

COUNCIL ON GOVERNMENTAL RELATIONS
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February 15, 2017

AGENDA

MEETING OF THE COUNCIL ON GOVERNMENTAL RELATIONS

WASHINGTON MARRIOTT HOTEL
February 23-24, 2017

Planning information for the upcoming meeting of the Council on Governmental Relations was sent to the COGR Listserve in early January 2017. Those planning to attend should make hotel reservations at the Washington Marriott Hotel at 1221 22nd Street, N.W., Washington, D.C. and should send registration notices along with registration fees to the COGR office. There is a block of rooms reserved for COGR participants and **must be booked by Friday, February 3, 2017 (extended)**. After this block fills, reservations will be accepted only on a space and rate available basis. There may still be rooms available at the hotel, but not at the COGR rate. For reservations already made, changes should be made by telephone to the hotel (202-872-1500) and by email to the COGR office at trusso@cogr.edu. Meeting registration cancellations must be received in writing, preferably via email to trusso@cogr.edu, **no later than Friday, February 17, 2017** to receive a refund of the registration fee.

Thursday, February 23, 2017

- 8:30 a.m. **Registration**
- 10:00 a.m. – 11:00 a.m. **Thursday Morning Concurrent Sessions** –

Single Audit Under the Uniform Guidance

Partners from KPMG and PwC, plus a representative from the AICPA, will provide perspectives on Single Audits being conducted under the Uniform Guidance. We encourage you to raise specific examples, or concerns, that are relevant to your institution.

Universities' Implementation of the NIH Single IRB Policy

In follow-up to the October COGR meeting presentation, COGR board and committee members Sara Bible, Stanford University; Martha Jones, Washington University; Kerry Peluso, Emory University; and Cindy Kiel, University of California, Davis, will provide an update on implementation of the NIH Policy on the Use of a Single IRB for Multi-Site Research. The presentation will include the approach each institution is taking to implement the policy and establish costs. Current guidance and FAQs will also be discussed.

- 11:00 a.m. – 11:15 a.m. - **Break**

- 11:15 a.m. – 12:00 Noon **Thursday Morning Single Session** –

What to Expect of Enactment of Legislation to Reduce Research Regulatory Burden

Three bills with implications for how federally funded research is regulated were passed in December 2016 and subsequently signed into law. The 21st Century Cures Act sets in motion many of the recommendations made by the National Academies Committee on Federal Research Regulations and Reporting Requirements. The law includes a Research Policy Board made up of federal members from agencies that fund academic research and non-federal members from academic or other non-profit research institutions with the goal of reducing regulatory burden for federally funded research. The bill also includes a number of other measures aimed at reducing regulatory burden. The American Innovation and Competitiveness Act (AICA) includes an interagency working group with similar objectives, and both the AICA and the National Defense Authorization Act create a \$10,000 or higher micropurchase threshold. We will discuss all aspects of these bills with implications for research institutions, how the new laws are being implemented, and how COGR is engaging and will engage in the implementation process. There will be some discussion on what to expect from the new administration and congress; the regulatory freeze, and the recent executive order “Reducing Regulation and Controlling Regulatory Costs.” Kei Koizumi, Visiting Scholar for Science Policy, AAAS, and former Assistant Director for Federal R&D, White House Office of Science and Technology Policy, will join us as a discussant.

- 12:00 Noon – 1:00 p.m. – **Buffet Lunch**
- 1:00 p.m. – 2:00 p.m. – **Maria Zuber, Chair, National Science Board** Dr. Maria T. Zuber, Chair of the National Science Board and Vice President for Research at MIT. Dr. Zuber will discuss her vision for the NSB and the recent development of NSF Ideas for Future Investment.
- 2:00 p.m. – 2:30 p.m. – **F&A Survey Update and Executive Summary.** An update to the membership on the results of the F&A Survey and the roll-out schedule of reports.
- 2:30 p.m. – 2:45 p.m. - **Break**
- 2:45 p.m. – 4:00 p.m. – **Human Subjects Regulations – NIH sIRB Policy and the Common Rule**

