

Update on the Requirement for Instruction in the Responsible Conduct of Research

Notice Number: NOT-OD-10-019

Update: The following update relating to this announcement has been issued:

- [April 19, 2011](#) - See Notice NOT-RR-11-005 This Notice updates the requirement for Training in the Responsible Conduct of Research (RCR) with respect to NCRR Science Education Partnership Award (SEPA) (R25) applications.

Key Dates

Release Date: November 24, 2009

Issued by

National Institutes of Health (NIH), (<http://www.nih.gov>)

Purpose

The purpose of this Notice is to update NIH policy on instruction in the responsible conduct of research, convey some of the consensus best practices that have evolved in the research training community over the past two decades, and to provide access to additional information that may be useful to institutions and individuals in meeting their obligations under NIH policy. Specifically this Notice: 1) develops principles based on 20 years' experience of providing instruction in responsible conduct of research by the scientific research community; 2) is more specific about who should participate, how often instruction should occur, and the form that instruction should take; 3) addresses issues that have arisen as the practice of biomedical, behavioral and clinical science has evolved; and 4) provides guidance to applicants, peer reviewers and NIH staff in determining how well specific plans for instruction in responsible conduct of research compare with the best practices accumulated over the past two decades by the research training community.

Applicability

This Notice applies to all NIH Institutional Research Training Grants, Individual Fellowship Awards, Career Development Awards (Institutional and Individual), Research Education Grants, Dissertation Research Grants, or other grant programs with a training component that requires instruction in responsible conduct of research as noted in the Funding Opportunity Announcement.

Background

In 1989, the NIH published its first Notice of policy concerning instruction in responsible conduct of research in the NIH Guide ([Volume 18: Number 45, December 22](#)). This Notice required that institutional training grant applications include a description of activities related to instruction about responsible conduct of research. A subsequent Notice ([NOT-OD-94-200 NIH Guide Volume 23, Number 23, June 17](#)), published in 1994, updated all previous Notices and required that applications for institutional research training grants lacking a plan for instruction in responsible conduct of research be returned without review, established review procedures, and established the minimum requirements for an acceptable plan. Similar requirements were subsequently adopted for instruction via research education grants, individual fellowships, and career awards as funding opportunity announcements for these programs were published.

In the ensuing years, there have been a number of developments related to instruction in responsible conduct of research. The scientific community has responded by developing innovative courses, workshops, research projects on instruction in responsible conduct of research, and instructional materials. Congress has enacted laws establishing the [Office of Research Integrity](#) to promote integrity in biomedical and behavioral research supported by the U.S. Public Health Service. The NIH Institutes and Centers (ICs), NIH peer review committees, and the scientific communities participating in NIH research have all evolved standards for what constitutes responsible conduct of research and an acceptable plan for instruction in this area. Legislation in this area initially focused on activities that fall under the formal definition of Research Misconduct. Federal Regulations define Research Misconduct as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results (http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf). It does not include honest error or honest differences in interpretations or judgments of data. However, it is well appreciated by all that responsible conduct, as opposed to misconduct, encompasses many other aspects of ethical behavior in the practice of scientific research.

The practice of biomedical research continues to evolve in terms of the interaction of participants (team research) and participating disciplines, emerging technologies in both the laboratory and in the publishing arena, and in the interactions of academic, medical, and for-profit enterprises. Acknowledging these changes, and drawing on the experiences of the past two decades, this Notice clarifies and updates NIH policy on instruction in responsible conduct of research.

Definition

For the purpose of this Notice, responsible conduct of research is defined as the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

Basic Principles

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

1. Responsible conduct of research is an essential component of research training. Therefore, instruction in responsible conduct of research is an integral part of all research training programs, and its evaluation will impact funding decisions.
2. Active involvement in the issues of responsible conduct of research should occur throughout a scientist's career. Instruction in responsible conduct of research 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 responsible conduct of research.
4. Research faculty of the institution should participate in instruction in responsible conduct of research 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 by course participants and faculty; i.e., on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.
6. Instruction in responsible conduct of research must be carefully evaluated in all NIH grant applications for which it is a required component.

Policy

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 must receive instruction in responsible conduct of research. This policy will take 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. 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. This 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.

Instructional Components

NIH recognizes that instruction in responsible conduct of research 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 responsible conduct of research. 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 responsible conduct of research.

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 participation of research training faculty members in instruction in responsible conduct of research are highly encouraged. While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction. 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 (see below), or unusual and well-justified circumstances.

