FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research Notice Number: NOT-OD-22-055

Key Dates

Release Date:

February 17, 2022

Related Announcements

NOT-OD-10-019 - Update on the Requirement for Instruction in the Responsible Conduct of Researc

NOT-RR-11-005 - Modification of PAR-10-206: NCRR Science Education Partnership Award (SEPA) (R25)

NOT-OD-21-152 - Extension of COVID Flexibilities for Instruction in the Responsible Conduct of Research

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY (AHRQ)

HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)

Purpose

By way of this Notice, the National Institutes of Health (NIH), Agency for Healthcare Research and Quality (AHRQ), and Health Resources & Services Administration (HRSA) reaffirm the principle that education in the responsible conduct of research is a fundamental element of research training and announce updates to their existing policy and guidance for such instruction. In particular, this Notice provides new recommendations on the format, frequency, and timing of instruction in the responsible conduct of research (RCR) and suggests additional topics for consideration.

Background and Related Information

NIH last updated its policy on RCR instruction in Fiscal Year 2010, with the publication of an NIH Guide Notice (NOT-OD-10-019) that reflected the evolution of biomedical research and incorporated experiences and lessons learned in the two decades since the introduction of the initial requirement for RCR instruction in National Research Service Award research training grants in 1990.

Since the 2010 update, both the 2018 <u>NIH Strategic Plan for Data Science</u> and the <u>Federal Strategic Plan for STEM Education</u> have underscored the need for further education and training in secure and ethical data use. More recently, in responding to the COVID public health emergency, universities have created new options for RCR instruction, leveraging advances in video conferencing and other technologies. Lastly, in late 2020, the Department of Health and Human Services (HHS) Office of Research Integrity gathered feedback from the research community about best practices, challenges, and needs related to teaching RCR and promoting research integrity.

Updated Policy

Reflecting these developments, the HHS components that support research training and related activities are now providing new guidance on the format, frequency, and timing of RCR instruction, as well as additional topics for consideration. With the exception of the new recommendations for the RCR instructional components described below, the policy and guidance set forth in NOT-OD-10-019 remain in place.

Instructional Component Recommendations

- Format of Instruction: Discussion-based instruction in the responsible conduct of research is expected to remain a key feature of RCR training and to include substantive face-to-face interaction among participants and faculty. However, recognizing that advances in video conferencing now allow for effective "face-to-face" discussions to occur electronically, institutions may wish to consider incorporating video conferencing options into their RCR instruction, provided that those options are utilized in a way that fosters discussion, active learning, engagement, and interaction among the participants. At the same time, video conferencing should not be the sole means for meeting the requirement for RCR instruction, and a plan that employs only video conferencing will not be considered acceptable, except in the circumstances described in NOT-OD-10-019, such as short-term research training and research education programs.
- Frequency and Timing: Existing policy and guidance call for RCR instruction to be undertaken at least once during each career stage, and at a frequency of no less than once every four years. As institutions consider how to optimize the timing and delivery of instruction in the responsible conduct of research, they are encouraged to bear in mind the value of ongoing and discipline-specific training as individuals progress in their research careers. For example, while broad-based instruction in the responsible conduct of research is often appropriate early in graduate school; a more tailored, discipline-specific approach may better fit the needs of advanced graduate students and those who have transitioned to postdoctoral status. If advanced students and postdoctorates have been exposed to the full range of topics traditionally included in RCR instruction early in their scientific training, it may make sense for their ongoing and/or subsequent RCR training to focus on subjects most relevant to their fields, and institutions may wish to consider this approach, where applicable.
- **Subject Matter**: Developments in the conduct of research and a growing understanding of the impact of the broader research environment have led to a recognition that additional topics merit inclusion in discussions of the responsible conduct of research. For context, those additional subjects appear in bold among the list of topics traditionally included in most acceptable plans for RCR instruction, cited in NOT-OD-10-019, and appearing below:
 - a. conflict of interest personal, professional, and financial and conflict of commitment, in allocating time, effort, or other research resources
 - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - c. mentor/mentee responsibilities and relationships
 - d. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
 - e. collaborative research, including collaborations with industry and **investigators and institutions in other countries**
 - f. peer review, including the responsibility for maintaining confidentiality and security in peer review
 - g. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
 - h. secure and ethical data use; data confidentiality, management, sharing, and ownership
 - i. research misconduct and policies for handling misconduct
 - i. responsible authorship and publication
 - k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Implementation

Institutions are expected to begin to incorporate the changes described in this Notice into their plans for RCR instruction for the 2022-2023 academic year and in new and renewal applications for research training, career development, research education and dissertation research grants beginning with the September 25, 2022 due dates.

At the same time, institutions are reminded that as long as the COVID public health emergency continues, flexibilities in the method of instruction in the responsible conduct of research remain in place. RCR training may be completed fully online during the public health emergency and grant recipients need not seek prior approval to do so.

Inquiries

Please direct all inquiries to:

NIH

Division of Biomedical Research Workforce Office of Extramural Research National Institutes of Health Website: https://researchtraining.nih.gov

Email: NIHTrain@mail.nih.gov

AHRQ

Francis D. Chesley, Jr., M.D.

Director, Office of Extramural Research, Education, and Priority Populations

Agency for Healthcare Research and Quality

E-mail: Francis.Chesley@ahrq.hhs.gov

Weekly TOC for this Announcement NIH Funding Opportunities and Notices