

Hot Topics &
Emerging Issues:

A Broad Look at
COGR's Agenda

Session Overview:

David Kennedy,

Costing and Financial
Compliance

Hot Topics &
Emerging Issues:
The Legislative
Landscape

Tobin Smith, Vice President
for Science Policy and
Global Affairs,
Association of American
Universities (AAU)

Hot Topics & Emerging Issues

Research Security & Intellectual Property (RSIP) Committee

- Elizabeth Peloso (Chair), University of Pennsylvania
- Alexandra Albinak, Johns Hopkins University*
- Allen DiPalma, University of Pittsburgh
- Cindy Kiel, Stanford University*
- Michael Moore, Augusta University*
- Dan Nordquist, Washington State University*
- Jennifer Ponting, University of Chicago
- Sophia Herbert-Peterson, Georgia Institute of Technology
- Kenneth Porter, University of Maryland*
- John Ritter, Princeton University*
- Fred Reinhart, University of Massachusetts*
- Janna Tom, University of California*
- Robert Hardy (COGR Staff)

*At-large members

Research Security & Intellectual Property (RSIP)

- **Research Security:**
 - DOJ Ends China Initiative
 - Pending Legislation
- **Export Controls: New Russian Sanctions and Other Developments**
- **Cybersecurity: New CMMC Model**
- **Intellectual Property: Serious Challenges to Bayh-Dole**

DOJ Announces End of the China Initiative

- February 23 Assistant AG Speech at George Mason
- New Strategy for Countering Nation-State Threats Announced
- Cites Concerns About Bias and Chilling Effect of China Initiative
- Current Cases will Continue but Higher Bar for Future Cases
- Must Be Criminal Misconduct with Clear Connection to U.S. Security
- Federal Funding Agencies Otherwise Responsible (OSTP Guidance)
- Civil/Administrative Remedies More Appropriate

Pending Research Security Legislation

House-Passed COMPETES and Senate-passed USICA Security Issues

USICA:

- **Section 3138** on CFIUS Review of Foreign Gifts/Contracts \$1M + Related to R&D on Critical Technologies
- **Section 6124** Lowering Section 117 Reporting Threshold to \$50k & requiring faculty reporting of foreign gifts and contracts
- **Section 2308** requiring NSF to develop a plan to identify sensitive or controlled research areas and provide background screening, **Section 2526** mandating NSF to collect copies of any contracts, agreements, or documentation related to PRC entities

Research Security Legislation (continued)

COMPETES

- Section 90304 lowers the Section 117 disclosure requirement to \$100,000 (\$250,000 for gifts or contracts with a particular foreign source over three years) and requires institutions to maintain a searchable database of faculty disclosures of foreign gifts/contracts over \$50k for the previous five years.
- Section 10306(d) requires NSF to take various steps to address security concerns (provide security training, etc.)
- “Malign” foreign talent recruitment programs prohibitions
- Conference negotiations to resolve differences

Export Controls

- New Russian Sanctions Announced by Commerce/BIS February 24
- Adds New Controls for Russia to 58 ECCNs, Policy of Denial for Exports to Russia Requiring Licenses, Restrictions on Military End Use Items, 49 Russian Entities Added to Entity List
- OFAC Additions to Sanctions Lists
- Emerging Technologies:
 - October 16, ANPRM: Certain Brain-Computer Interface (BCI) Emerging Technology
 - January 2022: BIS delayed implementation of Oct 21, 2021 interim final rule establishing new controls on certain cybersecurity items for NS and AT reasons, along with a new License Exception ACE (the implementation date is March 7, 2022).

Cybersecurity

- DOD Announces Changes to Planned CMMC “2.0” Program
- Program Reduces from 5 to 3 Risk Levels Previously with 3rd Party Assessment Requirement Removed from Level 1
- Level 2 assessments were to be bifurcated between self-assessments and 3rd Party
- February 11 Announcement: Third Party Assessments Now To Be Required for Level 2
- CMMC Responsibility Moved from DOD Acquisition to CIO
- Rulemaking To Be Completed Within Two Years
- CMMC Academic Advisory Council Finally Established
- NIST 800-171 Security Requirements To Be Updated This Year

