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From: Chief of Naval Operations (N093)

Subj: DEPARTMENT OF THE NAVY HUMAN RESEARCH PROTECTION PROGRAM (DON HRPP) TRAINING AND EDUCATION GUIDANCE

Ref: (a) DoD Instruction 3216.02, "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research"
(b) SECNAVINST 3900.39 (series), "Human Research Protection Program"
(c) "Minimum Education Requirements for DoD Personnel Involved in Human Research Protection" 16 August 2012
(d) Marine Corps Order 3900.18, "Human Research Protection Program"
(e) DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection"
(f) Title 48, Code of Federal Regulations, Parts 207.172; 235.072; and 252.235-7004, Defense Federal Acquisition Regulation Supplement (DFARS), "Protection of Human Subjects"
(g) DoD Instruction 3210.7, "Research Integrity and Misconduct"

Encl: (1) Department of the Navy Research Roles and Descriptions

1. Purpose. To provide Department of the Navy (DON) training and education guidance in applied research ethics and human research protections for DON personnel, Department of Defense-DON collaborators, and DON-supported extramural performers as prescribed in references (a) through (g).

2. Background. The DON is committed to upholding the highest standards of research conduct, including the ethical treatment and protection of human subjects in research. Research protections require understanding and knowledge of ethical principles, regulations, and policies and procedures that

govern the conduct, monitoring, and support for human subject research.

3. There are two sections of this Guidance: Navy and Marine Corps Commands and Intramural Institutions, and Extramural Performers and Collaborators.

4. General Requirements.

a. Navy and Marine Corps Commands and Intramural Institutions

(1) In accordance with references (b), (c), and (d), all personnel who conduct, review, approve, support, manage, or oversee DON-supported human subject research are required to complete initial and continuing research ethics training appropriate to their roles and responsibilities.

(2) Personnel will complete their required training before assuming their DON human research protection duties. Personnel may assume their duty position, but may not be involved in any research protection activities until required human research and ethics training is complete.

(3) Commands and institutions must ensure initial and ongoing research ethics training and education for all personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing research involving human subjects.

(4) Enclosure (1) lists the roles of research personnel who must comply with the provisions of this guidance.

(5) Education and training requirements apply regardless of type of support, funding, or area of research and must be completed prior to reviewing, approving, or conducting research involving human subjects or human-subject data.

(6) Required training shall be repeated at least every three years. Due to constantly evolving ethical and regulatory issues, DON commands shall determine training requirements for the interim years.

(7) Institutions may access DON-provided online training

to meet the established training requirements.

(8) Personnel must complete any additional training when changing research roles and responsibilities. For example, an investigator who becomes an Institutional Review Board (IRB) member must complete the additional training for that role.

(9) DON IRBs must verify and document that principal investigators (PIs) meet appropriate training requirements prior to accepting research protocols for scientific or IRB review.

(10) Confirm that all other personnel involved in human subject research have met training requirements appropriate to their role and level of responsibility.

(11) Verify that Command HRPP staff members and others involved in research with human subjects meet any other training requirements related to human research protections, for example, the Health Insurance Portability and Accountability Act (HIPAA) or Responsible Conduct of Research (RCR). Training in RCR includes topics in research misconduct. See reference (g) for additional information.

(12) Ensure training and education for investigational agent use for Force Health Protection as required in reference (b).

(13) For IRBs or offices that support IRBs: verify that all PIs, associate investigators (AI), and other key research personnel have met appropriate training requirements prior to recommending approval of research, and complete additional training as appropriate.

(14) Maintain personnel training documents (electronic and/or paper copy). At a minimum, the training documentation must include the individual's name; title of the training or course; date(s) of training or date completed.

(15) Determine and describe training requirements for research support personnel in command-level HRPP policies and procedures. Research support personnel are persons who conduct clinical or research procedures; provide assistance to

review committees; are responsible for access and release of private identifiable information (PII) (e.g., through work with medical records and information systems); persons who conduct laboratory, pharmacy, radiology, or other procedures; legal counsel; etc.

(16) Develop procedures for implementing and monitoring compliance with this policy.

b. DON Human Research Protection Official (HRPO). Personnel serving as a DON HRPO must complete the DON HRPP-provided online training course titled "DON Human Research Protection Officials (HRPO).

c. DON HRPP Responsibilities. It is the responsibility of the DON HRPP to:

(1) Develop training and education guidance.

(2) Establish and provide initial and continuing research ethics and human subject protections training and education programs.

(3) Verify completion and documentation of research ethics and human subject protections training during (a) review of DoD-Navy Assurances and DoD Addendums to the FWA; and (b) visits to DON commands and institution HRPPs.

(4) Maintain access to centralized electronic training documentation for the DON HRPP-provided online training program for all DON-affiliated personnel.

