

Human Research Protections Program (HRPP)

*Approved
by the
Academy
Board of
Regulation
Review*

**Headquarters
United States Military Academy
West Point NY 10996-1197
1 December 2025**

UNCLASSIFIED



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***USMA Regulation 70-25**

Effective 1 December 2025

Human Research Protections Program (HRPP)

By Order of the United States Military Academy
Superintendent:

Official:

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Lieutenant General, United States Army
Superintendent


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Colonel, United States Army
Chief of Staff, USMA

History. This regulation is a minor revision and supersedes USMA Regulation 70-25, Human Research Protections Program (HRPP) dated 10 February 2025. The portions affected by this revision are listed in the summary of change.

Summary. This regulation specifies responsibilities and procedures for the conduct and coordination of human subject research at the United States Military Academy (USMA).

Authorities. The authorities for this regulation are Title 32, United States Code, Part 219, Protection of Human Subjects; DoDI 3216.02.

Applicability. This regulation applies to USMA under the authority of the Superintendent in his capacity as the Institutional Official (IO) for the HRPP, as recognized under USMA's DoD Assurance to conduct human subject research. This program excludes West Point tenant units and activities, which are not covered under the DoD Assurance, except as specifically mentioned herein.

Proponent and exception authority. The proponent of this regulation is the USMA HRPP.

Suggested Improvements. Users are invited to send comments and suggested improvements to HRPP@westpoint.edu.

Distribution. This regulation is available in electronic format only.

*Expiration date of this Regulation: until superseded or rescinded.

SUMMARY of CHANGE

USMA REG 70-25

Human Research Protections Program (HRPP)

This minor revision, dated 1 December 2025

- Removed references to the Collaborative Academic Institutional Review Board (CAIRB)
- Removed special requirements for research that includes physiological monitoring, previously required by the CAIRB
- Removed requirement for Cadet researchers to submit a CV or biosketch with protocol submissions
- Removed requirement for external researchers listed on a protocol to submit a signed data sharing or data use agreement
- Added a requirement for external researchers to submit an External Researcher Agreement
- Added conduct investigation and honor board data (previously prohibited in other USMA regulations and policies) to a list of data prohibited for use in research
- Removed references to the 2018 Common Rule revisions
- Updated references to "End of Academic Year Annual Report" to be consistent throughout the regulation
- Removed several figures and appendices that are now more appropriately shared on other platforms
- Updated language to be consistent with the updated DoDI 3216.02
- Updated office names to reflect recent USMA organizational changes
- Updated language to comply with recent Executive Orders

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Chapter 1

Introduction

The Human Research Protections Program (HRPP) is the United States Military Academy's (USMA) system of interdependent elements that implements policies and practices to protect human subjects participating in research. The HRPP includes the personnel, policies, procedures, and practices to review, monitor, and support research for ethical and regulatory compliance. The USMA Institutional Official (IO) delegates authority to the Alternate Institutional Official (AIO) to execute some actions related to the HRPP. (See section 3-1.c. for a list of delegable actions.) The IO delegates oversight responsibility for the HRPP to the USMA Human Protections Director (HPD), who has a comprehensive knowledge of all aspects of the institution's systematic protections for human subjects and is the institutional expert on human subject research issues.

1-1. Purpose of the HRPP

- a. The USMA HRPP facilitates West Point's human subject research program in a safe, efficient, effective, and legal manner.
- b. The HRPP outlines specific policies and procedures for the execution of human subject research at USMA. USMA will operate under a DoD Assurance and ensure compliance with federal, state, Department of the Army (DA), DoD, and USMA regulations, laws, and policies for human subject protections. These protections extend to the participants' rights, privileges, and privacy; mental and physical health; and emotional well-being.
- c. The HRPP assigns roles, responsibilities, and training requirements for all personnel who participate in or support research at USMA.
- d. The HRPP explains the procedures and requirements for the entire review process including submission, review (scientific, regulatory, and ethical), and post-approval compliance monitoring. The HRPP describes additional reviews that may be required for certain types of research.
- e. The HRPP describes the unique characteristics of USMA as an institution and Cadets and military service members as participants and how these impact the review, approval, and execution of research at USMA.
- f. The HRPP lists the requirements for conducting research with external organizations.
- g. The HRPP describes best practices and requirements for data management related to the conduct of human subject research.
- h. The HRPP ensures accurate and comprehensive transition of HRPP responsibilities and duties when there is a change in the IO, AIO, or HPD.

1-2. References

See Appendix A for the list of references.

1-3. Associated Publications

The following publications govern the execution of research at USMA. This regulation is nested within and is not intended to conflict with any of the following:

- a. 45 CFR 46, *Protection of Human Subjects*
- b. 32 CFR 219, *Protection of Human Subjects*
- c. DoDI 3216.02, *Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research*
- d. Army Regulation 70-25, *Use of Volunteers as Subjects of Research*

1-4. Responsibilities

See section 3 for the roles and responsibilities.

1-5. 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. To conduct comprehensive review of research protocols (including scientific, conflict of interest, and ethical reviews);
- b. To ensure ethically sound participant-investigator interactions;
- c. To provide ongoing (and risk-appropriate) research monitoring throughout the conduct of the study; and
- d. To execute education and quality improvement activities.

1-6. Scope and Applicability

e. This regulation applies to the United States Military Academy including the Office of the Superintendent, Office of the Dean of the Academic Board, Office of the Commandant, Directorate of Admissions, Office of the Directorate of Intercollegiate Athletics, United States Military Academy Preparatory School, and the USMA Band. These agencies report directly to the Superintendent, USMA, in his capacity as the IO for the HRPP, as recognized under USMA's DoD Assurance to conduct human subject research. This regulation applies when personnel in these organizations are investigators, research staff, or human subjects. This program excludes West Point tenant units and activities, which are not covered under the DoD Assurance. Some tenant units have their own HRPP or may be covered under their higher unit's HRPP (e.g., Keller Army Community Hospital).

f. The following types of research will not be conducted or 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; or
- (2) Research involving prisoners of war as subjects (in accordance with DoDI 3216.02 4.4.2).

1-7. Guiding Principles

a. Human subject protection is an institutional responsibility. This HRPP outlines USMA's 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 research participant.

b. USMA recognizes the rights and welfare of human subjects and ensures they are adequately protected.

c. USMA subscribes to the Belmont Report which was written in 1979 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This National Commission was established following the exposure of unethical methods used in the Tuskegee Syphilis Study. The Belmont Report outlines three basic principles of conducting ethical research with human subjects:

- (1) Respect for persons (applied in ways such as obtaining informed consent, considering privacy and confidentiality, and adding protections for vulnerable populations or those with diminished autonomy);
- (2) Beneficence (applied, for example, by weighing risks and benefits); and
- (3) Justice (applied, for example, by the equitable selection of subjects).

d. USMA will comply with all applicable federal, state, DoD, DA, and USMA laws, regulations, and policies.

e. 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. USMA actively promotes ethical research by conducting thorough and timely reviews of research proposals with appropriate feedback to investigators. It also promotes ethical research by disapproving proposals that fail to meet federal, state, DoD, DA, and USMA standards for quality research or that place participants at unnecessary risk.

1-8. Organization Statement

a. *HRPP Mission.* To provide education and support for Cadet and faculty research and to foster collaborative relationships with external researchers and regulatory partners while ensuring compliance with all applicable regulations.

b. *HRPP Vision.* USMA HRPP is a community of Cadets, researchers, and administrators with diverse backgrounds and perspectives who collectively produce high-quality research, while striving to meet high ethical standards.

c. *HRPP Core Values.*

- (1) Justice: Sharing the benefits and risks of research among participants in an equitable manner
- (2) Respect: Treating all individuals with dignity
- (3) Vigilance: Considering the potential experience of research participants and all possible outcomes
- (4) Service: Prioritizing efforts to facilitate research execution
- (5) Education: Maximizing proficiency of the USMA research community through outreach and effective communication

1-9. Organizational Structure

a. The HRPP involves a system of interdependent components (Figure 1-1) that design, review, support, and oversee human subject research. The key components are:

- (1) Human subjects participating in research;
- (2) Institutional leaders, including Department Heads and Center Directors, who provide the vision and support for high-quality research programs and the leadership to foster a culture of ethical research;
- (3) Investigators who design and conduct ethical research, and analyze data and report results;
- (4) Independent reviewers who assess the scientific merit and validity of the research;
- (5) Exempt Determination Officials who review research that does not require IRB review (or requires Limited IRB Review) and ensure participants are protected;
- (6) The IRB, which is responsible for reviewing the ethical integrity of non-exempt research (see section 6-6) and for keeping the participants' rights and safety as top priority;
- (7) Independent monitors of research; and
- (8) Higher-level oversight for the application of all governing regulations.

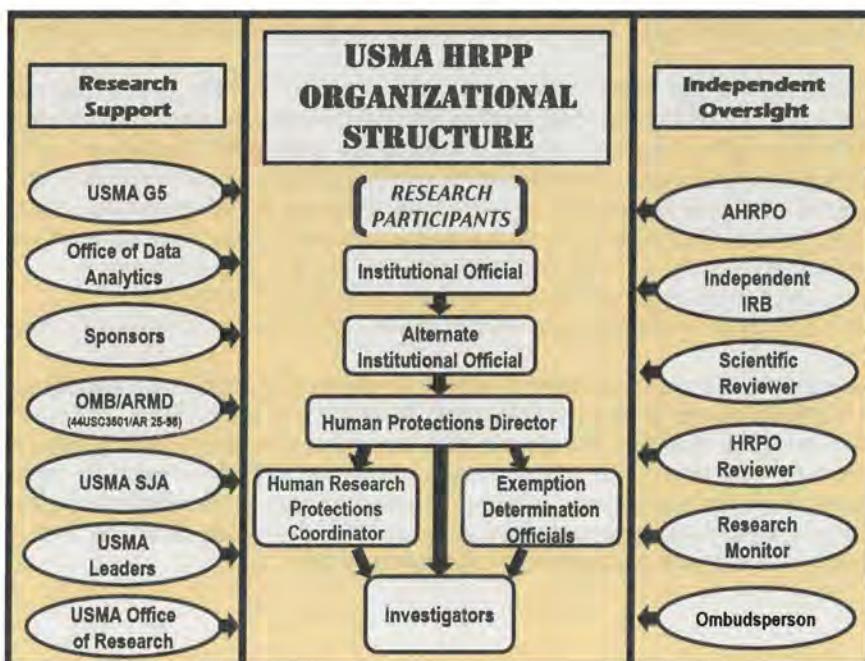


Figure 1-1. USMA HRPP Organizational Structure (See Glossary of Terms for explanation of terms.)

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 organization leaders.

(3) The USMA HPD will coordinate closely with the USMA Office of Research to ensure both academic and institutional research policies support the HRPP.

Chapter 2

USMA Assurance

2-1. Scope of the USMA Assurance

a. An Assurance of Compliance is an official legal document in which an institution, not an IRB, commits to a federal department or agency its compliance with the requirements set forth in the Common Rule (32 CFR 219.103). It assures that all activities related to human subject research be guided by the ethical principles set forth in the Belmont Report and comply with all federal regulations.

b. Assurances are approved by either the Department of Defense (DoD) or Department of Health and Human Services (HHS). DoD institutions proposing to engage in non-exempt human subject research must have a DoD Assurance prior to the recruitment of human subjects. All Army institutions engaged in non-exempt human subject research must have a DoD Assurance approved by the Secretary of the Army who has delegated authority to The Surgeon General (TSG) of the Army. All USMA employees and agents reporting directly to the USMA Superintendent, conducting or collaborating in human subject research, operate under this Assurance. See section 1-6 for a complete description of the parameters of the USMA Assurance.

c. Approval of an Assurance requires a written HRPP (this document) and, if the institution conducts non-exempt human subject research, an IRB registered with the Army Human Research Protections Office (AHRPO) and a written IRB Standard Operating Procedures (SOP). The Collaborative Academic Institutional Review Board (CAIRB) was convened in August 2016 and was disbanded in December 2023. USMA currently relies on other institutions for the IRB review of non-exempt research.

d. The Institutional Official (IO) signs USMA's Assurance. At USMA the IO is typically the Superintendent. Whenever an IO is replaced, the Assurance must be updated and sent to 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 USMA HRPP within 30 days of the arrival of the new IO.

e. The IO can delegate some actions to the Alternate Institutional Official (AIO) who, at USMA, is typically the Dean of the Academic Board.

f. The HPD is appointed by the IO to be the primary point of contact for the USMA HRPP and to play a key role in ensuring that the institution fulfills its responsibilities under the DoD Assurance. The HPD will exercise operational responsibility for the HRPP and oversee the HRPP to ensure all human subject research is conducted in accordance with applicable federal, DoD, DA, and USMA regulations.

g. Whenever there is a significant change to the USMA HRPP – such as a change in USMA IO, AIO, or HPD, new policies or procedures, new Institutional Agreements for IRB Review (IAIR), or new Memoranda of Agreement or Understanding (MOA/MOU) – notice of the change together with a copy of the new documents will be sent to AHRPO for the official USMA Assurance file. Before a new USMA HPD can be appointed by the IO, the prospective USMA HPD must complete education and training, must be approved by 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.

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

2-2. Institutional Agreement for IRB (IAIR) Review

a. An IAIR is a formal agreement between two or more institutions, signed by all parties, to establish which institution will be the IRB of record and to outline the responsibilities of each.

b. In accordance with (IAW) the Common Rule, IRB review should be conducted by a single IRB, to reduce the burden of research oversight.

c. There are many factors that influence which IRB will be the IRB of record including the Principal Investigator's (PI) institution, the nature of the research, and the risks to participants.

d. When collaborating with non-DoD institutions USMA may rely on the non-DoD institution's IRB if all the following conditions are met:

- (1) USMA determines the non-DoD institution has an appropriate federal Assurance or that a federal Assurance is not required;
- (2) The non-DoD institution's IRB is registered in accordance with Subpart E of 45 CFR 46;
- (3) USMA completes an administrative review of the protocol to ensure all applicable local and DoD requirements are addressed in the protocol (see section 7-6 for a complete description of this review);
- (4) USMA and the non-DoD institution (including if the non-DoD institution uses an independent IRB) enter into an IAIR specifying that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02;
- (5) AHRPO approves the agreement to rely on the non-DoD institution's IRB; and
- (6) USMA, while conducting research in collaboration with non-DoD institutions with or without DoD support, complies with all requirements in DoDI 3216.02 pertaining to DoD-conducted research.

e. IAW DoDI 3216.02 1.2.j., AHRPO has the authority to determine and document that the use of a single IRB is not appropriate for the particular context of the proposed study.

f. If USMA is the lead site for a non-exempt study and there are investigators from other institutions engaged in the research, an executed IAIR is required, unless both institutions are within the DoD.

2-3. Individual Investigator Agreement (IIA)

An IIA is a formal agreement between an institution and an individual who is not otherwise affiliated with an assured institution to establish that the individual is covered by the institution's Assurance. The agreement describes the responsibilities of an individual investigator who is engaged in human subject research for the purpose of conducting research. The IIA must be executed before research can begin. Each investigator must be covered by an Assurance or must execute an IIA.

Chapter 3

Roles and Responsibilities

3-1. Institutional Official (IO)

- a. Traditionally, the USMA Superintendent serves as the IO.
- b. The IO:
 - (1) Signs the DoD Assurance for the Protection of Human Subjects and bears full responsibility for the conduct of research covered by this Assurance in compliance with applicable federal, state, local, and international laws and requirements;
 - (2) Evaluates and approves the USMA Human Research Protections Program (HRPP) and standard operating procedures (SOPs) in compliance with DoDI 3216.02;
 - (3) Enforces compliance with the terms of the Assurance and the HRPP through a program of post-approval compliance monitoring of human subject research;
 - (4) Designates a HPD as the primary point of contact for the Institution's HRPP; and
 - (5) Provides resources to execute the institution's HRPP, including experienced, well-qualified HRPP staff, continuing education and training for personnel involved in the HRPP; meeting space for the IRB; and staff sufficient to support HRPP functions such as determinations, IRB review, scientific review, compliance monitoring, record-keeping, and oversight of research.
- c. The IO can delegate the following activities to the Alternate Institutional Official (AIO):
 - (1) Appointing or suspending IRB members and chairs;
 - (2) Appointing Exemption Determination Officials (EDO);
 - (3) Periodic evaluations of IRB members;
 - (4) Ensuring IRB members and support staff are trained;
 - (5) Recruiting qualified IRB members including nonscientist and unaffiliated;
 - (6) Overseeing IRB operations;
 - (7) Reviewing and signing research and IRB agreements;
 - (8) Being the point of contact (POC) for IRB correspondence;
 - (9) Being the POC for federal and Army regulators for routine queries;
 - (10) Exercising authority to receive IRB determinations of noncompliance, initiate additional investigations, and mandate corrective action plans;
 - (11) Ensuring investigators are trained;
 - (12) Managing funds and resources supporting HRPP; and
 - (13) Reviewing and approving policies and procedures.
- d. The IO cannot delegate the following activities:
 - (1) Completing required IO training;
 - (2) Signing the DoD Assurance;
 - (3) Ensuring the IRB functions independently, and that the Human Protections Director (HPD) and IRB Chair/Deputy Chair have direct access to the IO;
 - (4) Ensuring adequate resources for the HRPP, including subject matter experts (SMEs) and support staff to implement the HRPP; and
 - (5) Exercising authority to ensure IRB determinations and other HRPP requirements are implemented within the institution.
- e. The IO may disapprove any IRB-approved or exempt human research project. However, the IO may not overrule an IRB's disapproval determination to conduct human research projects.
- f. New IOs must promptly complete Army Human Research Protections Office (AHRPO) approved training and sign an updated Assurance. The HPD must submit updated Assurance paperwork to AHRPO within 30 days of the arrival of the new IO.

3-2. Alternate Institutional Official (AIO)

Traditionally, the Dean of the Academic Board acts as the AIO to ensure the overall regulatory compliance of USMA. Typically, at USMA the IO delegates some activities to the AIO. (See section 3-1.c. for a list of delegable actions.)

3-3. Human Protections Director (HPD)

- a. Is a designated federal DoD employee who possesses a comprehensive knowledge of all aspects of the institution's HRPP and has oversight responsibility as delegated by the IO.
- b. Serves as the primary point of contact for the USMA HRPP and for issues regarding the processing of human subject research protocols, adjudication of various issues, notifications of scientific and IRB actions, and progress of event reporting from field or regulatory offices.
- c. Plays a key role in ensuring that USMA fulfills its responsibilities under the DoD Assurance.
- d. Ensures constructive communication among the HRPP staff, EDOs, IRB Administrator, IRB Members, investigators, research participants, USMA leadership (e.g., Department Heads, Office of Research, Center Directors, etc.) AIO, and IO, as a means of maintaining a high level of awareness regarding the ethical conduct of research and safeguarding the rights and welfare of participants.
- e. Ensures that the USMA Assurance is maintained and updated as needed.
- f. Acts as liaison with the AHRPO and maintains active communication with this organization with respect to the state of the USMA HRPP. Provides periodic metrics to AHRPO and ensures all mandatory reporting is completed within the time periods stipulated by the applicable regulations.
- g. Educates USMA leadership how to establish and maintain a culture of compliance with DoD and federal regulations and institutional policies relevant to the protection of human subjects.
- h. Supervises all USMA EDOs. Periodically audits all EDOs to ensure regulatory compliance that the determinations were correct, supported by sound reasoning, and in accordance with (IAW) appropriate regulations.
- i. Ensures all required additional reviews are completed including Human Research Protections Officials (HRPOs), Component-Level Administrative Reviews (CLARs), administrative reviews, etc.
- j. Acts as a liaison with the Office of the Staff Judge Advocate (SJA) to procure legal reviews when required [e.g., informed consent documents, command support letters (CSLs), etc.].
- k. Oversees all aspects of HRPP training at USMA including for AOs/AIOs, HRPP staff, IRB members, investigators, and Cadet investigators.
- l. Ensures that human subject protections records that are locally filed are maintained appropriately and are accessible, upon request, to authorized DoD officials.
- m. Communicates with the IRB, appropriate institutional officials, and AHRPO regarding noncompliance, suspensions, terminations, Unanticipated Problem Involving Risks To Subjects or Others (UPIRTSOs), and other critical events.
- n. Ensures the post-approval compliance monitoring (PACM) program occurs IAW this regulation and oversees all PACM activities including random or for-cause audits, and those resulting from any UPIRTSO, adverse event (AE), or deviation.
- o. Reports all PACM outcomes to the IO/AIO, IRB, reviewing EDO, Human Research Protection Official (HRPO), AHRPO, and other regulatory oversight bodies, as applicable.
- p. Ensures that the IRB reviewing USMA protocols is provided with local community and cultural factors that may affect the ethical review of protocols both initially and for continuing review, when required.
- q. Ensures that human subject research does not commence until:
 - (1) An approved DoD Assurance covering the research exists,
 - (2) The research has been approved by an IRB, and
 - (3) The research has been approved by the appropriate command authority.

3-4. Human Research Protections Program (HRPP) Staff

- a. Act as an SME to guide investigators as they navigate the regulatory process. Provide appropriate training to investigators and IRB members to ensure regulatory compliance with ethical standards. Communicate with all other personnel in the HRPP to increase efficiencies and ensure compliance.
- b. Assist all research personnel with the use of electronic submission platforms including Cayuse, eIRB, and other systems.
- c. Assist the HPD in updating, maintaining, and storing HRPP research records and tracking documents.
- d. Monitor the HRPP@westpoint.edu mailbox to ensure timely response to submissions and other inquiries.
- e. Review protocol packets for submission to EDOs or an IRB to ensure they are complete and meet regulatory standards for submission.

- f. Act as a liaison with SJA to procure legal reviews when required (e.g., informed consent documents, CSLs, etc.).
- g. Conduct PACM of research and any other compliance monitoring as requested by the HPD or IRB or as necessary by regulatory guidance.

3-5. Human Research Protections Official (HRPO)

a. A HRPO is a federal employee appointed by AHRPO to conduct administrative reviews IAW DoDI 3216.02, of DoD-supported research when contracts for DoD-supported research are awarded to non-DoD institutions. This review ensures that the research is in accordance with the requirements of the Defense Federal Acquisition Regulation Supplement (DFARS) clause, or comparable requirement, to ensure compliance with the DoD human subject research requirements. (See section 9-3 for a complete description of the HRPO review.)

- b. Completes the HRPO reviews independently from the HRPP review.
- c. Maintains all training required by AHRPO.

3-6. Exemption Determination Official (EDO)

a. An EDO is a federal DoD employee who, sufficiently qualified through experience and expertise, is designated to review research to determine whether the research involves human subjects and, if so, whether such research is exempt from 32 CFR 219.

