

Section VI: HRPP and IRB Processes and Procedures

6.1 Authority and Responsibilities of the Naval Academy's Institutional Review Board (IRB) and the Naval Academy's Human Research Protection Program (HRPP) Office

- a. The Academy's IRB is an administrative body, composed of scientists, engineers and nonscientists, appointed by the Superintendent of the Naval Academy to protect the rights and welfare of human subjects recruited to participate in research activities under the auspices of the Naval Academy. Although the Academy's IRB is responsible for the reviews and recommendations to the Superintendent regarding approvals of any proposed human subject research at USNA, it shares the responsibility for maintaining an institutional culture of respect for individuals, their privacy and the data about them with all other constituencies at USNA.
- b. IRBs at Department of the Navy activities perform a Government, and not merely an advisory, function in the research review and approval process. In particular, the Academy's IRB is responsible for reviewing and recommending approval or disapproval of all proposed research involving human subjects, funded or not, conducted under the auspices of the U.S. Naval Academy. This responsibility extends to human subject research conducted by USNA faculty, midshipmen or staff, NAPS faculty or midshipman candidates, and includes human subject research conducted by non-USNA investigators on/with USNA students, personnel, and/or facilities.
- c. The Academy's HRPP office is responsible for the collection, management, access, and safeguarding of all USNA human subject research institutional records, generated as a result of human subject research projects conducted under the cognizance of the U. S. Naval Academy.
- d. No research project that directly or indirectly involves human subjects or that uses data about human subjects may be initiated nor may subjects for such projects be solicited or enrolled until after the research protocol has been reviewed by the Academy's IRB and subsequently approved by the Superintendent, in accordance with operating procedures outlined in Section X of this policies and procedures manual.
- e. The Academy's HRPP office will ensure that the institution and the investigators who perform research under the auspices of the Naval Academy bear full responsibility for such research, including the responsibility for compliance with applicable federal, state, and local laws, applicable Department of the Navy regulations, SECNAV instructions, and USNA policies and instructions.
- f. The Academy's HRPP office and the Academy's IRB will recognize the need for appropriate additional safeguards in research involving subjects who are likely to be vulnerable to coercion or undue influence, such as midshipmen at USNA, midshipman candidates at NAPS, children, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, subordinates, active duty military, and others in situations that may contribute to their vulnerability.

g. The Academy's HRPP office and the Academy's IRB will foster an environment at the Naval Academy that encourages and promotes communication among all relevant parties, with the goal of establishing and subsequently maintaining a high level of awareness and responsibility regarding the protection of human research subjects and the data about the subjects. Further, the Academy's IRB and the Academy's HRPP office must cultivate an atmosphere of collegiality and cooperation with researchers while maintaining the highest level of vigilance for the protection of human subjects.

h. The Academy's HRPP office will exercise appropriate administrative oversight to ensure the effective application of the IRB's practices and procedures as they apply to the protection of the rights and welfare of human research subjects, while not becoming intrusive into the fundamental, discipline-specific methodologies of the research, study or project. The Academy's HRPP office will monitor compliance with applicable federal, state, and local laws, regulations, and instructions; will monitor the processes and functions of the Academy's IRB; will monitor the actions and practices of the research investigators; and will monitor compliance with the policies and procedures described in this manual at the Naval Academy, at the Naval Academy Preparatory School, and with extramural collaborators to USNA personnel.

i. The Academy's IRB will operate and meet in a timely fashion such that its activities are not the cause of significant and/or unnecessary delays in the initiation or the continuation of a research project.

j. At least two meetings of the Academy's IRB will be held each year. One of these meetings must be focused on administrative, education and training issues. Pursuant to the research activities at USNA and the need for meetings to review and approve study protocols, the Academy's HRPP office may establish a regular, more frequent meeting schedule for the Academy's IRB so as to remain current with the federal, state and local regulations, policies and instructions that apply to the Academy's IRB authority and responsibilities. The schedule and content for these meetings will be coordinated with the Director of the Academy's HRPP office.

6.2 Operational Responsibilities of the Academy's IRB

The Academy's IRB will

a. review all research directly or indirectly involving human subjects that is to be conducted under the jurisdiction of the Naval Academy. Consistent with the type and risk level of the proposed research, and as permitted by the Assurance approval issued to USNA by the Navy Surgeon General, some of these reviews may be conducted, on behalf of the Academy's IRB, by the Chair or Vice Chair of the IRB.

b. review any proposed changes to an already-approved human subject research protocol, before the roles of the human subjects and/or the use of the data about the human subjects may be modified.

c. determine whether to (1) recommend approval to the Academy's Superintendent on a submitted human subject research protocol; (2) require modification(s) to unacceptable research protocols in order to secure an approval; or (3) recommend to the Superintendent that a proposed research protocol that would directly or indirectly involve human subjects or data about human subjects at USNA not be approved.

d. determine, in accordance with the criteria found in section 111 of reference (c) of Enclosure (1) and, where applicable, Subparts B, C, and D of reference (b) of Enclosure (1), that the protections for human research subjects and the data about them are adequate in all submitted research protocols and in the execution of the human subject research itself.

