

**THE UNITED STATES ARMY
COMMAND AND GENERAL STAFF COLLEGE**

Bulletin 40

Research within the Command and General Staff College (CGSC)

(Effective Until Rescinded or Superseded)

CGSC Quality Assurance Office
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1. Purpose. This bulletin provides information on research procedures within the US Army Command and General Staff College (CGSC),

2. Applicability. This bulletin applies to all CGSC schools and directorates, and non-CGSC individuals/institutions requesting to use CGSC personnel in survey research.\

3. Scope. All research performed under the auspices of the Institute, including collaborative research conducted with one or more entities. Research in which human participants are involved must be reviewed and approved by the CGSC Institutional Review Board (IRB) or by such other review body as shall be designated by the CGSC IRB.

4. References.

- a. CGSC Human Research Protection Program (HRPP) Plan
- b. CGSC Institutional Review Board (IRB) Standard Operation Procedures (SOP)
- c. CGSC Scientific and Scholarly Validity Review Procedures
- d. CGSC Exempt Determination Guide
- e. Code of Federal Regulations (45CFR46). 2001.
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- a. "Belmont Report," 1979.
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- b. Department of Defense Instruction 1100.13, "Subject: Surveys of DoD Personnel", 21 November 1996
- c. Army Regulation 600-46, "Attitude and Opinion Survey Program". Headquarters, Department of the Army, 01 November 1979
- d. Army Regulation 70-25, "Use of Volunteers as Subjects for Research", 25 January 1990
- e. HQ TRADOC Memorandum, subject: "Survey Policy Clarification" dated 1 November 2002
- f. DOD Directive 3216.02. Protection of Human Subjects and Adherence to Ethical Standards in DOD Supported Research. March 25, 2002. DOD human research regulations apply to all human participant research conducted by a DOD Component (i.e., extramural) through a contract, grant, cooperative agreement, or other arrangement (DOD Directive 3216.02 para 2.2).
- g. Department of Health and Human Services (DHHS) Regulations (45 CFR Part 46). DHHS regulations at 45 CFR Part 46 Subpart A, enforced by the Office for Human Research Protections (OHRP), constitute the Federal Policy (Common Rule) for the protection of human subjects.

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h. Department of Defense (DOD) Regulations (32 CFR Part 219). In January 1991, the DOD joined 16 other Executive Branch Departments and Agencies in simultaneously adopting the Common Rule. Codified by the DOD as 32 CFR Part 219, the Common Rule is the same as that codified by DHHS as Subpart A of the DHHS regulations at 45 CFR Part 46, but does not include the additional DHHS Subparts. However, DOD policy, at DOD Directive 3216.02 para 4.4.1, requires that research involving pregnant women, fetuses, neonates, prisoners, and children meet the additional protections of the 45 CFR Part 46 Subparts B, C, and D. The Army Assistant Surgeon General for Force Health Projection through the Army Human Research Protections Office (AHRPO) enforces the DOD regulations for Army research activities.

i. Title 10 United States Code Section 980: Limitations on use of humans as experimental subjects. December 28, 2001.

j. DOD Instruction 3210.7: Research Integrity and Misconduct. May 14, 2004.

f. DOD Instruction 8910.01: Information Collection and Reporting

5. Institute Commitment to Protecting Human Subjects. CGSC 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 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. As part of this Assurance, CGSC must develop procedures for conducting human subject research in a responsible and ethical fashion. The procedures for implementing these requirements are provided in the CGSC IRB Standard Operating Procedures (SOP) and referenced documents.

6. Engaged in Research. CGSC becomes engaged in human participants research whenever one of the following occurs:

a. The research is conducted by or under the direction of any employee or agent (students are agents) of the Institute in connection with Institutional responsibilities;

b. CGSC employees or agents intervene or interact with human subjects for purposes of research;

c. CGSC employees or agents obtain individually identifiable private information about human subjects for purposes of research;

d. The research involves the use of CGSC's nonpublic information for any purpose of the research including, but not limited to, identifying or contacting prospective human research subjects.

