

## ***Section IX: Human Subject Research Categories and Criteria***

### 9.1 General Information Applicable to All Categories of Review

a. Per references (b) and (i) of Enclosure (1): Prior to any activity on a research project that directly or indirectly involves human subjects or the data about human subjects, the proposed research must be reviewed and appropriate IRB review procedures must be determined. Three categories of IRB review exist: “Exempt”, “Expedited” and “Full”.

b. No investigator may expend any funding, regardless of source, on research projects that involve human subjects (directly or indirectly as participants or via data about the human subjects) without prior review of the proposed project via the Academy’s IRB process and approval by the Superintendent.

c. Per reference (i) of Enclosure (1), the principal investigator on a research project **may not** make an independent decision of IRB applicability. The principal investigator may, within the protocol submission process to the Academy’s IRB, make a preliminary classification of the human subject research category (“Exempt”, “Expedited” or “Full”) that he/she believes best describes the proposed research. A proposed research effort involving human subjects, either directly or indirectly, or using or collecting data about human subjects, may not proceed until after:

1. the Academy’s HRPP office receives the protocol submission and initiates the Academy’s IRB review process.

2. the Academy’s IRB (or the Chair of the Academy’s IRB as appropriate to the submission and the permissions / restrictions of the Academy’s DoN Assurance approval), recommends approval of the proposed research activity to the Superintendent, and

3. the Academy’s Superintendent approves the IRB’s recommendation regarding the proposed activity.

d. The principal investigator (PI) will be notified of the Superintendent’s decision with respect to approval or disapproval and of the project approval number, in writing, by the Academy’s HRPP office. The PI may begin data collection activity / analysis on the project, solicit human subject participants, distribute informed consent forms to the human subject participants selected for the study, etc., only after he/she has been notified of the approval number assigned to the project.

e. New Projects: To obtain a preliminary classification of a protocol, the principal investigator proposing the research project completes an on-line “project description” form available via the Academy’s IRB webpage. Information on the review process for a new project will be available on the webpage, and also can be obtained from the Academy’s HRPP office.

f. Amending an Approved Project: If the principal investigator wishes to change any aspect(s) of the research methodology of an approved project, the PI must submit an amendment to the Academy's HRPP office. Changes to a project might include, but are not limited to, increasing the involvement of the human subjects, altering how the human subjects are involved, and modifying how the human subject data generated in the project will be used. All amendments to a project must be submitted to the Academy's HRPP office for review via the Academy's IRB process.

g. Upon receipt of a complete amendment to an approved project, the Academy's HRPP office will initiate the Academy's IRB review of the amendment.

h. All amendments to a research protocol, informed consent documents of the research, and supporting documentation of the project must be submitted and reviewed via the Academy's IRB process and subsequently approved by the Superintendent prior to the implementation of *any* aspect of the proposed changes to or alterations of the project. In particular:

(1) The principal investigator should never presume that a proposed change in methodology of a project can be undertaken without a review by the Academy's IRB and a subsequent approval of the proposed change by the Superintendent.

(2) The original protocol approved by the Superintendent can proceed, as approved, while the amendment(s) to the original project is (are) being reviewed by the Academy's IRB and acted upon by the Academy's Superintendent.

(3) The proposed changes to an approved project cannot be implemented until after the PI has received notification from the HRPP office of the approval recommendation by the Academy's IRB and of the approval decision by the Superintendent on the requested change(s).

i. Clarification of IRB Terminology

1. "Exempt" does **not** mean "excluded from any review". As noted above, "Exempt" is one of the three categories of projects or studies that directly or indirectly involve human subjects and/or the data about human subjects. The "Exempt" category applies to projects that appear to involve negligible or low risks to the human subjects and the data about them, and must fall within the "Exempt" categories as defined in reference (c) of Enclosure (1). 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.

2. “Expedited” does **not** mean “an abbreviated or cursory review”. The “Expedited” category applies to projects that appear to involve minimal risks to the human subjects and the data about them. An “Expedited” research protocol submitted to the Academy’s IRB for review must contain all of the same supporting documentation and elements as a protocol classified as “Full”. The review *process* is the only thing that changes between “Expedited” and “Full” protocols. Guidance on the defined categories of “Expedited” 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.

j. Classified Research

1. Per reference (i) of Enclosure (1), classified research projects with human subjects must receive approval from the Secretary of Defense (SECDEF) before any aspects of the project can begin. Project participants may not be solicited, informed consent documents may not be distributed, data collection may not begin, etc., until after the principal investigator has received written notification from the Academy’s HRPP regarding the Academy’s IRB recommendation for approval of the protocol, the Superintendent’s endorsement of the approval recommendation, and the SECDEF’s approval of the project.

