Responsible Conduct of Research and Research Compliance

Discussion led by
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Assistant Vice Chancellor for Research
The Age of Enforcement

Era of Compliance Process - Previous ≈50 years of research compliance focused on development of compliance infrastructures and education of researchers.

Age of Compliance Enforcement - “I like to call this the age of enforcement…There is no longer any question about what the rules are, there is no longer any forgiveness of any significant amount in the system for lax enforcement, for failure to comply.” (Kathleen Merrigan, Secretary of Agriculture, April 6, 2010)
When Non-Compliance Occurs
Universities Penalized for Violations

- Stanford U – Inflated research overhead cost - $1.2 M
- U of Washington – Billing fraud - $35 M
- U of Texas – Underpayment of royalties - $12 M
- U of Minnesota – Misuse of federal grants - $32 M
- NYU Medical Center – Inflated grant costs - $15.5 M
- U of Penn. – Human subjects, conflict of interests - $514 K, closed center
- Northwestern U. – Inaccurate grant effort reporting - $5.5 M
- U of California – Mischarging research grants - $3.9 M
- NYU - $1.4 M, Penn - $1.6 M, Johns Hopkins $1.1 M – Preferred lenders
- U of Med and Dentistry of NJ - overbillings, political activity, no-bid contracts, inappropriate admissions - Dissolved and transferred to Rutgers
- U of Tennessee – Export control violation – Criminal charges
- UCLA – Death from lab accident – Criminal charges
- Penn State – Sexual assault – Criminal charges
- Iowa State – Research misconduct - $7.2M, criminal charges
- ETSU (athletics study), Cornell (Facebook study), Minnesota (Psych trials) – IRB reputational harm
Importance of an Academic Compliance Program

Risk Minimization

• Financial Risks & Operational Risks
• Health & Safety Risks
• Reputational Risks

Better Image, Improved Relationships, Greater Trust

• Community
• Sponsors and Regulators

External Pressures

• Governmental Expectations (e.g. DHHS OIG, NIH, NSF, etc.)
• (Possibly) Reduced Fines and Penalties

Greater Efficiency and Improved Outcomes

• Elimination of uncertainty and confusion about roles and responsibilities
• Better quality research, operations
• Identifying and addressing problems early
• Reducing likelihood of government audits & investigations
• Better trained workforce
Compliance Begins with Institutional Leadership

In order to fulfill our mission of serving the people of Tennessee and beyond through the discovery, communication and application of knowledge, we must be committed as a statewide workforce to promoting responsible and ethical behavior in everything we do.

— Dr. Joe DiPietro, University of Tennessee President

In our journey to the Top 25, reducing our risks, maintaining integrity in our research and scholarly activities, and protecting all of our faculty, staff, and students will be vital to helping us reach or collective university goals.

— Dr. Jimmy Cheek, UT Knoxville Chancellor
Shared Values

• Honesty – Conveying information truthfully and honoring commitments

• Accuracy – Reporting finding precisely and taking care to avoid errors

• Efficiency – Using resources wisely and avoiding waste

• Objectivity – Letting the facts speak for themselves and avoiding improper bias
Federal Sentencing Guidelines
Compliance Program Requirements

Programs should be based on requirements of the Federal Sentencing Guidelines for Organizations

Due diligence and promotion of an ethical culture minimally require the following:

1. Written standards of conduct and policies and procedures

2. Designating a compliance officer and other appropriate bodies (e.g., compliance oversight committee)
Federal Sentencing Guidelines
Compliance Program Requirements

3. Effective education and training

4. Audits and evaluation techniques to monitor compliance

5. Reporting processes and procedures for complaints

6. Appropriate disciplinary mechanisms

7. Investigation and remediation of systemic problems

8. Risk assessment necessary for design and operation of the compliance program (Section 8B2.1(c))
Research Compliance - a Misnomer

“Compliance, n. a yielding, disposed to oblige, conforming to the wishes of others”
“There is perhaps no other environment where this term’s connotation evokes such rancor” - R. Emery

Principal Investigator/Institutional Responsibility:

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Research Grants Administration
Research Grants - Pre-award
Research Grants - Post-Award
- Effort Reporting & Cost Sharing
- Allowability of Expenditures
- Sub-recipient Monitoring
- Grant reporting

Export Regulations
Dept. of Commerce - Dept. of Defense
*Export of “Sensitive” Information and Technologies

Laboratory Safety
Compliance Program Components

Shared Accountability Model

- Departmental Controls
- Training and Support
- P&P, Risk Assessment, and Monitoring
- Compliance Officers

http://research.utk.edu/compliance/faculty-led-compliance-and-safety-committees/
Encouraging responsible and ethical conduct of research critical for scholarly excellence, as well as building public trust during our quest for new knowledge.

Compliance Officers

Robert Nobles, Assistant Vice Chancellor

Isaac Bader
Radiation Safety Specialist

Shawn Drake
Radiation Safety Specialist

Kristine Hershberger
IRB Compliance

Barbara Hall
Laser Safety Specialist

Laura Moll
IRB Compliance

Dairin Malkemus
Export Control & Conflict of Interest Committee

Sara Mulville
IRB Specialist

Brian Ranger
Biosafety

Marsha Smith
Radiation Safety Specialist
Responsible Conduct of Research

Professional Conduct in the Field of Research (“Professionalism and Integrity”) include:

- Protection of Human Research Subjects (OHRP)
- Care and Use of Research Animals (OLAW)
- Research Misconduct (ORI)
- Conflicts of Interest and Commitment
- Publication Practices, Responsible Authorship
- Data Acquisition, Management, Sharing and Ownership
- Mentor / Trainee Responsibilities
- Peer Review
- Collaborative Science
- Export Control
- Grant and contract compliance
- Laboratory Safety

iMedRIS
Who Powers Your Research?