USC Prepares for the HHS Conflict of Interest Regulations

As announced in the Winter 2012 Issue (http://ooc.usc.edu/research-compliance-newsletter), HHS has issued revised Conflict of Interest regulations which go into effect on August 24, 2012. The regulations impose significant new obligations on institutions and researchers who seek or have received support from the National Institutes of Health (NIH) or any other Department of Health and Human Services (HHS) sponsor (i.e. CDC, HRSA).

As of August 24, all HHS funded researchers must make an annual disclosure of all of their financial interests related to their USC job responsibilities before they will be able to submit proposals to HHS agencies or access funds on new or continuing HHS awards. HHS researchers must submit an annual disclosure even if they do not have any outside interests to disclose.

USC has developed an online system called, "diSClose," to assist researchers in making their disclosures. diSClose will be available for investigators to complete their annual HHS disclosures later this summer. More details on the release schedule and announcement of a new USC Conflict of Interest in Research Policy will follow.

Announcement of HHS Required Training Offering

Another requirement of the new HHS regulations is that all researchers with proposed or existing HHS support must be trained on the new requirements and the university’s policies and procedures to address them. The training must be completed on or before the effective date of the revised regulations, and at least once every four years thereafter. Once the rule goes into effect, training is required in order to engage in NIH funded research.

In order to satisfy the training obligation, six live sessions will be offered (four on the Health Sciences Campus and two on the University Park Campus). The sessions will last approximately one and a half hours and will explain the new rules and the steps the university is taking to ensure that researchers adhere to them. In particular, the sessions will provide training on how to use diSClose.

The available sessions currently scheduled are as follows:

Health Sciences Campus
July 9, 2012 at 12 pm -- Location: Aresty Auditorium (Harlyne Norris Research Tower)
July 23, 2012 at 12 pm -- Location: Aresty Auditorium (Harlyne Norris Research Tower)
August 6, 2012 at 12 pm -- Location: Aresty Auditorium (Harlyne Norris Research Tower)
August 20, 2012 at 12 pm -- Location: Aresty Auditorium (Harlyne Norris Research Tower)

University Park Campus
August 7, 2012 at 10 am -- Location: The Forum (Tutor Campus Center)
August 21, 2012 at 10 am -- Location: The Forum (Tutor Campus Center)

For those who are unable to attend the sessions, USC will also be offering on-line training via CITI (Collaborative Institutional Training Initiative). CITI currently provides required training at USC for those who conduct human subjects research. The on-line training will be available later this summer, and will be announced separately.

If you have any questions about the new regulations or the training, contact Benjamin Bell, bbell@ooc.usc.edu, or Daniel Shapiro, dshapiro@ooc.usc.edu, in the Office of Compliance, or call (213) 740-8258.

NIH Piloting Review of $1.5m PIs

The NIH recently announced pilot procedures for a Council review of research applications for principal investigators (PIs) with more than $1.5 million in annual NIH support. NIH noted that the pilot is designed to manage resources "during austere times," and "does not represent a cap on total NIH funding for any one investigator."

The pilot program is designed to evaluate investigator-initiated research project grants (RPGs) and will exclude requests for applications (RFAs). Investigators should continue to submit applications as planned but be aware of the additional layer of review.

Auditor Focus on Current and Pending Support

Several recent audits and reviews have focused on the requirement that applicants disclose other sources of funding on sponsored project applications. Sponsors use this information to avoid funding research already funded by other government and private entities. As a result of one audit, the Department of Justice recently charged a professor with research fraud for stating there was no other funding in a Department of Energy grant application after he had already received a grant from the NSF.

While agency requirements differ on when and how other sources of support must be disclosed, there are two general rules to keep in mind:

- Be transparent about current and pending sources of support in grant applications.
- Be explicit about the scope of work in grant applications, especially when applying for multiple projects in a similar area.
Additional resources are below or check with the sponsor for additional information:


**USC ISO Partners with the FBI**

The FBI National Counterintelligence Executive brings to you the following informational guidelines on things you should know before you travel and ways to protect intellectual property:

**Traveling Overseas with Mobile Phones, Laptops, PDAs, and Other Electronic Devices**

**Intellectual Property Protection - Safeguard Trade Secrets, Proprietary Information and Research**