FEDERAL DEMONSTRATION PARTNERSHIP

Redefining the Government & University Research Partnership

Rigor & Reproducibility, Research Integrity, and Public Data Access (Part II)

Diane Dean, NIH

Jim Luther, Duke University

Dr. Geeta Swamy, Duke University

Sara Bible, Stanford University

David Budil, Northeastern University

January 25, 2019

Agenda

- **Rigor & Reproducibility, Research Integrity, and Public Data Access**

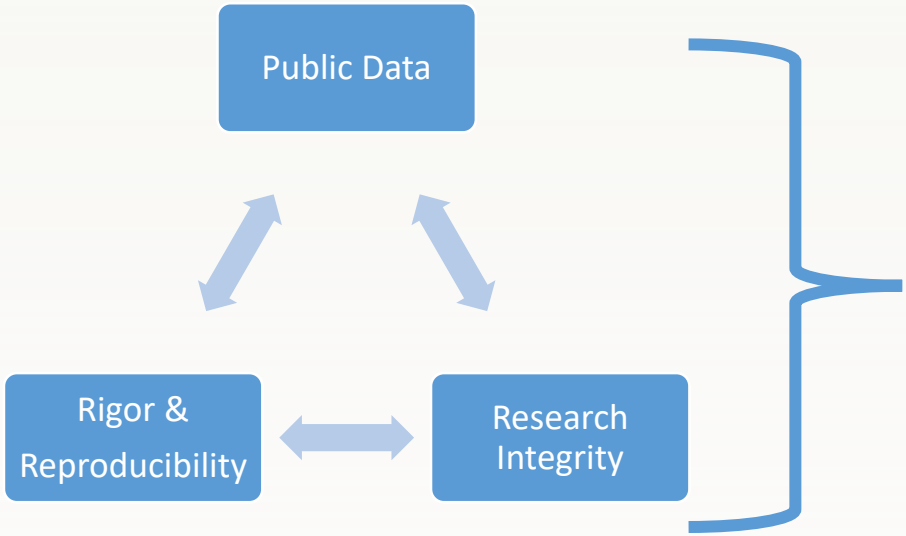
- **Topic:** The session will focus on sponsor initiated topics from an institutional/faculty perspective. In the recent past, there has been significant focus on Rigor & Reproducibility, Research Integrity, and Public Data Access. This triad of issues have broad burden, costing, and research quality issues and have significant points of integration that will support a dialogue with our federal sponsors, administrators, and faculty representatives about managing administrative burden, supporting our faculty, and managing costs. Results of the October 2018 AAU/APLU workshop on Accelerating Access to Research Data will be reviewed. We will also discuss the December 10, 2018 NIH Request for Information on Data Access.

Brief Overview of September 2018 Session

Administrative and Burden Perspective (Not Programmatic)

- **Diane Dean, NIH**
- **Jim Luther, Duke University**

September 2018 Meeting



Role of Institutional Oversight

Increasing Access to the Results of Federally Funded Science

- Issue: In February 2013, the OSTP issued a directive to develop a plan to support increased public acces[illegible] 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…"

September 2018 Meeting

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 ...

2018

September 2018 Meeting

Is science really facing a ...ility crisis?
Times Higher Education (THE) ... 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

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

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.

September 2018 Meeting

- "Remembering back to my days … I can recall myself saying something li…, 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.

Generative Discussion

- How is your institution dealing with these issues?
- What was your institution's reaction to "OPEN M…"
  - Concerns that an individual's behavior may h… …titutional implications (e.g. Special Award Condi…
- 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?

September 2018 Meeting

NIH Opening Comments

- Duke University - Dr. Geeta Swamy

  - Vice Dean and Associate Vice Provost for Scientific Integrity

A Culture of Research Integrity

Normative Ethics	Compliance	Rigor and Reproducibility	Social Value	Workplace relationships
Right versus wrong	Within bounds of laws, regulations, policies	Doing "good science"	Doing science that society values	Environment to conduct sound work

Five Dimensions of Research Ethics. Academic Medicine.93;550-555.