Bayh-Dole Challenges

- March-In: Cancer Patients Resubmit Petition Requesting NIH March-In on Xtandi Prostate Cancer Drug on Pricing Grounds
 - Original Petition Denied in 2016
 - Public Interest Groups (KEI, UAEM) and Congressional Pressures on NIH
 - NIH Promises Decision Soon (Possible Hearing?)
- DOE DEC: U.S. Manufacturing Preference Greatly Tightened and DOE Review/Approval Required of Any Change in Control or Ownership of DOE-Funded Inventions
 - Encouraging More Domestic Manufacturing High Priority for Administration
 - High-Level Discussions of Expanding DOE Requirement to Other Agencies
- Should Either or Both of These Challenges Succeed, Serious Implications for Universities' Abilities to Commercialize Government-Funded Inventions

Hot Topics & Emerging Issues

Contracts & Grants Administration (CGA) Committee

- **Walter Goldschmidts, (Chair) Cold Spring Harbor Laboratory**
- **Stephanie Gray, University of Florida***
- **Charles Greer, University of California, Riverside**
- **Stephanie Endy, Brown University**
- **Jeff Friedland, University of Delaware**
- **Jennifer Lassner , University of Iowa**
- **Steve Martin, Indiana University***
- **Bruce Morgan , University of California, Irvine***
- **Lisa Mosley , Yale University**
- **Twila Reighley, Michigan State University**
- **Craig Reynolds, University of Michigan***
- **Jennifer Rodis, University of Wisconsin-Madison***
- **Pamela Webb, University of Minnesota***
- **Jackie Bendall (COGR Staff)**

*** At-large members**

What's on CGA's horizon?

Vaccine Mandate – Update

Continuing Resolution – Impact on agencies, institutions and us?

New changes to federal research funding agencies, what we need to pay attention to?

- **NSF TIP Directorate, NIH ARPA-H**



Vaccine Mandate – Federal Contractors/Subcontractors OSHA ETA 100> Employees

Background: Presidential Executive Order 14042 (September 9, 2021) directed the federal agencies to contractually require certain federal contractors and subcontractors to implement COVID-19 workplace safety measures, including a vaccine mandate with no “testing” option.

- Challenges of EO contested by many states in December 2021.
- Court issued nationwide injunction. Deadline for federal contractors and subcontractors to comply (Jan 18, 2022) has been removed.
- Employers may still choose to adopt voluntary vaccine mandates applicable to employees but must be cognizant of the states that have adopted laws limiting or banning vaccine mandates.
- Contractors and subcontractors that have accepted the FAR Deviation Clause may remain subject to the requirements regarding masking and social distancing in the workplace.
- OSHA Interim Final Rule – not subject to enforcement. Still remains a proposed interim final rule. Pending litigation continues in courts.

Continuing Resolution: Impact on agencies, institutions and us?

- Very conservative pay-lines for FY 2022
- 10% Commitment reductions for non-competing renewals, will they be fully reversed?
- Delays in launching new initiatives
- What about the NIH salary cap?
- NRSA stipend levels?

Changes at the Funding Agencies: What should we pay attention to?

NIH ARPA-H – \$6.5B over 3 years (NIH total 2022 PBR=\$52B, for a 21%)

- Focus on multiple time-limited projects with different approaches to achieve a quantifiable goal
- DARPA model to establish a culture of championing innovative ideas in health and medicine.
- Part of NIH? Run separately from NIH? Competition for annual budget appropriations?

NSF TIP Directorate - \$864.87M (NSF total 2022 PBR=\$10B, for a 20%)

- ~\$500M in new NSF funding; current, related programs moving to TIP from other directorates
- Funding for cross cutting initiatives – Innovation ecosystems; Partnerships; Technology frontiers; Translational impact

Hot Topics & Emerging Issues Research Ethics & Compliance (REC) Committee

- Naomi Schrag, (Chair), Columbia University
- Lynette Arias, University of Washington
- Theresa Colecchia, Johns Hopkins University
- Keri Godin, Brown University*
- Grace Fisher-Adams, California Institute of Technology*
- Karen Hartman, Mayo Clinic*
- J.R. Haywood, Michigan State University*
- Mary Mitchell, Mass General Brigham*
- Deborah Motton, University of California
- Kerry Peluso, Florida State University*
- Brian Smith, University of California, San Francisco*
- Geeta Swamy, Duke University*
- Ara Tahmassian, Harvard University*
- Debra Thurley, Pennsylvania State University*
- Kristin West (COGR Staff)

