

Committee Reports and Updates

Council on Governmental Relations Meeting
Washington Marriott Hotel
Washington, DC
February 22, 2018

COGR President Search Process

- Email sent to COGR members on January 29th
- Applications/nominations due by March 31st
- Send to Sara Bible at sbible@stanford.edu
 - expect a response
- Review of applications: spring – summer
- Goal: Announce new COGR president by October 2018

Nonprofit Funder – Research Institution Partnership Workshop

- COGR, the [Health Research Alliance](#), and [FasterCures](#) are leading a workshop on **May 16** aimed at fostering effective relationships between nonprofit research-funding organizations and research-performing institutions.
- The workshop will be convened by the [Government-University-Industry Research Roundtable](#) of the National Academies of Sciences, Engineering, and Medicine, and held in Washington, DC.

Nonprofit Funder – Research Institution Partnership Workshop

Areas of focus will include:

- Administrative requirements
- Indirect costs/research operating costs
- IP and tech transfer
- Overall principles for successful partnerships

Participation is by invitation, please contact Lisa Nichols at COGR if you would like to participate.

The meeting will also be webcast. Information on registering for the webcast will be distributed at a later date.

RESEARCH COMPLIANCE AND ADMINISTRATION

RCA Committee

Pamela Webb (Chair)	University of Minnesota
Allen DiPalma	University of Pittsburgh
Stephanie Endy	Case Western Reserve University
Jeffrey Friedland	University of Delaware
Jeremy Forsberg	University of Texas, Arlington
Walter Goldschmidts	Cold Spring Harbor Laboratory
Jennifer Lassner	University of Iowa
Michael Ludwig	University of Chicago
Steven Martin	Indiana University
Lisa Mosley	Yale University
David Norton	University of Florida
Twila Reighley	Michigan State University
Jackie Bendall	Director, COGR

NIH Prior Approval on Clinical Trial Fixed Price Subawards

- **Guests:**
 - **Sam Ashe**, Director, Division of Grants Policy, NIH
 - **Stephanie Scott**, Columbia University & FDP Subaward Subcommittee Co-Chair
 - **Jennifer McAllister**, Duke University, FDP Subaward Subcommittee
- **Goal: Streamline or eliminate prior approval requests to enter into clinical trial FP subawards or to exceed Simplified Acquisition Threshold**

Outcome after Discussion

COGR will recommend language to NIH, based on DOD language, that this category of FP subaward should be considered **capitation** (per patient, per participant, per procedure) rather than fixed amount subaward.

Capitation awards do not require prior approval nor are they subject to the simplified acquisition threshold limit.

If NIH approves ..

- The clarifying language would be added to the Grants Policy Statement (as opposed to FAQ)
- NIH would develop and issue staff guidance for ICs

Joint Costing-RRR-RCA Meeting with Andrea Brandon and Michelle Bulls

- Topics:
 - Reimagine Grants
 - Financial Conflict of Interest
 - **Subrecipient Monitoring**
 - Financial Expenditures Reporting Procedure
 - Personnel Expenses

Subrecipient Monitoring

- Also required under the 21st Century Cures Act
- **NIH and NSF will modify the Research Terms and Conditions to alter the subrecipient monitoring burden for those entities with clean audits and who are also prime grantees**
 - Overall relief will not extend to certain categories of high-risk subrecipients (e.g., small businesses)
 - Michelle doing a final review and then it will go to Andrea to clear it and then to OMB
 - Will include a recommendation for other agencies to also take advantage of this approach

Could it be????



Responsible Conduct of Research

- Guest:
 - Jean Feldman, Head, Policy Office, NSF
- **NSF does not envision any policy changes in RCR at this time**
 - Continuing to explore other opportunities (e.g., a new workshop, possibly webcast)
 - Expand marketing of their online ethics center
 - NSF has removed their old, outdated FAQs
 - New solicitation is out on RCR

RCR Discussion Recommendations

- Reconsider to allow online training (many improvements in recent years!)
- Reconsider feasibility of having to train very short duration NSF participants (e.g., summer two week programs)

NSF Sexual Harassment – Important Notice #144

- Will be released soon in the Federal Register for a 60 day comment period
 - NSB got to look at the draft Federal Register notice yesterday
- NSF intends to implement this separately (BEFORE the next regular PAPPG Guide)
- Will not include reporting for “allegations” but rather just for determinations/findings

