

Section XVII: Submission of Grant Applications for Projects Involving Human Subjects

17.1 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 human subjects unless the requirements of the applicable IRB policies for the protection of human subjects have been satisfied.

17.2 Federal and non-federal agencies require written documentation of an IRB approval of any proposed research that directly or indirectly involves human subjects and/or the data about human subjects before a grant award will be made. When the IRB approval must be submitted varies by funding agency. Some agencies require the IRB approval as part of the initial grant application, while others require the IRB approval before a grant award is made. It is the responsibility of the proposed project's principal investigator to learn and comply with the IRB review and documentation policy of the funding agency to which he/she is submitting a grant application.

Example: Per reference (r) of Enclosure (1), the National Institutes of Health (NIH) allows for the submission of a peer-reviewed grant application without inclusion of the approval by the IRB of the institution where the principal investigator (PI) is employed and where the research will be conducted. As part of the process at NIH, the review group considers whether the application includes the necessary safeguards to protect the rights, welfare and data of the human subjects who would participate in the research project. If the application is selected for funding, NIH requires the principal investigator for the project to submit the required IRB approval(s) before awarding the grant.

17.3 Federal and non-federal agencies require a current IRB approval before awarding a grant. If more than a year has elapsed between the initial IRB approval date on the proposed project and the anticipated grant award date, a renewal of the original IRB approval must be obtained by the principal investigator prior to the grant award date.

17.4 The grantee for funding is responsible for the protection of the rights and welfare of, and the data about, human subjects. Funding agencies consider it the responsibility of the project investigators to remain knowledgeable about the IRB requirements of their home institutions and the institutions of their research collaborators. Principal investigators are also held accountable for knowing the general HRPP policies established by the "Common Rule", as described in reference (b) of Enclosure (1).

17.5 The Academy's "IRB approval form" documents that a research protocol was reviewed via the Academy's IRB process and subsequently approved by the Superintendent. The approval date, length of the approval, category of the project ("Exempt", "Expedited" or "Full"), and project approval number assigned to the protocol is included in the documentation. Requests for an "IRB approval form" on an approved protocol should be submitted to the Academy's HRPP office.

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