- b. A prospective EDO must complete the following steps before appointment:

(1) The EDO must be nominated by a department head from a department that produces the volume of protocols that warrants their own EDO. A member of the HRPP staff can also be nominated by the HPD. Prospective EDOs must have human subject research experience.

(2) The prospective EDO completes AHRPO approved EDO training, in addition to human subject research training, before conducting reviews of activities that are "not research," "research but not human subject research," "excluded activity," or "exempt research."

(3) The prospective EDO must complete a trial period in which they review at least five protocols with oversight from AHRPO or the USMA HPD.

(4) Upon successful completion of at least five reviews, the IO/AIO must issue an appointment memo allowing an EDO to complete reviews independently.

c. An EDO receives protocols from USMA investigators, irrespective of ultimate level of review and completes an initial review to ensure they are complete and meet the standard of "research" and "human subject research" IAW 32 CFR 219.

d. An EDO reviews and makes a final determination of requests for exemption from human subject research requirements under applicable USMA, Army, DoD, and federal policies and regulations. The EDO should complete an initial review of all complete packets within 10 business days.

e. If a human subject research protocol does not meet the criteria for "not research," "not human subject research," "excluded activity," or one or more categories of "exempt research," the protocol will be referred to the HPD for processing.

f. Department EDOs can refer any protocol to the USMA HPD for any reason including conflict of interest, questions about risk, time constraints, etc.

g. EDOs can perform administrative reviews when they are required. (See section 7-6 for a complete description of administrative reviews.)

h. EDOs must maintain records of all determinations for at least three years (or six years if the research includes HIPAA-protected data IAW 45 CFR 164.316). At least quarterly, the EDO submits metrics to the HPD for submission to AHRPO.

i. Department EDOs serve as liaisons and SMEs to their assigned department on human subject research protections matters.

j. EDOs must ensure that they avoid any conflict of interest that may be present due to their relationships with the investigators. For example, an EDO should not review any research that is submitted by an investigator who is also in their chain of command or rating chain.

3-7. Institutional Review Board (IRB) Members

- a. IRB members should act as liaisons and research SMEs for their respective USMA departments.
- b. See the applicable IRB Standard Operating Procedures (SOP) for more information about specific IRB-related responsibilities.

3-8. Principal Investigator (PI)

- a. Acknowledges and accepts responsibility for protecting the rights and welfare of human subjects and for complying with all applicable provisions of this regulation; the USMA Assurance; applicable IRB SOPs; all applicable research laws and regulations under the authority of the DoD; and other federal, state, and local laws as they may relate to proposed human subject research.
- b. Possesses appropriate knowledge regarding human subject protections, ethics, and federal, DoD, Army, and state regulations to conduct the proposed research. The PI completes appropriate training and submits evidence of such training before submitting human subject research protocols for review. (See section 5-1 for a description of the training requirements.) The PI maintains valid training during the entire life cycle of all open research protocols.
- c. Does not exert undue influence or coercion on the EDO, HPD, IRB Administrator, or any IRB member. Open communication between the PI and the reviewer(s) during the review of the protocol is encouraged and will contribute to improved research. However, the EDO/IRB will make a determination based on their knowledge of the applicable regulations and the PI should not attempt to use academic or military rank or any other position of authority to influence their decisions.
- d. Complies with the training, monitoring, and human subject research guidance outlined in the USMA Assurance, this document, and policies and procedures of the IRB of record.
- e. Provides oversight for all Associate Investigators (AIs), research personnel, and Cadets involved with their study and ensures they are adequately trained and conduct their duties and responsibilities IAW ethical standards, regulatory requirements, and guidance set forth in the USMA Assurance, this document, and policies and procedures of the IRB of record.
- f. Does not begin any research activities prior to receiving documentation of a determination or an IRB approval, and confirmation from the HPD that all other required approvals have been obtained. **An investigator cannot make the determination that a research protocol is exempt, not human subject research, or not research.** Only an EDO can make these determinations.
- g. Obtains organizational and institutional approval of research activities prior to submitting to external agencies for funding and/or executing research at USMA.
- h. Conducts research activities in accordance with the normative, professional, and ethical standards for academic disciplinary scholarship.
- i. Understands the different roles and responsibilities of being a faculty or staff member vs. an investigator. The PI does not use the faculty or staff member role as a means of accessing data or information that an investigator cannot or should not access. The PI ensures that the protocol clearly delineates what activities will take place for research. The PI does not execute any research activities, prior to approval, that are possible because of the resources available to the faculty or staff member. Similarly, the PI understands that there is inherent authority in the role of a faculty or staff member. The PI will not use this authority as a tool to unduly influence potential research participants to consent to research. The PI must also understand that this authority exists in the faculty-student relationship regardless of intent and there is always the possibility of perceived undue influence. For more information about potential undue influence and coercion by USMA investigators, see section 11-7.
- j. Strictly complies with all aspects of approved research verbatim as written in the protocol documents. This includes the recruitment and enrollment of participants, the informed consent process, collection of data, document and data management, and reporting of results.
- k. When executing research that includes physiological monitoring of participants, the PI will:
 - (1) Ensure that the study is conducted, and any equipment and/or devices are used only as specified in the protocol and as approved by the IRB of record.
 - (2) Ensure that only qualified personnel operate the equipment used in research and where required, have met necessary training requirements.
 - (3) State whether incidental findings (IFs) are associated with the devices to be used. (See section 7-5 for a description of responsibilities related to the management of IFs.)

3-9. Associate Investigator (AI)

- a. Maintain current human subject research training. (See section 5-1 for more information about required training.) Be prepared to provide documentation of this training at all times during the period they are listed as an investigator on open protocols.
- b. Understand and comply with all responsibilities listed above in the PI section. While the PI is ultimately responsible for the conduct of the research, the AI should also be fully aware of all aspects of the research and can be found to be responsible in incidents of non-compliance or research misconduct.

3.10 Research Monitor/Ombuds person

a. A research monitor and/or ombudsperson is appointed by an IRB at their recommendation in cases when circumstances may warrant additional protections for participants (e.g., protocols that are greater than minimal risk, research that includes supervisor-subordinate relationships, situations where participants may be in a position of vulnerability, etc.). See the Glossary of Terms for definitions of minimal risk and greater than minimal risk.

b. IAW DoDI 3216.02 3.9.f.(6)(b), An ombudsperson must be appointed by the IRB for research involving recruitment of DoD-affiliated personnel in research that is both determined to be greater than minimal risk, as defined by 32 CFR 219, and when recruitment occurs in a group setting. The ombudsperson must be present during the participant recruitment, monitoring that the process includes the explanation that participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials. The ombudsperson should be available to address DoD-affiliated personnel's concerns about participation.

c. Specific responsibilities are described in the IRB appointment memo because they are unique to the IRB concerns for each protocol. Responsibilities can include ensuring the study is executed in accordance with the approved protocol, observing the recruitment and enrollment procedures, observing the informed consent process, monitoring participant safety, overseeing study interventions, etc.

d. The research monitor/ombudsperson must have expertise consistent with the nature of risks identified in the research protocol and must have experience with human subject research protections.

e. The research monitor/ombudsperson must present credentials including a current curriculum vitae (CV) and have current human subject research training commensurate with the protocol (i.e., biomedical human subject research training for biomedical protocols). (See section 5-1 for more information about required training.)

f. The research monitor/ombudsperson must not have a conflict of interest with the research or be in the chain of command of any of the investigators or participants.

g. The research monitor/ombudsperson has the authority to discuss the protocol with investigators and participants and to intervene when necessary, including stopping the research in progress or removing participants from the research, in order to protect the rights and welfare of the participants until the IRB can assess the situation.

h. The research monitor/ombudsperson must prepare reports of their observations and findings for the IRB in accordance with their instructions and must review reports of SAEs and UPIRTSOs.

3-11. Department Heads

a. Create a community and culture of high-quality ethical research by utilizing SMEs, including EDOs and IRB members, to mentor new and junior faculty and staff members as they establish their own research programs and fulfill the requirements of the USMA HRPP.

b. Ensure that research conducted within the department adheres to all regulatory standards and provide oversight of investigators within their control who are conducting human subject research.

c. Inform investigators and Cadets about institutional publication and presentation policies.

d. Require attendance for newly arriving faculty and staff at the HRPP portion of Arriving Faculty Education held each summer. Support periodic training of all department members as needed.

e. If appropriate, provide command support and approval for all research protocols in their purview.

f. Provide qualified personnel to be IRB members as needed.

g. Report known violations of compliance to the USMA HPD.

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

3-12. Office of the Staff Judge Advocate (SJA)

a. SJA or designee offers expert legal advice on regulatory compliance.

b. SJA or designee reviews all USMA-initiated human subject research non-exempt protocols to ensure regulatory compliance and compliance regarding lawful principles, paying particular attention to informed consent documents and other documents for signature.

c. SJA or designee provides legal reviews for agreements and documents associated with research [e.g., Cooperative Research and Development Agreements (CRADAs), DSAs, CSLs, etc.].

Chapter 4

General Information for USMA Investigators

4-1. Research Protocol

- a. A well-developed protocol is the first line of protection for research participants. It is important that the ethical principles of respect for persons, beneficence, and justice are addressed in the protocol and are upheld during the conduct of the research.
- b. The research protocol is a written, detailed plan by which research is to be conducted. A thorough protocol is written so that a person unfamiliar with the research could execute the research solely from the information contained in the protocol.
- c. The protocol is an agreement between the investigator and the institution and must be executed as written. Once the determination or approval is issued, investigators cannot deviate from the protocol prior to subsequent review and determination/approval, unless there is an immediate hazard to the participants.
- d. All research personnel who are engaged in the research must be listed in the protocol. Engaged means that the person either: 1) has direct contact with research participants or 2) has access to identifiable data.
- e. Contractors who are agents of USMA can act as Principal Investigators (PIs) or Associate Investigators (AIs). Contractors who are employed by a contracting agency with a Federalwide Assurance can be covered by that Assurance.
- f. A thorough literature review provides context and informs the research question and study design. It can protect the participants by ensuring that the research is sound and worth the risk to the participant and it allows the investigator to identify potential risks that may have been revealed in other studies.
- g. The research protocol must include a detailed plan for the recruitment and consent of potential participants with consideration of the unique environment at USMA to avoid any undue influence or coercion. (See section 4-4 and section 12 for more information.) In accordance with (IAW) the Belmont Report, potential research participants are autonomous agents who must be volunteers, must be informed about the research, and must consent to their involvement in the research.
- h. In social behavioral research, the potential loss of privacy or breach of confidentiality is often the biggest risk to participants. Accordingly, a meticulous data management plan is an important component of the protocol.

4-2. Educational Research

- a. Because USMA is an institution of higher learning, it is common for faculty members to conduct educational research.
- b. Some of this research will be determined to be exempt because it meets the criteria for category 1 exemption IAW 32 CFR 219.104(d)(1) that states – “Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.”
- c. Only a USMA Exemption Determination Official (EDO) can determine if the research is exempt. All requests for determination must be submitted to the USMA Human Research Protections Program (HRPP) through Cayuse. (See section 7-2 for information about submitting a request for determination.) This determination must be completed before the research activity can begin.
- d. All research activities that do not meet the criteria for exemption will be processed as non-exempt protocols and will be reviewed by an Institutional Review Board (IRB). (See section 7-4 for information about the review of non-exempt research.)

e. Because USMA is a unique environment, it is important that faculty members conducting educational research understand all the ways that Cadets can be in situations where they might be vulnerable, and more importantly that they address these issues in the research methods. This includes all aspects of research including recruitment, enrollment, scheduling, and data use. For more information about Cadets as human subjects, see section 11.

f. USMA investigators who are also faculty or staff members have access to databases containing private Cadet data, because of their responsibilities as faculty and staff. However, they may not access these databases for research until they receive an IRB approval or exempt determination specifically stating what data they may access and collect. Additionally, they must receive approval from the USMA Institutional Research Committee (IRC) to access the data. (For more information about accessing USMA data for research, see section 12-5.)

4-3. Command Approval

a. IAW DoDI 3216.02, if human subject research involves DoD-affiliated personnel, the PI must receive approval to conduct the research from a USMA official with command authority. There are several ways that investigators can obtain command approval for research, depending on the type of research and the resources (e.g., personnel, equipment, facilities, time, etc.) that will be used.

b. USMA investigators who are covered by the USMA Assurance can obtain command approval in the following ways:

(1) For exempt category 1 research [see 32 CFR 219.104(d)(1)], approval must be provided by the course director for the course in which the research will take place. If the investigator is also the course director or the research includes more than one course, approval must come from a higher level of authority within the department such as the program director, director of curriculum, division chief, deputy head, or department head. If the research includes more than one academic department, a command support letter (CSL) must be signed by an appropriate authority in each department or by the Dean of the Academic Board. If the research will take place in courses outside of the Dean's Directorate (e.g., Department of Military Instruction, Department of Physical Education, etc.) the same logic applies with the Commandant as the highest approval authority. If the research takes place in both the Dean's Directorate and outside the Dean's Directorate, appropriate approvals are required from each directorate or from a higher authority such as the USMA Superintendent or Chief of Staff.

(2) For exempt category 2 research [see 32 CFR 219.104(d)(2)], command approval is granted based on the population that will be recruited. All research that includes surveys of USMA personnel must receive adjudication by the IRC. The IRC operates under the authority of the USMA Steering Committee, so approval is considered command approval from the Commandant of Cadets. If the survey is administered to Cadets during activities that are not considered voluntary or free time, additional command approval may be required. The Director, Strategic Plans and Assessment (G5) or designee is the approval authority for all surveys administered to Cadets that are within the scope of institutional assessment or quality improvement.

(3) For exempt category 4 research [see 32 CFR 219.104(d)(4)] that proposes to use USMA institutional data, investigators must submit a request to the IRC to receive approval for the use of the data. The IRC approval is considered command approval from the Commandant of Cadets.

(4) For exempt research that recruits participants using Sona Systems, command approval will be provided by the Department Head, Department of Behavioral Sciences and Leadership (BSL), or their designee in accordance with the Sona System Standard Operating Procedures.

(5) For all non-exempt research (see section 6-6), a CSL must be provided from a person(s) that has authority over the study participants and all resources. For more information about scheduling research with Cadet participants, see section 11 of this regulation and USMA Regulation 1-1 Installations Administration Scheduling Activities.

(6) Some research may need more than one form of command approval based on the population that will be recruited and the other resources (e.g., facilities, equipment, time, personnel, etc.) that will be used.

- c. Multi-site research, in which the overarching PI is external to USMA, requires a CSL from the USMA Superintendent or Chief of Staff.
- d. External investigators must obtain command approval from the USMA Superintendent or Chief of Staff for access to USMA personnel for research. External investigators are not employees or agents of West Point. Investigators from tenant agencies on West Point who are not covered by the USMA Assurance are considered external investigators. (See section 1-6 for more information about units that report directly to the Superintendent that are covered by the USMA Assurance.)
- e. KACH investigators are considered external to USMA and therefore, require a CSL signed by the USMA Superintendent or Chief of Staff, to use USMA personnel as participants. A blanket CSL has been signed by the USMA Superintendent to allow KACH investigators to use USMA personnel as participants in limited situations. (See section 8-3 for more information about KACH.)
- f. If the study is multi-site and USMA is the lead site, CSLs are required from each performance site that enrolls military service members.
- g. Investigators who need to request a CSL from the Superintendent/USMA Chief of Staff must submit a request to the IRC. The IRC will discuss the impact of the research on USMA personnel and resources and will provide a recommendation to the Superintendent/USMA Chief of Staff. The final decision whether to support the research and provide a CSL will be made by the Superintendent/USMA Chief of Staff.
- h. For all other research that does not fit into any of the categories above, the Human Protections Director (HPD) will make the final decision about who can provide the appropriate command approval.

4-4. Informed Consent

- a. 32 CFR 219.116 outlines the general requirements for informed consent. 32 CFR 219.117 describes the documentation of informed consent.
- b. Informed consent is an important component of the first principle (respect for persons) of the Belmont Report. Human subjects are volunteers who are entitled to sufficient information about the research so that they can make an informed decision about their participation. They must understand the study purpose, study activities, time requirements, and the risks and benefits associated with their participation. They must know how their data is collected, what identifiers are used, and how their privacy will be protected. They should understand 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.
- c. Informed consent is a process, not a one-time event; it starts during the recruitment phase and continues through the end of the study. Any facts discovered during the conduct of research that could affect the safety or well-being of the participants or may affect their decision to participate in the research, must be disclosed to the participants immediately.
- d. Obtaining informed consent is required of all research, including exempt research, with a few exceptions. For example, investigators may use de-identified data in category 4 exempt research without obtaining consent. IRBs may also approve a waiver of informed consent in certain circumstances IAW 32 CFR 219.116(f)(3).
- e. With few exceptions, exempt studies require consent from the participants, but do not require a signed/documentated informed consent document. If an investigator elects to collect signed informed consent documents for an exempt research activity, the documents must meet the same criteria as for non-exempt studies, including the requirements for content, storage, and audit.
- f. For research that does not require signed/documentated informed consent, investigators can provide a participant information sheet. This document must be reviewed by the EDO/IRB. This document can provide similar information to an informed consent document and can help the participant decide whether to volunteer for the research. This has the added benefit of providing take-away information that the participant may want later such as contact information for the investigators.
- g. For non-exempt research, the PI will ensure that informed consent is obtained from every participant or the participant's legally authorized representative (LAR), unless the IRB has approved a waiver of informed consent or a waiver of documented informed consent. An investigator will seek informed consent only after the participant or LAR has had sufficient time and opportunity to consider whether to participate. An investigator will make every effort to not say or do anything that could give the perception of coercion or undue influence.

h. A copy of the informed consent document must be made available to the participant.

i. Investigators must only use the stamped informed consent document or participant information sheet approved for the study.

j. Obtaining informed consent using an electronic platform can offer benefits for both the participant and the investigator. Investigators are encouraged to make full use of the added features (e.g., interactive capabilities, videos, hyperlinks, etc.) of electronic consent to facilitate increased understanding of the research for the participant. Informed consent can be collected electronically if the process is reviewed by the EDO//IRB and certain conditions are met:

(1) The platform that is used must be secure with restricted access so that the confidentiality of the participant is protected.

(2) The participant must view an electronic informed consent document that is identical to the version that was reviewed/approved by the EDO//IRB, including the location of the signature. The informed consent document must be easy to navigate, must allow the participant to go forward and backward through the document, and must allow the participant to leave and return to the document at a later time.

(3) A copy of the informed consent document must be made available to the participant. This copy can be a hard copy or electronic version that is easily accessible by the participant.

(4) An electronic signature can be any computer-generated symbol or series of symbols that is authorized by the participant to indicate their signature and their consent to participate in the research. The electronic platform must capture the date that the participant signed the informed consent document.

(5) If the participant will access the informed consent document at a location separate from the investigators, they must have the ability to communicate with the investigators to ask questions before they provide their signature. Additionally, if an investigator is not present when the participant signs the form, there must be a method for confirming the identity of the signatory [e.g., signing the form using a Common Access Card (CAC)].

(6) The electronic platform that is used by the investigators must be able to output an electronic or hard copy version of the entire approved informed consent document for each participant, with a printed name, their documented signature, and the date of signature.

(7) Informed consent documents must be available (hard copy or electronic) at any time for audit and must be securely stored for three years following study closure (or six years if the research includes HIPAA-protected data IAW 45 CFR 164.316).

k. The most important information the participant will need to make an informed decision to participate must be provided to the participants first, using a bottom-line up front (BLUF) approach. A template is available from the USMA HRPP.

l. The informed consent document should clearly and in detail describe the kinds of questions the investigator will ask. This allows participants to choose whether they wish to divulge certain types of information or explore certain issues before participating in the study.

m. IAW DoDI 3216.02 3.9.f.(1), if the research involves DoD-affiliated personnel as participants and if the research includes any risks to their fitness for duty (e.g., health, availability to perform job, data breach, etc.), the informed consent document must inform DoD-affiliated personnel about these risks and instruct the potential participants to seek command guidance before participating.

n. IAW DoDI 3216.02 3.9.f.(5), military service members who are not yet eighteen years old, for the purposes of human subject research, can be considered adults and can provide informed consent as such. Investigators should carefully consider the necessity of including these participants.

o. In addition to the required elements, it is preferable for studies using USMA personnel to include contact information for the USMA HRPP in the informed consent document.

p. Informed consent documents must be clearly written and understandable to participants. The language must be non-technical (comparable to the language in a newspaper or general circulation magazine). Any scientific, technical, and medical terms must be plainly defined. Depending on the study population, it is often recommended that the informed consent document be written at the sixth to eighth grade reading level.

q. The informed consent document must be in a language in which the participant is proficient. If it is anticipated that some or all volunteers will not speak the primary language of the host country, all documentation provided to volunteers (e.g., informed consent document, participant information sheets, etc.) should be translated with a copy provided to the EDO/IRB for review. When informed consent will be obtained in a language other than English, documentation that the alternate language version is an accurate translation of the English version must be provided to the EDO/IRB. Documentation from a qualified translator certifying the translation must be provided along with the English and alternate language version of the informed consent documents.

r. When minors are included in research, a plan to obtain assent (i.e., agreement) from those with capacity to provide it or a justification for a waiver of assent should be provided. The IRB requires that age-appropriate assent forms be developed for use with minors when assent is obtained. Capacity to provide assent should also be considered for other populations that cannot provide informed consent and assent should be obtained whenever possible.

s. In cases where an individual is considered unable to give informed consent, a LAR may give consent on their behalf. State law (New York State Public Health Law Article 24-A) defines who may act as a LAR. A local IRB should be consulted for guidance regarding who can serve as a LAR for research at the research site. Examples of LARs include the parents or legal guardians of a child and caregivers for participants with impaired decision-making capacity.

t. The potential volunteer needs to have unimpaired reasoning abilities at the time of informed consent. Impairments of reasoning abilities include high levels of stress, illness, injury, intoxication, insufficient sleep, and other health problems.

u. IAW 10 USC 980, "Funds appropriated to the DoD may not be used for research involving a human being as an experimental subject unless: 1) the informed consent of the subject is obtained in advance or 2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

(1) Note that the definition of "experimental subject" is found in DoDI 3216.02 and has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

(2) An individual not legally competent to provide informed consent (e.g., incapacitated individuals, individuals with impaired decision-making abilities, minors, etc.) may not be enrolled as an experimental subject in a DoD-supported experiment unless participation in the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements.