Continuum of Research

Research Misconduct
Assumes willfulness to deceive

Financial Conflict of Interest
Disclose and manage to avoid bias

Best Practices in Research Integrity

Research Noncompliance
May or may not be intentional

Questionable Practices or "Sloppy Science"
Lack of good clinical or laboratory practice

- Openness
- Reproducibility
- Rigor

Building a culture of integrity at Duke

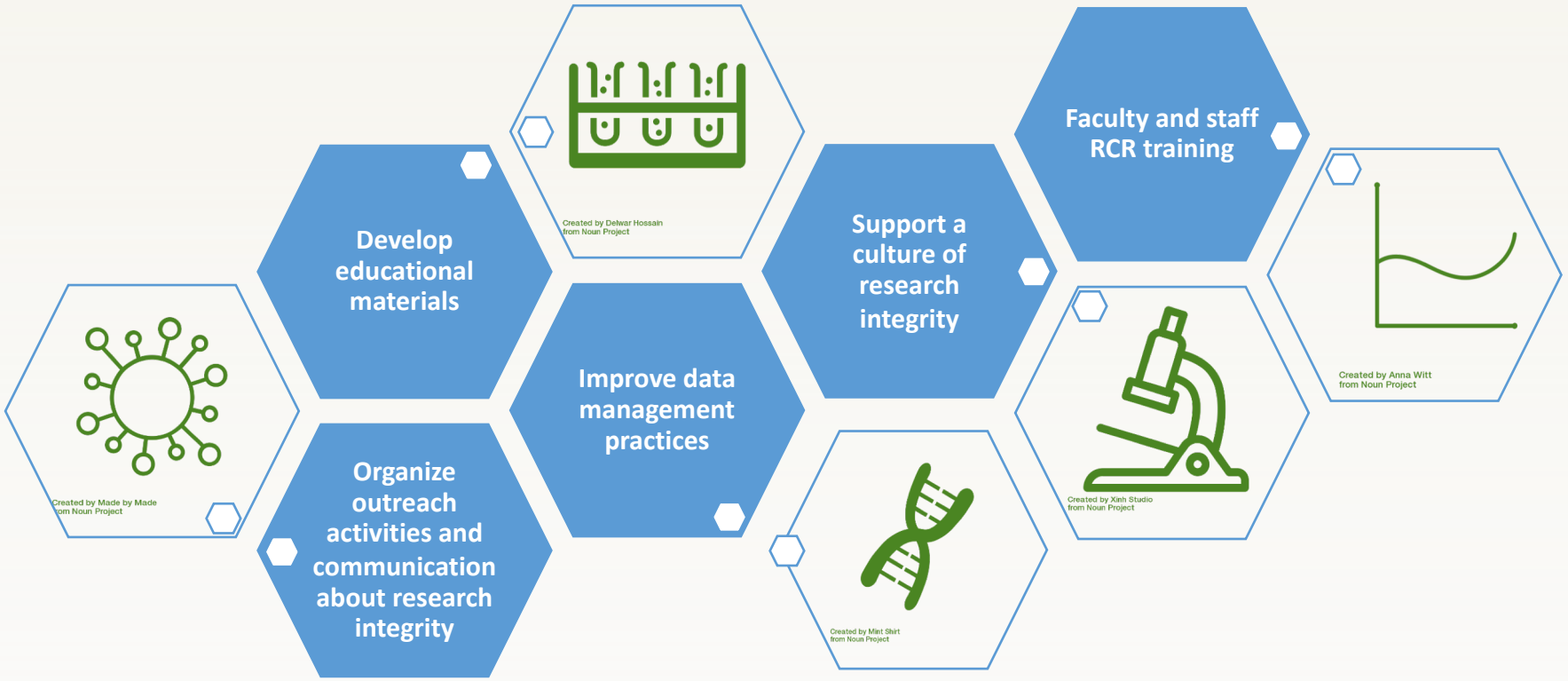
Duke | Office of Scientific Integrity

Duke | Office of Scientific Integrity

Geeta Swamy – Vice Dean & Associate Vice Provost for Scientific Integrity

ASIST Ana Sanchez	COI Greg Samsa	Incident Response Lindsey Spangler	Research Misconduct Donna Kessler	Clinical Quality Management Plan Lindsey Spangler
Research Resources	Individual & Institutional COI management	Coordinated Issue Resolution	Investigate allegations	Prospective research monitoring program
Education & Training		Risk Mitigation	Federal reporting	QA/QC measures

