

Responsible Conduct of Research (RCR) Training: Mandatory as outlined by federal agencies

National Institutes of Health (NIH)

NIH [NOT-OD-10-019](#) updates NIH policy on instruction in the responsible conduct of research (RCR). The Notice specifies who should participate in RCR training, how often instruction should occur, and the form that instruction should take. 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 RCR. The updated policy is effective for 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 **for 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.

NIH policy requires participation in and successful completion of instruction in RCR 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 expects institutions to maintain records sufficient to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

NIH also has determined that online courses are “not considered adequate as the sole means of instruction” – except for special or unusual circumstances. In the past, the frequency and duration of instruction were criteria used in the review of plans. Now, NIH expects at least eight substantive contact hours of instruction.

NIH expects instruction in RCR to recur throughout a scientist’s career. Institutions providing and individuals receiving NIH training and career development support are expected to undertake such training “at least once during each career stage, and at a frequency of no less than once every four years.” NIH notes that such training can occur when a trainee is not actually supported by NIH but, as with all requirements, documentation of all training is required. The reporting requirements are also greatly expanded.

National Science Foundation (NSF)

The National Science Foundation issued a revised suite of Award Terms and Conditions in December 2009 which includes implementation of RCR training for undergraduate and graduate students and post-doctoral fellows who will be supported by NSF to conduct research. Institutions are not required to submit RCR plans in proposals, but NSF reserves the right to review an institution’s RCR training plan at any time upon request. NSF also requires institutions to designate one or more persons to oversee compliance, and requires verification that NSF supported students/postdocs have received RCR training. This change affects new and continuation proposals submitted on or after January 4, 2010.

Federal Requirement Summary

NIH Updated RCR Policy

- Applies to any NIH training/research education/fellowship/career awards.
- Requires course attendance to be monitored and a certificate or documentation of participation to be maintained by institutions.
- Requires at least eight substantive contact hours of instruction (online courses are not considered adequate as the sole means of instruction).
- Expects instruction in RCR to recur throughout a scientist's career (at least once during each career stage, and at a frequency of no less than once every four years).
- Encourages individuals to assume personal responsibility for their instruction in RCR.
- Expects research faculty of the institution to 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.
- New proposals must include a plan for instruction in RCR, must address the five Instructional Components and must describe how participation in instruction in RCR will be monitored.
- Renewal applications must 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.
- The reporting requirements are greatly expanded.

NSF Revised Award Terms and Conditions

- Requires RCR training for undergraduate and graduate students and post-doctoral fellows supported by NSF to conduct research.
- Requires institutions to designate one or more persons to oversee compliance.
- Requires verification that NSF supported students/postdocs have received RCR training.
- Institutions are not required to submit RCR plans in proposals, but NSF reserves the right to review an institution's RCR training plan at any time upon request.

PBRC Compliance

General Requirements

RCR training is required for:

1. All trainees, fellows, participants and scholars receiving support through any applicable NIH training, career development award, and research education grant and any other NIH-funded programs supporting research training, career development, or research education that require instruction in RCR as stated in the funding opportunity announcements.
2. All undergraduate and graduate students and post-doctoral fellows who will be supported by NSF to conduct research.

PBRC RCR Training Plan

PBRC Division of Education currently conducts an ongoing training series on responsible conduct of research. **As of January 1, 2010, participation in the RCR Training Series is required for all trainees, fellows, participants and scholars receiving support through any NIH training, career development award, research education grant, and all undergraduate and graduate students and post-doctoral fellows who will be supported by NSF to conduct research.**

The PBRC RCR Training Series consists of at least 8 sessions per year, 60 minutes long, typically meeting once per month. There are new topics presented in the subsequent year (total of at least 16 unique topic areas covered in 2 year cycle). Sessions focus on the major topic areas identified by the USPHS as core areas for responsible conduct of research. A relevant case study is distributed electronically before each session. Lists of past lectures, including all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders, and current lecture schedule will be provided by the Division of Education.

In addition to this series, all new PBRC animal investigators are required to attend an orientation to responsible conduct of animal research before being allowed in the animal labs. Human researchers are required to complete a computer based training program on human subject protections.

For questions regarding the RCR Training Series, contact Dr. Phillip Brantley at 763-3046, or Phil.Brantley@pbrc.edu.

Oversight and Compliance

The PBRC Compliance Officer will oversee and monitor **institutional compliance**. Role will be taken for each RCR series lecture, and a certificate of completion will be provided to participants. A list of attendees will be forwarded to the PBRC Compliance Officer. The PBRC Compliance Officer and Sponsored Projects Office will review participation annually, at a minimum, and verify that applicable persons have received the minimum required instruction (8 contact hours).

Principal Investigators/participants must follow project-specific RCR plans, participate in RCR training activities, and report RCR training activities to the NIH, as required.

Application & Reporting Guidance

NIH New & Renewal 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 instruction in RCR 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.

Applications lacking a plan for instruction in RCR will be considered incomplete and may be delayed in the review process or not reviewed. See NIH [NOT-OD-10-019](#) for details and special considerations.

NIH RCR Plan Components

Proposals must include an RCR plan which addresses the **five Instructional Components** that will be used by reviewers to evaluate plans for instruction in responsible conduct of research.

1. **Format:** Substantial face-to-face discussions among trainees/fellows/scholars/participants, case studies, and participation of research training faculty members in RCR instruction is highly encouraged. **A plan that employs only online coursework for instruction will normally not be considered acceptable.**
2. **Subject Matter:** NIH provides recommended topics for most acceptable plans for instruction.
3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research.
4. **Duration of Instruction:** Instruction should involve substantive at least eight contact hours between the trainees/fellows/scholars/participants and the participating faculty.
5. **Frequency of Instruction:** Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years.

NIH Reporting Requirements

NIH reporting requirements have been expanded. Those who will submit continuation applications to applicable programs should carefully review the Reporting Requirements provided in the Notice.