



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

USNAINST 3900.2B  
2/ACDEAN  
9 OCT 2013

USNA INSTRUCTION 3900.2B

From: Superintendent

Subj: UNITED STATES NAVAL ACADEMY (USNA) HUMAN RESEARCH PROTECTION PROGRAM (HRPP) AND DEPARTMENT OF THE NAVY (DON) 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, 23 Jun 05  
(b) Department of Defense (DOD), Title 32 Code of Federal Regulations 219: "Protection of Human Subjects," 19 Aug 91  
(c) SECNAVINST 3900.39D  
(d) DODINST 3216.02  
(e) Surgeon General of the Navy memo Ser N093/0086 dtd 24 May 13  
(f) USNA HRPP Policies and Procedures Manual

1. Purpose. To establish and promulgate the policies and procedures for the USNA HRPP.

2. Cancellation. USNAINST 3900.2A. This directive is a complete revision and should be reviewed in its entirety.

3. Discussion

a. Every year, USNA engages in a robust program of research activities in support of the education and training of the Brigade of Midshipmen and Midshipman Candidates at the Naval Academy Preparatory School (NAPS). Some of this work clearly involves research on human subjects; some does not. 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 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; and/or (2) uses identifiable private information about an individual."

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d. Consistent with the requirements of references (c) and (d), USNA submitted a 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. By 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 the protection of 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 and/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 the solicitation of study participants, distribution of informed consent forms, data collection, data analysis, etc.) 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 his/her 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 and/or the 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 the purview of the USNA.

k. USNA HRPP policies and procedures apply regardless of the source, type (direct, reimbursable or gift), or level of funding of the research; whether the research is conducted at USNA or at non-USNA facilities but with

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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; and/or the source of the request or directive to conduct the research or study.

#### 4. Action

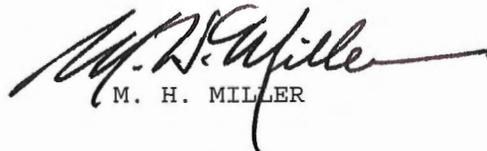
a. HRPP Office. The Director of the USNA HRPP office reports directly to the Superintendent, coordinates the daily activities of the HRPP office within the Academic Dean and Provost, and works closely with the Chair and membership of the USNA IRB.

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

c. It is the responsibility of all persons involved in research and persons in leadership positions at USNA to be cognizant of the contents of the HRPP policies and procedures manual.

5. Summary. As part of the DON Assurance application, USNA has guaranteed it will comply with all applicable federal, state, and local laws relating to the protection of 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 the protection of human subjects in research; regulations, policies, directives, and guidance of the DON and the DON HRPP; 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.



M. H. MILLER

Distribution:  
Brigade of Midshipmen (electronically)  
All Non Mids (electronically)  
NAPS (electronically)