Higher Education Compliance Distinction: Programmatic & Operational Compliance

“Big C” Compliance

Programmatic Compliance refers to the **programmatic**, overarching compliance program and infrastructure monitoring and managing compliance across the organization.

“how we’re going to do it”

“Little C” Compliance

Operational Compliance refers to the decentralized **operational** policies, procedures and monitoring guiding the day-to-day adherence to compliance requirements across an organization.

“what we’re going to do”
Higher Education Compliance
Leading Practice: Objective Big C Compliance

- **Role:** Institutional Compliance Officer
- **Reporting:** Audit Committee of the Board
- **Responsibility:** Developing a broad and comprehensive Compliance Program to identify risk and partner with “little c” owners to respond.
Higher Education Compliance
Benefits: Objective Big C Compliance

• A **proactive** approach to creating a comprehensive compliance program will allow a university to **manage its compliance risk** without imposing unnecessary constraints on the organization’s operations.

• Strong compliance programs benefit organizations by **reducing the risk** of significant non-compliance and **increases accountability and clarity of information** in order to aid in effective management.

• Compliance programs **reduce the negative impact of having non-compliance discovered** by regulators or funding agencies.
Higher Education Compliance Approach: Objective Big C Compliance

The Department of Health and Human Services utilizes a framework based on the OIG’s 7 elements of an effective compliance program.

- Additionally, we included the draft guidance materials from the OIG for recipients of Public Health Service (PHS) research awards as an 8th element.

1. Policies and Procedures
   - Implementing written policies and procedures that foster an institutional commitment to stewardship and compliance

2. Compliance Leadership
   - Designating a compliance officer and compliance committee

3. Training
   - Conducting effective training and education

4. Communication
   - Developing effective lines of communication

5. Monitoring
   - Conducting internal monitoring and auditing

6. Enforcement
   - Enforcing standards through well-publicized disciplinary guidelines

7. Corrective Response
   - Responding promptly to detected problems, undertaking corrective action, and reporting to the appropriate agency

8. Roles and Responsibilities
   - Defining roles and responsibilities across the institution and assigning oversight responsibility
Higher Education Compliance
Areas of Risk

Admissions
- Illegal Athlete Recruitment
- Other Illegal Recruitment
- Bribery
- Preferential Admissions
- Racial or Socioeconomic Fairness
- False Credentials, Personal Information, Test Scores, Etc.

Sponsored Research
- Research Integrity
- False Claims of Sponsored Funding
- Conflict of Interest
- Improper Financial Management and Reporting
- Poor Effort Reporting
- Foreign Influence
- Protection of Property and Information
- Fraud

Campus Safety
- Freedom of Association
- Gender Discrimination
- Sexual Assault
- False Statistic and Safety Reporting
- Campus Crime
- Greek Life
- Organizational Hazing
Admission Challenges
College Admissions Scandal: Introduction

In March 2019, eight institutions and fifty individual parents, exam administrators, college advisors, and athletic coaches are under investigation by the DOJ for involvement in the US’s largest college admissions scandal.

- Students admitted with false credentials or received exam assistance.
- Bribes ranged from $15K to $6.5M
- Admitted students mostly unaware of their parents’ actions.

Admission Challenges
College Admissions Scandal: An Example

As a result of the admissions scandal, Yale...

- Rescinded admission of one student admitted under false credentials.
- Announced an internal review of their admissions system with assistance from external investigators.
- Instituted new policies to perform a central review of student athletes by the Director of Athletics office, instead of accepting verification by each coach.

Sources: Yale Daily News, Salovey announces Yale actions in response to admissions scandal, March 15, 2019; Yale Office of the President, Frequently Asked Questions Related to Admissions Fraud Scheme, March 26, 2019
Admission Challenges
Affirmative Action: Introduction

The discussion of preferential treatment based on racial or socioeconomic status has ignited intense public controversy.

- Lawsuit against Harvard filed by Students for Fair Admissions went to trial.
- Similar lawsuit accuses UNC-Chapel Hill of using race “at every stage” of the admissions process.
- Recent conservative shifts in Supreme Court.

