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

Greg Demske, Chief Counsel, HHS-OIG  
HCCA Research Compliance Conference  
Orlando, Florida  
June 11, 2019



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## Topics

- **OIG's Role**
- **Risk Areas**
- **OIG Civil Money Penalties**
- **OIG Grant Self-Disclosure Program**








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**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.

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




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## Collaboration and Partnership

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



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




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## Misspent Research Funds

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






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## Risk Areas









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



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## Research Misconduct

- Financial impact
- Institutional safeguards
- Prevent, identify, report and deter






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## *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



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## *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



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## *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



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## *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



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## Cost Allocation/Accounting

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



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## *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.






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## *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



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## *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

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## *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.



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## *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



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## Sub-Recipient Monitoring

- Subrecipient Monitoring Audits
- Challenging Area
- OIG Audits

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**NORTHWESTERN UNIVERSITY DID NOT  
ALWAYS COMPLY WITH FEDERAL  
REQUIREMENTS TO PERFORM RISK  
ASSESSMENTS OF SUBRECIPIENTS, BUT  
CLAIMED ALLOWABLE COSTS**

Inquiries about this report may be addressed to the Office of Public Affairs at  
[PublicAffairs@oig.hhs.gov](mailto:PublicAffairs@oig.hhs.gov)




**Christa L. Jaramon**  
Deputy Inspector General  
for Audit Services

November 2018  
A-09-17-00018

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## Duplication and Overlap

- OIG work plan
- OAS planned item:  
review of NIH's internal  
controls for identifying  
duplicative grant  
funding within its 27  
institutes


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### WORK PLAN

Fiscal Year 2016

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## 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.

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**VULNERABILITIES IN THE  
HHS SMALL BUSINESS  
INNOVATION RESEARCH  
PROGRAM**


Daniel R. Levinson  
Inspector General  
April 2014  
OIG-04-11-0058

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## Improper Influence

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






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## 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



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## 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



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## 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**



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## Grant and Contract Fraud Enforcement under OIG's Civil Monetary Penalty Authority

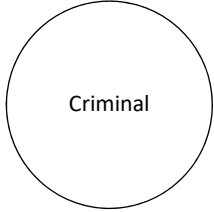


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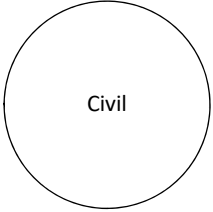
## Types of Fraud Enforcement Actions



**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

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## OIG CMP Basics

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



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## 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



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## 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.



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## 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



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## 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)



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## 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



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## What Conduct Could Violate New CMPL?

### Conflicts of Interest

- Less than arms length transactions
- Subaward decisions
- Consultants



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## 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



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## Federal award recipients should be responsible stewards of Federal funds



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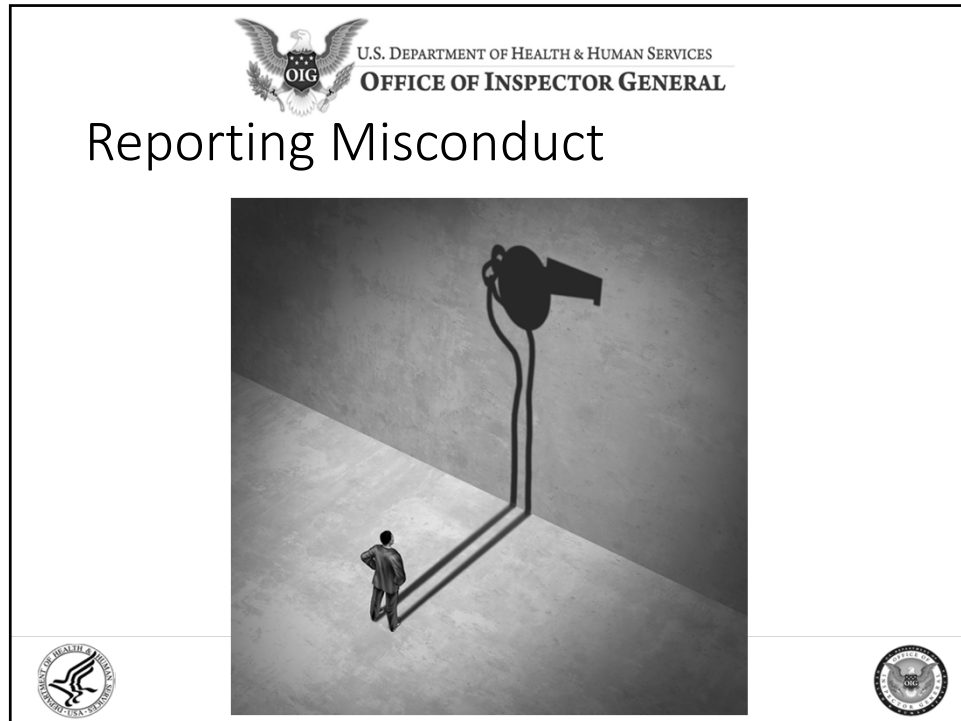
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## Compliance is Critical

- 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



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## 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



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## 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



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## Reporting fraud suspected of others

1-800-HHS-TIPS

or

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



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## Your Feedback for OIG

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

Email your suggestions  
for new OIG compliance  
resources



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