

## ***Section XVI: Using Midshipmen and/or Midshipman Candidates as Subjects in Projects***

### 16.1 Using Midshipmen and/or Midshipman Candidates as Subjects in Research Projects

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 conducted under its auspices, and to ensuring that the subjects of such endeavors are aware of the rights and the protections afforded to them by laws, regulations and instructions. Moreover, the Academy is required to assure the federal government that such safeguards are being provided and enforced, in general, and in particular, for all federally funded grants.

b. 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 study as well as the data about them. Additionally, protections are afforded to all researchers working on projects involving humans, to the U.S. Naval Academy, to all government and non-government research study partner institutions, and to the Department of the Navy (DoN). These protections extend to all members of the Naval Academy who are identified as subjects or as potential subjects of a research project that is reviewed by the Academy's IRB and subsequently approved by the Superintendent. These populations include, but are not limited to, all:

- 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

A more inclusive list of those defined as "protected populations" at the Naval Academy is provided in Section I of this policies and procedures manual.

### 16.2 Recruitment and Selection of Participants

a. Midshipmen, faculty and staff at 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 Naval Academy Preparatory School, to the U.S. Navy and/or to the U.S. Marine Corps. Naval Academy personnel and the data about them may not be used in any research activity simply as a matter of convenience.

b. All research projects that propose to involve midshipmen at the Naval Academy and/or midshipman candidates at NAPS as subjects in the study 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 endorsement, and the subsequent approval of the protocol by the Superintendent. No part of the proposed research may commence until the coordination, review and subsequent approval requirements have been satisfied.

c. Human subject research conducted in support of the mission of the Naval Academy and the Naval Academy Preparatory School or for the purpose of evaluating the effectiveness of the Naval Academy's and/or the Preparatory School's academic and professional programs must be reviewed and endorsed by the Academy's IRB and subsequently approved by the Superintendent before any aspects of the study may begin.

d. Superior to Subordinate

Regardless of the level of risk of the research, no superiors (civilian or military) may influence, in any manner, the decisions of their subordinates (civilian or military) with respect to participating as research subjects in any research activity.

e. "Research Fatigue"

1. Repetitive sampling of the same population results in "research fatigue". (An example would be repetitive surveys of all female midshipmen in a given class in the Brigade of Midshipmen at USNA.) Unless there is a clear and compelling reason to do otherwise, only random samples of participants can be used for research projects, surveys and focus groups. This is especially relevant when the potential respondents are midshipmen at USNA and/or midshipman candidates at NAPS.

2. Requests to deviate from a random sampling technique must be discussed, in detail, with the Director of Institutional Research (IR) before a research protocol is submitted to the Academy's IRB. Attention in the discussions should focus on the justifications for deviating from a random sampling of participants in the proposed project, and the impact on the proposed project if the request for a directed, rather than random, sampling technique is not approved.

3. The principal investigator for the research activity, as well as his/her USNA and non-USNA collaborators, are restricted from soliciting participants, distributing informed consent documents, or taking any other action to initiate the research until after the project has been reviewed and favorably recommended by the Academy's IRB and subsequently approved by the Academy's Superintendent.

### 16.3 Informed Consent

a. As noted in reference (i) of Enclosure (1): Voluntary informed consent is a fundamental precept to ethical research with humans, and as such, it begins with subject recruitment. Every care must be taken to identify eligible participants for a research study, to educate the possible participants and their legal guardians (as appropriate) to the goals and methodologies of the study, and to allow each selected recruit the opportunity to refuse to participate in the study.

b. Each potential participant in human subject research must have sufficient information to make an informed decision about participating in the proposed study. If a potential participant cannot physically, mentally or legally give informed consent for him or herself, the consent must be obtained in writing from the individual's legal guardian(s).

- c. When the potential participant is a minor or when he/she is mentally incapacitated, the written permission (with signature and date) of the individual's legal guardian is required on the informed consent paperwork.
- d. Additional information on informed consent is provided in Section IV of this policies and procedures manual.

