STRATEGIES FOR BUILDING A CULTURE OF INTEGRITY IN RESEARCH

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In March 2019, Duke settled a $112.5 million qui tam lawsuit with the federal government, filed by a former Duke research analyst.

The lawsuit alleged that a research technician fabricated data between 2006 and 2013, influencing a large amount of federal research funding.

Case was brought under the federal False Claims Act, which provides for treble damages and civil penalties against anyone who uses false statements to get a claim paid by the federal government.

Focus here was on false statements about research results in grant applications and progress reports.
Background  What Mattered in the FCA Case

• What reported data were false?

• Did the institution “know” that the data were false?
  – Institutional knowledge and vicarious liability.
  – “Red flags” and 20-20 hindsight

• Were the falsities “material” to the government’s decision to award the grant or make payments under the grant?
  – Would the grants have been awarded anyway?
  – What did the government do when it learned of the “false claims”?

• How much was the government damaged?

• These are not the same questions one asks in a research misconduct investigation.
The Back Story

• In late 2012, Duke discovered that a research technician in a pulmonary lab had been using a Duke procurement card for personal purchases and submitting doctored invoices. She was terminated in early 2013 and prosecuted for theft.

• Duke decided to look into the integrity of her other activities and quickly determined that the research data for a device measuring pulmonary function in mice (flexivent) had been frequently either manipulated or fabricated by the tech.

• The technician worked in a pulmonary laboratory that was labeled as a “core” facility in the program project grant funding the lab, but it was not recognized as an institutional shared service and therefore not subject to the same level of institutional oversight.

• Ultimately determined about 30 grants affected. 14 papers retracted and 21 corrections or expressions of concern issued.
The Back Story  Duke’s Response

• Duke began meeting with the large number of potentially impacted faculty, and began repeating experiments (new technician and under the supervision of a senior faculty in another department) to determine if results could be replicated.
  – Commencement of research misconduct proceedings began shortly after technician terminated.
  – Understandable desire to balance need for rapid response with fairness to researchers and the respondent.
  – Duke researchers notified their NIH program officers almost immediately after discovery of data issues that Duke was investigating concerns about data integrity.
  – Written notice to the funding agencies in June 2013.

• Note that the whistleblower had filed his lawsuit shortly after the tech was terminated for embezzlement and before Duke’s notice to NIH.
  – Duke did not know this at the time.
The Back Story What About the NIH?

• In discovery, it became clear that NIH program officers who had been told about potential data integrity issues took no action on the affected grants.
  – Apparently satisfied with waiting for conclusion of research misconduct process.
  – NIH has now imposed rules that if you find research misconduct behavior that impacts a grant, you have to tell the NIH as well as ORI – it’s not just a research integrity issue anymore.

• Office of Policy for Extramural Research Administration (OPERA) removed Duke’s Expanded Authority in April 2018.
  – Partially due to the research misconduct issues from 2005 and 2013, and concerns about willingness to enforce NIH rules and policies with our faculty.
  – Also required NIH approval of no-cost extensions, budget carry-forwards and required detailed budgets on modular grants. Importantly, NIH required a Duke response and action plan.
Background Lessons Learned

- If you find dishonest behavior in one area – look at everything the person has touched.

- Data management practices are key, ESPECIALLY in cores (true shared resources and any service perceived as a core by faculty). Anything bad that happens to data gets magnified by a core.

- Lab supervision is also critical. PIs need to understand how the equipment used in their labs operates (e.g., how the data are generated and stored), so that they can be retrieved readily if needed to justify claims made in grants and publications.

- Can’t approach all misconduct cases with normal processes; it takes too long.
  - A SWAT team approach is needed.
  - Earlier discussion with the government is always better, understanding that due process is still required for the respondent.

- Need to consider the role that PIs can be allowed to play in the institutional response.
  - Who decides if papers need retractions or corrections?
  - Who determines whether experiments need to be repeated and who pays for that?

- Organizational structure around scientific integrity is important.
  - Someone has to wake up everyday thinking about how to keep this front and center.
Background The Research Ecosystem

Who are the stakeholders?

