Guidance for Developing a Responsible Conduct of Research Instruction Plan for National Institutes of Health Funding Applications

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The National Institutes of Health (NIH) 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 receive instruction in the responsible conduct of research (RCR). This guide is intended to assist Principal Investigators (PIs) at the University of Oregon in developing RCR instruction plans in compliance with NIH requirements. Individual PIs are responsible for developing RCR instruction plans as part of funding applications and for implementing and reporting on those plans to NIH if funding is awarded.

Where in the application do I address the RCR requirements?

Different funding categories may have different requirements regarding the placement of the RCR instruction plan within the application materials and page limits for the RCR instruction plan. Please read the guidelines and instructions for the relevant funding opportunity announcement for specific requirements and procedures.

What information about RCR instruction should be included on the grant application?

Requirements may vary between funding categories. Please refer to the guidelines and instructions for the relevant funding opportunity announcement for specific requirements and procedures. In general, ***all Institutional and Individual new (Type 1) applications and renewal (Type 2) applications*** must include a plan for RCR instruction that addresses five instructional components. Additional requirements for particular funding categories are listed following the guidance below on the instructional components.

Instructional Components

For each form of training, provide a description of the following five instructional components:

- **Format:** Describe the format of the training (e.g. for-credit course, seminar series, workshop, small-group discussions, etc.).
    - o Training should include substantial face-to-face discussions.
    - o Online instruction is not considered adequate as the sole means of instruction expect in special cases of short-term training programs.
    - o For individual award applications, the plan may include individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research.

- **Subject matter:** Describe the topics that will be covered in the instruction.
    - o There are no specific curricular requirements, but acceptable plans for RCR instruction generally cover the following topics: conflict of interest; research involving human subjects; live vertebrate animal subjects in research; mentor/mentee responsibilities and relationships; collaborative research including collaborations with industry; peer review; data acquisition, management, sharing and ownership; research misconduct; responsible authorship and publication; and, the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research.

- **Faculty Participation:** Describe how participating faculty and sponsors/mentors will contribute to both formal and informal RCR instruction (e.g. as discussion leaders, speakers, course directors, informally though laboratory interactions, etc.).
    - For individual award applications, the role of the sponsor/mentor in RCR instruction must be described.

- **Duration:** Describe the duration of the training. This could include both the number of hours of class time and the total duration of the instruction (e.g. one-day workshop, semester-long course, year-long seminar series, etc.)
    - Acceptable training programs generally involve at least eight contact hours.
    - A semester-long program may be more effective than a one-day training program.

- **Frequency:** Discuss the frequency with which instruction will be undertaken, appropriate to the career stage of the individual(s) involved (undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels).
    - Instruction must be undertaken once during each career stage, and no less than once every four years.
    - Instruction should be appropriate to the career stage of the applicant (instruction for applicants in the early stages of their careers; participation as course directors, lecturers, or discussion leaders for applicants in middle or senior stages of their careers).
    - Instruction may take place in a year in which the individual is not actually supported by an NIH grant, as long as the instruction is documented.

Additional Requirements Based on Funding Category

Institutional new (Type 1) applications must also describe how participation in and successful completion of RCR instruction will be monitored and recorded, e.g. course attendance records, certificate of participation upon course completion, etc.

Institutional renewal (Type 2) applications must also:
- describe changes in formal instruction over the past project period and future plans that address any weaknesses in the current instruction in responsible conduct of research, and
- list all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period.

Individual new (Type 1) applications must also:
- document prior participation or instruction in RCR during the applicant's current career stage, including the date instruction was last completed, and
- describe the role of the sponsor/mentor in instruction in RCR.

Individual renewal (Type 2) applications must also describe instruction in RCR activities undertaken during the past project period.

What forms of training can I include in the plan?

A variety of formal and informal training mechanisms can be used to meet RCR requirements:

- Your department/college/school may offer a course that incorporates RCR content.
- Seminars, workshops, and discussion groups on RCR topics can be included in the training plan.
- Online RCR training may comprise part of your RCR instruction plan, but should not be used as the sole means of instruction except in cases of short-term training and research education programs.

- The University, through the [Collaborative Institutional Training Initiative (CITI)](#), offers on-line RCR training at no cost to the individual. This training takes approximately 4.5 hours to compete and includes the core topics of RCR: research misconduct; data management, sharing and ownership; conflicts of interest; collaborative research; human subjects; animal welfare; mentor/trainee relationships; peer review; and responsible authorship and publication practices. The training is available in four disciplinary areas: Biomedical Science, Physical Science, Social and Behavioral Science, and Humanities.
  - There are many other online RCR courses available, including courses developed by [Columbia University](#), [CMDITR](#), and the [University of New Hampshire](#).
- For individual awards, the plan may include individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their research activities and the societal impact of that research.
- Informal instruction can occur in the course of laboratory interactions and in other informal situations throughout the year.

Research Compliance Services can assist you in developing RCR programming or accessing RCR resources. For more information, please contact Sherry Lealess, Compliance Coordinator, at 541-346-0889 or slealess@uoregon.edu.

What information do I include in progress reports (Type 5 continuation applications)?

For Institutional Training, Education, and Institutional Career Development Awards: describe the nature of the instruction in RCR and the extent of trainee and faculty participation, including a description of any enhancements and/or modifications to the five instructional components from the plan described in the awarded application. Specific training faculty members who were contributors to formal instruction in RCR during the last budget period must be named.

For Individual Fellowships: provide a report specifically on instruction for the fellow in RCR, including subject matter covered, format, frequency and duration of instruction, or indicate when during a previous or future budget period instruction in RCR did or will take place. The report should discuss both formal and/or informal instruction in RCR and should note the extent to which the sponsor or senior fellow participated in these activities.

For Individual Career Development Awards: describe instruction in RCR, or participation as a course director, etc. in the case of senior career awardees, in both formal and informal instruction in RCR in the past budget period, if applicable. If RCR activities occurred in a prior budget period, the PI should note the date of occurrence. Any activities undertaken to individualize instruction appropriate to the career stage of the PI should be discussed.

For Dissertation Awards (R36): report on instruction in RCR under a separate heading. This section should describe participation in both formal and informal instruction in RCR in the past budget period, where applicable. If instruction occurred in a prior budget period, the report should note the date when formal instruction was last completed. Any activities undertaken to individualize instruction appropriate to the career stage of the individual should be discussed. The report will describe how the mentor participated in these activities.