

## ***Section I: Guiding Principles and Applicability***

### 1.1 Purpose

The purpose of this document is to ensure 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 (USNA). In furtherance of that purpose, this document prescribes policies and establishes review and approval procedures for the use and protection of human subjects involved in research. These policies and procedures apply to the involvement by human subjects in any research initiative, as well as to data about human subjects, as used in such research.

### 1.2 Ethical Principles and Respect for Persons

a. The U.S. Naval Academy subscribes to the highest levels of ethical practice and mandates that all activities related to human subject research at USNA and at the Naval Academy Preparatory School (NAPS) be guided by the ethical principles set forth in the 1979 report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled “Ethical Principles and Guidelines for the Protection of Human Subjects of Research”. This document, known as the *Belmont Report*, (reference (a) of Enclosure (1)), elucidates three basic ethical principles for the protection of human subjects involved directly or indirectly in research studies. These three principles are:

1. Respect for Persons. The Naval Academy recognizes the personal dignity and autonomy of individuals and affords special protection to persons with diminished independence or particular vulnerabilities, including prisoners, children, those who are mentally or cognitively disabled, pregnant women, and/or economically or educationally disadvantaged persons. Human subjects must be allowed to enter into a research project or study voluntarily and with adequate information to make an informed decision with respect to involvement.

2. Beneficence. The Naval Academy recognizes its responsibility to protect persons by maximizing the anticipated benefits of an activity while minimizing potential harm. In all cases, the possible risks to human subjects involved in a research initiative must be assessed against the potential benefits to the subjects, as well as against the improvement and expansion of knowledge that might be obtained as a deliverable of the research project.

3. Justice. The Naval Academy recognizes its obligation to execute a fair distribution of research benefits and burdens. In selecting human subjects for a research project, investigators must ensure that no group of participants is either consistently selected to participate, or consistently deprived of the opportunity to do so.

b. Collectively, these three principles provide the foundation of the Naval Academy’s policies and procedures for the protection of human subjects.

### 1.3 Regulations, Instructions and Policies, and the Responsibilities of the Institution

a. Unless specifically stated to the contrary, use of the terms “U.S. Naval Academy” and “USNA” in this document shall be considered as including the U. S. Naval Academy Preparatory School (NAPS), a subordinate command of the Academy located in Newport, RI.

b. The U.S. Naval Academy guarantees 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 and all its assigned personnel will adhere to the applicable Department of Health and Human Services (DHHS) and Department of Defense (DoD) regulations for the protection of human subjects in research; regulations, policies, directives and guidance of the Department of Navy (DoN) and the DoN Human Research Protection Program (HRPP); and the laws of the state of Maryland (for USNA) and of Rhode Island (for NAPS).

c. Enclosure (1) provides a list of the primary regulations, directives and instructions relevant to the protection of human subjects in research conducted in the United States. These include:

Reference (b): Title 45 CFR Public Welfare: Part 46 “Protection of Human Subjects”

Reference (c): Title 32 CFR National Defense: Part 219 “Protection of Human Subjects” (DoD version of Subpart A of 45 CFR 46)

Reference (d): Title 21 CFR Food and Drugs: Part 50 “Protection of Human Subjects”

Reference (e): Title 21 CFR Food and Drugs: Part 56 “Institutional Review Boards”

Reference (f): Title 10 CFR Armed Forces: Subtitle A: General Military Law, Section 980 “Limitation on Use of Humans as Experimental Subjects”

Reference (g): Department of Defense (DoD) Directive 3216.02, “Protection of Human Subjects and Adherences to Ethical Standards in DoD-Supported Research”, 25 March 2002.

Reference (h): Department of Defense (DoD) Directive 6200.2, “Use of Investigational New Drugs for Force Health Protection”, 24 November 2003.

Reference (i): Secretary of the Navy Instruction, SECNAVINST 3900.39D, “Human Research Protection Program”, 6 November 2006.

Reference (j): Department of Defense (DoD) Instruction 3210.7, “Research Integrity and Misconduct”, 14 May 2004.

Reference (k): U.S. Naval Academy Academic Dean and Provost Instruction, ACDEANINST 3920.3, “Integrity in Research and Scholarly Activity”, 4 February 2000.

Reference (l): Secretary of the Navy Instruction, SECNAVINST 5210.8D, "Department of the Navy Records Management Program", 31 December 2005.

Reference (m): Secretary of the Navy Instruction, SECNAVINST 5211.5E, "Department of the Navy (DoN) Privacy Program", 28 December 2005.

