

Section VII: Roles and Responsibilities

7.1 Department of the Navy Delegation of Authority and Responsibilities

- a. In reference (g) of Enclosure (1), the Secretary of the Navy (SECNAV) delegated the authority and responsibility for the Department of the Navy Human Research Protection Program (DoN-HRPP) to the Navy Surgeon General (SG), except for those responsibilities specifically retained by the Secretary of the Navy and those delegated to the Under Secretary of the Navy.
- b. The information in this section of the Academy's Human Research Protection Program (HRPP) policies and procedures manual is outlined in reference (i) of Enclosure (1). Adaptation of the descriptions of the roles and responsibilities has been incorporated to make the information specific to the U.S. Naval Academy.

7.2 Authority and Responsibilities of the Navy Surgeon General

- a. Per references (g) and (i) of Enclosure (1), the Navy Surgeon General is the sole authority for policy development, oversight, compliance, and on-going monitoring of the human subject research protection efforts in the Department of the Navy.
- b. The Navy Surgeon General holds the Department of the Navy's authority for approval of new Assurances, the renewal of current Assurances, and the acceptance of other institution's Assurances. The Navy Surgeon General also holds the authority to restrict, suspend or terminate a DoN Assurance.
- c. The Navy Surgeon General:
 - develops policies and programs for the DoN-HRPP.
 - establishes initial and on-going research ethics and human subject protection education and training within the DoN.
 - verifies completion and documentation of the research ethics and human subject protection education and training within the DoN.
 - reviews and, if appropriate, takes action on all allegations of non-compliance with human subject protections and all allegations of research misconduct.

7.3 Role of the Chief of Naval Research (CNR)

As described in reference (i) of Enclosure (1): The Chief of Naval Research (CNR) provides support and expertise to the Navy Surgeon General for human subject research protections in the Systems Commands, operational forces, training commands, and DoN-supported extramural performing institutions.

7.4 Roles and Responsibilities of the Institutional Signatory Official (ISO)

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

b. As prescribed by reference (i) of Enclosure (1), the Institutional Signatory Official:

- is authorized to act for the institution and to assume on behalf of the institution the obligations imposed by the federal regulations, DoD and DoN requirements for the protection of human subjects.
- will complete and document his/her initial and continuing research ethics and human subject protections training.
- will ensure initial and continuing research ethics and human subject protections training occurs for personnel at the U.S. Naval Academy.
- will obtain approval of a DoD Navy Assurance, from the Navy Surgeon General for the United States Naval Academy.
- will obtain a Federal Wide Assurance (FWA) for USNA when the Naval Academy is engaged in Department of Health and Human Services (DHHS) supported research.
- will submit a request to the Department of the Navy Human Research Protection Program (DoN-HRPP) for an updated Assurance approval whenever the Superintendent / ISO of the USNA command changes.
- will submit a timely request to the DoN-HRPP for a renewal of the DoD Navy Assurance approval, even if no changes have occurred, in order to maintain an active Assurance.
- will ensure that the human subjects' decisions to participate in all research studies, surveys and focus groups are voluntary and that the subjects are protected from any undue influences or coercions to participate in the activities.
- will establish an Institutional Review Board (IRB) at the Naval Academy, with responsibility and authority to review all studies directly or indirectly involving human subjects and/or the data about human subjects at the Naval Academy or at an off-site location that proposes to use USNA and/or NAPS personnel.
- will ensure that human subject research protocols are reviewed and evaluated by the Academy's IRB in compliance with all applicable federal, state and local laws, all DoD/DoN directives and in the manner prescribed by the DoN-HRPP.

