USMA Regulation 70-25

Research and Development

The Human Research Protection Program (HRPP)

Department of the Army
United States Military Academy
West Point, New York

UNCLASSIFIED
The Human Research Protection Program (HRPP)

MAOR

FOR THE SUPERINTENDENT:

OFFICIAL: 
CINDY R. JEBB, PhD
BG, Dean of the Academic Board
Associate Institutional Official

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Summary: This regulation specifies responsibilities and procedures for the conduct and coordination of Human Research at USMA. It incorporates USMA Policy Memorandum, Subject: Release of Data to Outside Agencies, 23 June 2006 and supersedes all prior versions of USMA Regulation 70-25.

Applicability: This regulation is applicable to all members of the Staff, Faculty, Cadet Corps, and other organizations or individuals who engage in human research at USMA. This includes military and civilian personnel, whether assigned or attached to USMA. This regulation applies when personnel in these organizations are part of the research staff, the investigators, or the human subjects. This program excludes West Point tenant units and activities. Tenant units are covered under their higher unit's HRPP.

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Chapter 1
Introduction

1-1 Purpose

a. Human Subject Research (HSR) is an activity that meets the federal definition of Research and involves participants that meet the federal definition of Human Subject.

b. For purposes of this policy, the following organizations are the component organizations covered under the USMA assurance: US Military Academy at West Point: Office of the Superintendent, Office of the Dean of the Academic Board, Office of the Commandant, Office of Admissions, Office of Intercollegiate Athletics, US Military Academy Preparatory School, and all centers of research.

c. The purpose of this regulation is:
   (1) To outline specific policies and procedures that implement USMA’s Assurance and ensure ongoing compliance with federal, DoD, Army, and state regulations, laws, and policies for human subject protection, specifically, the protection of the subject’s:
   • rights, privileges, and privacy;
   • mental and physical health; and
   • emotional well-being.
   (2) To outline specific policies and procedures for the required scientific, regulatory, and ethical review and approval of human research.
   (3) To establish and direct continuing education requirements for personnel involved in human research (Chapter 3).
   (4) To assign roles and responsibilities for the HRPP.
   (5) To ensure accurate and comprehensive transition of HRPP responsibilities and duties when there is a change in the Institutional Official, Associate Institutional Official, or USMA Human Protections Director (HPD).

1-2 References

a. 32 CFR 219, Protection of Human Subjects, July 1, 2018
b. DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research, November 8, 2011
c. DoD Instruction 6025.18, Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Health Care Programs, March 13, 2019
d. Army Regulation 70-25, Use of Volunteers as Subjects of Research, January 25, 1990
e. USMA Dean’s Policy and Operating Memorandum 5-1, Academic Research, August 16, 2010

1-3 Definitions

a. An Administrative review is conducted by the HPD to ensure compliance with regulations and policies applicable to HSR that is DoD conducted or research where DoD provides support or assistance.

b. Authorized Operational Activities are carried out solely in support of the DoD mission to provide military forces 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 examine DoD performance, quality, and capability, and which otherwise do not meet the definition of research in this issuance.

c. Biomedical research involves the use or investigation of a medical product, procedure, or intervention, including studies that fall under FDA regulations. USMA may conduct biomedical research with the approval of the Regional Health Command-Atlantic (RHC-A) IRB.
d. **Classified research involving human subjects** is research 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.

e. **Clinical research** is patient-oriented research conducted with human subjects, or research on the causes and consequences of disease in human populations involving material of human origin (such as tissue specimens and cognitive phenomena) for which an investigator or colleague directly interacts with human subjects in an outpatient or inpatient setting to clarify a problem in human physiology, pathophysiology or disease, or epidemiologic or behavioral studies, outcomes research or health services research, or developing new technologies, therapeutic interventions, or clinical trials as defined in Title 42, U.S.C.

f. **Command Support Letter (CSL)** is required for any external investigators to conduct research at USMA. This letter will affirm the specific parameters of access that an external investigator can have for the research. For example, it must include the amount and level of resources (equipment and space), access to subjects, and any other conditions for conducting the project. The CSL is signed by the lowest level of command authority, such as a department head. If more than one department is engaged or supports the project, the MAD will be signatory. If more than one MAD is engaged or supports the project, the USMA Chief of Staff or the Superintendent will sign the command support letter.

g. **Component Level Administrative Review (CLAR)** AHRPO must conduct an administrative review and approve all non-exempt research involving human subjects approved by a DoD institution when any of these conditions occur:

   1. The research will be conducted in a foreign country unless one of the following conditions apply: the research will be conducted by an established DoD overseas research institution and the research will be conducted in the host country, or the research will be conducted by a DoD overseas institution and will include only DoD personnel or U.S. citizens as human subjects.

   2. The research involves a collaboration with a non-DoD institution and the DoD institution is relying on the non-DoD institution's IRB, which is not composed of Federal employees. The DoD CLAR must be conducted before the research involving human subjects can begin to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural sensitivities of a foreign country if conducted in a foreign country. The CLAR is not intended to be an additional IRB review.

   3. The review must be conducted before the research involving human subjects can begin. The CLAR is not intended to be an additional IRB review.

h. **Confidentiality** is the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others in ways that are inconsistent with the understanding of the original disclosure, unless given permission.

i. **Deviation** indicates that there has been a departure or change (intentionally or unintentionally) from the originally approved protocol’s study methods or procedures. For example, enrolling more subjects than authorized or administering survey instruments not previously approved.

j. **Engaged in human subjects research** means that the institution’s personnel are conducting activities covered by Section 32 CFR 219.101(a) and DoDI 3216.02. An institution that is 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 regulatory or compliance standpoint is not engaged in the research involving human subjects (but is supporting the research).

k. **Exempt Determination Official (EDO)** has completed applicable ethics and AHRPO training to review protocols to determine if they are not research, not human subjects research, or meet one or more of the exempt criteria.

l. **Excluded activities** are those activities conducted or supported by the DoD which the DoD has specifically defined as not human subjects research.
m. **Extramural research** is research conducted by a Principal Investigator who is not an employee or agent of the USMA.

n. **Federal assurance** is the written document in which an institution, not an IRB, commits to a federal department or agency their compliance with the requirements set forth in the Common Rule. Institutions engaged in non-exempt HSR conducted or sponsored by the DoD or other federal agencies must have a federal assurance accepted by the federal agency sponsoring the research.

o. **Generalizable** describes the intent to contribute to the body of science of the discipline and makes an experiment or data collection research, regardless of publication. Research must be conducted according to approved protocols, even if findings are not presented or published. Research that never is published is still research.

p. **Greater than minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research is greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

q. **Human Protections Director (HPD)** is a federal employee at a DoD institution who, sufficiently qualified through experience and expertise, serves as the primary point of contact 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.

r. **Human Research Protections Official (HRPO)** is a federal employee designated by a DoD component to conduct administrative review of DoD-supported research in accordance with the requirements of the DFARS clause, or comparable requirement, and whose review of DoD-supported research is intended to ensure compliance with DoD HSR requirements. The HRPO review is done independent of the HRPP review.

s. **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.

 t. **Identifiable biospecimen** is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

 u. **Identifiable private information** is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

 v. **Incidental findings (IF)** is a finding that concerns an individual research subject that has potential health or reproductive importance; is discovered in the course of screening for, conducting, or analyzing results from research; and is beyond the aims of the study (i.e., occurring from variables not directly under study).

 w. **Individual Investigator Agreement (IIA)** is a formal agreement between USMA and an external collaborator who is not otherwise affiliated with an assured institution. This agreement establishes that, for a specific research project in which the PI is at USMA, the external collaborator can conduct non-exempt research involving human subjects under the USMA assurance. The IIA describes the responsibilities of the individual researcher and must be executed before research can begin.

 x. **Institutional Agreement for IRB Review (IAIR)** is a formal agreement between two or more institutions to establish which will be the IRB of record and must be signed by all parties. Where possible, there should be one IRB of record and only one IRB should be reviewing the study (typically the IRB of record for the primary investigator). USMA and/or the Collaborative Academic Institutional Review Board (CAIRB) have the authority to determine and document that use of a single IRB is not appropriate for the particular context of the proposed study.

 y. **Institutional employees or agents** from USMA refers to individuals who act on behalf of the institution, exercise institutional authority or responsibility, or perform institutionally designated activities.
“Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.

(1) Only government employees may be Principal Investigators on human subject research conducted at USMA.

(2) Contractors, volunteers, cadets, or others may participate in human subject research (HSR) under the supervision of a USMA employee.

(3) All persons listed on the protocol as investigators must be actively engaged in one or more of the following activities: consenting subjects, data collection, data analysis, and/or reporting of the results.

z. Institutional Official (IO) is the institution’s senior person who is legally authorized to represent the institution and who is authorized to establish and 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 HRPP. At USMA, the IO is the Superintendent. The IO has delegated certain activities to the Dean who serves as the Associate IO (AIO).

aa. Informed consent is both a process and a legal condition, as explained in the ethical principle of respect for persons. It is the condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also have unimpaired reasoning abilities at the time of consenting. Informed consent is required irrespective of the type of study. Depending on the nature of the study and the requirements of the IRB, the consent can be documented.

bb. Informed consent document (ICD) is the document that subjects must sign before participating in a research study, as determined by the IRB.

c. Institutional Review Board (IRB) provides ethical and regulatory oversight of research that involves human subjects by:

(1) Protecting the rights, welfare, and well-being of human research participants recruited to participate in research conducted or supported by USMA.

(2) Ensuring compliance with relevant local, state, and federal laws and regulations.

(3) Ensuring compliance with USMA, Army, and DoD policies and regulations.

(4) Employing the highest ethical standards for human research protections in all human subjects research by adhering to the ethical principles outlined in The Belmont Report.

dd. Interaction includes communication or interpersonal contact between the investigator and subject.

ee. 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.

ff. Intramural research is research funded by USMA, conducted at USMA, and conducted by a Principal Investigator who is an employee or agent of USMA.

gg. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and among themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

hh. Noncompliance refers to a failure (intentional or unintentional) of a person, group, or institution to act in accordance with the regulations, institutional policies governing human subject research, or requirements of or determinations by the IRB.

ii. Physiological monitoring (PM) is the process of gaining greater awareness of physiological functions primarily using instruments, equipment, or devices that provide information on the activity of those same systems.

jj. Post approval compliance monitoring (PACM) is the formal and systematic HRPP monitoring of research to confirm that HSR is being conducted in accordance with IRB approval or other HRPP regulatory determinations, institutional HRPP policy and procedures, and applicable federal laws and DoD policy.

kk. Primary data collection involves interaction with, or observation of, one or more people for the purpose of collecting data from or about them.
II. Principal Investigator (PI) is the person listed on the protocol who is ultimately responsible for the conduct of the research. There can be only one Principal Investigator on a protocol; all others would be associate investigators.

mm. Privacy means having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

nn. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

oo. Research involving a human being as an experimental subject is 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 10 U.S.C. 980.; it does not affect the application of 32 CFR 219. This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria of 32 CFR 219, and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

pp. Research misconduct can take many forms, including (but not necessarily limited to) fabrication or falsification of data; fabrication, falsification, or plagiarism in proposing, performing, or reviewing research; theft of ideas or direct plagiarism; intentionally conducting the research outside of the boundaries of approval; intentionally mishandling data about human subjects; failing to follow the instructions of the IRB or HRPP staff; violation of applicable HSR laws and regulations; and deliberate interference with the integrity of the work of others. Procedures for Addressing Academic Misconduct are contained in DPOM 5-1.

qq. Research means 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 policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. Research results do not have to be published or presented to qualify the experiment or data collection as research. For purposes of this policy, the following activities are deemed not to be research:

(1) 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.

(2) 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).

(3) 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.