4-5. Broad Consent

a. Until Department of Defense (DoD) and/or Army guidance is issued, the use of broad consent shall not be used for research conducted by USMA.

b. Broad consent may be obtained in conjunction with informed consent only with respect to the storage, maintenance, and secondary research uses of identifiable private information and identifiable biospecimens. When required, this is a separate document from the informed consent document (although they may be done at the same time).

c. Broad consent may be obtained for either exempt or non-exempt research studies, particularly if there is a possibility of using the data for secondary research.

d. Broad consent is applicable for exempt categories 7 and 8 [see 32 CFR 219.104(d)(7) & (8)] for secondary research use. If approved, the study will be considered as "exempt" and will not otherwise be subject to the provisions of the Common Rule.

e. If broad consent is used, the consent documents must be stored and indexed for as long as the broad consent is in effect (which may be indefinitely).

f. Studies which use data obtained from broad consent will be subject to a regular audit.

g. The broad consent document must include the following required elements. No alterations or waivers are permitted.

- (1) A description of any reasonably foreseeable risks or discomforts to the participant;
- (2) A description of any benefits to the participant or to others that may reasonably be expected from the research;
- (3) A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained;
- (4) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled;
- (5) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens, including sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;
- (6) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or investigators that might conduct research with the identifiable private information or identifiable biospecimens;
- (7) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);
- (8) Unless the participant or LAR will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the participant's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;
- (9) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the participant in all circumstances, a statement that such results may not be disclosed to the participant; and
- (10) An explanation of whom to contact for answers to questions about the participant's rights and about storage and use of the participant's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

4-6. Risk vs. Benefit

- a. IAW the second principle (beneficence) of the Belmont Report, investigators should 1) do no harm to research participants and 2) maximize possible benefits and minimize possible harms. Studies should present the least possible risk to participants given the context of the study objectives and the most current standard of safe practices.
- b. According to 32 CFR 219, "risk" has two components: the magnitude of harm and the potential for harm.
 - (1) The magnitude of harm is a measure of the seriousness of the possible harm. "Harm" is not limited to just physical harm; it could also include criminal or civil liability or damage to the participants' financial standing, employability, or reputation. A consideration of the magnitude of harm should include the severity, frequency, and irreversibility of the harm.
 - (2) The probability for harm is the likelihood of the incident occurring without extra protections.
- c. Minimal risk means that the magnitude and probability 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.
- d. If the magnitude of harm is high AND the probability for harm is high, the threshold for greater than minimal risk has been met.
- e. Oftentimes the source of most risk in social-behavioral research is the inadvertent disclosure of personal and sensitive information. The PI should carefully consider this risk and include measures in the protocol to protect intentional or inadvertent disclosure of personal and sensitive information.

f. Another source of risk in social and behavioral research is the stress that participants may feel 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, or questions about circumstances of military conflict 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. 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 should be built into studies when emotional distress may result from study procedures.

g. IAW DoDI 3216.02 3.8.b., the definition of minimal risk does not include the inherent occupational risks that certain participants face in their everyday life such as those encountered by military service members. Therefore, risk for Cadets at USMA should be considered as if they were typical civilian college students. For example, a protocol that requires a participant to complete the Indoor Obstacle Course Test (IOCT) should be evaluated for risk based on the enrollment of typical civilian college students.

h. The PI must provide an adequate description of the potential benefits of a non-exempt research project in the protocol. An adequate description in these documents allows the IRB to determine whether the potential benefits outweigh the potential risks. An adequate description of anticipated benefits in the informed consent document allows potential participants to make an informed decision whether to participate.

i. Vague promises to benefit science or society are not adequate descriptions of benefit in an informed consent document or protocol. When there is no direct benefit to participants, they must be told what the researcher is trying to learn and why.

j. Compensation to participants and/or the fact that participants may find it rewarding to be helpful, are not considered benefits in the risk/benefit analysis.

k. Research which offers no benefits to the DoD, Army, USMA, or academic discipline should not be considered for execution at USMA. Likewise, research in which the risk to participants outweighs the benefits should not be considered.

l. Non-exempt research requires a more thorough consideration of risk and benefits.

m. Irrespective of risk level or type of review, investigators should carefully and thoughtfully consider ways to mitigate risk, with respect to both the magnitude and probability of harm.

n. IAW DoDI 6025.23 4.i., research participants injured in DoD-conducted research may obtain care for such injuries at a DoD medical treatment facility on a space-available basis during the pendency of the research study. This includes research performed by DoD-affiliated personnel who are collaborating with a non-DoD institution.

4-7. Compensation for Research Participants

IAW 24 USC 30, payment to federal employees and active-duty military personnel for participation in research while on duty is limited to blood collection and may not exceed \$50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol. Non-monetary incentives in the form of extra credit can be offered. (See section 11-6 for more information about extra credit.)

4-8. Deception Research

a. Deception studies are systematic investigations that would leave the participant unaware or misled regarding the nature or purpose of the research.

b. Deception studies are permitted at USMA but may not be considered for an exemption.

c. USMA accepts the need for certain types of studies to employ strategies that include deception. However, employment of such strategies must be justified.

d. 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.

- e. If a deception study is proposed, the investigator must:
 - (1) Justify the use of deception as part of the research design,
 - (2) Include a description of the manner of deception and how the deception will take place,
 - (3) Provide an explanation as to why deception is necessary to this protocol,
 - (4) Present a description of whether the deception results in any increased risk to participants,
 - (5) Provide an indication of whether the deception may affect a participant's willingness to participate in research,
 - (6) Include a description of the post-study debriefing that includes offering the participant the option to withdraw their data from the study,
 - (7) Provide a description of any previous use of deception in similar research and a summary of any actual harms or reactions from participants to the use of deception,
 - (8) Present a description of alternatives to deception that were considered and an explanation as to why these alternatives were rejected, and
 - (9) Include confirmation that the study meets the criteria for a waiver or alteration of consent.

4-9. Conflicts of Interest (COIs)

Investigators must be free to pursue an objective scientific inquiry free from undue influence or coercion. Research participants must be informed about any potential COIs that exist with the research personnel. Therefore, every member of the research team must provide a declaration of potential COIs. All conflicts must be considered for the investigator and for their immediate family members. Potential COIs can include:

- a. Professional relationships (e.g., personal, professional, academic, etc.), activities, or commitments related to this research protocol that are (or may reasonably appear to be) a conflict. Investigators should consider employment and chain of command relationships that could present conflicts (e.g., supervisors/subordinate personnel or faculty/students, future potential employer, etc.).
- b. Conflicts that may arise from associations, such as consulting arrangements, management responsibilities or equity holdings in the research sponsor, vendors, providers of goods, contractors, or subcontractors for this research.
- c. Immediate associations that may present financial or non-financial interest with the research sponsor, including receipt of grants, honoraria, income, or stock or stock options (not including mutual funds) as payment.
- d. A member of the investigation team or a close family member being a part of an advisory board or having an academic appointment with the research sponsor.
- e. A member of the investigation team or a close family member having an ownership or royalty interest in any intellectual property (e.g., patents, copyrights, licensing agreements, etc.) related to this protocol.
- f. A member of the investigation team or a close family member currently employed by, or under consideration for future employment with the research sponsor, vendors, providers of goods, contractors, or subcontractors for the protocol.

4-10. International Research

- a. Research conducted outside of the United States is considered international research unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are U.S. citizens.
- b. Additional regulatory reviews and documentation may be required from both the international site and the IRB or EDO to ensure ethical conduct of the research and consideration of the host country's customs, traditions, norms, language, and practices. It is imperative that investigators start the process early and request a consultation with the HPD during the initial planning stages.
- c. The U.S. Department of Health and Human Services publishes the International Compilation of Human Research Standards which outlines the standards of human subject research in 131 countries.
- d. All non-exempt human subject research conducted by USMA faculty, staff, or Cadets, regardless of funding source or the location at which the research will be conducted, requires a review IAW the procedures outlined by the IRB. A Component-Level Administrative Review (CLAR) is also required for human subject research conducted in a foreign country IAW DoDI 3216.02 3.5.b(1)(a).

e. If some of the protocol documents will be translated to a language other than English, the PI must submit both the English and translated versions of each document. The PI must also submit a signed memorandum from a person with adequate qualifications, to attest to the accuracy of the translation of all documents. This memo must state the qualifications of the translator and must list the specific documents that were reviewed.

f. The PI must submit a signed memorandum from a person with a thorough and complete knowledge of the local context in which the research will be executed. This memorandum must attest that the research is appropriate in consideration of the local customs, traditions, norms, language, and practices. This memo must also include a statement of the signatory's qualifications and experiences.

g. Depending on the population that will be recruited for participation in the study, a CSL may be required. The HPD will determine whether this is a requirement.

h. IAW DoDI 3216.02 1.2.g., the PI is required to provide written notification to the U.S. Central, U.S. Africa, U.S. European, U.S. Indo-Pacific, and U.S. Southern Commands of human subject research that is to be conducted or supported in their area of responsibility before the research proceeds. This does not apply to research performed within the U.S. or at DoD institutions overseas.

i. Investigators who wish to enroll participants who are members of foreign militaries or governments, should consult with the USMA G3 prior to initiating the research. This does not include Cadets who are assigned to USMA as foreign Cadets or semester-long exchange Cadets.

4-11. Cayuse

USMA uses Cayuse as an online submission platform for all research requiring review, except for non-exempt research that will be sent to an external IRB for review. Investigators should submit all requests for determination and administrative review packets in Cayuse.

4-12. eIRB

eIRB is the online submission platform used by many Army HRPPs and all Defense Health Agency Military Treatment Facilities. USMA investigators who will submit to external IRBs must use the platform required by the IRB. For assistance with access to eIRB, contact the USMA HPD at HRPP@westpoint.edu.

Chapter 5

Training Requirements

Investigators who enroll human subjects in research require a specialized knowledge base that goes beyond that provided through traditional scientific or research methods training. Research personnel should possess a core body of knowledge relating to the ethical design and conduct of research to maximally protect human subjects. USMA leaders must ensure that investigators and other individuals engaged in research with human subjects within their directorates are adequately educated to perform their respective duties.

5-1. Human Subject Research Training Requirements

a. Human subject research training can be in the area of social and behavioral research, biomedical research, or another area that is appropriate for the protocol. The training is valid for three years and can be renewed for an additional three years by repeating the course or by completing refresher training.

b. Training Requirements by Role:

(1) Investigators (including principal, associate, and Cadet investigators) engaged in exempt or non-exempt research, must complete approved human subject research training prior to initiating research. The USMA Human Protections Director (HPD) will approve all human subject research training. Investigators must maintain current training throughout the entire life of the protocol by completing a refresher course before the expiration of their training (every three years.) Proof of training that is valid for the entire life of the protocol must be included with all protocol submissions and maintained in the Regulatory Binder (see section 3-8.n. for more information about the Regulatory Binder.)

(2) External investigators must comply with the training requirements of the reviewing institution.

(3) Research Monitors and ombudspersons must maintain current human subject training during the time period in which the specific aspect of the protocol that they are assigned to oversee is occurring. For example, if the ombudsperson has been tasked to oversee the recruitment, informed consent, and enrollment of human subjects, they must maintain current training throughout the time period when these research activities are occurring.

c. Investigators who engage in biomedical research, utilize data that is protected by the Health Information Portability and Accountability Act (HIPAA), or submit research to an external IRB, may be required to complete additional training modules as dictated by their specific protocol or by the external institution's Human Research Protections Program (HRPP). For all USMA-reviewed research, the USMA HPD will determine which training is appropriate.

d. Investigators who are accessing protected health information (PHI) must complete HIPAA training. This training is available through the DoD's Joint Knowledge Online website for training.

e. Personnel who are found to have been involved in incidents of noncompliance, deviations, or other deleterious events may be required to complete remedial training before they can continue their engagement in research. These additional training requirements will be specified in the investigation and report documents.

f. All research personnel (HRPP staff and investigators) are responsible for maintaining current training and tracking expiration dates to ensure they complete refresher training before it expires. They are also responsible for maintaining their own training records and must be able to produce them on demand as requested by regulatory officials. Required training certificates must be submitted with all protocol submissions.

g. The Collaborative Institutional Training Initiative (CITI) Basic Course is one example of acceptable human subject research training. For questions about other acceptable forms of training (such as through the National Institutes of Health), please contact the USMA HPD at HRPP@westpoint.edu. The CITI Training course is self-paced and is divided into several modules. It can be taken all at once or in parts and takes approximately three hours to complete. Each module includes a quiz that requires a passing score of 80%. Quizzes may be repeated until a passing grade is achieved. Once completed, the investigators must save the certificate or transcript page which is a required element of the protocol submission packet. CITI will maintain a copy of the certificate for future retrieval. For instructions on accessing the correct account and avoiding CITI program fees, please email HRPP@westpoint.edu. External investigators must complete CITI (or other) training through their home institutions. The USMA license does not cover external investigators.

5-2. Arriving Faculty Education

- a. Faculty and staff members who are likely to conduct human subject research should be informed of their responsibilities when they arrive at USMA to prevent an inadvertent violation of the policy set forth in this regulation.
- b. All departments who conduct human subject research should participate in HRPP training as part of the Arriving Faculty Education.
- c. This HRPP training serves to inform faculty and staff who are likely to conduct human subject research of their responsibilities. Knowing that not all faculty and staff members will conduct research, this training also addresses related topics that may be of interest to all participants such as historical case studies of the ethical treatment of human subjects; the use of race and sex in research; and other issues unique to Cadets, USMA, and the DoD. This training occurs during the initial summer when new faculty and staff arrive at USMA, to prevent the inadvertent violation of the policies set forth in this regulation.

5-3. Human Research Protections Program (HRPP) Staff

- a. The HRPP Staff must complete initial training in appropriate modules of human subject research training and must complete refresher training every three years.
- b. The HPD must complete Army Human Research Protections Office (AHRPO)-approved training prior to appointment as the institution's HPD.
- c. The HPD must complete HIPAA training annually. This training is available through the DoD's Joint Knowledge Online website for training.

5-4. Exemption Determination Officials (EDO)

- a. EDOs must complete AHRPO-approved training before conducting reviews of activities that are "not research," "research but not human subject research," "excluded activity," or "exempt research."
- b. EDOs must maintain valid human subject research training by renewing the training every three years.

5-5. Institutional Review Board (IRB) Members

- a. IRB members must maintain valid human subject research training by renewing the training every three years.
- b. IRB members must complete additional training as specified in the applicable IRB SOP.

5-6. Human Research Protection Official (HRPO)

HRPO Reviewers must maintain valid human subject research training by renewing the training every three years.

5-7. Institutional Official (IO)/Alternate Institutional Official (AIO)

- a. At USMA, the IO is traditionally the Superintendent of USMA and the AIO is the Dean of the Academic Board. These personnel turnover approximately every five years.
- b. The IO within 30 days of arrival at USMA, and the AIO within 90 days of arrival, must complete AHRPO-approved training with the USMA HPD. This training consists of information about their roles and responsibilities, the USMA HRPP, the USMA Assurance, IRBs used by USMA investigators, the role of AHRPO, and any current USMA research-specific issues.

5-8. Database Administrators

Personnel who are not researchers but who have access to research data for administrative purposes, must complete human subject research training every three years. This training can be focused on data management and security in the context of human subject research.

Chapter 6

Categories of Research

Descriptions and criteria for many categories of research are contained in federal codes and regulations. This section contains only brief descriptions. For more information, please refer to the linked codes and/or regulations.

6-1. Research

In accordance with (IAW) DoDI 3216.02, for an activity to be considered research it must fulfill two criteria: 1) it must be a systematic investigation, including research development, testing, and evaluation, and 2) it must be designed to develop or contribute to generalizable knowledge. Therefore, activities that do not meet both of these criteria are considered not research. Additionally, the following activities are deemed NOT to be research IAW 45 CFR 46.102(l):

- a. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- b. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- c. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- d. Authorized operational activities (as determined by each DoD Component) in support of intelligence, homeland security, defense, or other national security missions. Guidance and approval for determining authorized operational activities with regard to human subject research will be issued by the Department of Defense Directorate of Human Research Protections (DOHRP).

6-2. Human Subject Research

a. Human subject research are activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens.

b. IAW DoDI 3216.02, for an activity to be considered human subject research it must meet two criteria: 1) The investigator obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or 2) the investigator obtains, uses, studies, analyzes, or generates identifiable private information, personally identifiable information, or identifiable biospecimens.

6-3. Excluded Activities

The following activities conducted or supported by the DoD are not considered human subject research IAW DoDI 3216.02:

a. Activities carried out solely for purposes of diagnosis, treatment, or prevention of injury and disease under force health protection programs of DoD, including health surveillance pursuant to 10 USC 1074f, and the use of medical products consistent with DoDI 6200.02.

b. Health and medical activities as part of the reasonable practice of medicine or other health professions undertaken for the sole purpose of diagnosis, cure, mitigation, treatment, or prevention of disease in a patient.

- c. Activities performed for the sole purpose of medical quality assurance (see 10 USC 1102, and DoDI 6025.13 for more information about these activities.)
- d. Activities that meet the definition of operational test and evaluation as defined in 10 USC 139 (a)(2)(A).
 - e. Activities performed solely for assessing compliance, including occupational drug testing, occupational health and safety reviews, network monitoring, and monitoring for compliance with requirements for protection of classified information.
 - f. Activities, including program evaluation and surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results are only for the use of government officials responsible for the operation or oversight of the program being evaluated

6-4. Exempt Research

Exempt research is human subject research that meets specific federal criteria in 32 CFR Part 219, falling into one of the eight categories of exempt research listed at 32 CFR 219.104. Exempt human subject research must be initially determined as exempt by an IRB, its designee, or designated DoD Human Research Protections Program (HRPP) personnel, and then is exempt from further review.

6-5. Exempt Research Requiring Limited IRB Review

- a. A limited IRB review may be required for exempt categories listed in 45 CFR 46.104(d)(2)(iii), (d)(3)(i)(C), (d)(7), or (d)(8) to ensure appropriate protections are in place for identifiable private information and identifiable biospecimens.
- b. The limited IRB review examines whether there are adequate provisions to protect the privacy of participants and maintain the privacy of the data. This review should be conducted by an IRB member who is knowledgeable about these facets of research.
- c. If approved, the study will be considered as "exempt" and will not otherwise be subject to the provisions of the Common Rule.

6-6. Non-Exempt Research

IAW DoDI 3216.02, non-exempt research is human subject research that meets specific federal criteria in 32 CFR 219 and DoDI 3216.02 for minimal risk or greater than minimal risk.

6-7. Classified Research Involving Human Subjects

- a. See the Glossary of Terms for the definition of classified research involving human subjects.
- b. IAW DoDI 3216.02 3.5.b.(1), the Army Human Research Protections Office (AHRPO) must conduct a Component-Level Administrative Review (CLAR) of all non-exempt human subject research when the research constitutes classified human subject research as defined by DoDI 3216.02.
- c. IAW DoDI 3216.02 3.5.a.(8), if the research constitutes classified human subject research and USMA is relying on a non-DoD IRB for the review of the research, AHRPO must approve the Institutional Agreement for IRB Review (IAIR).
- d. IAW DoDI 3216.02 3.13.c., the DOHRP is the final approval authority for all DoD-conducted or DoD-supported classified human subject research. The USMA HRPP must submit the research protocol to the DOHRP for approval prior to executing classified human subject research.
- e. IAW DoDI 3216.02 3.16.c., substantial allegations of noncompliance related to classified human subject research must be reported immediately to the DOHRP.

Chapter 7

Procedures for the Review of Research

7-1. Documents for a Protocol Submission

All protocols submitted to the USMA Human Research Protections Program (HRPP) for review must be submitted through Cayuse unless they are going to an external Institutional Review Board (IRB). The documents required for a protocol review vary based on the category of research and other factors. A description of each document is listed below. A list of requirements by research category is provided in Table 7-1.

- a. *Protocol.* A protocol is required for all submissions. For more detailed information see section 4-1.
- b. *Informed Consent Document.* For a more detailed description of the entire informed consent process, see section 4-4.
- c. *Participant Information Sheet.* The investigator may elect to provide this document when the research does not require documented informed consent. (See section 4-4.f. for more information about this document.)
- d. *Request for a Waiver of Informed Consent.* An IRB may waive or modify the requirement for the investigator to obtain a signed informed consent document for some or all participants. The requirements for a waiver or alteration of documentation of informed consent are found in 32 CFR 219.116 and 117.
- e. *Health Insurance Portability and Accountability Act (HIPAA) Authorization.* This should be submitted if protected health information (PHI) is being collected from a covered entity. (See section 12-9 for more information about HIPAA.)
- f. *HIPAA Authorization Waiver.* A waiver from the requirements to obtain HIPAA authorization from participants may be obtained if the research meets the requirements in 45 CFR 164.512(i)(2)(ii).
- g. *Scientific Review.*
 - (1) The purpose of this review is to evaluate the scientific merit of the protocol, to assess the feasibility of study completion, to help the IRB members understand the underlying science of the study, and to ensure that the procedures follow generally accepted practice for that discipline.
 - (2) Scientific reviews must be conducted by an expert in the field of study with extensive knowledge of the research procedures. The reviewer may be internal or external to USMA. The reviewer may not be a member of the research team and must not have a conflict of interest with the project.
 - (3) The USMA HRPP staff will identify and appoint the scientific reviewer.
 - (4) The reviewer is expected to give a thorough, thoughtful, and honest synopsis of the study with an analysis of the methodology. The USMA Scientific Review of Research Protocol template is provided for the reviewer to ensure that all pertinent aspects of the research are addressed and that an evaluation of the scientific merit of the protocol occurs. The reviewer's expert opinion will be considered during the IRB deliberations.
- h. *Command Support Letter (CSL).* In accordance with (IAW) DoDI 3216.02, if the research involves Department of Defense (DoD)-affiliated personnel, the Principal Investigator (PI) must obtain command approval to execute the research. (See section 4-3 for more information about command approval.)
- i. *Curriculum Vitae (CV).* Each investigator listed on the protocol must provide evidence of having the competence and knowledge to conduct research in the field of inquiry. Investigators must provide a current CV, resume, or biosketch that details their education and experience in the discipline. Cadet investigators do not need to submit a CV or biosketch when the USMA HRPP is reviewing the research. When investigators submit research to external organizations for review they must comply with that organization's policies. (See Appendix B for a Sample Cadet Biosketch Template.)
- j. *Human Subject Research Training.* Each investigator listed on the protocol must provide documentation (including the date) of completed human subject research training. (See section 5-1 for training requirements.)
- k. *HIPAA Training.* Each investigator who will access or use PHI in their research must provide documentation (including the date) of completed HIPAA training. (See section 5-1 for training requirements.)

l. Conflict of Interest (COI) Statement. All COIs must be considered for all investigators and for their immediate family members. Investigators must declare their conflicts, or the absence of conflicts, using the USMA Conflict of Interest Disclosure form. (See section 4-9 for more information about conflicts of interest.)

m. Institutional Research Committee (IRC) Meeting Minutes. This is required for all investigators who will use USMA institutional data or who will administer a survey to USMA personnel. The IRC typically reviews requests after the HRPP review is complete. Investigators can submit the IRC request form with the protocol submission, to document that the request has been submitted, and the meeting minutes can be added later.

n. Data Collection Forms. If the study includes questionnaires, surveys, case study forms, screening forms, or other data collection documents (including paper and/or electronic versions), they must be submitted for review with the protocol packet.

o. Recruitment Materials. Any documents given to participants and/or used to recruit participants to include (but not limited to) posters, flyers, email invitations, videos, or telephone scripts, must be submitted for review to ensure that the recruitment fairly represents the study, it is clear that the participation is for research, and there is no undue inducement.

p. Equipment/Device User Manual. If the protocol includes physiological monitoring using equipment or a device, the investigator must submit the manufacturer's user manual.

q. External Investigator Agreement. Investigators external to USMA who will access or receive research data or USMA institutional data must sign an External Investigator Agreement. This document is a pledge to comply with the data use parameters described in the protocol as well as all federal, DoD, Army, and USMA policies applicable to the execution of the research.

r. Data Sharing Agreement (DSA). If there are personnel who are either internal or external to USMA who are not listed on the protocol as investigators because they are not engaged in the research, but they will access or receive research data or USMA institutional data, agreements [e.g., DSA, Data Use Agreement (DUA), or Memorandum of Agreement (MOA)] must be in place to govern the use, sharing, storage, and destruction of the data. This agreement must be signed by the receiver of the data or institutional representative and the USMA Associate Dean of Research.

s. Memorandum of Understanding (MOU)/MOA. If a USMA investigator is sharing resources with an external organization, they should consult with the Associate Dean of Research to determine if a MOU or MOA is required. A MOU is used to document a mutual understanding between any two or more parties that does not contain an expectation of payment, and under which the parties do not rely on each other to execute or deliver on any responsibilities. A MOA is used to document agreements and execute or deliver support with or without reimbursement between any two or more parties (DoDI 4000.19).

t. Cooperative Research and Development Agreement (CRADA) and other Technology Transfer agreements. If a USMA investigator is conducting cooperative research with an external organization, they should consult with the Associate Dean of Research to determine if an agreement is required. A CRADA is a written agreement between one or more federal laboratories and one or more non-federal parties under which the government, through its laboratories, provides personnel, facilities, equipment, or other resources with or without reimbursement (but not funds to non-federal parties). The non-federal parties provide personnel, funds, services, facilities, equipment or other resources to conduct specific research or development efforts that are consistent with the mission of the laboratory. See 15 U.S.C. 3710a and Army Regulation (AR) 70-57 for more information.

u. Institutional Agreement for IRB Review (IAIR) or Individual Institutional Agreement (IIA). If USMA is the lead site for a non-exempt study and there are engaged investigators from other institutions listed on the protocol, an executed IAIR or an IIA is required. (See section 2-2 and section 2-3 for information about agreements.)

