The United States Army
Combined Arms Center Education (CAC-E)

BULLETIN 940

Research Review and Approval

Institutions covered by this bulletin 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)

Dr. Maria L Clark, Human Protections Administrator (HPA)

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 22 April 2015.

1. Purpose. CAC-E is committed to promoting the ethical conduct of research in compliance with all applicable laws and regulations and in a manner that protects the human subjects involved. This bulletin provides information on research procedures within CAC-E schools and proponents.

2. Applicability. This bulletin applies to all CAC-E schools and directorates for all research supported or conducted within CAC-E by staff, faculty, students, or external researchers seeking to conduct research activities within CAC-E schools or directorates.

3. Scope. CAC-E conducted or supported research is primarily focused on environmental physiology, military operations, military or national history, academic learning, academic teaching and/or facilitation and educational environmental assessments. All Human Subjects Research (HSR) performed under the auspices of the Institute, including collaborative research conducted with one or more entities must be reviewed and approved by the Human Protections Administrator (HPA) and/or the CAC-E Institutional Review Board (IRB).

4. Policy. All research conducted by CAC-E personnel (military and civilian students, staff, and faculty) that involves human subjects (internal or external of CAC-E) must be reviewed by the CAC-E HPA or IRB for verification that DoD human subjects protection requirements have been met. All external requests for CAC-E support of research involving human subjects must also be reviewed by the CAC-E HPA or IRB. Non-exempt research must be conducted under a Federal Assurance and/or a DoD Assurance, have scientific review and IRB approval, and meet the human subject protection requirements imposed by the Department of Defense through DoDI 3216.02. After verification is provided by the HPA or IRB, CAC-E schools or departments may support the research. CAC-E support of the research requires an approval letter from the HPA or IRB Chair/Vice-Chair.

5. Laws, Regulations, and Guidance. Appendix A provides a list of laws, regulations, and guidance as well as CAC-E institutional guidance.

6. Assurance. CAC-E is committed to promoting the conduct of research in compliance with all applicable laws and regulations in a manner that protects the human participants involved. The Department of Defense (DoD) requires that any Army activity conducting, supporting, or participating in a human research effort, regardless of sponsor or subject area, hold a current DoD Army Assurance as granted by the Assistant Surgeon General for Force Projection through the Army Human Research Protections Office (AHRPO). As part of this Assurance, CAC-E must develop procedures for conducting human subject research in a responsible and ethical fashion. The procedures for implementing these requirements are provided in the CAC-E Human Research Protections Program (HRPP) Plan, the CAC-E IRB Standard Operating Procedures (SOP), and other referenced documents.

7. Human Research Protections Program (HRPP). CAC-E operates a Human Research Protection Program (HRPP) to oversee all research involving human subjects engaged in or supported by CAC-E Components and which occur within a wide range of military and social science fields. The CAC-E HRPP is a systematic and comprehensive program of interdependent elements that implement the Institution’s policies and procedures for the protection of human research subjects. The CAC-E HRPP Plan

defines organizational roles and responsibilities for the protection of human research subjects and establishes policies and procedures for implementation of the program and to ensure compliance with DoDI 3216.02.

8. Ethical Foundations. The ethical principles for human research covered by this HRPP, including protocols determined to be “exempt” under the Common Rule (32 CFR 219), are those set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (79 Federal Register (FR) 12065, April 17, 1979). The three foundational principles are as follows:

a. Respect for persons. Requires that potential subjects be given the information they need, in language they understand, to decide whether or not to participate in a study, and the time and opportunity necessary to make that decision, without pressure to participate. Autonomy further requires protection of subject privacy, confidentiality of data, and added protections for vulnerable populations.

b. Beneficence. Requires that researchers (and their institutions) minimize potential harm. This includes minimizing the nature, probability, and magnitude of potential harm, while maximizing potential benefits. The anticipated benefits of the research must outweigh the potential for harm to research subjects.

c. Justice. Requires that the benefits and burdens of research be shared fairly (e.g., equitable selection; equitable distribution of benefits). Subjects should be recruited based on their relation to the problem being studied rather than their easy availability, their compromised position, or their malleability. Investigators should base inclusion/exclusion criteria on those factors that most effectively and soundly address the research problem. For example, subjects should not be denied access to a study simply because they may not speak English. Also, the benefits of the research must be made available to the class of subjects who participated in the research (e.g., conducting a study upon a population that cannot reasonably anticipate to benefit from the results due to their economic, political, or social status would be unjust).