Sources: Inside Higher Ed, Affirmative Action Fight Shifts to UNC, January 22, 2019; Slate, Affirmative Action Is About to Face a Judicial Assault, February 12, 2019; The Boston Globe, In Harvard affirmative action case, judge appears skeptical.
Admission Challenges
Affirmative Action: An Example

Texas Tech University’s medical school has ended consideration of race in selecting candidates for admission.

- Showcases the Trump administration’s pursuit to limit the consideration of race in admissions.
- Civil rights groups argue that this agreement does not promote equal opportunity for minorities.

Sources: NPR, Texas Tech Medical School To End Use Of Race In Admissions, April 9, 2019; Inside Higher Ed, OCR Tells Med School to Stop Considering Race in Admissions, April 10, 2019
Admission Challenges
Compliance Impact: Regulatory Response

In response to the admissions scandal, California’s state legislature has proposed six new laws:

<table>
<thead>
<tr>
<th>Strengthening Checks and Balances on Special Admissions</th>
<th>Banning Preferential Admissions for Donors &amp; Alumni</th>
<th>Phasing Out Use of the SAT &amp; ACT</th>
</tr>
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<tbody>
<tr>
<td>Regulating College Admissions Consultants</td>
<td>Prohibiting Fraudulent Tax Write-Offs</td>
<td>Auditing Risks of Fraud in Admissions</td>
</tr>
</tbody>
</table>

Several states have replaced affirmative action programs with systems that guarantee a certain percentage of top high school students admission into public universities.

Source: Assembly member Phil Ting, Assembly members Propose College Admissions Reform & Oversight, March 28, 2019
Admission Challenges
Compliance Impact: Institutional Action

Conduct A Self-Assessment:

- Do you perform regular internal reviews of current admissions policies across the student life-cycle?
- Is a closer examination of students admitted through special situations warranted?

Preventative Actions:

- Conduct regular review of affirmative action programs to ensure compliance
- Exert more oversight / reform over students designated as athletic recruits
- Establish processes / automated flags to identify and focus review on high risk applications (e.g. special admits, those that name campus donors)

Sources: NPR, Why The College Admissions Scandal Hurts Students With Disabilities, March 14, 2019; The Chronicles of Higher Education, We Asked 20 Elite-College Admissions Deans About the Bribery Scandal. Here’s What They Said., March 19, 2019; Assembly member Phil Ting, Assembly members Propose College Admissions Reform & Oversight, March 28, 2019
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SPONSORED RESEARCH
Sponsored Research Compliance

Introduction

Compliance violations related to sponsored research, both programmatic and administrative, continue to come to light.
Sponsored Research Compliance
Research Misconduct: An Example

Duke University

Duke was found in violation of the False Claims Act and will pay $112.5 million.

- A coordinator falsified data on 30 grants worth $200M between 2006-2018 and was fired for embezzlement.
- Twelve research papers have been retracted from publication.

Duke has taken steps to improve research integrity:

| Appointed an Associate Vice Provost and Vice Dean for Scientific Integrity | Established an Office of Scientific Integrity | Required science and accountability plans for the School of Medicine |

Sponsored Research Compliance
Conflicts of Interest: An Example

Memorial Sloan Kettering Cancer Center

The chief medical officer of MSK, Dr. José Baselga, failed to disclose millions of dollars of payments from health care companies.

- Dr. Baselga failed to disclose industry ties in 60% of ~180 published research articles since 2013.
- An external investigation found other MSK top executives and board members had profited from relationships with biopharma and other corporate relationships.
- MSK is in the process of a COI and COC policy overhaul.

Sources: Endpoint News, Outside review confirms top Memorial Sloan Kettering executives flouted conflicts-of-interest policies — report, April 5, 2019; ProPublica, Top Official at Memorial Sloan Kettering Resigns After Failing to Disclose Industry Ties, September 13, 2018
**Sponsored Research Compliance Effort Reporting: An Example**

**Western Michigan University**

*Western Michigan enhanced compliance and controls through the implementation of the ECRT system.*

- Enhanced controls through a **system** - technology, process, training, and monitoring.
- Established consistent standards of compliance and accountability through clarity and access to information.
- Designed a solution that incorporates the institution’s payroll reporting policies, Uniform Guidance, NIH Salary limitations, and other sponsoring agency requirements.

