OIG’s Role in Grants Oversight, Grant Fraud, and Research Compliance

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HCCA Research Compliance Conference
Orlando, Florida
June 11, 2019

Topics

• OIG’s Role
• Risk Areas
• OIG Civil Money Penalties
• OIG Grant Self-Disclosure Program
**Mission:** To protect the integrity of HHS programs and the welfare of the people they serve.

**Vision:** To drive positive change in HHS programs and in the lives of the people served by these programs.

- Multidisciplinary
  - Investigations
  - Audits
  - Evaluations
  - Data Analytics
- Recommendations to HHS
- Improve economy, efficiency, and effectiveness
- Mitigate risk
Collaboration and Partnership

- Law enforcement partners – DOJ, FBI
- Other OIGs (NSF, NASA, DoD, and others)
- HHS Operating Divisions
- OIG Suspension and Debarment Official

When Research Misconduct Involves Potential Criminal Behavior: New Collaboration Strengthens Protection of U.S. Biomedical Research Funding
Misspent Research Funds

- Limited public funds
- Financial loss
- Lost opportunity
- Unsound science
- Erodes support for public investment in research

Risk Areas
• Research Misconduct
• Cost Allocation/Accounting
• Embezzlement
• Sub-Recipient Monitoring
• Duplication and Overlap in Funding
• Improper Influence

Research Misconduct

• Financial impact
• Institutional safeguards
• Prevent, identify, report and deter
Duke University

• March 2019
• $112.5 Million False Claims Act settlement
• Airway Physiology Lab
• Allegations: between 2006 and 2018, Duke knowingly submitted claims to NIH and EPA that contained falsified or fabricated data or statements related to 30 grants
• NIH Requirements

Duke University - Lessons

• Establish strong compliance programs and safeguards
• Create pathways for reporting improper conduct
• Take allegations and warning signs seriously
• Timely internal investigation and reporting to grants officials
Partners Healthcare and Brigham and Women’s Hospital

- April 2017
- $10 Million FCA settlement
- Allegations: lab and three researchers submitted falsified images and data in NIH grant applications related to the purported ability of stem cells to repair damage to the heart
- Partners disclosed to OIG and ORI, OIG coordinated with DOJ

Dr. Dong-Pyou Han

- Former Iowa State professor
- Falsified data to make it appear as though an experimental HIV vaccine controlled HIV/AIDS in rabbits
- Pled guilty to false statements to NIH (2015)
  - 57 months prison sentence
  - $7.2 million restitution
Cost Allocation/Accounting

• Indirect costs
• Improper reporting of costs
• Time and effort reporting

Columbia University

• July 2016
• $9.5 Million FCA settlement
• Columbia admitted to seeking and receiving cost recoveries at the higher on-campus indirect cost rate for over 400 mental health research grants, even though the research was primarily performed in space not owned or operated by Columbia.
**UT Health Science Center Houston**

- December 2018
- $2.39 Million FCA settlement
- Human Genomics Center
- Allegation: misappropriated unobligated funds remaining at the end of a grant term

**University of Florida**

- November 2015
- $20 Million FCA settlement
- Allegation: overcharging hundreds of grants for the salary costs of its employees, without documentation to support the level of effort claimed
University of North Texas Health Science Center

- February 2018
- $13 Million FCA settlement
- Self-disclosed to OIG and NIH that from 2011 through 2016, it had inaccurately reported time and effort spent by researchers on federally funded grants.

Alexander Neumeister

- October 2018
- Psychiatrist and Former Yale and NYU Professor
- Routinely used grant funds for personal expenses, personal travel, trips for family and friends, and meals.
- Guilty, 18 U.S.C. 641
  - 3 years probation
  - Criminal restitution
Sub-Recipient Monitoring

• Subrecipient Monitoring Audits
• Challenging Area
• OIG Audits

Duplication and Overlap

• OIG work plan
• OAS planned item: review of NIH’s internal controls for identifying duplicative grant funding within its 27 institutes
Duplication and Overlap

- Risk in SBIR funding
- Following up 2011 report “Vulnerabilities in the HHS Small Business Innovation Research Program”
- Recommended HHS improve procedures to check for duplication.