2. Subject Matter: While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
 - a. conflict of interest – personal, professional, and financial
 - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - c. mentor/mentee responsibilities and relationships
 - d. collaborative research including collaborations with industry
 - e. peer review
 - f. data acquisition and laboratory tools; management, sharing and ownership
 - g. research misconduct and policies for handling misconduct
 - h. responsible authorship and publication
 - i. 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 responsible conduct of research, they generally are not sufficient to cover all of the above topics. Additional detail regarding subject matter is available under Resources.

3. Faculty Participation: Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. 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 responsible conduct of research 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 responsible conduct of research 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 responsible conduct of research 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 responsible conduct of research 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 responsible conduct of research 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 responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research 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. This instruction can be documented as described below.

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 responsible conduct of research 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 responsible conduct of research. The duration of such instruction within short-term institutional programs should be appropriate for the total duration of the program and should be justified in the application. This is an instance where on-line instruction could be appropriate. Such

programs may also use innovative strategies to incorporate instruction in responsible conduct of research and to relate instruction in responsible conduct of research 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 responsible conduct of research 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 where an institution does not have an established formal mechanism for such instruction.

Application Procedures

1. Institutional Applications

- a. 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 instruction in responsible conduct of research will be monitored.
- b. 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 responsible conduct of research. 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

2. Individual Applications

- a. New (Type 1) applications must include a section on instruction in responsible conduct of research, 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 responsible conduct of research during the applicant's current career stage (including the date instruction was last completed) and propose plans to either receive instruction in responsible conduct of research 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 responsible conduct of research must be described.
- b. Where applicable, renewal (Type 2) applications must describe instruction in responsible conduct of research activities undertaken during the past project period as well as future plans in order to meet the frequency requirement as outlined above in Instructional Components.

Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process or not reviewed.

Peer Review

Reviewers will evaluate plans for instruction in responsible conduct of research as well as the past record of instruction in responsible conduct of research, where applicable. Reviewers will specifically address the five Instructional Components (Format, Subject Matter, Faculty Participation, Duration and Frequency) 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 principles set forth at the beginning of this Notice.

The plan for instruction in responsible conduct of research and the past record of instruction in responsible conduct of research, where 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 past record will be rated as ACCEPTABLE or UNACCEPTABLE. The results of the review of the plan for instruction in responsible conduct of research and the past record of instruction in responsible conduct of research, where applicable, will be reported as an administrative note in the summary statement and will 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. Institute or Center staff will apply the principles set forth at the beginning of this Notice to determine the acceptability of the revised plan.

Reporting Requirements

For Institutional Training, Education, and Institutional Career Development Awards:

Continuation (Type 5) applications must describe the nature of the instruction in responsible conduct of research and the extent of trainee and faculty participation as required in the PHS 2590. This report must include 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 responsible conduct of research during the last budget period must be named.

For Individual Fellowships:

Continuation (Type 5) applications must report specifically on instruction for the fellow in responsible conduct of research. This report must include subject matter covered, format, frequency and duration of instruction, or indicate when during a previous or future budget period instruction in responsible conduct of research did or will take place. The report should discuss both formal and/or informal instruction in responsible conduct of research and should note the extent to which the sponsor or senior fellow participated in these activities.

For Individual Career Development Awards:

Continuation (Type 5) applications must include a description of instruction in responsible conduct of research as required in the PHS 2590. This report should describe instruction, or participation as a course director, etc. in the case of senior career awardees, in both formal and informal instruction in responsible conduct of research in the past budget period, if applicable. If instruction, or participation as a course director, etc., 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):

Continuation (Type 5) applications must report on instruction in responsible conduct of research under a separate heading. This section should describe participation in both formal and informal instruction in responsible conduct of research in the past budget period, where applicable. If instruction occurred in a prior budget period, the PI should note the date when formal instruction was last completed. Any activities undertaken to individualize instruction appropriate to the career stage of the PI should be discussed. The report will describe how the mentor participated in these activities.

Compliance

NIH policy requires participation in and successful completion of instruction in responsible conduct of research by individuals supported by any NIH training/research education/fellowship/career award. It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion. NIH does not require certification of compliance or submission of documentation, but expects institutions to maintain records sufficient to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

Resources

The NIH Research Training website (<http://grants.nih.gov/training/extramural.htm>) includes additional information on instruction in responsible conduct of research and links to the Office of Research Integrity (<http://ori.hhs.gov/>), links to instructional materials, and examples of programs that have been regarded as good models for instruction in responsible conduct of research (<http://bioethics.od.nih.gov/researchethics.html>). The National Academy Press has just published the 3rd. edition of the classic, *On Being a Scientist*, and is available online at http://books.nap.edu/catalog.php?record_id=12192.

Inquiries

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