

MEMORANDUM

TO: NIH-Funded Research Investigators

**FROM: Cornelius W. Sullivan, Ph.D.
Vice Provost for Research**

DATE: August 2, 2000

**RE: USC WILL SPONSOR A PROGRAM REGARDING THE
PROTECTION OF HUMAN SUBJECTS IN RESEARCH TO
MEET NIH EDUCATION REQUIREMENT**

Beginning October 1, 2000, the National Institutes of Health (NIH) will require all investigators and "key personnel" conducting research involving human subjects to provide evidence that they have received education regarding the protection of human subjects participants. The requirement applies to all investigators submitting NIH applications for grants or proposals for contracts or receiving new or non-competing awards for research involving human subjects. Before funds are awarded, 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 involving human subjects. An institutional official must co-sign the description of the completed education. **The NIH has stated that awards will not be funded without evidence co-signed by an institutional official that the education requirements have been met.**

In order to assist investigators and personnel in meeting this requirement, the University of Southern California is sponsoring an education program entitled, "Understanding the Fundamentals: Responsibilities and Requirements for the Protection of Human Subjects in Research." The program consists of five (5) one-hour live sessions and will include information regarding the ethical principles for research with human subjects, an overview of the federal regulations and the informed consent process. The last session will cover topics that are specific to the Health Sciences and University Park campuses. Participants will need to pass a web-based examination at the end of the educational series in order to successfully complete the university's program and will be certified to conduct research with human subjects for three years. An agenda is attached.

A team of individuals who have significant expertise in this area has developed the program. The faculty presenters include: Alex Capron, Professor of Law and Medicine and a nationally renowned ethicist who serves as a member of President Clinton's National

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Bioethics Advisory Commission; Darcy Spicer, Associate Professor of Clinical Medicine and Chair of the Health Sciences Campus Institutional Review Board (IRB); and Marlene Wagner, Assistant Dean for Advancement and Alumni Relations in the School of Social Work and Chair of the University Park IRB. The program is co-sponsored by the Office of the Provost and the Office of Compliance, with assistance from USC Professional Development.

The University will monitor attendance at the sessions and successful completion of the web-based exam. The Provost's office will sign off on those applications, awards and proposals where the investigator and key personnel have successfully completed this program.

All investigators and research personnel doing human subjects research, regardless of their source of funding, are encouraged to attend this program.

The sessions will be provided twice each year at both the University Park and Health Sciences campuses. The fall 2000 series will begin in August 2000. The spring series will not begin until late January 2001.

IF YOU EXPECT TO SUBMIT TO THE NIH AN APPLICATION OR PROPOSAL FOR A GRANT OR CONTRACT OR IF YOU ANTICIPATE RECEIVING A NEW OR NON-COMPETING AWARD FOR RESEARCH INVOLVING HUMAN SUBJECTS THIS FISCAL YEAR, PLEASE ENSURE THAT YOU REGISTER FOR EITHER THE FALL OR SPRING EDUCATION PROGRAM IN ORDER TO PROTECT YOUR SOURCE OF SUPPORT.

Pre-registration for the program is required. Please call (213) 740-9412 to register via voicemail or contact the Office of Compliance at (213) 740-8258 if you have further questions.

Attachment

cc: Lloyd Armstrong, Jr., Ph.D.
Dennis Dougherty
Stephen J. Ryan, MD
Executive Research Compliance Committee