




# **AVOIDING REGULATORY PITFALLS IN RESEARCH ACTIVITIES – EYES WIDE OPEN!**

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APRIL 18, 2019



**REGULATORY ACTIVITY RELATED TO RESEARCH IS  
INCREASING  
AT THE FEDERAL LEVEL**

- **FEDERAL DOLLARS AVAILABLE ARE DECREASING**
  - **COMPETITION FOR FEDERAL FUNDING IS HIGHER THAN EVER**
  - **PRESSURE FOR LIMITED FUNDS IS HIGH**
  - **REGULATORY ENFORCEMENT IS A LUCRATIVE WAY TO IMPROVE COMPLIANCE**
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# HOW LUCRATIVE?

- 4 INSTITUTIONS
- \$170M+
- 4 YEARS
- RESEARCH-BASED FALSE CLAIMS
- FCA = TREBLE DAMAGES + PENALTIES

# FALSE CLAIM DEFINED

- KNOWINGLY FALSE INFORMATION SUBMITTED FOR
  - PAYMENT FROM FEDERAL FUNDS
  - RETENTION OF FEDERAL FUNDS
- RESULTS FROM KNOWINGLY:
  - SUBMITTING FALSE/FRAUDULENT INFORMATION FOR PAYMENT OR CAUSING SUCH
  - MAKING, USING, OR CAUSING A FALSE RECORD/STATEMENT THAT IS MATERIAL TO THE CLAIM OR PAYMENT
  - CONCEALING OR AVOIDING REPAYMENT OBLIGATION
  - CONSPIRING TO COMMIT ANY OF THE ABOVE

# WHAT IS “KNOWINGLY”?

- ACTUAL KNOWLEDGE

OR

- DELIBERATE IGNORANCE

OR

- RECKLESS DISREGARD FOR THE TRUTH



# THREE HOT TOPICS UNDER THE REGULATORY MICROSCOPE: KNOW YOUR ROLES AND RESPONSIBILITIES

## 1. COST ALLOWABILITY

- DOCUMENTATION, T&E, F&A

## 2. RESEARCH MISCONDUCT

- FRAUDULENT INDUCEMENT

## 3. OUTSIDE ACTIVITIES

- IP, PRIVATE COMPANIES
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# 1. COST ALLOWABILITY – DOCUMENTATION

## GRANT CHARGES MUST BE SUPPORTED BY ADEQUATE DOCUMENTATION

- ARE DATES AND LOCATIONS CONSISTENT WITH PROPOSAL?
- DO RECEIPTS/DOCUMENTS COVER ALL COSTS CLAIMED?
- ARE RECEIPTS/DOCUMENTS LEGIBLE?

11/15 – UNIV OF FLORIDA PAID \$20M FOR UNDOCUMENTED CHARGES, AMONG OTHER FALSE CLAIMS (INCORRECT F&A, INFLATED CHARGES BY MISREPRESENTING SUBCONTRACTOR COSTS)

# COST ALLOWABILITY – T&E

TIME AND EFFORT MUST BE ACCURATELY MEASURED, TRACKED, AND CHARGED

- WHAT METHOD TO YOU USE TO TRACK?
- HOW DO YOU VALIDATE?
- IS FTE BEYOND 100%?

2/18 – UNTHSC PAID \$13M; SELF-REPORTED THAT FOR 5 YEARS, IT FAILED TO ENSURE T&E REPORTS RELATED TO CERTAIN GRANTS WERE ACCURATELY & TIMELY REPORTED



# COST ALLOWABILITY – F&A

## THE CORRECT INDIRECT COST RATE MUST BE CHARGED

- ON OR OFF CAMPUS RATE?
- UNIVERSITY OR SUBCONTRACTOR RATE?

7/16 – COLUMBIA UNIV PAID \$9.5M FOR CHARGING ON-CAMPUS F&A AND NOT NOTIFYING HHS THAT MOST RESEARCH WOULD BE CONDUCTED OFF CAMPUS. ALSO NOTED THAT EFFORT REPORTS NOT COMPLETED BY INDIVIDUAL WITH “SUITABLE MEANS OF VERIFICATION.”