- may locally approve and certify human subject research within the limits of the authority issued via the Assurance approval of the Navy Surgeon General.
- must, upon receipt of an initial or continuing human subject research proposal package from the Academy's IRB, either:
 - (a) accept the recommendation of the Academy's IRB as presented.
 - (b) require additional safeguards, modifications that enhance the protection of the human subjects, or more frequent reviews than assigned by the Academy's IRB.
 - (c) not accept an approval recommendation of the Academy's IRB.
- must, upon receipt of an initial or continuing human subject research proposal package from the Academy's IRB, verify that all collaborator institutions (domestic and international) on human subject research protocols with USNA hold valid federal, DoD or DoN Assurance documents and IRB approvals before considering any approval recommendations submitted by the Academy's IRB.
- may not relax any safeguards or lengthen the project review period recommended by the Academy's IRB.
- may not approve a human subject research protocol that the Academy's IRB has recommended for disapproval.
- may require a review by the Academy's IRB in a convened meeting, and a recommendation for approval of a human subject research protocol that was initially classified as "Exempt" or "Expedited" by the Chair of the Academy's IRB.
- must submit a human subject research protocol to the appropriate external review authority (at the Assistant Secretary of the Navy or Secretary of the Navy level), per reference (i) of Enclosure (1), for research that involves classified research.
- may require Secretary of the Navy-level approval on the proposed research when it involves any of the protected classes of human subjects, such as prisoners, pregnant women and their fetuses, and mentally or cognitively compromised adults. The Academy's Human Research Protection Program office will advise the principal investigator (PI) for the proposed project of the need for additional approvals beyond the Superintendent's approval at USNA. When additional approvals are required, the Director of the Academy's HRPP office (not the PI) will serve as the USNA point-of-contact to the appropriate Secretary of the Navy office to request the required approval. (Additional information on protected classes of research subjects is provided in reference (i) of Enclosure (1) and in Section IV of this policies and procedures manual.)

- may require additional review of the proposed protocol if its approval may result in potential political or public embarrassment of the U.S. Naval forces, the U.S. Naval Academy, the Naval Academy Preparatory School, and/or of the human subject participants in the proposed research protocol. On a case-by-case basis, the Academy's Human Research Protection Program office will advise the Superintendent and the principal investigator (PI) for the proposed project of the need or wisdom for additional consultation and approvals beyond that of the Academy's ISO.
- must submit a human subject research protocol to the Navy Surgeon General, via the DoN-HRPP, for review and approval whenever the proposed research is outside the limits of the delegated local approval authority.
- will keep the Navy Surgeon General informed, via the DoN-HRPP, of all actions taken at the U.S. Naval Academy under the conditions of the DoD Navy Assurance approval.
- will submit a record of all human subject research protocols and supporting documentation on the disposition of the protocols to the DoN-HRPP for administrative review.
- will provide certifications of human subject research protocol reviews and approvals, as required, to funding organizations, sponsors, collaborators.
- will ensure an independent evaluation of a human subject research protocol for scientific merit prior to any review by the Academy's IRB.
- will ensure that the Director of the Academy's HRPP office and the Academy's IRB maintain appropriate and complete records on all IRB activities, all human subject research protocols submitted for review, and all studies approved for action.
- will not review or approve a human subject research protocol for which he/she is also an investigator or has an apparent conflict of interest. Such protocols shall be referred to the next higher echelon of command, with an approve / disapprove recommendation formulated by the Academy's IRB in a convened meeting. (For the Naval Academy, the Navy Surgeon General is the "next higher echelon of command" on all human subject research issues.)
- must be informed by the Director of the Academy's HRPP office of all allegations of non-compliance with human subject protections and of all allegations of research misconduct in studies involving human subjects and/or the data about humans subjects.

- will review, and if appropriate, will recommend action on any verifications of non-compliance and/or research misconduct in studies involving humans subjects and/or the data about human subjects at USNA.
- will report to the Director, DoN-HRPP and appropriate sponsors:
 - (a) unanticipated problems involving risks to human subjects in a study or others outside the study, and serious adverse events that occur in a study conducted at the Naval Academy.
 - (b) all restrictions, suspensions and/or terminations of previously approved human subject research protocols at USNA.
 - (c) the initiation and results of any investigations of any allegations of non-compliance and/or research misconduct associated with a human subject research study at USNA. These reports must be made to the DoN-HRPP Director, regardless of the findings of the investigations.
 - (d) all audits, investigations, or inspections of a DoN-supported human subject research protocol at USNA.
 - (e) all audits, investigations, or inspections of the Naval Academy's Human Research Protection Program (HRPP), as conducted by an outside entity such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP).
 - (f) significant communication, regarding compliance and oversight, between USNA and collaborating institutions conducting a human subject research study, with other federal departments or agencies.
- will allocate USNA resources to ensure that USNA (a) remains compliant with all federal regulations, DoD and DoN requirements for the protection of human subjects, (b) in possession of a valid DoD Navy Assurance approval, and (c) in possession of a valid Federal Wide Assurance (FWA) for USNA whenever the Naval Academy is engaged in Department of Health and Human Services (DHHS) supported research.
- will approve appropriately negotiated written agreements with participating institutions for collaborative research projects. (Additional guidance on this requirement is available in reference (i) of Enclosure (1) and in Section XVIII of this policies and procedures manual.)

