

Section III: Quality Assurance and Process Improvement Activities

3.1 Quality assurance and process improvement activities occur at academic institutions and at military installations on a regular basis. These activities are undertaken to assess on-going initiatives as well as one-time events.

3.2 Capstone and design project courses taken by midshipmen include classroom- or laboratory-based projects or demonstrations, with the student efforts focused on investigating or revalidating known concepts and/or principles. As such, these efforts do not constitute “research”. Additional examples of quality assurance and process improvement activities may include “food surveys” in dining halls, library visit surveys, and plebe advising surveys.

3.3 Per reference (b) of Enclosure (1), course and instructor critique forms in academic classes are educational instruments used to evaluate the quality of instruction to the midshipmen (or to the midshipman candidates at NAPS) and to improve the process of instruction. At the Naval Academy, for example, critique forms are used to gather feedback from the midshipmen with regard to the quality of their summer cruise experiences, military training evolutions, and varsity athlete experiences, and the information is gathered for the purpose of program evaluation and improvement. The use of these evaluations may or may not constitute “research” as defined in reference (b) of Enclosure (1), depending on the actual facts involved; and hence, their use may or may not be subject to the policies and procedures in this document. In each case, the principal investigator must seek a determination, in accordance with the policies and procedures outlined Section IX of this manual, as to whether or not his/her planned activity is subject to an IRB review.

3.4 Quality assurance and process improvement activities - such as surveys, questionnaires, interviews or focus groups - undertaken to assess the strengths and weaknesses of a program, to identify “best practices”, to evaluate educational endeavors and/or to monitor success in achieving the goals of a project may or may not meet the definition of “research” provided in Section 2.2 of this policies and procedures manual. While these activities often involve human subjects as respondents, the activities themselves may not be research projects. The use of these activities may or may not constitute “research” as defined in reference (b) of Enclosure (1), depending on the project, the data collected, how the data will be used, etc.; and hence, their use may or may not be subject to the policies and procedures in this document. In each case, the principal investigator must seek a determination, in accordance with the policies and procedures outlined in Section IX of this manual, as to whether or not his/her planned activity is subject to an IRB review.

3.5 It is the responsibility of the principal investigator of a project to recognize that studies initiated in response to an “assessment” need may also fit the criteria of research according to the definitions in references (b), (c) and (i) of Enclosure (1). Assessment and research are not mutually exclusive activities and project coordinators are *required* to be cognizant of and to comply with the instructions and policies that apply to both categories. It is incorrect and inappropriate to assume that an assessment activity is automatically not bound by the policies and procedures in this manual.

3.6 It is the responsibility of the principal investigator of a project to recognize that studies initiated in response to an “assessment” need may not constitute “research”, however, because of the nature of the assessment activity, the protection of the human subject participants and/or the data about them must be an important consideration. Therefore, while the activity may be conducted under the classification of “assessment”, the review process that affords the greatest protection for the human subjects and the data about them must prevail. In some instances, this protection is obtained via the Academy’s IRB process.

3.7 Per reference (i) of Enclosure (1) and as described in Section 1.5 of this policies and procedures manual, the project coordinator may **not** make the determination of the applicability of the Academy’s IRB process to activities that involve human subjects and/or the data (identified and/or de-identified) about them.

3.8 Questions as to the applicability of the policies and procedures in this manual to a quality assurance, process improvement or assessment activity must be directed to the Academy’s Human Research Protection Program (HRPP) office for resolution. This query must be submitted and a decision must be rendered by the Director of the HRPP office, in consultation with the Chair of the Academy’s IRB, before the activity is initiated. Individual principal investigators may **not** make these decisions for themselves. If the proposed activity is determined to be subject to the Academy’s IRB process, then the activity must be favorably endorsed by the Academy’s IRB and approved by the Superintendent before any aspects of the project may commence.