Table 7-1

Document Requirements for Each Category of Research

	Excluded Activities	Not Research	Not Human Subject Research	Exempt Research	Exempt Research requiring Limited IRB Review	Exempt Research with External Investigators	Non-Exempt Research	Non-Exempt Research with External Investigators
Protocol	Y	Y	Y	Y	Y	Y	Y	Y
Informed Consent Document or Waiver Request	M	M	M	M	M	M	Y	Y
HIPAA Authorization or Waiver Request	M			M	M	M	M	M
Scientific Review							Y	Y
Command Support Letter	M	M	M	M	M	M	M	M
Curriculum Vitae or Biosketch	Y		Y	Y	Y	Y	Y	Y
Human Subject Research Training	Y		Y	Y	Y	Y	Y	Y
HIPAA Training				M	M	M	M	M
Conflict of Interest Statement	M		Y	Y	Y	Y	Y	Y
IRC Meeting Minutes	M	M	M	M	M	M	M	M
Data collection forms (if applicable)	Y	Y	Y	Y	Y	Y	Y	Y
Recruitment Materials (if applicable)	Y	Y	Y	Y	Y	Y	Y	Y
External Investigator Agreement	M	M	M	M		Y	M	
Data Sharing Agreement	M	M	M	M	M	M	M	M
MOU or MOA						M	M	
CRADA or Technology Transfer Agreements						M	M	
IAIR or IIA							Y	

Y=Yes, M=Maybe

7-2. Request for Determination

a. A determination is a review by an Exemption Determination Official (EDO) to assign a category to the research. These categories are "not research," "excluded activity," "not human subject research," "exempt research," "exempt research requiring limited IRB review," or "non-exempt research requiring referral to an IRB." (See section 6 for a description of the categories of research.) The EDO will apply the principles of a regulatory review by following a systematic process and may use a decision pathway to assist with the determination (Figure 7-1).

b. Activities that are determined to be "excluded activity," "not research," "not human subject research," or "exempt," are not subject to Common Rule oversight but are subject to the requirements of the Belmont Report.

c. **Investigators cannot make a determination about their own projects.** This restriction is necessary to prevent issues from a real or perceived COI. Only a trained and appointed EDO can make the determination of the regulatory category of the study. The EDO may make a determination under the following conditions:

- (1) The EDO has no COI with the research project,
- (2) The EDO is not involved directly with the research project, and
- (3) None of the investigators are a superior or subordinate of the EDO.

d. The investigator must submit a Request for Determination packet for review by an EDO. (See Table 7-1 for more information about the required documents for a complete packet.)

e. Documented informed consent for exempt research is not required, however participants must be informed of the purpose, risk, benefits, and voluntariness of the research. There are multiple ways to achieve this requirement including, but not limited to, verbal informed consent and/or the use of a participant information sheet. The proposed method of obtaining informed consent will be reviewed by the EDO to ensure that the participants are adequately informed and protected. Informed consent is not required for research that is exempt under category 4 – secondary use of data.

f. The EDO will review complete packets and provide an initial review to the PI within ten business days of receipt. The purpose of the review is to 1) ensure that the methods protect the participants to the greatest extent possible and 2) to ensure that the protocol meets the requirements for the research category to which it will be assigned. It is common for the EDO to have questions and require clarifying edits to the packet. Therefore, the period of time between initial submission and final determination may be longer than ten business days if there are substantive changes required or if the PI does not promptly respond to the initial review.

g. The EDO will document the determination and justification for the decision in the study's official file using the EDO Checklist.

h. The EDO will provide a written determination to the PI and will include the exempt category and any additional review requirements.

i. Studies determined to be otherwise exempt but requiring a Limited IRB Review [exempt categories (2)(iii), (3)(i)(C), (7), and (8)], are forwarded to the IRB.

j. A determination from the EDO does not constitute command approval. In addition to the regulatory review requirements, the investigator may need to obtain command approval before conducting the research. (See section 4-3 for information about command approval.)

k. If the study is determined to be "not research," "not human subject research", "excluded activity," or "exempt research," then the PI may begin recruiting participants upon receipt of the determination, unless the EDO has specified in the determination notice that the project has additional review requirements.

l. Once the determination has been issued to the PI, no changes can be made to the protocol until there is a new review and determination of the modification. If any aspect of the study is changed or altered, the investigator is responsible for notifying the EDO prior to implementing the modifications, unless the modifications are required for the immediate health, safety, or security of the participants.

m. "Exempt" determination means exempt from compliance under IRB review processes. Exempt research does not require the submission of continuing reviews, annual reviews, or closure reports. However, this does not preclude the USMA HRPP or a higher regulatory body from conducting post-approval compliance monitoring (PACM) as needed.

n. If the protocol meets the regulatory definition of human subject research but it does not wholly and completely meet the criteria for an exemption, then it is non-exempt and will be referred to the USMA HRPP for processing and submission to an appropriate IRB. There may be additional required documents for a review of non-exempt research. (See Table 7-1 for document requirements.) The PI must secure IRB approval prior to conducting the study.

o. The investigator should securely store all regulatory documents (e.g., protocol, data collection forms, determination memo, etc.) for three years after study completion (or six years if HIPAA-protected data was collected).

p. The EDO will retain all paperwork related to the review of research in the official HRPP files for a minimum of three years after the determination (or six years if the research includes HIPAA-protected data).

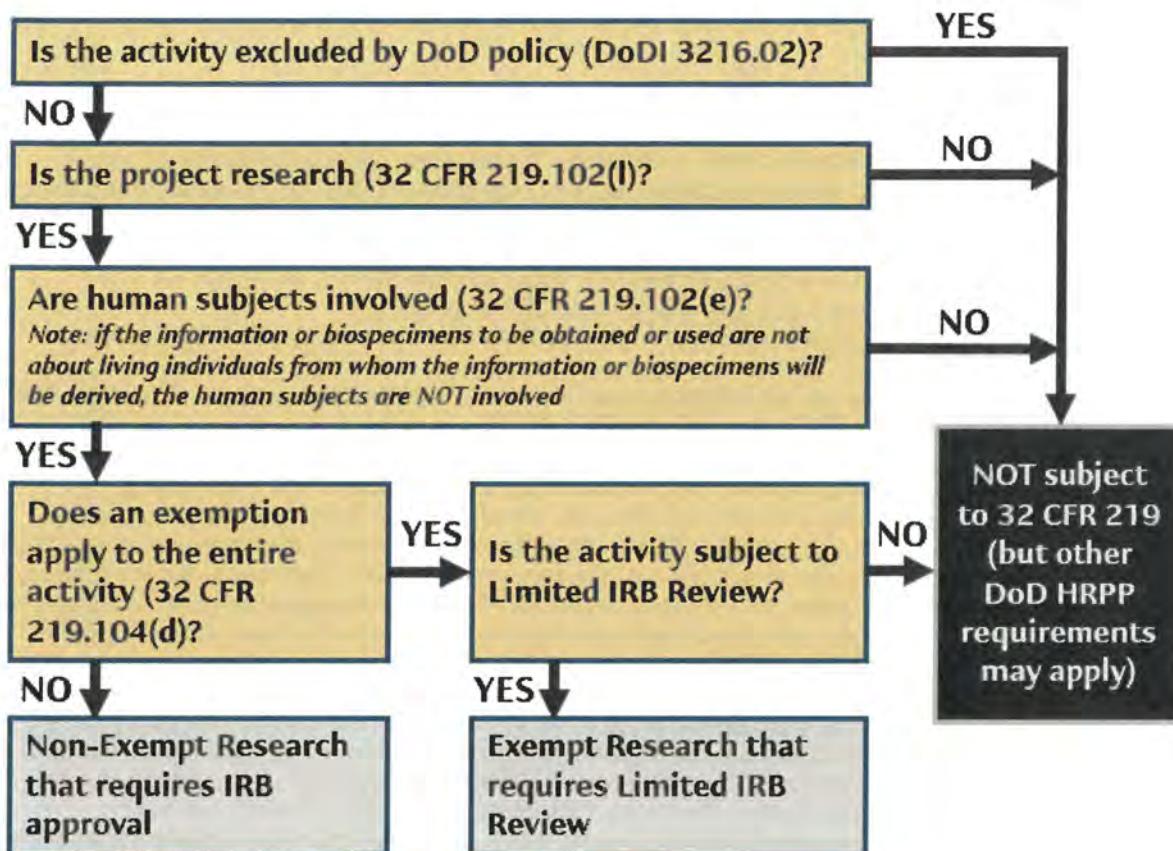


Figure 7-1. Determination Decision Pathway

7-3. Limited IRB Review

- A Limited IRB Review may be required for exempt categories (2)(iii), (3)(i)(C), (7), or (8) to ensure appropriate protections are in place for identifiable private information and identifiable biospecimens.
- The Limited IRB Review will be specific to the security data plan (exempt categories 2 and 3) or the use of broad consent (exempt categories 7 and 8) only; the IRB reviewer will not conduct an expedited review or expect documentation such as informed consent documents required in non-exempt research. See the IRB Standard Operating Procedures (SOP) for data security criteria and requirements. See 32 CFR 219.116(d) for broad consent elements.
- EDOs will conduct a standard protocol review, using the EDO Checklist. If it is determined that a Limited IRB Review is required, the USMA Human Protections Director (HPD) will submit the protocol and the completed EDO checklist to the IRB.
- In accordance with 32 CFR 219.109(a), the IRB may recommend approval, approval contingent upon modifications, or disapproval as exempt research for the protocol under which a Limited IRB Review is required.
- At the conclusion of the Limited IRB Review, the HPD will provide necessary documentation to the PI on the outcome. The HPD is responsible for ensuring the PI makes any directed modifications prior to the HPD providing an approval document. If the IRB approves the Limited IRB Review, the HPD will provide a determination letter to the investigator which includes the Limited IRB Review.
- If approved, the study will be considered as "exempt" and will not otherwise be subject to the provisions of the Common Rule. There is no requirement for continuing review of protocols that have been determined to require Limited IRB Review.
- If there is a modification to a protocol which previously required a Limited IRB Review, a new Limited IRB Review is only required if the EDO determines that there are changes to the privacy or confidentiality of the data.

h. Until DoD and/or Army guidance is issued, the use of broad consent shall not be used for research conducted by USMA.

7-4. Review of Non-Exempt Research

a. Human subject research that does not meet the criteria for exempt research must be reviewed by an appropriate IRB. The IRB provides initial and periodic review of the entire protocol packet (e.g., informed consent documents, recruitment letters, etc.) for regulatory compliance and adherence to ethical standards. The IRB has the "authority to approve, require modifications in (to secure approval), or disapprove all human subject research covered under" 32 CFR 219.109(a), including exempt research activities under 32 CFR 219.104 for which limited IRB review is a condition of exemption [32 CFR 219.104(d)(2)(iii), (d)(3)(i)(C), and (d)(7), and (8) and 32 CFR 219.109(a)].

b. The following are life-cycle actions which may require a submission and review by the IRB of record:

(1) 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 of record during the initial review of the protocol and will be documented in the initial approval letter. The IRB may change the continuing review requirements at any time during the life of the protocol based on the status of the protocol (e.g., enrollment is complete, all study visits are complete, etc.) or any concerns that the IRB has about the execution of the study. When required, the IRB will conduct continuing review of non-exempt research at intervals appropriate to the degree of risk, but not less than once per year. The investigator is responsible for submitting the continuing review packet to the USMA HRPP prior to the expiration of the study so that there is adequate time to review and approve the research before the expiration date. If the PI fails to submit a continuing review and receive approval prior to the protocol expiration date the research will be suspended until the continuing review is submitted and approved by the IRB.

(2) A modification request must be submitted when any aspect of the study is altered, including (but not limited to) changing methodology, adding or deleting investigators, changing the recruitment materials or procedures, changing the equipment or devices used, changing the study procedures, or altering the informed consent document or process. This modification packet should include a modification request form, an updated protocol (if applicable), an updated informed consent document (if applicable), and any other study documents with proposed changes. Substantive changes may trigger other required reviews. (See section 9 for a description of other potential required reviews.) The IRB may issue a new approved informed consent document. The investigator should be sure to only use this new informed consent document when consenting future participants. It is best practice to destroy all old unused versions of the informed consent document to ensure they are not accidentally used during the informed consent of new participants.

(3) A closure report can be submitted when the following activities are complete: enrollment, research-related interventions, data collection, and analysis of identifiable data. A protocol can also be closed if the PI has not completed the research objectives and has no plans to continue. Once closed, the investigators may not enroll new participants, conduct further analysis on identifiable data, or continue the study in any form. A study closure means that the IRB has concluded its review, approval, and oversight.

c. A complete submission packet for all life-cycle actions of non-exempt research must be submitted to the USMA HRPP for an initial review prior to submission to the IRB. The purpose of this initial review is to:

- (1) ensure that all required documents are included in the packet;
- (2) ensure that the methods meet the requirements of all USMA, Army, and DoD policies; and
- (3) to anticipate any obvious issues that will be flagged by the reviewer.

d. The HRPP initial review will be completed within ten business days. It is common for the HRPP to have questions for the PI or to require edits to the submission packet. Therefore, the period of time between initial submission and submission to the IRB may be longer than ten business days if there are substantive changes required or if the PI does not promptly respond to the initial review.

e. When the initial review is complete, the USMA HRPP will forward the documents to the appropriate IRB (see section 7-8) for review and will decide if there are additional required reviews (see section 9 for a description of other potential required reviews).

f. Investigators may be invited to attend IRB meetings if they have protocols under consideration. They should be prepared to provide a summary of the research and to answer all questions posed by the IRB members.

g. During the entire IRB review process, investigators are expected to promptly respond to IRB reviewers' questions and concerns to ensure prompt and efficient reviews.

h. Study execution may not begin until an IRB approval letter is issued, and all additional required reviews are completed. If a modification packet has been submitted, the proposed changes may not be executed until the modification approval letter is issued, unless the modifications are required for the immediate health, safety, or security of the participants. In this case, the investigator must notify the USMA HPD within one business day of this protocol deviation.

i. Investigators must conduct the study exactly as approved. If there are changes, modifications, deviations, or problems, they must be appropriately reported. (See Table 13-1 for reporting requirements.)

j. Research that has been approved by an IRB is subject to further appropriate review and approval or disapproval by the Institutional Official (IO)/Alternate Institutional Official (AIO). The IO/AIO may not approve research if it has not been approved by an IRB.

k. Investigators must keep all signed informed consent documents and all other study-related documents and files for a minimum of three years after the study has been closed (or six years if the research includes HIPAA-protected data IAW 45 CFR 164.316).

l. USMA HRPP will retain all paperwork related to the review of research in the official HRPP files for the same time periods.

m. For more information about requirements for the review of non-exempt research, see the applicable IRB SOP.

7-5. Non-Exempt Research that includes Physiological Monitoring

a. Physiological monitoring (PM) is the process of gaining greater awareness of physiological functions primarily using instruments, equipment, or devices. Non-exempt research that includes PM requires additional protections for the participants and includes investigator responsibilities and HRPP monitoring.

b. Devices must be used according to manufacturer's specifications, collect data they are designed to collect, be noninvasive or minimally invasive, and be no greater than minimal risk. Minimally invasive procedures are those activities that collect data with minimal discomfort or side effects that do not meet the definition of noninvasive (e.g., finger stick blood collection, saliva samples, etc.).

c. PM research will be reviewed by an IRB consistent with the level of risk. It can be reviewed using expedited procedures if it meets the criteria for any of the expedited categories.

d. While conducting research that includes the use of equipment or devices which collect physiological data, it is possible that clinical findings might result. These are called incidental findings (IFs). IFs are those results which are unrelated to the purpose of the study and are outside of normal ranges, as specified in the literature or manufacturer's guidance. These IFs might result in clinical implications or require medical intervention. An IF might be anticipated or unanticipated. An IF is a finding that:

- (1) Concerns an individual research subject that has potential health or reproductive importance;
- (2) Is discovered while 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).

e. Research protocols must have adequate provisions for screening and data monitoring to ensure the safety of participants. While carrying out these provisions, IFs may be identified. PIs have an ethical obligation to participants to assess the reasonably foreseeable potential for IFs, identify and assess the types of IFs possible, and establish 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 must follow the plan and procedures established for disclosure to the participants.

f. It is the PI's responsibility to note in the protocol whether IFs are associated with the devices to be used. If IFs are anticipated, the PI is responsible for:

- (1) Clearly listing the parameters of the IFs;
- (2) Developing a plan for the identification and assessment of IFs including specifying an expert who will be consulted with regard to the findings (if they are outside of the investigator's expertise);
- (3) Identifying which results will be reported to participants and the circumstances of the communications (who, when, where, and what); and

- (4) Developing a plan for further care for the identified participant which could include referral to a physician or provider, or information about alternate resources for obtaining care.
 - g. IFs and the management plan must be stated in the informed consent document.
 - h. IFs should be promptly reported to the USMA HRPP including a summary of the IF and the actions taken by the investigator.

7-6. USMA Administrative Review

- a. The USMA HRPP must complete an administrative review, using the USMA Administrative Review Checklist, for all research that uses USMA personnel as participants and is reviewed by an external IRB. This includes both exempt and non-exempt research.
 - b. The administrative review should not be redundant with the EDO/IRB review. The purpose of the administrative review is to ensure the reviewers considered local context during the review process and to ensure the protocol is in compliance with USMA, Army, and DoD policies and procedures.
 - c. This review can be completed before, after, or simultaneously with the determination or IRB review, but the research cannot begin until both reviews are complete.
 - d. The HRPP will complete this initial review within ten business days of submission of a complete packet.
 - e. Administrative reviews are not required for all protocol lifecycle actions submitted to the IRB of record. They are only required at the time of initial submission of the protocol; after adverse events, deviations, or noncompliance; and when there are substantive modifications including:
 - (1) Change in PI,
 - (2) Transfer of oversight to a new IRB,
 - (3) Change in methods that require a new CSL,
 - (4) Change in risk to participants,
 - (5) Change to the compensation for participants,
 - (6) Addition of vulnerable populations, or
 - (7) Significant increase in the amount of time required of participants.

7-7. Decision Appeals

- a. If an investigator disagrees with a decision made by either the EDO or the IRB, the investigator may appeal the decision.
 - b. To be considered for a change in the decision, the investigator must show that the decision was made in violation of policy or regulation or that there was clear prejudice on the part of the reviewer.
 - c. For all EDO determinations, the HPD is the first level of appeal. The HPD's decision can be appealed to the Army Human Research Protections Office (AHRPO).
 - d. For all non-exempt research, the procedures for appeal are governed by the IRB of record. Investigators should refer to the SOPs specific to that IRB.
 - e. The IO or AIO may disapprove any research that was previously approved by the EDO or IRB but cannot approve research that the EDO or IRB has disapproved.

7-8. Institutional Review Boards (IRBs)

- a. All non-exempt human subject research conducted or supported by the DoD must be reviewed and approved by a duly constituted IRB IAW DoDI 3216.02. Depending on the category of research and the population of the participants, there are several IRBs that USMA can utilize for the appropriate review of research.
 - b. IAW 32 CFR 219.114, institutions must rely on a single IRB for the review of cooperative research. IAW DODI 3216.02 1.2.j., if a DoD institution believes that the research is not subject to this provision, the Army Human Research Protections Office (AHRPO) may determine and document, that use of a single IRB is not appropriate for the particular context of the proposed research. Studies already in progress before 20 January 2020, will not be required to transition to a single IRB, nor submit exception documentation.

c. The following IRBs are typically used for review of USMA research:

(1) *U.S. Army Development Command (DEVCOM) Armaments Center (AC) IRB.* Occasionally, USMA investigators collaborate with investigators at U.S. Army Research Institute of Environmental Medicine (USARIEM). USARIEM relies on the services of the DEVCOM-AC IRB (for non-biomedical protocols) or MRDC IRB (for biomedical protocols) for review. In these instances, USMA investigators would rely on this IRB for review of research. Additionally, USMA investigators who propose to use prisoners as subjects, must use an IRB that is duly constituted to review this type of research with a vulnerable population. DEVCOM-AC IRB is constituted to conduct this type of review.

