

Policy Number: 56

Title: Department of Defense Supported Research

Date of Last Revision: 12/09/2010, 01/21/2011, 05/01/2013, 05/01/2016

Policy:

In 2006, the Department of the Defense (DoD) enhanced its human subject protection requirements, including the application of those requirements to extramural performers. UCI has signed an assurance with the DoD which requires that UCI apply DoD regulations and policies for the protection of human research participants when conducting, reviewing, approving, overseeing, supporting or managing DoD supported human subject research.

- I. The addendum is recognized by all components of the DoD including the Navy, Army and Air Force. Each branch of the DoD may have their own specific requirements for reviewing research that they support, and these requirements must be followed.
- II. Department of Defense Directive (DoDD) 3216.02 provides the definition of "research" and "experimental subject" including "An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction." (32 CFR 219.102(f), reference (c))
- III. Human Subject Research involves the DoD when any of the following apply:
 - A. The research is funded by a component of DoD (e.g.; Navy, Army, Air Force)
 - B. The research involves cooperation, collaboration, or other type of agreement with a component of DoD
 - C. The research uses property, facilities, or assets of a component of DoD
 - D. The subject population will intentionally include personnel (military or civilian) from a component of DoD

DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by DoD, and DoD personnel are not an intended population of the research.

- IV. **Application Supplement Form:** Researchers conducting DoD supported research must complete and submit to the IRB the UCI IRB DoD Supplement Form in addition to the protocol materials submitted to the IRB for initial review. The UCI IRB DoD Supplement Form can be found on the Office of Research (OR), Human Research Protection (HRP) Website at: <http://www.research.uci.edu/ora/forms/hrpp/DoDSupplementForm.doc>.

V. **Education**

- A. In addition to completing the UCI HRP education requirements, for research involving the DoD, all personnel who conduct, review, approve, oversee, support, or manage human participant research must *also* meet DoD requirements for research ethics training (initial and continuing education). It is the researcher's responsibility to comply with the DoD requirement.
- B. For the Department of Navy (DoN), researchers are required to complete the *CITI Training + 4 Additional Modules*.
For information on DoN Education requirements, refer to the attached documents & links:

- Department of Navy *Instructions for Principal Investigator education and training*
 - *Step by Step Instructions on How to Access the DoN Training Requirements*
 - *DoN Education and Training Policy for Research Ethics and the Responsible Conduct of Research*
- C. For other military branches (e.g. Army, Air Force), researchers should contact their DoD Liaison for specific information about education requirements.
- VI. **International Research:** When DoD-sponsored research is to be conducted outside of the U.S. or its territories and involves participants who are not United States (U.S.) citizens or DoD personnel, it requires the permission of the host country. The laws, customs, regulations and practices of the host country and those required by UCI, must be followed. An ethics review by the host country, or local DoD IRB with host country representation, is required. Evidence of permission to conduct the research in the host country by certification or local ethics review must be submitted to the UCI IRB prior to initiation of the project.
- VII. **Investigational Drugs, Biologics & Devices** – Certain DoD requirements may not apply when investigational drugs, biologics or devices are used for Force Health Protection in accordance with DoD Directive 6200.2 – Use of Investigational New Drugs for Force Health Protection (Aug. 1, 2000). [See SECNAVINST 3900.39D Para. 4b (5)].
- VIII. **Multisite Research**
- A. For DoD -supported multi-site research, a written agreement must be in place among UCI and the other sites. In the case of an Army supported project, the Army will generate this agreement as a contract. For other DoD components, UCI will work with the researcher to generate the agreement.
 - B. The DoD supplement form must clearly detail the roles and responsibilities of each party, at each site involved in the research.
- IX. **Planned Emergency Research** – For DoD supported research, the Secretary of Defense must waive the requirement of informed consent for planned emergency research.
- X. **Prohibition of Research with Prisoners of War**
- A. Research involving POWs is prohibited (those persons captured, detained or held under the control of DoD personnel).
 - B. The definition of a “prisoner of war” for the DoD component granting the addendum.
 1. Army definition: A prisoner of war is a combatant captured by the enemy and interned until the end of the current conflict: <http://www.army-technology.com/glossary/prisoner-of-war.html>.
 2. Navy definition: A prisoner of war is a detained person as defined in Articles 4 and 5 of the Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy : http://www.med.navy.mil/sites/nmrc/documents/secnavinst_3900_39d.pdf
- XI. **Reporting Requirements:** Any findings of serious and/or continuing non-compliance will be reported to the appropriate DoD official within 30 days of the determination.
- XII. **Research Involving Human Subjects for Testing of Chemical or Biological Agents** – Research in this category is generally prohibited with narrow exceptions for research for prophylactic, protective or other peaceful purposes that is conducted in accordance with 50 U.S.C. Section 1520a. [See DoD Directive 3216.2 Para. 4.4.5].