2. Protocols that involve classified research must be (a) submitted to the Academy’s HRPP in hardcopy format, and (b) evaluated by the Academy’s IRB in a convened meeting, using the same criteria as unclassified research. “Exempt” or “Expedited” review procedures may not be utilized.

3. Following the review by the Academy’s IRB, the protocol package will be forwarded to the Secretary of the Navy by the Academy’s HRPP office, with an approval or disapproval recommendation of the Academy’s IRB and an approval or disapproval recommendation of the Academy’s Superintendent included in the documentation. The Office of the Secretary of the Navy will coordinate the submission of the research protocol package to the Secretary of Defense. The approval decision of the Secretary of Defense must be received by the Academy’s HRPP office and disseminated in writing to the appropriate Academy personnel, including, but not limited to the principal investigator on the proposed project, before any activity on the project may begin.

4. Principal investigators who anticipate conducting classified research must initiate discussions with the Academy’s HRPP office far in advance of the planned start date for the project. The PI must allow sufficient time for the review of the protocol at the Naval Academy, and the processing of the approval request in the Defense Secretary’s office. Poor planning, failure to allow sufficient time for the multi-level review and/or delays in the review process do not warrant proceeding with the proposed project without the approval of the Secretary of Defense. Questions about the timeline for submissions that require SECDEF review and approval should be directed to the Academy’s HRPP office.

k. The standard requirements for informed consent apply to a research protocol, regardless of the categorization level (“Exempt”, “Expedited” or “Full”) of the proposed project and regardless of the classified or unclassified categorization of the human subject research being proposed. Additional information about informed consent is provided in Section IV of this policies and procedures manual.

## 9.2 “Exempt” Criteria and Review Process

a. **Criteria.** The “Exempt” category applies to projects that appear to involve negligible or low risks to the human subjects and the data about them, and must fall within the “Exempt” categories as defined in reference (c) of Enclosure (1). 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, per references (b) and (i) of Enclosure (1), the following categories include, but are not limited to, human subject research projects that might be evaluated via an “Exempt” IRB review process.

1. The research involves human subjects or data about human subjects, at negligible or low risks, through “intervention”, “interaction” and/or “private information”. Per reference (i) of Enclosure (1):

(a) **“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.

(b) **“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.

(c) **“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. The research does not generally involve as subject participants those who are subordinate to the principal investigator (including active duty military, midshipmen at USNA, or midshipman candidates at NAPS), children, prisoners, pregnant women, mentally disabled persons, economically or educationally disadvantaged persons, and any others in a situation that may contribute to their vulnerability.

In the event that midshipmen at USNA and/or midshipman candidates at NAPS are to be involved as participants in a project that has negligible or low risk and that would otherwise be classified as “Exempt”, the Academy’s HRPP office, in collaboration with the Academy’s IRB, may decide that the research protocol can be reviewed via a process appropriate for an “Exempt” project rather than via an “Expedited” or “Full” process. Examples of such projects may include those classified as quality assurance and process improvement activities, including “food surveys” in dining halls, library visit surveys, and plebe advising surveys. Determination of the level, depth and process of review required on such a project will be made on a case-by-case basis, so as to provide the maximum protection to the potential research participants while permitting a timely review of the research protocol.

3. The research does not involve the collection or recording of information which, if known outside of the research study, could potentially place the human subjects at risk of personal injury; criminal, civil, or conduct liability; be stigmatizing; or be damaging to the subject’s financial standing, ability to be commissioned in the military, or personal reputation.

4. The research does not involve the collection of information regarding sensitive aspects of the human subject’s behavior (*e.g.*, drug or alcohol use, sexual behavior, or illegal/dishonorable conduct).

