obtaining HRPP/IRB approval constitutes noncompliance.

(c) Minor deviation. An insignificant change (may be administrative) not affecting HSR scientific integrity or rights, safety, or welfare of human subjects.

(2) UPIRTSO. A UPIRTSO is an incident, experience, or outcome that meets all of the following:

(a) It is unexpected (in terms of nature, severity, or frequency) given HSR procedures described in protocol-related documents and characteristics of the subject population; and

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

(c) It suggests HSR places human subjects or others at a greater risk of harm (physical, psychological, economic, social harm) than was previously known or recognized, even if no harm occurred.

(3) Noncompliance. Noncompliance is failure of a person, group, or institution to act IAW 32 CFR 219, DoD 3216.02, DoDI 3216.02 DAF 40-402, USAFA HRPP, and associated references. Some deviations constitute noncompliance.

(a) Continuing noncompliance is a pattern of noncompliance suggesting likelihood that, without intervention, instances of noncompliance will recur. It includes a repeated unwillingness to comply with or a persistent lack of knowledge of how to comply with 32 CFR 219, DoD 3216.02, DoDI3216.02_DAF 40-402, USAFA HRPP, and associated references.

(b) Serious noncompliance is failure of a person, group, or institution to act IAW 32 CFR 219, DoD 3216.02, DoDI3216.02_DAF 40-402, USAFA HRPP, and associated references such that the failure could adversely affect rights, safety, or welfare of a human subject; place a human subject at increased risk of harm or cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of HSR data. Examples of serious noncompliance include:

1. Inadequate or delinquent informed consent documentation.

2. Not satisfying inclusion/exclusion criteria.

3. Unreported UPIRTSOs.

4. Mishandled samples or data.

5. Materially inadequate recordkeeping.

6. Intentional deviation from approved and permitted HSR or regulations.

(c) Alleged noncompliance is identified by:

1. An individual reports directly to the HRPP/IRB.

2. The HRPP/IRB learns of noncompliance through continuing review.

3. The HRPP/IRB finds it during PACM.

4. A HRPP stakeholder discovers it in casual conversation.

5. DAF COHRP discovers it during site assistance or site compliance visit.

6. Other associated institution(s), through funding or other venue, learns of alleged noncompliance.

(4) Research misconduct. Fabrication, falsification, or plagiarism in proposing, performing, of reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

21.3. UNDUE INFLUENCE.

a. Any HRPP stakeholder who feels undue influence is being exerted to review or approve a submission should report it immediately to the HPD and/or IO/AIO.

b. In the event there is undue influence, HRPP stakeholders are encouraged to contact DAF COHRP.

c. If HRPP stakeholders are approached regarding potential undue influence during recruitment or conduct of HSR, they should immediately report it to the HPD and/or IO/AIO.

d. Allegations of undue influence are investigated by HRPP staff. If allegations of undue influence are true or there is enough evidence to suspect it is true, the matter is referred to the HPD, IRB Chair, and IO/AIO.

21.4. COERCION.

a. Any HRPP stakeholder who feels coerced in HSR review should report it immediately to the HPD and/or IO/AIO.

b. In the event there is coercion by leadership or IO/AIO, HRPP staff are encouraged to contact DAF COHRP.

c. If any HRPP stakeholder is approached regarding possible coercion during recruitment or conduct of HSR, they should immediately notify the HPD.

d. Allegations of coercion are investigated.

(1) If allegations of coercion are true or there is enough evidence to suspect it is true, the matter is referred to the HPD, IRB Chair, and IO/AIO.

(2) The IO/AIO takes action based on HRPP staff recommendations.

21.5. REPORTING DEVIATIONS.

a. Deviation reports can be made by any HRPP stakeholder and must be submitted in writing to the HRPP (usafa.hrpp@afacademy.af.edu).

b. Reporting timelines depend on the nature of the deviation (see Table 21.1).

(1) Emergency deviations (always considered UPIRSTOs) are reported within one calendar day (see Table 21.1).

(2) Major deviations are reported within three business days (see Table 21.1).

(a) Implementing a planned deviation not arising from an emergency situation, to mitigate newly discovered risks to human subjects, or without prior HRPP/IRB review and approval is noncompliance. The HRPP/IRB investigates noncompliance.

(b) Major deviations (except to mitigate newly discovered risks to human subjects) are not implemented without prior HRPP/IRB review and approval.

(c) Approvals for prospective major deviation are submitted as amendments to the HRPP (usafa.hrpp@afacademy.af.edu).

(3) Minor deviations are reported within 30 calendar days or at continuing review (see Table 21.1).

(a) For exempt HSR and non-exempt expedited HSR, report minor deviations (may be administrative) within 30 calendar days (see Table 21.1).

(b) For non-exempt HSR, report minor deviations (may be administrative) at the next continuing review (see Table 21.1).

c. Deviation reports must include:

(1) A detailed description of the deviation.

(2) A detailed rationale describing whether the deviation is an emergency deviation (UPIRTSO).

(3) A detailed description of changes to procedures, inclusion/exclusion criteria, informed consent process, or other changes that have been implemented or proposed.

(4) An amendment request with the report if requesting HRPP/IRB review and approval of a deviation, whether implemented or not.

d. The IO/AIO is responsible for:

(1) Reviewing the emergency deviation (always considered UPIRTSO) report.

(2) Submitting the emergency deviation (always considered UPIRTSO) report (including event timeline) to DAF COHRP within five business days from when the UPIRTSO was first reported to the HRPP/IRB (see Table 21.1).

e. The HRPP is responsible for closing the deviation within 120 calendar days (see Table 21.1).

Table 21.1. Deviation Reporting Timelines.

Deviation	PI Notification to HRPP	IO/AIO Notification to DAF COHRP	HRPP Deviation Closure
Emergency (UPIRSTO)	1 calendar day	5 business days from initial report	120 calendar days
Major	3 business days	N/A	
Minor	30 calendar days (exempt HSR, non-exempt expedited HSR) or at continuing review (non-exempt HSR)	N/A	

21.6. REVIEWING DEVIATIONS.

a. If the deviation is an emergency deviation (always considered UPIRSTO), refer to 20.6.

b. If the deviation is a major or minor deviation:

(1) For exempt HSR, the HPD completes a deviation report and recommends action(s) to prevent recurrence.

(2) For non-exempt expedited HSR, the IRB Chair completes a deviation report and recommends action(s) to prevent recurrence.

(3) For non-exempt HSR, the convened IRB evaluates the deviation and recommends action(s) to prevent recurrence.

c. PI(s) are responsible for:

(1) Responding to requirements within 10 business days of the decision unless remediation requires substantial updates, fiscal expenditure, hiring, or legal negotiations.

(2) Keeping records of all deviations.

d. Deviations are included in the agenda and readaheads at the next convened IRB meeting.

21.7. REPORTING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS.

a. UPIRTSO reports can be made by any HRPP stakeholder and must be submitted in writing to the HRPP (usafa.hrpp@afacademy.af.edu).

b. UPIRTSOs must be reported within one business day of learning of the incident or event.

c. UPIRSTO reports must include:

(1) A detailed description of the event.

(2) A detailed rationale describing whether the event constitutes an UPIRTSO.

(3) A detailed description of changes to procedures, inclusion/exclusion criteria, informed consent process, or other changes that have been taken or are proposed.

d. UPIRTSOs are reported with an event timeline to the IO/AIO within one business day (see Table 21.2).

e. The IO/AIO is responsible for:

(1) Reviewing the UPIRTSO report.

(2) Submitting the UPIRTSO report (including event timeline) to DAF COHRP within five business days from when the UPIRTSO was first reported to the HRPP/IRB (see Table 21.2).

f. The HRPP is responsible for closing the UPIRTSO within 120 calendar days (see Table 21.2).

g. Reporting UPIRSTOs in multi-site HSR. USAFA PIs participating in multi-site HSR should only report UPIRTSOs. Normally, the site where the event happened or the HRPP/IRB at the coordinating site makes this judgment.

Table 21.2. UPIRTSO Reporting Timelines.

PI Notification to HRPP	HRPP Notification to IO/AIO	IO/AIO Notification to DAF COHRP	HRPP Problem Closure
1 business day	1 business day	5 business days from initial report	120 calendar days

21.8. REVIEWING UNANTICIPATED PROBLEMS INVOLVING RISKS TO SUBJECTS OR OTHERS.

a. For exempt HSR, the HPD immediately suspends HSR pending review. The HPD or designee (a person whose expertise is better suited to review the UPIRSTO) reviews the UPIRSTO and considers the following:

(1) Does the incident constitute an UPIRTSO?

(2) In light of the UPIRTSO, is the original risk determination (greater than minimal risk or minimal risk) still appropriate?

(3) In light of the new risks revealed by the UPIRTSO, does the HSR still satisfy the approval criteria in 32 CFR 219.111?

(4) What changes to the HSR procedures and informed consent process/ICD are required?

(5) Should currently enrolled or completed human subjects be notified of the newly discovered risks associated with the HSR?

(6) Is the UPIRTSO due to a deviation? If so, does it constitute serious and/or continuing noncompliance?

(7) Should the HSR be terminated?

b. For non-exempt HSR, the IRB Chair immediately suspends HSR pending review and requests an out-of-cycle convened IRB meeting as soon as possible. The IRB Chair or designee (a person whose expertise is better suited to review the UPIRTSO) reviews the UPIRSTO prior to the convened IRB meeting. The convened IRB considers the following:

(1) Does the incident constitute an UPIRTSO?

(2) In light of the UPIRTSO, is the original risk determination (greater than minimal risk or minimal risk) still appropriate?

(3) In light of the new risks revealed by the UPIRTSO, does the HSR still satisfy the approval criteria in 32 CFR 219.111?

(4) What changes to the HSR procedures and informed consent process/ICD are required?

(5) Should currently enrolled or completed human subjects be notified of the newly discovered risks associated with the HSR?

(6) Is the UPIRTSO due to a deviation? If so, does it constitute serious and/or continuing noncompliance?

(7) Should the HSR be terminated?

c. PI(s) are responsible for:

(1) Responding to requirements within 10 business days of the decision unless remediation requires substantial updates, fiscal expenditure, hiring, or legal negotiations.

(2) Keeping records of all deviations and UPIRSTOs.

(3) For non-exempt expedited HSR, tabulating all deviations and UPIRTSOs in the closure report.

(4) For non-exempt HSR, tabulating all deviations and UPIRTSOs in continuing report(s) and the closure report.

d. UPIRTSOs are included in the agenda and readaheads at the next convened IRB meeting.

