Responsible Conduct of Research and Faculty Support

Discussion led by
Robert Nobles, DrPH, MPH, CIP
Associate Vice Chancellor for Research

- “The scientific research enterprise, like other human activities, is built on a foundation of trust.”
  - Scientists trust that the results reported by others are valid.
  - Society trusts that the results of the research reflect an honest attempt by scientists to describe the world accurately and without bias.
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)
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
Focus on Research Misconduct:

- All OIGs (especially NSF, NIH, DOE) and PHS ORI have increased focus on misconduct
- Congress also has increased focus on misconduct
- Funding agencies run plagiarism software (e.g., iThenticate) on proposals and reports and contact RIOs
- Journals run plagiarism software (e.g., iThenticate) on manuscripts and contact RIOs
- Peer reviewers of proposals and manuscripts notice fabrication, falsification, plagiarism and contact journal editors/RIOs
- Colleagues report misconduct to RIOs
- Graduate students report misconduct to RIOs
- Faculty/staff from other institutions notify RIOs of misconduct
ORI News from July, 2015:

DOJ: Faculty member sentenced

Federal Register: Scientist debarred
Focus on Laboratory Safety

UCLA chemistry professor avoids prison time in fatal lab fire case

Yale Student Killed as Hair Gets Caught in Lathe

San Francisco VA Lab Faces Sanctions For Researcher’s Death

Texas Tech University Chemistry Lab Explosion

VA Lab 2012

The New York Times

Los Angeles Times

The University of Tennessee

ECSB U.S. CHEMICAL SAFETY BOARD

Texas Tech 2010

VA 2012

UCLA 2008

Yale 2011

UCLA 2010

Yale 2011

VA 2012
The Task Force on Laboratory Safety calls on all universities to embrace a renewed commitment to improve the safety culture for all academic research, scholarship, and teaching. We ask that college and university presidents publicize their commitment and expectations within their institutions. We ask that all academic institutions look beyond the traditional research laboratory to embrace a commitment to improving safety in research and teaching laboratories; in shops, studios, and stages; in teaching classrooms, and in the field.

The Task Force further recommends that the Association of Public and Land-grant Universities and the Association of American Universities, as the member associations of research universities, call upon all academic institutions to renew their commitment to improve the safety culture for all academic research, scholarship, and teaching. We call upon APLU and its Council on Research (CoR) to routinely recognize exemplary programs and to sponsor an annual safety culture award.
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
We Recognize the Reality

Dr. Newton is involved in the following activities:

• Teaches two courses → 20 hours a week 20/80 = 25%
• Mentors PhD students → 5 hours a week 5/80 = 6.25%
• Sits on two university committees → 5 hours a week 5/80 = 6.25%
• Consults his brother’s genetics company → 10 hours a week
• Manages three research projects:
  • Apple grant → 15 hours a week 15/80 = 18.75%
  • Gravity grant → 15 hours a week 15/80 = 18.75%
  • Wig contract → 15 hours a week 15/80 = 18.75%
• Prepares and writes grant proposals → 5 hours a week 5/80 = 6.25%

Total hours = 80 hours a week = Dr. Newton’s 100% effort
Compliance Supported by UT 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
Role of the Academic Compliance Program

- **Supporting Faculty for Research Success**
- **Minimize Risks**
  - Financial Risks & Operational Risks
  - Health & Safety Risks
  - Reputational Risks
- **Foster Relationships and Trust**
  - Community
  - Sponsors and Regulators
- **Reduce External Pressures**
  - Governmental Expectations (e.g. DHHS OIG, NIH, NSF, etc.)
  - (Possibly) Reduced Fines and Penalties
- **Improve Efficiency and 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*
Key Aspects of a Research Compliance Program
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
A closer look at two converging needs

**Research & Engagement**
- Ensure submissions are complete and ethical
- Ensure federal and UTK policies are upheld
- Ensure adequate training
- Ensure submitted protocols and research materials receive appropriate review
- Ensure research procedures and documentation are appropriate (post-approval monitoring, inspections)
- Ensure institutional liability is reduced

**Research Investigators/Teams**
- Develop and conduct relevant research
- Perform sound research methods
- Maintain proper documentation and compliance approvals
- Interact with subjects and research personnel in an ethical manner
- Maintain a research laboratory/office, including funding
- Analyze and report data
Quotes from ORI

- “In general terms, responsible conduct in research is simply good citizenship applied to professional life.”

- Researchers [are expected] to report their work honestly, accurately, efficiently, and objectively”

Reference: ORI Introduction to the Responsible Conduct of Research (2007)
In Closing