

**Department of Defense (DoD), Army
Specific and Unique Requirements
for
Human Research Protections
Combined Arms Center – Education (CAC-E)**

This document contains the specific and unique requirements for conducting non-exempt research involving Human Subjects in CAC-E.

Institutions covered by the CAC-E DoD Assurance include:

Command and General Staff College (CGSC)

Command and General Staff School (CGSS)

School of Advanced Military Studies (SAMS)

School for Command Prep (SCP)

The School of Advanced Leadership and Tactics (SALT)

**Western Hemisphere Institute for Security Cooperation
(WHINSEC)**

Army Management Staff College (AMSC)

Military Review and the TRADOC Culture Center (TCC)

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Note: If this document is printed, keep in mind that updates will be made and posted to the web as needed. Users of print versions should periodically cross reference the web version to be sure the most current policies are being followed. URLs and email addresses contained herein are current as of 4 September 2015.

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A. The Common Rule. Part 219 of title 32, Code of Federal Regulations (CFR) (also known as “the Common Rule”). The Common Rule is the adopted regulation for the protection of human subjects participating in human subject research. The most frequently cited version of the Common Rule is 45 CFR 46 from the Department of Health and Human Services (DHHS). The Department of Defense human subject regulation is 32 CFR 219 and is functionally equivalent to the 45 CFR 46.

B. The Belmont Report. All research involving human subjects that is conducted or supported by the DoD shall comply with 32 CFR 219 which incorporates the ethical principles of respect for persons, beneficence, and justice, as codified in page 23192 of volume 44 of the Federal Register, April 18, 1979 (also known as “The Belmont Report”).

C. DoDI 3216.02. DoD Instruction 3216.02 dated November 8, 2011 establishes policy and assigns responsibilities for the protection of human subjects in DoD-supported programs to implement 32 CFR 219, the Common Rule.

D. Assurances:

3. Federal-Wide Assurance (FWA). Through the FWA, an institution commits to Health and Human Services (HHS) that it will comply with the requirements in the HHS Protection of Human Subjects regulations at 45 CFR part 46.

4. DoD Assurance. A DoD institution engaged in non-exempt research involving human subjects shall have a DoD assurance of compliance consistent with DoDI 3216.02. The Department of Defense (DoD) has authorized a small number of officials to issue DoD assurances of compliance. The Army Human Research protections Office (AHRPO) issues DoD assurances within the Army DoD Component.

5. Combined Arms Center – Education (CAC-E) Assurance. AHRPO issued CAC-E Assurance designation number is: DoD-A10033. CAC-E is a DoD Institution within the U.S. Army Training and Doctrine Command (TRADOC). The CAC-E has an HRPP. The roles and responsibilities for the program are defined in the CAC-E HRPP Plan.

6. Non-DoD Institution. A non-DoD institution that is engaged in DoD-supported non-exempt research involving human subjects must hold a Federal-Wide Assurance consistent with 32 CFR 219.103 and comply with the additional requirements imposed by the DoD IAW DoDI 3216.02.

7. Individual Investigator Agreement (IIA). If the institution does not have a Federal assurance, an individual investigator associated with that institution may enter into an Individual Investigator Agreement (IIA) with a DoD- Assured institution, for the purpose of being covered under that institution’s Assurance. The IIA describes the responsibilities of the individual researcher who is engaged in human subject research and the responsibilities of the Assured institution.

E. Research Involving Human Subjects.

1. The DoDI 3216.02 defines DoD Institutional Approval and Oversight requirements for DoD conducted research involving human subjects.

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2. The DoD institution shall have policies and procedures to ensure the research involving human subjects has been approved by all required organizations before human subjects are recruited or any other research activities with human subjects begin. The IRB may approve a research protocol contingent upon its approval by other organizations (e.g., required reviews can be conducted in parallel).

3. DoDI 3216.02 defines research involving human subjects as “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 section 219.101(a) of 32 CFR (including exempt research involving human subjects) and this Instruction.

4. **Exempt Research.** DoDI 3216.02 defines exempt research involving human subjects as research involving human subjects where the only involvement of the human subjects in the research will be in one or more of the categories identified in 32 CFR 219.101(b), with the exceptions that the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, subpart C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

F. Institutional Review Board (IRB).

1. An IRB, in accordance with 32 CFR 219, shall approve all non-exempt research involving human subjects before any activities that involve human subjects can begin. An official cannot approve research that has been disapproved by the IRB in accordance with 32 CFR 219 (i.e., an IRB disapproval of a protocol cannot be overturned). The IRB must provide oversight of the ongoing research and review such research at intervals appropriate to the degree of risk, but not less than once per year.

