

To: University Faculty and Research Staff

From: Dr. Ralph D. Amado, Vice Provost for Research

Date: August 22, 2000

Re: Required Education in the Protection of Human Research Participants

Background

For funding beginning on October 1, 2000, or later the NIH requires education on the protection of human research participants for all investigators submitting NIH applications for research involving human subjects. This education requirement applies to new grants, proposals for contracts, and competing or non-competing awards.

Funds will not be awarded for competing and non-competing applications or contracts until human subject training has been completed 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 involving human subjects. Documentation of the training must be signed by the Authorized Institutional Official and submitted to NIH.

In addition, the University of Pennsylvania plans to require and provide web-based training to all investigators and research coordinators involved in human subject research independent of source of support. A timetable for doing so will be available shortly.

School of Medicine Training

The School of Medicine has presently developed a web-based program to provide the necessary state of the art training. The program includes video training on regulatory issues and Penn policies and procedures associated with the use of human subjects in research, including a test designed to demonstrate knowledge of the materials. The program (approximately 4 hours total) is broken into multiple modules and can be completed over multiple sessions to fit your schedule. Each module is a lecture-based video presentation with slides synchronized to display as the video progresses.

The initial Certification Program will consist of the following modules:

Expedited Review Certification:

- Module 1 The Historical Evolution of Human Subjects Protections
- Module 2 The Role of the IRB in the Protection of Human Subjects in Research
- Module 3 Conflicts of Interest

These modules satisfy the training and education requirements for NIH and for SOM investigators who only submit protocols for expedited review.

Full Review Certification:

- Module 4 Good Clinical Practices (FDA Regulations)

This additional module satisfies the training and education requirements for SOM investigators whose protocols require full committee review by the IRB.

Each user is required to demonstrate an understanding of the material presented by passing a test administered via the web. Completion of the modules will result in the generation of a certification letter to be signed by the Office of Research Services authorized official. This certification will satisfy the NIH requirement for education on the protection of human subjects. The web-based program is required for all SOM investigators and research coordinators.

Technical requirements to complete the program are available on the web at <https://www.med.upenn.edu/php-bin/compliance/index.pcgi> (you will need a PAS ID and password). If you do not have access to a web browser, or your computer does not meet these requirements, you may complete this program in the School of Medicine computer training facility, which is located at 202 Anatomy-Chemistry Building or in the Biomedical Library (for headphones see front desk). If you plan on using the SOM facility please contact Sabrina Turner at turners@mail.med.upenn.edu or call at (215) 573-8800 to ensure availability.

Interim Training for Non School of Medicine Principal Investigators

The Office of Regulatory Affairs has scheduled four 90-minute training sessions for non SOM Principal Investigators and for those unable to utilize the on-line web based program. These training sessions will cover:

- University requirements for review of research involving human subjects as described in the University's Multiple Project Assurance
- Key definitions of human subject involvement in research
- Definition of exempt versus expedited and full review
- Elements of informed consent and the process of obtaining informed consent
- Requirements for continuing review
- Requirements for reporting adverse events and changes to protocols
- Inter-relationship of the ORA, ORS and the Conflicts of Interest Standing Committee.

August 24, 2000 -- 3:00 p.m. at BRB II/III Auditorium

August 31, 2000 -- 9:00 a.m. at Stiteler Hall B6

September 8, 2000 -- 9:00 a.m. at Dunlop Auditorium (Stemmler Hall)

September 12, 2000 -- 3:00 p.m. at BRBII/III Auditorium

Please bring your Penn ID.

For further assistance or information please contact the Office of Research Services at 573-8596 or Office of Regulatory Affairs at 898-2614.