



DEPARTMENT OF THE NAVY
UNITED STATES NAVAL ACADEMY
121 BLAKE ROAD
ANNAPOLIS MARYLAND 21402-1300

USNAINST 3900.2D

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3 Oct 2016

USNA INSTRUCTION 3900.2D

From: Superintendent, U.S. Naval Academy

Subj: U.S. NAVAL ACADEMY HUMAN RESEARCH PROTECTION PROGRAM AND
DEPARTMENT OF THE NAVY ASSURANCE

Ref: (a) Department of Health and Human Services (DHHS), Title 45 Code of Federal
Regulations Public Welfare, Part 46 "Protection of Human Subjects," Subsection 102
(b) Department of Defense (DoD), Title 32 Code of Federal Regulations 219:
"Protection of Human Subjects"
(c) SECNAVINST 3900.39 (series)
(d) DoDINST 3216.02
(e) Surgeon General of the Navy memo Ser N093/16U0041 dtd 9 Jun 16
(f) U.S. Naval Academy Human Research Protection Program Policies and Procedures
Manual

1. Purpose. To establish and promulgate the policies and procedures for the U.S. Naval Academy (USNA) Human Research Protection Program (HRPP).

2. Cancellation. USNAINST 3900.2C dated 6 Oct 2015.

3. Scope and Applicability. All persons involved in research and all persons in leadership positions at USNA shall be cognizant of the contents of the HRPP policies and procedures manual.

4. Discussion

a. Every year USNA engages in a robust program of research activities to educate and train the Brigade of Midshipmen and midshipman candidates at the Naval Academy Preparatory School (NAPS). Some of this work clearly involves research on human subjects. However, the term "research" as defined in federal regulations (references (a) and (b)) and as used in the Secretary of the Navy instruction on human subject research (reference (c)), includes many activities in which USNA personnel commonly participate that are not normally considered research-related. These may include routine process surveys, interviews, and focus groups associated with academic assessment or program improvement.

b. Per references (a) through (c), research is defined as "any systematic investigation designed to develop or contribute to generalizable knowledge including but not limited to

any project, task, pilot study, experiment, investigation, study, clinical study, evaluation, or developmental effort or similar undertaking whether or not conducted or supported under a program that is officially considered research. Any effort, even if not considered research for other purposes, is nonetheless considered research for the purposes of this policy if it meets this definition."

c. Human subjects are defined in federal regulations as "individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project," and as "living individuals about whom an investigator conducting research (1) obtains data through interventions or interactions with the individual; or (2) uses identifiable private information about an individual."

d. Consistent with the requirements of references (c) and (d), USNA submitted a Department of the Navy (DON) Assurance application to the Surgeon General of the Navy. As required, a detailed policies and procedures manual for reviewing, approving, and conducting human subject research at USNA and NAPS was included as part of the application. Per reference (e), the USNA Assurance application was accepted and approved by the Surgeon General of the Navy.

e. This instruction promulgates HRPP policies and procedures for USNA. Via reference (e), the Surgeon General of the Navy approved the policies and procedures established by USNA to protect USNA and NAPS, the researchers at USNA and NAPS, the human subjects involved as participants in projects at these institutions, and the data about the human subjects used or collected in research projects, studies, and surveys. USNA HRPP policies and procedures in reference (f) are consistent with applicable federal, state, and local regulations, and with the DoD and DON instructions, directives, and requirements for protecting human subjects and the data about them in research. The electronic version of the USNA HRPP policies and procedures manual is available at:
<http://www.usna.edu/HRPP/>.

f. Consistent with the Surgeon General's Assurance approval, all projects within USNA jurisdiction that involve human subjects or data about them must be independently reviewed to determine the applicability of USNA's human subject research policies. This review shall be accomplished via the USNA Institutional Review Board (IRB) process. At the conclusion of the review, a recommendation on the proposed research must be forwarded to the Superintendent. The Superintendent, who has been designated by the Surgeon General of the Navy as the command's Institutional Official (IO), and single approval authority, may approve proposed studies that are forwarded by the USNA IRB with an affirmative endorsement.

g. Proposed projects that receive a negative endorsement via the USNA IRB process may not be approved by the Superintendent and the projects may not be conducted at USNA or NAPS.

h. No human subject activity on a proposed project (including soliciting study participants or distributing informed consent forms, data collection, or data analysis) may commence until the principal investigator receives written notification of the Superintendent's approval to begin the proposed project.

i. Under no circumstance may the principal investigator or anyone in their chain of command make an independent judgment on the applicability of the USNA IRB review and approval process to a proposed project that directly or indirectly involves human subjects or identified or de-identified data about them.

j. The USNA HRPP policies and procedures manual, submitted as one section of the DON Assurance application, describes the rights of, and protection for, all persons involved in human subject research, either directly or indirectly, conducted under USNA's purview.

k. USNA HRPP policies and procedures apply regardless of the source, type (direct, reimbursable, or gift), or level of funding of research; whether the research is conducted at USNA or at non-USNA facilities but with USNA involvement; whether the research uses any institutional or DON resources, facilities, or assets; whether the research is subject to any other federal regulations; and whether the research uses identified or de-identified data about human subjects. In addition, the HRPP policies and procedures apply regardless of the program, research, or study title; the nature (behavioral, biomedical, etc.) of the research; the security classification of the research; or the source of the request or directive to conduct the research or study.

5. Actions

a. HRPP Office. The Director of the USNA HRPP office reports directly to the Superintendent, and works closely with the Chair and membership of the IRB to coordinate the daily activities of the HRPP office. The HRPP Office contact information is: (410) 293-2533; HRPPoffice@usna.edu; Yard Mail Stop: 10M.

b. USNA IRB. Per references (a), (b), (c), and (e), USNA established an IRB, which is referred to as the "IRB." IRB membership is promulgated by a separate notice. The authority, duties, and responsibilities of the USNA IRB Chair, Vice Chair, and members are delineated in reference (f).

6. Summary. As part of the DON Assurance application, USNA has guaranteed it will comply with all applicable federal, state, and local laws relating to protecting human subjects participating in research conducted at or under the auspices of USNA. In particular, USNA, NAPS, and all personnel associated with USNA will adhere to the applicable DHHS and DoD regulations for protecting human subjects in research; regulations, policies, directives, and guidance of the DON and the DON Human Research Protection Program; and the laws of the states of Maryland (for USNA) and Rhode Island (for NAPS). In all

cases, the regulation, instruction, or policy that offers the greatest protection for the human subjects and the data about the human subjects must prevail.

7. Records Management. Records created as a result of this notice, regardless of media or format, must be managed per Secretary of the Navy Manual 5210.1 of January 2012.

8. Review and Effective Date. The Academic Dean's Office will review this instruction annually on the anniversary of the effective date to ensure applicability, currency, and consistency with Federal, DoD, SECNAV, and Navy policy and statutory authority using OPNAV 5215/40 Review of Instruction. This instruction will automatically expire 5 years after the effective date unless reissued or otherwise canceled prior to the 5-year anniversary date, or an extension has been granted."



W. E. CARTER, JR

Releasability and Distribution:

This instruction is cleared for public release and is available electronically only via USNA's Intranet Web site, <https://www.usna.edu/AdminSupport/Inst/>