

Section V: Education and Training

5.1 Fundamental Premise

To have a viable and unified Human Research Protection Program (HRPP) at the Naval Academy, education and training must occur for all those involved. 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 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 is accomplished via a well-established, Yard-wide education and training 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.

5.2 Human Subject Research Training

- a. In response to a Department of Defense (DoD) initiative to raise awareness of and to improve compliance with human research protections, all Department of the Navy (DoN) personnel who conduct, review, approve, support, manage, or oversee research are required to complete initial and continuing research ethics training. In response to this initiative, the Department of the Navy Human Research Protection Program (DoN-HRPP) developed an "Education and Training Policy for Research Ethics and the Responsible Conduct of Research" which is provided as reference (o) of Enclosure (1).
- b. Federal regulations require that all faculty, students and staff at USNA who are engaged in human subject research certify to the Academy's IRB via the HRPP office that they have completed a program of training in the ethics and best practices of human subject research before their research protocol is reviewed by the Academy's IRB and approved by the Academy's Superintendent.
- c. The Department of the Navy's Human Research Protection Program office has determined a list of training modules that must be completed by all human subject research investigators. (These can be accessed via the Academy's IRB website.) Additional modules are required when projects involve special categories of research and/or with participants from among a vulnerable population (*e.g.*, research with minors). Questions about these additional training requirements should be directed to the Academy's HRPP office.
- d. Training of all investigators (internal and external to USNA) on human subject research conducted at USNA and/or that involves human subjects at USNA, or the data about the human subjects, must be documented by the Academy's IRB. Questions about the training requirements for external collaborators should be directed to the Academy's HRPP office.

e. The Academy's HRPP office will ensure that all individuals involved in conducting, reviewing, approving, supporting, managing, or overseeing human subject research (1) complete the required initial training program and (2) participate in ethics training that includes a discussion on the protection of human subjects in research. As completed and prescribed by the training module directions, each participant must submit "proof of training" documentation to the Academy's HRPP office. Records of an individual's training must be kept on file in the Academy's HRPP office, with the records checked periodically for currency and accuracy of information.

f. The Superintendent, Senior Leadership Team (SLT) members, Division Directors, principal investigators (PIs) conducting research, research collaborators, Academy's IRB Chair and members, Academy's HRPP office staff, research administrators, department chairs, clinical care staff, and all other relevant persons at USNA must complete the appropriate training in human subject research and in ethics in accordance with DoD/DoN directives and as prescribed by the Department of the Navy - Human Research Protection Program (DoN-HRPP).

g. In the event that a person's role with respect to human subject research changes, it is the individual's responsibility to initiate contact with the administrative staff of the Academy's HRPP office to determine what additional training, if any, is required as a result of his/her new role and responsibilities.

h. The Academy's IRB members and administrative staff must complete relevant research ethics and human subject protection training before reviewing any proposed human subject research protocols. Questions about these training requirements should be directed to the Academy's HRPP office.

i. Researchers at another institution, laboratory or command who seek to collaborate with USNA personnel on human subject research projects must agree to conduct the research in accordance with Department of the Navy regulations for the protection of human subjects. This includes, but is not limited to, completing the requisite DoN research ethics and human subject protection training and, as appropriate, securing an approved DoD Navy Addendum to the institution's current Federal Wide Assurance.

j. Research investigators (principal, secondary and associate; internal and external to USNA) must complete the appropriate research ethics and human subject protection training prior to the review of the research protocol by the Academy's IRB and subsequent approval of the project by the Academy's Superintendent. This training requirement applies to all key personnel working on the project as well as to any administrative staff maintaining the data about the human subjects and/or the data collection instruments used in the project. Those with an ancillary involvement in the proposed project must complete the appropriate training modules for his/her role in the research, prior to supporting the research effort. Questions about these training requirements and how non-USNA personnel can access the required DoN training should be directed to the Academy's HRPP office.

k. Midshipmen at USNA may serve as research co-investigators with USNA faculty members. In this role, the midshipman's research role shifts from that of "participant" to "investigator", and as such, additional on-line training modules must be completed. It is the responsibility of the faculty co-investigator for the project to assist the midshipman as he/she completes these new requirements and to ensure that the midshipman submits all "proof of training" documentation to the Academy's HRPP office. Records of a midshipman's training should also be retained by the faculty mentor and by the midshipman. Questions about these additional training requirements should be directed to the Academy's HRPP office.

l. Midshipman candidates at NAPS may not serve as research co-investigators.

