

## ***Section XX: Allegations of Non-compliance and Research Misconduct***

### **20.1 Policy Statement**

It is the policy of the U.S. Naval Academy (USNA) to uphold the highest standards of integrity in research, scholarship and related activities. Faculty and staff at the Naval Academy and at the Naval Academy Preparatory School (NAPS) are expected to adhere to USNA and NAPS institutional standards and instructions applicable to research in general, as well as to the federal, state and local laws, Department of Defense (DoD) and Department of the Navy (DoN) regulations, and the Secretary of the Navy (SECNAV) and USNA instructions in place to protect and safeguard the personnel of the Naval Academy and the Naval Academy Preparatory School.

### **20.2 Roles and Responsibilities with Respect to Non-compliance and Research Misconduct**

#### **a. Naval Academy Superintendent**

1. The Superintendent, as the Institutional Signatory Official (ISO) for the Naval Academy, assumes on behalf of the institution the obligations and responsibilities directed by federal regulations, DoD and DoN requirements, and the SECNAV instructions for the protection of human subjects and the data about them.

2. Per reference (i) of Enclosure (1), the Institutional Signatory Official:

- 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 that are conducted at USNA, or involve human subjects or data about human subjects from USNA, or involve USNA personnel as participants in the research as collaborators or as investigators.
- shall review, and if appropriate, 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.
- shall report, to the Director of the DoN-HRPP and to the appropriate sponsors of the study, the initiation and results of any investigations of any allegations of non-compliance and/or research misconduct associated with a human subject research study. These reports must be made, regardless of the findings of the investigations.

b. The Academy's HRPP Office

1. The Director of the Academy's Human Research Protection Program (HRPP) must be immediately notified of all allegations, investigations and outcomes of non-compliance or misconduct with respect to projects directly or indirectly involving human subjects and/or the data about them.

2. Consistent with reference (i) of Enclosure (1) and in collaboration with the Academy's IRB, the Director of the Academy's HRPP office will adapt the procedures defined in reference (k) of Enclosure (1), "Integrity in Research and Scholarly Activity", to initiate and coordinate all investigations of alleged non-compliance and/or research misconduct with respect to human subject protections. The HRPP Director will immediately notify the Superintendent of the allegation(s) and the initiation of an investigation. At the conclusion of the review and investigation, the HRPP Director will provide a summary of the allegation(s) and of the findings of the investigation to the Superintendent. As appropriate, the Director of the HRPP will recommend actions on a case to the Superintendent.

c. The Academy's IRB

The Academy's IRB is an administrative body, composed of scientists, engineers and nonscientists, appointed by the Superintendent 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 review and recommendation to the Superintendent regarding approval 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. In the event of allegations of non-compliance and/or research misconduct, the Academy's IRB will assist the Director of the Academy's HRPP, as appropriate to the case, in the investigation of the allegation(s).

d. Principal Investigators and Collaborators

1. The principal investigator on a protocol that directly or indirectly involves human subjects and/or the data about human subjects is responsible for ensuring that the research project, survey or focus group study is conducted in compliance with the protocol, design and informed consent process endorsed by the Academy's IRB and subsequently approved by the Superintendent. It is the responsibility of the principal investigator and each of his/her USNA and non-USNA collaborators to comply with the policies and procedures defined in this policies and procedures manual when the projects are conducted at USNA or when they are conducted elsewhere but involve USNA personnel and/or the data about them.

2. In all cases, it is expected that the methodologies used in projects involving human subjects and/or the data about them will follow accepted scientific protocols, that the projects will have scientific merit, and that appropriate precautions will be taken to minimize the risks to the human subject participants and to safeguard and protect the data.

e. Additional information about the roles and responsibilities of the Superintendent, the Academy's HRPP office, the Academy's IRB, and the principal investigators is detailed in Section VII of this policies and procedures manual.

### 20.3 Investigations of Allegations of Non-compliance or Research Misconduct

a. The integrity of the Naval Academy faculty, staff, midshipmen at USNA and midshipman candidates at NAPS requires that any allegations of non-compliance and/or research misconduct with respect to projects, surveys, studies or initiatives that involve human subjects and/or the data about the subjects must be dealt with in an equitable and timely manner. Because of variations in factors such as the nature of the alleged non-compliance or misconduct, the seriousness of the allegation, the possibility of miscommunications or disputes with respect to the facts, and the possible involvement of institutions, agencies, or commands external to the Naval Academy, the course of action required to investigate and resolve questions of non-compliance will vary from case-to-case.

b. In general, the procedures defined in reference (k) of Enclosure (1), "Integrity in Research and Scholarly Activity", will be followed for cases of alleged non-compliance or misconduct with respect to projects directly or indirectly involving human subjects or the data about them. On a case-by-case basis, adjustments in the identities of personnel advised of the allegations, included in the investigation, etc., will be made, appropriate to the organizational affiliation of the researcher for the non-compliance or misconduct. Questions as to the oversight, responsibility and process for any investigation of alleged non-compliance or research misconduct, as it applies to the protection of human subjects and/or the data about them, should be addressed to the Director of the Academy's HRPP office.

### 20.4 Concerns

When adapting the procedures defined in reference (k) of Enclosure (1) to a specific case, all involved persons should be concerned with:

- a. the responsibility of the principal investigators and the Naval Academy to the Navy, to the scientific community, to the collaborating institutions, agencies and commands, and to the public to uphold the highest standards of integrity in research.
- b. the need for all principal investigators and all collaborators on the project to comply with the policies and procedures defined by the Naval Academy, the regulations of the DoD and DoN, and the federal, state and local laws when conducting research projects, surveys, and focus groups with human subject participants and/or with the data about the humans subjects.
- c. the importance of maintaining standards of investigation and a review of the allegations of non-compliance and/or research misconduct that are consistent with the highest expectations of integrity among those engaged in the research enterprise.

- d. the need to protect the rights and the reputations of all individuals, including the person who is alleged to have been engaged in the non-compliance and/or research misconduct, as well as the person(s) who has (have) made the allegation.
- e. the need for maximum confidentiality of the details and the specific roles of those involved throughout the investigation and beyond. The expectations of confidentiality, particularly by those about whom allegations of non-compliance and/or research misconduct have been made, must be met to the greatest extent possible.
- f. the need for a non-secrective and logical investigative process. While the confidentiality with respect to individual persons must be maintained, an open and impartial investigative process that follows a chain-of-command structure and that does not violate any individual's rights must be established. The process must be credible and applicable to all, with no possibility of bias and/or favoritism.
- g. the requirement to resolve allegations of non-compliance and/or research misconduct with respect to the Naval Academy's regulations regarding human subject research, in a timely manner, and with care and objectivity.
- h. the requirement to allow for ample opportunities for all relevant parties to the allegation to be heard during the investigation phase.
- i. the requirement to record and maintain complete and organized notes during the investigation phase, the discussion phase and the decision phase of the review of any allegation of non-compliance and/or research misconduct.