

Southern Illinois University Carbondale

Institutional Plan to Meet Various Sponsoring Agency Responsible Conduct of Research (RCR) Training Requirements

BACKGROUND

The National Science Foundation (NSF) announced in the August 20, 2009, *Federal Register* the implementation of Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science (America COMPETES Act (42 U.S.C. 1862o-1). Effective January 4, 2010, NSF required the proposing institution's Authorized Organizational Representative to certify that the institution has adopted a plan to provide appropriate training and oversight in the responsible and ethical conduct of research (RCR) to undergraduate and graduate students, and post-doctoral researchers who will be supported by NSF to conduct research. The requirement also applies to any sub-award originating from an NSF grant. These requirements exclude conference, symposium, workshop, or travel proposals.

The National Institutes of Health (NIH) issued Notice NOT-OD-10-019 on November 24, 2009 as an update to their policy on instructional requirements in the responsible conduct of research. This policy 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, as well as any other NIH-funded programs supporting research training, career development, or research education that require instruction in the responsible conduct of research as stated in the relevant funding opportunity announcements. Requirements include both formal and informal instructional components, with substantial face-to-face training and active participation of Principal Investigators/mentors.

The USDA National Institute of Food and Agriculture (NIFA) instituted responsible conduct of research training requirements for awards subject to the February 2013 (and subsequent) Research Terms and Conditions. NIFA policy requires that program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in the research project receive appropriate training and oversight in the responsible and ethical conduct of research and that documentation of such training will be maintained.

PURPOSE OF THIS PLAN

This plan was developed in order to meet the various requirements of federal agencies when the University receives funding from those sources, which includes pass-through funds received via another institution. To simplify the application of the training and oversight requirements, and to provide the broadest benefit to our students and post-doctoral researchers, the plan covers all affected personnel participating in any federally-funded project that requires RCR training. The plan has been designed to complement the efforts of individual researchers who provide training and mentoring within their laboratory or research setting.

Because of the disparity between the RCR requirements of various sponsors, there is no one-size-fits-all solution to providing RCR training. This plan recognizes that and so allows the Principal Investigator (PI) to design and deliver RCR training tailored to the specific sponsoring agency's requirements.

GOALS OF THE PROGRAM

This RCR training program will:

- Reinforce the University's commitment to excellence in research
- Introduce trainees to fundamental principles of Responsible Conduct of Research
- Provide an overview of terms, concepts and policies related to RCR
- Develop skills to identify and address ethical dilemmas in research
- Describe campus resources available to support researchers with RCR concerns
- Foster a culture of open discussion of ethical dilemmas in classroom, laboratory and office settings

DEFINITIONS

Affected personnel – principal investigators, program/project directors, faculty, staff, graduate students, undergraduate students or post-doctoral personnel (regardless of institutional title or appointment) participating in projects funded by an applicable project, including students participating in an experiential research program. Early career faculty holding NIH K-awards are also included as affected personnel.

Applicable projects - federally-funded (or via pass-through federal funding) research or training grant that requires RCR training as part of the solicitation, award or funding agency guidelines.

APPLICABILITY

The training and oversight outlined by this plan applies to any principal investigators, program/project directors, faculty, staff, graduate students, undergraduate students or post-doctoral personnel (regardless of institutional title or appointment) participating in research or training projects funded by an applicable project (including via pass-through federal funding) and early career faculty holding NIH K-Awards. These students, staff, post-doctoral personnel and faculty are considered *affected personnel*, which extends to students who are participating in federally-funded experiential research program (e.g., research experiences for undergraduates).

The plan also applies to students, graduate or undergraduate, who participate in a research experience through the Center for Undergraduate Research and Creative Activities who are participating in an applicable project.

This RCR training plan is not intended to supplant the training requirements that might be imposed on a principal investigator by conditions of the solicitation or grant program. PIs should be cognizant of those requirements and can use the RCR training provided by this plan to complement or supplement any training that they are required to provide as a condition of an award.

