



DEPARTMENT OF THE ARMY

U.S. ARMY COMMAND AND GENERAL STAFF COLLEGE
100 STIMSON AVENUE
FORT LEAVENWORTH, KANSAS 66027-2301

CAC-E STUDENTS AS SUBJECTS, REVIEWER CHECKLIST

Policy for Non-CAC-E conducted research: CAC-E students are not permitted to participate as human subjects in any form of research being conducted at a CAC-E facility, or with CAC-E support, unless all of the following approvals are obtained, in the sequence indicated:

1. Approval by non-CAC-E institution IRB (or an exempt determination) has been received by the CAC-E HPA
2. CAC-E HPA or CAC-E IRB Chair concur with IRB or exempt determination given
3. CAC-E HPA or CAC-E IRB Chair recommend institutional approval for the conduct of this study given
 - (1) Due consideration of the research benefits versus risks, the time and effort required of students for participation, and potential distraction or conflicts with the educational and military objectives of CAC-E students; and a favorable finding;
and
 - (2) After ensuring that the requirements in Section 2 (below – CAC-E conducted research) have been met.
4. Written approval has been obtained

Policy for CAC-E conducted research: No principal investigator, regardless of his/her Service affiliation, is permitted to use mandatory military assemblies or formations to inform or recruit students for human subjects research. All recruitment must be in accordance with DoDI 3216.02 and IRB requirements. Recruitment processes must not subject students to coercion or influence through the hierarchical command structure of the military. In making this determination the IRB will ensure that the following requirements have been met, or seek a waiver from a requirement after due consideration by the full IRB.

1. Recruitment utilizing a briefing will be divided into two separate and distinct phases:
 - (a) An informational briefing in which the purpose(s), methods, risks, benefits, issues of confidentiality, time commitment, and other pertinent issues regarding the specific research project and human subject volunteers are discussed; and
 - (b) An enrollment session in which human subjects volunteer to participate by reading and signing an informed consent document.
2. Section, department, unit, command officers or senior noncommissioned officers (NCOs) in the chain-of-command shall not be present during research subject enrollment sessions in which members under their command are afforded the opportunity to participate as research subjects. Officers and NCOs so excluded shall be afforded an opportunity to participate as research subjects in a separate enrollment session if included in the target population.

3. Civilian or military faculty who may exercise authority over or influence grades, class standing, or future assignments of students may not be present during enrollment sessions for students.
4. The HPA, an IRB member, or an ombudsman not connected in any way with the proposed research may be present to monitor that the voluntary nature of participation is adequately stressed and that the information provided about the research is adequate and accurate.
5. Following any informational briefing, time must be allowed for questions from potential participants when officers and NCOs in the chain-of-command and faculty are not present. If the principal investigator (PI) is within the chain-of-command and/or a faculty member, then he or she may stay to answer general questions, but then must exit the meeting to allow students to ask specific questions of an individual who is not in an authority relationship with them. In these cases, the principal investigator may wait outside the room to serve as a resource and allow another person associated with the protocol to remain in the room specifically to answer questions.
6. Sufficient time must be given between the informational briefing and enrollment session to allow students to thoughtfully consider their participation.
7. The above procedures do not preclude students volunteering for a study in which one of their professors is an investigator. A concern this possibility raises is that students could be influenced by this awareness. The CAC-E IRB must evaluate this concern carefully if it is germane to a protocol it is reviewing.
8. All other criteria for approval established by 32 CFR 291.111 and DoDI 3216.02 have been met.