5. The research does not involve any form of deception.

6. The data-collection procedures proposed in the research generally do not pose a risk greater than can be faced in a normal day-to-day routine. Research that involves human subjects (other than those identified in federal regulations as members of a vulnerable population) may ultimately be classified as “Exempt” if there is no foreseeable risk to the subjects. Research protocols that involve midshipmen and/or midshipman candidates will be considered on a case-by-case basis, as described in 9.2.a.2 above.

7. The research is conducted in established or commonly accepted educational settings and involves normal educational practices. Such practices include assessments of instructional strategies, teaching methodologies, instructional techniques, curricula, or classroom management methods. The efforts do not involve the human subjects outside of regular academic measurement, educational testing, or observed public behaviors. (Additional information about academic and educational measurements and surveys is provided in Section III of this policies and procedures manual.)

8. The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, with the information recorded anonymously. (*i.e.*, so that the individual human subject cannot be identified, directly or indirectly, through identifiers linked to the subject or methodology)

9. The research involves the collection or study of existing data, documents, or records. Per reference (b) of Enclosure (1), this includes “research involving the collection or study of existing data, documents, records, pathologic specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects”. Examples of “existing data” that are “publicly available” would include the aggregated data in the Naval Academy’s institutional data repository (maintained in the Institutional Research office), data in the Department of Education’s Institutional Post-Secondary Education Data System (IPEDS), data in the National Survey of Student Engagement (NSSE) database, data in the National Center for Education Statistics (NCES) database, or data in the Higher Education Research Institute’s Cooperative Institutional Research Program (HERI/CIRP) database. These sources must be either publicly available or the information must be recorded anonymously (*i.e.*, in such a manner that the individual human subjects cannot be identified, directly or indirectly, through identifiers linked to the subject or methodology). Data such as that just described can be used in assessment initiatives internal to USNA for process improvement. (See Section III of this policies and procedures manual for additional information.)

10. Any other criteria as defined in references (b) and (i) of Enclosure (1).

b. The use of “de-identified” human subject data in a proposed research project does not, by itself, justify classification of a research protocol as “Exempt”.

c. “Exempt” Review Process. A research protocol that the principal investigator believes to be “Exempt” will be described on a research project description form available via the Academy’s IRB webpage and submitted electronically to the Academy’s HRPP office. Following receipt of the form by the HRPP office, the usual process will be for the Chair of the Academy’s IRB to review the project information. The PI will then be advised by the Academy’s HRPP office that the proposed research activity falls into one of the following categories:

- Recommend Approval as Submitted. If the Chair (or Vice Chair) of the Academy’s IRB determines that the research is “Exempt” (*i.e.*, human subjects will be subjected to negligible or low risks), the data about the human subjects is adequately protected, there are no vulnerable population participants in the proposed project, and the project is acceptable as described, then the Academy’s IRB Chair may recommend the proposed research for approval to the Superintendent. If approved by the Superintendent, the protocol will be recorded by the Academy’s HRPP office via a unique approval number in the Academy’s IRB database. When notified by the Academy’s HRPP office of the approval number for the protocol, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.

- Requires Clarification for Approval: If the proposal lacks sufficient information concerning the role of the human subjects in the proposed research and/or the use and safeguarding of the data about the human subjects, then the Academy's HRPP office will interact with the PI to gather more detailed information on the proposed project. If this additional information addresses the concerns and the proposed research can indeed be classified as "Exempt", the proposed research will be reviewed by the Academy's IRB Chair and will be eligible for an approval recommendation to the Superintendent. If recommended to and approved by the Academy's Superintendent, the protocol will be recorded by the Academy's HRPP office via a unique approval number in the Academy's IRB database. Following notification of the approval number for the protocol, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.
- Deferred to the Next Level of Review: If the research proposal lacks sufficient information concerning the role of the human subjects in the proposed research and/or the use and safeguarding of the data about the human subjects, and additional information from the PI does not address the concerns, or if the project submission does not support "Exempt" status or if the proposed project involves participation by members of one of the vulnerable population groups (without consideration of the exclusion described for midshipmen or midshipman candidates in 9.2.a.2 above), then the proposed research must be deferred to a higher level of IRB review.

### 9.3 "Expedited" Criteria and Review Process

a. Criteria. According to reference (b) of Enclosure (1), research that involves human subjects or the personal data about human subjects may be reviewed using "Expedited" IRB procedures under certain conditions. Guidance on the defined categories of "Expedited" 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 following categories include human subject research projects that might be evaluated via an "Expedited" IRB review process.