(2) *U.S. Army Medical Research and Development Command (MRDC) IRB.* Occasionally, USMA investigators conduct biomedical research. Biomedical research is defined as a study designed to develop the practices or technologies for medical detection or prevention, treatments, or diagnosis for patients, including any Food and Drug Administration (FDA) drug, dietary supplement, or medical device studies. When USMA investigators need IRB review of biomedical research, this research will generally be submitted to the MRDC IRB.

(3) *DEVCOM Army Research Laboratory (ARL) IRB.* Many USMA investigators collaborate with investigators at ARL. In these situations, it is sometimes most efficient for the ARL IRB to review these research protocols.

(4) *Other DoD IRBs.* There may be situations when it would be appropriate and most efficient to rely on other DoD IRBs (e.g., the collaborating investigators or participants are not located at USMA). The investigators and the USMA HRPP will work together to decide what IRB is most appropriate for the review of each protocol.

(5) *Non-DoD IRBs.* In rare cases, it may be appropriate to rely on a non-DoD IRB for review of research. When this happens, there are additional review and oversight requirements to ensure that all DoD, Army, and USMA policies are adhered to, and DoD-affiliated personnel are adequately protected.

Chapter 8

Collaborative, Multi-Site, and External Research

USMA supports quality research efforts that inform decisions by the Department of Defense (DoD), the Army, and USMA leadership. USMA also recognizes that while USMA is a rich environment for research activities, the resources of faculty, staff, and Cadets are limited and must be closely guarded.

8-1. Definitions

- a. Collaborative research is research conducted by investigators who are covered by the USMA Assurance, working with investigators who are external to USMA.
- b. Multi-site research is research that is conducted using the same methods at more than one performance site. Typically, there is a lead site with a lead Principal Investigator (PI) who is responsible for providing oversight and direction for the entire study.
- c. External research is research conducted at USMA solely by investigators who are not employees or agents of USMA, and who are not covered by the USMA Assurance.

8-2. Requirements for Collaborative, Multi-site, and External Research

- a. The Institutional Review Board (IRB) of record will be determined based on many factors, including but not limited to, the nature of the research, the institution of the PI, and the risks to participants.
- b. When an external IRB is relied on for the review of non-exempt research, all unaffiliated institutions/investigators must have a signed Institutional Agreement for IRB Review (IAIR)/Individual Investigator Agreement (IIA) or other agreement in place to document the responsibilities of all parties, unless all institutions are in the DoD. (For more information about agreements, see section 2-2 and section 2-3 of this regulation.)
- c. If the research is submitted to an external IRB and proposes to recruit USMA personnel as participants, the USMA Human Research Protections Program (HRPP) must conduct an administrative review to ensure that the research protocol meets the regulatory requirements of the DoD, Army, and USMA. (See section 7-6 for information about the administrative review.)
- d. Each institution engaged in collaborative or multi-site non-exempt human subject research must have a current Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) Federalwide Assurance (FWA) or DoD Assurance.
- e. Each engaged investigator must provide credentials to establish their ability to conduct the research. A curriculum vitae (CV) or biosketch, documentation of human subject research training (per local policy), and a conflict of interest disclosure form (for non-exempt research only) must be provided prior to approval. A description of roles and responsibilities of study personnel may be requested during the review process to assist in the determination of which institutions are engaged in the research.
- f. A command support letter (CSL) signed by the USMA Superintendent or Chief of Staff is required for multi-site and external research, when the research uses USMA personnel as human subjects and the overarching PI is external to USMA. (See section 4-3.g. for information about obtaining this CSL.)
- g. The IRB or the USMA HRPP may determine that a research monitor or ombudsperson is required. This is to ensure that there is an independent monitor with expertise consonant with the unique aspects of the USMA environment and with service-specific requirements. The IRB/HRPP will approve a written summary of the duties, authorities, and responsibilities of the research monitor and/or ombudsperson. (See section 3-10 for a description of the research monitor's responsibilities.)

8-3. Keller Army Community Hospital

- a. Keller Army Community Hospital (KACH) is a tenant organization that does not fall under the USMA Assurance. Additionally, KACH-conducted research generally requires review by an external biomedical IRB. Therefore, KACH protocols that propose to use USMA personnel as participants, require an administrative review conducted by the USMA HRPP. (See section 7-6 for information about the administrative review.)

b. Research conducted by KACH may be covered by a blanket CSL signed by the USMA Superintendent. The USMA Human Protections Director (HPD) will determine if the study will be covered under the blanket CSL during the administrative review process.

(1) This blanket approval is limited to clinical research specifically designed to meet the objective of safety and effectiveness (efficacy) of medications, devices, diagnostic products, and treatment regimens intended for human use. This may include research for the prevention, treatment, or diagnosis of a disease.

(2) Research not covered under the blanket CSL includes studies which use Food and Drug Administration (FDA) investigational drugs or devices, genome studies, or experimental medical procedures which are determined to be greater than minimal risk.

(3) This approval does not include access to previously collected identifiable Cadet data obtained for admission, education, training, or athletic purposes.

(4) The blanket CSL does not include social/behavioral science studies which do not fall under the definition of biomedical research.

c. All research that does not meet the parameters of the blanket CSL will require a protocol specific CSL from the USMA Superintendent or Chief of Staff. (See section 4-3.g. for information about obtaining this CSL.)

d. Cadets who participate in KACH research activities are not excused from standing academic and other duty requirements.

e. KACH will brief USMA leaders on current and projected clinical studies that involve faculty, staff, Cadets, or beneficiaries as participants.

Chapter 9

Other Required Reviews

9-1. USMA Institutional Research Committee (IRC)

- a. The purpose of the IRC is to synchronize and adjudicate data and survey requests for all research and assessment efforts connected to institutional data. Institutional data includes all data collected and stored by USMA including Cadet grades, admission test scores, etc.
- b. Faculty and staff members who collect and have access to USMA institutional data are not entitled to use this data for research without the proper approvals.
- c. All investigators of exempt and non-exempt research that propose to use USMA institutional data must submit a request to the IRC for consideration and approval.
- d. All investigators who propose to collect information (e.g., surveys, interviews, focus groups, etc.) from USMA personnel must submit a request to the IRC for consideration and approval. In accordance with (IAW) Army Regulation (AR) 25-98, information collection is defined as written verbal reports, applications (forms), schedules, surveys (including focus groups), questionnaires, reporting or recordkeeping requirements in any format and collected through any media.
- e. As resources allow, the Office of Institutional Research (OIR) acts as a trusted agent for investigators who request de-identified data sets using the safe harbor method
- f. IRC reviews are separate and independent of the USMA Human Research Protections Program (HRPP) review of research.

9-2. Component-Level Administrative Review (CLAR)

- a. A CLAR must be conducted for all non-exempt protocols involving human subjects IAW DoDI 3216.02 3.5.b.(1) when any of the following conditions apply:
 - (1) Human subject research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are U.S. citizens.
 - (2) The research requires a waiver of informed consent pursuant to Subsection (b) of 10 USC 980.
 - (3) The research is fetal research, as described in sections 289g – 289g-2 of 42 USC 241.
 - (4) Large-scale genomic data (LSGD) is collected from DoD-affiliated personnel.
 - (5) The research constitutes classified human subject research as defined by DoDI 3216.02.
 - (6) Research is required to be approved by the Department of Defense Directorate of Human Research Protections (DOHRP).
- b. The CLAR occurs in coordination with the USMA HRPP review and/or IRB review.

9-3. Human Research Protections Official (HRPO) Review of Funded Research

- a. Research which receives external funding must be conducted IAW USMA Regulation 150-6. All funded research must be coordinated with the USMA Office of Research at research@westpoint.edu.
- b. The USMA HRPP will work with investigators to help determine if a HRPO review is required and will assist with the submission of the protocol packet. The HRPO review occurs in coordination with the USMA HRPP review and/or IRB review.

c. DoD regulations require that the DoD include specific language in contracts or other comparable agreements (such as grants, assistance agreements, and cooperative research and development agreements) that might include research involving human subjects. This language identifies the awardee requirements and responsibilities and requires that any research involving human subjects supported by the award be reviewed and approved by a designated DoD HRPO prior to the implementation of the research. A HRPO review must be conducted for all protocols involving human subjects IAW DoDI 3216.02 3.5. 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. At a minimum the HRPO review must:

(1) Concur with the extramural institutions regarding the activities they have determined to be either research not involving human subjects or research involving human subjects that is exempt from the regulatory provisions of 32 CFR 219.

(2) Confirm that the institution has a Federalwide Assurance (FWA) appropriate for the conduct of non-exempt research involving human subjects. If DoD institutions are engaged in the extramural research, they must have a DoD Assurance.

(3) Review the research protocol for compliance with DoDI 3216.02, accept the IRB determination of level of risk, ensure that the study is compliant with applicable DoD regulatory requirements, and approve the protocol prior to implementation.

(4) Review and accept IRB-approved substantive changes to an approved research protocol before they are implemented.

(5) Ensure compliance with the DFARS clause.

(6) Ensure the IRB conducts an appropriate continuing review for non-exempt research when the IRB determines it is needed.

(7) When all or part of the research involving human subjects is being executed outside of the United States, the HRPO must confirm all applicable host national laws and requirements of the foreign country have been met and confirm the IRB considered cultural sensitivities in the setting where the research will take place. The Principal Investigator (PI) must provide adequate information to the HRPO regarding national laws and requirements and the cultural context in which the research will take place.

d. For protocols involving multiple research sites and/or multi-institutional collaborations on a single study, the HRPO must review and approve site specific documentation prior to the initiation of research.

e. The funding awardee is responsible for overseeing execution of the research and must include similar language in subcontracts that support research involving human research. This funding awardee must:

(1) Allow DoD representatives to independently review and inspect the awardee's research. This may include access to identifiable information or protected health information (thus, subjects must be informed).

(2) Allow DoD representatives to prohibit research that is determined to present unacceptable hazards or is non-compliant with DoD regulatory requirements.

(3) Apply these policies to all funded human subject research, whether or not it is determined to be exempt from the regulations.

9-4. Security Review for Large-Scale Genomic Data (LSGD) Research

a. The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, such research requires administrative, technical, and physical safeguards commensurate with risk, including the secondary use of sharing of de-identified data or specimens.

b. IAW DoDI 3216.02, a Security Review must be completed by the Army Human Research Protections Office (AHRPO) for research involving LSGD collected from DoD-affiliated personnel, including the secondary use or sharing of de-identified data or specimens. This is an administrative review to ensure the research protocol includes administrative, technical, and physical safeguards for protecting their confidentiality both during and after the conduction of research.

c. All research that includes LSGD must be approved by the DOHRC.

d. All research involving LSGD collection from DoD-affiliated personnel will apply an U.S. Department of Health and Human Services (HHS) Certificate of Confidentiality (CoC) pursuant to 42 USC 241 and Public Law 114-255.

9-5. Information Collections

IAW 44 USC 3501 et seq., and AR 25-98 all information collection activities (e.g., surveys, interviews, focus groups, etc.) must be reviewed and approved before implementation. This review is separate and independent from the USMA HRPP review. For more information contact USMA G5 or see AR 25-98, DoDM 8910.01, Volume 1 and DoDM 8910.01, Volume 2.

9-6. External Institution-Specific Reviews

- a. All assured institutions have their own HRPP and policies. When conducting research in collaboration with other institutions or when recruiting and enrolling participants from other institutions, investigators must comply with these policies.
- b. The USMA HRPP can assist with communicating with other institutions and complying with their requirements.

Chapter 10

Cadets As Investigators

10-1. Class Project vs. Research

Many majors and/or courses at USMA encourage or require Cadets to engage in projects that could be research. It can be challenging to discern which projects require regulatory review. The following guidelines are presented to provide the characteristics which are often used to distinguish between activities that may be considered class projects which do not require regulatory review and those projects which may be determined to be research requiring regulatory review. These are guidelines. None of these conditions are absolute and any questions should be directed to the USMA Human Research Protections Program (HRPP).

a. Class Project:

- (1) The purpose of the project is for the Cadet to learn about research methods, or
- (2) It is not intended to answer a research question or contribute to generalizable knowledge, or
- (3) It is an oral history type study designed to learn about an individual's experiences and not intended to contribute to generalizable knowledge, and
- (4) The project is small in scale with 10 or fewer participants, and
- (5) The project is not presented outside of the course or Projects Day, and
- (6) Data is destroyed upon completion of the project.

b. Research:

- (1) The purpose of the project is to attain new discoveries that will contribute to generalizable knowledge,

- (2) There is a systematic investigation, or
- (3) The results will be disseminated outside of the course or Projects Day.

c. The following traits, when present, may indicate a requirement for regulatory review, regardless of whether it is a class project or research.

- (1) USMA and/or Cadet data is used in the research,
- (2) Participants are randomized into treatment groups,
- (3) An intervention is utilized in the process of data collection,
- (4) Data collection techniques are invasive,
- (5) Data that will be collected are sensitive in nature (e.g., illegal activity, sexual orientation, mental health issues, etc.), even if the participant is given the option to not answer a question,
- (6) Recruitment occurs in public settings (e.g., by posting flyers or using social media platforms),
- (7) Vulnerable populations are recruited to be participants,
- (8) The project involves greater than minimal risk, or
- (9) Participants are not USMA personnel.

10-2. Cadets Engaging in the Protocol Submission of Research

a. The process of submitting a protocol for regulatory review can supplement the instruction provided in the classroom. Faculty and staff members teaching research methods are encouraged to direct their Cadets to engage in this process, even if the project would not ordinarily require regulatory review. Completing this process is a learning experience that will help Cadets prepare for executing research in graduate education. Obtaining a research determination or approval has the added benefit of providing more flexibility in using the data after the conclusion of the project.

b. Cadets who engage in human subject research are required to complete CITI Training or other human subject research training. Cadets who complete class projects are encouraged, but not required, to complete this training. (See section 5-1 for training requirements.)

c. Cadet investigators are NOT required to submit a curriculum vitae (CV) or biosketch with the protocol submission because they are not allowed to act in the role of Principal Investigator (PI).

d. Every Cadet project is unique. Questions about whether a project requires regulatory review should be directed to the USMA HRPP.

10-3. Responsibilities of Faculty and Staff Principal Investigators in Cadet Research

a. Faculty and staff members who teach research methods have the responsibility to include ethics training in their instruction and to make sure that projects are conducted in accordance with these ethical principles. They should also:

- (1) Guide Cadets through the regulatory process by discussing general principles of research ethics prior to the initiation of any research activities,
- (2) Teach Cadet investigators the appropriate way to interact with volunteer participants,
- (3) Provide the guidance necessary to ensure that volunteer participants do not sustain unintentional harm, and
- (4) Help Cadet investigators develop a data management plan that protects the participants to the greatest extent possible.

b. Faculty or staff members must fulfill the role of PI and assume full responsibility for the safe and ethical conduct of the research. Cadets cannot be PIs on a research project but should be listed as Associate Investigators (AIs).

c. Faculty and staff members must submit to the USMA HRPP any classroom, capstone, or thesis project that requires regulatory review. Faculty and staff must consider the time requirements for the appropriate review of the research and must submit the project in time to ensure the successful completion of the project.

d. Faculty and staff PIs must supervise all aspects of the research to ensure compliance with the approved protocol, with this policy, and with all other applicable regulations.

e. PIs must ensure that Cadet investigators are not recruiting Cadet subordinates to participate in the research.

f. PIs must promptly report all deviations, adverse events, UPIRTSOs, or other significant events. (See section 13 for reporting requirements.)

g. PIs oversee data management for the research to ensure compliance with the approved protocol and maximal protection for human subjects.

h. PIs maintain responsibility for all protocol documents (both hard copy and electronic) for three years after the closure of the protocol (or six years if the research includes HIPAA-protected data). They must store all documents with necessary security measures as outlined in the protocol. They must properly close the protocol when it is complete. If the PI is scheduled to PCS from USMA before three years after the protocol has been closed (or six years if the research includes HIPAA-protected data), they must transfer data/document management responsibilities to a knowledgeable colleague by submitting the appropriate modification paperwork to the USMA HRPP.

i. If the Cadet investigator is graduating or leaving USMA before the research is complete, the PI must submit modification paperwork to remove the Cadet from the protocol. Additionally, the PI must ensure that the Cadet has destroyed all copies of identifiable data sets to ensure they do not leave USMA-located devices and/or networks.

j. The faculty or staff PI follows all other roles and responsibilities of the PI as stated in section 3-8.

10-4. Cadet Data Use in Cadet Projects

Cadet data are considered personal and private information. Access will be granted to USMA data for research purposes only after an appropriate regulatory review and adjudication by the USMA Institutional Research Committee (IRC). Given the nature and sensitivity of Cadet data, particularly for current Cadets, investigators are discouraged from using this data for Cadet projects unless significant protections are in place to eliminate the identifiability of the data. Access to Cadet data for Cadet projects from the Office of Institutional Research (OIR), Office of Economic and Manpower Analysis (OEMA), Directorate of Admissions (DAD), Athletics [to include the Office of the Directorate of Intercollegiate Athletics (ODIA) and Army Athletic Association (AAA), and any contractors including Army West Point Athletic Association (AWPAA)], or the Registrar [to include the Academy Management System (AMS)] will only be granted with justification and approval from the IRC. Generally, it is recommended that all Cadet data be de-identified before being released; exceptions to this practice must be specifically justified in the data request and approved by the IRC. (See section 9-1 for information about the IRC.)

10-5. Cadet Investigators Graduating or Leaving USMA

a. PIs must ensure that study data possessed by Cadet investigators has been securely stored and is being maintained by the faculty or staff PI on USMA networks before Cadets graduate or leave USMA. Cadets may not retain possession of data after they leave USMA without a signed External Investigator Agreement. (See section 7-1.q. for information about this form.) Some exceptions are possible with limited de-identified data sets. All questions should be referred to the USMA HRPP.

b. PIs who supervise Cadet researchers who are leaving USMA should submit a modification to remove the Cadet from any active protocols including any open non-exempt protocols and any exempt protocols that are still in the data collection or data analysis phase.

10-6. International Research

There are many additional layers of reviews and approvals that must be completed when engaging in international research. These reviews include the consideration of local regulations and customs, cultural sensitivities and norms, and/or local language and dialects. Human subject review boards outside the United States often have additional requirements for foreign investigators. These reviews take much longer to complete than research completed at USMA and therefore, these projects are often not suitable for Cadet research because of academic calendar timelines. Cadets who are interested in participating in international research are encouraged to link up with an investigator with an existing research project, that has already obtained the necessary reviews and approvals, so that they can gain the desired research experience. (See section 4-10 for information about international research.)

Chapter 11

Cadets As Human Subjects

Extra care and appropriate oversight are required when Cadets are human subjects. The unique environment at USMA can make them prone to coercion and undue influence. It exposes them to an abundance of solicitations to volunteer because of the convenience for investigators to obtain information from them and about them. The access to their personal information by faculty and staff exposes them to higher risk of loss of privacy and breach of confidentiality.

USMA Human Research Protections Program (HRPP) personnel and investigators are both responsible for ensuring that Cadets are not being coerced or unduly influenced, and that the demands of research-related tasks do not interfere with a Cadet's performance in the academic, military, physical, and character programs. Additional safeguards must be considered to protect Cadets, and research protocols must be scrutinized to prevent either intentional or unintentional coercion, undue influence, or misuse/abuse of Cadet time.

11-1. Cadets as a Unique Population

- a. Cadets are military personnel and are subject to military law, the Uniform Code of Military Justice (UCMJ), and Army regulations.
- b. The Cadet honor code states that "a Cadet will not lie, cheat, steal, or tolerate those who do." The consequences for a Cadet who violates this code can be severe and can include separation from USMA. For this reason, it is important for investigators to understand and consider the ramifications of collecting data from Cadets that could invoke consequences of the honor code.
- c. Cadets are not like any other undergraduate students because they are military service members. They are conditioned to follow orders and any Commissioned or Non-Commissioned Officer (NCO) can exercise "general military authority" over them. Therefore, Cadets, by the nature of their low rank, age, and inexperience within the military structure, are most susceptible to coercion and undue influence compared with people in other organizations.
- d. USMA is a high-profile public institution with a national presence. USMA and Cadets are frequently highlighted in the press and there are myriad of websites and social media platforms that disseminate information about Cadets. For this reason, investigators must be cognizant of the data that they are collecting, and how these data could be combined with publicly available data to easily identify a Cadet participant.
- e. The nature and level of risk of the research 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 UCMJ including incarceration and dishonorable discharge.
- f. If the research includes any risks to the Cadet's fitness for duty (e.g., health, availability to perform job, data breach, etc.), the informed consent document must inform them about these risks and advise them to seek command guidance before participating in accordance with (IAW) DoDI 3216.02 3.9, f.(1).
- g. IAW DoDI 3216.02 3.8, b., when evaluating risk associated with research protocols, investigators and reviewers must not consider the inherent occupational risks that Cadets face in their daily lives. Instead, they must compare the risks to those experienced by average college students. For example, Cadets frequently engage in activities such as obstacle courses, mountaineering, combatives, contact sports, etc., but these activities are not common for average college students and the risk must be evaluated based on the average college student population.

11-2. Cadet Recruitment and Enrollment

- a. Cadets have the right to voluntarily participate in research, to withdraw from a study at any time for any reason without reprisal or recrimination, and to refuse to participate without consequences or loss of benefits the Cadet would otherwise be entitled to.

- b. Recruitment is the process by which potential participants are informed about the study. Recruitment materials, such as flyers, email messages, social media posts, newspaper ads, and phone calls, must be true, non-coercive, and must not highlight any potential monetary compensation. These recruitment materials must be reviewed and approved before recruitment begins. Auditors, research monitors, and ombudspersons may also observe recruitment methods.
- c. Cadets have a more complicated chain of command than other military service members. A typical legal chain of command exists consisting of tactical (TAC) officers and TAC NCOs. However, Cadets also participate in other organizations with command structures led by officers and DA Civilians in positions of authority, including academics, athletics, clubs, etc. Additionally, a Cadet chain of command is overlaid on these existing command structures. This system of authority introduces multiple layers of authority where a Cadet could perceive coercion or undue influence. Investigators must be aware of all these relationships and ensure that all aspects of the research (e.g., recruitment, enrollment, data collection, etc.) convey the complete voluntariness of the research activity.
- d. The chain of command (including the Cadet chain of command) cannot be involved in the recruitment of military personnel and must not order Cadets or Soldiers to participate in a research study.
- e. There are many strategies for avoiding chain of command issues in research including using civilian Associate Investigators (AIs), who are not instructors, to recruit and collect data, recruiting participants from different sections of the same course, sending recruitment emails from generic accounts, recruiting from subject pools, etc. Investigators should creatively consider all possible ways to avoid the possibility of perceived coercion, undue influence, or anything other than the complete voluntariness of participation.
- f. Enrollment involves selecting volunteers and obtaining their informed consent to participate as human subjects. The Principal Investigator (PI) ensures that selection of participants is equitable IAW the principle of justice in the Belmont Report. The PI should consider the purpose of the research and the setting in which the research will be conducted.