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

rr. Risk has two parts: the magnitude of harm and the probability of harm.
ss. *Secondary data collection* involves accessing information that is obtained about human subjects, either individually or in aggregate form, by a secondary source.

tt. *Secondary research* involves the summary, collation and/or synthesis of existing research. Secondary research uses primary research sources as a source of data for analysis.

uu. *Service members* are defined as 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.

vv. *Support* are funds that are provided by the DoD to non-DoD institutions for HSR through a grant, contract, or similar arrangement subject to the DFARS or comparable DoD regulations. Not included in this definition is the provision by DoD to non-DoD institutions of assistance, 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 personnel for recruitment, or data or specimens. Furthermore, this definition does not include DoD-conducted HSR, whether or not conducted in collaboration between a DoD institution and non-DoD institution.

ww. *Systematic investigation* is an activity that involves a prospective plan that incorporates data collection, either quantitative or qualitative, and data analysis to answer a question. This investigation would explain the collection and analysis of data that follows established discipline protocols for research.

xx. An *Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO)* is an unanticipated event which causes or has the potential to cause harm to subjects or others when ALL three of the following conditions are met:

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 informed consent document) and the characteristics of the human subject population being studied;
2. Is related or possibly related to participation in the research (“possibly related” means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
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.

### I-4 Applicability

a. This regulation applies to all research involving human subjects that is performed by USMA personnel, if any of the following apply:

1. The research is supported by USMA (“the institution”).
2. The research is conducted by or under the direction of any employee or agent of USMA in connection with institutional responsibilities.
3. The research is conducted by or under the direction of any employee or agent of USMA using any property or facility of this institution.
4. USMA’s nonpublic information is used to identify or contact human subjects or prospective subjects.
5. The research is funded by non-USMA resources, but the human subjects are assigned or attached to USMA (military or civilian personnel).
6. The research includes living human subjects, whether as the direct or indirect object of research.
7. The research involves human subjects for which the Department of Defense is providing at least some of the resources. Resources may include but are not limited to funding, facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD personnel for recruitment, or identifiable data or specimens from living

1-4
individuals. It includes both DoD-conducted research involving human subjects (intramural research) and research conducted by a non-DoD institution (extramural).

(8) The research is medical research designed for the diagnosis, treatment, and prevention of medical conditions and the maintenance of health may be conducted at USMA but will require the review by a medical IRB. These studies include any FDA-reportable drug or device studies.

(9) The research is engineering research that involves complex research designs or safety considerations that are outside the scope of expertise of the CAIRB will be referred to an appropriate engineering IRB.

(10) The research involves prisoners, but the IRB review will be conducted by an existing IRB which has the experience and expertise to review Subpart C.

b. The following types of research will not be sponsored by USMA. This means no funding, facilities, or employee work hours will be provided by USMA agencies for the following research:

(1) Research involving deliberate exposure of human subjects to nuclear weapons effects, to chemical warfare agents, or to biological warfare agents.

(2) Research involving prisoners of war as subjects (DoDI 3216.02, para. 4.4.2).

c. Implementation of this regulation will be provided in USMA POM.

1-5 Institutional Review Board (IRB)

a. The Common Rule requires the prospective review and approval of human research activities by a duly constituted Institutional Review Board (IRB), a committee whose primary mandate is to protect the rights and welfare of humans who are the subjects of research. All human research conducted or supported by USMA must be reviewed and approved by the IRB whose membership and procedures are on record with the AHRPO, unless the research is exempt.

b. The IRB of record for all non-exempt, non-medical research is the Collaborative Academic Institutional Review Board (CAIRB), hosted at the Command and General Staff College at Ft. Leavenworth KS. All non-exempt medical protocols will be reviewed by the Regional Health Command - Atlantic IRB (RHC-A IRB) at Eisenhower Army Medical Center at Ft. Gordon GA. Non-exempt protocols involving classified research, complex engineering research, or research on prisoners must be reviewed by the IRB at the Combat Capabilities Development Command (CCDC) – Armaments Center (AC) at Picatinny Arsenal NJ. Protocols submitted to those IRBs will do so IAW their submission and review procedures.

1-6 Assurance of Compliance

a. An Assurance of Compliance is an official legal document representing a commitment made by an institution to the Federal government. It assures that all activities related to human research be guided by the ethical principles set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research and comply with the Federal regulations.

b. Any institution, such as USMA, proposing to engage in human subjects research provides written assurance satisfactory to an agency head, such as the DoD, that it will comply with the requirements in the Common Rule (32 CFR 219.103).

c. Assurances are approved by either the DoD or DHHS. DoD institutions proposing to engage in non-exempt human research must have a DoD Assurance prior to the recruitment of human subjects. All Army institutions engaged in non-exempt human research must have a DoD Assurance approved by the Office of the Surgeon General (OTSG) of the Army. All USMA employees and agents conducting or collaborating in human research operate under this Assurance.

d. All institutions, such as USMA, must also have an HRPP that implements their Assurance. The HRPP must be organizationally separate from other institutions to be eligible for an Assurance. Each must also be able to provide appropriate oversight of the HRPP for the entire assured institution. Approval of an Assurance requires a written HRPP, an IRB registered with the AHRPO, and a written IRB SOP.

e. The IO signs USMA’s Assurance. Whenever an IO is replaced, the Assurance of Compliance must be renewed through the AHRPO. The USMA Human Protections Director (HPD) will notify AHRPO of
an upcoming change of the IO at least 90 days before the change so there will be enough time to conduct a review of the USMA Assurance and HRPP before the new IO is in place.

f. Whenever there is a significant change to the USMA HRPP – such as a change in USMA HPD, new policies or procedures, new Institutional Agreements for IRB Review, or new Memorandums of Agreement or Understanding – notice of the change together with a copy of the new documents as applicable will be sent to AHRPO for the official USMA Assurance file. Before a new USMA HPD can be assigned, the prospective USMA HPD must complete education and training, must be approved by the AHRPO, and must complete a robust turnover with the outgoing USMA HPD to ensure a complete and careful transition of duties and responsibilities for the protection of human subjects.

g. USMA’s Assurance usually expires every 36 months or as granted and must be renewed prior to expiration, even if no changes have occurred, to maintain an active Assurance. If USMA’s Assurance is suspended or terminated by the OTSG, all human research will immediately cease until a valid Assurance is in effect. Any restriction on the Assurance by the OTSG will be enacted immediately, until such restriction is removed.

1-7  USMA Activities that Involve Obtaining Information about Living Individuals and are Excluded from Review

USMA conducts many activities throughout a given year that involve obtaining information about human participants. The organization of the Academy facilitates the separation of these activities into three types; Not Research, Institutional Research, and Assessment Research.

a. Activities that are Not Research are conducted by USMA organizations solely to support or improve the operations of the Academy. These activities involve collecting information from or about living individuals, but are not considered research. Examples are the recruitment and selection of employees; the recruitment, selection, and enrollment of cadets; and course exams or end-of-course surveys.

b. Institutional Research supports the decision-making process of the institutional leadership. It is supervised, supported, conducted, and coordinated by G5-Strategic Plans and Assessment and governed by USMA Regulation 70-1 Institutional Research. These activities usually do not meet the federal definition of Research because they are not “designed to develop or contribute to generalizable knowledge.” They are designed, specifically, to solely support decision-making for this institution.

c. Assessment Research supports obtaining more complete knowledge and practice of a particular discipline and is not designed for generalizing results. It is done solely to support the efforts of informing teaching and learning and is coordinated by the Office of the Dean’s Academic Research Division (ARD) and conducted in accordance with (IAW) the Dean’s Policy and Operating Memorandum (DPOM) 5-1 Academic Research.

1-8  Categories of Human Subjects Research

Human subjects research projects are divided into categories that facilitate the required institutional reviews that are appropriate to the projects’ level of risk. Projects in these categories require official written approval prior to the recruitment of subjects.

a. Exempt Research

(1) Human subjects research that meets all the criteria of one or more of the eight exempt categories established in 32 CFR 219.104(d) will be referred to as “exempt human subjects research” or “exempt research” throughout this regulation. In summary, the eight categories are:

1. Educational Research
2. Interactions
3. Benign Behavioral Interventions
4. Secondary Research
5. Government Sponsored Research
6. Taste and Food Quality
7. Storage and Maintenance of Secondary Research using a limited IRB
8. Storage and Maintenance of Secondary Research using broad consent

(2) Investigators cannot make determinations of exemption on their own projects. They must submit the appropriate protocol application materials to an EDO in accordance with the published procedures in the USMA POM.

(3) The EDO reviews requests for exemption in accordance with regulatory guidance and institutional policy and makes official determinations independently from any particular stakeholder's determination. Recruitment of human subjects or collection of data from human subjects may not begin without a written certification of exemption from a trained EDO.

b. Non-Exempt Research. Human subjects research that does not qualify as exempt will be referred to as “non-exempt human subjects research” or “non-exempt research”. Principal Investigators develop research protocols for each project and submit the protocols according to the applicable details in the USMA POM.

1-9 Vulnerable Populations

a. Participation in research must be truly voluntary. Even when the study appears harmless, subjects must be informed that they do not have to participate. Simply informing subjects is not enough. They must fully understand that they may choose not to answer particular questions, not complete specific tasks, or stop participating at any time without any negative repercussions.

b. Potential subjects must be free from real or perceived coercion or undue influence which usually results when investigators have some level of authority over the potential subjects through rank or position. Circumstances that would make a subject feel pressured in any way must be avoided.

c. Certain populations are more susceptible to coercion or undue influence. These populations are referred to as vulnerable populations. Investigators and “the IRB should take into account the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, individuals with impaired decision-making ability, or economically or educationally disadvantaged persons.” (32 CFR 219.111(a)(3)) Pregnant women, prisoners, and children are provided additional safeguards in 45 CFR 46, subparts B, C, and D. Additional safeguards for other potential vulnerable populations must be established by USMA.

d. Safeguards employed for vulnerable subjects include, among many other strategies, assessing the decision-making capacity of potential participants, ensuring incentives are not coercive, allowing subjects adequate time to consider participation, using a neutral third party to recruit and enroll participants, and considering ways in which the setting of the consent process might include elements of coercion.

e. Military personnel, including cadets, are subject to military law, the Uniform Code of Military Justice, and Army Regulations. People in military-type organizations are considered vulnerable populations due to the structure, rules, and culture of these organizations. These personnel are more susceptible to coercion and undue influence than those in other populations. Military personnel of low rank, age, and experience are the most susceptible to undue influence and coercion.

f. Cadets are not like any other undergraduate students because they are members of the Regular Army. They are conditioned to follow orders and any Commissioned or Non-Commissioned Officer can exercise “General Military Authority” over them. Therefore, cadets and enlisted personnel, by the nature of their low position within the military structure, are vulnerable to coercion and undue influence.

1-10 Institutional Responsibilities

a. Institutional Official

(1) Ensures the institution bears full responsibility to comply with the requirements of 32 CFR 219; 10 USC 980; AR 70-25; AR 40-38; DoDI 3216.02; where applicable 21 CFR 50, 21 CFR 56, and 45 CFR 46 (Subparts B, C, and D) under the authority of the DoD and other Federal, State and local laws as they may relate to human subjects research.

(2) Signs the DoD Assurance for the Protection of Human Subjects.
(3) Establishes and maintains the policies and procedures for the HRPP and related research policies and procedures on behalf of USMA.

(4) Oversees the protection of human subjects, regulatory compliance, and the implementation of the HRPP for USMA.

(5) Oversees research investigators and staff and research management.

(6) Ensures that the HRPP is functional and adequately staffed and funded.

(7) Disapproves or terminates research approved by the IRB when the research violates USMA human subject protection standards addressed in this HRPP that are beyond the scope of the IRB.

(8) Enforces compliance with the terms of the Assurance and the HRPP, including the approval and enforcement of any IRB recommendations for the termination or suspension of a non-compliant research activity.