21.9. REPORTING NONCOMPLIANCE.

a. Alleged noncompliance reports can be made by any HRPP stakeholder and must be submitted in writing to the HRPP (usafa.hrpp@afacademy.af.edu).

b. Reporting timelines for noncompliance is three business days (see Table 21.3).

c. Alleged noncompliance reports must include:

(1) Nature of alleged noncompliance including dates, times, and locations.

(2) Whether UPIRTSOs occurred.

d. If noncompliance is identified through PACM, the audit is the noncompliance report.

e. The IO/AIO is responsible for:

(1) Reviewing the noncompliance report.

(2) Submitting the noncompliance report (including event timeline) to DAF COHRP for review, vetting, and potential submission to DAF/SG, OUSD(R&E), and other regulatory bodies within five business days (see Table 21.3).

f. The HRPP is responsible for closing the noncompliance within 120 calendar days (see Table 21.3).

g. If an HRPP stakeholder determined research misconduct occurred, it is reported to the IO/AIO and to DAF COHRP within 1 calendar day (see Table 21.3).

Table 21.3. Noncompliance Reporting Timelines.

PI Notification to HRPP	HRPP Notification to IO/AIO	IO/AIO Notification to DAF COHRP	HRPP Noncompliance Closure
3 business days	1 business day	5 business day from initial report	120 calendar days

21.10. REVIEWING NONCOMPLIANCE.

a. If the alleged noncompliance constitutes a deviation, the HPD or IRB Chair determine if a deviation occurred, and if a deviation occurred, whether it is significant enough to constitute serious and/or continuing noncompliance.

(1) The HPD or IRB Chair email the PI(s) an allegation of noncompliance was made and may request additional information. PI(s) provide requested information within three business days.

(2) The HPD or IRB Chair review and evaluate circumstances leading to the alleged noncompliance. This review may include: interviewing anyone related to the alleged noncompliance, examining HSR data, informed consent, inclusion/exclusion criteria, applicable approved HSR, and other pertinent information.

(a) If the HPD or IRB Chair determine the alleged noncompliance did not occur and there was no deviation, no PI(s) action is required.

(b) If the HPD or IRB Chair determine the alleged noncompliance occurred:

1. For exempt HSR, the HPD recommends action(s) to prevent recurrence.

2. For non-exempt expedited HSR, the IRB Chair recommends action(s) to prevent recurrence.

3. For non-exempt HSR, the convened IRB recommends action(s) to prevent recurrence.

(c) If the HPD or IRB Chair find evidence suggesting human subjects were at risk:

1. For exempt HSR, the HPD may suspend exempt HSR or adopt appropriate actions to protect safety and welfare of human subjects.

2. For non-exempt expedited HSR, the IRB Chair may suspend or adopt appropriate actions to protect safety and welfare of human subjects.

3. For non-exempt HSR, the convened IRB may suspend or adopt appropriate actions to protect safety and welfare of human subjects.

(d) If the HPD, IRB Chair, or convened IRB suspend HSR:

1. For exempt HSR, the HPD may conditionally reinstate HSR or recommend withdrawing institutional approval.

2. For non-exempt expedited HSR, the IRB Chair may conditionally reinstate HSR, terminate, or recommend withdrawing institutional approval.

3. For non-exempt HSR, the convened IRB may conditionally reinstate HSR, terminate, or recommend withdrawing institutional approval.

b. If the alleged noncompliance constitutes conducting HSR without HRPP determination, IRB approval, and/or institutional approval, the HPD or IRB Chair:

(1) Emails the PI(s) copying respective Research Director and Department Head (or equivalents), instructing to cease HSR activities and data collection.

(2) Requires PI(s) to submit a HRPP Determination Request.

(3) Investigates the activity, reviews the HRPP Determination Request, and determines if the activity is HSR.

(a) If the activity is NHSR:

1. The PI(s) may resume activities.

2. The Research Director and Department Head are copied.

(b) If the activity is exempt HSR:

1. The HPD weighs the level of risk to which human subjects were exposed, decides appropriate sanctions, whether (or when) data collection may commence, and categorizes noncompliance as serious and/or continuing.

2. The Research Director and Department Head are copied.

(c) If the activity is non-exempt expedited HSR:

1. The IRB Chair weighs the level of risk to which human subjects were exposed, decides appropriate sanctions, whether (or when) data collection may commence, whether to disapprove HSR, and categorizes noncompliance as serious and/or continuing.

2. The Research Director and Department Head are copied.

(d) If the activity is non-exempt HSR:

1. The next convened IRB meeting weighs the level of risk to which human subjects were exposed, decides appropriate sanctions, whether (or when) data collection may commence, whether to disapprove HSR, and categorizes noncompliance as serious and/or continuing.

2. The PI(s), Research Director, and Department Head are invited to attend the next convened IRB meeting.

c. If noncompliance possibly involves research misconduct, it is managed IAW DoDI 3210.07, Research Integrity and Misconduct.

(1) The HPD, IRB Chair, or convened IRB may institute research sanctions.

(2) The IO/AIO may institute disciplinary actions.

d. The HPD or IRB Chair is responsible for preparing a noncompliance report to the IO/AIO.

e. PI(s) are responsible for:

(1) Responding to requirements within 10 business days of the decision unless remediation requires substantial updates, fiscal expenditure, hiring, or legal negotiations.

(2) Keeping records of noncompliance events.

f. Noncompliance is included in the agenda and readaheads at the next convened IRB meeting.

21.11. INSTITUTIONAL NONCOMPLIANCE.

USAFA is responsible for following USAFA HRPP requirements and other applicable regulations as noted in this document.

a. Institutional noncompliance means noncompliance committed by USAFA HRPP staff responsible for administering and supporting the USAFA HRPP.

b. Institutional noncompliance may occur when there is a systematic failure to implement practices and procedures under a DoD assurance. Examples include:

(1) Failure to maintain records.

(2) Failure to apply appropriate review determination categories.

(3) Failure to report HSR suspension or termination.

CHAPTER 22: SUSPENSION OR TERMINATION

22.1. PURPOSE.

Outline conditions and procedures for suspending and terminating HSR.

22.2. BACKGROUND.

a. Definitions.

(1) Suspension. Any HRPP/IRB action pending review requiring HSR to stop for any length of time short of permanent.

(2) Termination. Any HRPP/IRB action requiring HSR to stop permanently.

b. Leading factors to suspension or termination of HSR include:

(1) PACM.

(2) Not submitting continuing reviews before expiration.

(3) Reports of noncompliance or UPIRTSOs.

(4) Complaints from human subjects, family members, or others.

c. HSR is suspended or terminated if:

(1) It is not conducted IAW federal, DoD, DAF, or USAFA regulations.

(2) It has been associated with unexpected serious harm to human subjects.

d. Authorities.

(1) Suspension. The HPD, IRB Chair, convened IRB, or IO/AIO can suspend HSR.

(2) Termination. The convened IRB or IO/AIO can terminate HSR.

22.3. REVIEW.

a. For exempt HSR, the HPD reviews documents related to suspension.

b. For non-exempt expedited HSR, the IRB Chair reviews documents related to suspension.

c. For non-exempt HSR, the next convened IRB reviews documents related to suspension. For problems of a serious nature, if there is insufficient time to wait until the next convened IRB meeting, the IRB Chair requests an out-of-cycle convened IRB meeting.

d. For all HSR, the IO/AIO reviews documents related to suspension.

22.4. SUSPENSION PROCEDURES.

a. The HRPP considers suspension an action pending review.

b. The HRPP considers alternative(s) to protect enrolled human subjects from harm resulting from withdrawal, including:

(1) Adding, removing, or limiting PI(s) responsibilities.

(2) Transferring human subjects to another PI(s) allowing continuation of HSR.

(3) Adding or modifying a monitoring plan (e.g., addition of an independent monitor, safety monitoring procedures).

(4) Re-consenting human subjects.

(5) Shortening non-exempt HSR continuing review timeframe.

(6) PI(s) contact current and/or former human subjects.

(7) Requiring follow-up of human subjects for safety reasons.

c. The HPD, IRB Chair, convened IRB, or IO/AIO document reason(s) for suspension.

(1) The HRPP Administrator emails PI(s) and respective Research Director and Department Head of suspension including reason(s). The email may include:

(a) Rationale for suspension.

(b) Procedural requirements needed to protect rights and welfare of enrolled human subjects.

(c) Whether follow-up of human subjects for safety reasons is permitted or required.

(2) The HRPP Administrator adds the suspension and associated documents to the next convened IRB meeting agenda and readaheads.

d. PI(s) notify enrolled human subjects of suspension and assess withdrawal procedures of enrolled human subjects considering their rights and welfare.

e. The IO/AIO notifies DAF COHRP of non-exempt HSR suspension within five business days.

22.5. TERMINATION PROCEDURES.

a. The HRPP considers termination a permanent action.

b. The HRPP considers alternative(s) to protect enrolled human subjects from harm resulting from termination, including:

(1) Adding, removing, or limiting PI(s) responsibilities.

(2) Transferring human subjects to another PI(s) allowing continuation of HSR.

(3) Adding or modifying a monitoring plan (e.g., addition of an independent monitor, safety monitoring procedures).

(4) Re-consenting human subjects.

(5) Shortening non-exempt HSR continuing review timeframe.

(6) PI(s) contact current and/or former human subjects.

(7) Requiring follow-up of human subjects for safety reasons.

c. The convened IRB or IO/AIO document reason(s) for termination.

(1) The HRPP Administrator emails PI(s) and respective Research Director and Department Head of termination including reason(s). The email may include:

(a) Rationale for termination.

(b) Procedural requirements needed to protect rights and welfare of enrolled human subjects.

(c) Whether follow-up of human subjects for safety reasons is permitted or required.

(d) How to appeal the termination within 30 days from date of notification.

(2) The HRPP Administrator adds the termination and associated documents to the next convened IRB meeting agenda and readaheads.

d. PI(s) notify enrolled human subjects of termination and assess withdrawal procedures of enrolled human subjects considering their rights and welfare.

e. The IO/AIO notifies DAF COHRP of non-exempt HSR termination within five business days.

CHAPTER 23: APPEALS

23.1. PURPOSE.

Outline conditions and procedures for appealing HRPP action(s).

23.2. BACKGROUND.

The HRPP limits appeal concerns to a review of procedures used to reach decision(s) (i.e., claims that the process was faulty in a way that creates a considerable risk that the outcome was incorrect) or grievances of sanctions imposed.

