Integrating Research Integrity with Corporate Compliance

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BRG Berkeley Research Group

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Introductions

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Overview

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1. Confirm increasing government scrutiny on compliance effectiveness, research compliance, and potential liability under the False Claims Act or other relevant statutes
2. Identify the basic elements of a compliance program
3. Identify and mitigate risk
4. Learn recommended approaches to research compliance effectiveness assessment and improvement

Government Enforcement Interest in Research

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Charter for National Academy of Sciences signed by President Lincoln, 1863

– Academy's definition of scientific misconduct: "fabrication, falsification, or plagiarism in proposing, performing, or reporting research."

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- Research misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. 42 CFR Part 93
  - Research misconduct does NOT include honest error or differences of opinion

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False Claims Act Signed by President Lincoln, 1863

Definition of False Claim: "any person…who shall make or cause to be made, or present or cause to be presented for payment…any claim against the Government of the United States…knowing such claim to be false, fictitious or fraudulent…shall be punished by fine and imprisonment…"

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Government Enforcement Interest in Research

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Table 1. Federal Obligations to U.S. Universities and Colleges for Research and Development, FY2016

(in millions of dollars)

Federal Agency	Academic R&D Obligations	% of Total Federally Funded Academic R&D
National Institutes of Health	$17,533.3	61.4%
National Science Foundation	$4,582.8	16.0%
Department of Defense	$2,459.5	8.6%
Department of Energy	$971.2	3.4%
National Aeronautics and Space Administration	$931.8	3.3%
Department of Agriculture	$924.7	3.2%
Other Agencies (combined)	$1,156.3	4.0%
Total	**$28,556.7**	**100%**

Source: CRS analysis of data from the NSF National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development Fiscal Years 2014-16, preliminary data, Table 10, at https://ncsesdata.nsf.gov/fedfunds/2014/html/FFS2014_DST_010.html.

Notes: Totals may not add due to rounding. Totals to do not include funding to university-administered Federally Funded Research and Development Centers.

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Stakeholders

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Convergence of Industry Standards and Regulatory Obligations

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Industry Standards

- *Integrity in Scientific Research Creating an Environment That Promotes Responsible Conduct(2002)*
- For the **individual** researcher research integrity "embodies above all the individual's commitment to **intellectual honesty** and **personal responsibility**. It is an aspect of moral character and experience.
- For an **institution**, it is a commitment to **creating an environment that promotes responsible conduct** by embracing standards of excellence, trustworthiness, and lawfulness . . ."

Regulatory Framework

- U.S. Federal Policy on Research Misconduct. Research misconduct is defined as **fabrication, falsification, or plagiarism** in proposing, performing, or reviewing research, or in reporting research results. Fabrication is making up data or results and recording or reporting them."

HHS Requirements for making a finding of research misconduct

42 CFR 93.104

- There be a significant departure from accepted practices of the relevant research community;
- The misconduct be committed intentionally, knowingly, or recklessly; and
- The allegation be proven by a preponderance of the evidence.

Regulatory Framework

- Federal agencies have ultimate oversight authority for Federally funded research, but research institutions bear primary responsibility for prevention and detection of research misconduct and for the inquiry, investigation, and adjudication of research misconduct alleged to have occurred in association with their own institution.*
- Legislation was enacted in the 114th Congress that addressed a number of the concerns, including the 21st Century Cures Act (P.L. 114-255), the American Innovation and Competitiveness Act (AICA, P.L. 114-329), and the National Defense Authorization Act for Fiscal Year 2017 (NDAA, P.L. 114-328). Enacted provisions addressed a subset of issues focused on specific agencies, including conflicts of interest disclosure, financial reporting, and subrecipient monitoring. Enacted provisions also addressed cross-agency efforts by directing the establishment of an advisory committee (Research Policy Board) with federal and non-federal stakeholders, as well as an interagency working group (WG) on federal research regulations.

*Office of Science and Technology Policy, Executive Office of the President). Federal policy on research misconduct. Federal Register. 2000;65:76260–76264.

Relevant HealthCare Research Funding

- For extramural research funded by NSF and NIH, institutions are generally responsible for undertaking an initial inquiry into allegations to determine if a full investigation is warranted, to notify the agencies when such investigations are initiated, and to provide the agencies with the investigation reports, findings, and recommended actions when they are concluded for review.**
- HHS requires institutions that receive PHS funding to keep an assurance on file with ORI specifying that they have policies and procedures in place that comply with HHS regulations, and that they follow their own policies, or to file a Small Organization Statement if they lack the necessary resources to provide an assurance. Institutions also need to file an annual report to ORI to keep their assurances active.
- Discharging the regulatory requirement to report ORI will not obviate the need to handle obligations under parallel authorities.

