



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

USNANOTE 3900
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14 OCT 2011

USNA NOTICE 3900

From: Superintendent

Subj: NAVAL ACADEMY 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, Human Research Protection Program
 - (d) DODD 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD Supported Research, "25 Mar 2002 - Certified Current as of 24 Apr 2007"
 - (e) Surgeon General of the Navy memo Ser M00R/10UM00R316 dtd 5 Nov 10
 - (f) USNAINST 3900.2, U.S. Naval Academy Human Protection Research Program (HRPP) Policies and Procedures
 - (g) USNANOTICE 5420 dtd 2 Sep 11, Institutional Review Board (IRB) Membership For Academic Year 11-12

1. Purpose. To provide an update on the status of human subject research at the United States Naval Academy (USNA).

2. Cancellation. USNA Notice 3900 dtd 31 Aug 10. This notice remains in effect until it is superseded.

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 at USNA 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), (b), and (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; and/or (2) uses identifiable private information about an individual".

d. Consistent with the requirements of reference (c), the Naval Academy 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

14 OCT 2011

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 Academy's Assurance application was accepted and approved by the Surgeon General.

e. Consistent with the Surgeon General's Assurance approval, all projects within the Naval Academy's jurisdiction that involve human subjects and/or data about them must be independently reviewed to determine the applicability of the Academy's human subject research policies. This review will be accomplished via the Academy's 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 Navy Surgeon General as the command's Institutional Official (IO), and single approval authority, may approve proposed studies that are forwarded by the Academy's IRB with an affirmative endorsement.

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

g. 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 (1) the affirmative endorsement of the protocol by the Academy's IRB process and (2) the Superintendent's approval to begin the proposed project.

h. Under no circumstance may the principal investigator or anyone in his/her chain of command make an independent judgment on the applicability of the Academy's 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. Similarly, in no case may the project be submitted directly to the Superintendent for an approval. All projects that involve human subjects and/or the data about them must be reviewed via the Academy's IRB process. There are no exceptions.

4. Actions

a. HRPP Office: A HRPP Office has been established at USNA. The Director of the HRPP office reports directly to the Superintendent, coordinates the daily activities of the HRPP office with the Academic Dean and Provost, and works closely with the Chair and membership of the Academy's Institutional Review Board.

The HRPP Office contact information is: 410-293-2533
HRPPoffice@usna.edu
Yard Mail Stop: 10M

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

c. HRPP Policies and Procedures Manual. The Naval Academy's Human Research Protection Program Policies and Procedures Manual, submitted as one section of the Department of the Navy 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 United States Naval Academy.

(1) The HRPP policies and procedures manual is available at <http://intranet.usna.edu/HRPP>.

(2) The 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 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

14 OCT 2011

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.

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

4. Summary

a. 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 Department of Defense regulations for the protection of human subjects in research; regulations, policies, directives, and guidance of the DON and the DON Human Research Protection Program; and the laws of the state of Maryland (for USNA) and of 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.

b. To have a viable and unified HRPP at USNA, everyone at USNA must be involved in and supportive of our policies. The Academy's IRB and administrators at USNA cannot be the only elements concerned with the protection of human subjects in research and with the proper access and supervision of the data collected on the human subjects. All constituencies of USNA and NAPS are legally and morally responsible for the ethical, humane, lawful, and professional treatment of human subjects in research projects, and for the proper safeguarding of the data about the subjects. Acceptance and active support of everyone's commitment to and accountability for a healthy research-ethics culture will be accomplished via a well-established, Academy-wide HRPP that emphasizes the complimentary roles of those involved in the protection of human subjects. In all endeavors, the intent to do the right thing – ethically and professionally – must remain the foundation of USNA's HRPP.

c. I personally take this responsibility seriously. It is my intention that the guiding instructions and laws will be executed to the best of our Academy's ability. I expect everyone on the Naval Academy team to actively support the Academy's HF

/S/
M. H. MILLER

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