

Plan for Instruction in the Responsible Conduct of Research

The UT MD Anderson Cancer Center and Rice University are committed to the highest ethical standards in conducting biomedical research. All trainees are required to go through a thorough curriculum before engaging in any activities associated with biomedical studies.

MD Anderson Cancer Center

Formal instruction in scientific integrity and the ethical principles of research is required through The University of Texas MD Anderson Cancer Center. All T32 Training Program trainees will be required to attend 10 hours of research training on enrollment. This instruction includes the following:

- History of Research and Ethics
- Evolution of Good Clinical Practice
- Scientific Integrity and Conflict of Interest
- Office of Protocol Research Organizational Chart and Databases
- Responsibilities of the Investigator
- Institutional Review and Approval Process
- Informed Consent
- Introduction to Protocol Data Management System
- Compassionate Use of Investigational Drugs (CIND)
- PI Override Process
- Elements of a Protocol
- Source Documentation
- Adverse Events
- FDA Inspections and Institutional Audits
- Institutional IND Policy

All trainees who will be handling animals as part of their research training are required to take the Institutional animal use training course (as described in the Animal Care and Use Handbook for Investigators) and provide documentation of completion to the Office for Research Administration. This training program consists of selected written and taped materials that introduce regulatory requirements, principles of humane care, use, and basic handling and methodology of targeted animal species.

All T32 Training Program trainees who will be handling radioactive materials as part of their research training are required to take the Institutional course, "The Safe Handling of Radioactive Materials in Research and Clinical Laboratories." This includes eight hours of instruction and is directed toward persons working with radioactive materials in research and clinical laboratories.

In addition, The University of Texas Graduate School of Biomedical Sciences, the sister institution, offers four ethics related courses: Ethics in Health Care I, Ethics in Health Care II, Technology on Trial: Interface of Science and Law, and The Ethical Dimensions of the Biomedical Sciences. These courses will be available as electives to the T32 trainees who want to receive a deeper perspective into ethics of clinical research.

Rice University

Rice University is strongly committed to creating and fostering a community of scholars engaged in the highest caliber of research and scholarship. Accordingly, the University and all of its constituencies including faculty, postdoctoral fellows, staff and students are committed to the common goal of developing and sustaining an environment where academic scholarship embracing the tenants of academic freedom and free scholarship may be undertaken. Rice's mission is to conduct cutting edge research in an environment where the ethical conduct of research is held paramount. The University has a long history of developing policies and practices that reinforce this need.

As members of the Rice University community, all faculty have the responsibility for sustaining the highest ethical standards of the institution, and of the research and academic communities in which they are members. Rice faculty also take seriously their responsibility of mentoring postdoctoral scholars in their transition to independent academic

careers. The Rice community is engaged in preserving and maintaining collegiality, investigative curiosity, and the responsible conduct of all aspects of scholarship including research and teaching.

In its effort to maintain the highest standards of integrity in research and scholarship, Rice University is dedicated to providing its students, postdoctoral scholars and others participating in the research enterprise with the training that will enable them to carry out their research and professional activities in a manner that reflects the values of honesty, accuracy, objectivity, and efficiency that lie at the core of research integrity. Training and education in the Responsible Conduct of Research (RCR) is one aspect of Rice's commitment to maintain the highest standards for research integrity among its research community, including undergraduate and graduate students, postdoctoral fellows, and faculty.

The expectation for all individuals engaged in research at Rice is that they will have a clear understanding and suitable training relevant to their research in the following areas:

- the roles and responsibilities of the mentor and trainee;
- the ethical conduct of research;
- research misconduct;
- responsible authorship and publication;
- data acquisition and laboratory tools; management, sharing and ownership;
- conflicts of interest: personal, professional, and financial;
- animal subjects in research;
- safe laboratory practices including issues pertaining to collaborations with industry;
- understanding the peer review process
- contemporary ethical issues in biomedical research and the environmental and societal impact of scientific research.

NIH specific requirement for training in Responsible Conduct of Research (RCR). Any trainee, fellow, participant, or a scholar supported now or in the future by funds received from the National Institutes of Health (NIH) using career development awards (K-series individual or institutional), research education T-series grants, and NRSA awards (F series), must complete the Collaborative Institutional Training Initiative (CITI) Responsible Conduct of Research online and the academic course UNIV 594 focused on RCR or participate in another form of approved in-classroom training.

Major learning modules of CITI course:

- Authorship (RCR-Basic)
- Collaborative Research (RCR-Basic)
- Conflicts of Interest (RCR-Basic)
- Data Management (RCR-Basic)
- Financial Responsibility (RCR-Basic)
- Mentoring (RCR-Basic)
- Peer Review (RCR-Basic)
- Plagiarism (RCR-Basic)
- Research Involving Human Subjects (RCR-Basic)
- Research Misconduct (RCR-Basic)
- Using Animal Subjects in Research (RCR-Basic)