*HHS. Title 42: Public Health Service (PHS). Part 93: Policies on Research Misconduct. Code of Federal Regulations. Jun, 2005.
*NSF (National Science Foundation). Research misconduct policy. Federal Register. 2002 March 18;67(11937)

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Relevant Research Funding Beyond HHS

- The Department of Defense (DOD) is an important performer and sponsor of research which can be related to healthcare. DOD issued a directive in 2004 that delegated to component agencies the responsibility for developing and implementing procedures to foster research integrity, including procedures for addressing allegations of research misconduct.*
- The Veterans Administration (VA) also has detailed policies and procedures for dealing with research misconduct allegations, with the most recent version being issued in early 2014 (VA, 2014). These policies and procedures were reviewed and revised prior to being reissued, with a number of substantive changes introduced to clarify roles and improve procedures for conducting inquiries and investigations and to harmonize VA's policies with those of the Public Health Service that are implemented by ORI.*

*Department of Defense, Research integrity and Misconduct. Instruction No 3210.7. 2004. http://www.dtic.mil/whs/directives/corres/pdf/321007p.pdf.
*Bannerman D. VHA Handbook 1058.02 Research Misconduct [PowerPoint slides]. 2014. http://www.va.gov/ORO/Docs/Presentations/vhahb1058_02_pres.pdf

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Examples of Interlocking Research Regulation

- The most obvious example of regulatory intertwining concerns the regulations designed to protect the human subjects of research in clinical trials and other settings. The basis of federal policy in the area of human subjects protection is the "Common Rule," covered in 45 CFR Part 46, of the Code of Federal Regulations, "Protection of Human Subjects," which covers research supported by federal agencies or subject to federal regulation, such as privately funded clinical trials that are subject to oversight by FDA.*
- Another area of regulation that has some relationship with research misconduct policies involves the requirements for disclosing and managing possible financial conflicts of interest in research. For example, HHS revised its policies toward financial conflicts of interest in PHS-funded research in 2011, which changed some of the reporting requirements of researchers and institutions (NIH, 2011).*
- Oversight of research animal care and use is governed by multiple laws and policies, including the Animal Welfare Act (7 U.S.C. 2131 et seq.) and the Health Research Extension Act (42 U.S.C. 201 et seq.). These acts require the establishment of standards for animal research and the formation of institutional IACUCs to evaluate and certify institutional compliance. Individual agencies may have additional regulatory and policy requirements.
- Further, FDA regulations [21 CFR parts 50 and 56] apply to research involving products regulated by FDA - federal funds and/or support do not need to be involved for the FDA regulations to apply. When research studies involving products regulated by FDA are funded/supported by HHS, the research institution must comply with both the HHS and FDA regulations. A table of significant differences between 45 CFR Part 46, Subpart A and 21 CFR Parts 50 and 56 is available on the FDA website.

*See Fostering Integrity in Research, National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Science, Engineering, Medicine, and Public Policy; Committee on Responsible Science. Washington (DC): National Academies Press (US); 2017 Apr 11.

* NIH. Responsibility of applicants for promoting objectivity in research for which PHS funding sought (42 CFR Part 50 Subpart F). 2011. http://grants.nih.gov/grants/policy/coi/coi_faqs.htm#3152.

Research Compliance Intersects and Depends on Broader Compliance Program Effectiveness at an Institution

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What IS Compliance?

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Compliance means meeting obligations associated with accepting Federal funds and accepting the responsibilities to conduct sound research and promulgate valid findings.

In research – many attribute such responsibility to the researchers them selves. This is a mistake. Institutions too much establish a system of controls to support science and assure:

1. Sound scientific and administrative judgments
2. Adherence with law, regulation and other Federal requirements
3. Prudent management

What IS a Compliance Program?

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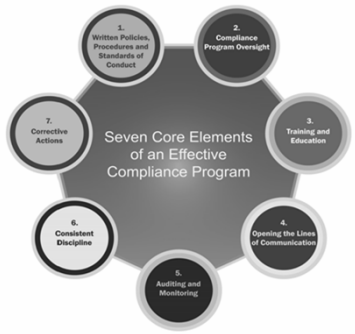
- Designed to prevent and detect wrong doing
- Teaches and encourages employees to conform to ethical and legal standards
- An organized, enterprise-wide, integrated and ongoing effort
- Requires partnership
- Uses internal controls to effectively monitor adherence to laws and other requirements
- Requires leadership

Who in Responsible for Compliance?

