



MEMORANDUM

Office of the Provost

Dr. Cornelius W. Sullivan
Vice Provost for Research

TO: Deans, Vice Presidents, Directors, Senior Business Officers, Principal Investigators

FROM: Cornelius W. Sullivan
Laura L. LaCorte

DATE: September 8, 2003

SUBJECT: Protection of Human Subjects in Research -
Education Recertification for NM Projects

Process for Recertification

Since October 2000, the National Institutes of Health (NIH) has required all "key personnel" conducting research on human subjects on NIH-sponsored projects to provide evidence that they have completed an education program regarding the protection of human subjects in research. "Key personnel" is defined in the Form 398 as individuals who are involved in the design and conduct of the study, including investigators and co-investigators on the respective project. The NIH does not provide funding until all key personnel have completed education in this regard. For each NM proposal involving human subjects, the university must certify that the key personnel on the project have satisfied the education requirement in order for the project to obtain funding.

As you know, USC developed a comprehensive education program in response to the NM mandate, which calls for key personnel to complete an education program every three (3) years in order to maintain their certification.

For many of you who completed your initial education in September 2000 and soon thereafter, your three-year certification period will expire beginning September - October 2003. You will need to be recertified in order for the university to represent that you are in compliance with the NIH's education requirement.

Key personnel on NIH grants can be recertified in one of two ways:

1. The university is providing an automatic recertification for those individuals who:

- Completed the human subjects education program between **October 2, 2000 and December 31, 2001** (i.e., attended the live sessions or watched the videos and passed the online exam); AND
- Have completed USC's online HIPAA education program.

Since the USC Office of Compliance maintains records in connection with both programs, they will determine who qualified for recertification and will provide that information directly to the Department of Contracts and Grants. The Department of Contracts and Grants will notify the NM of those key personnel who have been recertified and, therefore, eligible for NIH funding. This process will be completed between those respective offices. **No further follow up is required from investigators or their staff.**

2. For those investigators who are not required to complete the HIPAA education program (e.g, they do not conduct research involving identifiable health information), or who completed the initial human subjects education program on or after January 1, 2002, the university will be providing a series of one-hour live sessions beginning this fall, which also will be available by video and the web. Investigators and key personnel will be required to attend one 1-hour live or video presentation to obtain recertification. A schedule of classes as well as other information about the recertification requirements will be available on the compliance webpage at: www.usc.edu/compliance.

Individuals who received waivers from USC's program for initial certification most likely will be required to satisfy the recertification requirement set forth above. Individuals with waivers should contact the Office of Compliance for further clarification.

Changes to the Initial Education Program

As of this fall 2003, the current human subjects education program will be converted to an online program for first time participants. We believe that the program will be more accessible and easier to complete in this format. The program consists of several videos streamed over the web, followed by exam questions and case studies. Further information will be available on the Office of Compliance web site at: www.usc.edu/compliance.

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If you have any questions about the process for recertification for the changes to the current education program, please call the Office of Compliance at (213) 740-8258.

cc: Darcy Spicer, Chair, HSC Institutional Review Board
Marlene Wagner, Chair, University Park Institutional Review Board