# THE COST ALLOWABILITY LESSON: KNOW WHAT'S GOING ON WITH YOUR AREA'S GRANTS

NW PAID \$2.7M FOR FAILURES, INCLUDING TO OVERSEE GRANT ACTIVITY:

- DISBURSING FUNDS WITHOUT ADEQUATE DOCUMENTATION
- COMINGLING FUNDS FROM DIFFERENT AWARDS
- EXERCISING INSUFFICIENT OVERSIGHT OF ACTIVITY
- DISBURSING TRAVEL FUNDS AND PERSONAL EXPENSES WITHOUT ADEQUATE DOCUMENTATION AND BASED ON PI'S FRAUDULENT DOCUMENTS
- WAITING 2 YEARS TO NOTIFY NSF OF FRAUDULENT CLAIM

**EVERYONE AT EVERY LEVEL IS RESPONSIBLE FOR OVERSIGHT ACTIVITIES!**

## 2. RESEARCH MISCONDUCT

- GOVERNMENT REGULATORS: RESEARCH MISCONDUCT IS A “POTENTIALLY SIGNIFICANT OPPORTUNITY” DUE TO HIGH DAMAGES AVAILABLE UNDER FCA
- OCT 2018 – NIH ISSUED “CLARIFYING” NOTICE THAT **RESEARCH MISCONDUCT MUST BE REPORTED** TO NIH (IN ADDITION TO ORI) WHEN INSTITUTION “FINDS, LEARNS OF, OR SUSPECTS” MISCONDUCT THAT “IMPACTS OR MIGHT IMPACT” THE CONDUCT OF THE NIH RESEARCH AT THE INSTITUTION OR AT A SUBRECIPIENT. (EACH FEDERAL AGENCY HAS AN OIG.)

# WHAT CONSTITUTES RESEARCH MISCONDUCT?

- PHS/NSF – FABRICATION, FALSIFICATION, OR PLAGIARISM IN:
  - PROPOSING
  - PERFORMING THE WORK
  - REVIEWING RESEARCH
  - REPORTING RESEARCH RESULTS
  - FAILING TO REPORT/MANAGE CONFLICT OF INTEREST

**THAT INDUCES THE AGENCY TO MAKE THE AWARD OR PAY THE CLAIM**

# EXAMPLES OF FCA CLAIMS IN RESEARCH

- MISLEADING REQUEST FOR FUNDING/PROPERTY MADE TO AWARDING AGENCY
  - GRANT APPLICATION INCLUDING FALSIFIED IMAGE OR DATA
  - PROGRESS REPORTS WITH FALSIFIED IMAGE OR DATA
- INACCURATE CERTIFICATIONS OF COMPLIANCE (FINANCIAL REPORTS, ELIGIBILITY STATEMENTS)
  - “FULLY ACCOUNTABLE” FOR USE OF GRANT FUNDS
- PI PLAGIARIZED PUBLICATIONS OR DATA, THEN CITED IN LATER APPLICATIONS

# YOU HAVE AN OBLIGATION – DO YOU KNOW WHAT IT IS?

INDIVIDUALS WITH NIH FUNDING HAVE “OBLIGATION TO CONDUCT RESEARCH HONESTLY” AND AN “AFFIRMATIVE DUTY TO PROTECT [GRANT] FUNDS FROM MISUSE”

- AWARDEE “KNEW OR SHOULD HAVE KNOWN” THE LAB RELIED ON FALSIFIED DATA AND IMAGES
  - PROTOCOLS NOT FOLLOWED
  - RECKLESS RECORD-KEEPING
  - MULTIPLE DATA DISCREPANCIES

4/17 – BRIGHAM & WOMEN’S HOSPITAL SELF-DISCLOSED; PAID \$10M FOR FALSE DATA IN NIH APPLICATIONS AND CLAIMS FOR FUNDS IN HEART RESEARCH