* At-large members

Research Ethics & Compliance (REC)

- NIH FY 2022 Updated Guidance, Requirement for Instruction in the Responsible Conduct of Research ([NOT-OD-22-055](#)). Unless changed by NOT-OD-22-955, requirements of NOT-OD-10-019 remain in effect. **NEW ITEMS:**
- **Timeline:** Incorporate changes into plans for RCR instruction in the 2022-23 academic year and in new/renewal applications for research trg., career development, research education & dissertation grants beginning with 9/25/22 due dates.
- **Format** – Video conferencing can be used to **partially** fulfill requirement for face-to-face interaction among faculty and participants, but it cannot be the sole means for meeting this requirement except for “short term training program or unusual/well-justified circumstances.”
- **Frequency/Timing:** Reference to requirement for 8 contact hrs. has been deleted. New focus on discipline-specific training in later career stages.
- **Subject Matter** – The following topics have been added:
 - **COC** – allocating time, effort, or other research resources
 - **Safe research environment** -- free of sexual, racial, ethnic, disability & other forms of discriminatory harassment
 - **Peer review** – responsibility for maintaining confidentiality and security
 - **Data analysis**
 - **Lab tools** – including tools for analyzing data, creating or working with digital images, recordkeeping practices, including methods such as electronic lab notebooks
 - **Secure and ethical data use and data confidentiality**

Research Ethics & Compliance (REC)

- Dept. of Energy Interim Conflict of Interest Policy ([FAL 2022-02](#))
- Very similar to PHS FCOI Regulations ([42 CFR Part 50, Subpart F](#)), but some important differences:
 - Broader definitions of Significant COI, Financial COI, and Investigator
 - Possibility of differences in requirements among program offices
- COGR Meeting with DOE representatives to discuss questions regarding the policy. Take-aways:
 - DOE will issue FAQs in the near term to clarify certain aspects of the policy, including how the 180-day compliance period comes into play.
 - DOE will be issuing a NPRM for a final rule – timeline unknown at this point
 - Reporting logistics will be handled via program offices for the present
 - Organizational COI requirements addressed to procurement area
- DOE was unable to present at this meeting, but has agreed to present at June membership meeting

Research Ethics & Compliance (REC)

- Dept. of Justice's (DOJ) Clinical Trial Fraud Initiative: Criminal prosecution of persons/entities that fabricate clinical trial data or falsify medical records in trials to support FDA-regulated products.
- Recent cases:
 - [Unlimited Medical Research, Miami, FL](#)
 - [Tellus Clinical Research, Miami, FL](#)
- REC meeting with John Claud, Assist. Director, DOJ Consumer Protection Branch to discuss initiative. Take-aways:
 - Careful review of each case by DOJ to determine enforcement path
 - Consideration of “Red Flags” that may point to criminal prosecution -- Harm to humans; impact on vulnerable communities; evidence that results were completely fabricated; high level of fraud; large amount of money involved.
 - Monitor and test systems!

Hot Topics & Emerging Issue Costing and Financial Compliance (CFC) Committee

- Jeffrey Silber (Chair), Cornell University
- Sarah Axelrod, Harvard University
- Jeremy Forsberg, University of Texas at Arlington
- Joseph Gindhart, Washington University at St. Louis*
- Vivian Holmes, Massachusetts Institute of Technology*
- Cynthia Hope, Georgia Institute of Technology*
- Michael Legrand, University of California, Davis*
- Nate Martinez-Wayman, Duke University*
- Gerald Mauck , University of Denver
- Jennifer Mitchell, Northwestern University*
- Julie Schwindt, University of South Alabama*
- Marcia Smith, University of California, Los Angeles*
- Renotta Young, Columbia University*
- David Kennedy (COGR Staff)

* At-large members

The Costing Crystal Ball: Do all roads truly lead to F&A and Audit?

- Hopefully not!
- Heritage Foundation: *Indirect Costs: How Taxpayers Subsidize University Nonsense*
- NSF OIG: *Promising Practices for NSF Award Management*
- And why are we still talking about “procurement and rebates?”



F&A, audit, and oversight always will be “hot topics.” And while there is no magic bullet to offset these pressures, relationships help—we are committed to engagement with the IG and audit community, F&A negotiating agencies, OMB, etc.—and it makes a difference!?!