Improper Influence

- Peer Review
- Financial Conflicts of Interest
- Foreign Influence in Research
Peer Review

- Risks to the security of intellectual property
- Integrity of peer review process
- OEI planned work item will describe and assess NIH’s process for vetting prospective

Financial Conflicts of Interest

- Non Federal entities are required to manage financial conflicts of interest and report significant concerns
- OAS will review whether NIH has policies, procedures, and controls to ensure that foreign and domestic grantees disclose all sources of research support, financial interests, and affiliations.
- OAS will review NIH's oversight and monitoring of the financial conflicts of interest reported by grantee institutions
Foreign Influence in Research

• OIG engagement with NIH
• Congressional Focus
  • June 5, 2019, Senate Finance Committee Hearing
  • Foreign Threats to Taxpayer-Funded Research: Oversight Opportunities and Policy Solutions
  • OIG, NIH, HHS, and DHS
• Investigative Referrals from Congress to OIG

Grant and Contract Fraud Enforcement under OIG’s Civil Monetary Penalty Authority
Types of Fraud Enforcement Actions

**Criminal**
- Prosecutions
  - Judge/Jury
  - Guilt “beyond a reasonable doubt”

**Civil**
- Lawsuits
  - Federal False Claims Act
  - Judge/Jury
  - “Preponderance of Evidence”

**Administrative**
- Administrative Actions
  - Civil Monetary Penalty
  - Administrative Law Judge
  - “Preponderance of Evidence”

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**OIG Enforcement Authorities**

- **Civil Monetary Penalties Law (CMPL)**
  - § 1128A of the Social Security Act
  - 42 U.S.C. § 1320a-7a

- **OIG Exclusion Authority**
  - § 1128 of the Social Security Act
  - 42 U.S.C. § 1320a-7

- **21 Century Cures Act**
  - Congress extended CMPL to fraudulent conduct involving HHS grants, contracts, and other agreements
OIG CMP Basics

• Remedies
• Case Sources
• OCIG Evidence Gathering
• Demand Letter
• Appealable to Administrative Law Judge

OCIG’s Affirmative Litigation Goals

• Deter fraud, waste, and abuse in HHS programs

• Complement DOJ Enforcement Activities
  • Focus on individual accountability
  • Filling enforcement gaps

• Amplify Work of OIG
  • Build off the work of OAS, OEI, and OI
CMPL Offenses
42 U.S.C. §§ 1320a-7a(o)(1)-(5)

- Presenting a false or fraudulent specified claim under an HHS grant.
- Making a false statement or omission to HHS about an HHS grant.
- Making or using a false record related to an HHS grant.
- Concealing or improperly avoiding an obligation owed under an HHS grant.
- Failure to grant access to OIG.

What Conduct Could Violate CMPL?

Misstating facts in grant applications, progress reports, certifications, other documents submitted to HHS about, e.g.:

- Qualifications/eligibility
- Expenses and budget details
- Facilities
- Personnel
- Project status or results
What Conduct Could Violate New CMPL?

Submitting false claims:
- Charging for costs not incurred or unallowable costs
- Charging personal expenses against grant
- Charging more than one grant for same work
- In some cases, drawing down funds when not in compliance with grant terms (noncompliance/fraud)

What Conduct Could Violate New CMPL?

Falsifying documents and lying to grant officials:
- Manufacturing time and effort records
- “Dummy invoices”
- Lying to agency officials administering grant
- Falsifying test results or data
What Conduct Could Violate New CMPL?

Conflicts of Interest
- Less than arms length transactions
- Subaward decisions
- Consultants

Remedies
- Penalties: between $10,000 and $50,000 per act
- Assessments: recovery of up to 3 times the total amount of funds involved
- Federal health care program exclusion: no payment may be made by Medicare, Medicaid, or any other Federal health care program
- Exclusion is NOT Suspension/Debarment
Federal award recipients should be responsible stewards of Federal funds

Compliance is Critical

• Markers of a Robust Compliance Program
  1. Reporting
  2. Routine internal audits
  3. Written policies
  4. Written code of conduct
  5. Routine training
  6. Dedicated compliance officials

• Leadership commitment to compliance
Reporting Misconduct

OIG’s Grants Self-Disclosure Program
Self-Disclosure

• Mandatory disclosure
  • 45 C.F.R. § 75.113
  • Violations of Federal criminal law that involve fraud, bribery, or gratuity violations
  • Disclose to both:
    • HHS Awarding Agency
    • OIG

• Voluntary disclosures
  • Conduct that violates CMPL or impacts award, but does not trigger the requirements of 45 C.F.R. § 75.113

Benefits of Self-Disclosure

• Favorable treatment compared to affirmative investigation
• Track record in health care: faster, cheaper, less disruptive
• OIG coordinates with awarding agencies
• Disclosure results in monetary CMPL settlement
Reporting fraud suspected of others

1-800-HHS-TIPS

or

OIG website:  http://oig.hhs.gov/

Your Feedback for OIG

• OIG Compliance Resource Portal
• Compliance Resource Ideas
• Questions about Self-Disclosure Program