Responsible Conduct of Research Training and Education Plan

RESEARCH COMPLIANCE SERVICES

Scope: The purpose of this institutional plan is to ensure appropriate training and oversight in the responsible and ethical conduct of research among members of the University of Oregon (UO) community engaged in research. This plan encompasses the National Institute of Health (NIH) and National Science Foundation (NSF) Responsible Conduct of Research (RCR) training requirements.

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I. Introduction

Ethical and responsible conduct of research is critical for excellence, as well as public trust, in science. The UO is committed to supporting its research community in upholding the highest ethical and professional standards in carrying out its work, and imparting these standards to future generations of scientists and researchers through education and training.

Research Compliance Services (RCS) is the support office at the University of Oregon designated to oversee compliance with RCR training requirements at the UO. RCS will provide a copy of this plan to research sponsors upon request.

II. Who Must Receive Training

Principal Investigators (PIs), UO students, faculty, and staff must identify and comply with funding agency requirements related to RCR. Funding requirements vary; researchers must check with the funder/sponsor for specific requirements. RCR training is strongly recommended for all members of the UO community engaged in research.

NIH and NSF have defined who must complete RCR training when receiving NIH and NSF awards:

NIH

Required for all trainees, fellows, participants, and scholars receiving support through any NIH institutional research training grant, career development award, fellowship award, research education grant, and dissertation research grant; or as otherwise stated in the relevant funding opportunity announcements.

NSF

Required for all undergraduate, graduate students, fellows, and post-doctoral researchers who will be supported by NSF awards (support includes salary or stipend). The RCR requirement flows down to all sub-awardees, including international organizations. Undergraduates, graduates, and postdoctoral researchers

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supported on the award to conduct research must be trained in the responsible conduct of research.

III. Researcher Responsibilities

All researchers are expected to engage in a responsible conduct of research training as an essential component of promoting research excellence.

Principal Investigators (PIs) are responsible for:

- Identifying those individuals working on their sponsored projects who must receive RCR training,
- Determining the most appropriate format, content and instruction for RCR training in line with sponsor requirements,
- Determining if a funder has requirements for RCR and developing a RCR plan that meets those specific requirements,
- Reporting as required under the terms of the specific funding program,
- Submitting a RCR training plan prior to the expenditure of any sponsored research funds, and
- Maintaining sufficient records to demonstrate that all applicable personnel have received the required RCR instruction.

IV. Elements of Researcher RCR Plans

Researchers must describe both content and format of their RCR plans. The plan must describe how participation in instruction in RCR will be monitored. All RCR plans must specify the time line for individuals' completion of RCR training. Researchers are encouraged to contact RCS in the development of RCR plans.

A. General Training Plan Content Guidance

Most acceptable plans include the following subject matter for instruction:

- conflict of interest personal, professional, and financial
- policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- mentor/mentee responsibilities and relationships
- collaborative research including collaborations with industry
- peer review
- data acquisition and laboratory tools; management, sharing and ownership
- research misconduct and policies for handling misconduct
- responsible authorship and publication
- the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

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B. NIH Training Plan Content

For NIH, the RCR plan must incorporate the following five specific instructional components:

- **Subject Matter** the curriculum of most acceptable plans includes the subject matter listed in Part A above.
- **Duration** the duration of instruction is recommended to be at least eight contact hours over a period of time.
- **Frequency** instruction should be appropriate to the career stage of the individuals receiving training and must be undertaken at least once during each career stage, and at a frequency of no less than once every four years.
- **Faculty Participation** faculty are highly encouraged to participate in and contribute to formal and informal instruction in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.
- **Format** significant face-to-face interaction and discussion is expected to occur among trainees, fellows, scholars, and/or participants. Online instruction alone is not sufficient to satisfy the training requirement; however, for participants supported by short-term programs lasting six or fewer months, online instruction may be acceptable.

V. Options for Completing Training Requirements

Researchers may choose from the following courses and training offerings to help satisfy RCR requirements:

- Qualifying courses offered at the UO (see below for how to obtain qualification)
- The Collaborative Institutional Training Initiative (CITI) online program
- Training developed by Research Compliance Services (RCS)
- Training developed by the Principal Investigator (PI) or other RCR experts

VI. How to Obtain Course Qualification

RCS will approve courses that qualify as satisfying appropriate RCR content. Faculty or staff may apply to RCS to have existing or newly proposed courses, workshops, or other programs approved as qualifying RCR courses. The criteria and process for obtaining this approval is explained below.

- Initiate course qualification with RCS by providing a request letter and the class syllabus or the workshop/program description.
- RCS will review and approve courses, workshops, and other programs that satisfy RCR requirements. RCS will maintain a record of qualifying courses.
- Significant changes to the course syllabus or description should be communicated to RCS.
- Re-qualification is required every four years.

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VII. UO RCR Monitoring, Tracking, and Reporting

Verification of RCR training includes completion certification through online training (CITI) or individual course completion records.

Documentation of required RCR training completion may occur through the following:

- RCR course attendance, monitoring, and course completion tracking by individual instructors and/or PI
- Online RCR training modules and course completion records available through CITI

PIs are responsible for providing Research Compliance Services documentation that the RCR requirements have been satisfied upon request. Researchers are responsible for adhering to the funder/sponsor RCR monitoring, tracking, and reporting requirements in addition to complying with UO requirements.