REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

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NOTICE: OD-00-039

Update: The following update relating to this announcement has been issued:


(Also see Notice NOT-OD-08-054)

National Institutes of Health

Policy: Beginning on October 1, 2000, the NIH will require education on the protection of human research participants for all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects.

Background

To bolster the Federal commitment to the protection of human research participants, several new initiatives to strengthen government oversight of medical research were announced by HHS Secretary Shalala on May 30, 2000. This announcement also reminds institutions of their responsibility to oversee their clinical investigators and institutional review boards (IRBs). One of the new initiatives addresses education and training. This NIH announcement is developed in response to the Secretary’s directive.

Implementation

Before funds are awarded for competing applications or contract proposals involving human subjects, investigators must provide a description of education completed in the protection of human subjects for each individual identified as “key personnel” in the proposed research. Key personnel include all individuals responsible for the design and conduct of the study. The description of education will be submitted in a cover letter that accompanies the description of Other Support, IRB approval, and other information in accordance with Just-in-Time procedures. The use of a cover letter is also acceptable for contract proposals. After October 1, 2000, investigators submitting non-competing renewal applications for grants or annual reports for research and development contracts that involves human subjects research must also include a description of such education in their annual progress reports. This NIH policy will eventually be superceded by the DHHS Office of Research Integrity’s institutional assurance on the responsible conduct of research, which is described below.

Related Training Requirement

The Office of Research Integrity (ORI), Department of Health and Human Services, is developing a policy to implement an extension of the training requirement on the responsible conduct of research (RCR) to all persons supported by PHS research. The protection of human subjects in research will be included in the RCR institutional assurance. A draft of this policy will be posted for comment on the ORI website in June, 2000.
Educational Resources

While all investigators need education in the basics of human subjects research, some may elect more intensive study if their work involves especially difficult topics or special populations. Many institutions already have developed educational programs on the protection of research participants and have made participation in such programs a requirement for their investigators. The NIH does not plan to issue a list of “endorsed” programs. Rather, the NIH points out that a number of curricula are readily available to investigators and institutions. For example, all NIH intramural investigators and research administrators who oversee clinical projects are required to complete an on-line tutorial on the protection of human research subjects. This training can be accessed on the web site of the NIH Office of Human Subjects Research at http://ohsr.od.nih.gov/. While this training module was developed for NIH staff, it can be used by other institutions seeking to meet training requirements in this area.

To facilitate education and the development of curricula, the NIH launched a website on bioethics in 1999. (See http://www.nih.gov/sigs/bioethics/) This site is replete with resources (>4500 references) on a broad range of relevant topics, including human subjects in research, medical and healthcare ethics, and the implications of genetics and biotechnology. This website also contains a broad set of annotated web links, including some attached to training programs. In addition, the University of Rochester has made available its training program for individual investigators. Their manual can be obtained through CenterWatch, Inc. (http://www.centerwatch.com)

To address longer-term needs, the NIH has two program announcements to support training on ethical issues related to research and human subjects. The first announcement provides support (T15) for institutions to conduct short-term courses in research ethics. (See http://grants.nih.gov/grants/guide/pa-files/PA-99-051.html) The primary objectives of the T15 program are to increase knowledge among investigators regarding research ethics and to protect human participants in clinical protocols. The second announcement supports career development of individuals who are committed to a career in research ethics. These individuals will be able to serve as resources in the institutions and as catalysts in discussions of critical ethical issues in research. (See http://grants.nih.gov/grants/guide/pa-files/PA-99-050.html)

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

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