1. Prior to recommending approval of a protocol to the Superintendent, the Academy's IRB, in consultation with the Academy's HRPP office, may require the data safeguards during the project, as described by the principal investigator, to be strengthened. Under no circumstance may the Academy's IRB, the Academy's HRPP office, or the Superintendent relax the safeguards proposed by the principal investigator.

2. Although it is expected to be a rare case rather than the norm, as a condition of approval on the project, the Academy's IRB may recommend or the Superintendent may independently decide that the data collected during the project be destroyed at the conclusion of the study due to the sensitive nature of the data and the potential harm to those subjects who participated in the study should the data inadvertently be released. In these cases, the data (in all formats) will be destroyed under the supervision of the Academy's HRPP office.

e. determine that, as required by federal, state or local regulations, legally effective informed consent will be obtained from each proposed research participant unless a waiver or alteration is obtained from the Academy's IRB, and that all research that directly or indirectly involves human subjects will be pursued in a methodology that meets the requirements of sections 116 and 117 of reference (c) of Enclosure (1).

f. determine the applicability of and compliance with reference (f) of Enclosure (1) when the research involves interventions with human subjects who cannot give their own informed consent (*e.g.*, minors).

g. comply fully with the requirements of applicable federal polices and guidelines on human subject research, including those concerning notification of sero-positivity, counseling, and confidentiality of subjects.

h. conduct on-going reviews of all approved research involving human subjects, at intervals appropriate to the degree of risk, but in no case less than once per year.

i. meet at the request of the Chair of the Academy's IRB, a member of the Academy's IRB, the Director of the HRPP office, or the Superintendent to consider any matter concerned with the rights and welfare of human subjects in research.

j. determine, in consultation with the Director of the Academy's HRPP office, whether to recommend to the Superintendent a suspension or termination of an approval of a human subject research activity in accordance with section 113 of reference (c) of Enclosure (1) due to

1. noncompliance with this reference, this policy document, or the Naval Academy's original approval requirements,
2. unexpected serious harm to the research subjects,
- or 3. reasonable cause.

k. report promptly to the Director of the Academy's HRPP office, via the Chair of the Academy's IRB:

- any unanticipated problems or injuries involving risks to human subjects or to others.
- any serious adverse events that occur in a human subject research project.
- the initiation of and results of each investigation of alleged non-compliance with human research protections regardless of the findings in the investigation.
- the initiation of and results of each investigation of research misconduct regardless of the findings of the investigation.
- any suspension or termination of a Naval Academy approved human subject project.
- all audits, investigations, or inspections of DoN-supported research.
- all audits, investigations, or inspections of the Academy's HRPP conducted by an outside entity (*e.g.*, the Federal Drug Administration (FDA) or the Office of Human Research Protections (OHRP)).
- all significant communications between institutions collaborating with the Naval Academy on human subject research projects.
- all significant communications with other federal departments and agencies regarding HRPP compliance and oversight.

6.3 Operational Responsibilities of the Academy's HRPP Office

The Academy's HRPP office will promptly notify the Academy's Superintendent and the DoN-HRPP:

- when there is a change in the membership on the Academy's IRB.
- in the event of any adverse or unanticipated occurrences in a research project.
- if there is any serious or continuing non-compliance by a researcher.
- when there are suspensions or terminations of previously approved DoD-DoN supported research.
- at the initiation of and results of all investigations of alleged non-compliance with human research protections regardless of the findings.

- at the initiation of and results of all investigations of research misconduct regardless of the findings.
- when there are unanticipated problems involving risks to subjects or others and serious adverse events.
- of all audits, investigations, or inspections of DoN-supported research.
- of all audits, investigations, or inspections of the Academy's HRPP conducted by an outside entity, (*e.g.*, the FDA or the Office of Human Research Protections (OHRP)).
- of all significant communication between the institutions conducting the research and other federal departments and agencies regarding compliance and oversight.