2. When a DoD institution relies upon the IRB of another DoD institution, there must be a written agreement defining the responsibilities and authorities of each organization in complying with the terms of each institution’s Federal assurance and the DoDI 3216.02.

3. **DoD IRB.** DoD institutions shall rely on an IRB whose membership consists of members who are Federal employees; Service members; individuals covered by 5 USC Sections 3371-3376 (also known as “The Intergovernmental Personnel Act of 1970, as amended”); or individuals appointed as experts or consultants in accordance with 5 USC Section 3109 and meet all requirements defined in DoDI 3216.02.

4. **Non-DoD IRB.** DoD institutions engaged in non-exempt research involving human subjects and collaborating with a non-DoD institution may rely on the non-DoD institution’s IRB if these minimum conditions are met:

- a) The collaborating non-DoD institution has an appropriate Federal assurance.
- b) The involvement of DoD personnel in the conduct of the research involving human subjects is secondary to that of the non-DoD institution.

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c) The DoD institution, the non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each organization in complying with the terms of the Federal assurances and the DoDI 3216.02 (i.e., have an Institutional Agreement for IRB Review or similar agreement). The CAC-E HPA shall approve the terms of the agreement prior to the DoD institution's engagement in the research involving human subjects.

5. Contracts and Agreements. Contracts and Agreements that support Human Subjects Research. A DoD institution that provides support through a grant, contract, or other written agreement must ensure that the institution conducting the research involving human subjects is aware of its obligation to comply with the requirements of DoDI 3216.02 and 32 CFR 219.

a) To support compliance, all such written agreements must contain the Defense Federal Acquisition Regulation Supplement (DFARS) clause in accordance with section 252.235-7004 of title 48, CFR.

b) The non-DoD institution shall comply with the terms of the DFARS clause or comparable language used in the agreement supporting the research involving human subjects.

6. The CAC-E Human Protections Administrator (HPA) must conduct an appropriate administrative review of the research involving human subjects to ensure it is in compliance with DoD policies and procedures prior to the CAC-E's engagement in the research.

G. DoD Institutional Review and Oversight.

1. The DoD institution shall have policies and procedures to ensure the research involving human subjects has been approved by all required organizations before human subjects are recruited or any other research activities with human subjects begin. The IRB may approve a research protocol contingent upon its approval by other organizations (e.g., required reviews can be conducted in parallel).

2. Non-DoD institutions shall comply with DoDI 3216.02 requirements as applicable to them. They are not required to comply with provisions of the Instruction either solely directed to actions of the DoD Components or specifically limited to DoD-conducted research involving human subjects.

3. Research and Exempt Determination. When a non-DoD institution determines either an activity is not research involving human subjects or is exempt research involving human subjects, the DoD IRB or HPA must concur with the performing institution's determination before an activity can begin.

4. Expedited Review. IRBs may use expedited review procedures under 32 CFR 219.110(a) to review minimal risk, non-exempt research involving human subjects using materials (e.g., data, documents, records, or specimens) that have previously been collected for any purpose, provided the materials were not collected for the currently proposed research.

5. Scientific Review. The DoD institution shall have policies and procedures to require scientific review of non-exempt research involving human subjects and to

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ensure this review is considered during the IRB review process. When a non-DoD institution is conducting non-exempt research involving human subjects, the IRB review must consider the scientific merit of the research, as required by 32 CFR 219.111. The IRB may rely on outside experts to provide an evaluation of the scientific merit.

6. Surveys. The CAC-E Personnel Survey Control Officer (PSCO) is a member in the Quality Assurance Office (QAO) who ensures all surveys meet regulatory requirements and provides a Survey Control Number (SCN) for all surveys administered within CAC-E schools. Data regarding Army active duty members must meet Army information security requirements IAW DoDI 8910.01. Use of online systems must be approved prior to data collection.

7. Foreign Location. When the research is being conducted in a foreign country whose laws and regulations are applicable to that research, the DoD institution shall confirm that all applicable national laws and requirements of the foreign country have been met in addition to the requirements in this Instruction. The IRB shall also consider the cultural sensitivities in the setting where the research will take place.

