

Section X: Research Proposal Submissions to the Academy's IRB

10.1 Submitting an "Exempt" or "Expedited" Research Protocol

- a. When a principal investigator plans to conduct research using human subjects and/or data about human subjects, he or she must obtain (1) permission to perform that planned work from the PI's chain of command, (2) an approval recommendation from the Academy's IRB, and (3) an approval decision from the Academy's Superintendent before any research participants can be recruited, any informed consent forms can be distributed, any data collection or data analysis can begin, etc. These requirements apply to ALL research, as defined in references (b) and (i) of Enclosure (1), with human subjects and/or the data about human subjects, and includes all surveys, focus groups and interviews.
- b. As part of the preparation of the research protocol and before any submission to the Academy's IRB, the principal investigator must discuss the proposed project with his/her immediate supervisor and with his/her Division Director or SLT member (as appropriate) and must obtain favorable endorsements of the concept and general plan of the project. Guidance on the format for these endorsements and how they are provided to the Academy's IRB is available from the Academy's HRPP office.
- c. With positive endorsements from his/her chain of command, the PI must request that his/her immediate supervisor complete the required "Evaluation of Scientific Merit" on the proposed project. Guidance on the preparation of this evaluation is provided in Section XI of this policies and procedures manual, and is also available from the Academy's HRPP office.
- d. Only protocols with positive endorsements from the PI's chain of command can be submitted to the Academy's IRB.
- e. The initial entry point for obtaining an approval recommendation of the proposed project via the Academy's IRB process, and an approval decision on the project by the Superintendent to perform the planned work is via an electronic submission on the Academy's IRB website. When the PI inputs the required information as requested within the electronic webpage forms, the Academy's HRPP office will receive the submission for review and processing. Additional information on the protocol submission and subsequent routing process is available on the Academy's IRB webpage and from the Academy's HRPP office.
- f. If the protocol submission is complete, the Academy's IRB review process will commence. Projects that appear to involve negligible or low risks to the human subjects and the data about them (*i.e.*, the "Exempt" category in the human subject research classification system) or projects that appear to involve minimal risks to the human subjects and the data about them (*i.e.*, the "Expedited" category in the human subject research classification system), can usually be reviewed by knowledgeable and experienced individuals such as the IRB Chair or Vice Chair, outside of a convened meeting of the Academy's IRB.

g. During the review of the protocol submission, the Academy's HRPP office will keep the principal investigator informed as to the progress and timeline of the review, what additional information is required to complete the review, if the protocol can be reviewed outside an IRB meeting or if it must be reviewed during a convened meeting of the Academy's IRB, if/when the protocol has been favorably endorsed by the IRB and recommended for approval to the Superintendent, etc.

10.2 Submitting a "Full" Research Protocol

- a. Projects that involve or may involve "higher than minimal" risks to the human subjects and the data about them (*i.e.*, the "Full" category in the human subject research classification system) must be reviewed during a convened meeting of the Academy's IRB and must be approved by the Academy's Superintendent prior to the selection of participants for the project, the distribution of informed consent forms, the collection of any human subject data, and/or the analysis of any datasets.
- b. As part of the preparation of the research protocol and before any submission to the Academy's IRB, the principal investigator must discuss the proposed project with his/her immediate supervisor and with his/her Division Director or SLT member (as appropriate) and must obtain favorable endorsements of the concept and general plan of the project. Guidance on the format for these endorsements and how they are provided to the Academy's IRB is available from the Academy's HRPP office.
- c. With positive endorsements from his/her chain of command, the PI must request that his/her immediate supervisor complete the required "Evaluation of Scientific Merit" on the proposed project. Guidance on the preparation of this evaluation is provided in Section XI of this policies and procedures manual, and is also available from the Academy's HRPP office.
- d. Only protocols with positive endorsements from the PI's chain of command can be submitted to the Academy's IRB.
- e. Protocols for these "Full" projects must be submitted in hardcopy format, via the PI's immediate supervisor and the PI's Division Director or SLT member (as appropriate), as described in Section 10.3 (below). All components of the research protocol are submitted, as a complete package, to the Academy's HRPP office.
- f. If the protocol submission is complete, the Academy's IRB process will commence. The first step will involve a "risk-level" assessment by the Director of the Academy's HRPP office, in consultation with the Chair of the Academy's IRB. Projects that involve "higher than minimal" risks to the human subjects and the data about them (*i.e.*, the "Full" category in the human subject research classification system) will be reviewed during a convened meeting of the Academy's IRB. Projects that meet the minimal risk level rather than the "higher than minimal" risk level will be reviewed via the "Expedited" process (as described in Section 10.1 above), normally outside of a convened meeting of the Academy's IRB.