(9) The following activities can be delegated:
   - Appointing or suspending IRB members and chairs
   - Periodic evaluations of IRB members
   - Ensuring IRB members and support staff are trained
   - Recruiting qualified IRB members including nonscientist and unaffiliated
   - Overseeing IRB operations
   - Reviewing and signing research and IRB agreements
   - Being POC for IRB correspondence
   - Being POC for federal and Army regulators for routine queries
   - Ensuring researchers are trained
   - Managing funds and resources supporting HRPP
   - Reviewing and approving policies and procedures

(10) The following activities cannot be delegated:
   - Completing required IO training
   - Signing the DoD Assurance
   - Ensuring the IRB functions independently, and that the HPA and IRB Chair have direct access to the IO
   - Ensuring adequate resources for the HRPP, including subject matter experts and support staff to implement the HRPP
   - Exercising authority to receive IRB determinations of noncompliance, initiate additional investigations, mandate corrective action plans, and
   - Exercising authority to ensure IRB determinations and other HRPP requirements are implemented within the institution.

b. USMA Human Protections Director (HPD)

(1) The IO delegates oversight responsibility for the HRPP to the USMA HPD, who has a comprehensive knowledge of all aspects of the institution’s systematic protections for human subjects.

(2) Is qualified for a faculty appointment and has experience conducting research.

(3) Ensures constructive communication among the IRB Administrator, investigators, human subjects, and institutional official, as a means of maintaining a high level of awareness regarding the ethical conduct of research and safeguarding the rights and welfare of subjects.

(4) Arranges for ready access to the institution’s Assurance, copies of pertinent Federal regulations, policies and guidelines related to the involvement of human subjects in research, as well as institutional policies and procedures.

(5) Educates the USMA Major Activity Directors to establish and maintain a culture of compliance with DoD and Federal regulations and institutional policies relevant to the protection of human subjects.

(6) Ensures that all research personnel have completed appropriate human subjects research and ethics training.
(7) Ensures that human subject protection records that are locally filed are maintained appropriately and are accessible, upon request, to authorized DoD officials.

(8) Ensures the appropriate regulatory review of USMA research protocols by an EDO.

(9) If the EDO determines that a protocol does not meet exempt criteria, the HPD will assist the investigator in completing the appropriate packet for submission to the IRB for a higher review.

(10) Will review all protocol packets for submission to the IRB to ensure they are complete and meet regulatory standards for review.

(11) Will conduct all post-compliance monitoring of all non-exempt research.

(12) Will conduct any other compliance monitoring as requested by the IRB or as necessary by regulatory guidance.

(13) Will provide appropriate training to cadets, investigators, and IRB members to ensure regulatory compliance with ethical standards.

(14) Ensures prompt reporting to the IRB of proposed changes in a research activity and ensuring that such changes in approved research, during the period for which IRB approval has already been given, are not initiated without IRB review and approval, except when necessary to eliminate apparent, immediate hazards to the subject.

(15) Ensures the prompt reporting to the IRB, appropriate institutional officials, and AHRPO: any unanticipated injuries or problems involving risks to subjects or others; any serious and continuing noncompliance with the regulations or requirements of the IRB, and any suspension or termination of IRB approval for research.

(16) Ensures that appropriate oversight mechanisms to ensure compliance with the determinations of the IRB have been implemented.

(17) Ensures that the IRB reviewing the USMA protocols is provided with local community and cultural factors that may affect the ethical review of protocols both initially and for continuing review.

(18) Ensures that human subjects research does not commence until:
   - An approved DoD Assurance covering the research exists,
   - The research has been approved by the IRB, and
   - The research has been approved by the Superintendent or his designated representative.

(19) Serves as the central point of contact for issues regarding the processing of human subjects research protocols, adjudication of various issues, notifications of scientific and IRB actions, progress or event reporting from field or regulatory offices.

(20) Monitors the safe and ethical use of equipment that collects physiological data for research according to established USMA and departmental policy and regulations.

(21) Maintains current copies of all departmental policies, including equipment appendices, on a dedicated and accessible internal webpage linked off of the Human Subjects Research Activities webpage.

(22) Screens all protocols to ensure that protocols which include the use of physiological monitoring equipment adhere to the departmental policies and training certifications.

(23) Coordinates and annually conducts audits of the physiological monitoring activities within Academic Departments to enhance the United States Military Academy’s research community’s understanding of physiological monitoring research. Audits will include the systematic review of departmental policies and equipment with each department Point of Contact (POC). This review will ensure the policy reflects the most accurate and timely information for safe and effective use of equipment or devices. During the annual review, any equipment no longer in use will be removed from the policy. If changes are necessary to the policy or appendices, an updated policy must be provided by the department.

(24) Reviews the documentation of maintenance and training in all post-compliance, random, or for-cause audits, including those resulting from any UPIRTSO, adverse event, or deviation.

c. Exempt Determination Official (EDO)

(1) All EDOs must complete AHRPO-approved certification training before conducting reviews of activities that are not research, research but not HSR, and exempt determinations. Only faculty with research experience can be an EDO and only with departmental approval.

(2) Receives protocols from USMA investigators, irrespective of ultimate level of review.
(3) Reviews all protocols to ensure they are complete and meet the standard of “research” and “human subject research” IAW 32 CFR 219.

(4) Reviews and makes a final determination of requests for exemption from human subjects research requirements under applicable USMA, Army, DoD, and Federal Policy and Regulations.

(5) The EDO will submit their determinations to the HPD for processing.

(6) Serves as liaison to the USMA community on human subjects research protection matters.

(7) The HPD will conduct periodic audits of all EDOs to ensure regulatory compliance that the determination was correct, supported by sound reasoning, and IAW appropriate regulations. If the HPD also does the exempt determinations, an external HPD will conduct periodic audits to ensure regulatory compliance.

(8) If, in the course of an audit, an EDO decision results in non-compliance, the study will be referred to the IRB for appropriate review. Subjects will be notified if the IRB determines that study was greater than minimal risk and an informed consent should have been executed. The IRB may allow subjects to be re-consented.

(9) The IRB will determine the disposition of any data collected while the study was not in compliance due to the incorrect determination.

(10) The HPD will determine the corrective action for incorrect determinations, including retraining, second reviews, or to discontinue the EDO’s authority to conduct reviews.

d. Department Heads/Major Activity Directorates

(1) Ensures that research conducted within the department/directorate adheres to all regulatory standards and serves as signatory for all non-exempt research protocols.

(2) Establish procedures to determine when investigators within their organizations are engaged in human subjects research activity regardless of whether a research proposal has been submitted.

(3) Develops and implements policies and procedures for the safe and ethical use of equipment and devices that collect physiological data within their department.

(4) Designates the departmental point of contact (POC) for maintaining the equipment logs and documentation pertaining to equipment and training. POC will establish a tracking mechanism for required training consistent with departmental norms for other mandated training requirements.

(5) Ensures that only those trained on the safe operation of the equipment or devices will use the equipment or device.

(6) Ensures that facilities or equipment are adequately maintained and serviced throughout the study, including maintaining the documentation of manufacturer’s maintenance recommendations.

(7) Annually audit equipment used in physiologic monitoring activities to ensure that the policy regarding the use of the equipment reflects the most accurate and timely information for its safe and effective use. During the annual review, any equipment no longer in use will be removed from the policy. If changes are necessary to the policy or appendices, an updated policy must be provided by the department to the HPD.

(8) Provide oversight of investigators within their control who are conducting human subjects research.

(9) Establish an awareness program to ensure personnel understand the purpose and scope of the HRPP.

(10) Provide qualified personnel to be voting members of the IRB when necessary. The CAIRB SOP describes their responsibilities.

(11) Monitor compliance of approved research conducted by or on personnel within their organization. Ensure it is conducted according to the approved protocol.

(12) Monitor safety and establish data and research monitoring plans or boards as needed.

(13) Report violations of compliance to the USMA HPD.

(14) Address indemnification and contract issues when contractors are used to conduct all or part of the research.

(15) Conduct quality assurance and quality improvement for the program as a whole.
Ensure Information Owners or Data Owners identify Personally Identifiable Information (PII), evaluate the risk of loss or unauthorized disclosures, assign Impact Categories for electronic PII, and establish appropriate protection measures for PII in other media.

Department heads are responsible for developing policies on the safe and ethical use of equipment and devices that collect physiological data within their departments. The USMA HPD will review all policies to ensure that they are compliant with current human subjects research regulations.

a) At a minimum, the policy must include clear and comprehensive guidance on the equipment/devices’ safe use, operation, maintenance, operator training or certification, and potential incidental clinical findings if required.

b) The policy governing the use of each piece of equipment used in research will include:

- The description of the intended use of the equipment, including specific descriptions of the equipment, the URL to the manufacturer’s website, and pictures of the equipment.
- Risks and safeguards that explain in detail foreseeable risks and steps taken to mitigate the risks.
- Training and certification, if required by the manufacturer, detailing the training requirements, certification, recertification, and documentation.
- Incidental clinical findings, if applicable, must be explained. Incidental clinical findings would be those results which are outside of normal ranges, as specified in the literature or manufacturer’s guidance, which might result in clinical implications. If there is a potential for incidental clinical findings, the policy should reflect the appropriate measures to respond to the findings.
- Any maintenance required of the equipment/device according to manufacturer’s recommendations and how that maintenance will be documented.
- The departmental POC for maintaining the equipment/training logs and documentation.

e. Dean of the Academic Board. The Dean has the additional responsibility to ensure the overall regulatory compliance and to convene an investigation where serious or continued non-compliance occurs. At the IO’s discretion, the Dean may also serve as the AIO. The following activities can be delegated to the AIO:

- Appointing or suspending IRB members and chairs
- Periodic evaluations of IRB members
- Ensuring IRB members and support staff are trained
- Recruiting qualified IRB members including nonscientist and unaffiliated
- Overseeing IRB operations
- Reviewing and signing research and IRB agreements
- Being POC for IRB correspondence
- Being POC for federal and Army regulators for routine queries
- Ensuring researchers are trained
- Managing funds and resources supporting HRPP
- Reviewing and approving policies and procedures

f. Faculty Advisors

(1) Assumes full responsibility for the safe and ethical conduct of research of their students.

(2) Ensures that any classroom, capstone, or thesis study that develops or contributes to generalizable knowledge will submit a determination request or protocol for review. Studies which meet the regulatory definition of research will be reviewed according to current regulatory and policy research guidelines. Faculty are encouraged to consider the time requirements which may be required for other than exempt research studies.
Guide students through the IRB process by discussing general principles of research ethics with the class/student prior to the initiation of any project involving human subjects.

Acts as Principal Investigator (PI) for student research projects.

Supervise the students throughout the human subjects research project.

Determine whether projects are designed to meet the regulatory standard for research and require IRB review. The advisors will educate and assist students with the process.

Discuss research ethics with the students.

Advise students conducting international studies on understanding the local customs and ethics. If the project involves research in a non-US setting, then considerations of local regulations and customs must be understood and satisfied.

Monitor student activity, paying special attention to recruitment, confidentiality, privacy, level of risk, voluntary participation and withdrawal, and informed consent.

Assure that any unanticipated or adverse events are reported to the USMA HPD.

g. The Principal Investigator

Acknowledges and accepts responsibility for protecting the rights and welfare of human subjects and for complying with all applicable provisions of this regulation including 32 CFR 219; 10 USC 980; DoDI 3216.02; AR 40-38, AR 70-25; where applicable 21 CFR 50, 21 CFR 56, and 45 CFR 46 (Subparts B, C, and D) under the authority of the DoD; and other Federal, State, and local laws as they may relate to proposed human subjects research.

Acquires appropriate knowledge regarding human subject protections, ethics, and federal, DoD, DA, and state regulations to conduct the proposed research. Complete appropriate training before submitting human subjects research protocols for review. Submit evidence of such training with each research protocol.