11-3. 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." For Cadets this includes protecting the time they have available for their studies and other required duties.
- b. Cadets are commonly recruited to be 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 human subjects by considering all research projects, program assessments, and other activities that compete for their time.
- c. Cadets are required to complete several 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. Investigators who use surveys to collect data must demonstrate that the research is necessary and warrants the use of Cadet time.
- d. Investigators must use their expertise to calculate the smallest possible sample sizes that can be used to yield statistically valid results.
- e. Investigators should calculate time requirements for their study and design methods to minimize the impact on Cadet time. Investigators should carefully consider each aspect of their study to minimize number of visits, survey questions, etc.
- f. Investigators should consider whether their study can be completed by using populations of military service members that do not include Cadets.
- g. Cadets may participate in research activities during "Commandant time" (non-academic hours) at the discretion of the Commandant of Cadets, including during Cadet Basic Training, Cadet Field Training, Sandhurst, military training, and other non-academic times. Research is not permitted in the barracks spaces without specific permission from the Commandant of Cadets, unless the research is being conducted by a Cadet researcher IAW the research protocol. The United States Corps of Cadets (USCC) may issue additional guidance further restricting the above as desired.

h. IAW DPOM 02-02, Cadets may not participate in research during Term-End Examinations (TEEs). During this period, the primary duty of all Cadets is to prepare for and take scheduled TEEs. No other activities or duties involving Cadet participation may be scheduled without the written approval of the Dean.

i. Cadets who are corps squad athletes may participate in research activities during athletic practice or competition at the discretion of the Army West Point Athletic Department (AWPAD). AWPAD may issue additional guidance further restricting the above as desired.

j. Cadet candidates at the United States Military Academy Prep School (USMAPS) may participate in research activities during non-academic hours at the discretion of the USMAPS Commandant, including during indoctrination, Sandhurst, military training, and other non-academic times. Research by any investigator is not permitted in the barracks spaces without specific permission from the USMAPS Commandant. USMAPS may issue additional guidance further restricting the above as desired.

k. Research conducted during Cadet activities must be designed to be as unobtrusive as possible and may not interfere with the training mission. Additionally, all investigators must adhere to all health and safety directives from the training officials for that activity as well as published guidance.

11-4. Use of Class Time

a. Research on the practice of teaching and learning 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.

b. Class time may not be used for recruiting participants or collecting data for research unless the research is about the practice of teaching and learning or if it is used as a teaching opportunity such as in a research methods class. Cadets have the right to have class time devoted to classroom activities appropriate to meeting the objectives of the course. If class time is to be used for research, the investigator must obtain an exception to policy from the Dean and command approval from the department head.

c. There are times when a course requirement is also a research data collection tool. A Cadet can participate in these activities to meet course requirements without having their data included in the research by withholding their consent. Prior to executing research, the investigator must clearly inform the students which activities are course requirements, which are for research only, and which are for both. The investigator must then obtain informed consent to use the data for research unless the research meets the requirements and has been determined to be exempt under category 4 IAW 32 CFR 219.104(d)(4).

d. Except for pedagogy studies, faculty and staff are discouraged from using their own students as participants in their research. Cadets have the right to be free from any undue inducement or bias that might result when an investigator is also their instructor. In cases where the instructor is also an investigator, there are many strategies to decrease or eliminate perceived undue inducement or bias including having AIs recruit and collect data, delaying the collection of data until the conclusion of the course, blinding the instructor to the participant list, etc. (See section 11-7 for information about coercion and undue influence.)

e. Beyond the considerations outlined above, academic departments may impose their own additional constraints on using Cadets as research participants.

f. The Dean may issue additional guidance further restricting the above as desired.

11-5. Compensation and Incentives

a. Active-duty service members may receive small, token incentives for participation pursuant to DoD guidelines. The incentives may not be sufficient to entice a subject to participate who otherwise would not have done so (e.g., substantial extra time off).

b. Cadets cannot be compensated (beyond extra credit and/or food) for participation in research while on duty. For the purposes of research, Cadets are considered on duty at all times except when they are in a leave status.

c. Monetary compensation to Cadets (and all DoD-affiliated personnel) for participation in research while on duty is prohibited in accordance with Title 5, U.S.C., with particular reference to Subparts G and H, with some exceptions for purposes IAW with 24 USC 30.

d. Active-duty service members may receive up to \$50 for a 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 (24 USC 30).

11-6. Extra Credit

a. Extra credit can be given to Cadets who participate in a research project only when alternative means of obtaining equivalent extra credit (requiring equivalent effort) are made available to Cadets who do not wish to volunteer as research participants.

b. The protocol should describe the alternatives to ensure that Cadets are not being unduly influenced to participate. For example, requiring a Cadet to complete a two-hour assignment is not equivalent to participating in a research study for 30 minutes, and this could be considered an undue inducement.

c. The informed consent process should clearly state that there is an option to withdraw at any point without consequences. Whenever possible, extra credit should be given even if the Cadet later decides to withdraw from the study.

d. 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 3% of the overall course grade.

e. Cadet "subject pools"

(1) "Subject pools" are often used where students enrolled in 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) Departments that have subject pools must also have a policy that governs access, use, and alternative means to obtain extra credit.

(3) Investigators who recruit from "subject pools" external to USMA are required to include the subject pool policies and procedures with a non-exempt research protocol when they submit their research study for regulatory review and approval.

11-7. 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 scrutinized when Cadets are involved. Cadet, faculty, and staff investigators should take care to avoid the unintentional or perceived coercion or undue influence that may occur when potential subjects are Cadets.

b. Faculty and staff investigators must avoid involving their own students as research participants whenever possible. Similarly, they must avoid involving Cadets who are in other organizations in which the faculty or staff member has a position of authority, such as athletic teams and clubs. Faculty and staff members who wish to involve their own students as participants should be able to provide a valid reason, other than convenience, for selecting those students as participants such as for 1) research on the practice of teaching and learning or 2) when participation is part of the learning experience for the students.

c. In instances where investigators can provide a valid reason for involving their own students in their research, it is required that someone other than the instructor obtain informed consent and collect the data. When this is not possible, other methods can be considered for obtaining informed consent and collecting data that would not reveal to the instructor whether a specific student participated in the research project until after final grades have been determined. The students should be informed of these procedures in the informed consent process. In addition, it is generally recommended that the investigator provide a recruitment flyer or letter to a subject pool, general student population, or both so that the student is the one who initiates contact with the investigator.

d. Faculty and staff investigators should seek another population of participants that are equally suited to the research question (e.g., another class section not taught by the investigator, recruitment by another instructor, or blinded-coded data so that participants 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.

- e. A Cadet participant's current instructors, members of their Cadet chain of command, their coaches, and their tactical officers, cannot be present during any recruitment or informed consent activities for research that does not meet the exceptions listed above (e.g., research is related to the practice of teaching and learning or participation is part of the learning experience).
- f. If Cadet participants feel they have been unduly influenced to participate in a study, they should immediately inform the USMA Human Protections Director (HPD), the IRB of record, or the Inspector General (IG).
- g. A Cadet who is a potential volunteer needs to have unimpaired reasoning abilities at the time of informed consent. Impairments of reasoning abilities include high levels of stress, illness, injury, intoxication, insufficient sleep, and other health problems.

11-8. Use of Cadet Data

- a. Protection of privacy and confidentiality is an important aspect of human subject protections. It is an application of the principle of autonomy (respect for persons) from the Belmont Report. Participants have the right to expect that the data collected about them during a research study will be adequately protected from disclosure outside of the research team. A breach of confidentiality is often the greatest risk to participants in social and behavioral human research. It could place the participants at risk of significant harm, including damage to reputation, threat to employment, loss of insurance coverage, or risk of lawsuits or criminal prosecution.
- b. Information that is collected for a Cadet Observation Report (COR), a Periodic Development Review (PDR), a Conduct Hearing, a Misconduct Hearing, or an Honor Investigative Hearing cannot be used for research purposes to include any form of the data (even if it is de-identified). These activities are compulsory, not voluntary. The data is sensitive and is collected without informed consent. This violates several ethical principles of human subject research. Access to this data for activities that are NOT research can only be granted by the USMA Institutional Research Committee.
- c. Neither USMA nor any of its agents may supply an investigator with the names of Cadets or email addresses for research purposes without prior regulatory review and approval. Likewise, an investigator with knowledge of Cadet names because of teaching or involvement in other USMA-related activities may not use that knowledge to generate a list of Cadet names or email addresses for research purposes.
- d. Publicly displayed (paper or electronic) sign-up sheets may not be used for research that is recruiting Cadet participants.
- e. IAW DoDI 3216.02 3.14.b., a DoD institution conducting human subject research may request a Certificate of Confidentiality (CoC) pursuant to 42 USC 241. (See section 12-2.f. for more information about CoCs.)
- f. In special circumstances requiring additional safeguards to prevent potential criminal civil prosecution of the participant, there may be a requirement to destroy all data that can identify the participants.
- g. For more information about protecting Cadet data, see section 12.

Chapter 12

Data Management and Security

The United States Military Academy (USMA) 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 (DoD), and the U.S. Army. There are specific considerations regarding general data collection requirements for maintaining privacy and confidentiality. Additionally, there are unique data collection requirements imposed on USMA by its higher headquarters. Protection of privacy and confidentiality is an important aspect of human subject protections and is an application of the principle of autonomy (i.e., respect for persons) from the Belmont Report.

12-1. Definitions

- a. *Privacy*. Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.
- b. *Confidential*. 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.
- c. *Anonymous*. Data collected without identifiers. If a combination of variables would allow identification of a participant, the data is not anonymous. Data collected face-to-face (e.g., interviews, focus groups, etc.) cannot be considered anonymous.
- d. *De-identified*. See section 12-3.c. below.
- e. *Coded*. Data that are stripped of all direct participant identifiers, but each record has its own research ID or code which is linked to identifiable information such as name or medical record number. The key that links the identifiers with the codes must be separate from the coded data set. This key may be held by someone on the research project team [e.g., the Principal Investigator (PI)] or it could be held by someone outside of the research project team (e.g., database manager). If a key exists, it is possible to re-identify the participants and the data is not considered de-identified. A coded data set may include limited identifiers under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). To comply with HIPAA, the code itself may not contain identifiers or parts thereof such as medical record number, participant initials, or derivatives of social security number (SSN).

12-2. Privacy and Confidentiality

- a. All research protocols should have an appropriate data protection plan. In many cases risk to privacy and confidentiality can be greatly reduced by careful procedures specified in the protocol. Investigators must conduct a risk assessment of the possible loss of privacy and confidentiality and include these possible risks and associated mitigation strategies in the protocol. The investigator must describe plans to protect the identity of the participant and the confidentiality of the research records (e.g., coded data, file passwords, network security, physical security, etc.). Furthermore, investigators must describe who has access to the data and under what circumstances confidentiality may be broken.
- b. Informed consent documents should describe what data is collected, how it is collected, how long it will be maintained, how it will be stored (i.e., identified, coded, de-identified, etc.), whether it will be shared, when it will be destroyed, and what protections are in place to protect the privacy and confidentiality of the participant.
- c. Without appropriate safeguards, problems may arise with long-term retention of records. When additional safeguards are needed to prevent potential criminal or civil prosecution of the participant, the IRB may require the destruction of all data that can identify the participant. Participants should be informed whether the data collected will be retained, and if so, for what purpose, for how long, and whether and when data will be de-identified and destroyed.
- d. A special situation arises for audio/video recordings and photographs, since these media provide additional potential means for participant identification. Investigators must secure participant informed consent explicitly mentioning these practices. They should also explain plans for secure storage, final disposition, and destruction of such recordings.

e. 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 participants at risk of significant harm. Reputations or employment potential may be damaged. Insurance coverage may be jeopardized. Lawsuits or criminal prosecution could result.

(2) The nature 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 Cadets or Soldiers for research cannot guarantee that certain information will be kept confidential. If in the process of conducting research, a Cadet or Soldier discloses information that poses a reasonable threat of serious harm to the participant or others, the investigator has a legal obligation and duty to immediately take action to prevent harm. There are many ways to ensure the safety of Cadets and escort them to appropriate care including through the legal chain of command and/or other services such as the Center for Personal Development (CPD) and/or Keller Army Community Hospital (KACH). All research that intends to collect data that may identify these types of threats must include a detailed plan of action to manage the threat and prevent future harm. The reviewers must carefully consider these plans to ensure the best possible care for Cadets and Soldiers while protecting their privacy to the greatest extent possible. As soon as it is practical, the PI should notify the USMA Human Protections Director (HPD) according to the procedures for a serious adverse event. (See section 13-5 for more information about serious adverse events.)

(4) The requirement to report information that a person poses a reasonable threat of harm to themselves does not apply to civilian participants. However, if the threat of serious harm is urgent and eminent, the investigator should help the civilian participant seek immediate care.

f. In accordance with (IAW) DoDI 3216.02 3.14.b., a DoD institution conducting human subject research may request a Certificate of Confidentiality (CoC) pursuant to 42 USC 241.

(1) All research involving large-scale genomic data (LSGD) collected on DoD-affiliated personnel are required to apply a CoC. (See section 9-4 for more information about LSGD research.)

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

(3) Exceptions to the CoC must be listed in all informed consent documents, IAW DoDI 3216.02 and as stated in 42 USC 241.

12-3. Use of Identifiers

a. Investigators must make every effort to safeguard Personally Identifiable Information (PII) by following appropriate DoD, Army, and USMA procedures on data security. The loss of PII must immediately be reported to the USMA HPD and the USMA Privacy Office and, if it is secondary data, to the original data owner.

b. There are two types of personal identifiers that are used to associate individuals with PII - direct identifiers and indirect identifiers.

(1) Direct identifiers are those data elements which provide a direct link to an individual or relatives, employers, or household members of an individual whose data are in a system of records. Table 12-1 lists direct identifiers as defined under the HIPAA Privacy Rule (45 CFR 160).

Table 12-1
Direct Identifiers

1	Name
2	All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocode
3	All elements of date (except year) for dates directly related to an individual, including birth date, admission date, discharge date, separation date, date of death, and all ages over 89 and all elements of date (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older
4	Telephone number
5	Fax number
6	Electronic mail address
7	Social Security number
8	Medical record number
9	Health plan beneficiary number
10	Account number
11	Certificate/License number
12	Vehicle identifiers and serial number, including license plate
13	Device identifiers and serial number
14	Web universal resource locator (URL)
15	Internet protocol (IP) address number
16	Biometric identifier (e.g., DNA, fingerprint, voiceprint, etc.)
17	Full face photographic/video images and any comparable image
18	Any other unique identifying number, characteristic, or code, such as a Cadet PIN (Note: This does not include a unique code number assigned by an investigator during data collection.).

(2) Indirect identifiers are data elements that do not permit individual identification when used alone but may lead to direct identification when combined with other information. The more these variables are used in combination, the more likely it is that the data can become identifiable. Investigators should not ask for any more demographic information than is absolutely required for the research objective. Table 12-2 contains a partial list of indirect identifiers.

Table 12-2
Indirect Identifiers

1	Age
2	Sex
3	Sexual Orientation
4	Race
5	Ethnicity
6	Nationality
7	Religion
8	Years, for dates directly related to the individual (e.g., year of birth, graduating year, etc.)
9	All geographic subdivisions within a country but greater than or equal to a state
10	Vehicle make/model
11	Physical characteristics (e.g., hair color, eye color, height, weight, etc.)
12	Disability
13	Device make/model
14	Qualifications (e.g., educational degrees, certificates, licenses, etc.)
15	Accounts
16	Unique affiliations (e.g., clubs, professions, sport teams, etc.)
17	Unique titles (e.g., academic or military rank, etc.)

c. Data sets are considered de-identified if they are:

- (1) Individualized but do not contain direct or indirect identifiers,
- (2) Individualized, do not contain direct or indirect identifiers, and cannot be re-identified by the nature of the data,
- (3) Aggregated (tabular) and contain only indirect identifiers,
- (4) Not provided at the individual level of analysis, or
- (5) Aggregated (tabular) and the individual information cannot be recovered from the tabulations.

d. Investigators must take into consideration that the likelihood of individuals being identified increases with specificity and extensiveness of the data (e.g., exact age vs. age range), size of the population (e.g., small sports teams and minorities at USMA), and specificity of the geographic region (e.g., Cadets from North Dakota).

12-4. Primary vs. Secondary Data

The requirements for data collection depend on whether the data being collected is primary data or secondary data. Investigators must understand the differences between each type and how to manage data after it is collected.

a. Primary data collection involves interaction with, or observation of, one or more participants for the purpose of collecting data from or about them.

b. Secondary data collection involves accessing information obtained about human subjects that was originally collected for some other primary activity or purpose.

(1) Research with secondary data that contain personal identifiers is subject to the requirements of this regulation. Research with secondary data that do not contain personal identifiers is considered "not human subject research" and is exempt from these requirements.

(2) Secondary data that was originally obtained for another research project and contains personal identifiers may be used only when the original informed consent allows the information to be used in this manner (including broad consent), when new informed consent is obtained, or when the data have been de-identified. All data secured with broad consent and the associated broad consent documents must be stored and maintained in accordance with the terms of the broad consent (which may be indefinitely).

(Until Department of Defense (DoD) and/or Army guidance is issued, the use of broad consent shall not be used for research conducted by USMA.)

(3) Secondary data obtained from a system of records may have additional restrictions associated with that system of records.

12-5. Access to USMA Data

a. USMA investigators who are also faculty or staff members have access to databases containing private Cadet data, because of their responsibilities as faculty and staff. However, they may not access these databases for research until they receive an IRB approval or exempt determination specifically stating what data they may access and collect.

b. Access to USMA data from the Office of Institutional Research (OIR), Office of Economic and Manpower Analysis (OEMA), Directorate of Admissions (DAD), Athletics [to include the Office of the Directorate of Intercollegiate Athletics (ODIA) and Army Athletic Association (AAA), and any contractors including Army West Point Athletic Association (AWPAA)], or the Registrar [to include the Academy Management System (AMS)] will only be granted with approval from the USMA Institutional Research Committee (IRC).

c. Given the nature and sensitivity of Cadet data, investigators are discouraged from using these data (particularly on current Cadets) for Cadet research projects.

d. Generally, it is recommended that all Cadet data be de-identified before being released. Exceptions to this practice must be specifically justified in the protocol.

e. OIR can assist USMA investigators by acting as a trusted agent by aggregating and merging data and providing de-identified data sets using the safe harbor method.

f. Freedom of Information Act (FOIA) requests are handled by the USMA FOIA office in compliance with their policies and regulations.

12-6. System of Records

a. The following privacy laws and regulations may apply to investigators at USMA:

(1) The Privacy Act of 1974, 5 U.S.C. §552a – as amended,

(2) The Freedom of Information Act (32 CFR 285-299), and

(3) The Health Insurance Portability and Accountability Act of 1996 (HIPAA) (45 CFR 160, 162, & 164).

b. A "Privacy Act" "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying particular assigned to the individual.

c. Under the Privacy Act, USMA's systems of records are the Academy Management System (AMS), Academy Candidate Files, and the OEMA database. This includes DAD data, grades or other measurements used for academic progress reviews (e.g., AMS), and health information generated for surveillance and treatment purposes [e.g., Cadet Illness and Injury Tracking System (CIITS)].

d. Information that is generated for research purposes only (e.g., involving no standard of care treatment, etc.), maintained only by the investigators involved in the research, and not maintained in a system of records, is research information. Informed consent may be required to obtain such information.

e. Investigators may obtain de-identified data sets from a system of records without informed consent if they do not have direct access to the identifiable records and the data owner creates the de-identified data set and provides it to the investigators. Investigators who plan to use de-identified data in this manner should submit a protocol to an Exemption Determination Official (EDO) to request a determination.

f. Data sets are considered "identifiable data sets" if they contain direct identifiers or they are individualized and contain a sufficient number and type of indirect identifiers that could enable identification of an individual. Identifiable data can be extracted from a system of records in three ways:

(1) The investigator obtains informed consent from each individual whose record will be accessed. In this case, investigators may access the records.

(2) A person designated as a trusted agent creates and provides to investigators a de-identified data set, using the safe harbor method, which excludes all 18 direct identifiers in Table 12-1.

(3) A trusted agent creates and provides to investigators a limited data set, which excludes the 18 direct identifiers in Table 12-1, but may contain dates (e.g., admission, discharge, birth, death, etc.), and city, county, precinct, and zip codes.

12-7. Data Sharing

a. Data collected at USMA belong to USMA and may not be shared, transferred, or exchanged with anyone outside of the research team without prior authorization.

b. Investigators who plan to share data with their co-investigators who are external to USMA must clearly describe in the protocol the status of the data (e.g., coded, de-identified, etc.) and how the data will be shared and transferred. The external investigator must sign a USMA External Investigator Agreement that lists the responsibilities of the external investigator during the execution of the research.

c. In some instances, research data is shared with collaborators who are not engaged in the research and are therefore not listed as an investigator on a research protocol. In this case, the collaborators are required to sign a Data Sharing Agreement or Data Use Agreement prior to receiving research data. See section 7-1.r. for more information about these agreements.

12-8. Study Closure and Records Retention

a. The PI is responsible for maintaining all documentation of human subject research (both exempt and non-exempt) for a minimum of three years after completion or termination of the study (or six years if the research includes HIPAA-protected data) IAW 21 CFR 56.115(b) and 45 CFR 164.316. This requirement includes all regulatory documents, informed consent documents, data collection forms, surveys, etc. Any exceptions to this policy must be documented in the protocol, and the PI is required to comply with the approved protocol as written. Research records can be audited by the USMA Human Research Protections Program (HRPP) or by other regulatory organizations, such as the Army Human Research Protections Office (AHRPO), during this time period.

b. If a PI is scheduled to leave USMA before three years after the protocol has been closed (or six years if the research includes HIPAA-protected data), the PI must transfer custody and responsibility for the secure storage and maintenance of study records (both paper and electronic) to a knowledgeable colleague so that the records are maintained for the required period. The PI must enact this change by submitting the appropriate modification paperwork to the HPD or the IRB of record.

c. On or before the date of closure, the data must be disposed of in accordance with the written procedures in the approved protocol. Unless the protocol specifically states, the PI must comply with the following:

- (1) Any data retained must be permanently rendered free of all PII. The keys linking identifiers with codes and other identifying documents (other than the informed consent documents), must be destroyed, unless broad consent was secured. If the data is permanently de-identified, the process for de-identification must be described in the research protocol or in the protocol closure report.
- (2) Informed consent documents must be stored without study identification numbers.
- (3) Permanently de-identified data may be used for secondary analysis in future studies if the informed consent document included that provision or if broad consent was secured. Any new research protocols must be submitted for review and approval.
- (4) All data secured with broad consent and the broad consent documents, must be stored and maintained for as long as the terms of the broad consent specify (which may be indefinitely). Only the identified data collected with broad consent may be used in subsequent studies.
- (5) Retention of research materials or potential uses of data not already specified and approved in the current protocol must be reviewed and approved as a new protocol.
- (6) Until Department of Defense (DoD) and/or Army guidance is issued, the use of broad consent shall not be used for research conducted by USMA.

