Responsible Conduct of Research

Discussion led by
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Mission

- **Foster** excellence in research, scholarship and creative activity across all disciplines
- **Promote** transdisciplinary discovery
- **Facilitate** external partnerships to enhance the discovery enterprise and its impact to society
- **Protect** researchers from common and invisible threats
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)
UTK Institutional Compliance Committee Responsibilities

• Implement the university compliance risk assessment process.
• Identify regulatory areas that present significant compliance risk and the responsible office/compliance officer.
• Review risks and determine priorities to address.
• Help functionally responsible offices overcome barriers to compliance.
• Coordinate effort to assess plans of corrective action.
• Foster transparency through active communication.
UTK Top Risk Areas

- **Equity and Diversity**
  - Title IX, Disability, and Discrimination

- **Finance and Administration**
  - Safety, Emergency Management, Sponsored Project Accounting, and Information Technology

- **Research and Engagement**
  - Human and Animal Subject Research, Export Controls, Scientific Misconduct, and Laboratory Safety
We Recognize the Reality

Dr. Newton is involved in the following activities:

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

Total hours = 80 hours a week = Dr. Newton’s 100% effort
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
RCR Infrastructure Overview

Encouraging responsible and ethical conduct of research critical for scholarly excellence, as well as building public trust during our quest for new knowledge.

- Fostering shared-governance by appointing faculty led compliance committees
- Providing training, review, oversight, and inspections/audits for:
  - Human and animal research
  - Laboratory Safety (Biologics, Radiologics, Chemicals)
  - Export Controls of materials, activities, and personnel
  - Research Conflicts of Interest
- Providing tools to prevent Research Misconduct, including Plagiarism
- Partnering across the university to provide information and resources for:
  - Publication Practices, Responsible Authorship
  - Data Acquisition, Management, Sharing and Ownership
  - Peer Review
When Non-Compliance Occurs
Universities Penalized for Violations

• 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
Duke University settles research misconduct lawsuit for $112.5 million

By Science News Staff Mar. 25, 2019, 1:50 PM

Duke University will pay $112.5 million to the U.S. government to settle a lawsuit brought by a former employee who alleged that the university included falsified data in applications and reports for federal grants worth nearly $200 million. The university will also take several steps “to improve the quality and integrity of research conducted on campus,” including the creation of a new advisory panel.
UTK Researchers Penalized

Former University of Tennessee Professor John Reece Roth Begins Serving Four-Year Prison Sentence on Convictions of Illegally Exporting Military Research Data

KNOXVILLE, TN—On January 18, 2012, John Reece Roth, a former professor of electrical engineering at the University of Tennessee (UT) in Knoxville, began serving a four-year prison sentence for his September 2008 convictions. Roth had been on bond pending his appeals, all of which were unsuccessful. He self-surrendered to the federal correctional facility in Ashland, Kentucky.
The Dilemma

Competitiveness and National Security

Openness in Research
Recent Federal Actions

NIH letters asking about undisclosed foreign ties rattle U.S. universities

By Jeffrey Mervis | Mar. 1, 2019, 1:55 PM

The National Institutes of Health (NIH) has recently sent letters to dozens of major U.S. research universities asking them to provide information about specific faculty members with NIH funding who are believed to have links to foreign governments that the Bethesda, Maryland–based institute did not know about.
Recent Federal Actions (2)

• DOE:
  • The national labs are developing policy first for employees that require them to: 1) disclose participation and 2) choose whether to remain a participant of the foreign talent program or remain a national lab employee (cannot do both).

• NSF:
  • All proposers must disclose current, past, and planned future funding sources and disclose all funding sources including summer support, provision of lab equipment, etc.
  • NSF is creating a form to make it more clear what categories are to be reported. The form will be saved in a system and will be updatable.
Recommendations for Universities

• Communication and Awareness
  • Implement a Broad Educational Campaign to raise awareness and improve disclosures
  • Develop practices to safely host visitors, including international delegations
  • Consider implementing pre-travel safety briefings for international travel to selected countries
Recommendations for Universities (2)

• Risk Mitigation
  • Assess the physical, technical, and administrative controls for sensitive data and equipment
  • Enhance computer security for international travel to certain regions
  • Receive financial and commitment disclosures
  • Develop policies and procedures for any identified areas of research security
Recommendations for Universities (3)

• Ongoing Monitoring
  • Consider developing a list of ‘flags’ that may trigger a recipient organization to conduct an audit particularly if inconsistent with funding
    • Parameters may include: frequent foreign travel; lab resources inconsistent with funding; unexpected or inappropriate assets; personnel count disproportionate to funding; publishing frequently with collaborators outside the U.S., especially if no other authors are from the home recipient organization
  • Consider initiating post-travel follow-up questionnaires for research-related trips to select countries
UTK Researchers Penalized

- Human Subjects
  - UTK PhD degree revoked for accessing information without IRB approval
  - Faculty member reprimanded for guiding students to proceed with research without IRB approval
  - Student denied use of thesis data collected internationally after procedures were altered without approval (delayed graduation)
UTK Researchers Penalized

• Radiation Safety
  • Faculty member suspended from lab use for 6 months due to ongoing contamination
  • Faculty member suspended from the use of radiologics for 1-year for failure to follow protocols

• Animal Welfare
  • Faculty member suspended from work with animals for 6 months due to graduate student treatment of animals
  • Program staff terminated as a result of noncompliance
Research Misconduct at UTK

• More than 30 allegations of research misconduct assessed within the last 36 months at UTK, and included:
  • Plagiarism of text
  • Plagiarism of ideas
  • Research tampering
  • Lab recycling text without proper citation
  • Publishing erroneous content without faculty consent/knowledge

• Other questionable research practices have been noted
  • Use of quotation marks
  • Copyright
  • Terms of service violations
  • Text recycling
  • Multiple journal submissions
  • Authorship attribution
UTK Researchers Penalized

• PhD Student dismissed prior to graduation for publishing an article without advisor consent (article contained research misconduct)
• Multiple RM committees looking into plagiarism, falsification, and fabrication allegations
• **Question**: How will you prepare your research team for research excellence?
UTK Compliance Program Components

Shared Accountability Model

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

- Top 25 Research and Academic Institution
- Enhanced Partnerships and Public Trust
- Risk Minimization
- Excellence in Teaching, Research, and Public Service
In Closing
Questions?

THE UNIVERSITY OF TENNESSEE KNOXVILLE
OFFICE OF RESEARCH & ENGAGEMENT