PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

I. Responsible Conduct of Research (RCR) Coursework: The [University] School of Medicine ([redacted]) is committed to the maintenance and promulgation of high ethical standards in research and patient care. The School of Medicine played an integral role in the establishment of a new [University] Center for Bioethics, a focal point of leadership both locally and nationally. Trainees in this T32 program will be required to complete [redacted], "The Responsible Conduct of Research" course, at the [redacted]. [Redacted] has two main overarching objectives;
1) to introduce researchers to concepts related to being a responsible scientist throughout the course of their careers; and 2) to help trainees recognize potential issues that may arise in their careers and to develop a skillset to deal with these issues as a responsible researcher. The topics covered in this course are those recognized to be important and required by federal funding agencies such as the NIH and NSF. The topics are also relevant to those encountered by trainees and researchers at all levels. Thus, at the end of this course, T32 trainees will be able to distinguish and apply best practices for responsible research. They will be able to recognize and adopt behaviors that embody responsible conduct, and they will know how to respond if or when irresponsible conduct occurs. Upon the satisfactory completion of this course, the trainees in this T32 program will meet the basic NIH requirements for formal training in responsible conduct of research.

Format: [Title redacted] is a didactic course involving both in-person instruction and feedback components, requiring active participation on the part of both faculty and students. The course is designed to encourage interaction and discussion, particularly amongst trainees at different levels. A mix of guest lecturers, case studies, group projects, and individual study are employed. Grading for the course is based on attendance and competency demonstrated by a written essay of responsible practices in diverse research settings.

Subject matter: Covered topics include data management, publication and authorship, research misconduct, live animal research, human subjects research, peer review, conflicts of interest, mentoring, interactions with the IRB, review of laws and regulations governing biomedical research, professionalism, ethics, morality and the justification of research, responsible research: a view from the trenches, the declaration of Helsinki, the Belmont Report, and the Common Rule.

Faculty Participation: This course features experienced [redacted] faculty from a variety of scientific backgrounds, providing students with knowledge, experience, and methods needed to solve ethical dilemmas.

Duration: The course is a semester long course (1 credit hour). The course meets on [redacted] from [redacted] PM.

Frequency: The course is required of all trainees and is taken at the beginning of the trainees first year on the T32 grant. Trainees will be encouraged to re-take the course as content changes.

Syllabus:
Course Name: [redacted] -The Responsible Conduct of Research
Course Description: This course is designed to introduce the learner to the professional and ethical standards and expectations of those conducting scientific research. The course will introduce major concepts in the field of responsible conduct of research and will provide resources for further study in what will be a continuing education throughout the learner's scientific career. Completion of the course meets the basic NIH requirements for formal training in the responsible conduct of research.

The format of the course is a combination of lecture and discussion. Lectures will provide background information, and cases will be used to illustrate issues of research ethics. Students will apply concepts from lectures during small group discussions. To facilitate discussion, **attendance is required**. Attendance is also required to fulfill the NIH requirements for Responsible Conduct of Research training.

Course-level Student Learning Outcomes

By the end of the course, students will be able to:
1. Discuss important concepts and issues related to being a responsible scientist.
2. Distinguish practices that are responsible from those that are irresponsible.
3. Implement behaviors that lead to responsible conduct.
4. Recognize and respond appropriately to irresponsible conduct encountered during the learner's career.
5. Develop practices for ongoing education in the responsible conduct of research.

Date	Session Topic
Aug. XX	Introduction to Responsible Conduct of Research
Sept. X	Research Misconduct
Sept. X	Human Subjects Research
Sept. XX	Live Animal Research
Sept. XX	Societal Responsibility of Biomedical Researchers—Guest lecturer: [redacted], MD
Sept. XX	Peer Review; Conflicts of Interest; Mentoring
Oct. X	Data Management; Authorship & Publication; Collaboration

II. Additional training in RCR: In addition to [redacted] completion, principles of RCR will be reinforced in other T32 programming. All faculty mentors will be required to have training in RCR. RCR issues will be discussed in individual lab meetings and meetings with mentors.

Finally, trainees will be required to complete specific training through the Office of Research Compliance as it applies to their individual research projects. The Office of Research Compliance (ORC) ensures IU conducts its educational, research, and clinical activities in a manner that is consistent with regulatory, statutory, and organizational requirements. This collaborative effort throughout the entire [redacted] community is designed not only to achieve compliance, but also to establish the highest ethical standards governing pre-clinical and clinical research activities. Several educational opportunities (eLearning Videos & Training Guide, CITI Training Modules, ORC Sessions, and Workshop) are offered to faculty, staff, and trainees. Depending on the scope of their research projects, trainees will complete the following trainings and maintain annual recertifications.

- The [University] subscribes to the Collaborative Institutional Training Initiative (CITI) online education and training programs. All trainees who directly interact with study subjects are required to complete CITI training. Specifically, trainees involved in research involving human subjects have to take and pass the Human Subject Research CITI educational course (either Biomedical or Social and Behavioral educational track, depending on their type of research) before submitting a clinical protocol to the IRB and/or participating in any clinical trial involving human subjects.
- The NIH Policy on Good Clinical Practice (GCP) Training for NIH Awardees Involved in NIH-funded Clinical Trials establishes the expectation that all NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in GCP, consistent with principles of the International Conference on Harmonization (ICH). The principles of GCP help assure the safety, integrity, and quality of clinical trials by providing a standard for ensuring clinical trial compliance, implementation, data collection, monitoring, and reporting (e.g., safety data, accrual reports, study status, protocol deviations, unanticipated problems, or final data), and outline the responsibilities of Institutional Review Boards (IRBs), investigators, sponsors, and monitors. The [University] Human Subjects Office (HSO) now enforces and verifies the NIH GCP training completion requirement for applicable personnel on NIH-funded clinical trials as a condition of IRB approval. Therefore, any of our trainees who participate in interventional clinical trials will be required to complete this GCP course. In addition, the Good Laboratory Practice (GLP) educational course is made available to the research community, including our trainees, as an option to satisfy annual training requirements.
- Since all research utilizing viral vectors, plasmid vectors, or other infectious agents, transgenic/knock- out animal, transfer of recombinant DNA or synthetic nucleic acid molecules into human participants, genetically modified plants, transactive or infectious proteins, prion protein, and biohazards (i.e. human tissue & fluid) are required by the Office of Research Compliance to undergo Institutional Biosafety Committee review, trainees working in such laboratories are required to take an online biosafety training.

- The Research Integrity Office at [redacted] was created in XXXX to provide the university with robust resources devoted to not only research misconduct case adjudication, but also the proactive education and prevention of research misconduct. This office oversees both the Responsible Conduct of Research educational opportunities as well as the information and presentation of materials regarding research misconduct at [University]. The educational series they offer is composed of, but not limited to, the following topics: Mentorship, Collaborative Science, Authorship, Publications, Research Misconduct, Intellectual Property, Data Management, and Peer Review. Ongoing educational opportunities are available throughout the year on the [redacted] campus and trainees are encouraged to attend these sessions.
- Trainees who perform experiments in laboratory animals will be required to take the Working with the [redacted] CITI educational course and the Occupational Health and Safety for Training Personnel Working with Research Animals course.