g. During the review of the protocol submission, the Academy's HRPP office will keep the principal investigator informed as to the progress and timeline of the review, what additional information is required to complete the review, if the protocol must be reviewed during a convened meeting of the Academy's IRB or if can be reviewed via the "Expedited" process, if/when the protocol has been favorably endorsed by the IRB and recommended for approval to the Superintendent, etc.

10.3 Components of a Protocol Submission for a Convened Meeting of the Academy's IRB

All properly prepared research protocol packages for the Academy's IRB must contain:

a cover memorandum (A template is provided on the Academy's IRB website).

an abstract of the proposed research, study, survey or focus group.

a detailed project protocol that includes a(n):

1. background section.
2. problem statement.
3. discussion of the roles of the human subjects in the research, surveys, focus groups, interviews, or other aspects of the project.
4. discussion of the physical protection measures (as appropriate to the project) for the human subjects during the research.
5. discussion of the method(s) that will be used to protect the identities of the human subjects during the project and after its completion.
6. discussion of how the human subjects will be selected and enrolled in the study. (Surveys involving the midshipmen at USNA and/or the midshipman candidates at NAPS must use *random* sampling methodologies unless a compelling reason can be made to the Academy's IRB to do otherwise.)
7. discussion of how the informed consent of the human subjects will be obtained and recorded. (A copy of the proposed informed consent document must be included as part of the research protocol package.)
8. discussion of how the human subject protections and disclosures, required by law, policy and instruction, will be accomplished.
9. description of how the data about the human subjects will be protected during and after the study.

10. description of how the data will be used. (*i.e.*, publish, present, use in an internal assessment review, etc.) (See clarification note below.)
11. description of who will have access to the data during and after the study. (*e.g.*., Are there plans to share the data with investigators, commands, etc., external to USNA? See Section XIV of this policies and procedures manual for additional information on this aspect of a project.)
12. description of the method(s) of investigation and the investigator's expertise in and experience with the described methodologies.
13. description of the role of any external collaborators to the proposed project. (The identities, academic credentials and contact information for each collaborator must be included in the research protocol.)
14. description of the funds (by account) that will be used to support the project (*e.g.*, direct, gift or reimbursable account # ____; or none required)
15. statement as to the value of the project to the Naval Academy, to the Naval Academy Preparatory School, to the Naval Forces and/or to the field of study.
16. copies of the documentation for the required DoN human subject training certifications of the PI and of the key research personnel (at USNA and elsewhere) on the project. (Each certificate must be current. Additional guidance on the training requirements can be obtained from the Academy's HRPP office.)
17. copies of the DoD Navy Assurances of non-USNA Navy collaborators, a copy of the SG-approved DoD Navy Addendum to a FWA for each non-federal collaborator, and copies of appropriate agreements such as an Institutional Agreement for IRB Review.

Clarification notes for # 10:

- a. The scope of research does not require that the results obtained from human subject research projects be published, presented, or ultimately used.
- b. The approve or disapprove decision on research, survey or focus group protocols involving human subjects may not be linked with or contingent upon the plans of the researcher to present or publish the research outcomes and conclusions.
- c. No person or entity at the Naval Academy may direct that the results of a project, survey or focus group be published or be withheld from publication as a condition for approval of the study.

10.4 Process Issues and Questions

- a. Questions about the preparation or submission of research protocols, the required components, the timeline for a review, the status of a protocol submitted for review and approval, etc., should be addressed to the Academy's HRPP office.
- b. Requests to meet with the Academy's IRB during its review of a submitted protocol should be made in writing, via the principal investigator's immediate supervisor and Division Director or SLT member (as appropriate), to the Academy's HRPP office. Guidance on the timeline for meetings, how to have a protocol added to an upcoming agenda for the Academy's IRB, etc., can be obtained from the Academy's HRPP office.