

Grant Number: 5T15AI07564-02

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Project Title: A SHORT COURSE AND CERTIFICATE PROGRAM IN RESEARCH ETHICS

Description:

This proposal aims to develop and evaluate a weeklong course on ethical issues in research with human subjects. In addition, a small number of interested individuals will be offered additional training in human subjects research issues, through participation in a Certificate Program in Research Ethics. Certificate participants will be poised to serve as resources to their communities on these issues. Specific aims of this proposal are: 1) To develop a course on ethical issues related to research with human subjects; 2) To offer the course to individuals who are involved in human subjects research, including active researchers, IRB chairs, members and administrators; 3) To provide additional education and training in human subjects research issues to a select group of interested individuals through a Certificate Program; 4) To evaluate this training program through surveys of course and certificate participants; 5) To develop a plan for continuation of the course after the expiration of the grant, including the possibility of a Web-based learning program.

The weeklong course *Ethical Issues in Research with Humans: Past, Present and Future* was first offered June 14-18, 1999. A packet of all materials associated with this course, including the brochure, agenda and syllabus are available at the March 31, 2000 meeting for your information. We aimed for 60 participants in the June 1999 course; 61 participants were admitted and ultimately 55 participants attended. Course participants represented at least 29 institutions in 14 different states. Our participants self-reported their experience in human subjects issues to be basic (22), intermediate (32), or advanced (7). Thirty-three participants were active researchers, 42 participants were affiliated with IRBs and 15 were both affiliated with IRBs and were active researchers. We awarded one waiver to a junior researcher and five waivers to minority course participants (4 Native American, 1 Hispanic). A listing of represented institutions and a participant roster is included in the packet.

The 1999 course was evaluated in two ways. First, specific aspects of the structure and content of the course and the presentations of all faculty were evaluated using 6-point Likert scales. Questions with open-ended responses also were included in this evaluation. The course evaluation tool can be found in the packet. A total of 44/55 (80%) course participants completed this evaluation; the course received an overall score of approximately 5.1/6.0. Second, course participants' expectations for the course and their knowledge and skills in areas relevant to considering human subjects issues were evaluated prior to the beginning of the course and immediately post course. These participant evaluation tools can be found in the Appendix. 51/55 participants completed the pre course evaluation; 39/55 participants completed the post course evaluation. This data is currently being tabulated and analyzed by Clarence Braddock, MD, the evaluator for the course.

The first distance learning Certificate Program is underway. Ten of the 55 participants in the June 1999 course applied and 6 were accepted. The Certificate Program distance learning workbook and a brochure describing the Certificate Program are included in the packet. Certificate Program candidates are required to complete six learning modules. Four modules are required and the candidate chooses 2-3 additional modules. Three of the required modules address core competencies in ethical protocol design and IRB review and the additional required module is an evaluated lecture to their communities. Candidates have completed the first three required modules to date.

In accordance with the original proposal, we will offer the course two more times, scheduled for June 12-16, 2000 and June 11-15, 2001. Brochures describing the June 2000 course can be found in the packet. During year 2, the course will be expanded to include research nurses, project managers and others who are highly involved in human subjects issues. At least 40 requests to participate in the 1999 course were received from individuals in this category; the number of participants will be expanded to 75; we will institute a one year follow up of our June 1999 course participants to assess the impact of the course on their human subjects-related activities and attitudes. This instrument is under development; we will evaluate the first experience of the Certificate Program; we will begin to consider the possibility of a Web-based learning program.

There are two general issues I have encountered as this project has developed and that I would love to discuss with other PIs. First, in the course of working with our course participants and certificate program candidates, they have discovered and have shared with me information about noncompliance with federal and/or state regulations pertinent to human subjects at their institutions. In some cases, this noncompliance has been egregious in nature. Happily one particular situation is now being addressed by the institution under the direction of our course participant, but others are outstanding. I am thinking about my responsibilities now that I possess this information and how best to support our candidates as they struggle with these issues. Second, it is apparent that the course and certificate program are having an effect at the institutional level and this is extremely exciting and gratifying. However, capturing the full extent of such effects is a real challenge for our evaluation because the issues of noncompliance are so sensitive that often our course participants are reluctant to even discuss such issues except under conditions of complete confidentiality.

The first year our project research assistant, Peter Poon, created an annotated bibliography of ethical issues associated with research with human participants (see packet). We will place this document on the Department of Medical History and Ethics web site.

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