1. The research involves the collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

2. The research involves the use of medical devices. In these studies, the devices must be cleared and approved for marketing. Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for "Expedited" review. These include studies of cleared medical devices for new indications. Examples are:

physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.

weighing or testing sensory acuity.

magnetic resonance imaging (MRI).

electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography.

moderate exercise, muscular strength testing, body composition assessment, and flexibility testing, where appropriate, given the age, weight, and health of the individual.

3. The research involves materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

4. The research involves 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.

5. The research involves 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. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects outlined in sub-sections 101(b)(2) and (b)(3) of reference (b) of Enclosure (1). This listing refers only to research that is *not* exempt from the HHS regulations.)

6. The research involves the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior where the subjects will not be anonymous or where the use or potential use of the data will be beyond internal assessment or process improvements. In these studies, the confidentiality of each human subject must be strictly maintained and the information must not be recorded anonymously. (*e.g.*, Use will be made of audio-or videotapes, names will be recorded, etc., even if they are not directly associated with the data, etc.) Section III of this policies and procedures manual provides additional information on quality assurance or process improvement activities that involve human subjects.

7. Per Title 63, Federal Register 60364 – 60367 of 9 November 1998, the “Expedited” review procedure may be used for a continuing review of human subject research previously reviewed by the Academy’s IRB and approved by the Superintendent, as follows:

- (a) “where
  - (i) the research is permanently closed to the enrollment of new subjects;
  - (ii) all subjects have completed all research-related interventions; and
  - and** (iii) the research remains active only for long-term follow-up of the subjects;
- or (b) where no subjects have been enrolled and no additional risks have been identified;
- or (c) where the remaining research activities are limited to data analysis.”

8. The “Expedited” review procedure may **not** be used when identification of the human subjects and/or their responses would reasonably place the participants at risk of personal injury; criminal, civil, or conduct liability; be stigmatizing; or be damaging to the subject’s financial standing, ability to be commissioned in the military or personal reputation when reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

9. Additional criteria are contained in references (b) and (i) of Enclosure (1).

b. “Expedited” Review Process. Research, directly or indirectly involving human subjects or the data about human subjects, and that the principal investigator believes to be eligible for “Expedited” IRB review will be described on a research project description form available via the Academy’s IRB webpage and submitted electronically to the Academy’s HRPP office. Following receipt of the form by the HRPP office, the usual process will be for the Chair of the Academy’s IRB to review the project information. Following the review, the PI will be advised by the Academy’s HRPP office that one of the following outcomes applies to the proposed activity.

- Recommend Approval as Submitted: If the Chair or Vice Chair of the Academy’s IRB determines that the research is acceptable as proposed and that it fits the “Expedited” review procedures, then the proposed research may be recommended for approval to the Superintendent. Once approved by the Superintendent and recorded by the Academy’s HRPP office via a unique approval number in the Academy’s IRB database, the PI will be notified by the Academy’s HRPP office of the approval recommendation and the Superintendent’s approval decision. Following notification of the approval number for the protocol, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.

- Requires Clarification for an Approval Recommendation: If the proposal lacks sufficient information about the roles and protections of the human subjects in the proposed research, then the Academy's HRPP office will interact with the PI to gather more detailed information on the proposed project. If the additional information addresses the concerns, the proposed research will be reviewed by the Academy's IRB Chair and the project may be recommended for approval to the Superintendent. If approved by the Superintendent, the protocol will be recorded by the Academy's HRPP office via a unique approval number in the Academy's IRB database. Following notification of the approval number for the protocol, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.
  
- Deferred to the Next Level of Review: If the proposal lacks sufficient information concerning the role of the human subjects in the proposed research and additional information from the PI does not address the concerns, the proposed research protocol will be deferred to the Academy's IRB for further review. As a matter of practice, proposals submitted as "Expedited" but considered by the Chair of the Academy's IRB to involve greater than minimal risk (either real or with the potential of being real), will be remanded to the Academy's IRB for review.

#### 9.4 "Full" Criteria and Review Process

a. Criteria. According to reference (b) of Enclosure (1), the following criteria automatically require a "Full" review, in a convened meeting, by the Academy's IRB.