- XIII. **Research Related Injury:** DoD supported research requires the research site to make arrangements for the provision of treatment for research related injuries and some DoD components require that participants not bear any costs related to such treatment. Researchers should contact their DoD funding unit's liaison to determine specific requirements. Also see See HRP Policy and Procedure # 26.
- XIV. **Research/Medical Monitor**
- A. For research involving more than minimal risk to subjects, an independent medical monitor must be named. Medical monitors should be physicians, dentists, psychologists, nurses or other healthcare providers capable of overseeing the progress of research protocols, especially issues of individual subject / patient management and safety. Medical monitors shall be independent of the investigative team and shall possess sufficient educational and professional experience to serve as the subject advocate. The IRB may require the above monitoring for studies involving no more than minimal risk, if appropriate.
 - B. The IRB may require that the medical monitor discuss the research progress with the principal investigator, interview subjects, consult on individual cases or evaluate adverse event reports. Medical monitors must promptly report discrepancies or problems to the IRB.
 - C. Medical monitors have the authority to stop a research study in progress, remove individual subjects from a study and take whatever steps are necessary to protect the safety and well-being of research subjects until the IRB can access the medical monitor's report.
- XV. **Scientific Merit Review**
- A. For studies that involve DoD supported research with human subjects, new IRB Applications and substantive modifications to approved research must undergo scientific merit review prior to IRB review.
 - B. Independent scientific review requirements are different depending on the branch of the DoD as follows:
 1. Navy: Independent scientific review is required per the Secretary of the Navy Instruction 3900.39D
 2. For other branch requirements, researchers should contact their program officer.
 - C. Scientific review and approval by the Chao Family Comprehensive Clinical Trials Protocol Review and Monitoring Committee (CTPRMC) and by the IRB in conjunction with the Biostatistics, Epidemiology and Research Design (BERD) unit in the Institute for Clinical and Translational Science (ICTS) **does** suffice for this requirement but must occur prior to IRB review.
 - D. In the absence of an external review or an established internal review mechanism, researchers should make arrangements with their chair or dean for an *ad hoc* scientific review.
- XVI. **Special Populations**
- A. DoD supported research that affects vulnerable classes of subjects (e.g., fetuses, pregnant women, human in vitro fertilization, prisoners or children) shall meet the protections of 45 CFR Part 46, Subparts B, C, and D.
 - B. Researchers must ensure additional protections for military research subjects to minimize undue influence.
 - C. If research involves cognitively impaired adults, there must be a direct benefit to the subject.
 - D. Researchers must comply with DoD limitations on research when consent by a legally authorized representative is proposed.
- XVII. **Studies Involving DoD Personnel**
- A. When research involves U.S. military personnel, policies and procedures require limitations on dual compensation as follows:

1. Prohibit an individual from receiving pay from more than one position for more than 40 hours of work in one calendar week;
 2. The policy includes temporary, part-time, and intermittent appointments.
 3. Individuals may receive compensation for research activities if the research activities take place outside of scheduled work hours.
- B. When research involves U.S. military personnel policies and procedures include additional protections for military research participants to minimize undue influence as follows:
1. Officers are not permitted to influence the decision of their subordinates;
 2. Officers and senior non-commissioned officers may not be present at the time of recruitment;
 3. Officers and senior non-commissioned officers have a separate opportunity to participate;
 4. When recruitment involves a percentage of a unit, an independent ombudsman is present.

XVIII. **Studies Involving DoD Personnel and the Use of Surveys**

- A. Surveys involving DoD personnel, including U.S. military personnel, typically require DoD survey review and approval. When appropriate, the research project is reviewed and approval by the IRB prior to DoD approval. This includes:
1. Research where DoD personnel and civilian personnel (working with the DoD) are asked to complete surveys; but not when researchers funded by the DoD are conducting survey on non-DoD personnel.
 2. Specific DoD component requirements are as follows:
 - a. Army: Researchers must request approval via the "Request for Approval for Approval to Survey Department of Army Form"
 - b. Navy: Researchers must refer to the Navy Survey Policy.
 - c. Researchers should contact their program officer for Air Force requirements.
 - d. DoD- Wide Research: Researcher must follow the DoD Instruction on Surveys of Military Personnel (surveys across branches of the DoD).

XIX. **Waiver of Informed Consent:** If the research subject meets the definition of "experimental subject", a waiver of the consent process is prohibited unless a waiver is obtained from the Secretary of Defense.

References:

32 CFR 219

DoD: SECNAVINST 3900.39D, para 8c(6)

DoDD 3216.02, Sect. 4.4.3, 4.4.3.2.