Advancing Scientific Integrity, Services & Training (ASIST)



Responsible Conduct of Research (RCR)

- Reproducibility in Research
- Ethical and safety considerations for human and animal experimental subjects
- Research Misconduct
- Conflict of Interest
- Mentorship/Training
- Collaborative Research
- Data Management/Best practices in daily research activities
- Science in Society

RCR for Faculty and Staff

- **Goal:**
  - Conduct ongoing, **required** training all Faculty and Staff **engaged** in research must complete RCR training
  - Separate training for grad students/post-docs

Complete 1 RCR credit from an 100-level course every 3 years

AND

Complete 1 RCR credit from an 200-level course every 3 years

- RCR 100 courses: online self-directed courses
- RCR 200 courses: collaborative learning courses

Clinical Quality Management Program

- Replaces previous retrospective internal reviews
- Focus on consenting, prospective, site-based clinical research studies that are not externally monitored or don’t have an ongoing approved monitoring plan
- Policy and tools developed to aid Quality Management Reviewers in completing clinical quality management plans and reviews
- All plans and reviews are completed in REDCap and accessible by central staff
- Complete implementation across all clinical research units by June 30, 2019

Research Town Hall Series

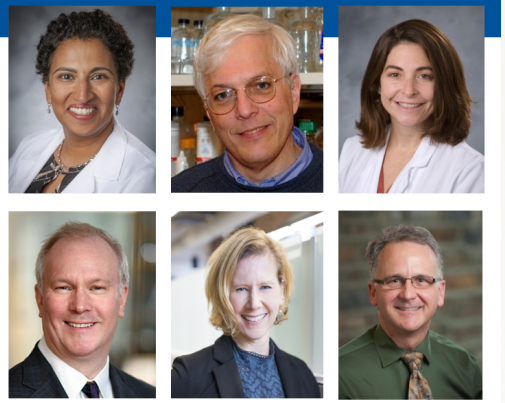
- **Goal:** Create forum to discuss new research initiatives and best practices

- **Approach:**
  - Monthly town hall events
  - Selected events will count for faculty/staff RCR credit

Created by Berkay Sargın from Noun Project

Research Town Hall Series

Research Townhall
Improving Grants from a Reviewer's Perspective



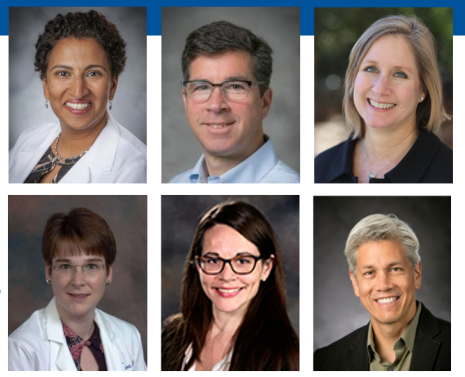
December 3, 2018

4:00 - 5:00pm • Great Hall, Trent Semans Center

Geeta Swamy, *Vice Dean and Associate Vice Provost for Scientific Integrity*
Dan Kiehart, *Professor of Biology, Dean of Natural Sciences*
Heather Whitson, *Associate Professor of Medicine, Deputy Director Center for the Study of Aging and Human Development*
Colin Duckett, *Vice Dean for Basic Science for School of Medicine*
Amy Corneli, *Associate Professor in Population Health Science*
M. Anthony Moody, *Associate Professor of Pediatrics*

Previous grant reviewers reflect on how reviewing grants has impacted their own approach to grant writing.