- Institutions
- Individuals

Seven Elements: Each Element Must Fit Institutional Needs



7 HABITS OF EFFECTIVE ORGANIZATIONS

1) Reasonable Compliance Standards and Procedures

2) Specific High-level Personnel Responsible

3) Due Care in Assignments with Substantial Discretionary Authority

4) Effective Communication of Standards and Procedures

5) Establish Monitoring and Auditing Systems and Reporting System (whistleblowing without fear of retaliation)

6) Consistent Enforcement of Standards through Appropriate Mechanisms (including failure to detect)

7) Respond Appropriately to the Offense (reporting to law enforcement, modify program, prevention)

·Federal Sentencing Guidelines U.S.S.G. §§ 8B2.1, 8C2.5(f), & 8D1.4(c)(1)

Research Compliance: Understanding and Mitigating Risk

Risk Management: Issues to Consider

- Labs with higher volume of grants and staff
- PIs with high volume and value of grants
- Scientists physically detached from oversight of labs Scientists advancing across grants with similar or duplicative findings
- Junior scientists with inadequate mentoring and /or independent support
- Human resource complaints that increase and could connect to other underlying issues, or the sheer risk of undue pressure on lower level scientists Trouble with research enrollment and efforts to make exceptions
- Approaches rushed through IRB
- Defensive unwillingness to consider efforts to replicate and transparently consider methodology and data

Risk Management: More Than Just a Few Bad Apples

- Address risk by accepting key issues that typically exist when fraudulent conduct occurs.
- Understand "Ethical Amnesia"*
- **Opportunity** – eliminate opportunities for research misconduct in your institution – oversight, audits, monitoring
- **Pressure** – acknowledge and mitigate professional researcher's pressure to win funding, publish (or perish), promulgate new science no matter the consequence, blindly follow in the footsteps of leading scientists
- **Rationalization** – Continually explain ethics and what can otherwise lead to individuals deviating from ethics and sound judgment. Rationalizations is a "focus on meeting goals at all costs can lead to rationalization of unethical behavior and can divert attention from the ethics of said behavior. This is particularly problematic in a situation of near-compulsion to rescue a failing project, which can lead to concealing negative outcomes."

*Maryam Kouchaki, Francesca Gino, Memories of unethical actions become obfuscated over time, PNAS May 16, 2016. 201523586; published ahead of print May 16, 2016. https://doi.org/10.1073/pnas.1523586113.

*Barbara K Redman, Arthur L Caplan, Improving research misconduct policies: Evidence from social psychology could inform better policies to prevent misconduct in research, First published: 10 March 2017, https://doi.org/10.15252/embr.201744110

Understand Risk that an Individual May Make an Unethical Decision

Opportunity
- Usually personal reputational value or financial
- Patterning questionable behavior
- Excessive autonomy
- Scientists independent due to stature and ego
- Ability to control and change data – lack of any transparency

Pressure
- "Identifying situational pressures that can sway a person's moral compass"
- Personal and institutional pressure
- PhD students competing for limited positions
- Scientists competing for limited NIH and other Federal awards

The Fraud Triangle

Identify Risk at Different Levels
- Divisions of the Institution
- Laboratories
- Leading Scientists
- Students Beholden to Principal Investigators

Rationalization
- The idea that "everyone is doing it"
- The ability to persuade yourself that something you otherwise know is wrong is really OK
- No one will get hurt
- I have a serious data problem but my hypothesis is true and worthy of continuing, I just need to show it differently – by removing outliers
- I have a data problem so I will just adjust it. Then I'll be able to rectify later.

*American criminologist Donald R. Cressey
* Maryam Kouchaki, Francesca Gino, Memories of unethical actions become obfuscated over time, PNAS May 16, 2016. 201523586; published ahead of print May 16, 2016. https://doi.org/10.1073/pnas.1523586113.

