FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Costing and Procurement Updates

Joe Gindhart, Washington University in St. Louis

Doug Backman, University of Central Florida

Nate Martinez-Wayman, Duke University

Jim Luther, Duke University

Diane Dean, NIH

September 7, 2018

Agenda

- Procurement Update
- DHHS LOC G “Pooled” Account
- Admin Burden Perspective
  - Public Data Access
  - Rigor & Reproducibility
  - Research Integrity

Procurement

- **Uniform Guidance officially implemented for first fiscal year starting 12/26/2017 or later**
- **Codified at Title 2 Part 200.317 – 326**
  - **Use GPO's e-CFR site (www.ecfr.gov)**

Pre-Session Survey Responses

- 67% have updated Sole Source process, mostly to reference UG allowable circumstances
- 20% have MPTs >$10K; many still at $5K
- ~50-50% split on application of MPT; single transaction (not item) v. item in aggregate over life of project; hard to apply!
- Most common Procurement audit concerns relate to SSJ (sub's documentation; validity of scientific reasons)

Sole Source Justification

- "Procurement by noncompetitive proposals", at 2 CFR 200.320(f)
  - One of the 5 methods on the "bear claw"
    - Not related only to Small Purchases (>MPT)
  - Allowed in only 4 circumstances
    - Available from a single source
    - Public exigency
    - Agency "expressly authorizes" base on written request
    - After multiple solicitations, only 1 vendor is adequate

Requesting MPT >$10K

- OMB Memorandum M-18-18 (6/20/18)
- Implements statutory changes set forth in NDAA for Fiscal Years 2017 and 2018
- Clarifies approval process for MPT >$10K
- Federal Cognizant Agency Contacts:
  - DHHS – Andrea L. Brandon
  - ONR – Wade Wargo (ACO at ONR Regional Office)
  - Other – Mary Tutman or Gil Tran

Requesting MPT >$10K

- Requests for approval should be submitted to the institution's cognizant Federal agency for indirect cost rates… The cognizant Federal agency will assign review of the request to the appropriate office within the agency to determine whether to approve, and will maintain records and justification of all approvals. The request should include the threshold level being requested and the justification(s) for it based on the criteria above per Section 2 I 7(b) of the NDAA for FY2017.

UG Procurement @FDP

- FDP UG Procurement List FDP-UG-PROCUREMENT-L@LSW.NAS.EDU
- Monthly Conference call
- Lunch discussion at FDP Meeting
- BJ Pivonka – Univ of Connecticut
  - bj.pivonka@uconn.edu

UG Procurement @ WashU

- **Effective 6/5/18 & Enforcement on 7/1/18**
  - **>$10K for all Sponsored funds**
    - **Quotes/Bids required**
  - **>$25K for all other funds**
    - **Follow normal bid process**

WashU Bid & Quote Process

- **Document via Supplier Selection Justification form(SSJ)**
- **Provide quotes/bids from the selected vendor and at least one other**
- **Comparable info on the item (brand, model #, item description, unit…)**
- **In writing from vendor**

WashU System Edit

- **Warning message: “This order exceeds a dollar amount that may require additional documentation, per the UG, prior to approval. Please submit a completed SSJ and quotes to Purchasing Services …”**

UG Procurement @ Duke

- **Effective & Enforcement on 7/1/18**
  - **MPT remains $10K for all funds**
  - **Quotes or SSJ required**
  - **Adjusted SSJ form, cross-walked 5 reasons to 4 allowable circumstances**
  - **Also applies to selection of higher quote**

DHHS LOC – G Account

- The original “pooled” (G) letter of credit account from DHHS is winding down
- Established in March 1984 (?)
- Project cycle includes: Active, Inactive and Closed
- Quarterly PMS 272 reporting was very cumbersome during all paper environment

