**June 2012 COGR Meeting Agenda**

Author: COGR Staff

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# COUNCIL ON GOVERNMENTAL RELATIONS

**1200 New York Avenue, N.W., Suite 750, Washington, D.C. 20005**
**(202) 289-6655/(202) 289-6698 (FAX)**

**May 15, 2012**

## AGENDA

## MEETING OF THE COUNCIL ON GOVERNMENTAL RELATIONS

**WASHINGTON MARRIOTT HOTEL**
**June 7 and 8, 2012**

Planning information for the upcoming meeting of the Council on Governmental Relations was sent to the COGR Listserve in April 2012. 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. Those planning to attend will want to make their travel and hotel reservations. There is a block of rooms reserved for COGR participants. After this block fills, reservations will be accepted only on a space and rate available basis.

The hotel has established May 22, 2012 as the cut-off date for receipt of reservations. There may still be rooms available at the hotel, but these would not have the COGR rate. For reservations already made, changes should be made by telephone to the hotel (202-872-1500) and by FAX to the COGR office (202-289-6698). Cancellations must be received in writing, via fax or mail, no later than Thursday, May 31, 2012 to receive a refund of the registration fee.

**Thursday, June 7, 2012**

- 8:30 a.m. **Registration**

- 10:00 a.m. – 11:45 a.m. – **Thursday Morning Sessions** – There will be three concurrent sessions:

- **Financial Reporting, Cash Requests, Electronic Systems, and the Burdens They Bear – Managing a Federal Labyrinth**

  The momentum behind enhancing accountability and transparency at the Federal government level remains strong. This has been demonstrated over the past five years in the form of FFATA, ARRA, and most recently, the DATA (H.R. 2146 was passed by the House on April 26th and a separate version currently is being prepared for consideration by the Senate) and GRANT Acts.

  Also, we constantly must workaround agency-specific activity such as the expected 2013 release of a new NSF Cash Payment system and recent system/access changes with DOD's Wide Area Workflow system (WAWF). And if that is not enough, Executive Order 13576, "*Delivering an Efficient, Effective, and Accountable Government*" (issued June 13, 2011) reinforces the theme of accountability and transparency via the creation of the Government Accountability and Transparency Board (GATB).

This session will include several Case Studies of how institutions manage the Federal financial reporting and post-award management burden, and will address these questions:

- How do institutions organize around Federal reporting and post-award management (e.g., financial reporting, invoicing/payment systems, etc.)? Are there "effective practices"?
- Do differences in practices employed, expectations, and systems used by each Federal agency create inefficiencies?
- Which agency-specific reporting practices, expectations, and/or systems are the most problematic? The best?
- How did institutions organize around ARRA reporting and how sustainable would these models be if similar reporting is implemented under the DATA Act?
- How can our community quantify / demonstrate the reporting and post-award management burden to Federal policymakers? Can we quantify the burden in terms of cost of systems, cost of doing business, cost of compliance, etc.?

While one important take-away could be the identification of "effective practices" currently being employed at research institutions, even more important may be the crystallization of new advocacy/talking points that can succinctly demonstrate the real cost burden associated with Federal financial reporting and post-award management.

- **The Challenge of MTAs**

The continuing proliferation of Materials Transfer Agreements (MTAs) is requiring increased staff resources and efforts at many COGR member institutions, involving both sponsored research and tech transfer offices. In a recent AUTM survey of approximately 80 U.S. and Canadian universities two-thirds reported receiving 100 or more incoming MTAs in 2008, with 25% reporting receiving more than 300, the majority from other academic institutions. Yet for academic-academic transfers, only 31% reported receiving the NIH Uniform Biological Material Transfer Agreement (UBMTA) and 15% the NIH Simple Letter Agreement (SLA). An AUTM working group has been developing information on barriers to use of the UBMTA/SLA and best practices. Representatives of the working group will discuss the status of the group's discussions and potential suggestions. NIH representatives will provide an update and demonstration of the new NIH electronic MTA system (Transfer Agreement Dashboard) aimed at streamlining the process. While some institutions have committed to transferring materials without formal agreements in certain circumstances (as called for in a recent National Academy report), the burden of MTAs does not appear to have significantly diminished. This session will focus on whether it is possible to develop new or updated standardized agreements that will receive widespread use, and the potential role of NIH in this process.

- **Financial Conflicts of Interest: Policy and Procedures for NIH Regulations** - The membership asks; we deliver. We'll revisit the topic of implementing the Public Health Service/National Institutes of Health (PHS/NIH) Promoting Objectivity in Research (a.k.a. Financial Conflicts of Interest – FCOI) regulations during this discussion. We encourage members to pose questions before the meeting (as well as during the discussion) for our experts (YOU!) to answer. One topic to be discussed will be designing a process to preserve and, in

the future, collect data on the costs and burdens of implementing the new regulations. This data preservation and collection effort will be in preparation for NIH's planned evaluation of the regulations in three years. Our ability to effectively describe the burden and costs of implementation – particularly with regard to the change in the de minimis, public accessibility and travel disclosure requirements – will strengthen a request for changes. Other topics could include: training strategies (how and when); travel disclosure (criteria for review) and managing foreign subawardees' compliance. On the latter question, a proposed model subawardee FCOI policy will be presented and discussed as a strategy for minimizing the prime awardee's responsibilities. We welcome your questions; your expertise; and your ideas.