9. Defining Research. The HRPP governs activities that constitute research involving human subjects. As such the first determination is, does the activity meet the definition for research involving human subjects.

a. DoDI 3216.02 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.

b. 32 CFR 219.102(d). Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

c. 32 CFR 219.102(f) Research. The term research designates an activity designed to test a hypothesis or permit conclusions to be drawn and, thereby, to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships).

d. A systematic approach involves a predetermined method for studying a specific topic or answering a specific question. Activities that are “systematic investigations” may include:

- Observational studies;
- Interviews (including focus groups) or survey studies;
- Group comparison studies;
- Assessment tool development/ validation;
- Program evaluation;
- Interventional research;
- Some pilot projects.

e. Activities NOT normally considered systematic investigations include:

- Training activities (e.g., individuals being trained to perform a certain technique, such as marksmanship).
- Activities involving individuals, where the objective of the activity is to teach proficiency in performing certain tasks or using specific methods.

f. Intent to contribute to generalizable knowledge typically requires that results (or conclusions) of the activity are intended to contribute to theoretical knowledge about a topic in a manner intended to allow application in other settings. In cases where the intent of the activity changes after it has begun (e.g., findings from an activity intended solely for internal purposes lead to a desire to disseminate the results for application outside the program), the research use of the data collected for another purpose must be reviewed by the IRB.

g. Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or Identifiable private information.

h. Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

i. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

j. Within the definition of human subject, the term “obtaining” means receiving or accessing information, data, or specimens for research purposes. Obtaining includes when an investigator uses for research purposes data already in the possession of the investigator.

k. DoD Personal Information. Within the Department of Defense (DoD), additional guidance as to what constitutes “personal information” is available in DoD 5400.11-R, which applies to systems of records maintained by the DoD. Section DL1.14. defines personal information 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 personally identifiable information (e.g., 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).” While this definition is not applicable to human subject research conducted under 32 CFR 219 (the Common Rule), when investigators access systems of records covered by DoD 5400.11-R, additional protections may apply.

l. CAC-E research activities typically include:

(1) **Master of Military Art and Science.** CGSS and SAMS offer the Master of Military Art and Science (MMAS) degree program. As part of that program students are required to write a thesis or monograph. These documents are published and are typically focused on military history and/or operations. Students seeking to conduct interviews or surveys must consult with the HPA or IRB to ensure their research activities are in compliance.

(2) **CAC-E Students.** On occasion a student attending one of the CGSC schools is also attending an external (civilian) school or university and may apply to CAC-E to conduct research to meet the external program requirements.

(3) **CAC-E Staff and Faculty.** Staff and Faculty independently, or as part of their duty, conduct research in such areas as curricula development, program evaluation, and infrastructure evaluation. Staff or faculty members are encouraged to continue their professional development and may request the ability to conduct research projects within CAC-E.

(4) **CAC-E Quality Assurance Office (QAO) Program Evaluation.** The QAO is tasked to conduct evaluations of educational programs, courses, and curricula within CGSC. This involves observations, focus groups, surveys, interviews, and curriculum reviews. All results are used only by Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program. These activities are NOT research involving human subjects. However, all surveys must have a QAO survey control number.

(5) **Command Research.** QAO supports Command research regarding student quality of life issues, staff and faculty issues, Command Climate, and other research interests designed to improve the CAC-E and CGSC environment and/or processes. These activities are typically NOT research involving human subjects. If the research

involves human subjects and the results will be used in a way that generalizable and made publically available it must be submitted to the HPA who will determine if the research is exempt or requires further IRB review.

(6) **TRADOC Approved Research.** CAC-E receives research requests from TRADOC, the Army Research Institute (ARI), and other Army or DoD organizations through the chain of command to support or conduct research involving human subjects. All such requests, whether seeking support from the main campus or from one or more satellite campuses, must be routed through the CAC-E HPA who will review all such requests for compliance with DoDI 3216.02 and establish the required local record and documentation. TRADOC or ARI approval of research does not eliminate necessary IRB procedures regarding HSR. TRADOC may NOT approve non-exempt HSR that has not been DoD IRB reviewed and approved.