DHHS LOC

- Project Close-out, total expense figure on all three should agree:
  - FFR/FSR (final)
  - PMS 272 Report (active document)
  - General Ledger
- Timing varies on FFR and 272 reporting (lags)
- DHHS issues “Closed Status”, then project falls off report

Complexities to Reporting

- Multiple g/l accounts for each project
- Carryovers and Deficits
- Unobligated balances & Relinquishments
- Volume of projects and report due dates
- Cash posted by project vs. pooled account
- Employee turnover and knowledge transfer

Final G Account Issues

- Total payments exceeds reported expenses
- Total payments exceed authorizations
- Identify issue, but DHHS has closed project
- Unidentified transactions on 272 report
- Current expenses cannot be reimbursed

Pre-Session Survey Responses

- **Survey asked a qualitative question to gauge volume and nature of reconciliation challenges**
- **Most respondents have ongoing reconciliation issues/concerns; a few did have but since resolved**
- **Follow-up survey or questionnaire will be more granular on which number, size of the number, etc.**

PMS Guidance Review

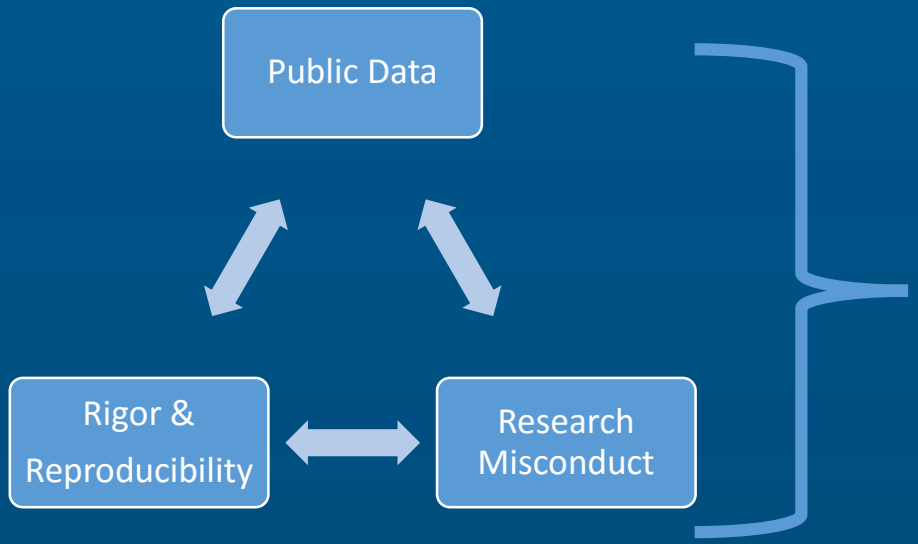
- **Previous FDP session in May 2016**
  - http://thefdp.org/default/assets/File/Presentations/PMSProjectMay2016.pdf **[slides 11-33]**
  - **Dan Evon reviewed specific steps to identify and resolve financial discrepancies to support closing pooled accounts in PMS**
- **Positive outreach to PMS Director, Dan Long**
- **Primary "issue resolution" pathway remains PMS Liaison**

PMS – Next Steps

- Guidance document under development (PMS training resources; tips related to queries; transaction code definitions; etc.)
- Actively collecting experiences/ documentation of challenges
- Identify common threads and problem-solve with PMS
- Interested?