12-9. HIPAA-Protected Data Considerations

a. Protected Health Information (PHI) is individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records. These data 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 specified in the covered entity's business plan on sharing data to non-covered entities IAW DoDI 6025.18. The following requirements must be met before PHI will be provided for research to USMA investigators:

- (1) The research team members who are accessing PHI must complete HIPAA training and the certificates of training must be included in the protocol submission;
- (2) Study participants must sign a HIPAA Authorization Form, or the IRB must approve a Waiver of HIPAA Authorization for research;
- (3) The roles regarding who will handle PHI must be identified in the protocol; and
- (4) A plan for protecting, storing, and destroying the PHI must be described in the protocol.

b. CIITS is owned by USMA and stored on USMA servers. However, although USMA is not a covered entity, this system contains sensitive health information and must be protected as such. Data may be extracted from this system only when the protocol has been reviewed and receives an exempt determination or IRB approval, and the investigator has received approval from the IRC.

12-10. Best Practices for Data Security

a. Hard copy research data forms (sometimes called case report forms) should not contain any direct identifiers. These forms should be stored with double locks (i.e., in a locked file cabinet located in a locked office).

b. Electronic research data should not be stored in the same document as direct identifiers. Electronic data files should be protected by passwords and stored on secure networks in locations that are only accessible by the authorized investigators.

c. Study IDs should not contain any identifiers or research data. For example, female participants should not be assigned codes that contain an "f," participants in the control group should not be assigned codes that contain a "c," and participants born in the year 1996 should not be assigned codes that contain "96."

d. Informed consent documents should not contain study IDs or any research data.

e. Keys that link identifiers with unique study IDs (i.e., codes) should be stored in separate locations from the coded research data. The key document should not contain any information other than the identifier and the code; no research data should be included in this document.

f. Documents with direct identifiers and documents with coded data should be stored in separate locations. This is true for both hard copy and electronic copy documents.

Chapter 13

Compliance Monitoring

USMA personnel are expected to comply with the provisions of the References and this regulation, in both letter and spirit. This strict adherence is necessary to provide uniformity in the execution of the USMA Human Research Protections Program (HRPP) and to create conditions that will promote public trust.

13-1. Post Approval Compliance Monitoring (PACM)

a. PACM is defined as formal and systematic HRPP monitoring to confirm that human subject research is being conducted in accordance with (IAW) Institutional Review Board (IRB) approval or other HRPP regulatory determinations, and all applicable federal, DoD, Army, and USMA policies. USMA HRPP personnel will conduct both for-cause and routine (not for-cause) PACM activities on an ongoing basis. The USMA Human Protections Director (HPD) is responsible for initiating PACM and ensuring successful completion.

b. For-cause audits are usually based on "red flags" such as frequent deviations, missed deadlines, or poor-quality documents. Issues can also be identified through life cycle actions, information obtained from other studies conducted by the same Principal Investigator (PI), a complaint from a whistleblower or research participant, or allegations of noncompliance reported to the USMA HRPP or the IRB of record. A for-cause audit may include small portions of the protocol or may be a complete audit of the entire protocol and all associated documents. Depending on the circumstances surrounding the initiation of a for-cause audit, HRPP personnel may conduct the audit without prior notice.

c. Not for-cause audits are routinely scheduled. The audit schedule is based on factors such as the length of time since the last audit, the risk level of the research, or the experience of the PI. Based on findings during the audit, the number of audits for each protocol may be increased or decreased as needed to fully evaluate regulatory compliance over the entire life of the protocol.

d. Newly approved non-exempt protocols will progress through a cycle of mini audits that are each focused on one aspect of compliance. When a protocol is open for an extended period, the protocol may continue through the audit cycle more than once. Faculty and staff members at USMA have myriad responsibilities and conducting research is just one. Focused mini audits allow the investigator to meet all compliance requirements without carving out large portions of time to devote to audit activities. Additionally, scheduling mini audits utilizes a "just-in-time" approach - the mini audit addresses the phase of research in which the investigator is currently engaged. This allows the auditor and investigator to identify issues and/or best practices early in the process and further develops a collaborative working relationship that will foster trust and open communication. There are three phases to the mini audit schedule:

- (1) Regulatory Binder mini audits are normally scheduled in the first weeks after initial IRB approval.
- (2) Informed consent mini audits are scheduled based on the informed consent and enrollment timeline of the protocol. This mini audit should take place at the beginning of the consenting period so that any identified issues can be addressed early in the process. This mini audit covers all aspects of informed consent. HRPP personnel may inspect the signed informed consent documents, assess the storage and security practices, confirm participant eligibility, and/or observe the informed consent process with the investigator and participant(s).
- (3) Study data and forms (both hard copy and electronic) mini audits are scheduled based on the timeline of the protocol. This mini audit should be scheduled at the beginning of the phase of research when data and forms are being generated, collected, processed, and secured, so that any issues can be identified and addressed early in the process.

e. Audit process:

(1) HRPP personnel will notify the PI of intent to conduct a PACM and will provide USMA audit checklists and other information to help the PI prepare for the assessment. In the case of a for-cause audit, depending on the circumstances precipitating the audit, HRPP personnel may not provide prior notice.

(2) Checklists or other documentation will be completed for all audits. At the conclusion of the assessment, the auditor will complete a detailed report that summarizes audit findings, lists any recommended or required corrective actions, and specifies the date when all required corrective actions must be completed.

(3) Mini audits are focused on one aspect of protocol execution. However, if there are concerning findings, any audit, and for-cause audits especially, may expand to include any aspect of the protocol. This could include a review and assessment of study record management, informed consent processes, participant eligibility, staff qualifications, participant protections measures, data storage and destruction procedures, confidentiality procedures, and/or equipment maintenance records. It may also include observation of the informed consent process and research procedures, or interviews with investigators, research staff, or participants.

f. Post audit actions:

(1) The auditor will provide on-the-spot feedback and education to the investigators during audit activities.

(2) At the end of the audit, the auditor will provide the report, including findings with any required or recommended corrective actions, findings of Unanticipated Problem Involving Risk To Subjects and Others (UPIRTSOs), or findings of noncompliance, to the HPD and PI (and overarching PI if the study is multi-site). The PI will store a copy in the regulatory binder and the HPD will store a copy in the HRPP files. If there are significant findings or findings of serious or continuing noncompliance, the HPD will share the outcome of the audit with the Institutional Official (IO)/Alternate Institutional Official (AIO). The HPD may also provide the final report to the IRB of record, Army Human Research Protections Office (AHRPO), or other regulatory agencies as appropriate.

(3) The PI must respond to all required corrective actions in a time specified in the audit report. The HPD will ensure that the PI complies with these requirements.

(4) If the audit raises urgent safety or regulatory concerns, the auditor will notify the HPD and IO/AIO (and, if non-exempt, the IRB of record) immediately to determine if a suspension is warranted pending further review, to protect human subjects. Otherwise, the HPD will inform the IRB of record (if non-exempt) of any findings and any recommended corrective actions at the subsequent IRB meeting.

(5) Upon review of the audit report, the HPD and/or IRB may determine that additional actions are necessary. These actions could include but are not limited to suspension or termination of the research, retraining for the PI and research staff, or further investigation and consideration regarding serious and/or continuing noncompliance, or research misconduct.

(6) The HPD will report to AHRPO all instances of serious or continuing noncompliance, serious adverse events (SAEs), UPIRTSOs, and any terminations or suspensions of research within five days of the report's completion.

g. At a minimum, 20% of all open non-exempt protocols will go through at least one mini audit annually.

13-2. End of Academic Year Annual Report

a. USMA is an academic institution with frequent personnel turnover. Rotating military personnel are normally assigned to USMA for a period of three years and Cadets graduate after completing 47 months of instruction and development. Most personnel changes occur during the summer months between academic years. For this reason, it is important to actively monitor protocols during this time to ensure that personnel changes are adequately addressed to remain in regulatory compliance.

b. During the spring semester of each year, HRPP personnel will distribute an End of Academic Year Annual Report form to each PI who has an open non-exempt protocol. This form is designed to be a quick self-check to ensure that no protocol actions are required. PIs who have open exempt protocols will receive an email with content that is similar to this form, but they will not be required to submit a form to the HRPP.

c. PIs should submit the completed End of Academic Year Annual Report form to HRPP@westpoint.edu no later than the end of the spring semester. The PI should also follow-up with HRPP personnel to initiate any required actions. HRPP personnel will review all forms and follow-up with any questions concerning the status of the protocol and/or research personnel.

13-3. Exemption Determination Official (EDO) Audits

a. The HPD will review determinations by the EDOs to ensure regulatory compliance that the determination was correct, supported by sound reasoning, and IAW appropriate regulations. If the HPD is also an EDO, another USMA EDO or an external EDO will conduct an audit of HPD actions to ensure regulatory compliance.

(1) If, during an audit, it is discovered that an EDO decision resulted in noncompliance, the study will be referred to an IRB for appropriate review. The IRB will decide when and whether the research can continue and the appropriate route to approval.

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

(3) Participants will be notified if the IRB determines the study was greater than minimal risk and an informed consent document should have been collected.

b. The HPD will determine the corrective action for EDOs who complete incorrect determinations. These actions could include retraining, increased oversight, or the discontinuation of the EDO's authority to conduct reviews.

13-4. Adverse Events

a. In social behavioral research, an adverse event (AE) is any untoward or unfavorable physical, psychological, social, legal, or economic occurrence in a human subject, including any abnormal sign, symptom, or disease temporally associated with participation in the research, whether or not related to participation in the research.

b. Anticipated AEs are those events that pose a risk to participants but are identified and mitigated in the IRB-approved research protocol.

c. A UPIRTSO is an AE that is unanticipated and is not identified in the research protocol. A UPIRTSO may also include any unexpected event that jeopardizes the successful completion of the research project or causes the investigator to deviate from an approved research protocol. A UPIRTSO 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 ("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.

d. PIs of non-exempt research must report all AEs that do not impact the safety of subjects or others to the IRB of record at the time of continuing review for research requiring continuing review or within 90 days for non-exempt research not requiring continuing review.

e. PIs of non-exempt and exempt research must report all UPIRTSOs to the HPD by email at HRPP@westpoint.edu or in person within 1 business day of learning of the event. The HPD will notify AHRPO and the IRB of record (if the research is non-exempt) within 5 business days of receiving the initial report.

f. PIs of exempt research must report any AEs to the HPD by email at HRPP@westpoint.edu or in person within 10 business days of learning of the event. The HPD will determine whether the research remains exempt or needs to be reviewed by an IRB.

g. If anyone is harmed as a direct or indirect result of participating in research, it must be reported to the HPD by email at HRPP@westpoint.edu or in person within 1 business day or as soon as it has been identified. This should be followed by a more comprehensive written report within 10 business days. If the research is non-exempt, the HPD will notify the IRB of record and AHRPO within 5 business days of receiving the initial report.

h. The PI, IO/AIO, HPD, research monitor, ombudsperson, or IRB of record may halt the study in cases of an AE to better assess the situation and ensure the continued safety of the participants. The IRB will make the determination if the event is likely related to participation in the research and if the study can be continued without modification.

13-5. Serious Adverse Events (SAE)

a. An AE is considered serious if in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or participant and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

b. PIs must report SAEs to the HPD by email at HRPP@westpoint.edu or in person within 1 business day. This should be followed by a more comprehensive written report within 10 business days. The HPD will notify the IRB of record and AHRPO within 5 business days of receipt of the initial report.

c. The PI, IO/AIO, HPD, research monitor, ombudsperson, or IRB Chair may halt the study in cases of a SAE to better assess the situation and ensure the continued safety of the participants. The IRB will make the determination if the event is likely related to participation in the research and if the study can continue without modification.

13-6. Protocol Deviations

a. Because of its inherent uncertainty, human subject research does not always go as planned. USMA distinguishes between inadvertent/unanticipated deviations and deliberate noncompliance and research misconduct.

b. A deviation indicates that there has been a departure or change (intentionally or unintentionally) from the originally approved protocol.

c. A deviation is minor if it does not adversely affect participants or the integrity of the study data. Minor deviations must be reported to the HPD as soon as possible but no later than at the time of continuing review for non-exempt protocols that require continuing review or within 90 days for exempt research or non-exempt protocols that do not require continuing review.

d. A deviation is major if it may adversely affect participants' rights, safety, welfare, or willingness to continue participation, or may affect the scientific design of the study or the integrity of the resultant data. Major deviations must be reported to the HPD by email at HRPP@westpoint.edu or in person within 1 business day. If the research is non-exempt, the HPD will notify the IRB of record and AHRPO within 5 business days of receiving the report. Within 10 business days, the PI must follow up with a complete written report including a description of the deviation and the plan to mitigate its negative effects, and the plan to minimize or eliminate future occurrences.

13-7. Noncompliance

- a. Noncompliance refers to a failure (intentional or unintentional) of a person, group, or institution to act IAW the regulations, institutional policies governing human subject research, or requirements of or determinations by the IRB of record, by the investigators or research staff, or any member of the HRPP, including the IRB or IRB administrative staff. All investigators and HRPP personnel are responsible for understanding all policy and regulation requirements.
- b. Serious noncompliance refers to actions that place the health, safety, or confidentiality of participants at increased or unnecessary risk.
- c. Continuous noncompliance refers to repeated occurrences of noncompliance that indicates a concern about the competency of the investigator to continue to conduct research.
- d. Serious or continuing noncompliance with this regulation by USMA personnel must be reported directly to the USMA HPD. The USMA HPD will inform the IO/AIO and IRB Chair (for non-exempt research) IAW the IRB SOP as well as AHRPO as required by 32 CFR 219.103 and DoDI 3216.02.
- e. IAW DoDI 3216.02 3.16.c., substantial allegations of noncompliance related to classified human subject research must be reported immediately to the DoD Directorate of Human Research Protections (DOHRP).
- f. 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 noncompliance. Military personnel, including Cadets, should consult DoD Directive 7050.06, *Military Whistleblower Protection*.
- g. When there are allegations of noncompliance, the HPD will conduct a for-cause audit. (See section 13-1 for information about the procedures for conducting a for-cause audit.)
- h. In the case of suspected noncompliance involving research that was not reviewed by an IRB, the USMA HPD will conduct a for-cause audit. The HPD will determine if there is noncompliance and if it is serious or continuing noncompliance. If there is serious or continuing noncompliance, the HPD will notify the IO/AIO. Investigators found to have committed noncompliance may have their research privileges suspended and may be subject to other disciplinary actions. The IO/AIO will determine what actions are appropriate.
- i. In the case of suspected noncompliance involving IRB-approved research, the HPD will notify the IRB of record before conducting a for-cause audit, in addition to notifying the IO/AIO. The IRB may elect to defer the for-cause audit to the HPD or may elect to conduct an additional investigation. At the conclusion of the audit, the HPD will share the audit report with the IRB. The IRB will determine if there is noncompliance and if it is serious or continuing noncompliance. At the determination of the IRB, investigators who commit serious or continuing noncompliance may not be allowed to conduct human research at USMA. The HPD will convey the findings of the IRB to the IO/AIO. The IO/AIO will determine if additional disciplinary actions are appropriate.
- j. At the conclusion of the audit, the HPD or IRB of record should make a determination about the disposition of the data. If appropriate to protect human subjects, the HPD and IRB have the ability to sequester data.
- k. Allegations of noncompliance raise difficult issues for the accused. All audits and investigations should be conducted promptly and carefully while protecting the privacy and confidentiality of all involved individuals to the maximum extent possible. If the audit reveals that the allegations were unfounded, every effort should be made to restore and protect the reputation of the accused investigator.
- l. Serious or continuing noncompliance with this regulation that is attributed to systemic factors may lead to the cessation of all human subject research at USMA until appropriate corrective measures are taken.

13-8. Research Misconduct

- a. Research misconduct is distinct from noncompliance. It can take many forms, including (but not necessarily limited to) fabrication (making up data), falsification (changing or omitting data), and plagiarism (using other's ideas without attribution) in proposing, performing, or reviewing research.
- b. DoDI 3210.7 specifies detailed procedures and standards for the DoD for the prevention of research misconduct.

c. Accusations of research misconduct and associated investigations at USMA are handled IAW USMA Regulation 150-6.

13-9. Violations of the Privacy Act

Violations of the Privacy Act will be handled by the USMA Privacy Office IAW all associated regulations.

13-10. Summary of Reporting Requirements

Table 13-1 contains a summary of reporting requirements listed in this chapter.

Table 13-1

Reporting Requirements

Definitions	Reporting Requirements
Adverse Event – any abnormal, untoward, or unfavorable occurrence in a human subject occurring during or in close proximity to the end of the subject's participation in the research, whether or not considered related to participation in the research	Reporting requirements are dictated by the category of event – serious, anticipated, or unanticipated (UPIRTSO).
Serious Adverse Event – an adverse event in which the subject dies, is at substantial risk of dying (whether at the time of intervention or as a result of continued exercise of intervention), is hospitalized, becomes disabled or otherwise permanently harmed, or when other intervention is required to prevent permanent harm to the subject	Must be <i>reported promptly</i> (within 1 business day) to the USMA Human Protections Director (HPD) by email at HRPP@westpoint.edu or in person. Within 10 days, a complete written report must follow the initial notification. The HPD will notify the IRB and AHPRO within 5 business days or receipt of the initial report.
Anticipated Adverse Event – an event that poses a risk to the subject, but is identified and mitigated in the protocol	Must be reported no later than at the time of continuing review (for protocols requiring continuing review) or within 90 days (for protocols not requiring continuing review) unless the risks to subjects require other immediate action.
UPIRTSO – (also described as an unanticipated adverse event) is any incidence, experience, or outcome that meets all three of the following conditions: 1) is unexpected, 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 than was previously known or recognized, even if no harm has actually occurred	Must be <i>reported promptly</i> (within 1 business day) to the USMA HPD by email at HRPP@westpoint.edu or in person. If the research is non-exempt, the HPD will notify the IRB and the AHRPO within 5 business days of receiving the initial report.
Deviation – incident involving a departure from the IRB-approved protocol in the actual conduct of the study, resulting from the action of the participant, investigator, or staff	Reporting requirements are dictated by the category of event – minor or major.
Minor Deviation – deviation that does not adversely affect human subjects or the integrity of the study data	Must be reported to the HPD as soon as possible but no later than at the time of continuing review (for non-exempt protocols that require continuing review) or within 90 days (for exempt research or non-exempt protocols that do not require continuing review).

Major Deviation – deviation that may adversely affect subjects' rights, safety, welfare, or willingness to continue participation, or may affect the scientific design of the study or the integrity of the resultant data	Must be <i>reported promptly</i> (within 1 business day) to the HPD via email at HRPP@westpoint.edu or in person. The HPD will notify the IRB within 5 business days of receiving the report. Within 10 business days, a complete written report must follow the initial notification and must include a description of the deviation, the plan to mitigate its negative effects, and the plan to minimize or eliminate future occurrences.
Noncompliance – a failure (intentional or unintentional) of a person, group, or institution to act IAW the regulations, policies, or requirements or determinations of the IRB	Anyone (including investigators, research staff, human subjects, or anyone who witnesses research noncompliance) can report suspected noncompliance to the HPD.
Serious Noncompliance – noncompliance that places the health, safety, or confidentiality of participants at increased or unnecessary risk	Must be <i>reported promptly</i> to the USMA HPD who will inform the IO/AIO and the IRB Chair (for non-exempt research).
Continuing Noncompliance – noncompliance that is repeated and indicates a concern about the competency of the investigator to continue to conduct the research	Must be <i>reported promptly</i> to the USMA HPD who will inform the IO/AIO and the IRB Chair (for non-exempt research).

