

UNIVERSITY OF SOUTH ALABAMA

Guidelines for Instruction in the Responsible Conduct of Research: NIH Institutional Training Grants, Fellowship Awards, Career Development Awards, Research Education Grants, Dissertation Research Grants and National Research Service Award Applications

Investigators and trainees of specific NIH grant awards must receive instruction in the responsible conduct of research (RCR). Designated NIH training grant applications must include a description of the plan to provide trainees with formal and informal instruction on scientific integrity and ethical principles in research. Plans for RCR instruction must address the subject matter, format, degree of faculty participation, trainee attendance, and the frequency of instruction. Frequency of Instruction are described in detail in the NIH policy announcement (see link below) and should be reviewed in detail when preparing proposals for which they are applicable. The plans should be developed to meet the specific needs of the trainees. The NIH revised policy on RCR Instruction is available at (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>)

As training programs at USA are exceedingly diverse, it is not feasible to develop a single, institution-wide curriculum that meets the needs of each and every program. Furthermore, because RCR is most effective in the scope of our daily activities, each training grant application should include a plan that has been tailored to meet the specific needs of the trainees in that program.

An array of institutional resources is available to the Principal Investigators and Program Directors to assist with training efforts. These resources are described in the boilerplate language below. Principal Investigators and Program Directors should incorporate the information in their applications as necessary.

RCR Boilerplate for NIH Training Grant, Career, or NSRA Applications

For the convenience of applicants, we provide prototype language that can be used to address NIH proposal requirements to explain specifically how RCR education will be provided during your training period:

Plan for Instruction in the Responsible Conduct of Research:

- The Responsible Conduct of Research is part of the educational and outreach activities supported and planned by the Office of Research Compliance and the Office of the Vice President for Research. Campus-wide RCR instructional programs are offered to the university community to increase knowledge and promote best practices in the conduct of research. Programs are announced via mass email and distributed by the Office of Research Compliance and Assurance. Online registration is required for purposes of sending reminder notices and tracking participant attendance. These seminars are especially useful for postdoctoral research trainees and junior faculty members with NIH or other research awards who seek training in RCR instruction and ethical research practice. Likewise, this program meets the mandatory requirements for trainees under NIH training grants (NIH T, K & F). Signed rosters are maintained by the Office of Research Compliance and Assurance to document attendance. Attendees are provided a certificate of attendance documenting participation, contact hours, and subject covered. Topics include the traditional nine RCR topics as defined by the HHS Office of Research Integrity in addition to areas involving bioethics and fiscal management and stewardship.
- Educational activities of individual departments and training programs in the responsible conduct of research are supplemented by campus-wide lectures offered to faculty, staff and students throughout each calendar year. Programs, which are offered quarterly, include speakers from USA as well as visitors from other institutions. Each participatory session is one and a half hours and is facilitated by people knowledgeable in the field, including research faculty, research administrators and outside experts. Sessions will accommodate up to 30-40 people and seating divided into tables to facilitate small group case study discussions. In many instances, each group will be presented with a different case study for review and

discussion. This program format combines didactic and small group discussions providing opportunities for participants to engage in communicating important issues relating to research responsibilities.

- All students and postdoctoral fellows involved in the aforementioned NIH program are required to complete training in research compliance issues. The method of delivery for RCR training is determined by education level and involves various alternatives including on-line tutorials and face-to-face sessions. This tiered approach provides flexibility for colleges/departments to develop research ethics training as it applies to professional codes of conduct. The duration of RCR instruction for short-term trainees (six months or less) should be appropriate for the total duration of the program and justified in the application. For these reasons, short-term trainees must receive online instruction by completion of the Collaborative Institutional Training Initiative (CITI) RCR modules, which are available in the following four discipline specific research areas: biomedical, physical science, social and behavioral, and humanities.

Supplemental instruction may also be provided dependent on program requirements.

As applicable to the project/program:

- Training with respect to biosafety and blood borne pathogens is completed if handling biological hazards.

- Training in use of animals is required for any student (predoctoral or short-term) planning on utilizing animals in their research. Trainees complete the on-line tutorial on "Working with the IACUC". Additional species-specific training is required prior to use of animals in the laboratory. The Department of Comparative Medicine also offers 'one-on-one' training sessions with DCM veterinary staff or supervisors, handout materials, and specialized training seminars throughout the year. Trainees will be encouraged to take advantage of these additional seminars when they are pertinent to their work.

- Training in the protection of human subjects is required to be completed using the on-line tutorial on "Human Participants Protection Education for Research Teams" developed by NIH.

Specific to College of Medicine applicants:

- For *predoctoral* students, responsible conduct of research and regulatory compliance are initially addressed through the Introduction to Research Methods course (IDL 577) in the Basic Medical sciences PhD core curriculum.

- Predoctoral trainees are required to enroll in the one semester course in "Research Integrity" offered by the Graduate School. This course uses Macrina's text "Scientific Integrity." Through a weekly one hour discussion format, the course covers a variety of issues, including data management and ownership, mentor/trainee relationships, publications and responsible authorship, peer review, collaborative science, human subjects, research involving animals, research misconduct, and conflict of interest and commitment.

- Additional issues related to publication, authorship and copyright are discussed in the graduate course on Effective Scientific Writing (IDL 641).

- Other training opportunities related to Responsible Conduct of Research are not formalized but will appear within special topics courses or workshops.

- Short-term trainees are provided training related to biosafety, occupational health, radiation safety and laboratory/chemical safety during the summer research seminar series. In addition, selected ethical issues and career survival skills issues are addressed during this seminar series.

Documenting Compliance with RCR Education

Progress reports on the type of instruction provided, topics covered, format, and participation must be included in future competing and non-competing application.

External RCR Resources

- AAAS and NAS: [Online Resource on Research Integrity and Scientific Misconduct](#)
- NIH: [NIH Requirement for Instruction in the Responsible Conduct of Research in NRSA Training Grants](#)
- HHS Office of Research Integrity: [Introduction to the Responsible Conduct of Research](#)
- HHS Office of Research Integrity: [RCR Educational Resources](#) webpage
- NIH: [Training in the Responsible Conduct of Research Resources](#) page
- NIH: [Sharing Biomedical Research Resources](#)
- National Postdoctoral Association: [RCR Toolkit](#)
- [On Being A Scientist](#), 3rd edition, 2009