OFFICE FOR EDUCATION & QUALITY IN CLINICAL RESEARCH

GUIDANCE #1

Additional Requirements for Research Involving the Department of Defense (DoD)

1. Overview

This guidance is for investigators and staff involved with research involving the Department of Defense (DoD). One of the following criteria must be met to be considered DoD research.

- **A.** The research is funded by a component of the Department of Defense. Components include, but are not limited to the Army, Navy, Air Force, Marine Corps, or Coast Guard. This also includes the military academies, the National Guard, National War College, and other DoD facilities and agencies.
- **B.** The research involves cooperation, collaboration, or other type of agreement with a component of the DoD.
- **C.** The research uses property, facilities, or assets of a component of the DoD.
- **D.** The subject population will intentionally include military or civilian personnel from a component of the DoD.
  NOTE: DoD policies and requirements do not apply when DoD personnel incidentally participate as subjects in research that is not supported by the DoD, and DoD personnel are not the intended population of the research.

2. Applicable Regulations and Guidelines

32 CFR 219
DoD: Instruction 3216.02
Dual Compensation Act
OPNAVINST 5300.8B
SECNAVINST 3900.39D
10 USC 980

3. Education

Initial and continuing research ethics and human subjects protections education must be completed by all personnel who conduct, review, approve, oversee, support, or manage human subjects research. The involved DoD component may evaluate the education policies to ensure that personnel are qualified to perform the research, based on its complexity and risk. Additional education or professional certification may also be required. Notification of any additional DoD required training will be communicated to the Human Subjects Research Committee (HSRC), Office for Education and Quality in Clinical Research (OEQCR), and/or the Investigator as appropriate. It is the Principal Investigator's responsibility to ensure that research staff has completed all appropriate educational requirements as mandated by the DoD policy.

4. Review of Research

The following elements of research review will be implemented and documented as required by regulations.

- **A.** The definition of minimal risk is based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include the inherent risks certain categories of human subjects face in their everyday lives. For example the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder,

pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain).

B. Scientific merit of the research will be considered by the HSRC for non-exempt research.

5. Research Monitor

A. A research monitor is required for research involving greater than minimal risk, although one may be required for a portion of the research or studies involving no more than minimal risk, if deemed appropriate.

B. The research monitor must be appointed by name and be independent of the research team.

C. The monitor may be an ombudsman or a member of the data safety monitoring board.

D. There may be more than one research monitor (e.g. if different skills or experience are needed).

E. The HSRC must approve the monitor's duties, authorities, and responsibilities.

F. The duties of the research monitor are determined on the basis of specific risks or concerns about the research and may include the following:

i. Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to subjects or others, oversee data matching, data collection and analysis).

ii. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.

iii. Report observations and findings to the Office for Human Subjects Research (OHSR) or a designated official.

iv. The research monitor has the authority to:

a. Stop a research study in progress.

b. Remove individuals from the study.

c. Take any steps to protect the safety and well-being of subjects until the OHSR and/or HSRC can assess.

6. Conflict of Interest

For research that has a reported conflict of interest, approval will not be granted until documentation of resolution from the HHRI Conflict of Interest Committee has been received and approved by the OHSR and/or HSRC. The OHSR and/or HSRC will ensure that informed consent forms for applicable research include a disclosure of any remaining conflicts of interest if required to comply with the requirements of the DoD component.

7. Research Using Experimental Subjects

A. When research involves "experimental subjects," the following must apply:

i. The definition for "research involving a human being as an experimental subject" is: an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria, and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

ii. If consent is to be obtained from the experimental subject's legal representative, the research must intend to benefit the individual subject.

1. The determination that research is intended to be beneficial to the individual experimental subject must be made by the HSRC.

iii. 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 Assistant Secretary of Defense for Research and Engineering.

iv. For classified research, waivers of consent are prohibited.

v. If the research subject does not meet the definition of "experimental subject," the OHSR and/or HSRC may waive the consent process.

B. Research involving pregnant women, prisoners, and children is subject to the DHHS Subparts B, C, and D as appropriate.

C. Research involving prisoners of war is prohibited.

8. Investigators

A. Investigators cannot make the determination that research meets the requirements for exemption.

B. When the research involves U.S. military personnel, the following additional protections for military research subjects to minimize undue influence are required.

i. Officers are not permitted to influence the decision of their subordinates.

ii. Officers and senior non-commissioned officers may not be present at the time of recruitment.

iii. Officers and non-commissioned officers have a separate opportunity to participate.

iv. When recruitment involves a percentage of a unit, an independent ombudsman is present.

C. All research involving more than minimal risk, where primary involvement is from the DoD, provisions for research-related injury must follow requirements of the DoD component.

i. Human subjects will be protected from medical expenses (not otherwise provided or reimbursed) that are the direct result of participation in a research project involving more than minimal risk. Participants are protected from research-related medical expenses.

ii. The OHSR/HSRC will ensure that the disclosure for research-related injury follows the requirements of the DoD component as determined and communicated through the terms and conditions of the sponsored awarding documents.

iii. OHSR informed consent guidelines must be used.

D. Additional safeguards for research conducted with international populations must be documented.

i. Permission to conduct research in that country by certification or local ethics review must be documented and documentation provided by the researcher.

ii. The researcher must provide documentation that all local laws, regulations, customs and practices will be followed.

E. When research involves U.S. military personnel, the following limitations on dual compensation are required:

i. U.S. military personnel participants, including those with temporary, part-time, and intermittent appointments, may not receive pay from more than one position for more than 40 hours of work in one calendar week.

ii. An individual may not be compensated for research if the subject is involved in the research during duty hours.

iii. An individual may be compensated for research if the subject is involved in the research when not on duty.

iv. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.

v. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the OHSR or HSRC according to local prevailing rates and the nature of the research.

F. An investigator must:

i. Comply with all provisions for research with human subjects when using investigational test articles (drugs, devices, and biologics).

ii. Comply with all record keeping requirements.

iii. Support oversight by the sponsoring DoD component (which may include DoD review of the research and site visits).

iv.

9. Submission and Reporting to the DoD

A. Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the OHSR and/or HSRC.

B. The following shall be promptly (no longer than within 30 days) reported to the DoD human research protection officer by the Institutional Official:

i. Any determination(s) of serious or continuing non-compliance.

ii. Any unanticipated problems involving risks to subjects or others.

iii. Any suspension or termination of DoD-supported research.

C. The following will be promptly (no longer than within 30 days) reported to the DoD human research protection officer:

i. When significant changes to the research protocol are approved by the HSRC.

ii. The actions of the CRC.

iii. Change of reviewing HSRC.

iv. When the organization is notified by any Federal department, agency or national organization that any part of the human research protections program is under investigation for cause involving a DoD-supported research protocol.

D. Disclosures for research-related injuries must follow the requirements of the specific DoD component.

9. Investigator Resources

A. Because of the uniqueness of DoD research and numerous requirements, including unique reporting requirements (see #8), an Investigator must work closely with the Office for Human Subjects Research and the Office of Grants & Contracts.

B. Early collaboration with the appropriate Grant Administrator and the OHSR is essential when planning DoD research.