8. Notifications. The non DoD-institution shall promptly notify the CAC-E Human Protections Administrator (HPA) of the following: when significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review, when the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol, and all unanticipated problems involving risks to human subjects or others herein known as UPIRTSOs, suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.

H. Waiver of Documented Informed Consent.

1. 32 CFR 219.116(c) and (d) identify conditions where an Institutional Review Board (IRB) may waive informed consent for DoD-conducted and DoD-supported research involving human subjects.

2. 10 USC 980 imposes limitations on this waiver of informed consent when using DoD appropriated funds. 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 of the subject or a legal representative of the subject is obtained in advance. The Secretary of Defense (SD) may waive this prohibition.

I. Classified Information. The use or collection of classified information is prohibited in any conducted research without SD prior approval. SD approval is sought through AHRPO.

J. Personal Information. DoD 5400.11-R defines personal information within the DoD as “Information about an individual that identifies, links, relates, or is unique to, or describes him or her, e.g., a social security number; age; military rank; civilian grade; marital status; race; salary; home/office phone numbers; other demographic biometric, personnel, medical, and financial information, etc. Such information is also known as

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personally identifiable information (i.e., information which can be used to distinguish or trace an individual's identity, such as their name, social security number, date and place of birth, mother's maiden name, biometric records, including any other personal information which is linked or linkable to a specified individual).

K. Uniform Code of Military Justice (UCMJ). Privacy and confidentiality risk assessment for military personnel requires serious consideration of the potential impact on a military career as information regarding alcohol or drug abuse, drunk driving, sexual or spousal abuse and sexual orientation can lead to actions under the UCMJ. Some medical and psychological diagnoses can lead to limitation of duties or discharge. For aviators and submarine personnel, losing flight/submarine qualified status or flight/submarine pay due to a physical or psychological concern is an issue. For additional risk considerations visit <http://www.au.af.mil/AU/AWC/AWCGATE/ucmj.htm> . [Articles 77-134](#) of the UCMJ are known as "punitive articles" (offenses which, if violated, can result in punishment by court-martial).

L. Additional Protections for Human Subjects. In addition to the requirements of 32 CFR 219, additional safeguards shall be provided for human subjects in all DoD-conducted or DoD-supported research involving human subjects who may be considered vulnerable due to their association with groups or populations specifically defined by Federal regulation and the DoDI 3216.02.

1. Vulnerable Populations (i.e. prisoners, children). Research conducted in CAC-E typically is conducted with DoD Personnel as Subjects (Military, Civilian, or Contractors). Please refer to the DoDI 3216.02 for specific guidance regarding the vulnerable populations.

2. Military Personnel as Subjects.

a) Service Members and Their Status as Adults. For purposes of legal capacity to participate in DoD-conducted or -supported research involving human subjects, all active duty Service members and all Reserve Component members in a Federal duty status are considered for purposes of this Instruction to be adults. The participation of such members is not subject to requirements 45 CFR 46, Subpart D regarding research involving children or minors. When Service members are under 18 years of age, students at Service Academies, or trainees, the IRB shall carefully consider the recruitment process and the necessity to include such members as human subjects.

b) The IRBs of DoD institutions may require the Principal Investigator (PI) to confirm that a Service member's Commander supports the member's participation in DoD-supported research involving human subjects. Generally a letter of support is needed from the Commander of military facilities or units in which recruitment will occur or the study will be conducted.

c) The Chain of Command should not be involved in the recruitment of military personnel and should not encourage or order soldiers to participate in a research study. The letter of support from the Commander should not be used as a recruiting tool with the military personnel.

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d) Service members shall follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty and off-duty.

e) Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers (NCOs)) are prohibited from influencing the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians) regarding participation as subjects in research involving human subjects.

f) Superiors of Service members (e.g., unit officers, senior NCOs, and equivalent civilians) in the chain of command shall not be present at any human subject recruitment sessions or during the consent process in which members of units under their command are afforded the opportunity to participate as human subjects. When applicable, the superiors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

g) For research involving Service members as human subjects that has been determined to be greater than minimal risk and when recruitment occurs in a group setting, the IRB shall appoint an ombudsman. For research involving Service members as human subjects, that has been determined to be NO greater than minimal risk and when recruitment occurs in a group setting, the IRB shall determine when it is appropriate to appoint an ombudsman. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.