Reference (n): Federal Privacy Act (5 USC 301, 552a (1994)).

d. Issues pertaining to the protection of human subjects involved in research studies are constantly evolving. At times, conflicts between applicable regulations may exist or may appear to exist. References (b) through (f) and reference (n) of Enclosure (1) carry the force of law and as such, supersede administrative regulations such as references (g) through (m) of Enclosure (1). All directives promulgated by the Department of Defense and subsequently by the Department of the Navy (DoN) supersede all local directives and instructions unless a state or local regulation provides greater protection of the human subject. In all cases, the regulation, instruction or policy that offers the greatest protection for the human subjects and the data about the human subjects shall prevail.

e. Pursuant to the requirements of references (b), (c) and (i), the United States Naval Academy has established an "Institutional Review Board (IRB)", which shall be referred to as the "Academy's IRB" throughout the remainder of this policies and procedures manual.

f. Requests for guidance concerning the resolution of questions, concerns or apparent conflicts in the application of the human subject protection regulations, instructions and/or policies should be directed to the Director of the Academy's Human Research Protection Program (HRPP), who is assigned responsibility for the administration and implementation of the human subject research protection program at the U.S. Naval Academy.

#### 1.4 Applicability

a. The policies and procedures defined in this manual apply to all research conducted at or on behalf of USNA that directly or indirectly involves human subjects and/or the data about human subjects. Specifically, these policies and procedures apply

1. regardless of the source, type (direct, reimbursable or gift) or level of funding of the research;
2. whether the research is conducted at the Naval Academy or at non-USNA facilities;
3. whether the research uses any institutional or DoN resources, facilities or assets;
4. whether the research is subject to any other federal regulations;
5. whether any USNA and/or DoN employee or agent (in connection with his/her official duties) conducts, directs or participates in the research;

6. whether the research uses USNA's or DoN's non-public information (including data, documents, records, and/or specimens) to identify or contact human research subjects or prospective subjects;
7. whether the research uses identified or de-identified data about human subjects;
8. regardless of the program, research or study title;
9. regardless of the nature (behavioral, biomedical, etc.) of the research;
10. regardless of the security classification of the research.
11. regardless of the source of the request or directive to conduct the research or study.

## 1.5 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. Some of this involves research on human subjects, such as certain projects conducted by the Biometrics Laboratory or the Human Performance Laboratory or some LEAD program studies of midshipman performance. Much of the Naval Academy research does not involve human subjects, and much of what the Naval Academy does in fulfillment of its mission is not what one normally would call research. However, the term "research" as defined and used in the Secretary of the Navy instruction on human subject research, reference (i) of Enclosure (1), includes many activities in which Naval Academy personnel commonly participate that are not normally considered research-related. These include routine processes such as midshipman food quality surveys and focus groups associated with academic assessment or program improvement.

b. To ensure the safety of all human subjects involved in research and to safeguard the data about human subject participants, the Secretary of the Navy has directed that only experienced and knowledgeable individuals such as the IRB Chair can determine and document whether activities, broadly defined as "research" under reference (i), are exempt from an in-depth protocol review conducted during a meeting of the Academy's IRB. **THE PRINCIPAL INVESTIGATOR MAY NOT DECIDE HOW HIS OR HER OWN PROJECT, THAT INVOLVES HUMAN SUBJECTS AND/OR THE DATA ABOUT HUMAN SUBJECTS, IS CATEGORIZED BY OR AFFECTED BY THE POLICES AND PROCEDURES IN THIS MANUAL.** No human subject activity (including data collection and analysis), broadly defined as "research" under Secretary of the Navy guidance in, reference (i), may commence until the principal investigator receives authority to do so under the procedures delineated in Section IX of this policies and procedures manual.

## 1.6 Affected Populations

The Naval Academy's Human Research Protection Program (HRPP) policies and guidelines are designed to protect the human subjects directly or indirectly involved in any research as well as the data about them that is gathered or used in the research project. Additionally, protections are afforded to: (1) all USNA researchers working on projects involving human subjects; (2) all government and non-government research collaborators of Naval Academy personnel; (3) the U.S. Naval Academy; and (4) the Department of the Navy. The protections afforded by the policies and procedures in this manual extend to all members of the Naval Academy who are identified as possible subjects in potential projects or who are selected as participants in human subject research projects, surveys, and/or focus groups that are favorably reviewed and recommended for approval by the Academy's IRB and subsequently approved by the Superintendent of the Naval Academy. These populations include, but are not limited to:

- members of the Brigade of Midshipmen at the Naval Academy (USNA)
- midshipman candidates at the Naval Academy Preparatory School (NAPS)
- civilian and military faculty (including tenure-track, term, visiting and adjunct faculty)
- civilian employees
- military personnel assigned to the Naval Academy complex
- civilian contract employees engaged in work connected to or in support of USNA activities
- residents of the Naval Academy and their families
- candidates, sponsor families, visitors and guests participating in USNA-sanctioned activities or functions
- populations connected to or associated with the Naval Academy who are not otherwise covered by human subject research protections via other DoD/DoN policies.