Appendix A

References

44 U.S. Code 3501, et seq

Paperwork Reduction Act

10 U.S. Code 980

Limitation on use of humans as experimental subjects

45 CFR 46

Protection of Human Subjects

45 CFR 164

Security and Privacy

21 CFR 11

Electronic Records; Electronic Signatures

21 CFR 50

Protection of Human Subjects

21 CFR 56

Institutional Review Boards

32 CFR 160

Defense Acquisition Regulatory System

32 CFR 162

Productivity Enhancing Capital Investment (PECI)

32 CFR 219

Protection of Human Subjects

32 CFR 299

National Security Agency (NSA) Freedom of Information Act Program

32 CFR 312

Office of the Inspector General (OIG) Privacy Program

DoD Directive 7050.06

Military Whistleblower Protection

DoD Manual 6025.18

Implementation of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule in DoD Health Care Programs

DoD Manual 8910.01, Volume 1

DoD Information Collections Manual: Procedures for DoD Internal Information Collections

DoD Manual 8910.01, Volume 2

DoD Information Collections Manual: Procedures for DoD Public Information Collections

DoD Instruction 3210.7

Research Integrity and Misconduct

DoD Instruction 3216.02

Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research

DoD Instruction 4000.19

Support Agreements

DoD Instruction 6025.13

Medical Quality Assurance (MQA) and Clinical Quality Management in the Military Health System (MHS)

DoD Instruction 6025.18

Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule Compliance in DoD Healthcare Programs

DoD Instruction 6025.23

Health Care Eligibility Under the Secretarial Designee (SECDES) Program and Related Special Authorities

DoD Instruction 6200.02

Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs

Army Regulation 25-98

Information Management Control Requirements Program

Army Regulation 70-25

Use of Volunteers as Subjects of Research, (under revision)

USMA Regulation 1-1

Installations Administration Scheduling Activities

USMA Regulation 150-6

Academy Research

Dean's Policy and Operating Memorandum (DPOM) 02-02

End-Of-Term Procedures

Charter

USMA Institutional Research Committee

USCC Policy Memorandum Number CC-18-15

Procedures and Instructions in Cases of Cadet Pregnancies

Collaborative Academic Institutional Review Board

Standard Operating Procedures

Institutional Review Board Policies and Procedures

Headquarters, United States Army Medical Research and Material Command (HQ USAMRMC), Office of Research Protections Institutional Review Board Office, HQ USAMRMC

Appendix B
Sample Cadet Biosketch Template

CDT First Name Last Name

Contact Information (Address, Email, Phone)

EDUCATION

United States Military Academy
Major:
Minor:

Expected Graduation Date:

COMPLETED COURSEWORK

List all coursework, especially if related to the research

LEADERSHIP POSITIONS

Platoon Sergeant for Cadet Basic Training 2020, 1st Detail

ADDITIONAL TRAINING

Air Assault School Graduate, Summer 2020

EXTRACURRICULAR ACTIVITIES

Member of Jewish Choir
Member of West Point Triathlon Club

AWARDS

A2 Cadet of the Quarter, Fall 2021

Glossary Of Terms

Section I **Abbreviations**

AE

Adverse Event

AHRPO

Army Human Research Protections Office

AI

Associate Investigator

AIO

Alternate Institutional Official

AR

Army Regulation

ARMD

Army Records Management Directorate

CAIRB

Collaborative Academic Institutional Review Board

CFR

Code of Federal Regulations

CLAR

Component-Level Administrative Review

CMP

Component Human Research Protections Program Management Plan

CoC

Certificate of Confidentiality

COHRP

Component Office of Human Research Protections

COI

Conflict of Interest

CRADA

Cooperative Research And Development Agreement

CSL

Command Support Letter

CV

Curriculum Vitae

DEVCOM-AC

Development Command - Armaments Center

DEVCOM ARL

Development Command Army Research Lab

DFARS
Defense Federal Acquisition Regulation Supplement

DoD
Department of Defense

DoDI
Department of Defense Instruction

DOHRP
Directorate of Human Research Protections

DSA
Data Sharing Agreement

DUA
Data Use Agreement

EDO
Exemption Determination Official

FDA
Food and Drug Administration

FWA
Federalwide Assurance

GTMR
Greater Than Minimal Risk

HHS
Department of Health and Human Services

HIPAA
Health Insurance Portability and Accountability Act

HPD
Human Protections Director

HRPO
Human Research Protections Official

HRPP
Human Research Protections Program

HSR
Human Subject Research

IAIR
Institutional Agreement for Institutional Review Board Review

IAW
In Accordance With

ICD
Informed Consent Document

IF
Incidental Finding

IIA
Individual Investigator Agreement

IO	Institutional Official
IRB	Institutional Review Board
IRC	Institutional Research Committee
LAR	Legally Authorized Representative
LSGD	Large-Scale Genomic Data
MOA	Memorandum of Agreement
MOU	Memorandum of Understanding
MRDC	Medical Research and Development Command
OMB	Office of Management and Budget
PACM	Post Approval Compliance Monitoring
PHI	Protected Health Information
PI	Principal Investigator
PII	Personally Identifiable Information
PM	Physiological Monitoring
POC	Point of Contact
SAE	Serious Adverse Event
SDO	Senior Designated Official
SJA	Staff Judge Advocate
SME	Subject Matter Expert
TSG	Surgeon General of the Army

UAE

Unexpected Adverse Event

UPIRTSO

Unexpected Problem Involving Risk To Subjects and Others

USARIEM

U.S. Army Research Institute of Environmental Medicine

U.S.C.

United States Code

USD(R&E)

Under Secretary of Defense for Research and Engineering

USMA

United States Military Academy

USMAPS

United States Military Academy Prep School

Section II**Terms****Activities Preparatory to Research**

An action taken in assessing the research question or hypothesis, such as accessing medical records, querying of databases for any type of individually identifiable health information, or any activity where PHI is accessed to prepare a research project

Administrative Review

Review of research to ensure compliance with regulations and policies applicable to HSR that is DoD conducted or research where DoD provides support

Adverse Event (AE)

Any untoward or unfavorable medical occurrence in a subject, including any abnormal sign (for example, abnormal physical exam or lab finding), symptom, or disease temporally associated with the subject's participation in the research, whether or not related to the subject's participation in the research

Anonymous Data

Data collected without identifiers. These data may be coded, but the code does not contain identifiers or parts thereof such as medical record number, subject initials or derivatives of social security numbers and is not linked with subject identifiers. If a combination of variables would allow identification of a subject, the data is not anonymous. Additionally, data collected face-to-face (e.g., interviews, focus groups) cannot be considered anonymous because the investigator is able to identify the data as belonging to the subject.

Associate Investigator

An individual, regardless of title, with responsibility for execution of the research. Only personnel whose activities make their institutions engaged in human subject research should be listed.

Assurance

Document wherein an institution engaged in research involving human subjects commits to comply with the federal rules for the protection of human subjects

Authorized Operational Activities

Activities carried out solely in support of the DoD mission to provide military forces information needed to deter war and to protect the security of the United States. These activities are subject to approval by the DoD Component head or Secretary of Defense, including subordinate agencies heads who have been delegated authority to study, evaluate, improve, or otherwise assess DoD performance, quality, and capability.

Biomedical Research

The use or investigation of a medical product, procedure, or intervention, including studies that fall under FDA regulations. USMA may conduct biomedical research and it will generally be submitted to the U.S. Army Medical Research and Development Command (MRDC) IRB.

Biospecimen

A sample of biological material, such as blood, urine, tissue, cells, DNA, RNA, or protein

Certificate of Confidentiality (CoC)

Document issued by the National Institutes of Health (NIH), HHS authorizing persons engaged in biomedical, behavioral, clinical, or other research related to mission areas of the NIH to protect the privacy of human subjects of sensitive research against compulsory disclosure in any federal, state, or local judicial, administrative, or legislative proceeding to identify human subjects. A CoC may be requested by a DoD Component or a contractor, grantee, or other non-federal entity conducting DoD-supported research involving human subjects. See DoDI 3216.02 3.14.b.

Certification

Official notification by an institution that HSR has been reviewed and approved by an IRB

Classified Research Involving Human Subjects

Research involving human subjects where classified material is necessary to adequately perform IRB review and oversight; required to obtain effective informed consent of participants; or, by design, communicated by or to research participants.

Clinical Research

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 42 USC 241.

Clinical Trial

A clinical study in which participants are assigned to receive one or more interventions (or no intervention) so that researchers can evaluate the effects of the interventions on biomedical or health-related outcomes. The assignments are determined by the research protocol. Participants may receive diagnostic, therapeutic, or other types of interventions. A clinical trial requires registration at clinicaltrials.gov.

Coded Data

Data that are stripped of all direct subject identifiers, but in this case each record has its own research project ID or code, which is linked to identifiable information such as name or medical record number. The linking file must be separate from the coded data set. This linking file may be held by someone on the research project team (e.g., the PI) or it could be held by someone outside of the research project team (e.g., database manager). If a linking file exists, it is possible to re-identify the subjects and the data is not de-identified. A coded data set may include limited identifiers under HIPAA. To comply with HIPAA, the code itself may not contain identifiers or parts thereof such as medical record number, subject initials, or derivatives of social security number (SSN).

Collaborating Institution

An institution engaged in human subject research through the involvement of its investigators in at least one aspect of research, including research project development, subject recruitment, screening or informed consent processes, performance of research interventions, interactions, conducting data analysis, and/or presentation/publication of results. Collaborating institutions also may be institutional performance sites.

Collaborative Academic Institutional Review Board (CAIRB)

Institutional Review Board (IRB) formed by members from the United States Military Academy (USMA), Command and General Staff College (CGSC), and Army War College (AWC). The CAIRB existed from August 2016 through December 2023 when it was dissolved.

Collaborative Research

Research projects executed by investigators from at least two different institutions with generally equivalent, but perhaps different, contributions to the conduct of the research

- Simple: research conducted at one institution with involvement from one or more institution's investigators.
- Complex: multi-site research developed by a lead institution or sponsor, perhaps in collaboration with others, that takes place at two or more performance sites.

Command Support Letter (CSL)

Formal memorandum that is required for any external investigators and some others (see section 4-3) to conduct research at USMA. This letter will affirm the specific parameters of access that an 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.

Common Rule

Regulation adopted by multiple federal departments and agencies for the protection of human subjects in research. The DoD's implementation is 32 CFR 219 while the HHS is 45 CFR 46, Subpart A (DoDI 3216.02, Glossary, Part II).

Component-Level Administrative Review (CLAR)

AHRPO must conduct an administrative review [also known as a component-level administrative review (CLAR)] of all non-exempt human subject research when any of the following conditions occur:

- Human subject research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are U.S. citizens.
- The research requires a waiver of informed consent pursuant to Subsection (b) of 10 USC 980
- The research is fetal research, as described in Sections 289g - 289g-2 of 42 USC 241.
- LSGD is collected from DoD-affiliated personnel.
- The research constitutes classified human subject research as defined by DoDI 3216.02.
- Research is required to be approved by the DOHRP.

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.

Continuing Noncompliance

A pattern of noncompliance that suggests the likelihood that, without intervention, instances of noncompliance will recur. A repeated unwillingness to comply with DoDI 3216.02 or a persistent lack of knowledge of how to comply with DoDI 3216.02, Glossary Part II.

Cooperative Research And Development Agreement (CRADA)

Legal agreement between a federal laboratory and one or more non-federal parties. CRADAs offer the federal and non-federal institutions the opportunity to leverage each other's resources when conducting mutually beneficial research and development.

Data Use Agreement (DUA)

An agreement between the covered entity and the recipient of a limited data set

De-Identified Data

Data that the investigator is unable to identify as belonging to any particular subject because either (1) it does not contain any direct or indirect identifiers (e.g., code key linking subjects to the data), or (2) there are built in firewalls (e.g., an official data agreement) that prohibit any of the investigators accessing any identifiable data (e.g., the code key) and/or attempting to re-identify the data

Deviation

A departure or change (intentionally or unintentionally) from the originally approved protocol's study methods or procedures (e.g., enrolling more subjects than authorized or administering survey instruments not previously approved)

DoD-affiliated personnel

Service members, reserve service members, National Guard members, DoD Civilians, and DoD contractors

DoD Assurance

A written document stating an institution will comply with 32 CFR Part 219 (the Common Rule), and DoD and DoD Component policies

DoD Institution

A DoD entity which conducts activities that may be HSR

Engaged in Human Subject Research

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).

Excluded Activities

Are those activities conducted or supported by the DoD which the DoD has specifically defined as not human subject research IAW DoDI 3216.02.

Exemption Determination Official (EDO)

A federal employee at a DoD institution who, sufficiently qualified through experience and expertise, is designated to review research to determine whether the research involves human subjects and, if so, whether such research is exempt from 32 CFR 219.

Exempt Human Subject Research

HSR that meets specific federal criteria in 32 CFR 219, falling into one of the eight categories of Exempt research listed at 32 CFR 219.104. Exempt HSR must be initially determined as Exempt by an IRB, its designee, or designated DoD HRPP personnel, and then is exempt from further review. See also non-exempt HSR.

Extramural Research

Research conducted by a Principal Investigator who is not an employee or agent of the USMA

Federal Assurance

Written document in which an institution, not an IRB, commits to a federal department or agency its compliance with the requirements set forth in the Common Rule.

Federalwide Assurance (FWA)

A Federalwide Assurance which is only issued by the Department of Health and Human Services (HHS). This is required when research is funded by HHS.

For-Cause Audit

Audit with justification

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.

Greater Than Minimal Risk (GTMR)

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

HIPAA Authorization

Written authorization by a patient for use of their protected health information for research IAW DoD Manual 6025.18.

HIPAA Identifiers

Any of the following identifiers along with health information:

- Names;
- Geographic Subdivisions smaller than a state, except for the first three digits of the zip code;
- All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all elements of date (including year) for those over 89;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators (URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voiceprints;
- Full-face photographic images and any comparable images; and
- Any other unique identifying number, characteristic or code

Human Protections Director (HPD)

The federal employee at a DoD institution who is sufficiently qualified through experience and expertise and 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

Human Research Protections Official (HRPO)

A federal employee designated by a DoD Component or institution to conduct administrative review of DoD-supported research in accordance with the requirements of the DFARS, or comparable requirement, and whose review of DoD-supported research is intended to ensure compliance with DoD HSR requirements.

Human Research Protections Program (HRPP)

An institution's system of interdependent elements that implement policies and practices to protect human subjects involved in research. An institution with an HRPP may or may not hold a DoD or federal Assurance.

Human Subject

A living individual about whom an investigator (whether professional or student) conducting research:

- Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
- Obtains, uses, studies, analyzes, or generates personally identifiable information or identifiable biospecimens.

Human Subject Research (HSR)

Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge and involve a living individual about whom an investigator conducting research obtains information or biospecimens through intervention or interaction with the individual, or identifiable private information, or biospecimens.

HRPO Review

A review by a HRPO after an initial non-DoD HRPP determination of not human subject research or exempt human subject research or IRB approval (for non-exempt human subject research). The purpose of the HRPO review is to ensure compliance of a DoD-supported activity with the requirements identified at DoDI 3216.02 3.6.b prior to initiation of the DoD-supported portion of the human subject's research conducted by the non-DoD institution.

Identifiable biospecimen

A biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

Identifiable private information

Private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Incidental findings (IF)

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)

Individual Investigator Agreement (IIA)

An agreement between an investigator and an assured institution where the investigator acknowledges that they are primarily responsible for upholding the standards as set forth in the institution's Assurance; meanwhile, the institution agrees to extend its Assurance, or "cover," the individual investigator

Individually Identifiable Data

The Common Rule defines individually identifiable as "the identity of the subject is or may be, readily ascertained by the investigator or associated with the information." An identifier includes any information that could be used to link research data with an individual subject. In a small or narrowly defined subject population this could include a variable like military rank. Data may also be identifiable if a combination of variables could potentially identify a subject.

Individually Identifiable Health Information

Any information collected from an individual (including demographics) that is created or received by a health care provider, health plan, employer, and/or health care clearinghouse that relates to the past, present, or future physical or mental health or condition of an individual, or the provision of health care to an individual or the past, present, or future payment for the provision of health care to an individual and identifies the individual and/or to which there is reasonable basis to believe that the information can be used to identify the individual.

Information collection

Written verbal reports, applications (forms), schedules, surveys (including focus groups), questionnaires, reporting or recordkeeping requirements in any format and collected through any media (IAW Army Regulation 25-98).

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 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.

Informed Consent Document (ICD)

A document (e.g., in paper or electronic form) via which the required elements of informed consent are communicated to subjects IAW 32 CFR 219.116 and via which subjects' agreement to participate in the research is documented IAW 32 CFR 219.117

Institution

Any public or private entity, which conducts activities that may be human subject research

Institutional Agreement for IRB Review (IAIR)

A formal agreement between two or more institutions to establish which will be the IRB of record and must be signed by all parties. When 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).

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.

Institutional Official (IO)

An institution's senior person who is legally authorized to represent the institution and who is authorized to establish and is responsible to maintain the HRPP for the institution. The IO is responsible for the institution's DoD or federal Assurance and IRB, if these elements are part of the institution's HRPP. At USMA, the IO is the Superintendent. The IO has delegated certain activities to the Dean who serves as the Associate IO (AIO).

Institutional Review Board (IRB)

Provides ethical and regulatory oversight of research that involves human subjects by:

- Protecting the rights, welfare, and well-being of human research participants recruited to participate in research conducted or supported by USMA.
- Ensuring compliance with relevant local, state, and federal laws and regulations.
- Ensuring compliance with USMA, Army, and DoD policies and regulations.
- Employing the highest ethical standards for human research protections in all human subject research by adhering to the ethical principles outlined in The Belmont Report.

Interaction

Communication or interpersonal contact between the investigator and subject

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

Intramural Research

Research funded by USMA, conducted at USMA, and conducted by a Principal Investigator who is an employee or agent of USMA

IRB Member

Individuals appointed in writing to serve the Institutional Review Board (IRB). Primary IRB members have full voting rights and responsibilities. Alternate members serve in the absence of the primary IRB member with full voting rights and responsibilities during that period.

Large-Scale Genomic Data (LSGD)

Data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analysis; and gene expression data; etc.

Research involving LSGD includes, but is not limited to, projects that involve generating the whole genome sequence data for more than one gene from more than 1,000 individuals or analyzing 100 or more genetic variants in more than 1,000 individuals.

Legally Authorized Representative (LAR)

An individual or judicial or other body authorized under applicable law to informed consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research

Local Context

Applicable law and local standards, knowledge of institutional policies and capacity, investigator and study staff qualifications, and community and subject considerations

Minimal Risk

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

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

Non-Exempt Human Subject Research

HSR that meets federal criteria in 32 CFR 219 and this regulation for minimal risk or greater than minimal risk

Ombudsperson

A person who acts as an impartial and objective advocate for human subjects participating in research

Personally Identifiable Information (PII)

Information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual

Physiological Monitoring (PM)

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

Post Approval Compliance Monitoring (PACM)

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, applicable federal laws and regulations, and DoD policy

Prescreening

A process of assessing potential subjects for possible inclusion in a research project based on compatibility with pre-determined inclusion/exclusion criteria prior to obtaining informed consent. This is typically a cursory look into the medical records or census to determine if a patient may be eligible for a research project. This is generally conducted under a partial HIPAA waiver of authorization if investigator does not have a treatment relationship with the subjects.

Primary Data Collection

The interaction with, or observation of, one or more people for the purpose of collecting data from or about them

Principal Investigator (PI)

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 are Associate Investigators.

Privacy

Having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others

Private Information

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)

Protected Health Information (PHI)

The HIPAA Privacy Rule defines PHI as individually identifiable health information that is transmitted or maintained in any form or medium (electronic, oral, or paper) by a covered entity or its business associates, excluding certain educational and employment records

Protocol

A document that describes the background, rationale, objectives, design, methodology, and organization of a research investigation. In HSR, the protocol is frequently synonymous with the application for approval of a research study to an IRB.

Reportable Events

Occurrences required to be reported to appropriate institutional officials, DoD Component officials, and/or OUSD(R&E) IAW 32 CFR 219, DoDI 3216.02, and/or DoD Component policies (e.g., (i) any unanticipated problems involving risks to subjects or others or any serious or continuing noncompliance with this regulation or the requirements or determinations of the IRB; and (ii) any suspension or termination of IRB approval)

Repository

A storage site and mechanism by which identifiable human tissue, blood, genetic material, or data are stored or archived for future use in research by multiple investigators or multiple research projects

Research

A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this regulation, whether or not they are conducted or supported under a program that is considered research for other purposes. Research results do not have to be published or presented to qualify the experiment or data collection as research.

Research Involving a Human Being as an Experimental Subject

An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of 10 USC 980; it does not affect the application of 32 CFR 219.

Research Involving Human Subjects

Activities that include both a systematic investigation designed to develop or contribute to generalizable knowledge AND involve a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Activities covered by 32 CFR 219.101(a) (including exempt research involving human subjects) and DoDI 3216.02, Glossary Part II.

Research Misconduct

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. Research misconduct does not include honest error or differences of opinion.

Procedures for addressing research misconduct are contained in USMA Regulation 150-6.

Research Monitor

Individuals with expertise consonant with the nature of risk(s) identified within the protocol, whose role is to protect the safety and well-being of human subjects

Risk

Has two parts: the magnitude of harm and the probability of harm. The probability and magnitude of harm or discomfort anticipated in the research. Risks of research with special populations "should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, Soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain)." DoDI 3216.02 3.8.b.

Scientific Review

Review required for all non-exempt research involving human subjects to ensure the scientific merit of the research. If the IRB does not evaluate the scientific merit itself, the IRB must consider the scientific review during the IRB review of the project. [DoDI 3216.02 3.6.b(6)(a)1].

Screening

Process of actively assessing a potential subject for inclusion in a research project based on compatibility with pre-determined inclusion/exclusion criteria, ability and willingness to complete the research project, and other factors. Informed consent must be obtained prior to screening procedures that use protected health information or involve procedures that a subject would not normally undergo.

Secondary Data Collection

Accessing information obtained about human subjects that was originally collected for some other primary activity or purpose

Secondary Research

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

Security Review

Administrative review of research involving large-scale genomic data collected on DoD-affiliated personnel to ensure compliance, in accordance with the CMP, as well as administrative, technical, and physical safeguards for protecting confidentiality

Serious Adverse Event (SAE)

An adverse event or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse. [21 CFR 312.32(a)]

Serious Noncompliance

Failure of a person, group, or institution to act IAW DoDI 3216.02 and its references such that the failure could adversely affect the rights, safety, or welfare of a human subject; place a human subject at increased risk of harm; cause harm to a human subject; affect a human subject's willingness to participate in research; or damage or compromise the scientific integrity of research data. (DoDI 3216.02, Glossary Part II)

Service Members

Individuals appointed, enlisted, or inducted for military service under the authority of the DoD. The Military Services are the Army; the Navy, including the Coast Guard under circumstances involving the declaration of war; the Air Force; the Marine Corps; and the Reserve components. Members of the Reserve components are included when in a duty status.

Significant Risk

Significant risk device means an investigational device that:

- (1) Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (2) Is purported or represented to be for a use in supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
- (3) Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health and presents a potential for serious risk to the health, safety, or welfare of a subject; or
- (4) Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

Special Population

Population pools that do not meet the federal regulations of vulnerable subjects but who may be open to undue influence or coercion based on their roles in an organization or their cognitive abilities

Support

Funds or assistance that are provided by the DoD to non-DoD institutions for HSR through a grant, contract, or similar arrangement subject to the DFARS or other applicable DoD regulations, such as the DoD Grant and Agreement Regulations. Included in this definition is the DoD's provision of assistance to non-DoD institutions, whether or not through collaboration between DoD and non-DoD institutions, such as facilities, equipment, personnel (investigators or other personnel performing tasks identified in the research protocol), access to or information about DoD-affiliated personnel for recruitment, or data or specimens. This definition does not include DoD-conducted HSR, whether or not conducted in collaboration between a DoD institution and non-DoD institution.

Systematic investigation

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.

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:

- 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;
- 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
- 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.

Unexpected Adverse Event (UAE)

Adverse event occurring in one or more subjects in a research project, the nature, severity, or frequency of which is not consistent with either:

- The known or foreseeable risk of adverse events associated with the procedures involved in the research project as described in:
 - the research project-related documents, such as the IRB-approved research project, any applicable Investigator Brochure, and the current IRB- approved informed consent document, and
 - other relevant sources of information, such as product labeling and package inserts; or
- The expected natural progression of any underlying disease, disorder, or condition of the subject(s) experiencing the adverse event and the subject's predisposing risk factor profile for the adverse event.

Vulnerable Populations

When they are involved in research as participants, pregnant women, human fetuses, and neonates; prisoners; and children and considered vulnerable populations and are subject to special protections IAW 45 CFR 46 Subparts B, C, and D.

Waiver or Alteration of Informed Consent

A determination by an IRB to approve a consent procedure which omits one or all the required elements of informed consent IAW 32 CFR 219.116(d).