1. A "Full" review of a research protocol is required when identification of the subjects and/or their responses would reasonably place the subjects at risk of personal injury; criminal, civil, or conduct liability; be stigmatizing; or be damaging to the subject's financial standing, ability to be commissioned in the military or personal reputation unless reasonable and appropriate protections will be implemented such that risks related to any invasion of privacy and/or breach of confidentiality are no greater than minimal.

2. A "Full" review of the research protocol is required when the research involves prisoners, fetuses, pregnant women, the seriously ill, or mentally or cognitively compromised adults as human subjects of the research.

3. A "Full" review of the research procedure is required when the research involves the collection of information regarding sensitive aspects of the subject's behavior (*e.g.*, drug or alcohol use, illegal conduct, sexual behavior).

b. Standards for Approval of a “Full” Proposal

1. According to reference (b) of Enclosure (1): To recommend approval to the Superintendent of research categorized as “Full”, the Academy’s IRB must determine that both of the following requirements are satisfied. The risks to human subjects must be minimized:

by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, **and**

whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to human subjects are reasonable (a) in relation to the anticipated benefits, if any, to subjects, and (b) in relation to the importance of the knowledge that may reasonably be expected to result from the study. In evaluating risks and benefits, the Academy’s IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The Academy’s IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

3. Selection of human subjects for research recommended for approved by the Academy’s IRB to the Superintendent must be done in an equitable manner. In making this assessment, the Academy’s IRB should take into account the purposes of the research and the setting(s) in which the research will be conducted. The principal investigator must also be mindful of the requirement for random sampling techniques and the harm that results from “research fatigue”. (Additional information about random sampling and “research fatigue” is provided in Section IV of this policies and procedures manual.)

4. The Academy’s IRB should be particularly cognizant of the special problems of and issues associated with research involving vulnerable populations, such as children; prisoners; pregnant women; mentally disabled persons; economically or educationally disadvantaged persons; or active duty members of the military (including midshipmen at USNA and midshipman candidates at NAPS). Additional safeguards must be included in the proposed research protocol to protect the rights and welfare of these subjects.

c. “Full” Review Process

1. Research or data collection that involves greater than minimal risk must be reviewed in a convened meeting by the Academy’s IRB and approved by the Superintendent before the research can be initiated. This review is based on a detailed research protocol submitted, as hardcopy, to the Academy’s HRPP office, via the researcher’s chain-of-command. The protocol must be specific in nature, including descriptions of how the human subjects will be directly or indirectly involved in the project, how the data will be analyzed, how the data will be stored, how the data will be used, who will have access to the data during the study and beyond, etc. A copy of the proposed informed consent documentation for the project must be included as part of the protocol package.

2. The protocol must include the names and complete contact information for the principal investigator and for all associated researchers at USNA and elsewhere. The contact information must include each researcher’s organizational affiliation and employment position. (e.g., Associate Professor at the University of \_\_\_\_; senior staff scientist at \_\_\_\_ Laboratory; etc.)

3. The protocol must include a copy of the human subject research training certification for each researcher (USNA and non-USNA), as well as for other personnel associated with the project. The training must meet the requirements of the DoD and the DoN, regardless of the affiliation of the non-USNA researchers. Each training certificate must include the name of the person, the name of the person’s home institution, and the date the training was completed. Additional information about the education and training requirements are described in Section V of this policies and procedures manual.

4. The research protocol must include specific information as to the funding support (source, proposed use, etc.) for the proposed project. The Academy’s IRB will pay particular attention to those projects affiliated with a federal funding source or to those projects that might involve a conflict of interest.

5. Protocols that lack sufficient detail and/or are submitted with incomplete information will not be considered by the Academy’s IRB until after the deficiencies are addressed. The Academy’s HRPP office will notify the principal investigator of any obvious deficiencies in the proposal submission.

6. As part of its review, the Academy’s IRB may consider inviting subject matter experts to determine (a) if the research proposal is acceptable for the research discipline area, (b) if it provides the maximum amount of protections possible for the human subjects involved in the project, and (c) if the proposed research justifies the risks. Circumstances which may warrant additional scrutiny include:

- complex projects involving unusual levels of risk.
- medical protocols or physical interventions not initiated by medical professionals.
- projects by investigators with a history of non-compliance and/or research misconduct.