DoD Instruction 3210.7

DoD Instruction 6200.02

AFRL Instruction 40-402

Reference for Researchers: Obtaining Approval for a Survey of U.S. Army Personnel

Procedure Number: 56.A

Title: Procedure for Researchers Submitting an IRB Application that Involves DoD

Procedure:

The purpose of this procedure is to provide guidance for compliance with Department of the Defense (DoD) enhanced human subject protection requirements.

I. Lead Researcher (LR) Responsibilities

- A. New IRB Applications and substantive modifications to approved research must undergo scientific merit review prior to IRB review.
- B. Submission Documentation
 - 1. Investigators conducting, DoD supported research with human subjects (including research that qualifies for exempt status) must complete and submit the following documents with their e-IRB Application:
 - a. Completion of Education and Training
 - b. Independent Scientific Review
 - c. UCI IRB Department of Defense Supplement Form
 - d. Lead Researcher and Co-investigator CVs
 - e. Data Collection Forms/Case Report Forms
 - f. FDA letter for IND or IDE (as applicable)
 - g. FDA Form 1571 and FDA Form 1572 (as applicable)
 - h. Survey research requirements (as applicable)
 - i. A waiver of consent (as applicable) obtained from the Secretary of Defense.
- C. Researchers must follow UCI policies and procedures for addressing financial and other conflicts of interest (See HRP Policy # 25).
- D. Post-Approval Instructions
 - 1. Documentation: Principal Investigators (PIs) and the UCI HRP are responsible for maintaining certain documentation in their files. PIs are also responsible for submitting documentation to DoD prior to starting an IRB-approved study and upon subsequent reviews by the IRB (addenda, continuing reviews, etc.). DoD uses such documentation to conduct a "headquarters-level administrative review." DoD HRPP requires certain IRB documentation that is not maintained by the PI (such as IRB meeting minutes). These items will be sent directly from the UCI HRP to DoD. UCI HRP will notify the PI when these documents are sent.
 - 2. Department of Navy (DoN) documentation requirements:
 - a. Office of Naval Research (ONR)
 - b. Department of the Navy Human Research Protections Program (DON HRPP)
- E. Contracts and Awards - In addition to requirements set for the by the funding agency, researchers conducting human subject research supported by the DoD or its components must comply with contracting requirements and processes required by UCI Sponsored Projects Administration.
- F. The contact information for submission to ONR is provided at the ONR website above. The contact information for submission to the DoN HRPP is:

Department of the Navy
Office of Research Protection (M00R)
Bureau of Medicine and Surgery
2300 E St., NW
Washington, DC 20372-5300

Fax: 202-762-0976 E-Mail: human.research@med.navy.mil

- G. Continuing Education
 - 1. The DoD requires researchers to complete continuing human subject protections training every 3 years.
- H. Modifications to Approved Research
 - 1. When submitting modifications to previously approved research, researchers should review the Defense Supplement to ensure that it still accurately reflects the research. A revised supplement should be submitted (and any additional documentation) if necessary.
 - 2. If the modification involves substantive changes (e.g., new procedures, a new subject population), evidence of scientific review and approval is required prior to IRB review.

II. IRB Committee Responsibilities

- A. The materials listed in the Lead Researcher's section of this policy will be reviewed by the IRB at subcommittee or at a convened IRB meeting depending on the level of risk to participants.
- B. In addition to the above materials Committee members will receive the IRB Reviewer's Checklist and any applicable Supplementary IRB Reviewer Checklist initiated by the HRP staff during the administrative review process. The reviewers must provide their completed and signed checklists to the HRP team.
- C. Written determination by a designated institutional official (other than investigators) whether research meets criteria for exemption.
- D. The IRB determines the review interval appropriate to the degree of risk, but not less than once per year.
- E. The IRB reviewer(s) may request that the study be approved, minor modifications required, tabled for re-review by subcommittee, tabled for review by full Committee.
- F. When revisions are requested, the modified documents are re-reviewed and, if acceptable, approval is granted.
- G. The Chairperson or his/her Designee verifies and signs the Approval Letter.

III. HRP Staff Responsibilities

- A. The Administrator will pre-review the DoD Supplement Form and request any necessary revisions and/or documentation to meet the DoD requirements.
- B. The HRP team prepares the "IRB Reviewer Checklist" and any Supplemental Checklists for the Reviewer(s) during the administrative review process.
- C. The Administrator will assist reviewers in obtaining additional information that may be requested regarding the DoD requirements from the LR.
- D. Letters requesting revisions from the Reviewer and approval letters are drafted using the appropriate template which includes a citation to the specific permissible category or categories justifying the expedited review.
- E. New approvals, modifications, and continuing reviews are processed according to corresponding IRB policies and procedures.
- F. Appropriate database entries in HPS are completed.
- G. Approved documents are processed.
- H. The Protocol File is collated and filed.