Ensures that all associate investigators involved with the study are adequately trained and knowledgeable regarding human subject protections, ethics, and federal, DoD, DA, and state regulations applicable to the proposed research prior to submitting a research proposal.

Complies with the training, monitoring, and human subjects research guidance outlined in the USMA Assurance, USMA Human Research Protection Program, and policies and procedures of the IRB of Record.

Obtains official written determination regarding the following, as appropriate:

- That a proposed activity involving human volunteers does not meet the definition of research and/or involve human subjects.
- That a human subjects research project meets the criteria for an exemption as defined in 32 CFR 219 and has obtained a determination from the EDO.
- That a determination has been made that human subjects research project meets the criteria for an exemption, and has obtained approval through a Limited IRB Review, if required.
- That a human subjects research project meets the criteria for IRB approval IAW 32 CFR 219.
- That an activity involving cadets as human subjects meets the requirements DoDI 3216.02.

Prepares and submits a research protocol or request for exemption to the EDO prior to recruiting human subjects. Research will not begin until the investigator has written confirmation of approval or exemption. An investigator who intends to involve human subjects in research will not make the final determination of human subjects research or of exemption from applicable Federal, Army, or USMA regulations.

When required, provides a copy of the IRB-approved consent document to each subject at the time of consent, unless the research is exempt or the IRB has specifically approved to waive this requirement.
Ensures that associate investigators and research personnel conduct their duties and responsibilities IAW ethical standards, regulatory requirements, and guidance set forth in the USMA Assurance, USMA HRPP, and policies and procedures of the IRB. Additionally, the PI is responsible for ensuring that only qualified personnel operate equipment used in research and where required, have met necessary training requirements.

Must adhere to the institutional and departmental policies on the safe and ethical use of equipment and devices that collect physiological data.

Ensures that the equipment/device comply with all applicable departmental and Academy policies, including that only properly trained and certified personnel operate the equipment.

Must include the departmental policy on the safe and ethical use of any devices/equipment with the protocol.

Must state whether IFs are associated with the devices to be used. See section 3-14 for description of responsibilities related to the management of IFs.

Ensures that the study is conducted, and any equipment is used only as specified in the protocol and as approved by the IRB.

Reports promptly, to the IRB, any proposed changes to an IRB-approved research activity. The changes shall not be initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

Reports promptly, to the EDO, any proposed changes to an exempt research activity. The changes shall not be initiated without prior EDO review and approval, except where necessary to eliminate apparent immediate hazards to the subjects.

Reports all adverse events (AEs), serious adverse events (SAEs) and Unanticipated Problem Involving Risks to Subjects or Others (UPIRTSO) promptly to the HPD and IRB, including incidents involving the use of equipment and devices in research.

Maintains files for each research project to be available for inspection by the USMA HPD, IRB, AHRPO, or any Federal Agency. This includes, but is not limited to, the research protocol, IRB Approval or Exemption documentation, signed consent forms, and (where appropriate) equipment maintenance logs and equipment training certifications.

Ensures all subjects, or their representatives, are fully informed of the nature of the research to include potential risks to subjects.

Selects subjects in strict accordance with the inclusion/exclusion criteria outlined in the approved research protocol for non-exempt research.

Implements the research activity as it was approved by the EDO or IRB.

Maintains adequate safeguards for the protection of complete research records and ensures the confidentiality and security of all information obtained from and about human subjects.

Maintains research files for a minimum of 3 years after the study has been closed.
Chapter 2
Program Overview

Human subject protection is an institutional responsibility. Therefore, USMA requires a comprehensive program to guide the conduct of activities involving human subjects and create an organizational culture in which the institutional leadership promotes the highest ethical standards and dedication to the welfare of every study participant. This chapter describes important aspects of this program.

2-1 Goals
The following three goals were established by the AHRPO for all Army HRPPs:
   a. Recognizes the rights and welfare of human subjects research participants and ensures these are adequately protected.
   b. Is guided by the ethical principles of respect for persons, beneficence, and justice as set forth in The Belmont Report, and is conducted with the highest level of expertise and integrity.
   c. Complies with applicable federal, DoD, and DA laws and regulations.

Additionally, USMA is committed to the promotion of ethical research and academic freedom within the Army. The promotion of ethical research includes educating investigators, supervisors, and leaders on the proper conduct of research activities in a manner that advances knowledge while protecting human subjects as required by law and policy.

2-2 Objectives
The objectives of the USMA HRPP are to ensure that:
   a. Human subject welfare is of central concern to the investigator(s) and staff. Researchers should take steps to both minimize the level of harm to which subjects may be exposed and treat subjects with dignity and respect throughout the study.
   b. The investigator(s) who designed the study, those who will collect the data, and others who interact with human subjects are appropriately trained and well qualified to conduct research with humans and to perform all study procedures.
   c. The investigator(s) who designed the study, those who will collect the data, and those who oversee the research have no financial or other conflicts of interest that could bias the study or negatively affect human subject welfare, and unavoidable potential for conflict has been disclosed to the subjects before enrollment and adequately managed throughout the study.
   d. The proposed study has been reviewed by neutral authorities to ensure that:
      (1) the question(s) asked are important;
      (2) the protocol is feasible, well designed, and likely to result in an answer(s) to the research question(s);
      (3) the risks have been minimized and do not outweigh the potential benefits (even if the subjects will not directly benefit); and
      (4) subjects are given all the information necessary to make an informed decision about participation in a language and at an intellectual level they can understand.
   e. An advocate or friend can help explain the details of the study to subjects if necessary or desired.
   f. Human subjects understand that they are free to refuse to participate or to withdraw from the study without fear of retribution or loss of benefits to which they are otherwise entitled.
   g. The IRB will monitor the progress of non-exempt longitudinal studies, and if new information pertinent to the protocol becomes available during the study that might be important to subjects, the research team will share it with subjects and adjust their individual involvement as appropriate. Similarly, if the risks are greater than first believed or if the intervention is found to be successful earlier than predicted, the study should be reviewed by the IRB for possible termination or modification.
   h. Provisions are in place to cover the cost of subjects’ medical and rehabilitation services should they experience an adverse event related to the research.
   i. The data analysis is of high quality and free from bias, and study findings are reported to the scientific community and human subjects, regardless of the outcome.
2-3 Key Components

a. The HRPP is a program that involves a system of interdependent components (Figure 1). The key components are:
   1. Participants involved in research;
   2. Investigators carrying out research;
   3. Officials or boards responsible for reviewing the scientific validity and freedom from conflict of interest of the research;
   4. The IRB, which is responsible for reviewing the ethical integrity of the research and for keeping the subjects’ rights and safety as top priority;
   5. Departments, Activities, or other organizational units responsible for analyzing data, reporting study results, and designing, overseeing, and conducting research;
   6. The monitoring bodies, ombudsman programs, and data collection centers; and

b. Components must fully understand their roles and responsibilities and they must cooperate and communicate effectively to achieve the HRPP goals.
   1. The investigator must make sure that communication and interaction are maintained with each research participant throughout the course of the research project.
   2. The USMA HPD ensures that required communications take place among the research investigator, IRB staff, review committees, and institutional officials.
   3. The USMA HPD will coordinate closely with the Academic Research Division (ARD) to ensure both Academic and Institutional research policies support the HRPP.
2-4 Essential Functions
The HRPP is a program of systematic and complementary functions designed to ensure the adequate protection of research subjects. The four essential functions of the HRPP are:

a. Comprehensive review of research protocols (including scientific, conflict of interest, and ethical reviews).
b. Ethically sound subject-investigator interactions.
c. Ongoing (and risk-appropriate) research monitoring throughout the conduct of the study.
d. Quality improvement and compliance activities.

2-5 Research Determination Decision Process
a. Only a trained Exempt Determination Official (EDO) can make the determination of the regulatory status of the study.
b. An EDO may use a decision tree matrix to determine how to review research (Fig. 2). The first step is to determine if the research meets the criteria for excluded activities, as determined by the DoD. Next, the decision is made if the research fits the regulatory definition of research, and if so, does it meet the regulatory definition of human subjects research. Finally, the determination is made if the study meets one or more of the criteria for an exemption. If not, then the study must be referred to an IRB for further review. Only trained EDOs can make the determination of not research, research not involving human subjects, or exempt. Investigators may not self-determine.
c. Departments with sufficient human subject research capacity may designate a person to complete the training and be the departmental EDO under the guidance of the HPD.

Figure 2. Research Determination Decision Tree
2-6 Quality Improvement Activities
As part of a continuous quality improvement program, the USMA HPD will meet periodically with the heads of departments conducting human research to discuss the adequacy of the HRPP. The Associate Dean for Academic Research or designee may also be in attendance. Topics addressed in the discussion may include:
   a. Whether the program is meeting its stated goals.
   b. Review of the volume and scope of human research projects conducted by USMA personnel.
   c. Review of the volume and scope of collaborative research conducted between USMA personnel and non-USMA organizations.
   d. Review of the time demands placed on cadets by human research projects.
   e. After-Action Reports (AARs) of cases of non-compliance, if any, to determine if any systemic improvements are required.
   f. Determination of causes for unreasonable delays in the approval process, if any.
   g. Possible ways to streamline procedures while maintaining or improving the level of protection of human subjects.
The USMA HPD will submit recommendations to the IO for approval of modifications to any portion of the HRPP as appropriate. Any approved modifications will be submitted to the AHRPO for review and approval before implementation.

2-7 Access to Institutional Data for Human Subjects Research
The United States Military Academy is a military organization that functions as an academic institution. Therefore, it is subject to all the rules and regulations imposed on it by the U.S. Government, the Department of Defense, and the U.S. Army. There are specific considerations regarding general data collection requirements for maintaining privacy and confidentiality and the unique data collection requirements imposed on USMA by its higher headquarters. Access to institutional data for HSR purposes can be considered under the prevailing conditions of sound research design and the appropriate protections in place to ensure data security and confidentiality of the data.
   a. Personally Identifiable Information (PII). Investigators must make every effort to safeguard “Individually Identifiable Private Information” and treat it as PII by following appropriate Army and USMA procedures on data security.
   b. If information is generated for research purposes only (involving no standard of care treatment, etc.), maintained only by the investigators involved in the research, and is not maintained in a system of records, the information is research information. Informed consent may be required to obtain such information.
   c. Cadet data are considered personal and private information. Access will be granted to AMS data for research purposes only with a determination review. Given the nature and sensitivity of cadet data, these data (particularly on current cadets) is discouraged from being used for cadet projects. Access to cadet data for cadet projects from OIR, OEMA, Admissions, Athletics, or the Registrar (to include AMS) will only be granted with justification and approval from the data owners. As a routine practice, all cadet data will be de-identified before being released; exceptions to this practice must be specifically justified in the data request and approved by the data owner.
   d. Investigators may obtain non-identifiable data sets from a system of records without informed consent if they do not have direct access to the identifiable records and the secondary source creates the non-identifiable data set and provides it to the investigators.
   e. Medical data collected by a covered medical entity (like KACH) are specifically protected by HIPAA and other regulations. These data may be used in research by USMA investigators according to DoD policies and procedures pertaining to HIPAA Compliance and as covered by the medical entity’s business plan on sharing data to non-covered entities.
Chapter 3
General Requirements
This chapter describes requirements that apply to all human research projects (exempt and non-exempt). The investigators, MADs, USMA HPD, and IRB share the responsibility to ensure that these requirements are being met. Investigators must comply with any additional departmental and institutional requirements for safe and ethical conduct of research.