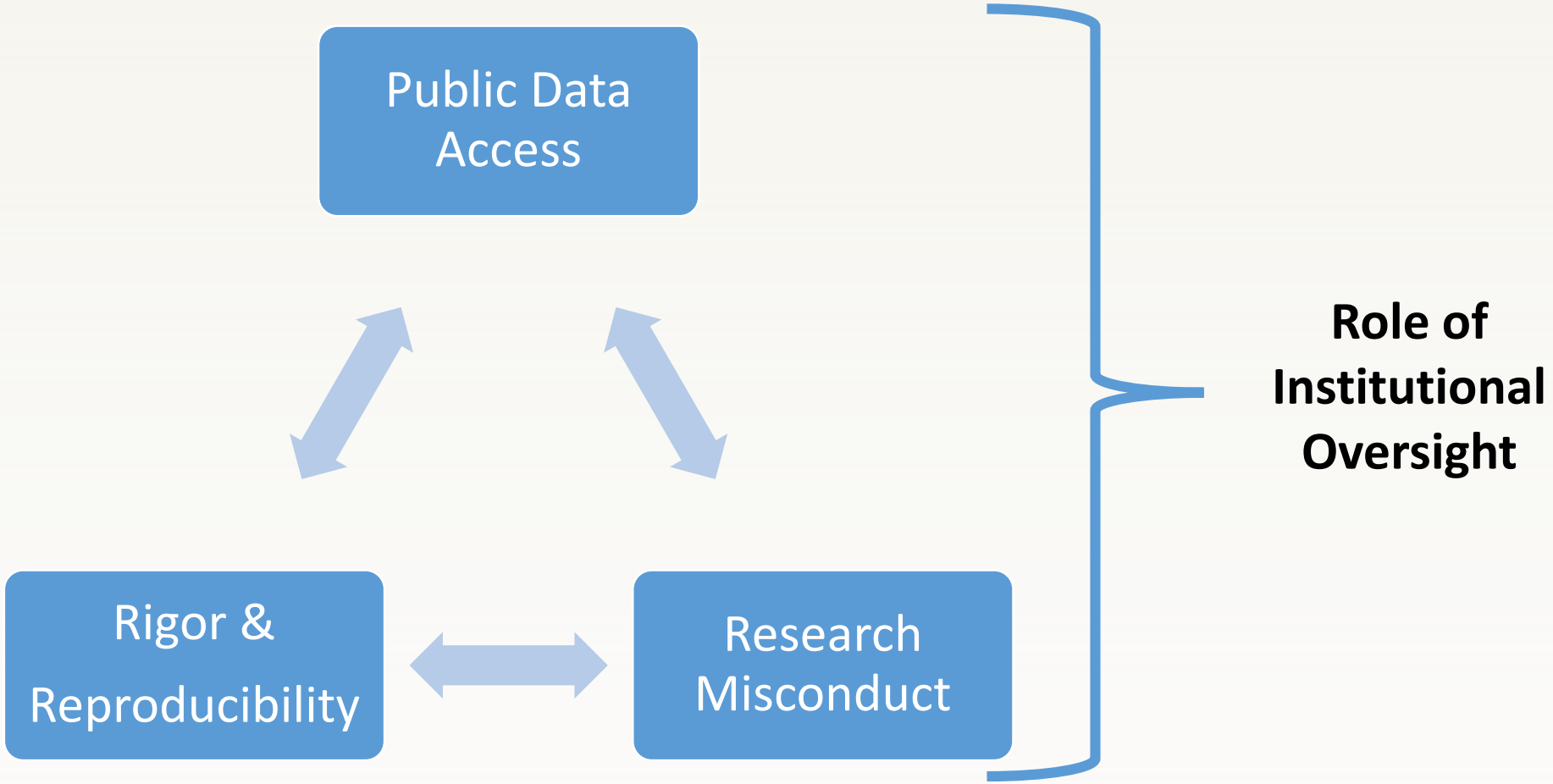
nate.martinez-wayman@duke.edu

Diane Dean, NIH
Jim Luther, Duke University



Role of Institutional Oversight

Administrative and Burden Perspective (Not Programmatic)



Public Data Access

Increasing Access to the Results of Federally Funded Science

Reminder

- Issue: In February 2013, the OSTP issued a directive to … develop a plan to support increased public access to the results of R&D…
- Requirement
  - Results include all peer reviewed publications and **supporting digital data** produced as part of federally funded research, as well as related metadata
  - Data to be "**stored for long-term preservation and publicly accessible** to search, retrieve, and analyze in ways that maximize the impact and accountability of the Federal research investment…"