Sources: Office of Research and Innovation at Western Michigan University, [ECRT (Payroll Confirmation)](https://example.com), September 11, 2018
Sponsored Research Compliance
Compliance Impact: Institutional Action

Conduct A Self-Assessment:

• Have you conducted a review of internal controls impacting financial AND programmatic compliance in sponsored research?
• How is the scientific integrity of research studies monitored and regulated at your institution?
• Is technology leveraged as a component of internal control?

Preventative Actions:

• Exert appropriate oversight of study teams and labs performing research
• Allow for appropriate hotlines / communication channels to escalate concerns
• Respond quickly to internal allegations or concerns of research fraud
• Perform regular reviews of internal controls and financial management practices and focus continuous improvement efforts on areas of risk

Source: JD Supra, When Research Misconduct Violates the False Claims Act: Lessons from Duke’s $112.5M Settlement, April 3, 2019
Federal intelligence, security, and science agencies and members of Congress have expressed increasing concern regarding various forms of foreign interference on research performed at U.S. universities. National Institutes of Health has referred several allegations regarding foreign influence in biomedical research to federal investigators.
Sponsored Research Compliance
Foreign Influence: An Example

Chairman of Harvard University’s chemistry department was arrested for failing to disclose millions of dollars in research funding from China.

• The chairman misled the DOD and NIH about participation in foreign engagement and unreported foreign income.
• Concern has arisen that racial profiling is used to target researchers.
• Institutions across the country have been notified by the NIH about concerns around similar occurrences due to the result of hidden transfers of information, know-how and time.

The Section 1286 of the FY 2019 National Defense Authorization Act (NDAA) requires the Department of Defense to work with academic institutions performing defense research to:

| Support protection of intellectual property, controlled information, key personnel, and information about critical technologies relevant to national security | Limit undue influence, including through foreign talent programs, by countries to exploit science, technology, and innovation enterprise | Support efforts toward development of domestic talent in relevant scientific and engineering |

Source: U.S. Congress, H.R.5515, January 3, 2018
Data Analytics allows for the process of examining data sets in order to draw conclusions about the information they contain. Other “technology” opportunities for compliance:

- Deploying Data Analytics as a proactive tool for risk identification.
- Aggregating and comparing data to conduct risk-based audits to focus monitoring and management efforts on foreign influence risk.
Jacob - can we talk about a visual here? I stink at SMART ART!

Marisa Zuskar, 2/20/2020
Foreign Engagement Compliance
Compliance Impact: Institutional Action

Conduct A Self-Assessment:

- Consider leveraging data analytics as part of a risk self-assessment!
- What are your processes and procedures for gauging identifying foreign engagement across operational units?
- Who is responsible for ensure sponsor reporting on foreign components of research is accurate and consistent?

Preventative Actions:

- Conduct an education campaign to ensure consistent, accurate disclosure of foreign support.
- Communicate with faculty about potential security threats and provide reminders of federal and university disclosure and export controls requirements.
- Consider implementation of additional campus policies and practices, such as international research committees, to bolster security and mitigate risk.

Source: University of California Berkley Research, Research Compliance, n.d.
Sponsored Research Compliance
Institutional Review Board (IRB): Introduction

The IRB serves as an objective third party oversight entity, governed by Federal Regulations, with the purpose of protecting and managing risk to human subjects involved in research.

- IRB’s are designed to promote the safety and well-being of human participants and to consider the concerns of the general public.
- There is a strong importance to ensure adherence to the ethical values and principles of the research as well ensuring the scientific validity of the research and actions.

Source: Plymouth State University, Why is the IRB Important?, n.d.
Sponsored Research Compliance
Human Research Case Study: An Example

University of California San Diego

UC San Diego is under a formal whistleblower investigation for putting thousands of people at risk by not following basic rules meant to protect human research.

- The university is accused of withholding risk information, pressure of approval, and ignoring concerns about COI.
- The director of regulatory affairs was overseeing both requests and approvals for the research review process – resulting in a role conflict.
- Concern has risen that many institutions are not strong enough in enforcing human subject research compliance.