In follow-up to an October 24 letter requesting delayed implementation of the NIH sIRB Policy and September 23 letter identifying implementation concerns, COGR has been working with NIH staff to resolve issues related to implementation. Michelle Bulls, Director, NIH Office of Policy for Extramural Research Administration (OPERA); Diane Dean, Director, Division of Grants Compliance and Oversight, OPERA; and Samantha Tempchin, Assistant Grants Compliance Officer, OPERA, will discuss current guidance. Topics to be discussed include differentiating and tracking “primary” and “secondary” review activities; removing IRB costs from indirect costs rates; use of service or “recharge” centers for all IRB activities; NIH’s position on administrative supplements and IT infrastructure grants; and applying for exemptions.

A revised Federal Policy for the Protection of Human Subjects, the “Common Rule,” was published on January 19, 2017. The final rule does not expand the definition of “human subject” to include non-identified biospecimens; extend Common Rule coverage to non-federally funded clinical trials; or adopt the privacy and security provisions proposed in the NPRM. The rule does mandate the use of a single IRB for multisite studies across Common Rule agencies. Jerry Menikoff, Director, HHS Office for Human Research Protections, will discuss the final rule and its implications for research. The rule is currently subject to a 60-day review period by the new administration.

- 4:00 p.m. – 4:15 p.m. - **Break**
- 4:15 p.m. – 5:30 p.m. – **Public Access** RCA will convene a panel discussion to share concerns and seek audience participation on the data aspects of the [OSTP memo](#). The panel will be moderated by Jackie Bendall, COGR along with panel members, Jim Luther, AVP Finance & Compliance Officer, Duke University, Stephanie Endy, Assoc. VP for Research, Case Western University and Tobin Smith, VP for Policy, Association of American Universities (AAU). The panel will provide a regulatory overview of the OSTP Public Access requirements for publications and data, current status of various agencies, the AAU and APLU public access working group initiative and a discussion on the costing implications and implementation and operationalization aspects of the public access mandate.
- 5:30 p.m. – 8:00 p.m. – **Cocktail Reception & Buffet Dinner**

Friday, February 24, 2017

- 7:30 a.m. – 8:30 a.m. - **Buffet Breakfast**
- 8:30 a.m. – 9:15 a.m. **NSF Intergovernmental Personal Act Program and Pilot**

Erwin Gianchandani, Deputy Assistant Director, Directorate for Computer and Information Science and Engineering, NSF, will discuss the agency’s management of the Intergovernmental Personnel Act (IPA) Program. NSF’s use of IPAs is greater than that of any federal agency, with 176 NSF IPAs in FY15 primarily acting as program officers and executives. NSF’s Independent Research and Development Program allows IPAs to spend up to 50 work days a year on independent R&D and over 90% of IPAs participate in the program. The program also allows IPAs to return to their home institution regularly to attend to research and institutional obligations. In response to two OIG reviews, NSF has developed a pilot program for 2017 to address concerns about cost. Dr. Gianchandani will discuss the benefits of the IPA program and details of the pilot.

- 9:15a.m.-10:00 a.m. – **AUTM Update** Stephen Susalka, Ph.D, CLP, Executive Director of the Association of University Technology Managers (AUTM) will provide an update on current AUTM activities and initiatives.
- 10:00 a.m. – 10:15 a.m. – **Break**
- 10:15 a.m. – 10:45 a.m. – **OMB Update.** Update on the Uniform Guidance (OMB has been invited, acceptance is pending).
- 10:45 a.m. – 12:00 Noon – **COGR Committee Reports**
 - Research Compliance and Administration**
 - Contracts and Intellectual Property**
 - Costing Policies**
 - Research & Regulatory Reform**
 - (Members are encouraged to submit advance questions and issues for Friday morning’s discussion to trusso@cogr.edu)**
- 12:00 Noon – **Adjournment**