#### 16.4 Active Duty Military Personnel

- a. Active duty military personnel (including midshipmen at USNA and midshipman candidates at NAPS) serve in an environment where the ability to make a voluntary decision not to participate in a research effort could possibly be compromised. Potential participants cannot be required, compelled, ordered or coerced into participating in any form of research. This applies equally to assessment activities, surveys and focus groups. Participation cannot be mandated; nor may it be ordered by the chain-of-command within a military organization.
- b. Actions such as requiring subjects to sign documents verifying participation or sanctioning penalties (to include administrative and conduct actions by superiors) for declining to participate in a research project, survey or focus group is strictly prohibited.
- c. Subjects in a study, survey or focus group cannot be required, compelled, ordered or coerced into discussing the results of their participation in the research (such as revealing their responses on a survey) to anyone outside of those immediately responsible for the research protocol, survey or focus group.
- d. When an individual informed consent form is required for participation in a research study, survey or focus group: Senior officers, non-commissioned officers and midshipmen superior to the potential participant may **not** present the informed consent paperwork to their subordinates. In the case of senior to junior requests, the need for an informed consent must be presented by an independent person so as to avoid all appearances of chain-of-command pressure, direct or implied orders, etc.

#### 16.5 Emancipated Minors

- a. Age seventeen (17) is the minimum age to join the military; nevertheless, a volunteer who is seventeen must have the written permission of a parent(s) or a legal guardian to enlist in military service. In Maryland, there is no specific law declaring a member of the military (including those at the service academies) emancipated from his or her parents. Once a minor reaches age 18 in Maryland, he/she is emancipated regardless of military status. Similar ambiguity exists in Rhode Island state law.

b. As a result of the lack of clarity in the federal and state laws, midshipmen at the Naval Academy (USNA) and midshipman candidates at the Naval Academy Preparatory School (NAPS) in Rhode Island who are under the age of 18, as well as visitors to USNA or to NAPS who are under the age of 18, may complete surveys and/or participate in research studies only after an informed consent form has been discussed with the legal guardians of the potential participant and the approving signatures of the guardian(s) have been obtained. All informed consent issues must be addressed before the minor may participate in the proposed activity.

## 16.6 Responsibilities of Course Instructors, Principal Investigators and Co-investigators

Midshipmen at the Naval Academy and midshipman candidates at NAPS may be involved in research projects as research subjects. Their involvement may be via traditional courses, via research project courses, or via an initiative not associated with an academic course.

### a. Traditional Courses:

When midshipmen at the Naval Academy and/or midshipman candidates at NAPS are the human subjects in research projects conducted in traditional courses, the principal investigator must:

1. Serve as a USNA or NAPS faculty or staff member. The PI may **not** be another midshipman or a midshipman candidate at NAPS.
2. Comply with all applicable federal, state and local laws, DoN regulations, and SECNAV and USNA instructions that address the protection of the human subjects and the data about them. Failure of the principal investigator to comply with the requirements to safeguard the research subjects in a project, survey or focus group and to safeguard the data collected about the subjects constitutes non-compliance and may constitute research misconduct. (Additional information about these two topics can be found in Section XX of this policies and procedures manual.)
3. Inform all students in the course (participants as well as non-participants in the study) about the federal laws, the DoN regulations, the SECNAV and USNA instructions, and the human protection policies and procedures in this manual that are in effect to protect and safeguard human subjects participating in curriculum activities and research efforts. As part of this briefing, the instructor should advise the students that any misuse or unauthorized disclosure of the data can result in both civil and criminal penalties.
4. Obtain written notification of the results of the Academy's IRB review and of the subsequent approval decision of the Superintendent on the protocol before beginning any participant selection, data collection, or data analysis activity on the project.
5. Comply with all requirements for the management of the informed consent aspects of the project, as discussed in Section 16.3 above and as described in more detail in Section IV of this policies and procedures manual.

b. Research Project Courses and Trident Scholar Program Projects at USNA:

When midshipmen at the Naval Academy and/or midshipman candidates at NAPS serve as human subjects in projects conducted in research project courses or as part of a Trident Scholar Program project at the Naval Academy:

1. Midshipmen may serve as co-investigators on research projects conducted through “midshipman research project courses” or through the Trident Scholar Program at the Naval Academy. In each of these activities, the student-researcher midshipman is the lead investigator and he/she is mentored by one or more USNA faculty members. For the purposes of any review of a research protocol or project by the Chair of the Academy’s IRB, by the Academy’s IRB and/or by the Academy’s HRPP office, the student-researcher midshipman and the faculty mentor are co-investigators.