TRAINING

1. Online CITI Training

SIUC has subscribed to the Collaborative Institutional Training Initiative (CITI) RCR training

program. This training can be accessed at www.citiprogram.org. All affected personnel are required to complete this training within two months after their appointment to an applicable project. Personnel can choose from a number of additional modules based upon their interest.

Personnel should retain a copy of their certificate of completion until they have completed their program of study with the University.

2. Courses

PHRM 540 – Responsible Conduct of Research is offered as a 1 credit hour pass/fail course every other fall (odd years) and is designed to meet the NIH requirements for applicable programs. Affected personnel subject to the NIH policy may enroll in this course in the first semester in which it is offered following their appointment to an applicable project. This training is to be in addition to CITI training.

3. Individual Training by the Principal Investigator

Students and post-docs supported by an applicable project may need to be provided continuing education in RCR topics. These activities can include mentoring or one-on-one and group sessions conducted by the Principal Investigator. The PI should maintain records and include these activities in progress reports to the funding agency. PIs should note that NIH-funded projects require this level of activity and that any federal agency can request documentation of RCR training of research personnel at any time. Resources for training materials and recordkeeping are available on the OSPA website.

4. Principal Investigator Training

In addition to NIFA project specific RCR requirements for faculty and staff, all PIs are strongly encouraged to complete the CITI RCR training in order to provide quality mentorship in RCR.

NOTE: 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, as well as any other institutionally-required compliance training (e.g., biosafety, radiological safety, hazardous chemicals, etc)..

FREQUENCY OF TRAINING

Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. Senior fellows and career award recipients may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the requirements, instruction in responsible conduct of research is not grant-dependent. That is, the RCR training may take place, in appropriate circumstances, in a year when the student, trainee, fellow or career award recipient is not actually supported by a grant.

Affected personnel are cautioned that it is their responsibility to maintain the necessary documentation of training. PIs, in particular, are responsible for maintaining records of RCR training completed by affected personnel on applicable projects on which they are the lead PI. See also the section on Oversight.

OVERSIGHT

1. PI Responsibilities

The PI is responsible for ensuring that the appropriate training is completed and documented for all affected personnel on his/her applicable research project. The PI must inform affected personnel of the RCR training requirement at the time of their appointment, the allotted time for completion, and consequences for not meeting the requirement. The PI is also expected to maintain documentation of all training pertaining to RCR for up to three years after the grant funding the applicable program terminates.

2. Affected Personnel Responsibilities

Affected personnel must be able to produce documentation of their CITI training and participation in all required RCR training provided by the University.

3. Office of Sponsored Projects Administration (OSPA)

OSPA will provide each PI at the time of the award announcement a copy of this plan, a link to RCR resources and a contact to answer any questions pertaining to RCR training requirements. Auditing of affected personnel listed on Human Resources-generated federal grant reports will be conducted by the OSPA staff on at least a semi-annual basis. In cases where it is determined that the project is non-compliant, the OSPA Director will immediately notify the principal investigator. Institutional notifications will consist of:

First Notice - to principal investigator about the RCR requirement.

Second Notice - to principal investigator to correct the deficiency.

Third Notice - to chair, dean and fiscal officer about ramifications of non-compliance.

Fourth Notice - to the Vice Chancellor for Research detailing non-compliance.

Sub-awards to other institutions are subject to the same requirements as the prime recipient. OSPA staff responsible for sub-awards to other institutions will ensure that the terms and conditions of the agreement include certification from the sub-award authorized official that RCR training conditions will be met.

TRAINING TAKEN AT OTHER INSTITUTIONS

Affected personnel who can provide proof of RCR training taken at other institutions may provide that evidence for evaluation by the OSPA Director. The OSPA Director will make a determination if the previous training is acceptable in lieu of, or in addition to, some or all of the required training detailed in this plan. In no case will training taken more than four years prior to the affected personnel's appointment to a research project be accepted. The requirements for frequency of training, as described above, will still apply.