



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

USNANOTE 3900  
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SEP 21 2007

USNA NOTICE 3900

From: Superintendent

Subj: NAVAL ACADEMY HUMAN RESEARCH PROTECTION PROGRAM (HRPP) AND  
DEPARTMENT OF THE NAVY (DON) ASSURANCE

Ref: (a) Surgeon General of the Navy memo Ser M53/05M53HRU0242 dtd 12 Aug 05  
(b) Department of Health and Human Services (DHHS), Title 45 Public Welfare, Part 46:  
"Protection of Human Subjects", Subsection 102, 23 Jun 05.  
(c) Department of Defense (DOD), Title 32 National Defense, Part 219: "Protection of Human  
Subjects", 19 Aug 91.  
(d) SECNAVINST 3900.39D, Subj: Human Research Protection Program of 3 Nov 06  
(e) Surgeon General of the Navy memo Ser M00R/07UM00R242 dtd 21 Aug 07

1. Purpose. To provide an update on the status of human subject research at the U.S. Naval Academy.
2. Cancellation. USNA Notice 3900 dtd 8 Nov 06. This notice remains in effect until it is superseded.
3. Background Information

a. Per reference (a), the Surgeon General (SG) of the Navy provided formal notice that the United States Naval Academy (USNA) "does not hold an approved Department of the Navy Assurance and therefore is not authorized to conduct or approve research involving human subjects." The Surgeon General directed that until the DON Assurance application process was completed by USNA and until the Academy's Assurance application was approved, the United States Naval Academy could not grant approval for any research studies involving human subjects.

b. The notice cancelled in paragraph 2 above, issued by the Naval Academy Superintendent, required all research that directly or indirectly involved human subjects and/or the data about human subjects immediately cease at the U.S. Naval Academy. USNA has been in this cease and desist status with respect to human subject research since that time.

4. Scope

a. Every year the Naval Academy engages in a robust program of research activities in support of the education and training of the Brigade of Midshipmen at the U.S. Naval Academy and the 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 (b) and (c)) and as used in the Secretary of the Navy instruction on human subject research (reference (d)), includes many activities in which Naval Academy personnel commonly participate that are not normally considered research-related. These include routine process surveys, interviews, and focus groups associated with academic assessment or program improvement.

b. Per references (b), (c) and (d), research is defined as "any systematic investigation designed to develop or contribute to generalized 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".

#### 5. New Information

a. In August 2007, consistent with the requirements of reference (d), 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 at NAPS was included as part of the application. By reference (e), the Academy's Assurance application has been accepted and approved by the Surgeon General.

b. 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 Signatory Official (ISO), and single approval authority, may approve proposed studies that are forwarded by the Academy's IRB with an affirmative endorsement.

c. 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 the Naval Academy or at the Naval Academy Preparatory School.

d. 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.

e. 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.

#### 6. Actions - Effective immediately

a. HRPP Office. A Human Research Protection Program Office has been established at the Naval Academy. The Director of the HRPP office will report directly to the Superintendent, will coordinate the daily activities of the HRPP office with the Academic Dean and Provost, and will work closely with the Chair and membership of the Academy's Institutional Review Board.

(1) Until relieved, the Acting Director of the HRPP Office is Dr. Linda Mallory.

(2) The HRPP Office contact information is: 410-293-2533  
[HRPPoffice@usna.edu](mailto:HRPPoffice@usna.edu)  
Yard Mail Stop: 10M

b. Academy's IRB. Pursuant to the requirements of references (b), (c), (d) and (e), the Naval Academy is establishing an "Institutional Review Board (IRB)", which shall be referred to as the "Academy's IRB". The following appointments are effective immediately and shall remain in effect until the appointees are relieved:

- (1) Chair of the Academy's IRB: Professor Stephen E. Frantzich  
Professor of Political Science
- (2) Vice Chair of the Academy's IRB: Professor Joyce E. Shade  
Deputy Director of Research and Scholarship  
Office of the Academic Dean and Provost
- (3) Additional membership of the Academy's IRB will be promulgated by separate notice.

(4) The authority, duties and responsibilities of the Academy's IRB Chair, Vice Chair and members are delineated in detail in the Naval Academy's HRPP policies and procedures manual (discussed below).

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 will be disseminated by the HRPP office to the Naval Academy by separate distribution.

(2) The HRPP polices 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 the Naval Academy 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 polices 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.

(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 Polices and Procedures Manual.

## 7. Summary

a. As part of the DON Assurance application, the U.S. Naval Academy has guaranteed that 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 the U.S. Naval Academy. In particular, the Naval Academy, the Naval Academy Preparatory School and all personnel associated with USNA will adhere to the applicable Department of Health and Human Services (DHHS) and Department of Defense regulations for the protection of human subjects in research; regulations, policies, directives and guidance of the Department of Navy 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 Human Research Protection Program at the Naval Academy, everyone at USNA must embrace this culture shift and everyone must be involved in and supportive of this new way ahead. 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 the Naval Academy and of the Naval Academy Preparatory School 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 Human

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Research Protection Program that emphasizes the complimentary rather than adversarial 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 the Naval Academy's Human Research Protection Program.

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 Human Research Protection Program efforts.

/S/  
J. L. FOWLER

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All Mids (electronically)  
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