Risk Management: Recommendations from the Field

- "Validate instruments to measure organizational research climate for internal use to identify toxic climates and devise interventions for improving research climate."
- "Assure that the institution's Research Integrity Officer (RIO), and the Chief Compliance Officers, and any other persons who receive allegations of research misconduct and oversee administration, are well trained and look beyond individual cases to identify trends and patterns."
- Initiate practical, real world "discussions within departments and research teams about scientific practices and ethical violations to develop shared norms for research."
- Ensure methodical "oversight of the quality of research being undertaken within the institution."
- Foster supportive professional relationships, collegiality, mentorship and transparency toward more open door communications across the scientific community.
- Consider monitoring and auditing toward more technologically advanced data driven prevention and detection efforts.
- "Reward and support those who appropriately bring violations of research integrity to attention."

*Barbara K Redman, Arthur L Caplan, Improving research misconduct policies: Evidence from social psychology could inform better policies to prevent misconduct in research, First published: 10 March 2017, https://doi.org/10.15252/embr.201744110

Risk Management: Understanding Risk

- What needs more review within your existing program – known risks?
- What offices operate more autonomously – with less oversight?
- Where are your blind spots?
- When you hear about other institution's issues and recent cases does it ring bells?
- What keeps you up at night? What more do you want to know about it and how would you start?

Observations from the Field

Compliance Under Government Directive

- NIH now requires Duke researchers to obtain prior approval for any modifications to new and existing grants. Any Duke researcher submitting a so-called "modular application" for a grant worth less than $250,000 per year must include "detailed budgets" justifying the costs.
- Duke faculty learned of the changes on 21 March, in a letter from university administrators. NIH stated that these new requirements are a result of its concerns about Duke's management of several research misconduct cases and grant management issues that date back to 2010, some of which have been widely reported like the Anil Potti case..

Learning from Duke Allegations: Timing Factors

- Relator allegations, in part, focus on delay at the University
- First, at the outset, the concerns and evidence of internal and outside researchers were not brought forward as formal allegations of misconduct but, rather, as concerns and questions about possible errors. However, those concerns mounted, and multiplied overtime.
- Second, the researcher whose work was being questioned was closely associated with a high-prestige researcher. Therefore, there was an unwillingness to question or probe in a timely manner.
- Third, the university response allegedly limited the scope of the initial inquiry inappropriately.
- Fostering Integrity in Research, National Academies Comment on Potential Explanations
- As is seen in other contexts such as financial or political misconduct, officials may have biases that filter how they hear concerns or lead to reluctance to make or aggressively pursue allegations of wrongdoing against powerful people in their own organization or against people closely associated with them.
- The researchers raising the concerns or questions may hesitate to move forward to a formal allegation, and the absence of an allegation may override for a time the suspicions of institutional officials based on an impartial assessment of the evidence. The path of least resistance might be to continue to delay action.

*See also Fostering Integrity in Research, National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Science, Engineering, Medicine, and Public Policy; Committee on Responsible Science. Washington (DC): National Academies Press (US); 2017 Apr 11.

Plan, Do, Check, Act: Cyclical Reinforcement -

- Reassess whether your program has adequate and properly deployed resources – be proactive, not just reactive. Have leadership deeply consider what documentary support backs the Annual Assurance to ORI (or other agencies)
- Test the way in which your institution handles its own internal reports/compliance, inquiry, and investigation – to ensure that the practices in action follow your written standards.
- Take seriously the obligation to ensure accuracy and completeness of statements made to funding agencies (grant proposals and other findings) to avoid the submission of false claims subject to increased scrutiny.
- When applicable, consider self-disclosure to other relevant government agencies. Discharging your duty to report to ORI does not obviate parallel duties to handle potential financial liabilities with the NIH (or other relevant funding agency) and DOJ and/or OIG.

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Consider Disclosure to Mitigate Potential Penalties and Government Decrees

- If the institution receiving Federal funding or the funding agency believes that criminal or civil fraud violations may have occurred
- The institution should consider promptly refer the matter to the Department of Justice, the Inspector General for the agency, and / or other appropriate investigative body

Recommendations for Each Compliance Element

Recommendations: Centralize and Coordinate

Element	Expert Recommendations
Designation of Compliance Officer or contact(s)	• Develop formal job description for a compliance liaison(s) for divisions / subdivisions / labs of a significant size. • Provide training for liaisons to ensure understanding of the position's operational demands, including the requirements set forth by the government and the institution to contribution to the institution's compliance operations. • Provide certain liaisons with more substantive training and potential Certification in Research Compliance.
Written Policies and Procedures	• Confirm, integrate, and correlate policies and procedures targeting specific risk areas. Avoid unnecessary independence for laboratories, principal investigators and staff – draft and implement reasonable monitoring and reporting policies.
Auditing and Monitoring	• Assign an individual charged with the responsibility of periodically review / randomly audit the systems for lab standards and procedures to determine if they are current and complete. • Periodically review records/logs/systems of records to ensure that documentation requirements are met.