23.3. SUBMISSION.

If PI(s) disagree with a HRPP action, the PI(s) emails an appeal to the HRPP within 30 calendar days of the action, justifying the nature of any claimed procedural error or perceived unfairness of sanctions.

23.4. REVIEW.

a. For exempt HSR, the HPD reviews the appeal, determines validity, and attempts to resolve with the PI(s).

b. For non-exempt expedited HSR, the IRB Chair reviews the appeal, determines validity, and attempts to resolve with the PI(s).

c. For non-exempt HSR, the convened IRB reviews the appeal, determines validity, and attempts to resolve with the PI(s).

d. The HRPP Administrator adds the appeal and associated documents to the next convened IRB meeting agenda and readaheads.

23.5. OUTCOMES.

a. An appeal is successful.

b. An appeal is unsuccessful.

(1) PIs may submit an appeal to the IO/AIO, copying the HRPP (usafa.hrpp@afacademy.af.edu).

(a) If the IO/AIO rejects an appeal, the HRPP action is final.

(b) If the IO/AIO reverses an action, HSR is not reinstated. HSR must be reviewed by the HRPP/IRB to determine if approval criteria in 32 CFR 111, 116, and 117 are satisfied or what requirements are needed to satisfy these criteria.

CHAPTER 24: QUALITY IMPROVEMENT

24.1. PURPOSE.

Describe HRPP quality improvement activities.

24.2. ACTIVITIES.

a. As part of a continuous quality improvement program, the HPD reviews the HRPP periodically and makes recommendations.

(1) The HPD identifies and corrects problems.

(2) The HPD identifies and shares best practices.

(3) Substantive and continuing trends are reviewed by the IO/AIO to identify program needs.

b. The HRPP staff provide metrics to stakeholders for overall program improvement.

c. Significant changes affecting other DoD organizations will be coordinated and approved through the DAF COHRP.

CHAPTER 25: CONTINUITY OF OPERATIONS PLAN

25.1. PURPOSE.

Described limited continuity of HRPP operations in case of government shutdown (see Appendix 7: Continuity of Operations Plan Email).

25.2. POINT OF CONTACT.

During a government shutdown, the Director A3/9, Operations and Strategic Analysis is excepted from furlough and will remain available as a POC.

25.3. SUBMISSIONS.

Because the HRPP will have neither administrative support nor quorum for convened IRB meetings, submissions will not be reviewed during a government shutdown. Any reviews or actions required to protect human subjects will be referred by the Director A3/9, Operations and Strategic Analysis to the DAF COHRP (usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).

25.4. REPORTABLE EVENTS.

The Director A3/9, Operations and Strategic Analysis reports the following to the DAF COHRP within five business days:

a. Allegations of serious and/or continuing noncompliance related to HSR that are substantiated by investigation and subsequent actions taken based on findings.

b. UPIRTSOs and subsequent actions taken based on findings.

c. Suspensions or terminations.

25.5. APPROVED HUMAN SUBJECTS RESEARCH.

a. Civilian-run studies must be placed on hold if there is no service member listed in the HSR as a PI or AI to assume responsibility.

b. If a service member is listed as an AI and will be assuming PI duties, a MFR must be placed in HSR records and emailed to the HRPP (usafa.hrpp@afacademy.af.edu).

25.6. EXPIRING CONTINUING REVIEWS.

Non-exempt HSR requiring continuing review that lapses must stop until the government shutdown ends and a continuing review is completed.

25.7. COMMUNICATION PLAN.

a. The Director A3/9, Operations and Strategic Analysis emails the following:

(1) MEs.

(2) DAF COHRP.

(3) PIs and AIs.

(4) HPD.

(5) HRPP Administrator.

(6) IRB members.

(7) Other HRPP stakeholders.

b. The content of the email includes:

(1) POC information for HRPP purposes.

(2) Pending actions will be delayed.

(3) New submissions will not be reviewed.

(4) Reportable events.

(5) Expiring continuing reviews.

c. An email example is included in Appendix 7.

CHAPTER 26: INACTIVE SUBMISSIONS

26.1. PURPOSE.

Streamline review processes by withdrawing submissions if responses or stipulations have not been addressed within 30 calendar days from the last communication.

26.2. BACKGROUND.

Failure to respond in a timely manner to requests from HRPP staff about incomplete submissions or administrative reviews is disruptive to the workflow and reduces productivity for both the research team and HRPP staff. Submissions without prompt action from the PI for a prolonged period may become scientifically outdated or insignificant to USAFA.

26.3. PROCESS.

a. Submissions to the HRPP without action taken by the PI over 30 calendar days will be administratively withdrawn from further review.

b. There may be a maximum of two attempts to contact the PI during the 30-calendar day period by HRPP staff.

c. Once a submission has been withdrawn, the PI will be notified by the HRPP via email.

(1) Initial determination submissions that are withdrawn will be deleted; no records will be kept.

(2) Submissions related to already permitted HSR will not be deleted; records will be kept.

d. A PI may resubmit.

e. Under extenuating circumstances, a PI may request to reactivate a withdrawn submission related to an already permitted HSR directly to the HPD. The HPD reserves the right to deny or approve reactivation requests.

GLOSSARY

G.1. ACRONYMS.

ACRONYM	MEANING
ABW	Air Base Wing
AD	Athletic Department
AF	Air Force
AI	associate investigator
AIO	alternate institutional official
AOC	Air Officer Commanding
BCT	Basic Cadet Training
CCLD	Center for Character and Leadership Development
CFR	Code of Federal Regulations
CITI	Collaborative Institutional Training Initiative
CLAR	component-level administrative review
CMP	component human research protection program management plan
CoC	certificate of confidentiality
COHRP	component office of human research protections
CoI	conflict of interest
CV	curriculum vitae
CW	Cadet Wing
DAF	Department of the Air Force
DAF/SG	Department of the Air Force Surgeon General
DAFI	Department of the Air Force Instruction
DF	Dean of Faculty
DFARS	Defense Federal Acquisition Regulation Supplement
DFBL	Dean of Faculty Behavioral Sciences and Leadership
DMDC	Defense Manpower Data Center
DoD	Department of Defense
DoDI	DoD instruction
DOHRP	DoD Office for Human Research Protections
DSAT	Dedicated Survey and Administrative Time
EDO	exemption determination official
EU	European Union
FDA	Food and Drug Administration
FTG	Flying Training Group
FWA	federal-wide assurance
GDPR	General Data Protection Regulation
HHS	Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
HPD	human protections director
HRPO	human research protections official
HRPP	human research protection program
HSR	human subject research

ACRONYM	MEANING
IAIR	institutional agreement for Institutional Review Board review
IAW	in accordance with
ICD	informed consent document
IIA	individual investigator agreement
IO	institutional official
IRB	institutional review board
LAR	legally authorized representative
LoS	letter of support
LSGD	large-scale genomic data
MDG	Medical Group
ME	Mission Elements
MERF	Minimum Education Requirements Memo
NHSR	Not Human Subjects Research
OHRP	Office of Human Research Protections
OMB	Office of Management and Budget
OPR	Office of Primary Responsibility
PACM	post-approval compliance monitoring
PI	principal investigator
PS	Preparatory School
SCN	survey control number
SG	Surgeon General
U.S.	United States
U.S.C.	United States Code
UPIRTSO	unanticipated problem involving risks to human subjects or others
USAFA	United States Air Force Academy
USD(R&E)	Under Secretary of Defense for Research and Engineering

G.2. DEFINITIONS.

Unless otherwise noted, these terms and their definitions are for the purpose of this document.

TERM	DEFINITION
administrative review	Review of research to ensure compliance with regulations and policies applicable to HSR that is DoD conducted or research where DoD provides support.
AIO	A person delegated authority and responsibility to fulfill the duties of the IO for the purposes of overseeing the institution's HRPP.
assistance	Non-financial resources that are provided by the DoD to non-DoD institutions for research, including, but not limited to, facilities, equipment, access to information about DoD-affiliated personnel for recruitment, access to DoD-affiliated personnel, data, or

TERM	DEFINITION
	specimens. Funds that are provided by the DoD through a contract or similar arrangement subject to the DFARS; grants, cooperative agreements, technology investment agreements; or other non-procurement awards are not considered assistance. Assistance is a subset of support.
assurance	See DoD assurance.
authorized operational activities	Activities carried out solely in support of the DoD mission to provide military forces information needed to deter war and to protect the security of the United States. These activities are subject to approval by the DoD Component head or Secretary of Defense, including subordinate agencies heads who have been delegated authority to study, evaluate, improve, or otherwise assess DoD performance, quality, and capability. It is the DAF position that HSR is designed to develop or contribute to generalizable knowledge and, thus, is not carried out "solely" in support of the DoD mission.
certification	Official notification by an institution that HSR has been reviewed and approved by an IRB.
classified research involving human subjects	Research involving human subjects where classified material is necessary to adequately perform IRB review and oversight, required to obtain effective informed consent of participants, or, by design, communicated by or to research participants.
Common Rule	The regulation adopted by multiple federal departments and agencies for the protection of human subjects in research. The DoD's implementation of the Common Rule is 32 CFR part 219; the HHS' implementation of the Common Rule is Subpart A of 45 CFR part 46.
continuing noncompliance	A pattern of noncompliance (see definition of noncompliance) that suggests the likelihood that, without intervention, instances of noncompliance will recur. A repeated unwillingness to comply with this publication or a persistent lack of knowledge of how to comply with this publication.
detainee	Defined in DoD Directive 2310.01E.

TERM	DEFINITION
DoD assurance	A written document stating an institution will comply with 32 CFR Part 219 (the Common Rule), and DoD and DoD Component policies.
DoD institution	A DoD entity which conducts activities that may be HSR. Includes DoD entities which support or provide research reviews (see DoDI3216.02 DAFI40-402 Table 2.10.) of activities that may be HSR.
DoD-affiliated personnel	Service members, Reserve Service members, National Guard members, DoD civilians, and DoD contractors.
DoD-conducted HSR	Research involving human subjects that is either performed by DoD personnel or is performed by DoD contract personnel with direct oversight by a key investigator who is federal employee of a DoD institution. See "engaged in HSR."
engaged in HSR	An institution is engaged in HSR when its personnel conduct the HSR on behalf of the institution. An institution is not engaged in HSR if their activities are limited to: funding; providing equipment; providing access to or information about potential human subjects (but not recruiting human subjects); providing data or specimens (either identifiable or not); or overseeing the research from a compliance standpoint. See also DoDI3216.02 DAFI40-402 para. 3.3.a.(2)(b).
excluded activities	The following activities conducted or supported by the DoD are not considered HSR: Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease under force health protection programs of DoD, including health surveillance pursuant to Section 1074f of Title 10, U.S.C., and the use of medical products consistent with DoDI 6200.02. Health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of diagnosis, cure, mitigation, treatment, or prevention of disease in a patient. Activities performed for the sole purpose of medical quality assurance (see Section 1102 of Title 10, U.S.C., and DoDI 6025.13).