(7) **Collaborative Research.** When CAC-E personnel collaborate research involving human subjects with other institutions, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with 32 CFR 219 and DoDI 3216.02. CAC-E maintains responsibility for its institutional activities in conducting the research, even if the project is reviewed by an external IRB. Guidance for collaborative research is provided in the CAC-E HRPP Plan.

(8) **External Researchers.** CAC-E receives requests from individuals and/or organizations external to CAC-E to support and sometimes conduct research involving personnel assigned to the college. This research typically seeks to survey or interview CAC-E students, staff, or faculty on military or educational subjects.

m. DoDI Exclusions. DoDI exclusions often seen within CAC-E include “Activities, including program evaluation, customer satisfaction surveys, user surveys, outcome reviews, and other methods, designed solely to assess the performance of DoD programs where the results of the evaluation are only for the use of Government officials responsible for the operation or oversight of the program being evaluated and are not intended for generalized use beyond such program.” Additional exclusions may be found in the DoDI 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research.

10. Responsibilities.

a. Deputy Commandant (DC).

(1) The CAC-E Deputy Commandant is responsible for enforcing compliance with applicable Federal and DoD regulations, Command polities and guidelines, the terms of the Assurance and applicable CAC-E policies, and IRB determinations concerning human subjects research activities. The day-to-day oversight of these responsibilities is delegated to the Institutional Official in accordance with (IAW) the CAC-E Assurance.

(2) The DC may exercise the final institutional authority for authorizing support and implementation of all research. The DC may not approve or allow CAC-E personnel to conduct, support, or participate in research that has not been formally approved by a DoD IRB. The DC may disapprove research regardless of IRB approval or disapproval but he may not approve or allow CAC-E conduct or support of research involving human subjects that has not been reviewed and approved by the CAC-E HPA or IRB.

b. Institutional Official (IO).

(1) The CAC-E Command and General Staff College (CGSC) Dean of Academics is the CAC-E IO responsible for establishing and maintaining the institutional HRPP.

(2) The IO enforces compliance with applicable federal and Department of Defense (DoD) regulations, Command policies and guidelines, the terms of the Assurance and applicable CAC-E policies, and Institutional Review board (IRB) determinations concerning human research activities.

(3) The IO may exercise the final institutional authority for authorizing support and implementation of all research. The IO may not approve research involving human subjects, or modifications to existing research protocols, that have not been approved by the IRB. The IO may not approve or allow CAC-E conduct or support of research that has been formally disapproved by the IRB. The IO may, however, impose additional requirements or restrictions regarding institutional support for the research, including a decision not to implement the proposed research (32 CFR 219.112).

c. School and Department Directors. The director of each CAC-E School or department is responsible for assuring that staff or faculty members conduct research in accordance with all applicable regulations, in a safe and ethical manner. Directors ensure Staff, Faculty, and Students follow HRPP Policies and Procedures and ensure all Staff Group Supervisors or other Staff and Faculty overseeing student research are properly trained to provide guidance and verify students conducting research are adhering to the HRPP and IRB requirements. School and Department Directors may not approve or allow CAC-E conduct or support of research involving human subjects that has not been reviewed and approved by the CAC-E HPA or IRB.

d. Human Protection Administrator (HPA). The HPA Review research applications and culminates all related documents. Assigns the research protocol control number. The HPA makes research and exempt status determinations. For non-exempt HSR, the HPA determines the IRB review level necessary (expedited or full IRB board review) and begins coordination of IRB review as necessary. The HPA notifies investigators of non-research or exempt determinations and decisions to approve or disapprove research studies or modifications. After disapproval actions, the HPA will provide the investigator written notification of the reasons for its decision, and will give the investigator an opportunity to respond in person, in writing, or both.

e. IRB Chair. The IRB Chair reviews research applications determined to meet criteria for expedited review. The IRB Chair will communicate with the PI for clarifications or modifications necessary for expedited approval. The IRB Chair notifies the PI, in writing, of decisions to approve or disapprove research studies or modifications required for approval. After disapproval actions, the IRB Chair will provide the investigator written notification of the reasons for its decision, and will give the investigator an opportunity to respond in person, in writing, or both.

f. Determination Official (DO). The DO makes research and exempt status determinations. For non-exempt HSR, the DO forwards the protocol to the HPA or IRB Chair who determines the IRB review level necessary (expedited or full IRB board review) and begins coordination of IRB review as necessary. For non-research or exempt determinations, the DO notifies investigators of non-research or exempt determinations

and forwards the protocol to the HPA for decision to approve or disapprove research studies or modifications. For disapproval actions, the HPA will provide the investigator written notification of the reasons for its decision, and will give the investigator an opportunity to respond in person, in writing, or both.

g. Institution Review Board (IRB).

