

Section XI: Evaluation of Scientific Merit

11.1 Evaluation of the Scientific Merit of Research Protocols Involving Human Subjects and/or the Data about the Human Subjects at USNA

- a. At the Naval Academy, the principal investigator's immediate supervisor (e.g., department chair) will serve as the evaluator of the scientific merit of a protocol for research projects involving human subjects and/or the data about human subjects. The associate chair of the department will serve as the alternate reviewer if the department chair is the principal investigator (PI) on a proposed project or if the department chair is unavailable for an extended period of time. As appropriate to the content of the research and to the department chair's own area of expertise, he/she may solicit comment on a proposal from a more experienced colleague in the department or elsewhere at the Naval Academy.
- b. For a principal investigator not associated with a department, the office or center director for the PI will serve as the evaluator of the scientific merit of a protocol for research projects involving human subjects and/or the data about human subjects. The office or center director will designate his/her alternate as necessary for the protocol requiring review. As appropriate to the content of the research and to the reviewer's own area of expertise, the evaluator may solicit comment on a protocol from a more experienced colleague in an academic department or in another center or office at the Naval Academy.

c. Evaluation of the Scientific Merit of Protocols at NAPS

The Commanding Officer of the Naval Academy Preparatory School (NAPS) will serve as the evaluator of the scientific merit of a protocol for research projects involving human subjects and/or the data about human subjects at NAPS. The NAPS Academic Dean will serve as the alternate reviewer if the Commanding Officer is unavailable for an extended period of time. The Commanding Officer may solicit assistance from the NAPS Academic Dean, a USNA Division Director or SLT member, and/or faculty or staff at the Naval Academy who have expertise in the topic of a protocol and/or in the methodologies of human subject research prior to completing the "Evaluation of Scientific Merit".

d. Department chairs and office or center directors may be asked, on an occasional basis, to review research proposals originating outside his/her chain of command. Examples of such proposals would be those from related USNA departments, divisions, offices or centers, or proposals from non-USNA investigators who are seeking permission to conduct human subject research at the Naval Academy. Examples include, but are not limited to:

- The protocol submitted by a principal investigator may be an interdisciplinary project and as such, it may involve faculty and staff from more than the PI's home department. The immediate supervisor for the PI would serve as the evaluator of the scientific merit of the research proposal, with input as appropriate, from the supervisors for the collaborators on the project.

- A proposed project may involve a principal investigator at the Naval Academy Preparatory School and an associate researcher at the Naval Academy. In this case, the Commanding Officer at NAPS would serve as the evaluator of the scientific merit of the research proposal, with input as appropriate, from the USNA supervisor of the associate researcher on the project.
- e. The reviewer's evaluation of the scientific merit of a protocol must be completed and submitted via an electronic form maintained on the Academy's IRB website. The submission will be routed through the PI's Division Director or SLT member, as appropriate, to the Academy's HRPP office.
- f. In addition to any comments provided by the evaluator, the credentials of the evaluator (that address his/her qualifications to evaluate human subject protocols) must be annotated on the "Evaluation of Scientific Merit" input to the Academy's IRB.
- g. The principal investigator may submit a research protocol on his/her proposed human subject research project to the Academy's IRB while the scientific merit evaluation is being completed via an on-line submission. However, the review of a research protocol by the Academy's IRB will not begin until all components of the protocol, including the evaluation of scientific merit, have been received by the Academy's HRPP office.

11.2 Criteria for Evaluating the Scientific Merit of a Research Protocol that Involves Human Subjects and/or the Data about the Human Subjects

Each human subject research project protocol will be evaluated using the following criteria as a guideline. More detailed guidance will be available to the evaluator as part of the directions for the on-line evaluation form that is available at the Academy's IRB website.

- Is the proposal a process of scientific inquiry and as such, does it meet the definition of research provided in Section II of this policies and procedures manual?
- Will living humans be involved in the project, if approved?
- Will data about human subjects be used in the project, if approved?
- Does the proposed methodology involve a survey and/or a focus group?
- Does the protocol include a clear statement of purpose?
- Does the methodology of the proposed research follow accepted scientific protocol?
- Have adequate procedures and safeguards been included in the protocol by the principal investigator to assure the validity of the data while ensuring its protection?