RESEARCH AND REGULATORY REFORM

Research and Regulatory Reform Committee

Lois Brako (Chair)	University of Michigan
Lynette Arias	University of Washington
Robin Cyr	University of North Carolina Chapel Hill
Marti Dunne	New York University
Charles Greer	University of California Riverside
J.R. Haywood	Michigan State University
Martha Jones	Washington University, St. Louis
Mary Mitchell	Partners Healthcare
Kerry Peluso	Florida State University
Suzanne Rivera	Case Western Reserve University
Naomi Schrag	Columbia University
Ara Tahmassian	Harvard University
Lisa Nichols	Director, COGR

General Data Protection Regulation

Mark Barnes, Ropes and Gray, LLP

- May 25, 2018 compliance date
- Processing and transfer of data across EU boundaries.
- Jurisdiction covers:
 - Businesses established in the EU
 - Marketing or promotion of services in the EU
 - Real-time monitoring of behavior of EU citizens
- Applies where data are collected in the EU, despite citizenship, but not to data on EU citizens collected in the U.S.

General Data Protection Regulation

- Draft guidelines on applying the consent requirements under GDPR. Comment period closed on January 23, 2018.
- Consent to transfer data to the U.S. which has less stringent protections. Unclear at this time whether institutions will need to re-consent.
- Specific bases to authorize. Basis for transfer versus use of data. Scientific or research purposes is another basis but has not yet been defined.

General Data Protection Regulation

- Much broader interpretation of “identifiable” and “sensitive”. Conflicts with U.S. human subjects regulations. SACHRP is writing a letter to the HHS Secretary.
- Take an inventory and document applicability for your institution (e.g., data, vendor contracts, marketing and web activities) and how requirements were addressed (e.g., implementing appropriate notices).
- Develop internal policies and procedures.
- Anticipate further discussion at the June COGR meeting

Meeting with HHS and NIH

- NIH is creating an internal task force to provide HHS with their data, as well as data put forward by AAU, COGR, AAMC and others, regarding the effectiveness and efficiency of the PHS COI regulations, revised in August 2011, as part of the HHS led review of federal COI requirements under the 21st Century Cures Act.
- Staff at OMB and other agencies are still working to stand up the Research Policy Board.

Discussion on Faculty Communication

Discussed communication channels between university administration and faculty.

- Use of faculty councils and policy committees
- Councils of deans and associate deans
- Weekly notices, news letters, Listserves and web pages

Targeted communication is most effective. Faculty have a lot of competing priorities. Which departments and investigators will be impacted most?

Identification of faculty with leadership positions in national societies and organizations (e.g., National Academies, AAAS, FASEB, and FDP).

COGR engagement with other organizations and societies representing faculty.

Research Quality Survey

COGR will be distributing a survey to assess institutional efforts to enhance research quality the **week of February 26**.

- What resources are offered centrally to help ensure research quality (e.g., statistical, training, grant proposal development support)?
- Do individual departments at your institution provide substantive reviews of research proposals for quality of design prior to submission for funding?
- Are there efforts to raise awareness of rigorous approaches to research and transparency in reporting?

Your participation would be greatly appreciated!!!

COSTING POLICY

Costing Policy Committee

Cindy Hope (Chair)	The University of Alabama
Sarah Axelrod	Harvard University
Michael Daniels	Northwestern University
Amanda Dotson	Texas A&M University
James Fortner	Georgia Institute of Technology
Joseph Gindhart	Washington University St. Louis
Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Lynn McGinley	University of Maryland, Baltimore
Jeffrey Silber	Cornell University
Marcia Smith	University of California, Los Angeles
Cathy Snyder	Vanderbilt University
David Kennedy	Director, COGR

Meeting with HHS and NIH

- Recognition of Payment Management System Issues
 - Quarterly Federal Cash Transaction Reports
 - DHHS 270 day close-out
- Micropurchase threshold

F&A Reference Document

- Comprehensive compilation including:
 - Primer
 - Myths versus facts
 - Pros and cons of current system
- Will present at June meeting

