Costing Committee Update

Cynthia Hope (Chair)	University of Alabama
Sarah Axelrod	Harvard University
Michael Daniels	Northwestern University
Vivian Holmes	Boston University
James Fortner	Georgia Institute of Technology
Joseph Gindhart	Washington University St. Louis
Vivian Holmes	Boston University
Michael Legrand	University of California, Davis
Nate Martinez-Wayman	Duke University
Lynn McGinley	University of Maryland, Baltimore
Michael Moody	Massachusetts Institute of Technology
Jeffrey Silber	Cornell University
Marcia Smith	University of California, Los Angeles
Cathy Snyder	Vanderbilt University
David Kennedy	Director, COGR

Costing Committee Update

COGR

- HHS/NIH Update
  - Cost/Finance issues
    - FCTR – can't say much but, promising
  - More later from RCA and RRR

Costing Committee Update

COGR

- F&A White Paper
  - Met with two external reviewers
    - Comprehensive analysis on F&A topics
    - Advocacy role for next attack on F&A
    - On-line roll-out in January 2019
    - Still need:
      - Executive summary
      - FAQs?
      - Bullet points for specific audiences?

Costing Committee Update

COGR

- DCAA audit of CSU cooperative agreement
  - Audit findings and agency (USACE) management decision indicate troubling expectations for timekeeping
  - RCA wrote COGR letter to USACE
    - Will provide additional information during their update

Research Regulatory Reform Committee

COGR

Lois Brako (Chair)	University of Michigan
Lynette Arias	University of Washington
Michelle Christy	Massachusetts Institute of Technology
Marti Dunne	New York University
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
Debra Thurley	Pennsylvania State University
Rodolfo Torres	University of Kansas
Lisa Nichols	Director, COGR

RRR Updates

- Research Rigor and Reproducibility – Survey report
- Human Subjects Research
  - Guidance on the revised Common Rule
  - NIH Clinical Trial Case Studies
  - NIH Proposal to Streamline Oversight of Human Gene Therapy Trials (Joint letter with AAU, AAMC, and APLU
- Animal Research
  - Survey findings on institutional administrative requirements for animal research
  - Continue to pursue elimination of congruency review
- Nonprofit Funder – Research Institution Partnership Workshop – November 7, 2018

RRR Oct 23 Meeting

- Brian Nosek, Co-founder and Executive Director of the Center for Open Science (COS)

  We discussed the COS Open Science Framework and its potential use as a platform for registering and reporting NIH-funded basic science research and how the center is working to facilitate reproducible research practices through badges, registered reports, and other mechanisms.

RRR & RCA Oct 23 Meeting

- Carrie Wolinetz, Acting Chief of Staff and Associate Director for Science Policy, NIH

  We discussed the August 20 letter from Francis Collins to investigators regarding failure to disclose foreign sources of income in other support. What is being described by federal staff as existing requirements does not resonate with universities understanding of what should be in other support. At issue are collaborations involving funding or commitments outside of institutional time.

RRR, RCA, & Costing Oct 23 Meeting

- **Andrea Brandon**, Deputy Assistant Secretary, Office of Grants and Acquisitions Policy and Accountability, Office of the Assistant Secretary for Financial Resources, HHS,
- **Michelle Bulls,** Director, Office of Policy for Extramural Research Administration, NIH on Wednesday.

Discussed progress on regulatory reform under the 21st Century Cures Act and the Research Business Models Working Group.

21st Century Cures Act

Section 2034 of the 21st Century Cures Act requires HHS and NIH to address a number of areas including:

- Conflict of Interest

  There has not yet been an evaluation of financial conflict of interest and whether the 2011 revisions to the HHS COI revisions were effective.

  NIH may begin an evaluation in November and will work collaboratively with the research business models working group which will be considering ways to harmonize COI requirements across agencies to reduce burden.

- Animal Research – No progress

Research Compliance & Administration

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
Steven Martin	Indiana University
Lisa Mosley	Yale University
David Norton	University of Florida
Twila Reighley	Michigan State University
Jennifer Rodis	University of Wisconsin-Madison
Jackie Bendall	Director, COGR

21st Century Cures Act

- SUBRECIPIENT MONITORING
  - NIH directive in 21st Century Cures Act to reduce subrecipient monitoring burden
  - NIH and NSF in process of proposing government-wide solution on this topic to Research Business Models (RBM) subcommittee

  - Recommended that we articulate subrecipient monitoring burden (risk assessment/audit review) to other federal agencies beyond NIH/NSF (e.g. DOE and USAID)
  - Anticipated Process:
    - Proposal to RBM within 1-2 months
    - RBM asked to provide feedback
    - Sent out for public comment (ANPRM?)