- studies which include investigators from other organizations.
- any other situation deemed necessary by the Academy's IRB to make an appropriate decision that the proposed project methodology protects the well-being of the human subjects and the data about the humans subjects.

7. During its initial approval review, the Academy's IRB will consider whether the degree of risk to the human subjects in the proposed research requires the Academy's IRB review more frequently than once per year. As a condition for its recommendation of approval to the Superintendent, the Academy's IRB may require modifications to the proposed protocol and/or to the storage of and access to the collected data.

8. During its initial review and in its approval recommendation to the Superintendent, the Academy's IRB must ensure that the research protocol makes adequate provision for monitoring the data collected to ensure the safety of the human subjects directly or indirectly involved in the research. These provisions must protect the privacy of the human subjects and must maintain the confidentiality of the human subject data.

9. During its review and in its approval recommendation to the Superintendent, the Academy's IRB 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.

10. The Academy's HRPP office will notify the principal investigator, in writing, of the Academy's IRB recommendations to the Superintendent regarding the proposed research and final approval or disapproval decision.

- Recommend Approval as Submitted: If the Academy's IRB, via a convened meeting, recommends that the Superintendent approve the proposed research protocol and the Superintendent subsequently approves it, that decision will be recorded via a unique approval number in the Academy's IRB database and the PI will be notified. Following notification by the Academy's HRPP office of the approval number for the protocol, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.
- Requires Clarification for an Approval Recommendation: If the proposal lacks sufficient information concerning the roles and protections of the human subjects in the proposed research and/or the protections associated with safeguarding the personal data about the human subjects, the Academy's HRPP office will interact with the principal investigator to gather more detailed information on the proposed project. If this additional information addresses the concerns of the Academy's IRB, the research protocol may be recommended for approval to the Superintendent. Once the protocol has been approved by the Superintendent and recorded via a unique approval number in the Academy's IRB database, the PI will be notified.

Following notification of the approval, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.

- Requires Changes and Concurrence for an Approval Recommendation: If the proposal requires changes to the protocol with respect to the roles and protections of the human subjects and their associated data in the proposed research, the Academy's HRPP office will interact with the principal investigator to explain the required changes. *If the PI agrees to the required protocol revisions*, the proposed project may be recommended for approval to the Superintendent. If approved by the Superintendent, the protocol will be recorded by the Academy's HRPP office via a unique approval number in the Academy's IRB database. Following notification, the PI may begin work on the project, within the parameters of the approval. The PI must retain a hardcopy of the evaluation outcome of the project in his/her records.

*If the PI disagrees with the required protocol revisions*, the protocol will be forwarded to the Superintendent with a negative endorsement of the protocol.

- Not Recommended for an Approval: Reasons for "not approve" endorsements include, but are not limited to:
  - (a) If the proposed research involves significant risks to the human subjects and the risks have not been addressed with adequate protections for the persons involved or if the data to be collected have not been afforded sufficient safeguards, then the Academy's IRB will not recommend the research protocol for approval by the Superintendent.
  - (b) If the proposed research involves risks to the human subjects and the Academy's IRB determines that the risks are too significant (regardless of the proposed protections), then the Academy's IRB will not recommend the research protocol for approval by the Superintendent.

## 9.5 Proposed Projects that are Not Approved

- a. Research projects involving human subjects that are not recommended for approval by the Academy's IRB may not be conducted at the Naval Academy or at the Naval Academy Preparatory School.
- b. Research projects that directly or indirectly involve Naval Academy personnel, Naval Academy Preparatory School (NAPS) personnel, or the personal data regarding USNA and/or NAPS personnel, may not be conducted elsewhere if the project is not reviewed and recommended for approval by the Academy's IRB and subsequently approved by the Academy's Superintendent.

## 9.6 Approval Period for Projects Involving Human Subjects

- a. Research projects that involve human subjects either directly or indirectly, or personal data about identifiable human subjects, may be approved for a period of not more than one calendar year from the date of the recommendation of approval by the Academy's IRB or the Chair of the Academy's IRB to the Superintendent.
- b. Approval of a human subject research project remains in effect only to the extent that the principal investigator conducts the research as proposed and as approved.
- c. Changes to the approved research protocols require review, via an amendment process, by the Chair of the Academy's IRB or by the Academy's IRB (as appropriate to the level and risks to the human subjects) and subsequent approval by the Superintendent. If the project research methodology is altered, the data use is changed, etc., from that of the approved project, and the PI does not submit an amendment to the Academy's IRB for review of the changes, the original approval of the research project is immediately null and void.