- Researchers
- Institutions
- Publishers
- Public
- Data Curators and Managers
- Research Sponsors & Non-Profit Orgs
Background **What are the stakes?**

- Harm to research participants
- Loss of research funding
- Data loss and publication retraction
- Inability to recruit top faculty and students
- Loss of sponsor confidence
- Loss of public trust
Background The Research Support Ecosystem@Duke
Key Principles Building a Culture of Research Integrity

- **Inclusive**: All stakeholders need to participate
- **Comprehensive**: Education, oversight and accountability
- **Multifaceted**: Holistic approach across all dimensions of research integrity
- **Pragmatic**: Provide resources and tools to make it “easy” to do the right thing
- **Empowering**: Empower community and stakeholders to speak up
Associate Vice President for Research and Vice Dean of Scientific Integrity
## Next Steps Creating Change

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Adapted from Mellor Talk at BMTS meeting, January 2020.
**Initiatives** Building a Culture of Integrity in Research

Initiatives Building a Culture of Integrity in Research

- RCR/RQR for ALL faculty, staff and administrators
- Support and promote open dialogue on integrity through interactive workshops and monthly town halls
- Onboarding for all new faculty campus-wide
- Provide resources for trainee and unit-level learning
  - Interactive board game for grad students/post-docs
  - RCR/RQR Toolbox

Initiatives Building a Culture of Integrity in Research

- Preservation/tracking of source data; use of centralized auditable systems (ERNs)
- Data Management plans required for all institutionally designated Shared Resources via departmental Research Quality Teams
- Guidance on data management best practices available publicly
- Required use of statistical core for trainees

Initiatives Building a Culture of Integrity in Research

- Institutionally designated Shared Resource and Core reviews
- Systematic review of high risk, high profile investigator-initiated research
  - first in human, rare disease, etc.
  - Institutional COI such as IP or equity
- Quality monitoring of Investigator-initiated clinical research

Initiatives Building a Culture of Integrity in Research

- Empowering the Community to establish a Speak-Up Culture in Research
- Establish expectations of professionalism via Science Culture and Accountability Plans
- Coordinate compliance/oversight units; promote regular communication between units
- Establish a review/resolution mechanism for problems not covered by regulations/policies
Initiatives  Building a Community of Integrity in Research
Infrastructure Make it possible

Local

• Research Data Repository – Duke Research Data Repository
• Data Catalog
• Data Curation Services

National/International

• DataShare, University of Edinburgh
Infrastructure Make it possible

Generate a common language

Local

• Define terms (ex. Data catalog, data repository)
• Break down misconceptions about data sharing (i.e. data sharing is not impossible for restricted data or large file types)

National/International

• Funder RFIs
• Define role of funder, publisher, institution and researcher in data sharing
Infrastructure Make it possible

Few institutions support restricted-use research data archiving

- Resource intensive technical infrastructure and human capital
- Carries inherent risk in the event of a data breach

Local
- Duke Protected Research Data Network
- Duke Protected Analytics Computing Environment

National/International
- DataVault, University of Edinburgh
User Interface  **Make it easy**

*Generate systems that are easy to access, easy to use*

**Local**
- myRESEARCHhome & myRESEARCHpath
- Research Data Repository
- DiscoverData@Duke

**National/International**
- Vivli Data Sharing Platform
- Dataverse
User Interface Make it easy

myRESEARCHhome: manage research portfolio & requirements

myRESEARCHpath: self-navigate DUKE'S research ecosystem
Communities **Make it normative**

**Local**
- Resource Offices (DOSI and DORI)
- Vice Chairs for Research, Deans Cabinets
- Research Town Hall meetings
- Shared dataset citations published on Scholars@Duke

**National/International**
- the Scholarly Publishing and Academic Resources Coalition (SPARC)
- Center for Open Science (COS)
- Committee on Publication Ethics (COPE)
- Research Data Alliance (RDA)
**Incentives** Make it rewarding

**Local**
- APT
- Rewards for sharing

**National/International**
- The Quality – Ethics – Open Science – Translation (Quest) Center for Transforming Biomedical Research
Policy **Make it required**

**Local**
- Research Handbook policy changes
  - Revised research misconduct policy
    - Focus on falsification, fabrication and plagiarism
    - Included in faculty AND staff
  - Open Science Policy
- Research Quality Management Program
  - Data Management and Sharing Planning
- Researcher Onboarding

**National/International**
- Funder Data Management and Data Sharing Policies
Questions We are here to help!

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