RESPONSIBLE CONDUCT OF RESEARCH

CITATION


REQUIREMENTS

NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, or dissertation research grant must receive instruction in the responsible conduct of research (RCR).

RCR is defined as the practice of scientific investigation with integrity. It involves awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

APPLICABILITY

This requirement applies to the following programs: D43, D71, F05, F30, F31, F32, F33, F34, 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.

This policy takes effect with 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.

BASIC PRINCIPLES

The following principles are based on several key concepts about RCR and best practices that have evolved over the past two decades' experiences:

1. RCR is an essential component of research training. Therefore, instruction in RCR is an integral part of all research training programs, and its evaluation will impact funding decisions. The goal of RCR training is for scientists to develop a scholarly understanding of the ethical and societal impact of their research.

2. Active involvement in the issues of RCR should occur throughout a scientist's career. Instruction in RCR should therefore be appropriate to the career stage of the individuals receiving training.

3. Individuals supported by individual funding opportunities such as fellowships and career development awards are encouraged to assume individual and personal responsibility for their instruction in RCR.

4. Research faculty of the institution should participate in instruction in RCR in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.
5. Instruction should include face-to-face discussions between course participants and faculty; i.e. online instruction may be a component of instruction in RCR, but this is not sufficient to meet the NIH requirement for such instruction except in special or unusual circumstances. Such circumstances may include short-term (e.g. summer) training.

6. Instruction in RCR must be carefully evaluated in all NIH grant applications for which it is a required component.

### PLAN FOR RCR INSTRUCTION

#### Institutional Applications

New (Type 1) applications must include a plan for instruction in responsible conduct of research. In addition to addressing the five instructional components, the plan must describe how participation in RCR instruction will be monitored.

Renewal (Type 2) applications must, in addition, describe changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current instruction in RCR. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application.

#### Individual Applications

New (Type 1) applications must include a section on instruction in RCR which is 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) as part of the Research Training Plan or Candidate Information and Career Development Plan. This section will document prior participation or instruction in RCR during the applicant’s current career stage (including the date on which instruction was last completed) and propose plans to either receive instruction in RCR or participate as a course lecturer, etc. depending on the applicant’s career stage. Such plans must address the five instructional components outlined above. The plan may include career stage-appropriate, 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. The role of the sponsor/mentor in instruction in RCR must be described.

Where applicable, renewal (Type 2) applications must describe instruction in RCR activities that were undertaken during the past project period as well as future plans in order to meet the frequency requirement, as outlined below in Instructional Components.

### EVALUATION GUIDANCE

Reviewers will evaluate plans for instruction in RCR as well as the past record of instruction in RCR, as applicable.
Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration, and Frequency) listed below, taking into account the characteristics of institutional programs or the unique circumstances outlined for short-term training programs, individual fellowships, career awards, and research education programs. The review will be guided ultimately by the basic principles listed above.

The plan for instruction in RCR and the past record of instruction in RCR, as applicable, will be discussed after the overall determination of merit of the application at large; the review panel’s evaluation of the plan will not be a factor in the determination of the Impact/Priority score. Plans and the past record will be rated as “Acceptable” or “Unacceptable.”

The results of the review of the plan for instruction in RCR and the past record of instruction in RCR, as applicable, will be reported as an administrative note in the summary statement and explain how the review panel determined its rating.

Regardless of the Impact/ Priority score, applications with unacceptable plans will not be funded until the applicant provides an acceptable revised plan.

INSTRUCTIONAL COMPONENTS

NIH recognizes that instruction in RCR occurs formally and informally in educational settings and that informal instruction occurs throughout the research training experience. The guidance provided below is directed at formal instruction in RCR. It reflects the accumulated experiences and the best practices of the scientific community over the past two decades. These practices have been incorporated into many of the best-regarded programs of instruction in RCR.

1. Format

Substantial face-to-face discussions among the participating trainees/fellows/scholars/ participants, a combination of didactic and small-group discussions (e.g. case studies), and the participation of research training faculty members in instruction in RCR are highly encouraged.

While online courses can be a valuable supplement to instruction in RCR, online instruction is not considered adequate as the sole means of instruction. A plan that employs only online coursework for instruction in RCR will not be considered acceptable except in special instances of short-term training programs (see below) or unusual and well-justified circumstances.

2. Subject Matter

While there are no specific curricular requirements for instruction in RCR, the following topics have been incorporated into most acceptable plans for such instruction:

1. Conflict of interest: personal, professional, and financial

2. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
3. Mentor/mentee responsibilities and relationships
4. Collaborative research, including collaborations with industry
5. Peer review
6. Data acquisition and laboratory tools, management, sharing, and ownership
7. Research misconduct and policies for handling misconduct
8. Responsible authorship and publication
9. The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in RCR, they generally are not sufficient to cover all of the above topics. Additional detail regarding subject matter is available under the Resources section below.

3. Faculty Participation

Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in RCR. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in RCR as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal RCR courses over a period of time.

4. Duration of Instruction

Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty. Acceptable programs generally involve at least eight contact hours. A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop, because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.

5. Frequency of Instruction

Reflection on RCR should recur throughout a scientist’s career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in RCR for the particular career stage(s) of the individual(s) involved. Instruction must be undertaken at least once during each career stage and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in RCR at least
once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in RCR by participating as lecturers and discussion leaders. To meet the above requirements, instruction in RCR may take place, in appropriate circumstances, in a year when the trainee, fellow, or career award recipient is not actually supported by an NIH grant. The intent of RCR policy is that training occurs every four years and at each career phase. Thus, an individual proposing a five-year award or an award in which a promotion to another career phase (such as a fellow’s promotion to assistant professor) should repeat training.

**SPECIAL CONSIDERATIONS BY TYPE OF AWARD**

*Institutional training and institutional career development programs (for example, T15, T32, T34, T90/R90, TL1, K12, or K30 programs):* Institutional programs are encouraged to provide instruction in RCR for all individuals associated with the program of training, regardless of their source of support.

*Short-term training and research education programs (for example, T35 and R25 programs lasting six or fewer months, short-term trainees supported on T15, T32, and T34 programs, and short-term participants in R25 programs):* The NIH recognizes that the duration of an institutional training or research education program should be considered in the design, implementation, and review of plans for instruction in RCR. The duration of such instruction within short-term institutional programs should be appropriate for the total duration of the program and justified in the application. This is an instance in which online instruction could be appropriate. Such programs may also use innovative strategies to incorporate instruction in RCR and to relate instruction in RCR to the scientific focus of the short-term program.

*Individual awards:* In keeping with the individual nature of these programs, fellows and scholars, along with their institutions and sponsors/mentors, are encouraged to tailor instruction in RCR to the needs of the individual. Thus, instruction may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. An individualized plan would also be appropriate in the rare instance in which an institution does not have an established formal mechanism for such instruction.

**RESOURCES**

The NIH Research Training website ([http://grants.nih.gov/training/extramural.htm](http://grants.nih.gov/training/extramural.htm)) includes additional information on instruction in RCR and links to the Office of Research Integrity ([http://ori.hhs.gov/](http://ori.hhs.gov/)), links to instructional materials, and examples of programs that have been regarded as good models for instruction in RCR ([http://bioethics.od.nih.gov/researchethics.html](http://bioethics.od.nih.gov/researchethics.html)).