

The University of Alabama
Office for Research Compliance
Responsible Conduct of Research (RCR) Plan

- I. Introduction**
- II. Federal Requirement**
- III. RCR Training Plan**
- IV. Other Resources**

I. Introduction

The University of Alabama strives to achieve excellence while pursuing its mission to advance the intellectual and social condition of the people of the state through quality programs of teaching, research, and service. An integral part of the University's strategic plan is to advance research and scholarship to be consistent with a top-tier university and to promote growth and national prominence in this area. The University of Alabama is committed to create a research climate that promotes faithful adherence to high ethical standards in the conduct of research and scholarship without inhibiting the productivity and creativity of persons involved in research. Responsible Conduct of Research (RCR) is a cornerstone of public trust and critical for advancement to national prominence and excellence in research. To further emphasize this commitment to excellence and the established strategic plan, the University has developed this RCR plan to describe the requirements for training and to provide information related to the fundamental areas of RCR.

II. Federal Requirements

National Science Foundation (NSF)

The America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act impacts the National Science Foundation in several ways. Effective January 4, 2010, NSF's implementation of section 7009 of this Act will also impact Universities. The language specified below provides NSF's implementation of section 7009. (see Federal Register notice at <http://edocket.access.gpo.gov/2009/E9-19930.htm>)

Institutional responsibilities:

a. An institution must have a plan in place to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research. As noted in GPG Chapter II.C.1e, institutional certification to this effect is required for each proposal.

b. While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review, upon request.

c. An institution must designate one or more persons to oversee compliance with the RCR training requirement.

d. Institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received training in the responsible and ethical conduct of research.

NSF has updated its Proposal and Award Policies and Procedures Guide (PAPP, http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/aag_4.jsp) to incorporate changes as required by the America COMPETES Act which allows each institution to develop and implement a responsible conduct of research plan that best meets the institution's need.

National Institutes of Health (NIH) Policy

Effective January 25, 2010, the revised NIH policy requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. This includes all new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2011. This Notice applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, TU2, and U2R. The NIH revised policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant funding opportunity announcements. (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html>)

New Institutional applications must include a plan for instruction in RCR, addressing the five instructional components outlined in the NIH policy and describing how participation in instruction in RCR will be monitored. Renewal Institutional applications must also describe changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction and must name all training faculty who served during the past project period.

New Individual applications must include a section on instruction in RCR, appropriate to the career stage of the applicant, as part of the Research Training Plan or Candidate Information and Career Development Plan. Plans must document prior RCR instruction (including last completion date) during the applicant's current career stage, propose plans for future receipt of instruction or participation in delivery (as appropriate for career stage), describe the role of the mentor in RCR instruction and address the five NIH RCR instructional components. Renewal Individual applications must describe RCR instruction activities undertaken during the past project period and future plans to meet the frequency requirement (fifth instructional component).

In addition, the reporting requirements for continuations should be reviewed to ensure reporting is complete and accurate.

The NIH suggests that the RCR instructional program include the following topics: conflict of interest, responsible authorship, policies for handling misconduct, policies regarding the use of human participants and animal subjects, and data management. The proposed plan must include the five instructional components, 1. Format, 2. Subject matter, 3. Faculty Participation, 4. Duration of Instruction and 5. Frequency of Instruction, are described in detail in the NIH policy announcement (see link above) and should be reviewed in detail when preparing proposals to which they are applicable. **Applications for funding under the identified programs that do not include a plan for RCR instruction are considered incomplete.** Statements within these components that are particularly noteworthy include, **"A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs, or unusual and well-justified circumstances."** and, **"Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years."**

Description of the programs specifically impacted by the NIH RCR training policy revisions include:

D71 - International Training Program Planning Grant

F05 - International Research Fellowships (FIC)

F30 - Individual Predoctoral NRSA for M.D./Ph.D. Fellowships (ADAMHA)

F31 - Predoctoral Individual National Research Service Award

F32 - Postdoctoral Individual National Research Service Award

F33 - National Research Service Awards for Senior Fellows

F34 - MARC (NRSA) Faculty Fellowships

F37 - Medical Informatics Fellowships

F38 - Applied Medical Informatics Fellowships

K01 - Research Scientist Development Award - Research & Training

K02 - Research Scientist Development Award – Research

K05 - Research Scientist Award

K07 - Academic/Teacher Award (ATA)

K08 - Clinical Investigator Award (CIA)

K12 - Physician Scientist Award (Program) (PSA)

K18 - The Career Enhancement Award

K22 - Career Transition Award

K23 - Mentored Patient-Oriented Research Career Development Award

K24 - Midcareer Investigator Award in Patient-Oriented Research

K25 - Mentored Quantitative Research Career Development Award

K26 - Midcareer Investigator Award in Biomedical and Behavioral Research

K30 - Clinical Research Curriculum Award (CRCA)

K99/R00 - Career Transition Award

KL1 - Linked Research Career Development Award

KL2 - Mentored Career Development Award

R00/K99 - Career Transition Award

R25 - Education Projects

R36 - Dissertation Award

R90/T90 - Interdisciplinary Research Training Award

T15 - Continuing Education Training Grants

T32 - Institutional National Research Service Award

T34 - MARC Undergraduate NRSA Institutional Grants

T35 - NRSA Short -Term Research Training

T36 - MARC Ancillary Training Activities (Grant) (NIGMS) <Title Revised>

T37 - Minority International Research Training Grants (FIC)

T90/R90 - Interdisciplinary Research Training Award

TL1 - Linked Training Award

TU2 - Institutional National Research Service Award with Involvement of NIH
Intramural Faculty

U2R - International Training Cooperative Agreement

In addition to the programs identified above, this policy also applies to any other NIH-funded programs supporting career development, research training, or research education that require instruction in responsible conduct of research as stated in the applicable funding opportunity announcements. Investigators should contact the Office for Sponsored Programs (8-5152) for assistance with identifying if the program requires inclusion of a plan for RCR instruction.