7.5 DoN-Supported Extramural Performers and Performance Sites

a. As an “extramural performer”, any individual or organization that is a party to a contract, grant, interagency transfer, or other agreement with any U.S. Navy or U.S. Marine Corps activity shares the responsibility for the appropriate protection of human subjects in collaborative research.

b. Prior to the award of the interagency agreement (regardless of format), the extramural institution must submit documentation to the DoN-HRPP office (with copy to USNA). This submission must include:

- documentation of an appropriate institutional Assurance (*e.g.*, FWA or DoD Assurance) or an application for a DoD Navy Assurance. In the event that the “extramural performer” holds an FWA but does not hold a DoD Assurance, then documentation of an application for a DoD Navy Addendum to the FWA must be submitted to the DoN-HRPP, with copy to USNA.
- written acknowledgement that the institution will comply with all applicable federal regulations, DoD and DoN requirements that protect human subjects.
- written acknowledgement that the “extramural performer” will comply with all USNA policies and procedures that protect human subjects and the data about them.
- documentation of the institution’s initial and continuing review by the Academy’s IRB and subsequent approval of the project by the Academy’s Superintendent.
- copies of the Naval Academy-approved informed consent form(s).
- copies of the Naval Academy-approved human subject research protocol.
- documentation of completed research ethics and human subject protections training by the principal investigator, all USNA collaborators, and all key research personnel at the extramural institution.

c. The extramural institution must submit documentation to the DoN-HRPP office (with copy to the Naval Academy’s HRPP office) and to all appropriate sponsors that describes:

- all suspensions or terminations of previously approved DoN-supported human subject research protocols at the institution or specific to the record of the extramural investigator(s) on the proposed human subject research project.
- the initiations and results of investigations of alleged non-compliance and/or misconduct issues with human subject protections at the extramural institution.

- any unanticipated problems involving risks to human subjects in a study or others outside the study, and serious adverse events that occur (or have occurred) in a study.
- all audits, investigations, or inspections of the extramural institution's human research protection program and Institutional Review Board (IRB), as conducted by an outside entity such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP).
- significant communication, regarding compliance and oversight, between USNA and collaborating institutions conducting a human subject research study, with other federal departments or agencies.
- all restrictions, suspensions and/or terminations of the institution's Assurances.

7.6 Academy's IRB

- 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. 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. The Naval Academy Superintendent appoints the Chair of the Academy's IRB, the Vice Chair of the Academy's IRB, and the members of the board.
- d. The Academy's IRB provides approval or non approval recommendations to the Superintendent on all human subject research protocols that involve human subjects and/or data about human subjects. These recommendations may be accepted by the Superintendent as submitted or not accepted when an approval has been recommended by the Academy's IRB but the Superintendent chooses to disapprove a protocol. The Superintendent may also defer an approval decision by referring the protocol back to the Academy's IRB for additional discussion, information and/or documentation.
- e. The Academy's IRB must determine, for each proposed USNA research activity involving human subjects and/or data about human subjects, whether the proposed activity must be subject to detailed IRB scrutiny and Superintendent approval before it may proceed.

f. Additional information about the roles and responsibilities of the Academy's IRB is provided in Section VI of this policies and procedures manual.

7.7 Chair of the Academy's IRB

a. The Chair of the Academy's IRB is appointed by the Superintendent of the Naval Academy.

b. The Chair of the Academy's IRB must complete and document the initial and continuing research ethics and human subject protections training.

c. The Chair of the Academy's IRB must brief the Superintendent and the Director of the Academy's HRPP on all activities and issues associated with the Academy's IRB and on-going human subject research projects.

d. In accordance with the permissions and restrictions of the DoN Assurance approval issued by the Navy Surgeon General, the Academy's IRB Chair may act on behalf of the Academy's IRB with respect to whether a proposed research activity involving human subjects or data about the human subjects is, in fact, "Exempt" under reference (c) of Enclosure (1), or whether the proposed activity may be addressed by "Expedited" IRB review procedures or whether the proposed activity must be referred to a convened meeting of the Academy's IRB for more discussion prior to submitting the IRB's recommendation on approval to the Superintendent.