TERM	DEFINITION
	Activities that meet the definition of operational test and evaluation as defined in Section 139(a)(2)(A) of Title 10, U.S.C. Activities performed solely for assessing compliance, including occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information. Activities, including program evaluation and surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results are only for the use of government officials responsible for the operation or oversight of the program being evaluated.
exempt HSR	HSR that meets specific federal criteria in 32 CFR Part 219, falling into one of the eight categories of Exempt research listed at 32 CFR 219.104. Exempt HSR must be initially determined as Exempt by an IRB, its designee, or designated DoD HRPP personnel, and then is exempt from further review. See also non-exempt HSR.
EDO	A federal employee at a DoD institution who, sufficiently qualified through experience and expertise, is designated to review research to determine whether the research involves human subjects and, if so, whether such research is exempt from Part 219 of Title 32, CFR.
federal assurance	A written document in which an institution, not an IRB, commits to a federal department or agency its compliance with the requirements set forth in the Common Rule.
FWA	A Federal-Wide Assurance which is only issued by the HHS. This is required when research is funded by HHS.
HPD	The federal employee at a DoD institution who is sufficiently qualified through experience and expertise and serves as the primary POC for the DoD institution's HRPP, and who plays a key role in ensuring that the institution fulfills its responsibilities under the institution's federal assurance or HRPP.
HRPO	A federal employee designated by a DoD Component or institution to conduct administrative review of DoD-supported research IAW the requirements of the DFARS, or comparable requirement, and

TERM	DEFINITION
	whose review of DoD-supported research is intended to ensure compliance with DoD HSR requirements.
HRPP	An institution's system of interdependent elements that implement policies and practices to protect human subjects involved in research. An institution with an HRPP may or may not hold a DoD or federal assurance.
HRPP plan	A written description of an HRPP. For requirements applicable to DAF institution-level HRPP plans, see DoDI3216.02 DAFI40-402 para. 3.3.a. and DoDI3216.02 DAFI40-402 Attachment 1.
HSR	Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens. Throughout this publication, references to HSR include both exempt and non-exempt HSR unless otherwise specified.
human subject	A living individual about whom an investigator (whether professional or student) conducting research: Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or Obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens.
IIA	An agreement between an investigator and an assured institution where the investigator acknowledges that they are primarily responsible for upholding the standards as set forth in the institution's assurance; meanwhile, the institution agrees to extend its assurance, or "cover", the individual investigator.
institution	Any public or private entity, which conducts activities that may be HSR.
IAIR	A DoD-harmonized agreement which allows an institution engaged in HSR to rely upon the IRB of another institution. An IAIR can

TERM	DEFINITION
	cover one, several, or all protocols in which the institution is engaged.
intervention	Includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
IO	An institution's senior person who is legally authorized to represent the institution and who is authorized to establish and is responsible to maintain the HRPP for the institution. The IO is responsible for the institution's DoD or federal assurance and IRB, if these elements are part of the institution's HRPP.
LSGD	Data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. Research involving LSGD may or may not also constitute HSR. Examples of research involving LSGD includes, but is not limited to, projects that involve generating the whole genome sequence data for more than one gene from more than 1,000 individuals, or analyzing 100 or more genetic variants in more than 1,000 individuals.
non-exempt HSR	HSR that meets specific federal criteria in 32 CFR Part 219 and this issuance for minimal risk or greater than minimal risk. In addition to the above, non-exempt HSR meets the definitions of "research" involving "human subjects" but does not meet the criteria where the only involvement of the human subjects in the research are in one or more of the categories identified in Section 219.104(b) of Title 32, CFR.
ombudsperson	A person who acts as an impartial and objective advocate for human subjects participating in research.
PACM	Formal and systematic HRPP monitoring of research to confirm that HSR is being conducted IAW IRB approval or other HRPP regulatory determinations, institutional HRPP policy and procedures, applicable federal laws and regulations, and DoD policy.
PI	The person leading the performance of research.

TERM	DEFINITION
protocol	A document that describes the background, rationale, objectives, design, methodology, and organization of a research investigation. In HSR, the protocol is frequently synonymous with the application for approval of a research study to an HRPP/IRB.
research	A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this issuance, whether or not they are conducted or supported under a program that is considered research for other purposes. The following activities are deemed not to be research: Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. Authorized operational activities (as determined by each DoD Component) in support of intelligence, homeland security, defense, or other national security missions. Guidance and approval for determining authorized operational activities with regard to HSR will be issued by the DOHRP.

TERM	DEFINITION
research involving a human being as an experimental subject	An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of Part 219 of Title 32, CFR.
research review authority	HRPP personnel responsible for reviewing activities that include (or may include) HSR to ensure compliance with this publication, its references, and the institution's HRPP plan. Includes EDOs, IRBs, HRPOs, and personnel with CLAR authority. For a description of each research review authority type, see DoDI3216.02_DAFI40-402 Table 2.10.
security review	Administrative review of research involving large-scale genomic data collected on DoD-affiliated personnel to ensure compliance, IAW the CMP, as well as administrative, technical, and physical safeguards for protecting confidentiality.
serious noncompliance	Failure of a person, group, or institution to act IAW this publication and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data.
service members	Individuals appointed, enlisted, or inducted for military service under the authority of the DoD. The Military Services are the Army; the Navy, including the Coast Guard under circumstances involving the declaration of war; the Air Force; the Marine Corps; and the Reserve Components. Members of the Reserve Components are included when in a duty status.
site visit	An in-person or remote visit conducted to evaluate compliance of an institution's HRPP (or a proposed HRPP). See paragraph DoDI3216.02 DAFI40-402 2.5.e.
staff assistance visit	An in-person or remote visit requested by an IO which may help an institution better understand the intent of this publication and allow an opportunity to provide training.
substantive change	An amendment to an approved item which changes it to the extent it requires new review prior to initiation.

TERM	DEFINITION
	Examples of substantive changes to HRPPs include, but are not limited to, establishment of a new IRB or other new research review authority function (i.e., not previously performed by the institution); changes in signatory officials (i.e., to the HRPP or assurance); or changes to the description of the institution. Examples of substantive changes to non-DoD conducted activities requiring HRPO approval prior to start per DoDI 3216.02, paragraph 3.6.b., as supplemented by this publication, include but are not limited to: 1. Addition of any condition identified in DoDI 3216.02, paragraph 3.6.a., as supplemented by this publication. 2. Addition of personnel representing institutions not identified upon initial HRPO review. 3. Change in the IRB's review procedure (e.g., from exempt to expedited, expedited to convened board, etc.). 4. Change in research-related activities that significantly affects an assessment of the risks and benefits of the study or substantially changes the specific aims or design of the study. 5. Addition of human subjects who cannot provide informed consent (see Section 980 of Title 10, U.S.C.). 6. Addition of a research site in a foreign country to include non-U.S. citizens as human subjects.
support	Funds or assistance that are provided by the DoD to non-DoD institutions for HSR through a grant, contract, or similar arrangement subject to the DFARS or other applicable DoD regulations, such as the DoD Grant and Agreement Regulations. Included in this definition is the DoD's provision of assistance to non-DoD institutions, whether or not through collaboration between DoD and non-DoD institutions, such as facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD-affiliated personnel for recruitment, or data or specimens. This definition does not include DoD-conducted HSR, whether or not conducted in collaboration between a DoD institution and non-DoD institution.

TERM	DEFINITION
	1. An activity is not considered to be DoD-supported by virtue of the following activities alone without further DoD action IAW the definition of "DoD-conducted HSR" herein. a. A DoD employee conducts the activity either with formal authorization to pursue an outside activity separate from their DoD position, or in an off-duty status or otherwise not working in a DoD capacity, and if the activity does not otherwise involve the DoD. b. DAF personnel exercise research review authority (see DoDI3216.02 DAFI40-402 Table 2.10.) for the activity. 2. There is a legal transfer (e.g., through sale or donation) of equipment from the DoD to non-DoD institution, when not done by the DoD for the purpose of enabling specific HSR, severs the relationship with the DoD, and the transfer is not considered DoD support.
suspension of IRB approval	Any IRB action to require HSR activity to stop for any length of time short of permanent. An action constitutes suspension regardless of the verbiage used by the IRB in taking such action.
UPIRTSO	Any incident, experience, or outcome that meets all three of the following conditions: 1. Is unexpected (in terms of nature, severity, or frequency) given the procedures described in the research protocol documents (e.g., the IRB-approved research protocol and ICD) and the characteristics of the human subject population being studied. 2. Is related or possibly related to participation in the research (in this publication, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research). 3. Suggests that the research places human 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.