Hope Springs Eternal …

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Reimagining Grants

- AWARD NOTICE COVER PAGE
- Standardized award notice cover page that contains data elements from the Data Act
  - Will need to finalize what elements need to be on cover page
  - Requires more care and thought than you might imagine:
    - If included, data elements likely to become long-term mandatory elements
    - May end up being included in reportable public datasets
    - Will wish to consider whether it is advantageous to include certain optional data elements on this page (e.g., carryforward, offsets)
    - Could potentially drive policy
  - We can expect to have an opportunity to provide feedback

CSU USACE Timekeeping Issue

1. Labor entries should be recorded daily;

2. Timekeeping systems should include controls which limit the number of employees for whom supervisors are responsible for approving labor and leave entries (limit suggested is 10);

3. PI should not have final control over both project expenses/budget and labor charges; if a supervisor makes a change to a labor expense allocation (e.g. if correction to project allocation was made), the change should be approved by the employee; and

4. University policies for de minimis time and effort are unallowable because less than 1% effort is material.

Lessons from Systems-Based Analysis of Biosecurity and Biodefense Policy

(Gryphon Scientific, National Defense University and Parsons)

- Mapped policy
  - How policies align to biodefense strategic intent
  - Policy gaps
  - What policy activities enhance or counteract other activities
- Designed a framework for analyzing the opportunity costs of new or changing regulations
- Created a framework for evaluating the successful implementation of biosecurity and biodefense policies
  - Activity-based evaluation
  - Outcome-based evaluation

Case Studies: Addition of Tier 1 Agents (2012 policy change)

- Sample of a Lesson Learned:
  - As costs for compliance increase, institutional decision to not engage in that type of research increases
    - Research is delayed
    - Workforce is adversely impacted (researchers drop out or have fewer skills needed nationally)
    - Research is re-directed to pathogens of lesser concern
    - Loss of infrastructure
      - Tier 1 certification is lost or not maintained
      - Visiting scholar programs are abandoned because to administratively burdensome or expensive to operate
- Can result in compromised national capacity

Contracts and Intellectual Property

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

NIST ROI RFI

- Return on Investment – Federal Technology Transfer
- Assn. comments:
  - No changes in Bayh-Dole are necessary
  - Robust patent system is essential for tech transfer – need to eliminate concerns about march-in rights, enforceability of patents and treatment of software
- Paul Zielenski, NIST Director of Tech Partnerships
  - Report coming out Nov. 15. Not NPRM; may comment
  - Bayh-Dole 1.1 - Regulatory clarification
    - March-in rights – not about consumer pricing, already have necessary authority
    - Clarifications – govt. use license, waiver of US manufacturing requirements, title back to inventor

NIST ROI RFI (cont.)

- Recommendations in report
  - Consistency across agencies
    - iEdison needs to be upgraded or replaced. NASA system could be alternative
    - CIP: need consistency across NASA
- Comments on RFI that were declined
  - No new funding
  - Not going to discuss ownership or copyright of data
- Recommended statutory changes
  - Allow USG to own copyright in some circumstances
  - Amendments to Stevenson-Wydler Act to allow agencies to regulate federal laboratory tech transfer

Nonprofit Foundation Research Institution Partnership Workshop

- Workgroups on Policies, F&A, IP
- Royalty Sharing/Total Cost of Research Subgroup
  - Expenses not paid by the funders – patents & F&A costs
  - Events or factors which will trigger when royalty sharing with funder begins
  - Percentage and total amount of royalty sharing funder will receive if an invention is successfully licensed (cap?)
  - Whether funder's ROI fairly reflects its contribution

Other issues

- NDAA implementation
  - Statutory basis for EAR
  - Emerging technologies
    - Revitalization of Commerce ETRAC effort
    - DOD – protection of critical technologies
- Controlled Unclassified Information (CUI)
  - Workshop – described in October update
  - Expect to NPRM by February
  - Based on DFARS 7012 – more specific legends, division in contract between CUI and non-CUI
  - DFARS may follow if all necessary elements are present
- Foreign Influence
  - FBI visits