## 1.7 Protected Populations and Using USNA Populations as Research Subjects

- a. The U.S. Naval Academy is committed to safeguarding the welfare, rights and privacy of all persons who participate as subjects in research projects or studies conducted under its auspices, and to ensuring that the subjects of such initiatives are aware of the rights and the protections afforded to them. Moreover, the Academy is required to assure the federal government that such safeguards are being provided and enforced for all federally funded grants.
- b. Midshipmen, midshipman candidates, faculty and staff of USNA may be used as subjects for research projects, surveys and/or focus groups when there is a clear and demonstrated benefit to the Naval Academy, to the U.S. Navy or to the U.S. Marine Corps.
- c. Data about USNA personnel may only be used when there is a clear and demonstrated benefit to the Naval Academy, to the U.S. Navy or to the U.S. Marine Corps.

d. Naval Academy personnel and the data about them may not be used in any research activity simply as a matter of convenience.

e. To prevent research overload or “research fatigue”, initiatives involving the Brigade of Midshipmen (or a segment thereof) at the U.S. Naval Academy and/or midshipman candidates of the Naval Academy Preparatory School may not commence until a human subject research protocol has been reviewed by the Academy’s IRB and approved by the Academy’s Superintendent.

- Generally, the priority for involving midshipmen at the Naval Academy in human subject research projects will be:
  1. projects requested by the U.S. Naval Academy Superintendent in response to a directive or suggestion of the Board of Visitors (BOV), the Chief of Naval Operations (CNO), the Inspector General or Congress.
  2. projects requested by the Office of the Commandant of Midshipmen.
  3. projects requested by the Office of the Academic Dean and Provost.
  4. all other projects at USNA.

f. All research involving midshipmen at USNA and/or midshipman candidates at NAPS as subjects of the research must be coordinated through the Office of Institutional Research (IR) at the Naval Academy. This coordination must be completed prior to the submission of a research protocol to the Academy’s IRB for review and subsequent approval by the Academy’s Superintendent. No part of the proposed research may commence until the coordination, review and subsequent approval requirements have been satisfied.

g. Research involving faculty at the Naval Academy as the human subjects in a project must be coordinated with the Academic Dean and Provost (or his/her designated representative) prior to the submission of the research protocol to the Academy’s IRB for review and subsequent approval by the Academy’s Superintendent.

h. Research involving faculty at the Naval Academy Preparatory School as the human subjects in a project must be coordinated with the NAPS Academic Dean (or his/her designated representative) prior to the submission of the research protocol to the Academy’s IRB for review and subsequent approval by the Academy’s Superintendent.

i. Research involving staff at the Naval Academy as the human subjects in a project must be coordinated with the Division Director or appropriate member of the USNA Senior Leadership Team (SLT) responsible for the staff, prior to the submission of the research protocol to the Academy’s IRB for review and subsequent approval by the Academy’s Superintendent.

j. Research involving staff at the Naval Academy Preparatory School as the human subjects in a project must be coordinated with the NAPS Commanding Officer prior to the submission of the research protocol to the Academy's IRB for review and subsequent approval by the Academy's Superintendent.

#### 1.8 Naval Academy Institutional Signatory Official

a. Per reference (i) of Enclosure (1), the Naval Academy's Institutional Signatory Official (ISO) is a senior institutional official (*e.g.*, the Commanding Officer or the Head of an Activity) authorized to act for the institution and to assume on behalf of the institution the obligations imposed by federal regulations, and the DoD and DoN requirements for the protection of human subjects.

b. The Superintendent is the Institutional Signatory Official for the Naval Academy (USNA) and for the Naval Academy Preparatory School (NAPS).

c. The USNA ISO will approve or disapprove human subject research conducted under the cognizance of the U. S. Naval Academy. The ISO may approve specific research protocols within the Naval Academy's jurisdiction only after review and an affirmative recommendation by:

- (a) the Academy's IRB Chair (or Vice Chair) for research eligible for "Exempt" or "Expedited" review, or
- (b) the Academy's IRB after a convened meeting,

and in a manner consistent with the conditions of the approval of the Naval Academy's DoD Navy Assurance issued by the Navy Surgeon General.

The ISO may not approve any human subject research protocol that the Academy's IRB has recommended be disapproved.

d. Additional responsibilities of the Academy's ISO are enumerated in Section 7.4 of this policies and procedures manual.