3-1 Ethical Principles Governing Human Subjects Research
Three primary ethical principles, established in The Belmont Report, apply to research covered by the HRPP.

a. Respect for persons (applied in ways such as obtaining informed consent, giving consideration to privacy and confidentiality, and adding protections for vulnerable populations or diminished autonomy)
b. Beneficence (applied, for example, by weighing risks and benefits)
c. Justice (applied, for example, by the equitable selection of subjects)

3-2 Risk vs. Benefit
Every study involving human subjects must be evaluated to determine whether the benefits of the research significantly outweigh the risk to the subjects. The objective is “to maximize possible benefits and minimize possible harms” (National Commission, 1979, p. 6)

a. Risk.
   (1) Risk is the probability and severity of harm or injury occurring as the result of participation in a research study. Human research projects may entail some degree of harm or injury to a person's physical or mental health, privacy, confidentiality, reputation, or socioeconomic well-being. Such risk must be identified as early as possible.
   (2) Risk Assessment must be conducted throughout the research process; from the development of the research question to the dissemination of the research results. An investigator must consider all possible risks to the subject and explain how those risks will be mitigated during the conduct of the study. This assessment must be included in the Research Protocol.

b. Risk Resulting from Study Questions/Surveys
   (1) In human subjects research, particularly social and behavioral projects, subjects may feel stress caused by the research questions or procedures. Questions to certain sample groups could raise painful memories or unresolved issues. For example, interviews of survivors of violence or other crimes may be very stressful. Questions about at-risk behaviors may cause embarrassment, feelings of guilt, or legal liability when that behavior is generally illegal or socially unacceptable.
   (2) Most psychological risks are minimal and transitory, but investigators must be aware of the potential for serious psychological or socioeconomic harm. Psychological support and referrals can be built into studies when emotional distress may be an outcome.
   (3) Probably the source of most risk from surveys or interviews would be the inadvertent disclosure of personal and sensitive information, even if the prompt did not specifically ask about it. The PI should include in the protocol measures to protect intentional or inadvertent disclosure of personal and sensitive information.

c. Benefits
   (1) The PI must provide an adequate description of the potential benefits of a non-exempt research project in a Research Protocol. An adequate description in these documents allows the IRB to determine whether the potential benefits outweigh the potential risks. A non-exempt Research Protocol must contain a written determination of scientific validity and potential benefit provided by an independent scientific review according to the IRB procedures. An adequate description of anticipated benefits in the consent form allows potential subjects to make an informed decision on whether to participate.
   (2) Vague promises to benefit science or society are not adequate descriptions of benefit in a consent form or research protocol. When there is no direct benefit to subjects, they must be told what the
researcher is trying to learn and why. The only exception would be a study in which deception is a necessary
and IRB-approved element of the design.

(3) Compensation to subjects is not considered a benefit in the risk/benefit analysis, nor is the
fact that participants may find it rewarding to be helpful.

3-3 Privacy and Confidentiality

a. Protection of privacy and confidentiality is an important aspect of human subject protection. It is
an application of the principles of autonomy (respect for persons) and beneficence from The Belmont
Report. Investigators must conduct a risk assessment of the possible loss of privacy and confidentiality and
include it in the Research Protocol or request for exemption.

(1) Privacy – having control over the extent, timing, and circumstances of sharing oneself
(physically, behaviorally, or intellectually) with others.

(2) Confidentiality – the treatment of information that an individual has disclosed in a
relationship of trust and with the expectation that it will not be divulged to others in ways that are
inconsistent with the understanding of the original disclosure, unless given permission.

b. Breach of Confidentiality Considerations

(1) A breach of confidentiality is often the greatest risk to participants in social and behavioral
human research. It could place the subjects at risk of significant harm. Reputations or employment may
be damaged. Insurance coverage may be jeopardized. Lawsuits or criminal prosecution could result.

(2) The kind and level of risk is determined by context. Breach of confidentiality for military
personnel requires serious consideration of the effects on their military career. Medical and psychological
diagnoses can lead to limitation of duties or discharge. Information regarding alcohol or drug abuse, drunk
driving, sexual assault, child abuse, or spousal abuse, could lead to actions under the Uniform Code of
Military Justice (UCMJ) including incarceration and dishonorable discharge.

(3) Investigators who collect information from soldiers or cadets for research cannot guarantee
that certain information will be kept confidential. They have a legal obligation and duty to report  if there
is information that a soldier or cadet poses a reasonable threat of serious harm to themselves or others, the
investigator must immediately report the information to the soldier’s or cadet’s chain of command.

(4) The requirement to report does not apply to civilian subjects.

c. Considerations for minimizing risks to invasion of privacy or breach of confidentiality.

(1) In many cases risk to privacy/confidentiality can be eliminated or reduced by careful
procedures designed to ensure the privacy and confidentiality of human subjects.

(2) Careful data collection and management procedures must be followed.

(3) Consent forms describing the kinds of questions the researcher will ask allow participants
to choose whether they wish to divulge certain types of information or explore certain issues.

(4) In a research protocol, the investigator must describe plans to protect the subject's identity
as well as the confidentiality of the research records.

(5) Without appropriate safeguards, problems may arise with long-term retention of records.
In special circumstances requiring additional safeguards to prevent potential criminal civil prosecution of
the participating human subject, the IRB may require the destruction of all data that can identify the
subjects. Subjects should be informed of whether the data collected will be retained, and if so, for what
purpose, what period of time, or whether and when data will be de-identified and destroyed.

(6) A special situation arises for video or taped data and photographs since these media provide
additional potential means for subject identification. Investigators must secure subject consent explicitly
mentioning these practices. They should also explain plans for final disposition or destruction of such
records.

3-4 Recruitment and Enrollment

a. Recruitment.
Recruitment is the process by which potential subjects are informed about the study. Recruitment materials, such as fliers, email messages, newspaper ads, and phone calls, must be true, non-coercive, and must not highlight any potential monetary compensation.

The EDO, HPD, or the IRB must review and approve recruitment materials before recruitment begins. They may also observe, or have a third party observe, recruitment methods. The USMA HPD may also require a review of recruitment materials for exempt human research projects before they are used to recruit subjects.

Ethical and regulatory requirements prohibit the undue influence or coercion of human subjects to take part in human research efforts or to remain in a study against their will. Investigators and research staff will ensure that this matter is strictly enforced during the informed consent process and in all other processes.

The perception of coercion to participate in studies must be avoided. Special care must be taken by investigators when using cadets or soldiers as human subjects to ensure that they understand that no recourse will be taken for refusing to participate in research. The Chain of Command will not be involved in the recruitment of military personnel and must not order cadets or soldiers to participate in a research study.

Active duty military personnel may not receive payment for participation in research while on duty. The only exception is blood donation, which may not exceed $50 per blood draw. Active duty research volunteers may not receive any other payment unless they are on official military leave status at the time of their participation in the study.

b. Enrollment. Enrollment involves selecting volunteers and obtaining their informed consent to participate as human subjects. The Principal Investigator ensures that selection of subjects is equitable. Consider the purpose of the research and the setting in which the research will be conducted. The PI should be particularly aware of the special problems of research involving vulnerable populations (i.e. cadets, soldiers, children, prisoners, pregnant women, etc.).

3-5 Investigator Compliance
In addition to the Principal Investigator’s responsibilities, all investigators (principal or associate) will:

a. Not exert undue influence or coercion on the EDO, HPD, IRB Administrator, or any IRB member.

b. Apprise the USMA HPD of any investigator’s noncompliance with the approved protocol. The HPD will notify the IRB and appropriate administrators.

c. For exempt studies: Inform the EDO of any change to an exempt study even if the changes are minor, such as adding/deleting members of the research team or making small modifications to instruments or procures. These changes must be reviewed to ensure the study remains in an exempt status. Changes which may take a study out of exempt status include the addition of subjects who are minors, addition of foreign research sites, collection of identifiable data, collection of medical data, collection of physiological data, addition of questions or data collection that would put subjects at risk, addition of research procedures or other interventions/interactions, etc.

d. For IRB-approved non-exempt studies:
(1) Seek IRB approval for any changes to the project, no matter how small, prior to commencing work on the project, unless the change is required to eliminate apparent immediate hazards to the human subjects. In that case, inform the IRB of the change as soon as possible.

(2) Notify the IRB of any unanticipated problem involving risks to subjects or others (UPIRTSO), adverse events, or any other issues which may arise that puts the subjects at risk or where someone has been harmed in the research.

3-6 Conflicts of Interest

a. A conflict of interest can result from financial compensation, the desire for professional advancement or fame, or the desire to make a scientific breakthrough. In 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research noted that “…investigators are always in positions of potential conflict by virtue of their concern with the pursuit of knowledge as well
as the welfare of the human subjects of their research.” A conflict of interest can exist for a person to review or make determinations concerning human subject research when either that person or a spouse is involved in the research, or stands to gain through financial compensation, professional advancement or fame, or scientific breakthrough.

b. Officials who are designated to review or make determinations on human research must not be involved in the research in any capacity. They must recuse themselves and defer the review to another designated official. This is necessary to avoid conflict of interest or the perception of conflict of interest.

c. Investigators may not make official determinations about whether an activity is human research, whether it is exempt, or whether non-exempt research is given an expedited or full review. Again, this is necessary to avoid conflict of interest or the perception of conflict of interest.

d. Investigators are obligated to disclose any possible significant conflict of interest in a Research Protocol submission or request for exemption. Further guidance on conflict of interest is described in the USMA POM.

3-7 Human and Fiscal Resources

a. The investigator and the investigator’s organization (Department/Branch/Division) must ensure the availability of resources sufficient to protect the rights and welfare of research participants, taking into consideration the research activities in which they are asked to participate. Necessary resources include adequate space, equipment, and personnel, as well as sufficient funding to complete human research studies.

b. Highly skilled professionals are required to staff, manage, and serve on boards and committees to review research. Evaluation of research protocols requires a variety of skills and knowledge, ranging from technical scientific design expertise to a strong working knowledge of the ethical literature. Both senior staff and faculty and IRB members should be familiar with the potential participant communities that will be enrolled and affected by a particular study. Even assuming that an individual (or a collection of individuals) possesses the needed skills, a rigorous and thoughtful review of protocols will still be time consuming.

c. IRB membership should be viewed as an institutional obligation, and those who serve on IRBs should receive release time from other job responsibilities without financial or academic penalty. MADs should allocate the necessary time and resources to personnel or committees to properly review each protocol. IRB members should be placed on orders and given credit for their contribution to the Academy’s research efforts.

d. The IO will allocate sufficient time for the USMA HPD to perform required functions, as well as office space, supplies, and funding for training (such as the DoD Human Research Protection conferences and the Public Responsibility in Medicine and Research (PRIM&R) conferences).

3-8 Education and Training

a. Research investigations that enroll human subjects require a specialized knowledge base that goes beyond that provided through traditional scientific training. Investigators, IRB members, the EDO, and the USMA HPD must complete initial and refresher training prior to engaging in human research activities covered under this regulation. They should all possess a core body of knowledge relating to the ethical design and conduct of a research protocol. MADs must ensure that investigators and other individuals substantively involved in research with humans within their directorates are adequately educated to perform their respective duties.

b. Faculty members who are likely to conduct human research should be informed of their responsibilities when they arrive at USMA to prevent inadvertently violating the policy set forth in this regulation.

c. Investigators must provide proof of human subjects training from an appropriate training source at least every three years or as required by regulation.

3-9 Collaborative/Cooperative Research between USMA and One or More Institutions
a. All USMA-supported human research, not just those sponsored by USMA researchers, will be submitted to the USMA HPD or EDO to ensure compliance with Army and USMA HRPP policy.

b. USMA employees and agents may conduct human research in collaboration with other civilian or military organizations as either a Principal Investigator (PI) or an associate investigator (AI). In such cases, there must be a clear and distinct assignment of roles and responsibilities for each research project.

c. Where appropriate, each institution involved in a single human research project must have an Assurance. The DHHS grants assurances for most civilian institutions in industry and higher education. The Office of Human Research Protection (OHRP) of the DHHS approves such assurances and provides compliance oversight. An OHRP-approved assurance is called a Federal-wide Assurance (FWA).

d. Each investigator must be covered by an Assurance or execute an Individual Investigator Agreement (IIA).

e. In the conduct of collaborative/cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with the Common Rule.

f. Extramural Research.