(1) For those proposed activities the Academy's IRB Chair determines meet the criteria for "Exempt" or "Expedited" review procedures, the Academy's IRB Chair may act for the IRB in recommending approval of the proposed activity to the Superintendent.

(2) The Academy's IRB Chair may request additional information and/or documentation from the PI of any "Exempt" or "Expedited" research proposals prior to making a recommendation regarding approval to the Superintendent.

(3) The Academy's IRB Chair may not recommend that the Superintendent *disapprove* any human subject research protocol considered by the Chair to be eligible for "Exempt" or "Expedited" review procedures. In the event that the Academy's IRB Chair believes a human subject research protocol in an "Exempt" or "Expedited" category should be disapproved, the protocol must be deferred to the Academy's IRB for review and discussion during a convened meeting.

e. The Academy's IRB Chair may not approve or disapprove any human subject research protocol.

f. Additional information about the roles and responsibilities of the Chair of the Academy's IRB is provided in Section VI of this policies and procedures manual.

7.8 The Director of the Academy's HRPP office and his/her staff:

- must document the initial and continuing research ethics and human subject protections training of the members of the Academy's IRB.
- must require Assurance certifications, interagency agreements and documentation from extramural performers on a collaborative human subject research activity that directly or indirectly involves USNA human subjects and/or the data about identifiable human subjects, prior to reviewing any proposal regarding the details of the activity.
- must consult with other USNA committees and offices, as appropriate, to ensure the safety of the humans subjects in a proposed research activity. (*e.g.*, the Safety Office, the Faculty Senate Academic Assessment Committee, or the Office of Institutional Research)
- must work closely with the Chair of the Academy's IRB to ensure the protection of human subjects in research projects conducted at USNA and to safeguard the data collected about the project participants.
- may suspend, in consultation with the Academy's IRB, any Naval Academy human subject research activity because of unanticipated problems that involve risks to human subjects within that research activity or to others outside the research activity, and/or because of serious adverse events that are occurring within a research activity. The Director of the Academy's HRPP office may also suspend previously approved human subject research activities that significantly deviate from the approved protocol. The Director may suspend any USNA human subject research activity for reasonable cause. Immediately after taking action to suspend a USNA human subject research activity, the Director of the Academy's HRPP office must notify the Superintendent of the actions taken and the basis for the suspensions.
- must investigate, review and, if appropriate, take action on any allegations of non-compliance and/or research misconduct with human subject protections at USNA or elsewhere when USNA personnel or the data about them are involved in the study. The Director of the Academy's HRPP office must undertake any investigations and/or reviews in consultation with the researcher's chain of command and with the Academy's IRB.
- must report to the Superintendent:
 - (a) all suspensions or terminations of previously approved human subject research protocols, studies or surveys.
 - (b) the initiation of investigations of alleged non-compliance and/or research misconduct with human subject protections.

- (c) unanticipated problems involving risks to human subjects in a study or others outside the study, and serious adverse events that occur in a study.
 - (d) all audits, investigations, or inspections of the Naval Academy's Human Research Protection Program (HRPP), as conducted by an outside entity such as the Federal Drug Administration (FDA) or the Office of Human Research Protections (OHRP).
 - (e) significant communication, regarding compliance and oversight, between USNA and collaborating institutions conducting a human subject research study, with other federal departments or agencies.
- f. Additional information about the roles and responsibilities of the Academy's HRPP office is provided in Section VI of this policies and procedures manual.

7.9 Responsibilities of Principal Investigators (PIs)

- a. Each principal investigator on a research project that involves human subjects must acknowledge and accept responsibility for protecting the rights and welfare of the human subjects participating in the activity.
- b. Per reference (i) of Enclosure (1): All principal investigators in a DoN-supported human subject research project internal to USNA must be current federal employees. (Status as a contractor or federal retiree alone is not sufficient to qualify individuals as principal investigators for such research.)
- c. Researchers conducting projects that directly or indirectly involve human subjects or the data about human subjects must comply with all applicable provisions of this policy manual, as well as with all relevant federal, state and local laws, DoD/DoN regulations, and SECNAV and USNA instructions.
- d. The principal investigator(s) must:
 - complete and document his/her initial and continuing research ethics and human subject protections training prior to submitting a research protocol to the Academy's IRB for review and prior to an approval decision being issued by the Academy's Superintendent.
 - ensure that all key research personnel involved in the research project or investigation (at USNA and elsewhere) complete the required ethics and human subject research training modules prior to submitting a research protocol to the Academy's IRB for review and prior to an approval decision being issued by the Academy's Superintendent.

