Responsible Conduct of Research (RCR) Overview

What and Why?

The responsible conduct of research (RCR) is a widely-accepted set of ethical and professional standards for conducting research, scholarship and creative work. It is critical to excellence and public trust in research. The UT research community is committed to maintaining the integrity of its research enterprise through the responsible and ethical conduct of all faculty, staff, students and postdoctoral scholars and fellows. RCR instruction and training is fundamental to the preparation and long-term professional development of current and future generations of UT researchers, scholars and creatives.

Resources

UT ORIED Division of Research Integrity & Assurance RCR website

US DHHS Office of Research Integrity RCR videos and resources

UT's Policy and Procedures on Responsible Conduct of Research (which is also UT's research misconduct policy, includes Appendix B Expectations of PIs

UT Code of Conduct

With RCR questions – or to report possible cases of research misconduct – contact Dr. Sarah Pruett, Assistant Vice Chancellor for the Responsible Conduct of Research, Institutional Research Integrity Officer (spruett1@utk.edu or 865-974-9918) or Jane Burns, Director of Research Integrity (janeburns@utk.edu or 865-974-3526).

Key Points

- ✓ UT leaders consider responsible conduct of research a high priority.
- ✓ RCR training is available for all UT researchers, and sponsor requirements for RCR training are increasing.
    - Students & postdoctoral researchers on **National Science Foundation (NSF)** projects are required to take RCR training; in mid-2023, NSF will also require *Principal Investigators and key personnel* to have RCR instruction.
    - All participants in **USDA National Institute of Food & Agriculture** research projects are required to have RCR training.
    - The **National Institutes of Health (NIH)** guidance calls for RCR instruction at least once during each career stage and at least once every 4 years. NIH requires RCR training for training, career development award, research education, & dissertation research grants. NIH has recently expanded RCR subject matter to include a safe research environment, secure and ethical data use, and data confidentiality.

Mentorship & a Safe Research Environment

What and Why?

Mentorship and providing a safe research environment are key element of responsible conduct of research and ensuring integrity of research.

Safe research environment includes physical safety, as well as psychological safety.

NIH has recently added safe research environment "(e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)" as a subject matter for RCR training,

Resources

Division of Research Integrity

Graduate School – Training & Mentorship

Graduate School – Independent Development Plans

International Student & Scholar Services

Office of Ombuds Services

UTK Workplace Bullying Procedure

Title IX Office

Human Resources – UT Employee Assistance Program

UT Institutional Compliance

Key Points

- ✓ Independent Development Plans can help faculty and protégés develop a formal structure for the mentoring process.
- ✓ Take advantage of University resources available to you provide and receive the best mentorship relationship and safe research environment. Offices listed above can help you establish processes and also help when problems occur.
- ✓ You are not alone.

Research Conflicts of Interest & Commitment

As a leading research institution, UT actively encourages researchers to translate knowledge they create through their research, scholarship, and creative work to the private and public sectors for the public good. Researchers are often rewarded by these outside organizations for their efforts, including through professional appointments, consulting fees, honoraria, travel support, and the sharing of royalties generated from the commercialization of their work, among other things.

To maintain public trust in research performed at or by UT researchers, the University adheres to an established conflict of interest policy. This policy aims to manage and mitigate any bias, or the perception of bias, in research.

Disclosures

- Disclosure of outside interests is required annually by both UTK and many federal agencies.
    - All outside activities and relationships which intersects with your UTK responsibilities in any way should be disclosed on the form.
    - Documentation can be uploaded into the form directly to provide further explanations.
    - Disclosure does not equal a conflict of interest. Most outside interests do not cause a conflict of interest and are actively encouraged to promote/enhance your field of expertise.
- Funding agencies may require disclosure of potential conflicts of interest in proposals as well as at the time of the award of funding.
- The directive of the Research Integrity office to actively manage and mitigate conflicts of interest, not outright prohibit an outside activity.
- Supervisors are asked to watch for and report potential conflicts of interest, not be the authority responsible for determining if a conflict exists.

COI Training & Questions

- PHS and DOE require an individual be trained on conflicts of interest every four years.
- For questions or to schedule Conflict of Interest/Outside Interest Form training for your unit, contact Scott Canner, Research COI Compliance Officer, at scanner2@utk.edu. For non-research COI questions, contact Jay Taylor Bailey at vtaylor@utk.edu or see the Division of Finance & Administration COI website.

