Issue 12, Fall 2016

This newsletter is prepared by the Office of Compliance and is intended to provide you with current information about research compliance issues. For additional information, to view past newsletters, or to provide comments about this or any future issues of this newsletter, please contact the Office of Compliance at (213) 740-8258 or at compliance@usc.edu.

The USC Help & Hotline can be used by all faculty, staff, and students to report suspected violations of an applicable law, regulation, or university

Nominate Your Ethics in Action Hero

DO YOU KNOW AN ETHICAL ROLE MODEL WHO:

- Demonstrates a commitment to our Code of Ethics?
- Serves as an example to others through their actions and decisions?
- Sets high standards for themselves and others in the workplace?

If you answered yes to any of these questions, the USC Office of Compliance would like you to let us know about your "Ethics in Action" hero today!

YOUR STORIES WILL BE FEATURED IN UPCOMING COMPLIANCE PUBLICATIONS AND NEWSLETTERS.

FORMAT	A write-up in 500 words or less in the body of the email or as a PDF or Microsoft Word attachment
CONTENT	Who is your Ethics in Action hero? How did they demonstrate a commitment to our Code of Ethics? How do they inspire others to do the same?
SUBMIT	Send email to compliance@usc.edu
DEADLINE	Friday, December 2, 2016

Heads Up! Changes from the NIH

The National Institutes of Health (NIH) has recently announced three policy changes that will affect researcher conducting human subjects research.

1) ***GCP Training*** - Effective January 1, 2017, the NIH will require investigators and trial staff conducting clinical trials to receive "good clinical practice," or GCP, training. The new requirement will be in

policy confidentially and without fear of retribution. The Help & Hotline can also be used to ask questions about applicable laws, regulations, and university policies that may impact your job duties.

*The USC Help & Hotline is staffed 24 hours a day, 365 days a year: (213) 740-2500 or file on the web and enter **UOSC** as the access code.*

addition to mandated training on human subjects protections. Because USC already mandates GCP training for investigators and staff involved in clinical trials, the impact of this rule change is likely to be minimal, but the NIH's new requirement highlights the importance of GCP training for those involved in the conduct of clinical trials. For more information on USC's GCP training, which is offered through USC's Office for the Protection of Research Subjects (OPRS), please visit: http://oprs.usc.edu/education/good-clinical-practice-gcp-training/

To review NIH's GCP training policy, please visit: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html

2) ***ClinicalTrials.gov Rule Expands Reporting*** - On September 16th, 2016, HHS issued a final rule that sets forth expanded requirements for registration and reporting results information to clinicaltrials.gov on FDA-regulated drug, biological, and device products. Simultaneously, NIH issued a complementary policy requiring registration and reporting results information to clinicaltrials.gov on all NIH-sponsored clinical trials, regardless of whether the trial is covered by the HHS Final Rule. Both the HHS Final Rule and the NIH Policy go into effect on applicable clinical trials with a primary completion date on or after January 18, 2017. Compliance with the expanded data elements will be required effective April 18, 2017.

Registration of an applicable clinical trial must be submitted no later than 21 days after enrollment of the first participant, and the data that must be reported includes participant flow; demographic and baseline characteristics; primary and secondary outcomes, as well as results of any scientifically appropriate statistical tests; and adverse event information. In addition, the rule requires submission of the full protocol and statistical analysis plan.

For a summary of the key changes in the new registration and reporting requirements, please visit:
HHS clinicaltrials.gov Final Rule
NIH Policy on Dissemination of Clinical Trial Information
Summary of changes to clinical trial reporting obligations

3) ***FOAs and Abolishment of Investigator-initiated Funding*** - On September 16, 2016, NIH issued a revised Policy on Funding Opportunity Announcements (FOA) for Clinical Trials. The Policy, which has a target effective date of September 27, 2017, provides that NIH will no longer accept clinical trial applications through 'parent' FOA announcements or through other FOAs that are not specifically designed to accept clinical trials. NIH will only sponsor clinical trials vis-à-vis clinical trials-specific FOA's that it issues. The change in large measure will abolish investigator-initiated funding for NIH-sponsored clinical trials.

To review the Policy, please visit:
NIH Policy on FOA's for Clinical Trials

Columbia University to Pay Back $9.5 million to the NIH to Settle Fraud Charges

The Justice Department recently announced that Columbia University has agreed to pay $9.5 million to resolve allegations that it improperly charged the National Institutes of Health (NIH) for facilities and administrative costs on more than 400 federal grants. Prosecutors alleged that the Ivy League school inflated the amount of money it charged for use of facilities from July 2003 to June 2015.

Universities generally negotiate different indirect cost rates for research conducted on-campus versus off-campus. The on-campus rate is usually significantly higher because of maintenance and operations expenses associated with buildings located on campus. According to the Justice Department, Columbia faculty carrying out federally sponsored research in off-campus buildings owned by the state of New

York inappropriately charged the higher on-campus rate on several hundred grants.

"It is disturbing that Columbia University, a prestigious institution, would improperly seek excessive cost reimbursements from NIH," said Scott J. Lampert, a special agent in the Office of the Inspector General's Department of Health and Human Services, in a statement. "Money gained by such behavior deprives other research programs of funds that could yield life-altering new treatments."

The federal government has been cracking down on researchers and research institutions that it believes are misusing grant money. Last year, the University of Florida paid nearly $20 million to settle allegations that it overcharged the government for the salaries of its employees without documenting their contributions and that it inflated the cost of services performed by a contractor. West Virginia's Wheeling Jesuit University agreed last August to pay $2.3 million to settle claims that it misappropriated research grant funding for over a decade. Around the same time, the National Science Foundation ordered Northeastern University in Boston to pay back $2.7 million for nearly a decade of allegedly mismanaging grant money from the agency.

Read the full article here: http://www.washingtonpost.com/news/grade-point/wp/2016/07/14/columbia-university-to-pay-9-5-million-to-settle-fraud-charges/

NSF OIG's Words to the Wise on Travel Cards May Help Awardees

Are university faculty and research staff who travel appropriately using institutional travel charge cards, "purchase cards" or similar credit cards? Are cards quickly cancelled when an employee leaves? Do workers receive training on how to use the cards? And is anyone checking to make sure the charges are appropriate, and imposing sanctions when they're not?

These were the questions the National Science Foundation Office of Inspector General (NSF OIG) recently explored during a review of two NSF travel card programs following a critical 2005 OIG audit. But the questions NSF is asking of itself also can help research compliance administrators at USC focus their efforts related to appropriate use and oversight of such cards.

While this was an internal review, travel reimbursements are also a chief focus of the ongoing NSF Data Analytics audits. All travel charged to sponsored awards must clearly benefit the award and be properly documented.

You can read more about NSF's internal review here: http://www.nsf.gov/oig/_pdf/15-2-008-travel-card.pdf