AVOIDING REGULATORY PITFALLS IN RESEARCH ACTIVITIES – EYES WIDE OPEN!

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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
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
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 do 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 “SUITEABLE 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.
QUESTIONS???