Online Resources

- UT Research Integrity Website
- UT Conflicts of Interest & Commitment Policy
- CITI Conflict of Interest Training
- Guidance for Researcher Outside Consulting Activity
- UT Employee OID Forms
- Guidance for What to Disclose
- UTK Faculty Handbook

Research Data

What and Why?

Retention, sharing and management of research data is fundamental to research integrity and support of scientific results. Some sponsors require Data Management Plans.

Resources

Sponsors requirements for Data Management Plans: NSF, NIH, and USDA NIFA

Final NIH Policy for Data Management and Sharing Plans, effective 1/25/23. See more at NIH DMSP Overview.

DMP Tool at UT Libraries: Data Management Plans

DMP description at UT Libraries Planning

UT Policy RE001 Appx A: Sharing, Retention, and Ownership of Research Data.

https://research.utk.edu/research-integrity/data-management/

Article: *Ensuring research integrity: The role of data management in current crises*

Key Points

✓ Develop DMPs as projects are planned. Ensure they meet sponsor requirements, if applicable.

✓ Update Data Management Plans during the life of a project, as needed.

Research Security & Export Control

What and Why?

The federal agencies that exercise regulatory authority for export control include:

- U.S. Department of State - (ITAR) military applications including nuclear, biological, and chemical weapons, missiles, or space technology.
- U.S. Department of Commerce – (EAR) commercial items with potential military application – "dual use". Licensing for proposed exports and re-exports of goods and technology from the United States.
- U.S. Department of Treasury - (OFAC) trade sanctions and embargoes; travel restrictions; supplying items and/or services of value based on US foreign policy and national security goals against targeted foreign countries and regimes, terrorists, international narcotics traffickers, those engaged in activities related to the proliferation of weapons of mass destruction, and other threats to the national security, foreign policy or economy of the United States.

Failure to comply with export control laws can lead to high fines and even jail time.

Resources

Website: https://research.utk.edu/research-integrity/research-security-export-control/

Stanford export control decision tree: http://export.stanford.edu/tree/

Contacts: utkexportcontrol@utk.edu or

- Chris Godfrey Compliance Officer, Export Control jgodfre8@utk.edu
- Mary Sechrist Facilities Security Compliance Officer mjourdan@utk.edu

Key Points

- ✓ UT is most often concerned with EAR or "dual use" items or technology having both commercial and military applications. We can get a ruling from The US Department of Commerce Bureau of Industry and Security, if we are unsure.
- ✓ "Deemed export" take place when a foreign national within the United States has access to export-controlled technology or source code.
- ✓ Often, university research does not require restrictions or licensing because it falls under the fundamental research exclusion (FRE). FRE applies for *technology* (not controlled *items*) if results are normally published or generally accessible to the public (without sponsor restricting publication or foreign nationals on the project).
- ✓ Correctly answer the export control questions in Cayuse, even if the FRE applies. Notify utkexportcontrol@utk.edu if you have questions about technology or items that may be export-controlled or if you have export-controlled projects that are not externally-funded.
- ✓ If visitors will engage in research in your department or laboratory, see Visitors Engaged in Research Policy and instructions *early in your planning* of the visit.

Environmental Health & Safety

The purpose of UT's Environmental Health & Safety (EHS) office is to ensure the safest, most healthful and environmentally responsible learning and work environment of any institution of higher learning. According to UTK Chancellor Plowman, safety is a cultural expectation at UT and the responsibility of everyone. See her video at https://ehs.utk.edu/.

Resources

Sandra Prior serves as Director of Environmental Health & Safety.

EHS Contact information

Much information can be found about EHS programs and training at the EHS website: https://ehs.utk.edu/

In addition to the EHS website, key information about Biological Safety, Radiation Safety, and the UTIA Safety Office is provided in the following pages.

Office of Biological Safety

What and Why?

Biosafety refers to the practices and procedures, containment equipment, and facility design that are necessary to safely work with disease causing infectious organisms/viruses, vectors of disease, recombinant and synthetic nucleic acid technologies, human or other animal tissues, biological toxins, or other biological materials that may pose a risk to human, animal, plant, or environmental health.

