Guidelines on Meeting the NIH Requirement for Instruction in the Responsible Conduct of Research

Note: These guidelines pertain specifically to certain grant awards from the National Institutes of Health. For awards from the National Science Foundation, see the <u>Plan to Provide Training and Oversight in the Responsible Conduct of Research to Students and Postdoctoral Researchers Support by NSF to Conduct Research.</u>

NIH requires that all trainees, fellows, participants, and scholars receiving support through any NIH training grant, career development award, research education grant, or dissertation research grant must receive instruction in the Responsible Conduct of Research (RCR). For the complete text of the requirement, see NIH's <u>Update on the</u> Requirement for Instruction in the Responsible Conduct of Research.

The process of meeting this requirement begins with the development of a tailored plan for RCR instruction for inclusion in the proposal for any of the NIH grants listed above. When evaluating the plan, peer reviewers consider the extent to which it addresses the following NIH-required instructional components:

Format

The instruction plan must include substantial face-to-face interaction. The use of case studies to promote small-group discussions is recommended. While on-line courses may be used as a supplement, they are not considered adequate as the sole means of instruction except in the case of short-term training and research education programs lasting six months or less.

Subject Matter

The following topics should be included in the planned RCR instruction:

- Collaborative research (including collaborations with industry).
- Conflict of interest.
- Data acquisition and laboratory tools: data management, sharing, and ownership.
- Human subjects, live vertebrate animals in research, and safe laboratory practices.
- Mentor/mentee responsibilities and relationships.
- Peer review.
- Research misconduct and policies for handling research misconduct.
- Responsible authorship and publication.
- The scientist as a responsible member of society.

Information regarding these topics is available from the resources listed below.

Faculty Participation

NIH highly encourages research faculty, including sponsors/mentors, to contribute to RCR instruction as discussion leaders, speakers, lecturers, or course directors.

Duration

Instruction should involve at least eight contact hours. NIH recommends a series of meetings/sessions as opposed to a one-day workshop.

Frequency

NIH stresses that reflection on RCR should recur throughout a scientist's career. For this reason, the instruction plan should consider how to optimize instruction in RCR for the particular career stage(s) of the individual(s) involved: undergraduate, post-baccalaureate, predoctoral, postdoctoral, or faculty level. Instruction must be undertaken at least once during each career stage and at least once every four years. Senior fellows and career award recipients may fulfill the requirement by participating in RCR instruction as lecturers and discussion leaders. For further details regarding the required contents of the RCR instruction plan, consult the relevant NIH program description.

During peer review, the instruction plan is found to be "acceptable" or "unacceptable." If the proposal is funded, the Principal Investigator (PI) is responsible for:

- Ensuring that the RCR instruction plan submitted with the proposal is carried out.
- Meeting NIH reporting requirements on RCR instruction.
- Maintaining records sufficient to document that the NIH-supported trainees, fellows, and/or scholars have received the required instruction.

Reports to NIH on RCR instruction, typically required at the end of each grant budget period, include topics such as:

- Subject matter covered.
- Instructional format.
- Frequency and duration of instruction.
- Any enhancements or modifications to the proposed instruction plan.
- Activities undertaken to individualize instruction appropriate to career stage.
- Research faculty members who contributed to the RCR instruction.

If instruction occurred during a prior budget period, the PI should note the date of occurrence. See NIH's <u>Update on the Requirement for Instruction in the Responsible</u> <u>Conduct of Research</u> for details on the RCR reporting requirements for each relevant type of grant award.

Records

The records that should be maintained to document RCR instruction will vary with each instruction plan. Following are some examples:

- Dates, times, and locations of small-group or other training sessions.
- Topics covered at each training session, including case studies used.
- Lists of trainees and research faculty/mentors attending each session.
- Certificates of completion when on-line courses are used as a supplement.

These records, which are subject to audit by NIH, should be maintained by the PI for a minimum of three years after award closeout. ORS staff are available to consult with PIs on strategies for collecting and maintaining the records and may ask to review them from time to time to help ensure that DePaul is meeting NIH standards in this respect.

Note: Contact Douglas Petcher (x27595) in the Office of Research Services if you have questions about the collection or maintenance of RCR training records, or if you have any other questions regarding these guidelines.

The following resources may be of help to those who are developing and implementing NIH-required RCR instruction plans:

NIH Training in the Responsible Conduct of Research Resource Page http://grants.nih.gov/training/responsibleconduct.htm

Introduction to the Responsible Conduct of Research: Office of Research Integrity http://ori.hhs.gov/sites/default/files/rcrintro.pdf

RCR Casebook: Office of Research Integrity

http://ori.hhs.gov/rcr-casebook-stories-about-researchers-worth-discussing

RCR Objectives: Office of Research Integrity http://ori.hhs.gov/rcr-objectives-delphi-study

The Research Clinic: Office of Research Integrity

http://ori.hhs.gov/TheResearchClinic

The Lab: Office of Research Integrity

http://ori.hhs.gov/thelab

General RCR Resources: Office of Research Integrity

http://ori.hhs.gov/general-resources-0

Collaborative Institutional Training Initiative (CITI)

https://www.citiprogram.org/

Access Instructions to CITI Training in RCR

http://offices.depaul.edu/ors/award-management/training/Pages/rcr.aspx

RCR Resources: National Center for Professional & Research Ethics

https://nationalethicscenter.org/nsf-rcr-requirement