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<td>David Kennedy</td>
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Costing Committee Update

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

F&A White Paper

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

- 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
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<td>Lois Brako (Chair)</td>
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<td>Suzanne Rivera</td>
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<td>Naomi Schrag</td>
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<td>Rodolfo Torres</td>
<td>University of Kansas</td>
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<td>Lisa Nichols</td>
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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.
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.

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

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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 a 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 ...
**21st Century Cures Act**

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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
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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