

## ***Section II: Definitions***

### **2.1 Glossary of Terms**

A glossary of terms associated with human subject research, extracted from several of the references in Enclosure (1), is provided as Enclosure (2) to this policies and procedures manual.

### **2.2 Definition of “Research” in the Human Research Protection Program (HRPP)**

- a. As stated in references (b), (c) and (i) of Enclosure (1): Research is any systematic investigation designed to develop or contribute to generalizable knowledge including but not limited to any project, task, pilot study, experiment, investigation, study, clinical study, evaluation, or developmental effort or similar undertaking, whether or not conducted or supported under a program that is officially considered research. Any effort, even if not considered research for other purposes, is nonetheless considered research for the purposes of this policy if it meets this definition.
- b. Research initiatives may include surveys, focus groups, observational studies, and any form of empirical and non-empirical strategy of inquiry.
- c. The scope of research does not require that the results obtained from human subject research projects be published, presented, or ultimately used. Nor may the approved or disapproved decision on research projects involving human subjects be linked with or contingent upon the plans of the researcher to present or publish the research outcomes and conclusions.

### **2.3 Definition of “Human Subjects”**

- a. “Human subjects” are defined in many of the federal regulations listed in Enclosure (1). Some references define human subjects as “individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project”. Others define a “human subject” as an individual who is or becomes a participant in research – either as a recipient of the test article or as a control on the project. In all cases, the definitions are very similar and they are written to afford the greatest protection to the human subjects involved in the research, project or study.
- b. In reference (i) of Enclosure (1), the Department of the Navy’s Human Research Protection Program (DoN-HRPP) defines a “human subject” as a living individual about whom an investigator (whether professional or student) conducting research obtains data through interventions or interactions with the individual; and/or uses identifiable private information about an individual.

c. The following definitions, extracted directly from reference (i) of Enclosure (1), and examples, provided by the DoN-HRPP, are provided to lend clarity to the just-referenced DoN-HRPP definition of “human subjects”.

1. **“Intervention”** includes both physical procedures by which data are gathered and manipulations of the subject or the subject’s environment that are performed for research purposes. Examples of “intervention” include, but are not limited to taking EEG measurements, drawing blood samples, and recording bone density measurements. “Intervention” also includes research conducted to evaluate alternative teaching methods.

2. **“Interaction”** includes communication or interpersonal contact between investigator and subject. Examples of “interaction” include, but are not limited to, interviews (face-to-face, phone or written), focus groups, and written or web-based surveys.

3. **“Private information”** includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. In an academic and training environment like the Naval Academy, numerous examples of “private information” exist. These include, but are not limited to: academic records, MIDS data on identifiable individuals, admissions information on identifiable candidates, medical records or physical readiness test records, and any database (generated internally or externally) that contains names, Social Security Numbers (SSN), alpha numbers or any other uniquely identifying labels for living human beings.

#### 2.4 Definitions of “Risk” Levels as They Pertain to Human Subjects

a. A risk is deemed to be “minimal” when some or all of the research or data collected from the research would present little to no risk to the human subjects involved in the research or study. As noted in reference (c) of Enclosure (1) and in Enclosure (2), the regulatory definition of “minimal risk” is: “the probability and magnitude of harm or discomfort anticipated in the research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical, physiological or psychological examinations or tests”.

b. No definitions of “negligible”, “moderate risk” or “high risk” are provided in the federal, state or local regulations, since each situation and research protocol is to be evaluated on its own merits relative to the definition of “minimal risk”.

## 2.5 Definitions of “Exempt” and “Expedited”, as applied to Human Subject Research

### a. “Exempt” Classification

1. In consonance with reference (i) of Enclosure (1) and the conditions of approval issued by the Navy Surgeon General for the Academy’s DoD Navy Assurance, “Exempt” human subject research protocols at the Naval Academy must be reviewed by the Chair or Vice Chair of the Academy’s IRB. A positive endorsement must be forwarded by the Chair or Vice Chair, and the protocol must be approved by the Academy’s Superintendent (as the ISO) before any activity on the proposed project may commence.

2. According to references (b) and (c) of Enclosure (1), the use of the “Exempt” IRB review process is limited to well-defined research categories, as defined in the federal register. Specific guidance on the defined categories of “Exempt” review in the federal register, and how these may apply to a specific human subject research project, can be obtained from the Director of the Academy’s HRPP office. In general, the categories include:

a. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as

(i) research on regular educational strategies, or

(ii) research on the effectiveness of or comparison among instructional techniques, curricula, or classroom management methods.

b. Research involving the use of educational tests (cognitive, aptitude, achievement) survey procedures, interview procedures or observation of public behavior, unless

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) Any disclosure of the human subjects’ responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability or reputation.

c. Research involving the collection or study of existing data, documents, or records if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

d. Additional categories of “Exempt” research involving human subjects that are less common at USNA are also listed in reference (c).