3. DoD Civilians as Subjects.

a) DoD Civilians shall follow their organization's policies regarding the requirement to obtain permission to participate in research involving human subjects.

b) Supervisors (e.g., military and civilian supervisors or anyone in the supervisory structure) are prohibited from influencing the decisions of their subordinates regarding participation as subjects in research involving human subjects.

c) Supervisors shall not be present at any human subject recruitment sessions or during the consent process in which DoD civilians under their supervision are afforded the opportunity to participate as human subjects. When applicable, supervisors so excluded shall be afforded the opportunity to participate as human subjects in a separate recruitment session.

d) For research involving civilians as human subjects and when recruitment occurs in a group setting, the IRB shall discuss appointing an ombudsman. The decision to require the appointment of an ombudsman should be based in part on the human subject population, the consent process, and the recruitment strategy.

M. Research Monitor. For research involving human subjects determined to involve more than minimal risk to human subjects, the IRB shall approve an independent research monitor by name. A research monitor may also be required for research involving only minimal risk. The duties of the research monitor shall be determined on the basis of specific risks or concerns about the research. The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities. The IRB or HRPP official shall communicate with research monitors to confirm their duties,

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authorities, and responsibilities. The CAC-E HPA may waive the requirement to have a research monitor on a case-by-case basis when the inclusion of a research monitor is not necessary to provide additional protections for human subjects.

N. Medical Expenses.

1. CAC-E shall establish procedures to protect human subjects from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in DoD-conducted non-exempt research involving human subjects that involves more than minimal risk. Such procedures may consist of utilizing the Secretarial Designee program during the period of the human subject's involvement in the research, which may be extended further upon the approval of the USD (P&R). DoDI 3216.02, Enc 3.10.b.

2. CAC-E is not required to establish procedures to protect human subjects from medical expenses when supporting non-exempt research involving human subjects performed solely by non-DoD institutions. DoDI 3216.02, Enc 3.10.b.

3. CAC-E Collaborative Research.

a) When collaborating with a non-DoD institution, the CAC-E shall establish procedures to protect human subjects from medical expenses that are the direct result of participation in non-exempt research involving human subjects and that are a direct result of research activities performed by DoD personnel. This does not apply to expenses resulting from the injury due to actions performed by the non-DoD institution(s) or when the DoD does not have the primary involvement in research at the collaborating institution.

b) When CAC-E personnel are conducting the research involving human subjects at the collaborating institution and the Department of Defense does not have the primary involvement, CAC-E is not required to have procedures to protect human subjects from medical expenses. For this purpose the determination of primary involvement shall be based on consideration of the type and portion of the DoD involvement in the collaborative research (e.g., research staff, human subjects, facilities, equipment, IRB, and all other assets).

c) When the collaboration is such that it is difficult to separate DoD involvement from that of the non-DoD institution, the Head of the Office of the Secretary of Defense (OSD) or AHRPO may waive this requirement to have procedures to protect human subjects from medical expenses.

O. Compensation.

1. Federal Personnel.

a) ON DUTY.

(1) 5 USC 5536 prohibits Federal personnel (civil servants or Service members) from being paid by any source other than their regular Federal salaries while they are on duty. Federal personnel participating as human subjects in non-DoD-conducted research while on duty may not be otherwise compensated for general research participation, even if the research is not federally funded or conducted.

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(2) Section 30 of title 24, U.S.C. provides an exception for Federal personnel (civil servants or Service members) participating as human subjects in research conducted by a non-DoD institution (whether or not the research is federally funded) to allow compensation up to \$50 for each blood draw.

b) OFF DUTY.

(1) Federal personnel (civil servants or Service members) participating as human subjects in Federally-funded human subject research conducted by a non-DoD institution may be compensated up to \$50 for each blood draw. However, if the research is not Federally funded, the human subjects may be compensated for blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the blood draw (i.e., the \$50 limitation per blood draw does not apply).

(2) Additionally Federal personnel while off duty may be compensated for research participation other than blood draws in the same way as human subjects who are not Federal personnel (i.e., compensated for participation in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research). However, payment to off-duty Federal personnel for general research participation must not be directly from a Federal source (payment from a Federal contractor or other non-Federal source is permissible).