6.4 Composition of the Academy's IRB

a. The Academy's IRB consists of eleven (11) members appointed by the Superintendent of the Naval Academy. The constituency outlined below provides representation from the major units at the Naval Academy concerned with research investigations that may directly or indirectly involve human subjects. The Naval Academy Preparatory School does not have a representative on the board. NAPS will, however, work through the Academy's IRB to secure approvals on all proposed research projects that directly or indirectly involve human subjects and/or the data about them.

b. Per reference (i) of Enclosure (1), the Academy's IRB must be composed of members who are current federal employees, individuals appointed under the Intergovernmental Personnel Act (IPA), or consultants consistent with the requirements established by section 3109 of Title 5 of the United States Code.

c. Membership

1. The voting members of the Academy's IRB are nominated to and appointed by the Superintendent. Except as noted below for specific appointments to the Academy's IRB, each voting member will serve in a two- or three-year appointment to the IRB, with the rotation cycle of a member determined at the time of appointment unless otherwise noted. All members of the Academy's IRB, except for the Chair, are voting members. The Chair does not vote except in the case of a tie among the voting members of the Academy's IRB.

2. The Chair of the Academy's IRB

(a) The Chair of the Academy's IRB is appointed by the Superintendent. He/she presides at the convened meetings of the Academy's IRB and briefs the Director of the Academy's HRPP office and the Superintendent on IRB issues. The Chair (a) ensures a quorum of the Academy's IRB voting membership is present to evaluate all human subject research proposals that require full reviews, (b) provides timely reviews and evaluations of research proposals involving human subjects and/or the data about them, and (c) ensures that all applicable laws, regulations, instructions, and policies are followed. The Chair may not delegate or defer the authority for and the responsibilities of this position except to the Vice Chair of the Academy's IRB.

(b) Pursuant to the conditions of the Assurance approval issued by the Navy Surgeon General, the Chair of the Academy's IRB may review human subject research protocols in the "Exempt" and "Expedited" categories and may make approval recommendations on these protocols to the Academy's Superintendent.

(c) Consistent with the Surgeon General's approval of the Naval Academy's Assurance, the review of a potentially "Exempt" or "Expedited" research protocol may be carried out by the Academy's IRB Chair or Vice Chair. As appropriate to the protocol, the Chair or Vice Chair may request additional reviews by other IRB members, consultants to the IRB, and/or subject matter experts. In reviewing the research proposal, the IRB Chair and Vice Chair may exercise all of the authorities of the IRB except that the reviewer may not disapprove the research under "Expedited" procedures. If the reviewer arrives at a negative endorsement of the proposed research, the protocol is automatically remanded to a convened meeting of the Academy's IRB for a review. A proposed research protocol evaluated via the "Expedited" process and negatively endorsed by the IRB Chair or the Vice Chair may only be disapproved by the Academy's Superintendent after the research protocol has received a full review by the Academy's IRB.

3. The Vice Chair of the Academy's IRB

The Vice Chair is designated by the Superintendent from among the voting members of the Academy's IRB. He/she acts on behalf of the Chair in his or her absence.

4. Four members will represent the Office of the Academic Dean and Provost.

(a) Three members will be nominated by the Academic Dean and Provost, with one each from among the full-time faculty within the three academic divisions (*i.e.*, Divisions I – Engineering and Weapons Division; II – Mathematics and Science Division; and III – Humanities and Social Sciences Division). Eligible faculty include tenured and tenure-track civilian faculty, Permanent Military Professors (PMPs), and rotating military faculty who have been stationed at the Naval Academy for at least one year. All appointees must have a demonstrated record of research and scholarship.

(b) The fourth representative, from the Office of Research and Scholarship, will be nominated by the Academic Dean and Provost and will serve until relieved.

5. Three members of the Academy's IRB will be nominated by the Commandant of Midshipmen. Eligible appointees include tenured and tenure-track civilian faculty in the Division of Officer Development, in the Division of Professional Development and in the Stockdale Center for Ethical Leadership. Permanent Military Professors (PMPs) and rotating military assigned to the Office of the Commandant who have been stationed at the Naval Academy for at least one year are also eligible for an appointment to the Academy's IRB. At least one of the three representatives must be an active-duty officer.

6. One member of the Academy's IRB will be nominated by the USNA Director of Athletics. Eligible appointees include civilian and military faculty and staff who have been stationed at the Naval Academy for at least one year and who are assigned to the Physical Education Department.

7. One member of the Academy's IRB will be nominated by the Director of the Institutional Research Office and will serve until relieved.

8. One member of the Academy's IRB will be from an organization that is independent of USNA. This person must be without any direct ties or connections to the Naval Academy and must be a current federal employee, an individual with an Intergovernmental Personnel Act (IPA) appointment, or a consultant whose work position meets the requirements established by section 3109 of Title 5 of the United States Code. The length of this member's appointment will be flexible, based on the availability of the individual but ideally it should be for a period of at least two years. This person can be nominated by a member of the USNA Senior Leadership Team (SLT) or a Division Director, by a current or former member of the Academy's IRB, by a member of the USNA community, or by another federal installation.