The Biosafety functions of the Environmental Health and Safety (EHS) Department (EHS-Biosafety) ensure that research, teaching, or diagnostic testing activities involving biohazardous materials are conducted safely and responsibly; U.S. Federal, state, and local regulatory mandates and guidelines applicable to biological research are followed; UT personnel and students are appropriately trained; and laboratories and associated facilities are regularly inspected.

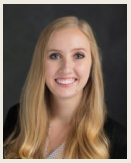
EHS-Biosafety also serves as the liaison between the research community and the Institutional Biosafety Committee (IBC), a committee of faculty experts and community representatives that reviews biological research protocols for safety and compliance.

Staff

Brian Ranger, MS, SM (NRCM), CBSP, is the Biological Safety Officer (BSO) for the University of Tennessee-Knoxville, Institute of Agriculture, and Graduate School of Medicine and the Program Leader for the Laboratory Safety Services (LSS) group in EHS. branger@utk.edu

Linda Hamilton, MPH, RBP Supervisor for LSS in EHS-Biosafety and the Assistant Biosafety Officer (ABSO) for the University of Tennessee-Knoxville, Institute of Agriculture, and Graduate School of Medicine. lhamil17@utk.edu

Daniel Thomas, Sr. Lab Safety Specialist for EHS-Biosafety
dthoma72@utk.edu



Carolina Dolislager, MS Lab Safety Specialist for EHS-Biosafety
cdolisl1@utk.edu

Christopher Baker, Lab Safety Technician for EHS-Biosafety
crb@utk.edu

Office of Biological Safety (continued)

Key Points

- ✓ Works with research faculty to ensure IBC registration of protocols involving recombinant or synthetic nucleic acids or other biohazards (e.g. infectious agents, biological toxins, human-derived materials, and venomous animals/poisonous plants)
- ✓ Provides initial and annual refresher training for research faculty, staff, and students
- ✓ Provides guidance for the acquisition of federal permits (i.e., CDC, USDA-APHIS, etc.) for the import, export, or interstate movement of biological materials
- ✓ Partners with EHS-Env to facilitate the packaging, pickup and disposal of regulated medical waste
- ✓ Ensures compliance with institutional, state, and federal regulations for the safe and responsible conduct of biological research through laboratory inspections and ongoing consultations

Additional information available at http://biosafety.utk.edu

Radiation Safety

What and Why?

The University of Tennessee Radiation Safety Department oversees all use of ionizing radiation and laser systems for the Institute of Agriculture and Ag Research and Experimentation Centers across Tennessee.

The Radiation Safety Department maintains the university's radioactive materials license and promotes worker and campus safety.

Resources

Radiation Safety Department:

414 East Stadium Hall
1425 Tee Martin Drive
Knoxville, TN 37996
(865) 974-5580

radiationsafety@utk.edu

Marsha Smith, Radiation Safety Officer

Key Points

- ✓ Researchers who would like to use radioactive materials must apply and be approved by UT's Radiation Safety Committee before you begin your research.
- ✓ Anyone working around radioactive materials or x-ray units should receive safety training before they begin working around these hazards.
- ✓ All x-ray equipment must be registered with the State of TN within 10 business days of arrival on campus.
- ✓ If you plan to use a Class IIIB or IV laser system, contact our department.

UTIA Safety Office

What and Why?

The UTIA Safety Office serves all four units at the Institute of Agriculture. We promote a safe and healthful work environment by providing support and services to the faculty, staff and students in the areas listed below.

Resources

The Safety Office website has program information & many resources:
http://utiasafety.tennessee.edu/
Office location: B008 Plant Biotechnology Building.

Steve Crouch is the UTIA Safety Officer. He can be reached at 865-974-4904 or mobile 865-382-2131. Much of his time is spent out of the office, so feel free to call or text if you need a quick response.

Jacob Payne is the UTIA Safety Coordinator and acts as the program lead for the laboratory safety program. He can be reached at 865-974-7144.

Areas of Support

- ✓ Laboratory Safety Program oversight. Work with PIs to develop Chemical Hygiene Plans, chemical inventories, test fume hoods, perform lab inspections, maintain up-to-date door signage, and provide general lab safety training.
- ✓ Coordinate hazardous waste disposal program. Waste pickups are scheduled monthly. If you would like to be added to the email list to receive information on waste pickup dates, contact us.
- ✓ Investigate accidents and evaluate chemical hazards; provide appropriate follow-up.
- ✓ Evaluate workplace health hazards related to chemical exposures, indoor air quality, ergonomics, and slip/trip/fall hazards.
- ✓ Update the campus Emergency Response Plan; liaise with departments and emergency responders to preplan for various emergencies that impact the campus. On-call 24/7 to assist in the event of spills, fires, and other facility emergencies.
- ✓ Conduct inspections for safety, health and environmental protection issues of all UT-owned facilities, including the AgResearch RECs and 4-H Camps.