2. Non-Federal Personnel.

a) Non-Federal personnel participating as human subjects in DoD-funded research may be compensated up to \$50 for each blood draw that meets the purpose of 24 USC 30.

b) Additionally non-Federal personnel may be compensated for participation in DoD-supported research for other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research. Payment for general research participation may come directly from a Federal or non-Federal source.

P. Allegations of Noncompliance. Noncompliance with DoDI 3216.02. The DoD Components shall respond to allegations of noncompliance with this Instruction. For allegations that involve more than one DoD Component or a non-DoD institution, the involved institutions should jointly determine and assign executive responsibility for responding to the allegation(s). For allegations involving a non-DoD institution, the DoD Component supporting the research involving human subjects shall ensure the allegation is properly investigated and reported to the DoD Component.

Q. Record Keeping.

1. 32 CFR 219 requires all institutions, including investigators, engaged in DoD-conducted or -supported research involving human subjects to retain records for at least 3 years after the completion of the research. This requirement includes documentation of all regulative study documents, investigator training and qualifications to conduct the study, communications between the HPA/PI/IRB, and other actions relevant to the HRPP.

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2. Records maintained by non-DoD institutions that document compliance or noncompliance with DoDI 3216.02 shall be made accessible for inspection and copying by authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

R. CAC-E HPA and IRB Review, Approval, and Oversight.

1. To the extent provided in 32 CFR 219.103, the non DoD-institution shall promptly notify the CAC-E HPA and/or IRB of the following: when significant changes to the research protocol are approved by the IRB, the results of the IRB continuing review, if the IRB used to review and approve the research changes to a different IRB, when the institution is notified by any Federal department or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol, and all UPIRTSOs, suspensions, terminations, and serious or continuing noncompliance regarding DoD-supported research involving human subjects.

2. At a minimum, CAC-E HPA must:

a) Confirm the non-DoD institution has a Federal assurance appropriate for the research in question.

b) Review the research protocol and accept the IRB determination of level of risk and approval of the study for compliance with DoDI 3216.02.

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

d) Ensure the IRB conducts an appropriate continuing review at least annually.

e) When the research involving human subjects is being conducted in a foreign country, confirm all applicable national laws and requirements of the foreign country have been met and confirm the IRB considered the cultural sensitivities in the setting where the research will take place.

3. If the non-DoD institution determines the activity is non-exempt research involving human subjects, the CAC-E HPA must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection). Such review and approval shall be based on confirmation that the research and non-DoD institution are in compliance with applicable regulations.

4. When the contract or other agreement may include research involving human subjects and if the non-DoD institution determines either the activity is not research involving human subjects or is exempt research involving human subjects, the CAC-E HPA must concur with the performing institution's determination before activity can begin.

REFERENCES and OTHER GOVERNING DOCUMENTS

- 5 United States Code (U.S.C.) 552a, The Privacy Act of 1974
- 10 U.S.C. 980, Limitations on use of humans as experimental subjects
- 18 U.S.C. 209, Salary of Government officials and employees payable only by United States
- 24 U.S.C. 30, Payments to donors of blood for persons undergoing treatment at Government Expense
- 32 Code of Federal Regulations (CFR) 219, Protection of Human Subjects
- 45 CFR 46, Protection of Human Subjects, Department of Health and Human Services Subparts B, C, and D
- 45 CFR 164, Security and Privacy
- Army Regulation (AR) 70-25, Use of Volunteers as Subjects of Research
- AR 340-21, Army Privacy Program
- AR 380-5, Department of the Army Information Security Program
- AR 600-46, Attitude and Opinion Survey Program
- DoD 5500.7-R, Joint Ethics Regulation, paragraphs 2-206 and 2-303
- Department of Defense Directive (DoDD) 5400.11 and 5400.11R, Department of Defense Privacy Program
- Department of Defense Instruction (DoDI) 1100.13, Surveys of DoD Personnel
- DoDI 3210.7, Research Integrity and Misconduct
- DoDI 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," November 8, 2011
- DoDI 5025.01, DoD Directives Program, October 28, 2007
- DoDI 8910.01, Information Collection and Reporting, March 6, 2007
- Executive Order 13526, "Classified National Security Information," December 29, 2009
- Page 23192 of Volume 44, Federal Register, April 18, 1979 (also known as "The Belmont Report")
- Public Law 107-347, "Confidential Information Protection and Statistical Efficiency Act of 2002 (CIPSEA)," December 17, 2002