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REFERENCES

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AFI 33-332, “Air Force Privacy and Civil Liberties Program,” March 10, 2020

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DoD Directive 2310.01E, “DoD Detainee Program,” August 19, 2014

DoD Directive 5134.01, “Under Secretary of Defense for Acquisition, Technology, and Logistics (USD(AT&L)),” December 9, 2005, as amended

DoD 5500.07-R, “Joint Ethics Regulation”

DoD Instruction 1100.13, “DoD Surveys,” January 15, 2015, as amended

DoD Instruction 3210.07, “Research Integrity and Misconduct”, 14 May 2004

DoD Instruction 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research,” April 15, 2020

DoD Instruction 6025.13, “Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS),” February 17, 2011, as amended

DoD Instruction 6025.23, “Healthcare Eligibility Under *the* Secretarial Designee Program and Related Special Authorities,” September 16, 2011, as amended

DoD Instruction 6200.02, “Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Program,” February 27, 2008

DoD Instruction 8910.01, “Information Collection and Reporting,” May 19, 2014

DoD Manual 6025.18, "Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs," March 13, 2019

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Executive Order 12333, "United States Intelligence Activities," as amended, August 18, 2010

Executive Order 13526, "Classified National Security Information," December 29, 2009

Federal Register, Volume 44, Page 23192, April 18, 1979

Federal Register, Volume 68, Pages 36929-36931, June 20, 2003

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National Institutes of Health, "The NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)," April 2016

Public Law 103-160, Section 252, "National Defense Authorization Act for Fiscal Year 1994," November 30, 1993

Public Law 107-347, "Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)," December 17, 2002

Public Law 114-255, "21st Century Cures Act," December 13, 2016

Uniform Code of Military Justice

U.S.C., Title 10

U.S.C., Title 24, Section 30

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US.C., Title 42

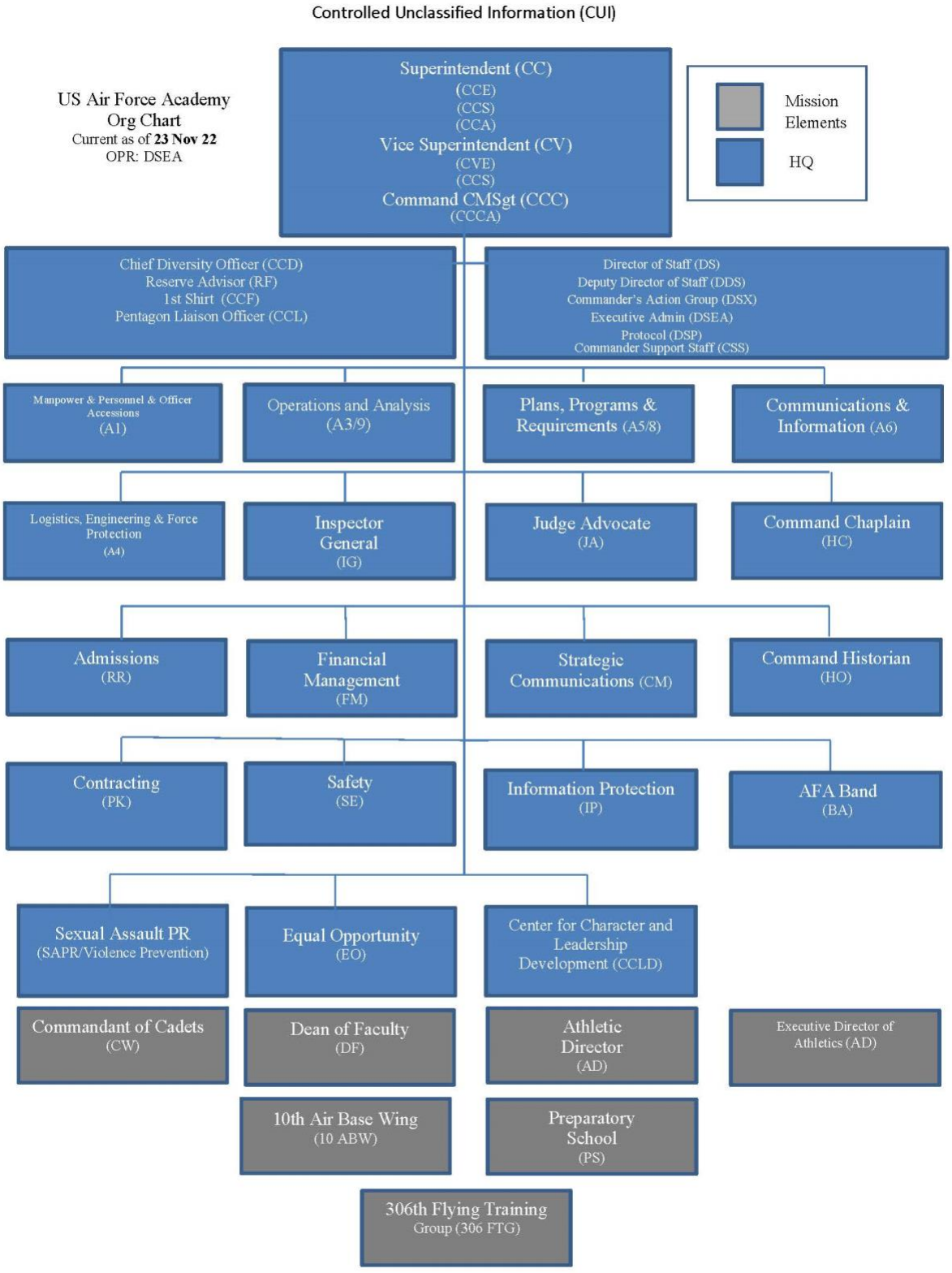
U.S.C., Title 5

U.S.C., Title 50, Section 1520a

FORMS

AF Form 847, “Recommendation for Change of Publication”
Office of Government Ethics Form 450, “Confidential Financial Disclosure Report”

APPENDIX 1: ORGANIZATIONAL CHART



APPENDIX 2: HUMAN SUBJECTS RESEARCH OFFICE OF RESPONSIBILITY AT USAFA (10 MDG)

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

14 Mar 22

MEMORANDUM FOR RECORD

FROM: HQ USAFA/A9 Human Research Protection Program

SUBJECT: Human Subjects Research Office of Responsibility at USAFA

References: (a) Title 32 CFR, Part 219, Protection of Human Subjects
(b) DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research
(c) DoDI 3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research
(d) USAFA HRPP Policies
(e) DHA Policies and Instructions

1. The HQ USAFA/A9 Human Research Protection Program (HRPP) sets policies for conducting human subjects research (HSR) at the Academy and the Human Protections Director (HPD) is responsible for the oversight of all activities which are (or might include) HSR conducted or supported by USAFA. With the realignment of the 10 MDG under the Defense Health Agency (DHA), roles and responsibilities for ensuring compliance, training, and monitoring fall across agencies. This memo provides clarifying guidance on the primary office of responsibility (DHA or USAFA) for reviewing and ensuring coordination between agencies for HSR at USAFA.

2. The following table classifies responsibilities based on the organizational owner of role or resource. When role and resource belong only to USAFA or 10 MDG, the parent organization will oversee the HSR. When human subjects are cadets, USAFA will be the primary office for HSR review, approval, and permission. USAFA's HRPP will oversee HSR including: (1) USAFA-conducted HSR using beneficiaries as human subjects; (2) USAFA-conducted HSR using a DHA data sharing agreement; and (3) USAFA-10 MDG collaborative HSR.

		Organization		Reviewing HRPP	
Role/Resource	**Category**	**USAFA**	**10 MDG**	**USAFA**	**10 MDG**
Human Subjects	Cadets	X		X	
	Beneficiaries*		X		X
Researchers	USAFA Staff	X		X	
	10 MDG Staff (Credentialed Providers)		X		X
	USAFA & 10 MDG Staff (Credentialed Providers)	X	X	X	

*Beneficiaries may include cadets as long as cadets are not the only population/sample.

3. All HSR requires a signed letter of support (see attachments) by the Office of Corollary Responsibility's Institutional Official (IO) or Alternate Institutional Official (AIO) as part of the Office of Primary Responsibility review.

4. Please contact Dr. Anna Aragon, anna.aragon@afacademy.af.edu, for questions related to this memo or the USAFA HRPP.

GARVER.JOHN.M.1083628720 Digitally signed by GARVER.JOHN.M.1083628720 Date: 2022.04.14 16:17:21 -06'00'
JOHN M. GARVER, Col, USAF
Director, Operations and Analysis

2 Attachments:
1. HSR Support (OCR: 10 MDG/CC)
2. HSR Support (OCR: USAFA/CC)

cc:
10 MDG/CC

APPENDIX 2: HUMAN SUBJECTS RESEARCH OFFICE OF RESPONSIBILITY AT USAFA (10 MDG)

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

XX Xxx XX

MEMORANDUM FOR 10 MDG/CoMS
ATTENTION: LT COL SARDA

FROM: [TITLE] [FIRST NAME] [LAST NAME], [ORGANIZATION/OFFICE SYMBOL]

SUBJECT: Human Subjects Research (HSR) Letter of Support

References: (a) Title 32 CFR, Part 219, Protection of Human Subjects
(b) DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research
(c) DoDI 3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research
(d) USAFA HRPP Policies
(e) DHA Policies and Instructions

1. I hereby seek support for the following HSR activity:

a. Protocol Title:

b. Principal Investigator(s):

c. Protocol Abstract (no more than 250 words):

\

2. 10 MDG Resources sought: [list resources, Collaborative USAFA/10 MDG HSR, Beneficiary Data (Data Sharing Agreement Required)]

4. Please contact [PI NAME], [PI EMAIL] for questions.

FIRST LAST, Grade, DAF
Title

1st Ind, 10 MDG/CoMS
Approve/Disapprove

MEREDITH SARDA, Lt Col, USAF

APPENDIX 2: HUMAN SUBJECTS RESEARCH OFFICE OF RESPONSIBILITY AT USAFA (10 MDG)

Chief of Medical Staff

2nd Ind, 10 MDG/CC
Approve/Disapprove

CHRIS GRUSSENDORF, Col, USAF
Commander

cc:
[REQUESTOR ORGANIZATION/OFFICE SYMBOL]
HQ USAFA/A9

DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE ACADEMY

XX Xxx XX

MEMORANDUM FOR [ORGANIZATION/OFFICE SYMBOL]

FROM: [TITLE] [FIRST NAME] [LAST NAME], [ORGANIZATION/OFFICE SYMBOL]

SUBJECT: Human Subjects Research (HSR) Letter of Support

References: (a) Title 32 CFR, Part 219, Protection of Human Subjects
(b) DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research
(c) DoDI 3216.02_AFI40-402, Protection of Human Subjects and Adherence to Ethical Standards in Air Force Supported Research
(d) USAFA HRPP Policies
(e) DHA Policies and Instructions

1. I hereby seek your support for the following HSR activity:

a. Protocol Title:

b. Principal Investigator(s):

c. Protocol Abstract (no more than 250 words):

3. USAFA Resources sought: [list resources, Collaborative USAFA/10 MDG HSR, USAFA Data (Data Sharing Agreement Required)]

4. Please contact [PI NAME], [PI EMAIL] for questions.

FIRST LAST, Grade, DAF
Title

1st Ind, [ORGANIZATION/OFFICE SYMBOL]
Approve/Disapprove

FIRST LAST, Grade, DAF
Title

cc:
[REQUESTOR ORGANIZATION/OFFICE SYMBOL]
10 MDG/CoMS

APPENDIX 2: HUMAN SUBJECTS RESEARCH OFFICE OF RESPONSIBILITY AT USAFA (10 MDG)

APPENDIX 3: GENERIC HUMAN SUBJECTS RESEARCH SUBMISSION PROCESS

Submission	Received through usafa.hrpp@afacademy.af.edu	Initial Determination Amendment Deviation, Problem, Noncompliance Closure
Administration	HRPP Administrator reviews submitted documents to ensure compliance, completeness, and reviewer level HRPP Administrator sends submission for review	HRPP Administrator and/or reviewers may correspond with PI or alternate for missing documents, letters of support, survey control number, etc.
Determination	Exemption Determination Official	Exempt
	IRB Member	Exempt Limited IRB Review Expedited
	Convened IRB	Non-exempt
Outcome	Approved	
	Approved with conditions	
	Disapproved	
Permission	Required prior to start Only if approved by HRPP/IRB	
	Authorities	Superintendent Vice Superintendent Director A3/9, Operations and Strategic Analysis

APPENDIX 4: FOLDER AND RECORD NAMING CONVENTION

A1.1. WHY.