Source: inewsource, Someone will get hurt’: Whistleblower alleges major problems in UCSD’s human research protections program, August 14, 2019
Human Subjects Compliance
Compliance Impact: Institutional Action

Conduct A Self-Assessment:

• Are processes and systems demonstrably compliant with regulations?
• Do you facilitate open communication with IRB/Institution on compliance matters beyond adverse event reporting?
• Do you have an established culture of compliance and well-communicated importance of human research protections?

Preventative Actions:

• Provide training and education on IRB requirements related to protocol design, consent processes, and reportable information
• Define processes and tools to explicitly consider each applicable regulatory criterion for approval during the review process
• Foster a top-down culture of compliance!
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CAMPUS SAFETY
Campus Safety
Introduction

Questions have risen around how universities report and handle allegations of sexual assault, freedom of association, and gender discrimination.

- The Clery Act has resurfaced in importance, with the recent issues in universities reporting and managing sexual assault cases.
- Administrators are grappling with unsafe off-campus activities that leave undergraduates vulnerable and jeopardize the fairness of single-sex organizations.

Students have sued Harvard for discouraging single-sex social clubs.

- Harvard has banned members from these organizations from holding campus-wide leadership positions.
- Students want the university to end sanctions against single gender organizations, arguing this violates their constitutional right to free association.
Charges were prosecuted on a fraternity at Penn State University and 18 of its members for the death of a student member.

• The fraternity faces 50 counts of hazing and 48 counts of furnishing alcohol to minors.
• Penn State enacted Timothy J. Piazza Anti Hazing Law which requires Pennsylvania schools to have policies and reporting procedures in place to stop hazing and to inform students and parents of what is happening on campus.

Campus Safety
Compliance Impact: Regulatory Response

Current DOE proposals to change Title IX have been considered duplicative of or hindering existing university efforts.

Focus is shifting from rights of the accuser to rights of the accused.

<table>
<thead>
<tr>
<th>Schools cannot investigate using “single investigator” or “investigator-only” model</th>
<th>Adopts the Clery Act definition of sexual assault</th>
<th>Appeals must be available to both parties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Explicitly requires basic due process of accused students</td>
<td>Requires written notice of allegations and an equal opportunity to review all collected evidence</td>
<td>Implement the right to cross-examination, subject to “rape shield”</td>
</tr>
</tbody>
</table>

Sources: USA Today, Students Afraid to Study Abroad Under Title IX Proposal, February 7, 2019; NPR, Former Title IX Official Outlines Changes to How Colleges Handle Sexual Assault Cases, November 19, 2018; Association of American Universities, Higher Education Associations Comment on Department of Education’s Proposed Title IX Rule, January 30, 2019; U.S. Department of Education, Secretary DeVos: Proposed Title IX Rule Provides Clarity for Schools, Support for Survivors, and Due Process for All, November 16, 2018.
Campus Safety
Compliance Impact: Institutional Action

Conduct A Self-Assessment:

• What precautions are taken to prevent Clery Act and Title IX violations?
• Are practices in place to allow for timely response, including institutional reporting?
• What structures are in place to empower students to act safely?

Preventative Actions:

• Require staff and students to take Title IX training courses.
• Implement policies, procedures and tools to encourage prompt reporting.
• Develop policies and procedures in alignment with guidance from the Handbook for Campus Safety and Security Reporting. Promote and support campus safety awareness campaigns.
• Create safe and inclusive spaces for students on campus.

Sources: Clery Center, Compliance Overview of Title IX, DFSCA, and FERPA; U.S. Department of Education, Handbook for Campus Safety and Security Reporting.
Closing: ACHIEVING BALANCE IN COMPLIANCE
Previous examples of institutional responses to risk situations are not always right for every situation. The compliance response should account for institutional culture, other controls and abilities.

- Compliance activities and internal controls should be balanced against process efficiency and the effectiveness of the control.
- Everyone has responsibility to adhere to or facilitate compliance, but each organization should define its risk thresholds and tolerances.
THANK YOU