Parallel Tracks of Legal Accountability for Research Misconduct in the United States

John R. Thomas, Jr.  Matthew W. Broughton
Caveats

• Opinions are based upon cases
• There are varied approaches at different funding agencies and OIGs
• We are talking today about systems
• Three forms of accountability:
  - Administrative
  - Civil
  - Criminal

• Accountability is applied haphazardly by different agencies.

• These “tracks” should be unified and harmonized.

Credit: http://www.ranker.com/list/confusing-road-signs/nathandavidson
Consequences — Big Picture

- **Criminal Law**:  
  - Punish  
  - Rehabilitate  
  - Deter

- **Civil Law**:  
  - Repay for damages  
  - Deter

Credit: iStock
Accountability Goals in Research Misconduct World

• Punish wrongdoers?
• Deter others/ Incentivize honesty in science and good scientific practices?
• Correct the scientific record?
• Return taxpayer funds to governments when they are wasted?
In the United States:
- NIH: 42 C.F.R. Part 93
- NSF: 45 C.F.R. Part 689

Process:
- Allegation
- Inquiry
- Investigation

Outcome: Suspension
Administrative

• Long process

• Against Researcher (not institution)

• Different agencies have different tools

• Results in Suspension (sometimes permanent)

• No grant funding returned to funding agency
Administrative Case Studies
Case Involved: Lab of Savio Woo

- Leading U.S. gene therapy scientist.

2005 —

- Research using two Fellows to test genetically engineered bacteria to fight cancer.

- Fellow No. 1, Zhiya Li
  - falsified histopathological data in 57 images reported in papers, etc.
  - Administrative Action
    - ORI found:
      - Li intentionally fabricated bar graphs for experiments that were never performed on cells that did not exist.
    - ORI ordered:
      - 5 year debarment from contracting with a U.S. Agency.
      - 5 year prohibition from serving on any NIH Committees, including Peer Review.
• Fellow No. 2 — Li Chen
  - ORI found:
    ◦ Chen intentionally fabricated genetic data and reused the same image claiming it to be from multiple experiments in four publications and grant applications.

  - ORI ordered:
    ◦ 3 year debarment from contracting with U.S. Government for grants, etc.
    ◦ 3 year debarment from serving in any advisory capacity to PHS, such as serving on Peer Review Panels.
Department of Surgery — Dr. Karen D’Souza

• 2010:
  - ORI found:
    ◦ that D’Souza falsely relabeled and/or spliced Western blot images and falsified data for experiments that were not performed or were from unrelated experiments.
• 2016: ORI ordered:
  • 2 years of restrictions on D’Souza’s ability to work on PHS-supported research - specifically:
    ✴ Institution employing her must advise ORI of her involvement and of their plan to supervise her.
    ✴ Her Supervisor must be familiar with D’Souza’s field of research and provide oversight.
    ✴ Any institution employing D’Souza must submit a certification to ORI that the data provided by D’Souza are based on actual experiments or are otherwise legitimately derived and that the data, procedures and methodology are accurately reported.
    ✴ No service on PHS Advisory Committees, Peer Reviews, etc.
    ✴ Had to retract a 2010 publication.
Civil

• False Claims Act (31 U.S.C. § 3729, et seq.)

• Liability attaches where:
  - Knowingly submitting false claim for payment to the United States Government.
Civil

- Can be against both researcher and institution as grantee.

- Can serve as basis for administrative action.
Civil Case Study
Van Gorp/
Cornell University Medical College

Facts:

Grant Application entitled: “Neuropsychology of HIV/AIDS Fellowship.”

Cornell Represented:

- Majority of fellows’ work will be spent with persons with HIV/AIDS.
- 75% time will be research and 25% time will be clinical work with persons with HIV/AIDS.
- Promised 14 “key” faculty members would contribute to project in substantive way.

One Fellow — Feldman - complained to NIH that none of Cornell’s promises were true.

NIH asked Cornell to investigate itself.

- Cornell found NO wrongdoing.

*United States ex rel. Feldman v. Van Gorp, et al., 2012*
Whistleblower/Relator (Feldman)  

Files qui tam civil case  
He WON!

Court awarded:  
- Damages in full amount of grant (x3)  
- Attorney’s fees  
- Costs

Why did he win? Because —  
- They lied to get grants.  
- An honest/truthful scientist did not get the grant.

*United States ex rel. Feldman v. Van Gorp, et al., 2012*
Criminal

- 18 U.S.C. 1031: Major Fraud Against U.S.
- 18 U.S.C. 1343: Wire Fraud
Criminal

Pros
• Faster
• Strong Deterrence

Cons
• Harsher
• May Discourage Reporting
• May be inappropriately individualized
Criminal Case Study
Criminal Case

- Researcher — Dr. Dong Pyou Han
- **Facts:**
  - He spiked rabbit sera samples with human HIV antibodies to give the appearance that the rabbits were producing the HIV antibodies.
  - The false data were reported to the National Institutes of Health in a research grant application and funded grant progress reports.
- **Charged:**
  - with faking HIV/AIDS research involving rabbits.
- **Guilty:**
  - Han pled guilty to two counts of making false statements to NIH to get grant funds.
- **Criminal Penalty:**
  - 4.5 years in prison.
  - Han must repay $7.2 million in grant funds received from the federal government using the false data.
Unequal Outcomes

Administrative

- Long Process (5+ Years)
- No Punishment
- No Recoupment of Grant Dollars
- Short Suspensions

Civil

- Long Process (3-6 Years)
- Individual/Institutional Accountability
- Recoupment of Grant Dollars
- Debarment/suspension

Criminal

- Shorter Process
- Harsh Individual Accountability
The Current System

University

Reporting

Short Suspension

Nothing

Prison

Institutional Financial
Financial Sector: FINRA/SEC

- FINRA: Self-Regulation
- SEC Remedies: Administrative, Civil, Criminal
- Broad Powers and Investigative Purview
Coordinated Approach

Criminal Prosecution

Civil Enforcement

Disciplinary/Administrative

Financial Industry Regulatory Authority
Ways to Improve

- Criminal
- Civil
- Administrative

Reporting