Standardize protocol folder format and record names, (2) shorten file paths, and (3) comply with HQ USAFA A9 recordkeeping practices. The naming conventions and HSR protocol folder format are not all inclusive; when in doubt, consult with the HPD.

A1.2. WHERE.

HQ USAFA A9/HRPP (SharePoint).

A1.3. WHO.

HRPP/IRB; stakeholders are encouraged to follow record naming conventions.

A1.4. EXAMPLES.

Spaces delimit words, not underscores.

Protocol Numbers

Protocol numbers are issued by the HRPP Administrator. Protocol numbers will consist of 4 parts: (1) acronym FAC, (2) FY in which the protocol was initially submitted to the HRPP/IRB, (3) four digits issued sequentially starting with 1; and (4) letters E for exempt or H for non-exempt or (H)E for protocols converted from the old common rule to the new common rule determined to be exempt.

Protocol numbers issued by an EDO. Protocol numbers will consist of 4 parts: (1) acronym FAC, (2) AY in which the protocol was initially determined, (3) four digits issued sequentially starting with 100; and (4) letter E for exempt.

Examples of USAFA HSR Numbers issued by the HRPP Administrator
FAC20210050H
FAC20150085E
FAC20120025(H)E

Examples of USAFA HSR Numbers issued by an EDO
FAC20210101E
FAC20150102E
FAC20120103E

ACTIVE Protocol Folder and Subfolder Format

ACTIVE protocol folders will consist of 1 folder and 2 subfolders.

The protocol folder name will consist of 5 parts: (1) USAFA protocol number, (2) alternate protocol number (if another IRB has reviewed the study), (3) protocol status in capital letters (ACTIVE), (4) lead institution abbreviation (10 MDG, DFBL, etc.), and (5) reminder date in format RYYYYMMDD.

The first protocol subfolder will consist of 2 parts: (1) protocol number and (2) word Email. This folder will contain all emails associated with the protocol.

The second protocol subfolder will consist of 2 parts: (1) protocol number and (2) word Files. This folder will contain files associated with administrative tasks, such as templates and memos.

Examples of ACTIVE Protocol Folder and Subfolders

FAC20120025H ACTIVE DFBL R20150505
- FAC20120025H Emails
- FAC20120025H Files

FAC20210031E ACTIVE OLEA R20240610
- FAC20210031E Emails
- FAC20210031E Files

FAC20200036H WRNMMC-2020-0289 ACTIVE 10MDG R20210506
- FAC20200036H WRNMMC2020-0289 Emails
- FAC20200036H WRNMMC2020-0289 Files

FAC20210017H ARL 21-014 ACTIVE DFBL R20220505
- FAC20210017H ARL 21-014 Emails
- FAC20210017H ARL 21-014 Files

CLOSED/WITHDRAWN/TERMINATED Protocol Folder and Subfolder Format

CLOSED/WITHDRAWN protocol folders will consist of 1 folder, 2 subfolders, and a closure/withdrawal memo.

The protocol folder name will consist of 3 parts: (1) protocol number, (2) destruction date in DYYYYMMDD format, and (3) protocol status in capital letters (WITHDRAWN, CLOSED, TERMINATED).

The first protocol subfolder will consist of 2 parts: (1) protocol number and (2) word Email. This folder will contain all emails associated with the protocol.

The second protocol subfolder will consist of 2 parts: (1) protocol number and (2) word Records. This folder will contain protocol records.

The files folder will be deleted.

The closure memo will be kept under the main protocol file.

Examples of WITHDRAWN/CLOSED Protocol Folder and Subfolders

FAC20120025H D20250325 WITHDRAWN
Subfolder: FAC20120025H Emails
Subfolder: FAC20120025H Records
Record: FAC20120025H DYYYYMMDD Withdrawn YYYYMMDD
FAC20120025H D20250325 CLOSED
Subfolder: FAC20120025H Emails
Subfolder: FAC20120025H Records
Record: FAC20120025H DYYYYMMDD Closure YYYYMMDD

Closure Memo Naming Convention

Closure memos of deleted protocols will consist of 4 parts: (1) protocol number, (2) destruction date in DYYYYMMDD format, (3) words Closure Memo, and (4) memo date in YYYYMMDD format.

Examples of Closure Memos

FAC20210050H D20300506 Closure 20270505
FAC20150085H D20200605 Closure 20170604
FAC20120025H D20210609 Closure 20190608

Email Naming Conventions

Email file names will consist of 9 parts: (1) protocol number, (2) word "Email," (3) email date in YYYYMMDD format, (4) who sent the email by position (PI, HPA, RC, IRB, etc.), (5) word "to," (6) who received the email by position (PI, HPA, RC, IRB, etc.), (7) preferably no more than 3 words to describe the topic (Amend 1, CR 2018, Initial Sub, etc.), (8) acronym FU for any follow-up conversations OR the abbreviation "Ack" for any receipt acknowledgements OR the acronym OOO for automatic Out of Office replies (if applicable), and (9) word ATTACH if any documents were included.

Examples of Emails

FAC20120025H Email 20210423 HPA to PI Amend 3 ATTACH
FAC20140043H Email 20180513 IRB to HPA Initial Sub Review ATTACH
FAC20130050H Email 20151212 RC to HPA Data Sharing FU
FAC20180026H Email 20200105 IRB to IRB ICD Ack
FAC20180026H Email 20190505 PI to HPA CR 2018 OOO

CITI Training Naming Convention

CITI training names will consist of 8 parts: (1) protocol number, (2) acronym CITI, (3) CITI affiliation, (4) training group or abbreviated course tile (G1, G2, G3, Biomed, etc.), (5) last name, (6) first name, (7) letter E for expiration OR letter C for completion OR letter P for passed followed by (8) date in YYYYMMDD format. If there is no date associated with the document, replace the letter followed by a date with the acronym ND (for No Date).

Examples of CITI Training

FAC20120025H CITI SGE G3 Smith Mary E20210423
FAC20150015H CITI SGE G4 Robinson Leticia ND
FAC20160025H CITI AFRL HSR Smith Robert E20180506
FAC20170009H CITI BAMC Biomed Smith Melissa C20190505

NIH Training Naming Convention

NIH training names will consist of 6 parts: (1) protocol number, (2) acronym NIH, (3) last name, (4) first name, (5) letter C for completed, and (6) completion date in YYYYMMDD format.

Examples of NIH Training

FAC20210050H NIH Weirath Mary C20180702
FAC20210050H NIH Robins Joseph C20180418
FAC20210050H NIH Johnson Tony C20170404
FAC20210050H NIH Jackson Joel C20150514

CV Naming Convention

CV names will consist of 5 parts: (1) protocol number, (2) acronym CV, (3) last name, (4) first name, and (5) CV or submission date in format YYYYMMDD.

Examples of CVs

FAC20210105E CV Jackson Mary 20150608
FAC20190058H CV Robins Meredith 20190305

Informed Consent Document (ICD) Naming Convention

ICD names will consist of 3 parts: (1) protocol number, (2) acronym ICD, and (3) expiration date in format EYYYYMMDD OR approval date in format AYYYMMDD.

Often, due to a continuing review (CR) or amendment, an ICD may be updated. In this case, the corresponding CR or amendment will precede the acronym ICD.

Examples of ICDs

FAC20150025H ICD E20170805
FAC20150025H CR 2020 ICD A20200805
FAC20150025H Amend 1 ICD E20170805

Submission Naming Convention

Submission names will consist of 4 parts: (1) protocol number, (2) reason for the submission such as continuing review and year (CR YYYY) or amendment and number (Amend #) or initial protocol, (3) abbreviation Sub, and (4) document date in YYYYMMDD format.

Examples of Submissions

FAC20150025H Initial Protocol Sub 20170805
FAC20150025H CR 2015 Sub 20170805
FAC20150025H Amend 1 Sub 20170805

Approval Naming Convention

Approval names will consist of 4 parts: (1) protocol number, (2) reason for the approval such as continuing review and year (CR YYYY) or amendment and number (Amend #) or initial protocol or closure report, (3) abbreviation App (for approval) or abbreviation Cond App (for conditional approval), and (4) document date in YYYYMMDD format.

Examples of Approvals
FAC20150025H Initial Protocol App 20170805
FAC20150025H CR 2015 Cond App 20170805
FAC20150025H Amend 1 App 20170805
FAC20150025H Closure App 20210305

Institutional Approval Naming Convention

Institutional approval names will consist of 4 parts: (1) protocol number, (2) acronym IO or AIO, (3) abbreviation "Perm," and (4) document date in YYYYMMDD format.

Examples of Institutional Approvals
FAC20150025H IO Perm 20170805
FAC20150025H AIO Perm 20170805

Amendment Naming Convention

Amendment names will consist of 5 parts: (1) protocol number, (2) abbreviation Amend and corresponding number, (3) type of document such as ICD or Sub or App or Protocol, (4) word "Marked" if the document has tracked changes or abbreviation "App" if the document has been approved, and (5) document date in YYYYMMDD format or document date in EYYYYMMDD format for ICDs with an expiration date.

Spaces delimit words, not underscores.

Examples of Amendments
FAC20150025H Amend 5 Protocol App 20170805
FAC20150025H Amend 5 Cond App 20170805
FAC20150025H Amend 5 ICD E20170805
FAC20150025H Amend 5 Sub 20210305
FAC20150025H Amend 5 ICD Marked E20170805

Continuing Report Naming Convention

Continuing report names will consist of 4 parts: (1) protocol number, (2) acronym CR followed by corresponding year, (3) type of document such as Sub or App or Review, and (4) date in format YYYYMMDD.

Examples of Continuing Reports
FAC20150025H CR 2020 Sub 20200805
FAC20150025H CR 2020 Cond App 20200805
FAC20150025H CR 2020 App 20200805
FAC20150025H CR 2020 Review 20210305

Initial Submission Naming Convention

Initial submission names will consist of 4 parts: (1) protocol number, (2) word "Initial," (3) type of document (Sub, Cond App, Cond App Response, ToC, etc.), (4) and date in format YYYYMMDD.

