



Compliance Update

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Learning Objectives

- Learn about the history of Compliance at Duke University.
- Learn about the mission of the Duke University Ethics & Compliance Office (DECO) and how our work plan and audit scope are defined and shaped by the OIG of the U.S. Health and Human Services Work Plans, past audits, and School of Medicine Administration concerns.
- Learn about the observations noted during recent reviews.

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History

- **The Past** – We conducted compliance reviews related to Human Subject Research Compliance, Clinical Trials Billing Compliance, HIPAA/HITECH, Research Financial Compliance and other regulatory risk areas identified as part of the institutional risk assessment within the School of Medicine and School of Nursing.
- **The Present** - As of August, 2013, the Institutional Ethics & Compliance Program merged with SOMCO under common leadership, DECO assumed responsibility for working with compliance liaisons throughout the institution related to monitoring of compliance risks through the Ethics and Compliance Monitoring section of the office.
- **The Future** - FY15 will feature the last step in maturation of the compliance program as the compliance auditing activities related to the academic campus are transitioned from the Office of Internal Audits to DECO.

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Mission

- It is the mission of the Duke University Ethics & Compliance Office to lead the initiative to ensure that the SOM, University and the SON conduct activities, whether related to education, research or clinical, in a manner that is both consistent with regulatory, statutory and common law, and reflective of the highest ethical standards.
- The role of the office is to provide expertise, consultation and assessment in matters of compliance as well as to facilitate implementation of a "compliant culture" appropriate to an academic medical center.

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Duke University Ethics & Compliance Office

- Provide vision for institutional compliance and articulates corporate values;
- Ensure that the program meets the elements of the Federal Sentencing Guidelines related to effective compliance programs;
- Define levels of acceptable risk;
- Visibly support compliance efforts; and
- Evaluate and respond to instances of noncompliance.

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DECO Responsibilities

- **Compliance Review Services (CRS)**
 - Research Financial Compliance
 - Highly Regulated Areas (IRB, IACUC, OESO, Select Agents, etc.)
 - Conflict of Interest Program
 - HIPAA Compliance/DLP
 - IT Security (in conjunction with the Office of Internal Audits)
- **Clinical Trials Quality Assurance (CTQA)**
 - Human Subject Research/Good Clinical Practice (GCP)
 - Clinical Trials Billing
- **Ethics & Compliance Monitoring**
 - Maintaining the inventory of laws, regulations, and policies with which the University must comply
 - Evaluating monitoring reports related to institutional compliance risks
 - Reviewing the annual risk assessment and summarizing the institutional compliance risks for senior leadership
 - Conflict of interest review for senior leaders and Board of Trustees

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What is Compliance?

- Doing the right thing
- Understanding your job responsibilities
- Following the rules, laws, and policies that apply to your work
- Asking questions
- Reporting compliance concerns

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What is the Cost of Non-Compliance?

- Loss of grant funding
- Loss of public and donor confidence and contributions
- Vulnerability to audits and lawsuits
- Large settlements/fines and corrective actions
- Administrative sanctions
- Damage to reputation

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What is the Cost of Non-Compliance?

“It takes 20 years to build a reputation and 5 minutes to lose it.”

Warren Buffett

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Risk areas were identified from:

- “High Risk Areas” of the OIG Work Plans
- Audit Findings and Investigational Results Occurring at Other Major Universities
- The School of Medicine’s Enterprise-Wide Risk Assessment, which included Risk Ranking, received from the Departments in the SOM
- Feedback from SOM and Health System Administration

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Identified risks were evaluated based on:

- **Financial impact** the non-compliant activity would have on the University
- **Reputational impact** the non-compliant activity would have on the University
- **Probability of occurrence**

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Most Significant Risk Areas or the “Top 5”

1. Clinical Trials Billing
2. Conflict of Interest
3. Human Subject Research
4. Research Financial Compliance
5. Health Insurance Portability and Accountability Act (HIPAA)

These risk areas receive a “yearly” review.

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Additional Risk Areas

1. Select Agents
2. Institutional Biosafety Committee
3. Anatomical Gifts
4. Export Controls
5. Institutional Review Board
6. CPDC Appointments
7. Pre-Award Office (Office of Research Administration)
8. Post-Award Office (Office of Sponsored Programs) (SOM Only)
9. Institutional Animal Care & Use Committee/Animal Welfare Assurance Office
10. Environmental Issues (Occupational & Environmental Safety Office)

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What would you do?

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What would you do?

Dr. Davis is transferring to the University of North Carolina at Chapel Hill. He is taking two R01 projects, one with a clinical trial, equipment, lab supplies, and office supplies. He is physically packing up all of his subject binders that contain subject reimbursement forms with social security numbers. Dr. Davis contacted all of his subjects in an unencrypted group email using his Gmail account and informed them that he would be conducting the HIV study in a new location. He has even loaded a freezer containing samples onto the bed of his pickup truck.

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What would you do?

Dr. Petrichko's assistant is trying to clear some corporate card receipts. Dr. P is always purchasing items from Target, Walmart and other big box stores rather than using internal systems such as Buy@Duke. She noticed that some of the items purchased did not appear to be legitimate charges, e.g., Febreze, Kleenex and Q-tips. She asked Dr. P about the charges and he said he gave his card to Tina to purchase some items for the lab, "I am sure the items are project specific, go ahead and approve them using my R01 that has the most money available." Dr. P was already upset with her for not clearing travel charges for seat upgrades and early check-in fees on his R01, so she didn't want to jeopardize her job and cleared the expenses anyway.

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What would you do?

Tara C is a visiting research fellow from China working in the oncology lab for the summer. She is responsible for consenting patients in which she often does in a group setting just outside the waiting room area. Since Tara will be visiting for a short period of time the research team decided not to list her on the delegation log and she is not considered key personnel. Tara returned to China at the end of the summer. A recent audit revealed that the original consent forms were missing. The consent forms could not be found in the medical records or in the research charts. The study team reached out to Tara and she indicated that she left the original consent forms in the bottom of an unlocked desk drawer.

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Reporting Compliance Concerns

The Integrity Line: 1-800-826-8109

Compliance and Fraud Hotline: 1-800-849-9793

- Compliance concerns can be reported anonymously
- Non-retaliation and non-retribution policy

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Duke University Ethics & Compliance Office

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Questions? What can we do to help you?