Public Health Service (PHS) Policy

In December of 2000, the Public Health Service issued a policy requiring all researchers supported by PHS funding to complete a program of instruction in the responsible conduct of research. Congress has suspended the policy and has asked the PHS to review the format and content of the policy. The Office for Research Integrity (ORI) is currently revising the policy and plans to re-release the policy in the future. The suspended policy required PHS supported researchers to engage in education on the following topics: data management and integrity, mentor/trainee responsibilities, publication practices and responsible authorship, peer review, collaborative science, human subjects, research involving animals, research misconduct, and conflict of interest and commitment. Research institutions nationwide are taking steps to implement RCR educational programs prior to the re-release of the policy. Upon implementation of the revised PHS policy, the Office for Research will assist faculty with addressing concerns and implementing required changes.

III. RCR Training Plan

Beginning January 4, 2010, all NSF proposal submissions will include an institutional assurance that the University has a plan in place to provide appropriate RCR education to all students and post docs who will be supported by NSF, should the award be made.

Upon award notification, students and post docs supported by the NSF awards resulting from proposals submitted on or after January 4, 2010 will be required to complete RCR online training. The University's procedures for notification, tracking and monitoring are intended to ensure required training is completed within three to five months of an individual beginning work on the project.

The University of Alabama has selected the Collaborative Institutional Training Initiative (CITI) online training to meet federal requirements in RCR. The CITI online courses are designed for faculty, staff (e.g. post docs), graduate students, and undergraduate students who have an interest or focus in the research areas targeted by federal support and serve to satisfy federal regulations that require RCR training as a part of grant and contract terms and conditions. The modules contain information about responsible conduct in research, case studies and quizzes related to each of the areas.

The CITI Program requires registration for use of its site. Each new user must register and create an individual username and password to gain access to the site by selecting "New Users Register Here" and selecting **UNIVERSITY OF ALABAMA** in the "Participating Institutions" drop down box. <http://www.citiprogram.org>

Faculty and staff who receive federal funding to conduct research or to supervise student researchers are responsible for ensuring all work is done in compliance with University, Federal and other applicable policies. The Office for Research Compliance (ORC) has been charged with overseeing compliance with RCR training requirements and will assist researchers in identifying and completing appropriate RCR training, instruction, and guidance.

There are nine core areas covered by the CITI training modules that address those recommended by NSF and NIH:

- Acquisition, management, sharing, and ownership of data
- Publication practices and responsible authorship
- Conflict of interest and commitment
- Research misconduct
- Peer review
- Mentor/trainee responsibilities
- Collaborative science
- Human subjects protections
- Animal welfare

PLEASE NOTE: These RCR courses are not substitute training courses for individuals who conduct research utilizing human participants or animals. If you plan to conduct research utilizing human participants or animals you must also complete the required basic training courses in those areas:

Human Subjects

All human subjects research projects must be reviewed by one of UA's Institutional Review Boards (IRB). Information about conducting Human Subject research and training requirements is available on the Office for Research Compliance website.

http://osp.ua.edu/site/irb_training.html

Animal Subjects

All animal research projects must be reviewed by UA's Institutional Animal Care and Use Committee (IACUC). Information about conducting animal research and training requirements is available on the Office for Research Compliance website.

http://osp.ua.edu/site/iacuc_training.html

Discipline Specific Online Courses

There are four discipline specific online RCR courses available as outlined below:

Biomedical Responsible Conduct of Research Course: This course is for investigators, staff and students with an interest or focus in Biomedical research.

Social and Behavioral Responsible Conduct of Research Course: This course is for investigators, staff and students with an interest or focus in Social and Behavioral research.

Physical Science/Engineering Responsible Conduct of Research Course: This course is for investigators, staff and students with an interest or focus in Physical Science or Engineering research.

Humanities Responsible Conduct of Research Course: This course is for investigators, staff and students with an interest or focus in Humanities research.

Individuals are required to complete only the most relevant discipline specific course.

Additional Training Options for NSF Students and Postdocs

NSF sponsored students and post docs will have the opportunity to attend at least one RCR workshop offered by the Office of Research Compliance (ORC). The ORC encourages attendance at one of these workshops within the first two years of the NSF sponsored project from which the individual is supported.

Additional Mandatory Training for NIH Students and Postdocs

NIH sponsored students and post docs will be **required** to attend at least two workshops during the first two years of project participation in order to meet NIH RCR training requirements. Workshops will be offered throughout the academic year beginning fall 2010. RCR training is required at least once during each career stage and at a minimum, of every four years.

Copies of Training Certificates

When a module is completed, a copy of the training certificate may be printed by logging into CITI (www.citiprogram.org), using one's username and password, and clicking the "Print" link under the Completion Reports column in My Courses. Copies of the training certificates should be forwarded to the Office for Research Compliance via campus mail to 152 Rose Administration or via email at rscompliance@fa.ua.edu. ORC will monitor for completion of the required on-line RCR training components and, for NIH funded students and post docs, required live (workshop) training.

IV. Other Resources

Office for Research Integrity Educational Material Clearinghouse

<http://ori.dhhs.gov/education/>

National PostDoctoral Association RCR Toolkit

<http://www.nationalpostdoc.org/publications/rcr/rcr-toolkit/302-nsf-2010-rcr-requirement>

NSF Proposal and Award Policies and Procedures Guide

http://www.nsf.gov/pubs/policydocs/pappguide/nsf10_1/index.jsp