Examples of Initial Submissions
FAC20150025H Initial Sub 20150505
FAC20150025H Initial Cond App 20150606
FAC20150025H Initial Cond App Response 20150610
FAC20150025H Initial Cond App ToC 20150606
FAC20150025H Initial App 20150705
FAC20150025H Initial Protocol App 20150705

Convened IRB Meeting Minutes Naming Convention

Convened IRB meeting minutes names will consist of 5 parts: (1) protocol number, (2) the acronym IRB, (3) the abbreviation Mtg, (4) the abbreviation Min, and (5) the date of the meeting NOT the date of when the document was signed.

Examples of Convened IRB Meeting Minutes
FAC20150025H IRB Mtg Min 20190808
FAC20150025H IRB Mtg Min 20210505

Table of Changes Naming Convention

Table of Changes names will consist of 4 parts: (1) protocol number, (2) corresponding action (CR 2018, Amend 7, Initial, etc.), (3) abbreviation ToC for Table of Changes, and (4) date in format YYYYMMDD.

Examples of Table of Changes
FAC20150025H CR 2017 ToC 20190808
FAC20150025H Amend 10 ToC 20210505
FAC20150025H Initial ToC 20210429

Individual Investigator Agreement (IIA) Naming Convention

IIA names will consist of 5 parts: (1) protocol number, (2) the acronym IIA, (3) the last name of the investigator, (4) the first name of the investigator, and (5) the date of the last signatory in the form YYYYMMDD.

Examples of IIAs
FAC20150025H IIA Smith Jonathan 20190808
FAC20150025H IIA Smith Peter 20210505
FAC20210055H IIA Johnson Mary 20210505

Institutional Agreement for IRB Review (IAIR) Naming Convention

IAIR names will consist of 4 parts: (1) protocol number, (2) the acronym pertaining to the institution providing IRB services, (3) the acronym pertaining to the institution receiving IRB services, and (4) date of the last signature.

Examples of IAIRs
FAC20150025H IAIR USAFA NMSU 20210603
FAC20150025H IAIR USAFA USUHS 20210721
FAC20210055H IAIR Georgetown USAFA 20210505

Letter of Support (LoS) Naming Convention

LoS names will consist of 4 parts: (1) protocol number, (2) acronym LoS, (3) supporting institution acronym (DFBL SONA, DFB, etc.), and (4) date in format YYYYMMDD.

Examples of LoS'
FAC20180019H LoS DFBL SONA 20210621
FAC20190001H LoS DFB 20190505
FAC20210005H LoS 10MDG 20210510

Deviation Naming Convention

Deviation names will consist of 4 parts: (1) protocol number, (2) abbreviation Dev, (3) deviation number (in consecutive order), and (4) date in format YYYYMMDD.

Examples of Deviations
FAC20180019H Dev 1 Sub 20210621
FAC20190001H Dev 1 App 20190505
FAC20180019H Dev 5 Sub 20220621
FAC20190001H Dev 5 App 20220625

Survey Naming Convention

Survey names will consist of 4 parts: (1) protocol number, (2) acronym SCN, (3) the corresponding numbers (19-14, 20-01, etc.), and (4) short description.

Examples of Surveys
FAC20150025H SCN 15-08 Cadet Assessment
FAC20150030H SCN 15-09 Nutrition Questionnaire
FAC20210025H SCN 21-10 Exit Interview

Survey Control Number (SCN) Naming Convention

SCN names will consist of 4 parts: (1) protocol number, (2) the acronym SCN, (3) the corresponding numbers (19-14, 20-01, etc.), and (4) date in format YYYYMMDD.

Examples of SCNs
FAC20150025H SCN 15-08 20150505
FAC20150030H SCN 15-09 20150609
FAC20210025H SCN 21-10 20210815

Component Level Administrative Review (CLAR) Naming Convention

CLAR names will consist of 3 parts: (1) protocol number, (2) acronym CLAR, and (3) date in format YYYYMMDD.

Examples of CLARs
FAC20150025H CLAR 20150505
FAC20150030H CLAR 20150609
FAC20210025H CLAR 20210815

Data Sharing Agreement (DSA) Naming Convention

DSA names will consist of 3 parts: (1) protocol number, (2) acronym DSA, and (3) date in format YYYYMMDD.

Examples of DSAs
FAC20150025H DSA 20150505
FAC20150030H DSA 20150609
FAC20210025H DSA 20210815

Cooperative Research and Developmental Agreement (CRADA) Naming Convention

CRADA names will consist of 3 parts: (1) protocol number, (2) acronym CRADA, and (3) date in format YYYYMMDD.

Examples of CRADAs
FAC20150025H CRADA 20150505
FAC20150030H CRADA 20150609

FAC20210025H CRADA 20210815

Conflict of Interest (CoI) Naming Convention

CoI names will consist of 5 parts: (1) protocol number, (2) acronym COI, (3) last name, (4) first name, and (5) date in format YYYYMMDD.

Examples of COIs

FAC20150025H COI Smith Jane 20150505
FAC20150030H COI Johnson Judy 20150609
FAC20210025H COI Garcia Bernie 20210815

Determination/Review Naming Convention

Determination/review names will consist of 5 parts: (1) protocol number, (2) topic (initial, amendment #, etc.), (3) abbreviation Det or Review, (4) last name of the reviewer, and (5) date in format YYYYMMDD.

Examples of Determinations/Reviews

FAC20150025H Initial Det Aragon 20150505
FAC20150030H Amend 5 Det Carson 20150609
FAC20210025H Initial Det Scharff 20210815

Audit Naming Convention

Audit names will consist of 5 parts: (1) protocol number, (2) the word audit, (3) an acronym representative of auditing authority (IRB, SGE, etc.), (4) a name or acronym representative of the audit document (App, Results, ToC, etc.), and (5) date in format YYYYMMDD.

Examples of Audits

FAC20150025H Audit IRB Results 20190808
FAC20150025H Audit SGE Results 20210505
FAC20150025H Audit IRB App 20210429

Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSOs) Naming Convention

UPIRSTO names will consist of 4 parts: (1) protocol number, (2) acronym UPIRTSO, (3) an abbreviation representative of the document (sub, memo, app, etc.), and (4) date in format YYYYMMDD.

Examples of UPIRSTOs

FAC20150025H UPIRTSO Sub 20190808
FAC20150025H UPIRTSO Memo 20210505
FAC20150025H UPIRTSO App 20210429

APPENDIX 5: SCIENTIFIC REVIEW EVALUATION

PI(s): _____
Protocol Number: _____
Protocol Title: _____
Date Completed _____
Reviewer CoI Yes/No

Criterion Scoring ***Comments are required for a score greater than or equal to 7 in all sections.**		
(1) Exceptional	(2) Outstanding	(3) Excellent
(4) Very Good	(5) Good	(6) Satisfactory
(7) Fair	(8) Marginal	(9) Poor

1) Significance Criterion Score: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Does the project address and important problem or a critical barrier to progress in the field?

Comments: _____

2) Investigator Criterion Score: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Are the PIs, collaborators, and other researchers well-suited to the project?

Comments: _____

3) Innovation Criterion Score: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches, or methodologies, instrumentation, or interventions?

Comments:

_____

4) Approach Criterion Score: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Is the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project?

Comments: _____

5) Environment Criterion Score: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment, and other physical resources available to the investigators adequate for the project proposed?

Comments: _____

OVERALL SCORE: (1) (2) (3) (4) (5) (6) (7) (8) (9)

Considers the above 5 criteria plus consideration of human subjects protections, regulatory affairs, biohazards, and intellectual property.

High Influence Project (1-3): Addresses a problem of high importance; OR has few or no weaknesses

Medium Influence Project (4-6): Addresses a problem of high importance but weaknesses in the criteria bring down the overall score; OR may be addressing a problem of moderate importance with few or no weaknesses.

Low Influence Project (7-9): Addresses a problem of moderate/high importance, but weaknesses in the criteria bring down the overall influence; OR may be addressing a problem of low or no importance with some or no weaknesses.

Comments: _____

Reviewer Name: _____

Reviewer Signature: _____

APPENDIX 6: RISK ASSESSMENT TOOL

A6.1. RISK ASSESSMENT.

PI(s): _____
Protocol Number: _____
Protocol Title: _____
Date Completed _____

Continuing Review Convened IRB	☐
Reviewing IRB _____	☐
Continuing Review Expedited	☐
Other _____	☐

	Points Value	Score	Notes
Unmonitored HSR Monitored HSR	2 1		
PI - First-Time PI PI - Experienced PI	2 1		
Number Authorized to Consent: Greater than Four Four or less	 2 1		
Greater than Minimal Risk Minimal Risk	2 1		
Population Sensitivity: Vulnerable Population Non-Vulnerable Population	 3 0		
Continuing Review Cycle: Short Cycle (<364 days) Annual	 2 0		
Status: Open to Accrual Long Term Follow-up Data Analysis Only	 2 1 0		
History of Non-Compliance: Non-Compliant Highly Compliant	 2 0		
	Total Score:		

A6.2. EXEMPT HSR SELF-ASSESSMENT TOOL.

PI(s): _____
Protocol Number: _____
Protocol Title: _____
Date Completed _____

PACM is a process to confirm accurate and consistent HSR performance. The most effective way to prepare for PACM is to re-read the permitted HSR carefully and objectively to confirm HSR staff are performing activities exactly as described in the approved/permitted HSR.

The HRPP is available to answer questions and help facilitate any necessary amendments and will use the USAFA HRPP Post-Approval Compliance Monitoring Audit Form.

Common Findings:

- Records are not stored as described in the permitted HSR.

- Data sheet(s) include variables not included in the permitted HSR.

If you note discrepancies in the procedures outlined in the permitted HSR, please add them to the Comments section so a corrective action plan can be discussed during PACM. Do not make any changes prior to discussing with the HRPP, unless changes are necessary to protect the subject from potential harm. PACM is not intended to "catch" you doing something wrong. Rather, PACM is designed to facilitate HSR by ensuring HSR is conducted IAW its determination/approval and identifying and correcting deficiencies.