7. Defining Research.

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a. The Common Rule defines “**research**” as “a systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.” Activities which meet this definition constitute research for purpose of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

b. 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). A systematic approach involves a predetermined method for studying a specific topic or answering a specific question.

c. Activities that are systematic investigations include:

- (1) Observational studies
- (2) Interviews (including focus groups) or survey studies
- (3) Group comparison studies
- (4) Test development
- (5) Program evaluation
- (6) Interventional research
- (7) Some pilot projects

d. All CGSC 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. All personnel must then complete continuing training in human participants protections and responsible conduct of research every one to three years, depending on their roles and responsibilities in human participant research, as outlined in this chapter. Individuals serving in several roles must complete the most comprehensive requirement.

e. All CGSC personnel (active duty, federal employees, and contract employees) who will be engaged in CGSC research must complete an initial education program prior to becoming involved in any research activity. This includes students assigned to CGSC. This requirement is currently fulfilled by completion of web-based training through the Collaborative Institutional Training Initiative (CITI). CITI offers courses oriented to biomedical or social-behavioral research. Personnel must achieve a score of 80% to receive CITI Certification of Training. The available modules (not all required for most research roles) are listed in Table 5, below, and can be found at: <https://www.citiprogram.org/>.

Table 1: HRPP Training Modules at CITI

Social-Behavioral Focus
History & Ethics – SBR
The Regulations and SBR
Informed Consent – SBR
Defining Research with Humans – SBR
Assessing Risks - SBR
Records-based Research
Overview
Group Harms – Research with culturally or medically vulnerable groups
Internet Research – SBR
Privacy & Confidentiality – SBR
Conflicts of Interest

(1) All personnel must complete three to six hours of appropriate, research-ethics-related continuing education every three years for as long as they are involved in the conduct, review, approval, or support of research. CGSC provides ongoing education and training opportunities specific to research personnel needs that meet these requirements.

(2) 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. Investigators and key research personnel are initially required to complete CITI Modules 1-8, 14, and 16 Behavioral. Continuing education requires completion of the CITI Refresher Modules or 6 hours equivalent every 3 years.

8. Responsibilities.

a. **Director, Graduate Degree Program (GDP).** The GDP Director is a member of the IRB who is qualified in reviewing research and making exempt determinations. The GDP Director provides a review of all research conducted by students toward achieving the MMAS degree. All proposed research not determined to be exempt research will be referred to the HPA.

b. **Human Protection Administrator (HPA).** Reviews research applications and culminates all related documents. Assigns the research protocol control number. The HPA determines exempt status. Organizes Institutional Review Board (IRB) review as necessary. The HPA will notify investigators of decisions to approve or disapprove research studies or of modifications required to secure IRB approval. 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.

c. **Quality Assurance Office (QAO).** The QAO is responsible for supporting and coordinating all of the activities of the Human Research Protection Program and serving as the liaison between the IRB, IO, and the research community.

- (1) Coordinates all matters that pertain to surveys administered within CGSC.
- (2) Monitor the administration of approved surveys to ensure compliance with regulations and instructions pertaining to each survey.
- (3) Protect the anonymity of research and survey respondents.
- (4) Organize the Scientific Review Committee.
- (5) Insure students and faculty are not overloaded with research project requests.
- (6) Eliminate redundant and trivial research requests.

d. **Institution Review Board (IRB).** The IRB will help to educate investigators regarding their responsibilities to conduct research in a way that minimizes any risks or harm to subjects and to comply with regulatory requirements and institutional policies and procedures. The IRB staff communicates directly with the PI of each study, who in turn communicates with other investigators involved in the research. However, in the conduct of its responsibilities, the IRB may query, require responses from, or otherwise communicate directly with any personnel involved with a human subjects research study, whether they are listed investigators or not, or with subjects themselves.

e. **Scientific Review Committee (SRC).** The SRC is an ad hoc committee charged with conducting a scientific review of human subject research including research exempt from the human subject protection regulations conducted by CGSC and CGSC investigators. The SRC review assesses the research's scientific quality and merit and the military relevancy. All research protocols must receive scientific review before submission to the CGSC IRB. The recommendations of the scientific reviewers and the actions taken by the investigator in response to these recommendations are submitted through the QAO to the IRB. The SRC Chair will determine whether reliance on another institution's scientific review or a supporting agency's peer review is satisfactory. The primary responsibilities of the scientific review process are to:

- (1) Ensure high scientific standards throughout the CGSC research program;
- (2) Evaluate the quality, appropriateness, and feasibility of research proposals;
- (3) Verify the study design and procedures are consistent with sound research design and will not unnecessarily expose participants to risk.

f. **School and Department Directors.** The director of each CGSC 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.

g. **Investigator.** As the individual responsible for the conduct of research, the investigator bears direct responsibility for protecting every research study participant. This responsibility starts with protocol design, which must minimize risks to study participants while maximizing research benefits. A Principal Investigator (PI) is assigned when a team of individuals are conducting a particular research. The PI and all members of the research team must comply with the findings, determinations, and requirements of the IRB or IRB of record. The PI is also 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. Additional investigator/PI responsibilities and those of other research team members are defined in the CGSC Investigator Manual.

Investigators will follow the Institution's HRPP and, when required, obtain a written determination that the proposed activity does or does not meet the DoDD 3216.02 definition of "human subject" and "research," and if the proposed activity is human subject research, obtain a written determination that the proposed human subject research does or does not meet the exemption criteria in 32 CFR 219.101(b).

Studies involving two or more investigators must appoint a Principal Investigator (PI) who assumes ultimate responsibility for his/her research study. All official IRB correspondence is addressed to the independent investigator, PI, or other personnel designated by the PI. Student investigators (e.g., MMAS students, residents, fellows) may serve as PI's but are required to designate a faculty advisor (committee chair) when submitting a research study to the IRB for review.

h. **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, for instance, if they are unable to meet the requirements of participation. 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.

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.

9. Research Request Process.

a. Individuals requesting to conduct research in CGSC will at minimum:

(1) Complete the Application for Survey Research and submit to the CGSC QAO. The application form can be found online at the CGSC website <http://www.cgsc.edu/qao>.

(2) Submit an electronic copy of proposed research instruments to the CGSC QAO or provide QAO with a copy of the instrument.

(3) Submit an electronic copy of the proposed consent form.

(4) Complete appropriate initial education modules through <https://www.citiprogram.org/> and submit completion certification of training documents.

(5) Become familiar with the CGSC Human Research Protection Program Plan and the CGSC Institutional Review Board (IRB) Standards of Operating Procedures (SOP).

b. Protocol Process. The CGSC Human Research Protection Program Plan, chapter 3 provides detailed information regarding the process for submitting research protocols and applications for survey research.

c. 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://www.cgsc.edu/qao/>.

10. 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.

11. 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.

12. Informed Consent.

a. Participation in survey 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.

b. Undue Influence. Professional ethics and regulatory requirements (32 CFR 219.116 and DODD 3216.2, paragraph 4.4.4.) prohibit the coercion of human subjects to take part in research efforts or to remain in a study against their will. In the informed consent process, and in all other processes, investigators and research staff will ensure that this mandate is strictly enforced. Officers and non-commissioned officers (NCOs) are specifically restricted from influencing the decisions of their subordinates to participate or not participate as research subjects. Officers and senior NCOs in the chain of command are required to be absent during research subject solicitation and consenting activities.

c. Additional guidance regarding informed consent requirements and documentation may be found in the CGSC Human Research Protection Program Plan Institutional Review Board (IRB) Standard Operating Procedures (SOP).

13. Complaints Regarding Human Participant Research.

a. Individuals wishing to report a complaint regarding a research may do so by contacting the Research Investigator, the Human Protection Administrator, the Dean of Academics, the Deputy Dean of Academics, or the Quality Assurance Office Director.

b. It is the responsibility of the investigator 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.

14. Essential Requirements. The guiding principles accepted as essential requirements for the ethical conduct of human subject research are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (1979) by The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (for more information, go to <http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>).

15. Proponent. Questions, comments, or recommended changes to this bulletin should be submitted to Quality Assurance Office, U.S. Army Command and General Staff College, Lewis & Clark Center, RM 4539, (913) 684-2029.

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