- 12:00 Noon – 1:00 p.m. – **Buffet Lunch**

- 1:00 p.m. – 2:00 p.m. – **Guest Speaker** –Tom Kalil, Deputy Director for Policy, OSTP - On April 9, 2012, the White House Office of Science and Technology Policy (OSTP) announced that it will convene a Grand Challenges conference this summer, highlighting the progress the Administration has made on existing Grand Challenge initiatives and recognizing new commitments and actions by Federal agencies, companies, philanthropists, universities, and non-profits to set and meet Grand Challenges. A number of organizations are already demonstrating the impact of setting sights on Grand Challenges. Tom will describe the Grand Challenges initiative in detail, how it fits into the President's Strategy for American Innovation, and the important role for research universities in this effort.

- 2:00 p.m. – 2:15 p.m. **– Break**

- 2:15 p.m. – 3:45 p.m. - **Dual Use Research of Concern: Federal Policy and Institutional Responsibilities** - The recently released US *Government Policy for Oversight of Life Sciences Dual Use Research of Concern* (DURC) describes the principles and processes for the government's review and management of "life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat." Amy Patterson, Director of the National Institutes of Health's (NIH) Office of Science Policy and Office of Biotechnology Activities (OBA), will join us to discuss the new government-wide policy and the implementation of the policy at the interagency and NIH levels. Dr. Patterson will describe the government's continuing interest in identifying institutional roles and responsibilities in "minimizing the risk of misuse of the knowledge, information, products, or technologies provided by [life sciences] research." She will be joined in this discussion of dual use research by William Mellon, Associate Dean for Research Policy at the University of Wisconsin-Madison, and Wayne Thomann, Director of Occupational and Environmental Safety at Duke University. Drs. Mellon and Thomann will focus their discussions on how institutions have been and can address the review and management of DURC. Their insight and expertise can offer examples of effective institutional practices for managing DURC in partnership with the Federal government.

- 3:45 p.m. – 4:00 p.m. – **Break**

- 4:00 p.m. – 5:30 p.m. **– NCATS: The Challenge of Translational Science -** On May 3 the new NIH National Center for Advancing Translational Science issued an RFI and RFA for the new NIH—Industry Pilot Program: "Discovering New Therapeutic Uses for Existing Molecules." This is a limited pilot program to explore new therapeutic uses for drugs made

available by three pharmaceutical companies (Eli Lilly, Pfizer, and AstraZeneca). Investigators will submit proposals for cooperative agreements to assess the efficacy of drugs rescued and repurposed for new disease areas. NIH has negotiated template Confidential Disclosure (CDA) and Cooperative Research (CRA) Agreements with each company, which will need to be executed by each investigator's institution with the company providing the drug candidate. Under the CRAs the company will receive an option for an exclusive commercial license to any new drugs developed under the program. If successful, NCATS plans to expand the program to include additional pharma and biotech companies and new therapeutic agents.

Dr. Thomas Insel, Acting Director of NCATS and the Director of the NIH Institute for Mental Health, will discuss the opportunities and challenges associated with the new program and other NCATS initiatives in a panel discussion. Joining him on the panel will be two COGR Board members: Dr. Charles Louis, Vice Chancellor, Research at University of California, Riverside and currently Chair of the COGR Contracts and Intellectual Property Committee and Dr. David Wynes, Vice President for Research Administration at Emory University and current COGR Board Chair. This will be a chance to learn firsthand about this new and highly visible NIH initiative and the opportunities and challenges it will present for COGR member institutions.

- 5:30 p.m. – 6:30 p.m. **- Reception**

- 6:30 p.m. - **Dinner**

**Friday, June 8, 2012**

- 7:30 a.m. – 8:30 a.m. - **Buffet Breakfast**

- 8:30 a.m. – 9:00 a.m. - **Association Update** – Matt Hourihan, Director, R&D Budget and Policy Program, American Association for the Advancement of Science

- 9:00 a.m. – 10:15 a.m. - **COGR Committee Reports**

  **Research Compliance and Administration**
  **Contract and Intellectual Property**
  **Costing Policies**

- 10:15 a.m. – 10:30 a.m. - **Break**

- 10:30 – Noon – **Continue Committee Reports –** Discussion of questions submitted by the membership **(Members are encouraged to submit advance questions and issues for Friday morning discussion to ataylor@cogr.edu)**

- 12:00 Noon – **Adjournment**

Attendance at COGR meetings is limited to employees of member universities, their governing boards and research foundations, affiliated hospitals and affiliated research institutes.