Research Financial Compliance: Federal Update

- **VP Biden Threatens to Cut Federal Funding to Medical Research Institutions That Fail to Report Research Results in a Timely Manner**
  - Regulation require that clinical trial results are reported online and the info is accessible to the public
  - A recently released report highlights “flagrant” violations of the reporting requirement by many of the largest medical research institutions
  - Pending Final rule will give NIH more “clout to crack down”
    - **Suggests NIH would shut-off funding at the institutional level rather than just the PI**
    - “Four of the top 10 recipients of NIH funding failed to report results or reported after required deadlines at least 95 percent of the time…”
    - Even NIH’s own staff scientists didn’t report results as required by law three-quarters of the time.”

Rigor & Reproducibility

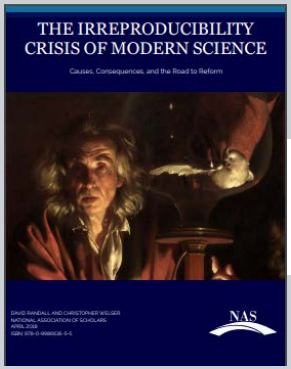
Reproducibility Crisis: In the News

1,500 scientists lift the lid on reproducibility : Nature News & Comment
https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970
by M Baker - 2016 - Cited by 362 - Related articles
May 25, 2016 - More than 70% of **researchers** have tried and failed to reproduce another scientist's experiments, and more than half have failed to reproduce their own experiments. Those are some of the telling figures that emerged from Nature's survey of 1,576 **researchers** who took a brief online questionnaire on ...

2016

2018

Is science really facing a reproducibility crisis?
Times Higher Education (THE) - Apr 23, 2018
Speaking to Times Higher Education after the presentation of the report, David Randall, director of **research** at the NAS and co-author of the report, said that the **reproducibility** crisis narrative had been an "ongoing, long-term and serious problem for the conduct of scientific **research**". Responding to the ...



The Irreproducibility Crisis of Modern Science offers overview of ongoing reproducibility debate

NAS
NATIONAL ASSOCIATION OF SCHOLARS
Defending Academic Freedom for 30 Years
1987–2017

Merck Wants Refunds from Universities when Sponsored Research Can't be Replicated

- Rosenblatt, EVP and CMO at Merck, stated that results from academic labs that cannot be replicated have caused drug companies to **waste millions of dollars and are a threat to the entire pharmaceutical industry**
  - 2012 data from Amgen identified "only six of 53 supposedly landmark academic papers stood up to efforts to reproduce the same results"
  - Both the costs of trying to replicate the work, which can reach over a $1M on its own, and the original support of the academic work can be forfeited
- Concerns about public relations impact of spreading concern to taxpayers about federally sponsored academic research.

Reproducibility Crisis: In the News

Researchers replicate just 13 of 21 social science experiments published in top journals

The Washington Post, August 27, 2018

- A research project attempted to replicate 21 social science experiments published between 2010 and 2015 in the prestigious journals Science and Nature. **Only 13 replication attempts succeeded**.
- The failures **do not necessarily mean the original results were erroneous**, as the authors of this latest replication effort note.
- In the replications that succeeded, the **observed effect was on average only about 75% as large as the first time around**.
- The researchers **conclude that there is a systematic bias in published findings**, "partly due to false positives and partly due to the overestimated effect sizes of true positives."
- submitted papers with novel results.

21 → **13**

https://www.washingtonpost.com/news/speaking-of-science/wp/2018/08/27/researchers-replicate-just-13-of-21-social-science-experiments-published-in-top-journals/?noredirect=on&utm_term=.86eb78b244c4

COMMENT

612 | NATURE | VOL 505 | 30 JANUARY 2014

NIH plans to enhance reproducibility

Francis S. Collins and **Lawrence A. Tabak** discuss initiatives that the US National Institutes of Health is exploring to restore the self-correcting nature of preclinical research.

chorus of concern, from and laypeople, contends omplex system for ensuring lity of biomedical research in need of restructuring[1,2]. he US National Institutes of , we share this concern and ome of the significant inter- we are planning.

s long been regarded as 'self- given that it is founded on the of prior work. Over the long principle remains true. In the

shorter term, h balances that onc have been hobble the ability of today others' findings.