- provide the research protocol to the Academy's IRB, via a webpage submission, for projects the PI assesses to be in the "Exempt" or "Expedited" review categories, via his/her preliminary evaluation.
- provide complete protocol packages for all proposed "Full" research projects being considered by the Academy's IRB, in hardcopy, according to the guidance and information detailed in Section X of this policies and procedures manual.
- provide the proposed informed consent form(s) for a project as part of the protocol submission.
- respond fully and promptly to inquiries and requests for information from the Academy's IRB, the Academy's IRB Chair, and/or the Academy's HRPP office.
- advise his/her immediate supervisor that an evaluation on the scientific merit of the proposed research project must be submitted prior to the review of the protocol via the Academy's IRB process. (Additional information on these submissions is available in Section XI of this policies and procedures manual.)
- obtain the informed consent of any prospective human subjects who may participate in an approved research project. NOTE: No research project that directly or indirectly involves 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 approved by the Superintendent.
- refrain from starting any data collection activity, solicitation of participants, etc., on a human subject research project until after the PI has received a project approval number, in writing, from the Academy's HRPP office.
- submit, via an amendment to the Academy's HRPP office, any proposed changes to the approved research protocol, including but not limited to, changes in research methodology, changes in the informed consent documents, procedures for collecting and analyzing data, and/or the focus of a previously approved research effort. These written amendments must be reviewed by the Academy's IRB and approved by the Superintendent prior to implementing the proposed changes, except where the changes are necessary to eliminate immediate hazards to the human subjects participating in the research or to others nearby.

In the case of protocol modifications made to mitigate immediate hazards, the principal investigator must promptly report the reasons for and the outcomes of the changes to the Chair of the Academy's IRB, who, in turn, will inform the Superintendent and the Director of the Academy's HRPP of the hazards and corrective actions. In all other cases, the principal investigator must wait for an Academy's IRB review and the Superintendent's approval before proceeding with the changes to the project addressed in the amendment(s).

- report promptly to the Director of the Academy's HRPP any unanticipated problems involving risks to human subjects participating in a research project and/or to others. The principal investigator must also report any adverse events, and any serious or continuing non-compliance issues associated with an on-going project.
- monitor the activities of all project collaborators (at USNA and elsewhere) as their actions pertain to the research project. The principal investigator is responsible for the conduct of all members of his/her team, and as such, the PI must ensure that the parameters of the research protocol are followed within the boundaries and under the conditions recommended by the Academy's IRB and approved by the Superintendent.
- ensure the research integrity of the investigation, and the safeguards established to protect all human subject data collected during the study.
- keep the Academy's HRPP office advised of the continuing or concluding status of a human subject research project, and provide the Academy's HRPP office a copy of each publication and/or presentation that results from a human subject project.
- must adequately and effectively de-identify data collected about human subject participants in the research prior to the public release (in any form and at any venue) of the research project results.

e. Principal investigators may not expend any funding, regardless of type and source, on a research project that directly or indirectly involves human subjects and/or the data about human subjects until the Academy's IRB review of the research protocol has occurred and until after the Superintendent's approval of the project has been obtained.

f. Principal investigators who fail to comply with the provisions of this policies and procedures manual and/or with all applicable federal, state and local laws, DoD and DoN regulations, and USNA instructions that address human subject research may be liable for legal sanctions under criminal or civil statutes, or may face administrative sanctions by the Naval Academy.

g. Additional information on the roles and responsibilities of principal investigators is provided in several sections of this policies and procedures manual. It is the responsibility of the PI to be familiar with the contents of this entire manual.