2. These projects may directly or indirectly involve human subjects as the focus of the research or survey. These projects may also involve data about humans, such as datasets obtained from research collaborators, from public websites, etc. In all combinations of involvement (*i.e.*, direct interactions with human subjects, no direct human subject involvement but datasets are used, or the human subjects are involved and datasets are required), it is the joint responsibility of the co-investigators to comply with all policies and procedures in this manual that apply to human subject research projects, surveys, etc., conducted at the Naval Academy, at a non-USNA site but with USNA human subject personnel, or in collaboration with non-USNA researchers at other locations.

3. It is the joint responsibility of the co-investigators to:

(a) Comply with all requirements for the management of the informed consent aspects of the project, as discussed in Section 16.3 above and in more detail in Section IV of this policies and procedures manual.

(b) Submit a research proposal to the chair of the midshipman’s academic major department for an evaluation of the scientific merit of the proposed project. The protocol must be specific with respect to how midshipmen at the Naval Academy and/or the midshipman candidates at NAPS will participate as subjects in the study and/or how data about the midshipmen or the midshipman candidates will be used, managed and protected in the project. In addition, the protocol must be clear as to the source and type of the data about the midshipmen or the midshipman candidates that will be used in the project if it is approved. (Additional information on this submission is available in Section XI of this policies and procedures manual.)

(c) Obtain written notification of the results of the Academy’s IRB review and the subsequent approval decision on the protocol by the Superintendent before beginning any participant selection activity on the project, initiating any data collection, distributing informed consent forms to the midshipmen and/or to the midshipman candidates participating as subjects in the study, and distributing any human subject datasets to the student-researcher.

(d) Complete all required human subject research training before starting any data collection on a project endorsed by the Academy's IRB and subsequently approved by the Superintendent. (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.)

c. Initiatives Not Associated with an Academic Course:

When midshipmen at the Naval Academy and/or midshipman candidates at NAPS are the human subjects in projects or studies conducted *outside* of traditional courses, research project courses or Trident Scholar Program projects, the principal investigator must:

1. Serve as a USNA or NAPS faculty or staff member. The PI may not be another midshipman at USNA or a midshipman candidate at NAPS.

2. Comply with all applicable federal, state and local laws, DoN regulations, and SECNAV and USNA instructions that relate to the protection of the human subjects and the data about them. Failure of the principal investigator to comply with the requirements to safeguard the research subjects in a project, survey or focus group and to safeguard the data collected about the subjects constitutes non-compliance and may constitute research misconduct. (Additional information about these two topics can be found in Section XX of this policies and procedures manual.)

3. Inform all human subject participants in the study about the federal laws, the DoN regulations, the SECNAV and USNA instructions, and the human protection policies and procedures in this manual that are in effect to protect and safeguard human subjects participating in research projects.

4. Obtain written notification of the results of the Academy's IRB review and the subsequent approval decision on the protocol by the Superintendent before beginning any participant selection activity on the project, initiating any data collection, etc., on the project.

5. Comply with all requirements for the management of the informed consent aspects of the project, as discussed in Section 16.3 above and as described in more detail in Section IV of this policies and procedures manual.

d. In all cases and regardless of the sponsoring venue for the project, it is expected that the methodologies used in projects involving human subjects and/or the data about human subjects will follow accepted scientific practices, that the proposed projects will have scientific merit, that the data will be obtained in an appropriate and authorized manner, and that appropriate precautions will be taken to minimize the risks to the human subject participants and to safeguard and protect the data about the human subjects. The fact that the human subjects are midshipmen at the Naval Academy or midshipman candidates at the Naval Academy Preparatory School in no way minimizes the obligations of the principal investigators to meet and comply with all requisite regulations and instructions.