Themes in Recent Federal Audits - NSF

- [Issued](#) 17 audits in FFY17 and 1 in FFY18
- Continued use of a small group of contractors for most external audits
- “Back to Basics” / Allowability:
 - Period of Performance
 - Necessity
 - Reasonableness
 - Compliance with institutional policy

- Near/post term expenditures; F&A above first \$25K on sub; participant support, travel, general expense (lunch); untimely travel reimbursement; bonus
 - Watch for resolution on aggregation of subawards.
- Unapproved sub, leave in violation of institutional policy, unallocable travel, unallowed pre-award costs, unallowable gym fee
- Near term expense, unallowable travel
- Equipment, travel, documentation, ACM\$ draw, unreasonable expenses, preaward costs outside of the period of performance
- Near term expense, improperly applied F&A, improper participant support, improperly allocated equipment
 - Watch for audit resolution on purchase of replacement equipment (recorders) and facility rental (participant support)
- Near term purchases, unreasonable travel, unreasonable participant cost expenditures, unallocable visa fees
- Equipment, near and post term expenditures, cost transfers, entertainment and alcohol costs, Pcard documentation, salaries above 2/9ths

Themes in Recent Audits - HHS

- Only 1 university audit published in FY17
- Initiative underway on subrecipient monitoring.
 - At least three known institutions
 - Focuses on incoming and outgoing subawards
 - Outgoing: Obtain backup documentation from the subawardee for sampled transactions as well as producing their own documentation.
 - Incoming: provide documentation for sample
- DOJ settlement this month
 - \$13.1M settlement, covering 6 years
 - Self disclosed
 - US Attorney stated institution “failed to ensure that its time and effort reports related to certain federally-funded grants were accurately and timely certified.”

Federal Audit Site

- OIGs post to [oversight.gov/reports](https://www.oversight.gov/reports)
 - Includes Ag, Commerce, Defense, Ed, Energy, HHS, DHS, HUD, DOJ, DOL, State, Interior, Treasury, Transportation, VA, EPA, NASA, NSF, NRC and more
 - 7500+ audits, investigations, reviews, etc. on their site. Most audits are not of university-based research activities.

CONTRACTS AND INTELLECTUAL PROPERTY

Contracts and Intellectual Property Committee

Patrick Schlesinger (Chair)	University of California, Berkeley
Alexandra Albinak	Johns Hopkins University
Cindy Kiel	University of California, Davis
Michael Moore	University of North Dakota
Dan Nordquist	Washington State University
Elizabeth Peloso	University of Pennsylvania
Jennifer Ponting	Harvard University
Fred Reinhart	University of Massachusetts, Amherst
John Ritter	Princeton University
Wendy Streit	University of California
David Winwood	Pennington Biomedical Research Center
Kevin Wozniak	Georgia Institute of Technology
Robert Hardy	Director, COGR

NIST ROI Initiative

- *Walter Copan, Under Secretary of Commerce for Standards & Technology, Director - NIST*
- Return on Investment Initiative
 - <https://www.nist.gov/tpo/return-investment-roi-initiative>
 - USG spends \$140B on R&D
 - Looking for *impact* of research, especially in the tech transfer area
 - Broader, societal impacts, not just financial return
 - Comparison of federal labs and university labs
 - Want to make sure that Bayh-Dole is working well for the country

NIST ROI Initiative

- Request for Information – March 2018
 - What is working well under Bayh-Dole?
 - What is not working well?
 - Where do we go from here
 - Request for data about tech transfer and other research impact metrics
- 3 workshops over March-May 2018
- Final report with recommendations by Sept.
- Concerns about re-opening Bayh-Dole
- Lead initiative in the Executive Branch

SRC Background IP Provisions

- Prior terms
- New JUMP program terms
 - New reach to IP of non-contract performers
 - Onerous due diligence process
 - Goal is *guaranteed* freedom to operate
- DARPA involvement
- Current JUMP status
- Likely impact: ALL future SRC awards, awards from SRC member companies

Other CIP Issues

- Legislative developments
 - I-Corps Expansion Bill
 - STRONGER Patents Act
 - Sovereign Immunity
- Issues Tracked
 - CUI – FAR clause now listed as March 2018 (9 months overdue)
 - Dept. of Education Open Licensing Requirement
 - Members receiving the requirement?