Human Research Protection Program

The mission of the Human Research Protection Program (HRPP) at the University of Tennessee, Knoxville is to:

- Safeguard and promote the health and welfare of human research subjects by ensuring that their rights, safety, and well-being are protected.
- Provide guidance and support to the research community in the conduct of research with human subjects.
- Assist the research community in ensuring compliance with relevant federal regulations, state laws, and university policies.
- Provide timely and high-quality education, review, and oversight of human research projects.
- Facilitate excellence in the conduct of human subjects research.

The HRPP achieves these goals by supporting the Institutional Review Board (IRB), conducting reviews of human subjects research, providing educational support to researchers, conducting Quality Assurance/Quality Improvement activities, and collaborating with other offices on campus as well as external IRBs when necessary.

Resources

Website at: tiny.utk.edu/hrpp
Email : utkirb@utk.edu
Phone: (865) 974-7697

Virtual Office Hours: **https://research.utk.edu/research-integrity/human-research-protection-program/**

Key Points

- ✓ Because the University receives federal funds for research, we are required to follow the Federal Policy for the Protection of Human Subjects ('Common Rule').
- ✓ If your research project is not considered Human Subjects Research, the Common Rule does not apply, and IRB review is not required. For help determining whether your project is Human Subjects Research contact us, or complete our determination worksheet.
- ✓ All IRB applications must be submitted online, through iMedRIS. The questions in this application help investigators to select the appropriate level of review.

CITI training is mandatory for each PI, Co-PI, Research Personnel, Advisors, and Student(s) listed on a human subjects application. For more information on training, visit https://research.utk.edu/research-integrity/human-research-protection-program/for-researchers/before-you-begin-2/citi-training/

Institutional Animal Care and Use Committee (IACUC)

What and Why?

The IACUC is a federally mandated committee composed of UT scientists, non-scientists, veterinarians and non-affiliated (community) members charged to oversee animal care and use on the Knoxville campus, the UTIA Research and Education Centers, and UT Medical Center, Knoxville. The IACUC and the protocol review process are regulated in part by the Animal Welfare Act and Regulations and the Public Health Service Policy. Prior to initiating any research or teaching activity, an animal use protocol must be submitted for review and approval. Upon completion of the review process, protocols are approved for a 3 year period. Any revisions to approved protocols or changes in personnel must be requested and approved prior to implementation of the change or using those individuals with the protocol activities.

Resources

IACUC Information can be found at the website https://iacuc.utk.edu/

For question or concerns, email iacuc@utk.edu or:

Dr. Melinda Hauser, IACUC Director: mhauser@utk.edu or 974-4047
Susan Ivey, IACUC Coordinator: ivey@utk.edu or 974-3631
Frankie McGinnis, IACUC Coordinator: fmcginni@utk.edu or 974-5547
Jerri O'Rourke, Compliance Coordinator: jorourk@utk.edu or 974-9074
Trent Gentry, Compliance Coordinator: tgentr12@utk.edu or 974-4996

On Call OLAC Veterinarian Information

iMedRIS Protocol Submission: https://iacuc.utk.edu/iacuc/protocol-application-submission/

Click here for IACUC Training Sign-up

Key Points

- ✓ The review and approval process is based on the procedural content of the protocol. A protocol may be reviewed by one of two methods: designated member review (electronic review) or discussed at full review during the monthly meeting of the IACUC. There are no "deadlines" for submission on our campus.
- ✓ The review and approval process involves an administrative review, a veterinarian review and the committee review. This process may take 2-10 weeks to resolve all protocol issues and concerns via communication between the PI, IACUC office staff, the veterinarians and the IACUC.
- ✓ All personnel involved in animal protocols are required to have appropriate training for performing the procedures, specific training on the IACUC's roles and responsibilities, and enrollment in the Occupational Health Program.
- ✓ All approved protocols are subject to a post-approval monitoring to ensure the protocol is being performed as written with the principal investigator being ultimately responsible for any issues noted.