Recommendations: Find Peers and Champions

Element	Recommendation(s)

Education and Training	• Create job descriptions with research compliance requirements
	• Provide both initial and recurrent training to laboratory staff that is relevant to the role and specific demands at the level of involvement a staff member may have.
	• Industry standards suggest that annual raining should be at least three hours and cover the following topics:
	  • Basic Scientific Methods, Documentation, Reproducibility, Fabrication, Falsification and Plagiarism
	  • Ethics
	  • Research Integrity Laws and Enforcement
	  • Prevention, Detection, and Obligation to Report include: (i) the operation and importance of the compliance program; (ii) the consequences of violating the standards and procedures set forth in the program; and (iii) the role of each employee in the operation of the compliance program.
	• Maintain written documentation (e.g. written or electronic certificates of completion from the training provider) that trainees have in fact completed such training
	• Invite feedback and provide case specific updated training to relevant staff

Recommendations: Invite Participation

Element	Recommendation(s)
Effective Communication	• Due to the extensive clinical research demands, establish a regular, formal compliance meeting by division to address preventive operations and mechanisms as well as any concerns arising. • Continue to improve and enhance open door policies and methods of reporting to superiors, mentors, and across and to higher levels of the organization. • Implement a formal communications plan in conjunction with less formal communication techniques, such as conspicuous notices posted in common areas and/ or the development and placement of a compliance blog where everyone in the practice can receive up-to-date compliance information (perhaps on recent cases and available peer to peer trainings). • Implement proper mentorship and training specific to an individual's scientific career and area of risk.

Recommendations: Detect and Enforce

Element	Recommendation(s)
Investigation and Reporting	• Integrate systems to address how the lab will respond to and report potential problems. • The institution's system should include a procedure that describes steps, escalation, and clearances prompt referral or disclosure to an appropriate Government authority or law enforcement agency. • Conduct root cause analysis and full internal assessment of all reports of detected violations.
Enforcement and Discipline	• Integrate a defined process for potential escalating discipline when concerns about individual's responsibility to contribute to compliance may arise. • Standardize procedures to ensure that violations of the practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual. • Consider role-specific disciplinary actions so that they are flexible enough to account for mitigation or aggravating circumstances. • Disciplinary actions could include: (i) warnings (oral); (ii) reprimands (written); (iii) restriction of access and roll ; (iv) probation and oversight/monitoring; (v) temporary suspension; (vi) termination; and (vii) referral for criminal prosecution.

Questions?

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Appendix

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Observations: Learning from Case Details

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• United States ex rel. Milam v. University of Tex. M.D. Anderson Cancer Ctr., 961 F.2d 46, 50 (4th Cir.1992).	• Milam discovered another researcher, Tofilon, produced false laboratory results funded by NIH grants. Milam filed False Claims Act action against University of CA, University of TX, and Tofilon. • 4th Cir. Affirmed lower court ruling of Milam's standing to bring suit
• John L. Ninnemann- University of Utah agreed to pay $950,000 and the University of California at San Diego agreed to pay $625,000 (1994)	• Payment to settle charges that University of UT and UCSD, respectively, helped cover-up scientific misconduct / falsification of research results by Dr. Ninnemann • "The [Justice] department said that it was the first time that […], the False Claims Act, had been used to recover money in a case of research misconduct […]"
• U.S. ex rel. Berge v. Board of Trustees of the Univ. of Ala., 104 F.3d 1453, 1457-1459 (4th Cir.), cert. denied, 522 U.S. 916 (1997).	• 4th Cir. Reverses lower court ruling and: a) awards Berge $498k on a False Claims Act claim; and b) awards Berge $265k in compensatory damages • As basis of her claim, Berge alleged that Univ. of Ala. made false statements to NIH in annual reports under its grant, including misleading NIH about amount of data computerized and through plagiarizing Berge's research
• US Ex Rel. Zissler v. Regents of the Univ. of Minnesota, 992 F. Supp. 1097 (D. Minn. 1998)	• Court granted Univ. of MN's Motion to Dismiss government's claims under False Claims Act, but denied Univ. of MN's Motion to Dismiss allegations of selling unlicensed drugs and reaping corresponding, illegal profits, fraudulent submissions for unreimbursable drugs to Medicare, and receiving illegal kickbacks