Research Town Hall
Whose Paper is it Anyway? A Discussion on Authorship



January 07, 2019

1:30 - 3:00pm • Great Hall, Trent Semans Center

Geeta Swamy, *Vice Dean and Associate Vice Provost for Scientific Integrity*
Michael C. Fitzgerald *Professor and Dir. of Graduate Studies, Department of Chemistry*
Cathleen Colon-Emeric, *Professor of Medicine and Office of Research Mentoring*
Raphael Valdivia, *Professor, Department of Molecular Genetics and Microbiology*
Elise Smith, *Fellow, National Institute of Environmental Health Sciences*
Jennifer Ahern-Dodson, *Assistant Professor of the Practice in the Thompson Writing Program*

Join us for an interactive discussion on authorship allocation, ordering and dispute resolution.

***Fulfills the faculty and staff RCR training requirement.**

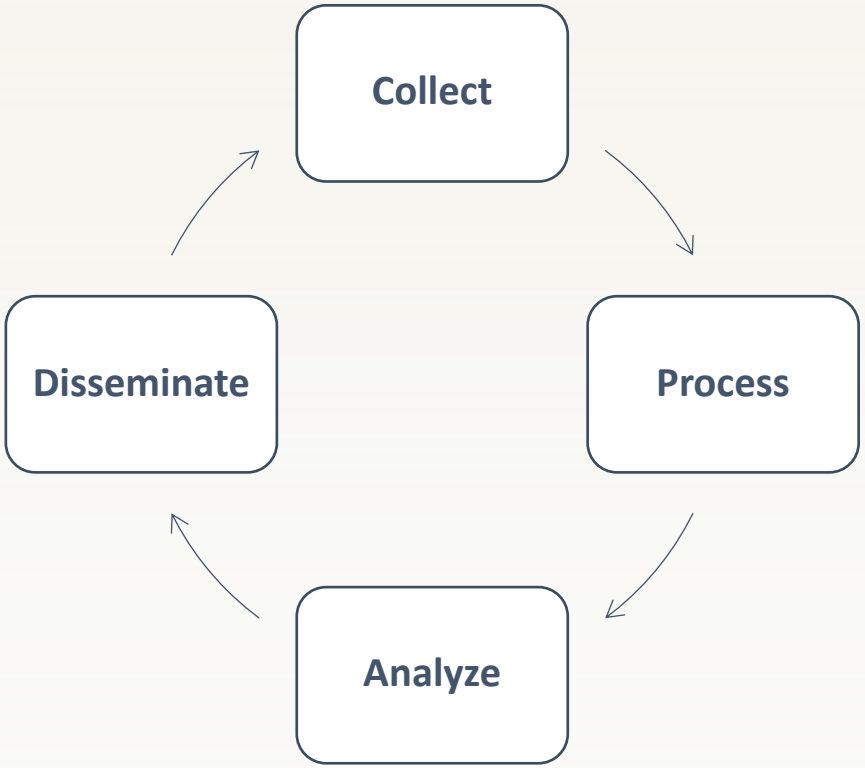
What one word would describe your experience of authorship assignment/dispute in your career?

Research Town Hall Series

- **Upcoming**
  - Plagiarism & Intellectual Credit (February)
  - SBIR/STTR (March)
  - LabArchives ERN (April)
  - Research Data Resources (April)
  - Foreign Collaborations and Influences in Research (May)
  - Speak Up – Empowering the Research Community
  - Ethics & Data Visualization

- **In Development**
  - Data Use/Data and Material Transfer Agreements
  - Library/Science & Society: Data Sharing at Duke
  - Grant development and compliance series
  - Research support round-up
  - Clinical Data Management series

