

SPECIAL NOTICE ON HUMAN SUBJECTS EDUCATION REQUIREMENTS

The National Institutes of Health has mandated that key personnel listed on NIH grant applications, which utilize human subjects, undertake a prescribed education program on the protection of human subjects in research. NIH has recently clarified the requirements. The following series of questions and answers should be useful to those of you who are using human subjects in your NIH projects:

- 1.** When is documentation required? For noncompeting applications, documentation must be submitted as part of the application. For competing applications (new and renewal proposals), NIH will request documentation at the same time it requests updated information on other support, etc. ("just in time"); consequently, documentation does not need to accompany new or competing renewal proposals.

- 2.** What needs to be documented? Successful completion of an education program for all key personnel listed on the NIH grant application. This includes any listed key personnel of subawardees as well as any consultants who are listed as key personnel.

- 3.** What is acceptable education in the protection of human subjects? Our IRB has determined that the only acceptable-to-NIH educational program we have at the Health Science Center is the reading of the book "Protecting Study Volunteers in Research: A Manual for Investigative Sites" (sometimes known as the Rochester book) and taking an examination on the book's contents. Information on the availability of the book and the examination is available from the IRB office (7-2351). It should be especially noted that while the HSC IRB has determined that reading the institution's Multiple Project Assurance will suffice in some cases for the training needs of the Health Science Center, this will not be sufficient to meet the NIH requirements.

- 4.** What is acceptable documentation? NIH has stated that a letter signed by the principal investigator/project director and the authorized institutional official documenting the education program will be sufficient. OSP has prepared a form that should be used; it can be accessed from the OSP UTHSCSA forms webpage: http://research.uthscsa.edu/osp/forms_ut.shtml. For those key personnel who are consultants or at another institution (as a subawardee), we will need documentation similar to the letter we are submitting to NIH.

- 5.** What if I have further questions? For questions concerning the education program itself, please contact the IRB office at x7-2351. For questions concerning the NIH proposal requirements, please contact the Office of Sponsored Programs at 7-2340.

The text of the NIH requirement can be read at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.