

### ***Section XIX: Financial Issues Associated with Research Involving Human Subjects***

19.1 Per reference (b) of Enclosure (1), federal funds administered by a department or an agency may not be expended on research projects that directly or indirectly involve human subjects or the data about identifiable human subjects unless the requirements of the applicable IRB policies for the protection of human subjects have been satisfied.

19.2 As noted in earlier sections of this document, the policies and procedures defined herein apply to **all** research studies conducted at or on behalf of the Naval Academy (USNA) and that directly or indirectly involve human subjects or the data about them. At USNA, these policies and procedures apply regardless of the source, type (federal, non-federal, direct, reimbursable, gift) or level of funding of the research; whether the research is conducted at USNA or at non-USNA facilities; and whether the research uses any institutional, DoD or DoN resources, property, facilities or assets.

19.3 Written notification of the Academy's IRB review and the Superintendent's approval of a protocol involving human subjects and/or the data about human subjects must be received by the principal investigator from the Academy's HRPP office before the PI may begin any aspect of the proposed research, including the commitment or expenditure of any federal funds in support of the project.

19.4 When **federal funds** are solicited and subsequently committed to a project involving human subjects and/or data about human subjects, all labor and material expenditures associated with the project must be properly documented during the course of the study. A final accounting record must be prepared and retained by the principal investigator at the conclusion of the project, and must be made available, if requested, to the federal funding agency or to the DoN-HRPP during any audit of the Academy's IRB.

19.5 Questions as to the applicability of the Academy's IRB policies and procedures to a funding issue on a project should be addressed to the Academy's HRPP office.