## 9.7 Uses and Protection of Data

- a. Data collected via approved human subject research studies cannot be used for any other purpose other than that stated in the research proposal submission and approval process. There are no exceptions to this policy.
- b. There will be no retroactive approval of data use.
- c. There will be no implied approval for the use of the data in any future research initiatives.
- d. It is the responsibility of all persons who have 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 and approval recommendation of the Academy's IRB and an approval decision by the Superintendent before sharing any human subject data (identified or de-identified) outside of the Naval Academy.
- e. The Naval Academy does not sell human subject research data sets.

## 9.8 Disputes

- a. If an "Exempt" or "Expedited" research protocol cannot be recommended for approval by the Chair of the Academy's IRB, the research protocol can be returned to the principal investigator for revisions and resubmission or it can be forwarded, as submitted, to a convened meeting of the Academy's IRB for further review and evaluation.

- b. In the event of a “not approved” recommendation to the Superintendent by the Academy’s IRB, the principal investigator for the project may provide additional written arguments and supporting materials to the Academy’s HRPP office for further consideration by the Academy’s IRB. In addition, the PI may request an opportunity to meet with the Academy’s IRB members to discuss the proposed project and the negative evaluation of the Academy’s IRB. Guidance on how this request is made and the timeline for doing so is available from the Academy’s HRPP office.
- c. A “not approve” recommendation on a research protocol by the Academy’s IRB may not be overturned or disregarded by the Academy’s Superintendent, such that the “not approved” recommendation results in an approved protocol.
- d. A research protocol that is recommended for approval by the Academy’s IRB but is subsequently not approved by the Academy’s Superintendent may not be submitted to the Secretary of the Navy, to the Navy Surgeon General, to the DoN-HRPP, and/or to another command for a reversal of the Superintendent’s decision.
- e. At the direction of the Academy’s Superintendent, a research protocol that is not approved via the Academy’s IRB / ISO process can be submitted by the Academy’s HRPP office to the Department of the Navy’s Human Research Protection Program (DoN-HRPP) office for a review opinion. The feedback from the DoN-HRPP must be provided to the Academy’s IRB as ancillary information, and must be considered in a convened meeting of the IRB. Based on the DoN-HRPP information in the context of the earlier protocol submission, the Academy’s IRB can reverse its “not approved” recommendation or it can affirm its original “not approved” recommendation. The reversed or affirmed recommendation must be transmitted to the Academy’s Superintendent for consideration. The Superintendent may stay with the original “not approved” decision or he/she may issue an approval of the project, based on the guidance and advice from the Don-HRPP office in the context of the new recommendation of the Academy’s IRB.
- f. A recommendation by the Academy’s IRB that a research protocol be approved can be overturned by the Superintendent if it is determined that it is in the best interest of USNA, NAPS, DoD, DoN and/or the perspective humans subjects that the project not proceed.
- g. A “not approved” recommendation by the Academy’s IRB cannot be countermanded by a Division Director or by a member of the Senior Leadership Team (SLT), such that the protocol is subsequently forwarded to the Superintendent for approval.

h. Appeals.

If, after meeting with the Academy's IRB, the principal investigator for a protocol remains dissatisfied with the Academy's IRB evaluation, he/she may submit an appeal of the "not approve" recommendation.

1. Per reference (c) of Enclosure (1), the appeal must be written and it must be signed by the principal investigator and dated.

2. The written appeal must be addressed to the Academy's HRPP office, via the principal investigator's chain-of-command and appropriate SLT member.

3. The PI's chain-of-command and/or SLT member (as appropriate to the affiliation of the principal investigator) may or may not choose to mediate further discussion between the principal investigator, the Academy's HRPP office and the Academy's IRB.

4. Once any mediation /appeal has concluded, the ultimate evaluation of and "not approved" recommendation by the Academy IRB is final. There is no further appeal.

5. If mediation facilitated by the principal investigator's chain-of-command and SLT member does not reverse a "not approved" recommendation by the Academy's IRB to the Superintendent, then no other USNA administrator may overturn the Academy IRB's "not approved" recommendation.