(1) Where possible, USMA encourages reducing the burden of research oversight by supporting research involving human subjects that is conducted by another institution. The USMA HRPP will coordinate the review of the research activity with the non-DoD institution by establishing an Institutional Agreement for IRB Review (IAIR), or an Individual Investigator Agreement if the investigator is not affiliated with an assured institution. Where possible, USMA will seek to eliminate duplicate reviews.

(2) When non-exempt human subjects research is performed by USMA personnel as part of their USMA duties (e.g., in pursuit of scholarly publications for which they will be given credit as USMA personnel), USMA is engaged in the research and the USMA assurance applies.

(3) USMA employees or agents who conduct extramural human research with an external research organization must abide by the USMA Assurance.

(4) All extramural human subject research conducted by USMA persons covered by the USMA Assurance, must be reviewed by the USMA HPD to ensure compliance with applicable federal and DoD regulations and to ensure compliance with Army and USMA HRPP policy. The investigators may not recruit subjects until the research project is determined to be exempt or approved.

(5) All research conducted by external investigators must have a command support letter signed by the appropriate command authority.

(6) If the research is funded by a non-DoD agency, there are additional requirements for approval and the protocol via a HRPO review.

(7) Any non-exempt studies funded by the Department of Health and Human Services must also have a Federal-Wide assurance, including USMA.

g. Human research is considered intramural research when the PI is an employee or agent of USMA, the research is funded by USMA, or the research is conducted at USMA.

3-10 Multi-Site Research

a. USMA personnel may conduct or participate in human research at sites other than West Point. When this occurs, there must be a clear distinction of roles and responsibilities for the conduct of the research project at each site.

b. Research Protocols or requests for exemption must include each location that the associated research activity will take place. Each location must have an investigator who will be held responsible for the activities at that location. The investigator and corresponding location must be identified in the research protocol or request for exemption. There can only be one PI on the protocol and that person will ultimately be responsible for the conduct of the study by all investigators at all sites.

3-11 Deception Studies. Deception studies are systematic investigations that would leave the subject unaware or misled regarding the nature or purpose of the research. USMA accepts the need for certain types of studies to employ strategies that include deception. However, employment of such strategies must be justified. In general, deception is not acceptable if, in the judgment of the IRB, the participant may have
declined to participate had they been informed of the true purpose of the research. Deception studies are permitted at USMA but may not be considered for an exemption. USMA POM outlines the specific requirements for conducting deception studies.

3-12 International Studies
When conducting international research, additional review and documentation are required from both the international site and the IRB. It is imperative that investigators start the process early and request a consultation with the HPD during the initial planning stages as additional regulatory reviews may be required to ensure ethical conduct of the research and that host country’s customs, traditions, norms, language, and practices are considered. The USMA POM outlines the specific requirements for conducting international research.

a. All non-exempt human subjects research conducted in a foreign country by USMA faculty, staff, or students, regardless of funding source or the location at which the research will be conducted, requires a review IAW DoDI 3216.02 and must include a Component Level Administrative Review (CLAR) by the Army Human Research Protection Office.

b. Exempt studies require documentation by an official of the host entity that a local ethics review has been conducted and the host entity will support the research effort. The host document along with the protocol will be reviewed for compliance with the U.S. standards for conducting research.

3-13 Physiological Monitoring Studies
Physiological monitoring is the process of gaining greater awareness of many physiological functions primarily using instruments, equipment, or devices (equipment) that provide information on the activity of those same systems. USMA HRPP supports physiological monitoring studies when done in support of human subjects’ research.

a. Biomedical research, which involves a medical product, procedure, or intervention, including studies that fall under FDA regulations that does not solely fall within the definition of physiological monitoring may be conducted at USMA, but will be reviewed by a medical IRB.

b. Physiological monitoring studies require additional protections for the subjects and include enhanced departmental policies, investigator responsibilities, and human protections monitoring. Please see USMA POM for guidance on these duties.

3-14 Incidental Findings
In the course of conducting research which includes the use of equipment or devices which collect physiological data, it is possible that clinical findings might result which may require medical interventions. An incidental finding might be anticipated or unanticipated.

a. An incidental finding (IF) is a finding that:
   (1) Concerns an individual research subject that has potential health or reproductive importance;
   (2) Is discovered in the course of screening for, conducting, or analyzing results from research; and
   (3) Is beyond the aims of the study (i.e., occurring from variables not directly under study).

b. Federal regulations require that studies have adequate provisions for screening, enrollment screening, and data monitoring to ensure the safety of participants. In the course of carrying out these provisions, information that is secondary to the goals of the research may be identified which may impact the safety and/or well-being of the participants. PIs have an ethical obligation to participants to assess the “reasonably foreseeable” potential for IF’s, identify and assess the types of IF’s possible, and formulate procedures to be followed for disclosure to the participants. The PI has primary responsibility in this process and must be knowledgeable in identifying and assessing the types of IFs possible, and the plan and procedures to be followed for disclosure to the participants.
Chapter 4
Non-Exempt Human Research Requirements
This chapter describes requirements that apply to non-exempt human research.

4-1 The Research Protocol Packet
a. A well-developed protocol is the first line of protection of human subjects. The research protocol is a written, detailed plan by which research is to be conducted. It is submitted to the USMA portal (hrpp@westpoint.edu) for an Initial Protocol Review for completeness by either the EDO or the HPD. Once reviewed by the HPD or EDO, investigators cannot deviate from the plan without approval. If the protocol is determined to not meet exempt criteria, it will be referred to the IRB.

b. PIs are required to write a Research Protocol for each separate human subjects research project, include appropriate documentation of current human subjects research training, and include a current CV detailing their expertise for conducting the research.

c. A research protocol packet consists of the written Research Protocol and all required enclosures. USMA investigators must use one of the Research Protocol templates found on the USMA HRPP portal. Refer to the USMA POM for descriptions of all required enclosures.

4-2 Documentation of Human Subjects Research Protection Activities
a. The HPD is responsible for maintaining and tracking the records of non-exempt human research projects for a minimum of three (3) years.

b. The PI is responsible for maintaining all documentation of non-exempt, human research projects for a minimum of three (3) years after completion or termination of the study as required by the Common Rule. If the PI intends to keep the records for longer than three years, the PI must document this in the protocol, and then is required to comply with the approved protocol.

4-3 Informed Consent
a. Human subjects of research are volunteers and entitled to sufficient information concerning the project so that they may make an informed decision concerning their participation. They must understand the purpose of the study, its demands on their time, the full nature of their contribution and risks, and whether their contribution is anonymous or with attribution. They must know that their privacy will be protected, that they may refuse to reply to any question or perform any task they find objectionable, and that they may withdraw from the study at any time without prejudicial consequences.

b. Informed consent is both a process and a legal condition. It is the condition whereby a person can be said to have given consent based upon an appreciation and understanding of the facts and implications of an action. The individual needs to be in possession of relevant facts and also have unimpaired reasoning abilities at the time of consenting. Impairments of reasoning abilities that might inhibit consent include illness, intoxication, insufficient sleep, and other health problems.

c. Informed consent is a process that helps potential subjects understand the key facts of a research study and what their participation will involve. It is conducted, initially, through a structured conversation and continues informally throughout the study. Any facts discovered during the conduct of research that could affect the safety or well-being of the subjects must be disclosed to the subjects immediately. Human subjects must participate willingly, after having been adequately informed about the research.

d. In reviewing non-exempt research, the IRB must anticipate and prevent serious ethical issues resulting from consent obtained from an individual who may not be capable of giving informed consent due to:

   (1) limited facts provided to the individual,
   (2) poor mental state or physical condition at the time of consent,
   (3) coercion or undue influence, or
   (4) limited or no understanding of the facts caused by inherent characteristics of the individual.

e. For non-exempt research, the PI will ensure that informed consent is obtained from every subject or the subject’s legally authorized representative. An investigator will seek consent only after the subject
or legally authorized representative has had sufficient time and opportunity to consider whether or not to participate. An investigator will make every effort to not say or do anything that could give the perception of coercion or undue influence.

f. Documentation of Informed Consent for Non-exempt Research.

   (1) Informed consent is documented on a consent form signed in blue or black ink by the subject or legally authorized representative. The content of the consent form is more important than the format. A template is provided on the USMA HRPP portal. A copy must be provided to the person signing the consent form, if a signed consent is required. Where appropriate, a copy of the document can be published on the USMA HRPP website.

   (2) Consent documents must be clearly written and understandable to subjects. The most important information to allow the subject to make an informed decision must be presented first. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Scientific, technical, and medical terms must be plainly defined. Depending on the study population, it is often recommended that the informed consent be written at the sixth to eighth grade reading level. The consent form must be in the primary language of the subject.

   (3) All consent forms of research conducted at USMA will contain the address to the USMA HRPP website and include the email address and phone number of the HPD.

   (4) An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects according 32 CFR 219.117(c), or allow alterations to the document. The investigator must request the waiver and clearly justify the reason for the request in the research protocol.

   (5) The USMA POM includes additional guidance on the informed consent process.
Chapter 5
Independent Review Process

5-1 Overview
This chapter describes the determinations and reviews of the independent review process to provide investigators and reviewers with the purpose and methodology of each type of review.

5-2 Human Subjects Research Determination
a. Investigators involved with a research project cannot make a final determination about their own projects. This restriction is necessary to prevent issues from real or perceived conflict of interest.
b. The Exempt Determination Official (EDO) makes the official determination of whether an activity described in a Research Protocol is research, human subjects research, exempt, or must be referred to an IRB. The EDO cannot be involved in the study directly or indirectly. He or she must be objective and free from conflicts of interest.
c. The EDO must have completed the AHRPO training to be designated as an EDO. The HPD will be responsible for monitoring exempt determinations and ensuring compliance with all applicable HRPP regulations.
d. Any departmental EDO will post the exempt determination application, applicable documents, determination checklist, and approval available in the HRPP portal. Departmental EDOs may only make determinations for not research, not human subjects research, or exempt research. If a study does not completely fit one of those categories, the study must be referred to the HPD for review and processing. The HPD will include the studies approved by a departmental EDO into the master USMA HRPP research tracking document.
e. The EDO will review Research Protocols submitted by Principal Investigators and respond to the PI within ten (10) working days of receipt. The EDO verifies four criteria:
   (1) The proposed research meets the criteria for excluded activities, as defined by the DoD;
   (2) The proposed activity meets the regulatory definition of research;
   (3) The proposed activity meets the federal definition of human subjects research; or
   (4) The proposed activity meets one or more criteria for an exemption.
f. The EDO will document the determination and justification for the decision as a part of the study’s official file.
g. The EDO will notify the investigator of the decision within 10 business days.

5-3 Administrative Reviews
USMA investigators engaged in non-exempt research involving human subjects and collaborating with a non-USMA institution may rely on a collaborating non-USMA institution’s IRB if these conditions are met:
a. A Component Level Administrative Review (CLAR) must be conducted for all non-exempt protocols involving human subjects IAW DoDI 3216.02 Encl 3.3.b.(1) when any of the following conditions apply:
   (1) The research will be conducted in a foreign country;
   (2) The research involves a collaboration with a non-DoD institution and the institution is relying on the non-DoD institution’s IRB, which is not composed of Federal employees;
   (3) The research permits a waiver of informed consent under the conditions described in the regulations;
   (4) The research involves any fetal research under the conditions described in the regulations; or
   (5) The research is required to be approved by either the ASD(R&E) or head of the OSD or DoD Component under the conditions described in the regulations.
b. A Human Research Protections Official (HRPO) review must be conducted for all protocols involving human subjects IAW DoDI 3216.02 Encl 3.4.a. when contracts for DoD-supported research
involving human subjects are awarded to non-DoD Institutions. This review must include that the research meets the requirements of the Defense Federal Acquisition Regulation Supplement (DFARS) clause under the conditions described in the regulations.

c. The USMA HPD must conduct an Administrative Review of research involving human subjects to ensure it is in compliance with USMA, Army, and DoD policies and procedures prior to the USMA institution’s engagement in the research, when any of the following apply:

(1) USMA researchers have relied on a non-DoD IRB, or
(2) The research is being conducted by researchers external to USMA.