## 16.7 Responsibilities of the Division Directors and Members of the Senior Leadership Team

Division Directors and members of the Senior Leadership Team (SLT) **must** remain cognizant of the contents of this entire document. Specific information about the roles and responsibilities of Division Directors and members of the Senior Leadership Team are detailed in Sections VII and XI of this policies and procedures manual. In particular, Division Directors and members of the Senior Leadership Team are responsible for:

- a. Ensuring that each research activity in his/her division, office or center that involves human subjects as participants or that directly or indirectly involves data about human subjects has been reviewed via the Academy's IRB process described in this policies and procedures manual and that a written notification of the IRB's endorsement and the Superintendent's subsequent approval of the project, has been obtained by the principal investigator prior to the start of any activity on the project.
- b. 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 (prior to any participation selection, data collection and/or data analysis activity on the project) within his/her division, office or center for all human subject research projects endorsed by the Academy's IRB and subsequently approved by the Superintendent.
- c. 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, provisions for the safeguarding of the data once it has been collected, and during the data analysis phase of the project. 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. 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 starting any data collection and/or data analysis on an approved project. (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. Ensuring the completion, by the principal investigator's immediate supervisor, of the required "Evaluation of Scientific Merit" on each proposed human subject research project to be carried out by an organizational unit or personnel under Division Director's or SLT member's cognizance. 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 protocol will be reviewed by the Academy's IRB.)
- f. Ensuring that all reports of unexpected or adverse events, with respect to the human subjects, and/or all irregularities with respect to the collection, handling and storage of data about the human subjects in a project conducted in his/her division, office or center, are forwarded promptly to the Director of the Academy's HRPP office and to the Chair of the Academy's IRB.

16.8 Responsibilities of the Office of Institutional Research (IR) and the Academy's Human Research Protection Program (HRPP) Office

When midshipmen at the Naval Academy and/or midshipman candidates at NAPS are the human subjects in projects or studies conducted *outside* of traditional courses, research project courses or Trident Scholar Program projects:

- a. As described in Section I of this policies and procedures manual: All research involving midshipmen at the Naval Academy and/or midshipman candidates at the Naval Academy Preparatory School as subjects of the study must be coordinated through the Office of Institutional Research (IR) at the Naval Academy. It is the responsibility of the principal investigator to initiate a discussion of the proposed project with the IR staff. No part of the proposed research may commence until the coordination with the IR staff, submission of a research protocol to the Academy's IRB, review and favorable endorsement by the IRB, and subsequent approval by the Academy's Superintendent has occurred.
- b. The HRPP office is responsible for ensuring that the required "Evaluation of Scientific Merit" on a proposed research project has been completed and submitted, by the appropriate person, prior to the protocol being submitted to the Academy's IRB for review. Additional information on this submission is available in Section XI of this policies and procedures manual.
- c. It is the responsibility of the Director of the Academy's HRPP office to ensure that appropriate protections have been included in the protocol for the data about USNA human subject participants during a 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 Academy's HRPP office is responsible for ensuring that research projects that involve midshipmen at the Naval Academy and/or midshipman candidates at NAPS as the human subject participants (in traditional courses, research project courses, Trident Scholar Program projects as well as outside these venues) have been reviewed via the Academy's IRB process described in this policies and procedures manual and that the Superintendent has approved the research protocols prior to any start of the projects, including participant selection, data collection, etc.
- e. It is the responsibility of the Director of the Academy's Human Research Protection Program office to ensure that midshipmen at USNA, midshipman candidates at NAPS, and faculty and staff of both institutions are only involved as human subjects in research projects, surveys and/or focus groups when there is a clear and demonstrated benefit to the Naval Academy, to the Naval Academy Preparatory School, to the U.S. Navy and/or to the U.S. Marine Corps.