(1) The CAC-E IRB has regulatory authority to disapprove research IAW 32 CFR 219.109(a) or require modification to secure approval. The CAC-E IRB also has the authority to suspend, or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. When necessary, the IRB may work directly with the investigator to secure modifications to the protocol before approval.

(2) The IRB Chair resides over the IRB committee for HSR requiring review by a convened IRB. The IRB Chair or IRB member designated as reviewer will communicate with the PI for clarifications or modifications necessary for IRB approval. The IRB Chair notifies the PI, in writing, of decisions to approve or disapprove research studies or modifications required for approval. After disapproval actions, the IRB Chair will provide the investigator written notification of the reasons for its decision, and will give the investigator an opportunity to respond in person, in writing, or both.

h. Director, Graduate Degree Program (GDP). The GDP Director is a member of the IRB who is qualified in reviewing research and making research determinations. The GDP Director provides a review of all research conducted by students toward achieving the MMAS degree. All proposed research determined as HSR or potentially HSR will be referred to the HPA.

i. MMAS Research Committee. The MMAS research chair and members of the committee are responsible for verifying students who conduct research follow procedures for conducting research both within CGSC and outside CGSC. For non-exempt HSR, the committee member who possesses a doctoral or comparable degree must complete a scientific review prior to the research application. Scientific Review documents and procedures are provided in the CAC-E HRPP Plan.

j. Principal Investigator (PI).

(1) A Principal Investigator (PI) is assigned when a team of individuals are conducting a particular research. One investigator must be designated as the PI for each research protocol. The PI and all members of the research team must comply with the findings, determinations, and requirements of the IRB or IRB of record.

(2) As the primary individual responsible for the conduct of research, the PI bears direct responsibility for protecting research subjects and ensuring that the protocol is implemented as approved by the IRB. This responsibility starts with protocol design, which must minimize risks to study participants while maximizing research benefits.

(3) In addition, the PI is responsible for maintaining investigator and subjects files, providing an adequate informed consent process as described in 32 CFR 219.116, and ensuring that subject privacy and confidentiality of data are maintained. The PI is responsible for the adequacy of both the informed consent document and the informed

consent process, regardless of which members of the research team actually obtain and document consent.

(4) The PI is responsible for conducting the study as approved by the IRB. When an event or new information prompts a revision to previously approved research, the protocol must be modified and approved by the IRB prior to implementation. The PI must promptly report to the IRB unanticipated problems involving risks to subjects or others (UPIRTSOs).

(5) The PI is responsible for ensuring continuing review of non-exempt research at least once per year as required by the IRB. If the protocol is not re-approved before IRB expiration, all research activities must stop until re-approval by the IRB.

k. Research Participants. Study participants (human subjects) may be viewed as having certain responsibilities as well. They can be expected to make every effort to comprehend the information investigators present to them so that they can make an informed decision about their participation in good faith. While participating, they should also make every reasonable effort to comply with protocol requirements and inform the investigators of any research-related problems. Subjects should notify study staff of new issues or concerns that might arise. Research participants may suggest changes to the study or informed consent, where appropriate. Study participants always have the right to withdraw from their participation in research at any time and for any reason without penalty or loss of benefits to which they would otherwise be entitled.

11. Research Request Process.

a. Research Application. All individuals or organizations seeking to conduct research must complete a Research Application and submit it to the CAC-E HPA. The CAC-E application form can be found online at the CGSC website http://usacac.army.mil/organizations/lde/cgsc/qao. If an application to another IRB has already been completed, a copy of it may serve as the research application for CAC-E. Once the application is submitted, the HPA will coordinate additional requirements to include:

(1) research proposal project plan
(2) proposed research instruments
(3) proposed informed consent form
(4) training certificates and resumes or CVs for all research team members
(5) Recruitment plan
(6) Data safety plan
(7) Additional required documents will be confirmed by the HPA.

b. Complete appropriate initial education modules through https://www.citiprogram.org/default.asp and submit completion certification of training documents.