6.5 Administrative Support to the Academy's IRB

a. An administrative staff member of the Academy's HRPP office serves as the Academy's IRB secretary. He/she prepares read-ahead copies of proposals for the members to review before the Academy's IRB meetings, schedules the meetings of the Academy's IRB, records complete minutes of the meetings, and records all votes (total; for; against; abstain) on each research proposal being considered. As the Academy's IRB secretary, the administrative member is the custodian of all records (hardcopy and electronic) of the Academy's IRB including research proposals, minutes, records of training, and any other documentation required by law, by regulation or by instruction.

b. In the event of an absence of the designated administrative staff support to the Academy's IRB, a substitute will be provided on an as-needed basis by the Director of the HRPP office, or at the request of the HRPP Director, by the Director of the Institutional Research office.

6.6 Consultants to the Academy's IRB

a. As needed, consultants may be asked to assist in the review of research protocols. Consultants may be from within the Naval Academy or may be external to USNA, dependent upon the protocol and the assistance required. Contributions of their expertise are voluntary and may be requested by the Chair, the Vice Chair or the IRB. Consultants are not voting members of the Academy's IRB. Consultants to the Academy's IRB include, but are not limited to:

b. HRPP Office. The Director of the Academy's Human Research Protection Program. He/she will regularly attend the meetings of the Academy's IRB, and will work closely with the Chair of the Academy's IRB.

c. Health Care Providers

Health care providers from the U.S. Naval Health Clinic, and/or other health care provider offices shall serve as medical consultants on human subject research proposals that may present physical interventions or risk.

d. Legal Experts

Legal experts, such as those in the Naval Academy's Judge Advocate General (JAG) office, in the Leadership, Ethics and Law Department, and on the Commandant's staff, may serve as legal consultants on human subject research proposals that involve legal questions and/or may require a legal review of the activities proposed in the research project. In addition to the aforementioned sources of legal consultants at the Naval Academy, legal personnel not affiliated with the Naval Academy may be contacted for legal advice and opinions.

e. Technical Experts

On a case-by-case basis, the Academy's IRB may solicit assistance and advice from other personnel at the Naval Academy, at the Naval Academy Preparatory School, and/or non-affiliated persons who have expertise in the topic and/or methodologies of a research protocol being considered by the Academy's IRB.

6.7 Conflicts of Interest

Except to provide information requested by the board, a member of the Academy's IRB will recuse him/herself from discussions and deliberations on any human subject research proposal in which he/she has an actual, apparent or potential conflict of interest (*e.g.*, He/she is the PI, co-PI, a funding source for the project, etc.) The status of the member who recuses him or herself from specific reviews and proceedings will be recorded in the minutes of the Academy's IRB meetings held to discuss the proposal in question. When a member recuses him or herself from an IRB meeting, the individual cannot be counted towards the quorum and cannot vote on the research protocol being considered by the Academy's IRB.

6.8 Academy's IRB Meeting Structure and Quorum

a. The Academy's IRB will meet at a time and place determined by the Academy's HRPP office. At least two meetings must be held each year, with the agenda of one of these two meetings focused on the administrative, education and training issues of the USNA's Human Research Protection Program (HRPP).

- b. The Academy's IRB must meet in a timely manner to provide for the expeditious review and evaluation of all protocols involving human subjects and/or the data about human subjects submitted to the board. The schedule of meetings must be with sufficient frequency as to ensure that a build up of unconsidered proposals does not develop. The length of a meeting will vary, depending on work-load and discussion by the board members.
- c. Meetings to consider the rights and welfare of human subjects in a specific, on-going project, survey, etc., will be scheduled by the Academy's HRPP office on an as-needed basis or as requested by interested or concerned parties to the project. To provide guidance and expertise on the applicable regulations, background to the project being discussed, and/or relevant information on procedural options available to the Academy's IRB, the Director of the Academy's HRPP must be included in these discussions and must attend these meetings.
- d. A quorum for the Academy's IRB will consist of at least six of the ten voting members. The Director of the HRPP office and consultants to the Academy's IRB are not considered when determining quorum.
- e. To convene a valid meeting of the Academy's IRB, the Academy's IRB Chair (or the Vice Chair in the absence of the Chair) and at least one of the voting members whose primary expertise is in a non-scientific area must be present.
- f. If the work of the Academy's IRB at a meeting will focus on projects that directly or indirectly involves medical issues, a health care provider consultant to the Academy's IRB must be present.
- g. The administrative support personnel to the Academy's IRB will ensure that all research protocols submitted for review are complete, that the requisite training of the research investigators and the key research personnel (USNA and non-USNA) associated with the project has been completed, and that the evaluation of scientific merit of the protocol has been properly prepared and submitted.
- h. Sections IX, X, and XI of this policies and procedures manual include additional information on the procedures for submitting proposals, the processes for IRB review and evaluation of scientific merit, etc.