STRATEGIES FOR BUILDING A CULTURE OF INTEGRITY IN RESEARCH

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Background What the Public Knows

- 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

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- 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.
 - <u>https://grants.nih.gov/grants/guide/notice-files/NOT-OD-19-020.html</u>
- 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



Background What are the stakes?

Harm to research participants	Loss of research funding	Data loss and publication retraction
Inability to recruit top	Loss of sponsor	Loss of
faculty and students	confidence	public trust



Background The Research Support Ecosystem@Duke



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Key Principles Building a Culture of Research Integrity

Inclusive	Comprehensive	Multifaceted	Pragmatic	Empowering
All stakeholders need to participate	Education, oversight and accountability	Holistic approach across all dimensions of research integrity	Provide resources and tools to make it "easy" to do the right thing	Empower community and stakeholders to speak up





Associate Vice President for Research and Vice Dean of Scientific Integrity

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Next Steps Creating Change

Policy	 Make it required
Incentives	 Make it rewarding
Communities	 Make it normative
User interface	 Make it easy
Infrastructure	 Make it possible

Adapted from Mellor Talk at BMTS meeting, January 2020.

















- 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

Scientific and Analytical Excellence



 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





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

my Training COURSES SYSTEMS	\$ 22	➡ my Approvals	• 22	PROJECTS FINANCES PERSONNEL IRB	RECOMMENDED FAVORITES ALL SOURCES
Upcoming	Due	Ay Proposal Attestation	0	ACTIVE AWARDS	Q Search Recommender
Duke Leadership Academy	01/28/2020	Ay Award Attestation	0	PI/ Co-PI/ FELLOW 0	Sorting by deadline; SEE WHAT'S NEW INSTEAD
Caro -		fin Sponsored Research	0	SENIOR / KEY PERSONNEL 0	Duke Clinical and Translational Science Institute (CTSI) -
HIPAA Privacy and Security Training OESO	10/24/2020	iForm	0	OTHER PROJECT ROLES 0	- Duke CTSI Population Health Improvement Collaboration Seed Awards
Compliance Update Training	12,05,72020	🛧 Travel	0	ROLE UNKNOWN	External Deadline: Rolling Agency: Duke University
OESO	121 Gar 2020	Procurement	0	NON-COMPETING RENEWALS	Amount: \$1,500
Fire/Life Safety OESO	12/05/2020	菁 Buy@Duke	0	IN PROCESS 0	Relevant? 🤡 😒
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cm	05/15/2021	Login to the R3 SAP inbox to view items	0	START PROPOSAL PROCESS	SUBMIT AN OPPORTUNITY
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Q Snarch All		MARY LOU ADDOR		Financial Summary Report One line financial summary of all funds	Feeling lost, unsure, or stuck?
Altmetrics View the online activity surrounding your scholarly	content	Instructor in the Nicholas School of the Environ	rment	Award Statement	ASK & QUESTION
Brand Guidelines - Duke	1*	Muhammad Abd-El-Barr Assistant Professor of Neurosurgery		Detailed view of budgeted vs. actual spending for all award-based research funds	New to Duke or need 1-on-1 support?
Business Objects - Crystal Reports	1\$	Baloh Ahi Harbern		Fund Balance Statement Detailed view of balances for discretionary and other codes	MEET WITH A NAVIGATOR
Calendar of Scientific Events A list of the upcoming scientific events listed on the	e Duke Event 🟠	Assistant Professor of Surgery		Transaction Statement	Know what you need but don't know where to go?
Calendar		Mohamad Dahia Abou Donia		Ust of financial transactions on codes during a specified fiscal period	CONNECT ME TO A RESOURCE

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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)

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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

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- 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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