(5) Provide access to training for all DON commands and personnel, as well as training on the unique DoD-DON human research protection requirements.

(6) Monitor and oversee implementation of command and institutional training and education programs.

(7) Assess, upon request, a command's existing training program(s) for equivalence with DON HRPP requirements.

5. Extramural Performers and Collaborators (non-DoD).

a. Submit documentation of completed research ethics and human subject protections training by the Institutional Official, IRB Chair(s), and the human research protections point of contact when applying for the DoD-Navy Addendum to the Federalwide Assurance (FWA).

b. Fulfillment of training requirements may be accomplished through completion of DON HRPP-provided online training for extramural performers and collaborators or through submission of institutional/organizational training. All signatories on the DoD-Navy Addendum must be knowledgeable of DoD and DON policies, procedures, and guidelines.

c. Submit documentation of completed research ethics and human subject protections training by principal investigators. PIs are responsible for ensuring all research staff members receive and document appropriate training.

A. F. Nordholm
By direction

Distribution:
DON HRPP Directory

Department of the Navy Research Roles and Descriptions

Research Role 1: Senior Naval and Command Leadership. Senior Navy and Marine Corps leadership including the Navy Surgeon General; Chief of Naval Research; Deputy Commandant, Combat Development and Integration; Commanders; Deputy Commanders; Chiefs of Staff; Chief Staff Officers; Commanding Officers; Executive Officers; Officers in Charge (or similar positions); Institutional Officials; Advisors to Institutional Officials; and DON members of the DoD Coordinating Committee for Human Subject Research Protection (CCHSRP).

Research Role 2: Directors, Department Chairs, Program Managers, Dept/Division Directors, and Program Officers. Directors, Chairs and Managers. Systems, Fleet, and Type Command (or equivalent) Directors, Department Chairs, Program Managers/Officers, Department Directors, and Division Directors.

Research Role 3: Investigators and Key Research Personnel.

a. Investigators including principal investigators, student investigators, associate investigators (and other similar terms), key research personnel (personnel who are participating in a limited and defined part of the research protocol under the direct supervision or guidance of an investigator), and Faculty Advisors for student investigators.

b. Medical/Research Monitors: Physicians, dentists, psychologists, nurses, or other research monitors who oversee the progress of research protocols, especially issues of individual subject/patient management and safety.

c. Data Safety Monitoring Board members: Personnel who monitor individual research studies for human subjects safety.

Research Role 4: Scientific Review Personnel. Scientific Review Board Chair(s) and board member(s).

Research Role 5: IRB Chairs, Vice Chairs and Members. Institutional Review Board (IRB) Chairs, Vice Chairs, and all members of the IRB, including Intergovernmental Personnel Act (IPA) and consultants. Others who act as consultants to the IRB are not required to have the same level of education as the

IRB members. Consultants should be educated on the ethics, policies, or other topics for which they are being asked to consult.

Research Role 6: DON HRPP and IRB Support Staff. Command HRPP and IRB support staffs, including Counsel directly supporting the HRPP, HRPP points of contact named in institutional Assurances, staff who are advising investigators, etc. and DON HRPP staff.

Research Role 7: Research, Clinical, and Study Coordinators, Research Administrators. Personnel responsible for conducting research under the supervision or guidance of investigators or personnel involved in the preparation and administration of research protocols including, research coordinators, clinical coordinators, study coordinators, and research administrators (and other similar positions).

Research Role 8: Research Support Personnel. Individuals who carry out clinical or research procedures, collect data, support review committees, and are responsible for access and release of private identifiable information (e.g., medical records personnel and information systems personnel). Research support personnel may also include persons who conduct laboratory, pharmacy, and radiology procedures, counsel, writers and editors supporting HRPP, and privacy officers.

Research Role 9: Midshipman, Cadets, and Officer Candidates. U.S. Naval Academy (USNA) Midshipmen, USNA Prep School students, and officer candidates assigned to the Naval Reserve Officer Training Corps (NROTC), Navy and Marine Corps Officer Candidate Schools (OCS), Seaman to Admiral-21 program, etc.

Research Role 10: Ombudsmen. Personnel who are not members of research teams, but have been appointed by IRBs or are identified in IRB-approved protocols to act on behalf of the IRB (Ombudsman) or on behalf of research subjects (Subject Advocate).

Research Role 11: DON Human Research Protection Officials (HRPO). DON personnel who review extramural performer's paperwork submitted prior to award of research involving human subjects for compliance with DoD and DON requirements and

reference (f) for contracts.

Research Role 12: DON-Supported Extramural Performers. Institutional Officials, IRB Chair(s), and human research protection program point of contact named in the DoD Addendum to the Federalwide Assurance; and extramural investigators.