c. Once all needed documents are compiled, the HPA will conduct a review to determine if the research meets the definition of research IAW DoDI 3216.02. If the request meets the definition of research, the HPA then determines if the research is exempt from IRB review. If the request is either not research or is research that meets

exempt criteria IAW the 32 CFR 219, the HPA will provide written approval or disapproval for the requested activities to proceed.

d. If the request is determined to be non-exempt human subjects research, the HPA will determine if the research meets criteria for expedited review or requires a convened IRB review. If the research meets criteria for expedited review, the IRB Chair or a qualified delegated person will ensure a scientific review has been completed and will conduct the expedited review. The IRB Chair, Vice IRB Chair, or HPA will provide written approval or disapproval for the requested research to proceed.

e. If the request is determined to require a convened IRB review, the IRB Chair and members will be scheduled to convene. The IRB Chair or delegated primary reviewer will ensure the scientific review is complete and coordinate any additional information needed for the convened IRB meeting. The IRB Chair, Vice IRB Chair, or HPA will provide written approval or disapproval for the requested research to proceed.

12. Scientific Review. Scientific review is an independent documented review that evaluates the scientific merit of a research protocol, and determines if the design and procedures are consistent with sound research design. All DoD conducted research must have a complete scientific review (DoDI 3216.02, Enc 3.3(a)(2). The review will include an evaluation of the quality, appropriateness, and feasibility of the research. All non-exempt research involving human subjects conducted by CAC-E shall undergo scientific review prior to IRB review. The scientific review will be coordinated by the HPA or the IRB Chair. MMAS research applications must include a scientific review completed by an MMAS committee member holding a doctoral or terminal degree.

13. Voluntary Participation and Informed Consent. Participation in research is completely voluntary and participants should receive adequate information about the research project to include the risks, benefits, what the research requires of them, and that their participation is voluntary. This information is normally contained in the cover letter that accompanies a survey questionnaire. In the case where the researcher conducts interviews, observations, or focus groups, the participants must be informed prior to the start of their participation in the project.

14. DoD Personnel as Subjects.

a. Military Personnel as Subjects.

(1) Service members shall follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty. Additionally a Service member’s ability to perform his or her military duties may be affected by participating during off-duty time (i.e., on leave or during non-duty hours). Therefore, Service members shall follow their Component and command’s policies for approving off-duty employment or activities. The IRBs of DoD institutions or HRPOs may require Principal Investigators to confirm that a Service member’s commander supports the member’s participation in DoD-supported research involving human subjects (DoDI3216.02).

(a) CAC-E Students may not be excused from scheduled educational activities to participate in research activities.

(b) CAC-E Faculty members may not recruit or conduct HSR with students whose grades or evaluations they may influence or control.

(2) 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 covered by this Instruction (DoDI3216.02).

(3) 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 (DoDI3216.02).

(4) 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. The ombudsman shall not be associated in any way to the research and shall be present during the recruitment in order to monitor that the voluntary involvement or recruitment of the Service members is clearly and adequately stressed and that the information provided about the research is clear, adequate, and accurate. The ombudsman may also be the research monitor (see section 8 of this enclosure). 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 for the purposes described in this paragraph. 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 (DoDI3216.02).

b. DoD Civilians as Subjects.

(1) DoD Civilians shall follow their organization’s policies regarding the requirement to obtain permission to participate in research involving human subjects. 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 covered by this Instruction (DoDI3216.02).

(2) Supervisors (e.g., military and civilian supervisors or anyone in the supervisory structure) 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 (DoDI3216.02).

(3) For research involving civilians as human subjects and when recruitment occurs in a group setting, the IRB shall discuss appointing an ombudsman for the purposes described in subparagraph e.(1)(d) of this section. 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 (DoDI3216.02).

15. Confidentiality.

a. Threats to confidentiality of research participants are a significant research risk. Many researchers gather some private information from participants that may include how an individual responded to questions, demographic information, education level, combat experience, etc.

b. Investigators must ensure confidentiality through such means as storing data in a locked cabinet in a secure location and using adequate computer security for electronic data. Additionally, data collected will be reported in a way that the identity of subjects is protected. In cases where the researcher feels identification of the subject(s) would make the research project/paper stronger, the researcher must obtain written permission from the subject(s) that authorizes the researcher to use his/her name in the researcher paper/project. If the research design does not contain a thorough plan for the protection of participant's confidentiality, the request will not be approved.