Research Data Life Cycle



Supporting Data Life Cycle

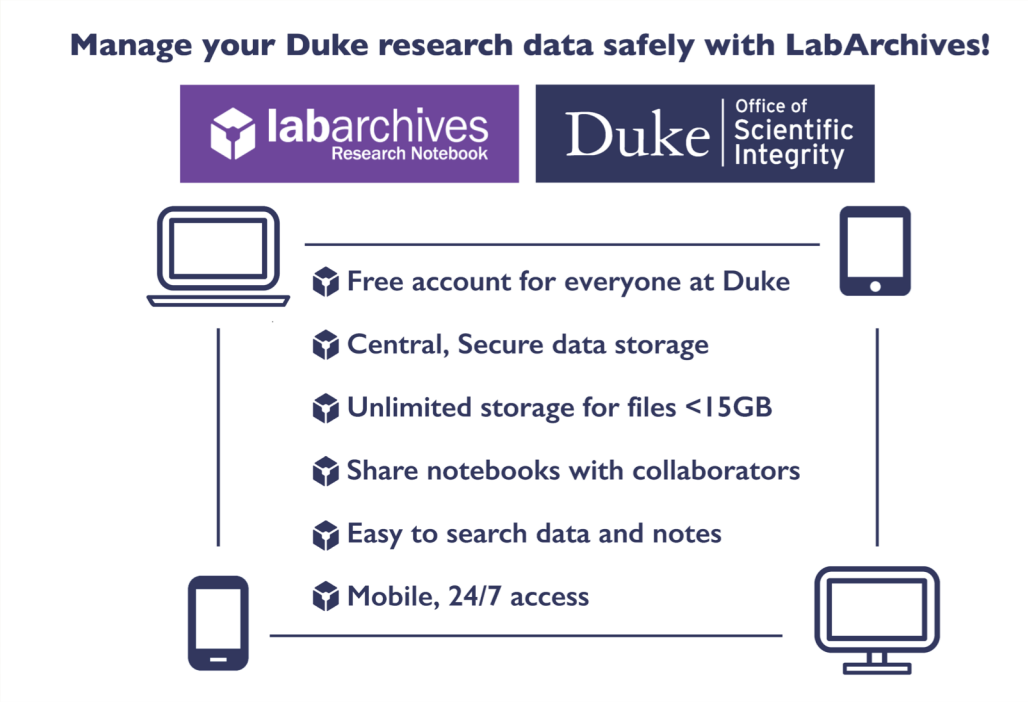
- **Electronic Research Notebooks (ERNs)** are used to electronically capture laboratory information

- **Multiple benefits:**
  - Data are searchable and accessible anywhere
  - Less/no paper notebooks
  - Secure storage in central location
  - Allows signing, file versioning, and activity tracking in support of data provenance
  - Data easily shared with PI and/or collaborators

Electronic Research Notebooks

- **Goal:** Centrally supported ERN system for SOM

- **Approach:**
  - Evaluated ERN options
  - Selected LabArchives ERN
  - Soft roll-out began Jan 2019 with full dissemination planned April 2019



Supporting Data Life Cycle

- Recently implemented a requirement for all wet research units in the School of Medicine to have a data management plan (DMP)
- Next steps
  - Refining DMP guidance document in collaboration with Duke Data and Visualization Services Data Management Consultants: Inclusive of all types of research ongoing at Duke
    - Best practices for organization, storage, roles and responsibilities along entire research life cycle
    - Resource list of Duke DMP tools, support offices, and policies
  - Refining DMP policy to consider the following
    - Expand to clinical and computational units
    - Required attestation
    - Periodic review/revision

Discussion

Time Permitting

AAU/APLU Workshop - Accelerating Access to Research Data

- 30 university teams and 4+ Federal agencies attended an October 2018 workshop
- Recommendations to Federal agencies:
  - Harmonize requirements for grant recipients
    - Including data management plans, data use agreement terms, and data sharing certifications
  - Recommend transparency on what data; how data sharing requirements will be monitored, evaluated, enforced; and when the data retention expires.
  - Use of the **FAIR** principles (findable, accessible, interoperable, and reusable)
  - Agencies should clarify and continue to explicitly note in their calls for proposals that costs to support a program's requirements for data accessibility are allowable as direct or indirect charges in research program budgets.
  - Weigh the cost of data access to the benefits of data access

AAU/APLU Workshop - Accelerating Access to Research Data

- Recommendations to universities:
  - Support faculty in developing a process to transfer stewardship responsibilities to the institution
  - Public access to data must be consistent with institutional policies on IRBs, COI and CUI
  - Determine best process for transfer of data when faculty move to another institution

Discussion and Questions