3. Per references (b) and (c) of Enclosure (1), research studies that involve any members of a designated vulnerable population (including minors) or that use or collect any data about one or more of the vulnerable populations may not be classified as “Exempt”, even if the project meets the descriptions outlined in sections a through c above. Additional information about children and minors is provided in Section 4.2 of this policies and procedures manual.

4. To ensure the safety of all human subjects involved in research and to safeguard the data about human subject participants, the Secretary of the Navy has directed that only experienced and knowledgeable individuals such as the IRB Chair can determine and document whether activities, broadly defined as “research” under reference (i), are exempt from an in-depth protocol review conducted during a meeting of the Academy’s IRB. **THE PRINCIPAL INVESTIGATOR MAY NOT DECIDE HOW HIS OR HER OWN PROJECT, THAT INVOLVES HUMAN SUBJECTS AND/OR THE DATA ABOUT HUMAN SUBJECTS, IS CATEGORIZED BY OR AFFECTED BY THE POLICES AND PROCEDURES IN THIS MANUAL.** No human subject activity (including data collection and analysis), broadly defined as “research” under Secretary of the Navy guidance in, reference (i), may commence until the principal investigator receives authority to do so under the procedures delineated in Section IX of this policies and procedures manual.

b. “Expedited” Review Procedures

1. On a case-by-case basis, human subject research can be reviewed under the “Expedited” review process:

(a) when the research involves no more than minimal risk to the human subjects and the research fits into one of the designated categories, as defined in reference (c), **and**

(b) when minor changes to previously approved research, during the period of one year or less, for which the approval was authorized.

Guidance on the “Expedited” review process can be obtained from the Academy’s Human Research Protection Program (HRPP) office.

2. The Navy Surgeon General (SG), when approving a Navy command’s Assurance, may grant permission to that command to follow the “Expedited” review procedures established by the Secretary of DHHS. However, the SG may issue a *restricted* or *limited* Assurance that requires the Navy command to review all “Expedited” research protocols during a convened meeting of the command’s IRB or through an alternative procedure such as one that involves a review by some but not all members of the command’s IRB rather than a single review and approval recommendation by the IRB Chair.

3. Consistent with the Surgeon General's approval of the Naval Academy's Assurance to use "Expedited" procedures, the review of a 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.

4. Specific proposed research for which the Academy's IRB may select "Expedited" review procedures (as authorized by the Surgeon General's approval of the Academy's DoN Assurance) include research that involves the collection of data through noninvasive procedures, and/or the collection of data from voice, video, digital, or image recordings made specifically for research purposes, where identification of the subjects and/or their responses would not reasonably place them at risk of criminal, civil liability, or conduct/honor violations; or be damaging to the subjects' financial standing, ability to be commissioned in the military, or personal reputation. "Expedited" review procedures may also be utilized for proposed investigations of individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

5. "Expedited" does **not** mean "an abbreviated or cursory review". A research protocol reviewed under "Expedited" procedures must contain all of the same supporting documentation and elements as a protocol reviewed during a convened meeting of the Institutional Review Board. The review process is the only thing that differentiates between research protocols evaluated under "Expedited" procedures and those reviewed by the "Full" IRB. The Academy's IRB Chair and Vice Chair can evaluate "Expedited" research protocols and these reviews may be done electronically. A meeting of the Academy's IRB need not be convened for "Expedited" reviews.

6. In all cases, it is the responsibility of the Academy's HRPP office and the IRB Chair to know and comply with the review permissions, restrictions and limitations delegated to the command by the Navy Surgeon General.

7. Additional information for the criteria and review process for a research protocol that may be evaluated under "Expedited" procedures can be found in Section IX of this policies and procedures manual.

## 2.6 Definition of “Informed Consent”

- a. Per Enclosure (2): “Informed consent” is “a person’s voluntary agreement, based upon an adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence.”
- b. Additional information on informed consent can be found in Section IV of this policies and procedures manual.

## 2.7 Definition of “Adverse Event”

As noted in Enclosure (2): An “adverse event” is an undesirable, unfavorable and unintended, although not necessarily unexpected, result of experimental interventions.

## 2.8 Definition of “Non-compliance”

- a. Per reference (i) of Enclosure (1): Non-compliance is a deliberate or inadvertent departure from or failure to comply with the federal regulations, DoD directives, DoN and SECNAV instructions, or Institutional Review Board (IRB) requirements for the protection of human subjects in research.
- b. Additional information on allegations of non-compliance and research misconduct can be found in Section XX of this policies and procedures manual.

## 2.9 Naval Academy Institutional Signatory Official

- a. Per reference (i) of Enclosure (1), the Naval Academy’s Institutional Signatory Official (ISO) is a senior institutional official (*e.g.*, the Commanding Officer or the Head of an Activity) authorized to act for the institution and to assume on behalf of the institution the obligations imposed by federal regulations, and the DoD and DoN requirements for the protection of human subjects.
- b. The Superintendent is the Institutional Signatory Official for the Naval Academy (USNA) and for the Naval Academy Preparatory School (NAPS).