Let's be clear: have no evidenc ducibility is abo In 2011, the Offic the US Departm Services pursu Even if this repr the actual proble

"Efforts by the NIH alone will not be sufficient to effect real change in this unhealthy environment."

Nature, Vol. 505, pp. 612-13, 30 January 2014

The Cornerstones of Research: Rigor & Reproducibility

Rigor

The application of rigor ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results.

Reproducibility

When a result can be reproduced by multiple scientists, it validates the original results and readiness to progress to the next phase of research.

Bias in Science & Publication

- **Publication Bias**
  - **74** Studies of 12 anti-depressants; 12,564 patients
  - **38** studies with positive results submitted to the FDA, of which 37 were published, 1 not
    - **36 with negative FDA results** 3 published, 22 not published
    - 11 published with data selection to appear positive
  - In literature, **94% of publications were positive** Turner: NEJM 2008;258:252-260

Source: Dr. Ross McKinney (AAMC)

Cases: Reproducibility and Research Misconduct

ORI produced 14 findings of scientific misconduct in 2016 and 2017, 28 findings in 2015, and 13 findings in 2014

XXX praised for transparency when they release results of a research misconduct investigation of prominent cancer researcher

XXX and YYY researchers were debarred due to falsified/fabricated data in three published papers and seven NIH grant applications

A post-doctoral fellow at NHLBI falsifies/fabricates data in two papers and supplemental material resulting in 3-year supervision of her research

ORI finds University of ZZZ grad student guilty of research misconduct and requires three years of supervision

Multiple investigations nail researcher at XXX and YYY SOM for falsification

University of XXX researcher falsifies data in three papers and submits to three year period of supervision

XXX Associate Professor investigated by UCR, NSF OIG, and ORI; debarred for three years with papers redacted or corrected

XXX Teaching Hospital settles research misconduct allegations for $10M; suit brought by researchers directing the work still pending

The Ethics of Scientific Publishing: Black, White, and "Fifty Shades of Gray" discusses that while scientific publishing has evolved, confidence has diminished

Wait…It's Not MY Grant?

Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

- "Remembering back to my days as a PI, I can recall myself saying something like "yea, on my NIH grant…" … We hear this confusion a lot. So, we thought it would be worthwhile to remind you about some of the respective roles of institutions and investigators working on an NIH award.
- For the most part, ***NIH makes awards to institutions,*** not people.

Wait…It's Not MY Grant?

Open Mike

Helping connect you with the NIH perspective, and helping connect us with yours

Dr. Michael Lauer is NIH's Deputy Director for Extramural Research, serving as the principal scientific leader and advisor to the NIH Director on the NIH extramural research program.

- The rules for all Federal awards - including uniform administrative requirements, cost principles, and audit requirements anticipate that **an institution/organization carries out a Federal award as the "recipient" of the award**. The institution designates individuals, including an "authorized organization representative" (AOR) the program director/principal investigator (PD/PI), to assume the responsibilities described below, in fulfilling the terms and conditions of their award."

Generative Discussion

- How is your institution dealing with these issues?
- What was your institution's reaction to "OPEN Mike"?
  - Concerns that an individual's behavior may have institutional implications (e.g. Special Award Conditions)
- What is your Faculty Culture and Tone at the Top for these issues?
  - Do you have Roles and Responsibilities that set tone for faculty accountability, role of institution in supporting PI and communication with sponsor?
- From an Admin Burden perspective, how can we support the faculty and sponsors in addressing these issues? Redefine the role of the central offices in communication with sponsor?

Discussion and Questions