7.10 Midshipmen as Co-investigators and Student-Researchers

- a. When human subjects or data about human subjects are used in research projects conducted by midshipmen: Before soliciting subject participants, distributing informed consent forms, starting any data collection activity on the project, etc., the Superintendent's approval of the project must be obtained via the Academy's IRB process. Working through the Academy's IRB process is the joint responsibility of the midshipman and faculty mentor co-investigators for the project.
- b. Additional information about the roles and responsibilities of the midshipman as a project co-investigator and student-researcher is detailed in Section XV of this policies and procedures manual.

7.11 Midshipmen at USNA and/or Midshipman Candidates at NAPS as Participants in a Study

Information about the roles and responsibilities of the midshipman at USNA and/or the midshipman candidates at NAPS as participants in human subject research projects, surveys, etc., is detailed in Section XVI of this policies and procedures manual.

7.12 Division Directors and Members of the Senior Leadership Team

- a. The Division Directors and Members of the Senior Leadership Team (SLT) are responsible for ensuring that appropriate protections for the human subjects participating in a research protocol or a classroom- or laboratory-based project or demonstration are in place within his/her division, office or center in the event that the proposed work is ultimately approved by the Superintendent via the Academy's IRB process.
- b. The Division Directors and Members of the Senior Leadership Team (SLT) are responsible for ensuring that research activities in his/her division, office or center that involve human subjects or the data about human subjects have been reviewed via the Academy's IRB process described in this policies and procedures manual and that a written approval of the project, issued by the Superintendent, has been obtained by the principal investigator prior to any implementation of the project.
- c. The Division Directors and Members of the Senior Leadership Team (SLT) are responsible for ensuring that appropriate protections are in place within the division, office or center for the data about human subjects during an approved project. This includes protections while the data are collected and provisions for the safeguarding of the data once it has been collected. Particular attention must be paid to the secure storage of the data and the restrictions in access to the data by anyone other than the project co-investigators.

d. The Division Directors and Members of the Senior Leadership Team are responsible for ensuring that all research investigators in his/her division, office or center who are planning a project that will directly or indirectly involve human subjects and/or the data about human subjects complete the required human subject research training before submitting a research protocol to the Academy's IRB. (Additional guidance on the education and training of persons conducting human subject research or working with data about human subjects can be found in Section V of this policies and procedures manual.)

e. The Division Directors and Members of the Senior Leadership Team (SLT) are responsible for ensuring completion of the required "Evaluation of Scientific Merit" on each proposed human subject research project within his/her division, office or center. Additional information regarding the required evaluation of scientific merit can be found in Section XI of this policies and procedures manual. (The evaluation of scientific merit must be completed before the research project protocol can be reviewed by the Academy's IRB. Additional information on this submission is available in Section XI of this policies and procedures manual.)

f. It is the responsibility of the Division Directors and Members of the Senior Leadership Team (SLT) to promptly and properly forward all reports of unexpected or adverse events, with respect to the human subjects in a project conducted in his/her division, office or center, to the Director of the Academy's HRPP.

g. Information about the roles and responsibilities of Division Directors and Members of the Senior Leadership Team (SLT) are detailed in Sections XI and XV of this policies and procedures manual. It is the responsibility of these individuals to be cognizant of the contents of this entire policies and procedures manual.

7.13 Persons with Access to Human Subject Data

a. It is the responsibility of all persons who have access to human subject data to ensure that the use of the data is justified and that the subject data is adequately safeguarded to protect the confidentiality of the data.

b. It is the responsibility of all persons using human subject data in the conduct of research to ensure that the use is conducted in a proper manner, and within the parameters of an IRB-reviewed project that has been approved by the Superintendent.

c. Finally, it is the responsibility of persons with access to human subject data to recognize that "access to information" does not automatically imply unfettered "permission to use" or "permission to disseminate" the data. It is the responsibility of all persons who have access to human subject data to solicit a review by the Academy's IRB and an approval by the Superintendent before sharing any human subject data (identified or de-identified) outside of the Naval Academy.

7.14 Extramural Research Collaborators

- a. Information about the roles and responsibilities of research collaborators external to USNA is detailed in Section XVIII of this policies and procedures manual.

- b. It is the responsibility of the USNA principal investigators (a) to inform their extramural collaborators of the Academy's IRB requirements and policies, and the federal regulations, DoD and DoN requirements in effect for the protection of human subjects, and (b) to monitor compliance throughout the project.