16. Research Approval. Research approvals are for a period of one year. Research intended to be longitudinal or lasting more than one year will receive a continuing review each year to ensure the research has not changed in such a way that the determination is no longer valid. Researchers wishing to continue their research beyond the one year approved must apply for continuation 30 day prior to the research expiration.

17. Closure Report. At the conclusion of the research project, the researcher must submit a copy of the "end of project data collection report" to the QAO. This report is available online at the CGSC website http://usacac.army.mil/organizations/lde/cgsc/qao. The Final Report should be submitted to the IRB by the Principal Investigator (PI) no later than 30 days before the expiration of IRB approval.

18. Research Records. The PI must retain all research-related records for a minimum of three years after the study is completed, terminated, or discontinued. Subject Files are to be kept in a secure location. Identifiable information should not be stored with coded or de-identified information. Investigator files must contain all documents submitted to the HRPP for HPA review, Scientific Review, and IRB Review, and the responses. All investigator records must be accessible for inspection and copying by the IRB or authorized representatives of DA or DoD at reasonable times and in a reasonable manner.

19. Rebuttal or Appeal of IRB Decisions. Upon written receipt of requested changes, investigators may appeal the IRB recommendations either in person or in writing. If the IRB decides to disapprove a research activity, written notification, including a statement of reasons for its decision, will be provided to the investigator. An appeal of a disapproved research study must be reviewed at a full board meeting. The response and study are reviewed by the IRB that made the original decision. Additional appeals to the IRB may be made by the investigator/PI.

20. Education & Training on Human Research Protections.

a. CAC-E Personnel. Initial and continuing education in the protection of research subjects shall be commensurate with the duties and responsibilities of DoD personnel conducting, reviewing or approving research involving human subjects.

(1) Individuals who contribute in a substantive way or who are engaged in the scientific development, design, or conduct of a study are considered investigators or key research personnel. This includes principal investigators, associate investigators, research assistants, research coordinators, study coordinators, research administrators, data entry/statisticians, and others.

(2) Individuals who provide oversight of research (committee chair or reader, instructor, or director) are considered to be reviewing or approving research.

(3) All CAC-E personnel (civilian, military, and contractor) involved in the conduct, review, approval, support, management, or oversight of human participants research are required to complete initial education and training in the responsible conduct of research and human subject protections prior to becoming involved in their research related responsibilities. All personnel must then complete continuing training in human participant protections and responsible conduct of research every one to three years. This includes students who will perform research activities involving human subjects.

(4) Training is primarily fulfilled by completion of web-based training through the Collaborative Institutional Training Initiative (CITI). CITI offers courses oriented to social-behavioral research. Personnel must achieve a score of 80% to receive CITI Certification of Training. The basic course can be found at: https://www.citiprogram.org. The CITI training refresher course must be completed every three years.

b. The HPA, IRB Chair, IRB Members, or AHRPO personnel may provide additional training on unique Department of Defense (DoD) requirements (per DoDI 3216.02 through CGSC FDP4 sessions.

c. Non-CAC-E Personnel. Individuals wishing to conduct research involving CAC-E personnel as human subjects are expected to meet the training requirements of their parent institution and provide documentation to the HPA as part of the protocol package.

d. Principal Investigator. Principal Investigator (PI) is responsible for ensuring that all individuals involved in the conduct of a study are qualified to do so by education and training. To that end, the PI will maintain in the investigator's master file for each study a current CV and certification of human subject protection training for all key personnel. This information must also be submitted with each Research Application. Application packets lacking the required CVs and evidence of training will not be reviewed. The completeness of training records will also be verified by the HPA at the time of IRB continuing review of a protocol.