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
Recordkeeping. **Answer by indicating whether copies of the following documents are on file. Provide explanations for any "no" answers or deviations.**				**Note: If documents are maintained electronically, a note-to-file indicating the location and who maintains them should be included.**
Approved HSR. Are original protocol and all amended versions, with clear version dates, maintained? Are				

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
HSR staff aware of any amendments to HSR procedures?				
Approvals and Amendments. Are the original determination/approval MFR, institutional approval, and all amendment approvals maintained?				
Scientific Review. Is the scientific review on file?				
Other . Are all data sharing agreements, survey approval documentation, information sheets, recruitment tools, data collection templates, case report forms, surveys, etc., as applicable, on file?				
HSR Staff. Are training, credentials, CoIs, etc., on file?				
LoS and Agreements. Are any relevant agreements, letters of support, etc., on file?				
History Log and Audits. Do you maintain a log of all individuals outside of HSR staff who have accessed HSR files?				Best practice – Not required
HSR Communications. How do you maintain communication among HSR staff, HRPP, sponsors, etc.?				Best practice – Not required

HSR COMPLIANCE		
Elements	**Response**	**Comments/Corrective Actions**
Enrollment. **Provide explanations for any deviations.**		
Number of subjects approved for		

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
the HSR.				
Number of subjects enrolled at time of visit. Is the number different from the number approved? Are any amendments needed?				
Number of subjects enrolled at other sites.				
Date of first human subject enrollment.				
Number of human subjects who have withdrawn. Have there been more withdrawals than expected? Are any amendments needed of HSR procedures (e.g., scheduling)?				
Protocol Lifecycle. **Answer the following. Provide explanations for any deviations.**				
Number of amendments submitted.				
Number of deviations submitted. Have any deviations occurred that have not yet been reported?				
Number of UPIRSTOs submitted.				
DATA MANAGEMENT				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
Enrollment Records. **Answer by indicating whether copies of the following items are on file. Provide explanations for any "no" answers or deviations.**				
Subject Enrollment Log. An enrollment log or master key indicates which individuals are subjects in the HSR.				
Data Collection. **Answer by Indicating whether copies of the following items are**				

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
on file and maintained appropriately. Provide explanations for any "no" answers or deviations.				
Data Collection Tools. Were all data collection tools used approved/permitted?				
Subject Privacy. Has subject privacy been protected as outlined in the approved/permitted HSR?				
Data Sheet. Have all data been entered into the HSR data sheet? Are data being recorded IAW the approved/permitted HSR (e.g., no additional variables)?				
Data Confidentiality. Are hard copies of data stored in a secured and locked location? Are electronic copies of data stored in a secure and protected server? Is all data stored IAW with approved/permitted HSR procedures?				
COMMENTS				

A6.3. NON-EXEMPT HSR SELF-ASSESSMENT TOOL.

PI(s): _____
Protocol Number: _____
Protocol Title: _____
Date Completed _____

PACM is a process to confirm accurate and consistent HSR performance. The most effective way to prepare for PACM is to re-read the permitted HSR carefully and objectively to confirm HSR staff are performing activities exactly as described in the approved/permitted HSR.

The HRPP is available to answer questions and help facilitate any necessary amendments and will use the USAFA HRPP Post-Approval Compliance Monitoring Audit Form.

Common Findings:

- The ICD was not dated by the human subject.

- The researcher conducting informed consent was not delegated that responsibility in the approved/permitted HSR.

- Records are not stored as described in the approved/permitted HSR.

- The data sheet includes variables not approved/permitted.

If you note discrepancies in the procedures outlined in the approved/permitted HSR, please add them to the Comments section so a corrective action plan can be discussed during PACM. Do not make any changes prior to discussing with the HRPP, unless changes are necessary to protect the subject from potential harm. PACM is not intended to "catch" you doing something wrong. Rather, PACM is designed to facilitate HSR by ensuring HSR is conducted IAW its determination/approval and identifying and correcting deficiencies.

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
Recordkeeping. **Answer by indicating whether copies of the following documents are on file. Provide explanations for any "no"**				**Note: If documents are maintained electronically, a note-to-file indicating the location and who maintains them should be included.**

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
answers or deviations.				
Approved HSR. Are original protocol and all amended versions, with clear version dates, maintained? Are HSR staff aware of any amendments to HSR procedures?				
Approved ICD. Are original versions and all amended ICDs, with clear version dates, maintained? Have all human subjects been consented using the appropriate (current) version of the ICD? How is version control handled?				
Approvals and Amendments. Are the original determination/approval MFR, institutional approval, and all amendment approvals maintained?				
Scientific Review. Is the scientific review on file?				
Documentation. Are all data sharing agreements, survey approval documentation, information sheets, recruitment tools, data collection templates, case report forms, surveys, etc., as applicable, on file?				
HSR Staff. Are training, credentials, CoIs, etc., on file?				
Research Monitor. Are training, credentials, and appointment letter on file?				
LoS and Agreements. Are any relevant agreements, letters of support, etc., on file?				

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
History Log and Audits. Do you maintain a log of all individuals outside of HSR staff who have accessed HSR files?				Best practice – Not required
Other Logs. Pre-screening log, enrollment log, HSR staff signature log, delegation of responsibility log, deviation log, training log, etc., as applicable, up to date and on file?				
HSR Communications. How do you maintain communication among HSR staff, HRPP, sponsors, etc.?				Best practice – Not required

HSR COMPLIANCE		
Elements	**Response**	**Comments/Corrective Actions**
Enrollment. **Provide explanations for any deviations.**		
Number of subjects approved for the HSR.		
Number of subjects enrolled at time of visit. Is the number different from the number approved? Are any amendments needed?		
Number of subjects enrolled at other sites.		
Date of first human subject enrollment.		
Number of human subjects who have withdrawn. Have there been more withdrawals than expected? Are any amendments needed of HSR procedures (e.g., scheduling)?		
Expiration date of current ICD.		
Protocol Lifecycle. **Answer the following. Provide**		

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
explanations for any deviations.				
Number of continuing reviews submitted.				
Number of amendments submitted.				
Number of deviations submitted. Have any deviations occurred that have not yet been reported?				
Number of UPIRSTOs submitted.				

DATA MANAGEMENT				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
Enrollment Records. Answer by indicating whether copies of the following items are on file. Provide explanations for any "no" answers or deviations.				
Subject Enrollment Log. An enrollment log or master key indicates which individuals are subjects in the HSR.				
Data Collection. Answer by Indicating whether copies of the following items are on file and maintained appropriately. Provide explanations for any "no" answers or deviations.				
Data Collection Tools. Were all data collection tools used approved/permitted?				
Subject Privacy. Has subject privacy been protected as outlined in the approved/permitted HSR?				

ADMINISTRATIVE COMPLIANCE				
Elements	**Is Element Addressed?**			**Comments/Corrective Actions**
	Yes	**No**	**N/A**	
HSR Data Sheet. Have all data been entered into the HSR data sheet? Are data being recorded IAW the approved/permitted HSR (e.g., no additional variables)?				
Data Confidentiality. Are hard copies of data stored in a secured and locked location? Are electronic copies of data stored in a secure and protected server? Is all data stored IAW with approved/permitted HSR procedures?				
COMMENTS				

APPENDIX 7: CONTINUITY OF OPERATIONS PLAN EMAIL

Send to: MEs, DAF COHRP (usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil), PIs and AIs (see HSR database), HPD, HRPP Administrator, IRB members, and Other HRPP stakeholders.

Subject: USAFA HRPP Continuity of Operations Plan

ALCON,

There will be limited continuity of HRPP operations during the government shutdown.

POC: Director A3/9, Operations and Strategic Analysis at 719-33-4153.

Review of submissions during a government shutdown. Because the HRPP will have neither administrative support nor quorum for convened IRB meetings, submissions will not be reviewed during a government shutdown. Any reviews/actions required to protect human subjects will be referred by the Director A3/9, Operations and Strategic Analysis to the DAF COHRP (usaf.pentagon.af-sg.mbx.afmsa-sge-c@mail.mil).

Reportable events during a government shutdown. The Director A3/9, Operations and Strategic Analysis will report the following to the DAF COHRP within five business days:

a. Allegations of serious or continuing noncompliance related to human subject research (HSR) that are substantiated by investigation, and subsequent actions taken based on the findings.

b. Unanticipated problems involving risks to human subjects or others and subsequent actions taken based on the findings.

c. Suspensions or terminations.

Status of permitted HSR. Civilian-run studies must be put on hold if there is no military member listed on the HSR as a PI or AI to assume responsibility. If a military member is listed as an AI and will be assuming the duties of the PI, a MFR must be placed in the protocol records and emailed to the HRPP (usafa.hrpp@afacademy.af.edu).

Expiring Continuing Reviews. Non-exempt HSR requiring continuing review that lapses must stop until the government shutdown ends and a continuing review is completed.

Col FIRST LAST.

Director A3/9, Operations and Strategic Analysis

United States Air Force Academy

Comm: (719) 333-XXXX

APPENDIX 8: BIANNUAL OUTREACH EMAIL

Send to: USAF Academy (all-inclusive) on June and January of every year.

Subject: USAFA Human Research Protections Plan (HRPP)

USAF Academy Team,

As an academic institution, USAFA engages in a variety of research activities. For example, there are about 23 academic departments and 24 research centers conducting research focusing on aircraft structures, aeronautics, physics, astronautics, and other fields.

But… did you know there are specific rules guiding how research must be conducted when people are the focus of a study?

USAFA has a Human Research Protections Program (HRPP) and an Institutional Review Board (IRB), entrusted with ensuring legal and ethical requirements are met by researchers and other stakeholders.

The USAFA HRPP is designed and resourced to match the needs of its human subject research (HSR) portfolio. Currently, USAFA has over 80 active HSR protocols. While most of the HSR protocols are social, behavioral, and educational, some include artificial intelligence. No two HSR protocols are the same! Each one has different procedures, seek to answer different research questions, and have different requirements based on specific characteristics.

While most have heard of the IRB, the IRB is a subset of the HRPP. The IRB meets periodically; IRB members conduct HSR reviews that do not require a meeting on a rolling basis. Alternatively, the HRPP manages all associated HSR facets such as education and training, post-approval compliance monitoring, conflict of interest disclosures, tracking submissions… Essentially, the HRPP manages the HSR portfolio from cradle to grave and its associated administrative elements.

Is HSR only conducted at USAFA by USAFA personnel only? No! As an academic institution, USAFA collaborates with DoD and non-DoD institutions. Got questions? Ask the USAFA HRPP!

Dr. FIRST LAST (USAFA HRPP Director and IRB Chair) and Ms. FIRST LAST (USAFA HRPP Administrator) jointly manage the USAFA HRPP. For inquiries or questions about the USAFA HRPP/IRB, to include whether an activity may/may not require HRPP/IRB review, please email: usafa.hrpp@afacademy.af.edu.