5-4 Exempt Research Determination

a. A well-developed protocol is the first line of protection of human subjects. The Research Protocol is a written, detailed plan by which research is to be conducted. It is submitted to the USMA portal (hrpp@westpoint.edu) for an Initial Protocol Review for completeness by either the EDO or the HPD. Once approved by the HPD or EDO, investigators cannot deviate from the plan without approval. If the protocol is determined to not meet exempt criteria, it will be referred to the IRB.

b. Human Research may be exempt from the requirements from the Common Rule if it meets all the criteria in one or more of the exemption categories described in 32 CFR 219.104(d). The EDO makes the official determination of exemption of human subjects research IAW 32 CFR 219.104(d). The EDO may exempt research under the following conditions:

(1) The EDO has no conflict of interest with the research project;
(2) The EDO is not involved directly with the research project;
(3) The Principal Investigator is not a superior or subordinate of the EDO; and
(4) Studies determined to be otherwise exempt but require a Limited IRB Review (exempt categories (2)(iii), (3)(i)(C), (7), and (8)), are forwarded to the IRB.

c. The primary duty of the EDO and IRB is to protect potential human subjects, regardless of the effect their decisions may have on the sponsor’s or the investigator’s plans. Therefore, they always err on the side of caution to ensure complete protection of human subjects. It is prudent to be risk averse when considering safety during research activities. If the category of a particular research project is ambiguous, the investigator should always be prepared to have a more thorough IRB review.

d. The investigator completes a Research Protocol and submits the request for determination to the USMA portal according to established procedures.

e. The data belong to USMA and may not be shared, transferred or exchanged with anyone outside of the research team without prior authorization. If any aspect of the study is changed or altered, the investigator is responsible for notifying the HPD prior to implementing the modifications.

f. The investigator is responsible for notifying the EDO or HPD of any changes to the protocol prior to implementing any modifications, unless the modifications are required for the immediate health, safety, or security of the subjects.

g. Exempt research does not require an annual continuing review or closure report.

5-5 Initial Protocol Review for Non-Exempt Studies

The initial review of a protocol is one of the most powerful tools for protecting research participants, because when used appropriately, it can prevent problems before the research begins. The role of the IRB is to provide participant protection through the careful ethical review of protocols, both at the outset and during the progress of a research project. All human subjects research which does not meet the criteria for exemption will be submitted IAW the reviewing IRB’s procedures.

5-6 Regulatory Review

The objective of this protocol review is to ensure the safe and ethical conduct of research and that human subject interests are fully recognized, represented, and protected. It is important that the ethical principles of respect for persons, beneficence, and justice are addressed in the Research Protocol and will be upheld during the conduct of the research.
a. The IRB provides the initial and periodic review of all non-exempt human subjects research studies. It has the “authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy, including exempt research activities under 32 CFR 219.104 for which limited IRB review is a condition of exemption (under 32 CFR 219.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8))” (32 CFR 219.109(a)).

b. The IRB ensures that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in a research study. An IRB reviews Research Protocols and related materials (e.g., informed consent documents and recruitment letters and brochures) to accomplish this purpose.

(1) The investigators must complete and submit at a minimum, a Research Protocol, an informed consent document or a request for a waiver, a scientific review conducted by an expert on the research but not connected to the research team, evidence of current human subjects research training from each investigator, a financial conflict of interest affirmation from each investigator, a current CV/resume (or transcript, if from cadets) from each investigator, and all pertinent study documents.

(2) If the study is funded from any source external to USMA, provide the Grant Application Proposal.

(3) If the study is a sponsored protocol, provide the original Sponsor Protocol

(4) If the study is multi-site and USMA is not the lead site, provide approval letters, minutes, amendments, continuing reviews, and any other relevant approval documentation from the other institutions. An IAIR (for sites with an FWA) or IIA (for individual agreements) may be required.

(5) If the study includes recruitment of study participants, provide advertisement flyers, e-mails, letters of support, information sheets, telephone scripts, and/or any study information that will be given to study participants.

(6) If the study includes devices or equipment for physiological monitoring, provide the departmental policy on human subject testing that includes the specific policy related to the safe operation of the device(s) proposed to be used in the study, and training/certification (if required).

d. The purpose of a scientific review is to consider the scientific merit and ensure sound research design.

(1) The scientific review form is provided with the CAIRB non-exempt materials.

(2) Scientific reviews must be conducted by an expert in the field of study with extensive knowledge of the research procedures. The person may be internal to USMA, as long as the person is not a member of the research team and does not have a conflict of interest with the project. It is the investigator’s responsibility to secure the reviewer.

(3) The reviewer is expected to give a thorough, thoughtful, and honest synopsis of the study with particular attention to the potential risks and benefits with an analysis of the methodology. The reviewer’s expert opinion will be important to the IRB deliberations.

e. By ensuring that properly constituted bodies review protocols for scientific merit and freedom from conflicts of interest, the IRB can focus its efforts on assessing whether the research protocol meets the ethical requirements and criteria specified in regulation and the reviewing IRB’s policy.

f. Expedited Review

(1) An expedited review is an IRB review by one or more IRB members outside of the convened meeting. In order to qualify for an expedited review, the study must meet one or more of the expedited criteria and be determined to be not greater than minimal risk. The Chair of the IRB or designated representative determines whether a study qualifies for expedited review. Refer to the reviewing IRB’s procedures for further criteria required to qualify for expedited review.

(2) Refer to the reviewing IRB’s procedures for a detailed description of its expedited review process.

g. Full Review.

(1) A full review means that proposed research is reviewed “at a convened meeting at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas.” (32 CFR 219.108(b))
(2) The IRB review is conducted IAW 32 CFR 219.109 IRB Review of Research. Proposed research is approved if the majority of members present agree that it meets all seven criteria found in 32 CFR 219.111 Criteria for IRB Approval of Research. At the conclusion of the review, the IRB makes one of the following determinations:

- Requires modification (to secure approval),
- Approval with modifications,
- Approval, or
- Disapproved.

(3) Refer to the reviewing IRB’s SOP for further criteria and procedures involved in the ethical review.

(4) Upon receipt of certification of IRB approval, the PI may begin the recruitment and enrollment of the research.

h. Research that has been approved by an IRB is subject to further appropriate review and approval or disapproval by the IO. The IO may not approve research if it has not been approved by an IRB.

5-7 Continuing Review

a. A continuing review may be required depending on the nature and duration of the project. The need and frequency of this review is determined by the IRB during the initial ethical review of the protocol. The IRB notifies the PI of this requirement in the written approval of the protocol.

b. The IRB shall conduct continuing review of research covered by this regulation at intervals appropriate to the degree of risk, but not less than once per year. The investigator must provide a memorandum to the IRB Administrator that contains a narrative progress report before the IRB meets to conduct the continuing review of the protocol.

c. The IRB may use the expedited review process to review modifications, which involve minor or administrative changes in previously approved protocols during the period for which approval is authorized. Minor changes are changes to an approved protocol, which do not affect the treatment, comfort, or degree of risk to the subject.

5-8 Annual Administrative Status Review

a. All non-exempt studies for which a continuing review is not required shall submit an annual administrative status review at the end of the academic year. This requirement is outside of the parameters of the IRB requirements.

b. The administrative status review will confirm the status of the study (open to active enrollment, open for data analysis, closed – study complete.) This form can be found on the HRPP website.

5-9 Amendment or Modification Review

a. An amendment review is required whenever the PI wants to make a change to a previously approved protocol. A written certification of IRB approval is required prior to implementing any changes, unless an immediate change is required to protect the safety of the subjects. In that case, the PI must notify the HPD and IRB of the change as soon as possible.

b. The IRB may use the expedited review process to review modifications, which involve minor or administrative changes in previously approved protocols during the period for which approval is authorized. Minor changes are changes to an approved protocol, which do not affect the treatment, comfort, or degree of risk to the subject. An example is the addition, removal, or change of an investigator.

5-10 Closure Report

a. If the investigators have completed all active data collection, completed all data analysis, have submitted for publication or presentation, or otherwise have concluded, a closure report must be provided to the HPD.
b. Investigators are required to keep study documentation for a minimum of three years (or as determined by the IRB) once the study has concluded.

c. Once the study has concluded, the data must be destroyed or de-identified, per IRB policy or guidance.
Chapter 6
Use of Cadets as Human Subjects
Extra care and appropriate oversight are required when cadets are used as human subjects. Cadets are considered a vulnerable population under the USMA HRPP. Their unique situation makes them vulnerable to coercion and undue influence. It exposes them to an abundance of solicitations to volunteer because of the convenience for researchers to obtain information from them and about them. The access to their personal information by faculty and staff also exposes them to higher risk of invasion of privacy and breach of confidentiality.

Institutional officials and investigators are both responsible for ensuring that cadets are not being coerced, unduly influenced, and that the demands of research-related tasks do not interfere with a cadet’s performance in the academic, military, and physical programs. Additional safeguards must be considered to protect cadets and studies must be carefully scrutinized to prevent either intentional or unintentional coercion, undue influence, or misuse/abuse of cadet time.

6-1 Cadet Rights
All cadets must be informed, prior to enrollment, that they have the following rights:

a. In accordance with the principles of free and informed consent, privacy, and confidentiality, and in consideration of the vulnerable nature of cadets as subjects, cadets have the right to a consent form that addresses key points of the study and informs them about the nature of the study.

b. Cadets have the right to be free from any coercion or bias that might result when a researcher is also evaluating them in a course.

c. Cadets have the right to privacy of personal information.
   (1) USMA may not supply a researcher with the names of cadets for research purposes.
   (2) A researcher with knowledge of cadet names as a result of teaching or other Academy-related activity may not use that knowledge to generate a list of cadet names for research purposes.
   (3) Sign-up sheets for research may not be used.
   (4) Cadet health and medical information are considered protected data and may only be used for research according to applicable laws and regulations guiding the use and dissemination of health information.

6-2 Use of Cadet Time
   a. The ethical principle of beneficence in The Belmont Report states that “persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being” (National Commission, 1979). Securing the well-being of cadets includes protecting the time they have available for their studies and other required duties.

   b. Cadets are commonly used as human subjects for various purposes. This is partly because of the convenience of obtaining data on such a controlled population. Unfortunately, this puts a strain on their available time and may hinder their successful performance and ability to graduate. It is necessary to protect the cadets from unnecessary use and overuse as subjects for this reason.

   c. Cadets are required to complete a number of surveys throughout their time at USMA. Each of these surveys takes very little time to complete. However, the accumulated time of all the surveys places a significant burden on the cadets. Therefore, the smallest possible sample sizes must be used that yield statistically valid results and a careful determination of time requirements must be undertaken in order to minimize the impact on the Cadet Corps.

   d. Class/training time may not be used for data collection for research, unless the research is about the practice of teaching and learning. This research includes those activities conducted in established or commonly accepted educational settings that specifically involve 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.
6-3 Research During Class/Training Time
a. Cadets have the right to have class/training time devoted to learning activities appropriate to meeting the objectives for the scheduled course. USMA prohibits the use of class/training time for the investigator’s research activities that are beyond the practice of teaching and learning. A cadet can participate in the research activity without having his or her responses included in data used for research by withholding their consent or saying at the onset that their data may not be used for research.

b. Unless the research question is directly related to class/training material, is directly related to improving the practice of teaching and learning, or the study process is being used as a teaching opportunity such as in a research methods class, the use of class time to recruit subjects or class time used to complete study instruments is prohibited.

c. Exceptions to policy are at the discretion of the MAD.