21. Complaints Regarding Human Participant Research.

a. Individuals wishing to report a complaint regarding a research may do so by contacting the Principal Investigator, the Human Protection Administrator, the Dean of Academics, the Associate Dean of Academics, the IRB Chair or Vice Chair, any IRB member, or the Quality Assurance Office Director. Any school or department director receiving a reported complaint will inform one of these individuals of the complaint.

b. It is the responsibility of the PI to notify the IRB of any subject or other individual's complaint regarding the research and report complaints that involve potential risks to subjects/others or result in a potential change in the risk/benefit ratio as a reportable problem (e.g., the school where the research is conducted complains that the

research assistant has not maintained her research notes in a confidential manner which may have potentially breached confidentiality) according to the "IRB Standard Operating Procedure Addendum: Reporting of Unanticipated Problems Involving Risks to Subjects or Others". The complaint may be reported at continuing review if it involves no risk to the subjects or others or does not change the risk/benefit ratio. Investigators are to cooperate with the IRB by making documents accessible, responding to written requests within the designated timeframe, and being available for questions by the IRB.

c. All complaints will be investigated and reported to the CAC-E IRB, any other involved IRB, CAC-E leadership, AHRPO, and the Office of the Surgeon General as warranted.

22. Contracts. CAC-E 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 DoD institution's engagement in the research. When a 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 HPA must concur with the performing institution's determination before activity can begin. Contracts for DoD-supported research involving human subjects must contain the Defense Federal Acquisition Regulation Supplement (DFARS) clause in accordance with section 252.235-7004 of title 48, CFR (Reference (n)). The DFARS clause (or similar language) is not required to be included in an agreement with another Federal department or agency that has adopted the Common Rule.

23. Point of Contact. Questions, comments, or recommended changes to this bulletin should be submitted to the Human Protections Administrator, Dr. Maria L. Clark, U.S. Army Command and General Staff College, Lewis & Clark Center, RM 4521, maria.l.clark.civ@mail.mil, (913) 684-7332, OR to the Quality Assurance Office RM 4539, (913) 684-2029.

W. Chris King, Ph.D., P.E.
Dean of Academics
U.S. Army Command and
General Staff College

CHRISTOPHER P. HUGHES
BG, U.S. Army
Deputy Commanding General

Appendix A – Regulations

Federal Regulations

Code of Federal Regulations

Title 32, Part 219 Protection of Human Subjects also known as the Common Rule (PDF, 2011) **Electronic Code of Federal Regulations** 32 CFR 219 (2011)
Title 48, Part 252.235-7004 Part 207.172, Federal Acquisition Regulations
Part 207.172 applies to human research
United States Code Section 980 of Title 10 (PDF, 2001), *Limitation on Use of Humans as Experimental Subjects*

Department of Health and Human Services

Title 21, Parts 50, 56, 312, 314, 600, 812 and 814, **Food & Drug Administration** (FDA) (2011)
Title 45, Part 46, Subpart B, *Additional Protection for Pregnant Women, Human Fetuses, and Neonates Involved in Research* (2001)
Title 45, Part 46, Subpart C, *Additional Protection Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects* (1978)
Title 45, Part 46, Subpart D, *Additional Protection for Children Involved as Subjects in Research (1983)*
Title 45, Parts 160 and 164, HIPAA Privacy Rule:
Standards for Privacy of Individually Identifiable Health Information (2002, Revised 2003)

Department of Education

Title 34, Parts 98 and 99, Student Rights in Research, Experimental Programs, and Testing (2009)

Department of Defense Regulations

AHRPO provides oversight of human research in accordance with the following DoD regulations:
DoD Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research (2011)
In addition, the following DoD policies contain provisions that are relevant to the protection of human subjects in research:
DoD Instruction 5134.01, Under Secretary of Defense for Acquisition, Technology, and Logistics (2005)
DoD Instruction 6200.02, Application of Food and Drug Administration (FDA) Rules to Department of Defense Force Health Protection Programs (2008)
DoD Instruction 6000.08, Funding and Administration of Clinical Investigation Programs (2007)
DoD Directive 2310.01E, Department of Defense Detainee Program (2006)
DoD Directive 5400.11 and 5400.11R, Department of Defense Privacy Program (2007)

DoD Instruction 6025.18, Privacy of Individually Identifiable Health Information in DoD Health Care Programs (2009)
DoD 6025.18-R, Health Information Privacy Regulation (2003)

Army Regulations

AHRPO provides oversight of human research in accordance with the following Army regulations:
AR 70-25, *Use of Volunteers as Subjects of Research* (1990)
AR 40-7, *Use of U.S. Food and Drug Administration-Regulated Investigational Products in Humans Including Schedule I Controlled Substances* (2009)

CAC-E Institutional Policies

CAC-E Human Research Protections Program (HRPP) Plan
CAC-E Institutional Review Board (IRB) Standard Operations Procedures