Observations: Learning from Case Details

• U.S. ex rel. Cantekin v. Univ. of Pittsburgh, 192 F.3d 402 (3rd Cir. 1999).	• Cantekin brought suit under the False Claims act against Bluestone / Univ. of Pittsburg for Bluestone's filing of NIH grant applications while also receiving industry funding for his research • The 3rd Cir. Court found industry funding relevant for assessing relevant conflicts of interest and concluded that Bluestone knowingly omitted industry funding from the application and submitted false claims
• United States ex rel. Gober v. University of Alabama at Birmingham, No. 01-cv-00977-VEH (N.D. Ala. settlement reached Apr. 14, 2005); United States ex rel.Meythaler v. University of Alabama at Birmingham, No. 04-00112-VEH (N.D. Ala. settlement announced Apr. 14, 2005).	• Settlement between parties: Univ. of AL paid United States $3.4m • Gober and Meythaler both filed qui tam actions against Univ. of AL under the False Claims Act for filing fraudulent NIH grant applications and unlawfully billing Medicare for services also billed other sponsors of the clinical research trials
• Dong-Pyou Han, Iowa (2005)	• Han sentenced to 57 months imprisonment for falsifying HIV/AIDS Research following guilty pleas to two counts of making false statements to the NIH. • Han also required to pay $7.2m in restitution to the NIH.
• William Everson, Kentucky (2009)	• Everson whistleblew against falsified research submitted by Eric Smart on a federal grant application • Investigators at HHS concluded falsified data appeared in 10 of Smart's published papers

Observations: Learning from Case Details

• U.S. ex rel. Resnick v. Weill Medical College at Cornell Univ., 2010 WL 476707, (S.D.N.Y. Jan. 21, 2010).	• Cornell settles for $2.6m the allegations it fraudulently obtained NIH research grants. This sum is 6% of the maximum possible recovery. • Relator Resnick challenged the settlement, arguing it curtailed future False Claims Act claims and dealt lightly with the College.
• U.S. ex rel. Daniel Feldman v. Willfred van Gorp and Cornell University Medical College (2d Circuit, 2012).	• The Second Circuit affirmed the lower court's ruling that "the appropriate measure of damages" was "the full amount the government paid based on materially false statements."[
• U.S. ex rel. Terri King v. Univ. of TX Health Science Ctr., 12-20795 (5th Cir. 2013).	• 5th Cir. Court affirms lower court's dismissal of King's claims that the Center violated the FCA • Dismissed claims for lack of subject-matter jurisdiction and for failure to state a claim upon which relief can be granted • Univ. of TX Center not subject to suit under the FCA's qui tam provisions
• In December 2014, the Regents of the University of California settled a suit for $499,700 based on allegations that the University of California, Davis submitted false and misleading statements in connection with obtaining grants from the U.S. Department of Energy and the National Science Foundation.	• The U.S. Attorney's Office for the Eastern District of California stated that the settlement "sends a clear message that recipients of federally funded grants must strictly adhere to the regulations applicable to those grants and fully and fairly disclose the information called for under these grants."[

Observations: Learning from Case Details

• U.S. ex. rel. Jones v. Massachusetts General Hospital, — F.3d —-, 2015 WL 1138442 (1st Cir. Mar. 16, 2015) (Jones II).	• "Jones has had the opportunity to present his claims in court before a jury. That jury ultimately concluded that Killiany did not intentionally falsify scientific data and that the application's statement that the study used blinded, reliable methods was not false. […], we find no reason to upset that determination, and the judgment of the district court [to dismiss Jones' motion for judgment]is, accordingly, AFFIRMED."
• United States of America et al v. Oregon Health and Sciences University, No. 3:2013cv01306 - Document 60 (D. Or. 2017)	• Court grants Oregon Health and Sciences University's Motion to Dismiss USA/relator Doughty's allegations that the University violated the FCA when it applied improper reimbursement rates to certain federally-sponsored projects.
• Brigham and Women's Hospital (2017)	• Brigham and Women's Hospital "has made significant enhancements to research integrity compliance protocols as a result of this event,"
• United States ex rel. Thomas v. Duke University, et al., W.D. Va., No. 4:13-cv-00017 (2017)	• False statements in scientific research potentially used to obtain funding. • A federal judge has rejected the University's request to dismiss a lawsuit that accuses Duke of major research fraud