6-4 Obtaining Approval for the Use of Cadet Time
Research involving cadet participation as human subjects must be approved by a designated USMA Official with command authority prior to being implemented. These officials determine whether the time requested is reasonable or may hinder a cadet’s performance in a particular program. They may approve the time requested, disapprove the research, or designate alternate time periods for the research to be conducted.

6-5 Avoiding Coercion and Undue Influence
a. An underlying principle of the regulations governing the involvement of human subjects in research is that the subject’s participation is voluntary and based upon full and accurate information. The voluntary aspect must be carefully scrutinized when cadets are involved. Cadets are considered a vulnerable population because of their susceptibility to coercion and undue influence. Cadet and faculty researchers should take care to avoid the unintentional or subliminal coercion or undue influence that may occur when potential subjects are cadets.

b. Faculty researchers, in particular, must avoid involving their own students as research subjects. Faculty who wish to involve their own students as subjects should be able to provide a valid reason, other than convenience, for selecting those students as subjects. Exceptions to policy may be granted by the appropriate command authority.

c. Faculty researchers should seek another population of subjects that are equally suited to the research question (e.g., another class section not taught by the researcher, recruitment by another instructor, or blinded/coded data collected by an associate so that subjects are not identified to the instructor). Students must be given an opportunity to decline participation without feeling as though their academic grades are in jeopardy.

d. A cadet subject’s current instructors, members of his or her cadet chain of command, his or her coaches, and his or her tactical officers, cannot be present during any recruitment or informed consent activities not related to the practice of teaching and learning.

e. If cadet subjects feel they have been coerced to participate in a study, they should immediately inform the USMA HPD, the IRB, or the Inspector General.

6-6 Extra Credit
a. Extra credit can be given to students who participate in a research project only when alternative means of obtaining equivalent extra credit with equivalent effort is made available to students who do not wish to volunteer as research subjects.

b. If extra credit is used as an incentive for cadets to participate in research, the combined total of all extra credit a cadet receives from participation in one or more research projects must not exceed 1% of the overall course grade.

c. Cadet “Subject Pools”
(1) "Subject pools" are often used where students enrolled in introductory courses are recruited by investigators from within an academic department for participation in research projects. The department may impose its own standards for the type of research that may be conducted in this setting and specify who may have access to such subjects and how access is obtained.

(2) Investigators who recruit from "subject pools" are required to include the subject pool policies and procedures with a non-exempt Research Protocol when they submit their research study to the IRB for review and approval.

d. Beyond the considerations outlined above, academic departments may impose their own additional constraints on using cadets as research subjects. The possibility of coercion of cadets (grades, extra credit, faculty pressure, etc.) must be addressed and avoided.

6-7 Use of Cadet Data in Research

a. Private, identifiable cadet data may only be used in research if the project is solely for internal assessment or quality improvement, or if the protocol has received an appropriate review and approval.

b. Cadet health and medical information are considered protected data and may only be used for research according to applicable laws and regulations guiding the use and dissemination of health information.
Chapter 7
Compliance Monitoring
USMA personnel are expected to comply with the provisions of the Common Rule (32 CFR 219) and this regulation in both letter and spirit. This strict adherence is necessary to provide uniformity in the implementation of the USMA HRPP and to create conditions that will promote public trust.

7-1 Monitoring of the Informed Consent Process
The HPD may evaluate the research participants’ understanding of research studies through monitoring of the informed consent process. This may be accomplished using a small test group from the sample to be studied. The test group will be asked questions about the informed consent process and their understanding of the proposed research.

7-2 Serious or Continuing Non-Compliance
Noncompliance refers to a failure (intentional or unintentional) to follow the regulations, institutional policies governing human subject research, or requirements of or determinations by the IRB by the investigators or research staff, or any member of the Human Research Protection Program, including the IRBs or IRB administrative staff. Serious noncompliance refers to actions that intentionally or unintentionally place the health, safety, or confidentiality of subjects at unnecessary risk.

a. Continuous noncompliance refers to repeated noncompliance that indicates a concern about the competency of the investigator to continue to conduct research.

b. Serious or continuing non-compliance with this regulation that is attributed to systemic factors may lead to the cessation of all human subjects research at USMA until appropriate corrective measures are taken.

7-3 UPIRTSOs

a. A UPIRTSO (Unanticipated Problem Involving Risks To Subjects or Others) is any incidence, 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 informed consent document) and the characteristics of the human subject population being studied;

(2) Is related or possibly related to participation in the research; and

(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.

b. UPIRTSOs that Impact Safety. USMA investigators must report any UPIRTSO that impacts the safety of subjects or others to the USMA HPD within 24 hours (via phone message, e-mail, or written report). This should be followed by a more comprehensive written report within 7 to 10 business days. The USMA HPD will notify the IRB Chair within 24 hours of receiving the initial verbal report.

c. UPIRTSOs that DO NOT Impact Safety. Investigators must report any UPIRTSO that does not impact the safety of subjects or others to the USMA HPD in a timely manner (within 10 business days).

7-4 Adverse Events

a. An Adverse Event (AE) is any abnormal, untoward, or unfavorable physical psychological, social, legal, or economic occurrence in a human subject, including any abnormal exam or test result, symptom, or disease, occurring during or in close proximity to the end of the subject’s participation in the research, whether or not considered related to the subject’s participation in the research.

(1) Anticipated adverse events are those events that pose a risk to subjects but are identified and mitigated in the protocol.

(2) Unanticipated adverse events are those events that are not identified in the protocol.

b. A Serious Adverse Event (SAE). An adverse event is considered serious if the subject dies, is at substantial risk of dying (whether at the time of intervention or as a result of continued intervention), is
hospitalized, becomes disabled or otherwise permanently harmed, or when other intervention is required to prevent permanent harm to the subject.

c. PIs must report all AEs to the IRB/HPD at the time of Continuing Review (for non-exempt research) and within 10 business days (for exempt research). The Principal Investigator must report SAEs with 24 hours to the HPD and IRB, including incidents involving the use of equipment and devices in research.

7-5 Deviations
a. A deviation indicates that there has been a departure or change (intentionally or unintentionally) from the originally approved protocol’s study methods or procedures.
b. Deviations must be reported to the HPD/IRB promptly following the PI’s knowledge of the event.

7-6 Academic Misconduct
USMA promotes the integrity of research conducted under its purview. MADs shall foster integrity in research activities and respond to allegations of research misconduct consistent with applicable laws and regulations. DoDI 3210.7 specifies detailed procedures and standards for the DoD for the prevention of research misconduct. Academic misconduct that is found or suspected, will be investigated IAW the procedures in DPOM 5-1 Annex B. Investigators found to have committed research misconduct may have their research privileges suspended and may be subject to other disciplinary actions.

a. Investigators and human subjects should report ethical violations, coercion of subjects, misleading of subjects, research misconduct, or other issues that a subject may find offensive or wrongful. Report and address concerns with the investigator’s supervisor, the IRB Administrator, the USMA HPD, the EDO, or the Inspector General’s office. Their contact information is found on the HRPP website.
b. No one should be prevented or discouraged from reporting suspected research misconduct. Personnel who are prevented from reporting misconduct or who have been threatened with reprisal for reporting or preparing to report misconduct should report such incidents to the Inspector General.
c. All federal employees are protected by the Whistleblower Protection Act (5 USC §1221(e)) and may file a complaint if they receive a negative personnel action for reporting research misconduct. Military personnel, including cadets, should consult DoD Directive 7050.06, Military Whistleblower Protection.
d. The authority to review and act on allegations of research misconduct by DoD employees or others working in DoD facilities (other than contractor employees or consultants) shall be placed at the lowest possible organizational level that allows an independent, unbiased, and equitable process. However, AHRPO has the right to exercise authorities that otherwise would be delegated to USMA.
e. The Dean of the Academic Board is responsible for gathering, reviewing, and determining appropriate misconduct-related information and documentation using appropriate USMA and Army investigative processes.
f. Investigative procedures must minimize disruption to research in process unless the research misconduct could result in a threat to public health or safety.
g. USMA may use existing procedures for intramural research institutions as long as they comply with the minimum regulatory requirements. This policy is not intended to supersede current civilian or military personnel management authorities.
h. USMA may use any available resources to respond to allegations of misconduct, including their Office of the Inspector General, legal counsel, and expert consultants.

7-7 Post Approval Compliance Monitoring
The HPD (or designees) will conduct both for-cause and routine (not-for-cause) post-approval compliance monitoring activities on an ongoing basis.
a. For-cause research audits are usually based on “red flags.” Examples of red flags include but are not limited to reporting of a high frequency of research project deviations, investigators who repeatedly miss deadlines, or investigators who submit poor quality documents. Issues can be identified through review of the research project or research project life cycle actions, through information obtained on similar studies
or studies conducted by the same PI, and through reporting of concerns to the IRB. A for-cause audit may stand alone or be initiated as part of an investigation into allegations of noncompliance. The HPD will notify the PI and the IO of the pending audit.

b. Not-for-cause audits will typically be routinely scheduled audits. The routine audit schedule will be based on such factors as the length of time since the last assessment and the risk level of research projects. The HPD will randomly select a representative sample of open, active exempt, and non-exempt research projects for audit, ensuring that no one investigator is chosen for more than one routine research audit. Based on audit findings during the audit, the number of research projects audited may be increased or decreased as needed to fully evaluate regulatory compliance.

c. HPDs (or designees) will notify PIs and the IO of intent to conduct compliance monitoring audits. USMA audit checklists and other information to aid the PI in preparation for the assessment.

d. Checklists or other documentation will be completed for all audit activities. At the conclusion of the assessment, the audit lead will complete a detailed report that summarizes audit findings and any recommended or required corrective actions. The report will be provided to the IO, HPD, and PI. Any required follow-up actions will be tracked to ensure timely resolution.

e. Any audit may include review and assessment of record management (e.g., PI master file, subject source documents, training records), informed consent/assent processes and related documents, subject eligibility, site regulatory administration, staff qualifications, research project compliance, subject protection measures, equipment audits, and adverse events. It may include observation of the informed consent process or research procedures and interviews with investigators and research staff, and research subjects.

f. The auditor(s) will provide on-the-spot feedback and education to PIs and research teams during audit/assessment activities.

g. At the end of the audit, the findings of the audit team, with any recommended corrective actions, will be provided to the PI, HPD, and the IO (and other parties as appropriate, such as the IRB).

h. If the audit raises urgent safety or regulatory concerns, the audit team will notify the IO and HPD (and, if non-exempt, the IRB) immediately to determine if a hold on new enrollment or research suspension is warranted pending further review of the audit report. Otherwise, the IRB of record will be informed of any findings and any recommended corrective actions at the subsequent IRB meeting.

i. Upon review of the audit report, the HPD may determine that additional actions are necessary. These actions could include but are not limited to suspension or termination of the research, training for the PI and research personnel, or further investigation and consideration regarding serious and/or continuing noncompliance.

j. If the audit raises urgent safety or regulatory concerns, the auditor(s) will notify the IO and HPD (and, if non-exempt, the IRB) immediately to determine appropriate actions to protect human subjects.
GLOSSARY

Abbreviations

AMEDD
Army Medical Department

AHRPO
Army Human Research Protection Office

CFR
Code of Federal Regulations

DA
Department of the Army

DHHS
Department of Health and Human Services

DOD
Department of Defense

EDO
Exempt Determination Official

FWA
Federal-Wide Assurance

HPD
Human Protections Director

HRPP
Human Research Protection Program

IR
Institutional Research

IRB
Institutional Review Board

KACH
Keller Army Community Hospital

MAD
Major Activity Directorate

OMB
Office of Management and Budget

OTSG
Office of the Surgeon General
PI
Principal Investigator

RDTE
Research, Development, Test, and Evaluation

SOP
Standard Operating Procedures