# DUKE MISSED THE HINTS

- LAB EMPLOYEE FABRICATED/FALSIFIED GRANT-FUNDED DATA FOR 8+ YEARS
- DATA WERE INCLUDED IN SEVERAL GRANT APPLICATIONS, PROPOSALS, PROGRESS REPORTS, AND PUBLICATIONS; INAPPROPRIATE CHARGES TO GRANTS WERE MADE
- DUKE HAD “HINTS” OF PROBLEMS DURING THE 8 YEARS
  - DELIBERATE INDIFFERENCE? RECKLESS DISREGARD?
- DUKE HAD \$200M IN FEDERAL GRANTS AT THE TIME

# COSTS TO DUKE?

- SETTLEMENT: \$112.5M
- RESTRICTIONS, INCLUDING ALL CHANGES TO GRANTS MUST BE APPROVED IN ADVANCE BY THE AWARDING AGENCY
- REPUTATIONAL



# WHY WAS DUKE RESPONSIBLE FOR A LAB TECH'S FRAUD?

- GRANT TERMS & CONDITIONS:
  - “FULLY ACCOUNTABLE” FOR USE OF GRANT FUNDS
  - RESPONSIBLE FOR ACTIONS OF EMPLOYEES AND OTHERS INVOLVED IN PROJECT
  - “AFFIRMATIVE DUTY TO PROTECT GRANT FUNDS FROM MISUSE BY ENSURING INTEGRITY OF WORK”
- NOTE THAT THE FCA ALSO INCLUDES CRIMINAL PENALTIES THAT CAN BE IMPOSED AGAINST RESEARCHERS AND STAFF

# 3. OUTSIDE ACTIVITIES

TRACKING & DOCUMENTING ACTIVITIES OUTSIDE OF THE “HOME” INSTITUTION

-START-UP COMPANIES (HAVE AGREEMENTS & COI MGMT. PLANS IN PLACE)

EFFORT? IP? RESOURCES? LICENSES?

-RELATIONSHIPS WITH OTHER UNIVERSITIES, NATIONAL AND INTERNATIONAL

\*NSF AND NIH, FOR EXAMPLE, REQUIRE PI AND OU TO CERTIFY:

- WE ENFORCE WRITTEN COI POLICY
- ALL FINANCIAL DISCLOSURES HAVE BEEN MADE
- COI ISSUES HAVE BEEN ADDRESSED PRIOR TO EXPENDITURE OR WERE DISCLOSED TO AGENCY IN “OTHER SUPPORT DISCLOSURES”

# TAKE-AWAYS FOR APPROVERS, RESEARCHERS, AND STAFF

- IF YOU DON'T HAVE DOCUMENTATION, IT DIDN'T HAPPEN – DON'T CHARGE THE GRANT OR THE UNIVERSITY FOR IT
  - RETAIN THE DOCUMENTATION FOR AT LEAST 5 YEARS, THEN ASK WHETHER YOU CAN DESTROY
- IF IT SEEMS SQUISHY, ASK FOR MORE INFORMATION. DON'T RELY ON A PRIOR SIGNATURE OR PRACTICE.
- DISCLOSE, DISCLOSE, DISCLOSE
- FOLLOW THE PROTOCOL, PROPOSAL, AND BUDGET, OR GET WRITTEN APPROVAL FROM THE SPONSOR TO CHANGE MATERIAL ITEMS

# TAKE-AWAYS, CONT'D

- REVIEW AND UNDERSTAND ALL OF THE TERMS THAT APPLY TO THE GRANT
  - GRANT TERMS      FEDERAL LAW (FCA, FOR EXAMPLE)      STATE LAW
  - OU POLICY      COLLEGE/DEPARTMENT POLICY      GRANT PROPOSAL
- IF YOU AREN'T SURE, ASK UNTIL YOU ARE!
- IF YOU BECOME AWARE OF A PROBLEM, INFORM SOMEONE WHO CAN HELP.

The image features a light gray gradient background with several realistic water droplets of various sizes scattered in the corners. The droplets have highlights and shadows, giving them a three-dimensional appearance. The text 'QUESTIONS???' is centered in the upper half of the image.

**QUESTIONS???**