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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

Orientation to Clinical Research Course Offered on February 12 and February 19th

The Office of Research, along with the Office for Protection of Research Subjects (OPRS), Clinical Trials Office (CTO), Clinical Investigations Support Office (CISO), Clinical Trials Unit (CTU) and the Office of Compliance, will be sponsoring the second two-day orientation course for research coordinators, data managers and new clinical investigators.

The course will be offered in two parts. The first session will be on Wednesday, February 12th and the second will be on Wednesday, February 19th. Both sessions will be from 8:00 a.m. to 12:00 p.m. in the Broad (CIRM) Center, 1st Floor Seminar Room on the Health Sciences Campus. Those who attend both sessions will receive a certificate of completion.

Topics include:

- University Offices and Entities
- Clinical Research Roles: An Overview
- Planning Research (Protocol Development) Contracting
- Financial Management and Budgeting
- Coordination of Ancillary Services/Support
- IRB and Human Subjects Protection
- iStar/Other Electronic Systems
- Coordinating a Study
- Compliance

To RSVP, visit http://www.usc.edu/esvp and use the word ***clinical*** as your registration code. For any questions, email: vprsch@usc.edu

NSF OIG Releases 2014 Workplan

The National Science Foundation (NSF) OIG recently published their 2014 Work Plan http://www.nsf.gov/oig/2014auditplan.pdf. As in the work plans from previous years, the NSF OIG is focused on two main areas:

- ***ARRA audits***: The NSF OIG will select awardees to audit their compliance with the Recovery Act, award terms and conditions, and federal administrative cost principles.
- ***Financial and Program Accountability***: The NSF OIG will continue to review annual Single Audit reports of NSF awardees and conduct quality control reviews of selected A-133 audits. Also included in this area are internal reviews of NSF programs

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and operations, including lessons learned from the government shutdown.

'Sunshine Act' Final Rule Clarifies the Handling of Research Payments

As of August 2013, "applicable manufacturers of drugs, devices, biologicals, or medical supplies" are required to report any payments or transfers of value of $10 or more to physicians and teaching hospitals. These payments will be reported to the Health and Human Services Centers for Medicare & Medicaid Services (CMS). CMS will then post these payments on a public database starting this summer. For more information on this rule, nicknamed the 'Sunshine Act', refer to the Summer 2013 Healthcare Compliance Newsletter: http://ooc.usc.edu/sites/ooc.usc.edu/files/pdfs/Healthcare-Compliance-Newsletter_Summer-2013.pdf

Of particular interest to our clinical researchers is the treatment of clinical trials and research grants from drug and device manufactures. These payments will be reported but will be listed in a separate section that distinguishes them from personal transfers of value such as consulting payments. Basic information such as the business address for the principal investigator and teaching hospital as well as the physician's name and specialty will be reported. The "total amount of the research payment, including all research related costs for activities outlined in a written agreement", "the name of the research study", and the "name(s) of any related covered drugs, devices, biologicals, or medical supplies" will also be reported.

For more information, please consult the Federal register Notice here: https://federalregister.gov/a/2013-02572

DHHS and NIH Salary Cap for 2014 Increases to $181,500

The NIH salary cap on extramural grants has been increased from $179,700 to $181,500 for the 2014 government fiscal year to reflect the increase in the Executive Level II salary cap.

As always, investigator effort can only be charged to an NIH award in proportion to the effort expended on the award. For example, if an investigator performs 10% effort in a given month on an award subject to the cap, he or she can charge 10% of the monthly cap rate. The monthly cap rate would be $181,500 divided by 12 months, or $15,125. The allowable NIH salary charge for the month would be 10% of $15,125, or $1,512.50. Any difference between 10% of the investigator's monthly salary and $1,512.50 has to be paid from another source.

The NIH has published additional guidance, available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-043.html

OMB Uniform Administrative Requirements, Cost Principles, and Administrative Requirements for Federal Awards Released

The Office of Management and Budget (OMB) released final guidance

titled "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" on December 26, 2013. This guidance is referred to as A-81, the "Super Circular", or the "OmniGuidance", and replaces eight existing OMB Circulars, including A-21, A-110, and A-133. OMB has been working on this guidance for over two years with the idea that it will reduce administrative burden, streamline operations and administration of federal awards, while also strengthening the government's oversight capabilities.

The Super Circular is expected to go into effect on December 26, 2014. There are several positive changes and also areas where further clarification is needed before the impact on colleges and universities will be clear. Several key changes are summarized below:

- 200.203 Notices of Funding Opportunities. This requires that funding agencies make funding opportunities available for at least 60 days unless the agency determines that a shorter availability period is needed. Funding opportunities must be available for at least 30 days in all cases.
- 200.306 Cost sharing or matching. Voluntary committed cost sharing is not expected in research proposals. This reduces the burden associated with identifying funds to be used for cost sharing and tracking cost sharing expenditures.
- 200.413 Direct costs. Direct charging of administrative and clerical salaries may be appropriate if all of the following conditions are met: (1) integral to a project or activity; (2) individuals can be specifically identified; (3) such costs are explicitly included in the budget or have the prior written approval of the Federal awarding agency; and (4) the costs are not also recovered as indirect costs.
- 200.453 Materials and supplies costs, including costs of computing devices. Materials and supplies used for the performance of a Federal award may be charged as direct costs. In the specific case of computing devices, charging as direct costs is allowable for devices that are essential and allocable, but not solely dedicated, to the performance of a Federal award.
- 200.461 Publication and printing costs. Colleges and universities may charge the Federal award before closeout for the costs of publication or sharing of research results if the costs are not incurred during the period of performance of the Federal award.