5.3 Initial Training and Continuing Training

a. Initial Training: Per reference (i) of Enclosure (1), all personnel who conduct, review, approve, support, manage or oversee research must complete initial training. Individuals involved in several roles within the research must complete the most comprehensive requirements. Guidance on the "research roles" and the required components of training will be maintained on the Academy's IRB website.

b. Continuing Training: Per reference (i) of Enclosure (1), all personnel must complete research-ethics continuing training depending on their roles and responsibilities in human subject research, with the frequency of the follow-on training dependent upon the individual's role in the research. Guidance on how this training requirement will be met at USNA and the schedule for it, by research role, will be promulgated annually by the Director of the Academy's HRPP office.

5.4 Individual and Academy Training Responsibilities

a. Individual Responsibility:

1. Per reference (i) of Enclosure (1), individuals are responsible for keeping accurate records of their initial and continuing training.

2. Documentation of current training for the principal investigators, co-investigators (including midshipmen and external collaborators) and all other key research personnel associated with a proposed project must be included as part of the protocol package submitted for review to the Academy's IRB. It is the PI's responsibility to ensure that the protocol submission documentation is complete.

b. Academy Responsibility:

1. Per reference (i) of Enclosure (1), the Naval Academy is responsible for verifying and storing training documents. At USNA, this responsibility is assigned to the Human Research Protection Program office, which will verify that each investigator (principle, secondary and associate) listed on a proposed research project, as well as the key research personnel who will assist with the project, has met all training requirements prior to any review of the research protocol submitted to the Academy's IRB.

2. As the Academy's IRB reviews a research protocol, the Academy's HRPP office must verify, with documentation, that the principal investigators, co-investigators (including midshipmen and external collaborators) and other key research personnel associated with a proposed project are current in their research-ethics training and that the training completed by each person was appropriate to the roles and responsibilities he/she will have in the proposed project.

5.5 Educating USNA Midshipmen and NAPS Midshipman Candidates

Midshipmen at the Naval Academy (USNA) and midshipman candidates at the Naval Academy Preparatory School (NAPS) who may become involved in human subject research either as subjects or investigators must be educated in the ethical principles of research, informed consent for research, surveys and focus groups, the privacy and confidentiality of data, and the care required to adequately safeguard data about human subjects. The logistics for the training evolutions for these populations will be coordinated, prior to their participation in a human subject research project, by the Academy's Human Research Protection Program office with the Commandant of Midshipmen at USNA and with the Commanding Officer at NAPS.

5.6 Education on the Academy's IRB and the Protocol Review Process

A culture of understanding and respect for the Academy's IRB and its processes is difficult to mandate or regulate, yet it is more important than any other single consideration in protecting the rights and welfare of human research subjects and the data collected about them. To promote this culture of respect, USNA personnel will be educated on the Academy's IRB function, its authority and its review and approval procedures for research protocols involving human subjects and/or the data about human subjects. The logistics and procedures for this continuing education effort will be coordinated by the Director and the administrative staff of the Academy's Human Research Protection Program.

5.7 Educating and Training the Members of the Academy's IRB

a. Research ethics and research regulations, especially as they apply to human subjects and the data about human subjects, are complex topics with changing standards and levels of complexity. It is the Naval Academy's responsibility to educate and train the members of the Academy's IRB on its mission, its function, and its tasks. Education and training on the federal, state and local regulations, policies and instructions that apply to the Academy's IRB authority, operation and procedures must be a component of USNA's efforts to develop a robust Human Research Protection Program (HRPP).

b. USNA recognizes the importance of continuing education for and professional development of the Academy's IRB members. The Director of the Academy's Human Research Protection Program is assigned primary responsibility for providing financial and administrative support of the Academy's IRB so that its responsibilities can be carried out appropriately and efficiently. This support includes educational resources such as textbooks, handbooks, brochures, periodicals, videotapes produced by professional IRB administrators and organizations, and continuing education of the Academy's IRB members via their USNA-funded attendance at conferences, web seminars, refresher courses, etc.

c. Training in the administrative procedures of the Academy's IRB will be scheduled annually with mini-training sessions offered on specific topics, as needed, throughout the year. The Director of the Academy's Human Research Protection Program is responsible for the coordination and scheduling of this training.