Responsible Conduct of Research – Requirements and Resources at OSU   10/14 kho

RCR requirements
The Principal Investigator (PI)/mentor must develop a discipline-specific, tailored plan for RCR training that meets the NIH requirements. The instructional plan is evaluated as a component of the NIH funding proposal and applications lacking an RCR instructional plan may be delayed in the review process or not reviewed. The PI is also responsible for ensuring that course attendance is monitored and that a certificate or documentation of participation is available upon course completion. The PI must also comply with the specific reporting requirements in continuation applications.

What grants require RCR plans?
NIH's requirements are most detailed and mandate that trainees on an NIH institutional research training grant (T32, T35, D43), individual fellowship (F30, F31), career development award (K01, K08, K22), research education grant (R25), or other grant programs that have a significant training component have a <u>minimum of eight hours of formal instruction at least once during each career stage and at least every four years</u>. This policy affects all new, renewal, and noncompeting applications. http://www.niaid.nih.gov/researchfunding/sop/pages/respconductresearch.aspx

NSF requires institutional assurance that RCR plans are in place and reserves the right to request the actual plans for review. At this time, specific plans are not required to be included in applications. http://www.nsf.gov/bfa/dias/policy/rcr.jsp

USDA requires all NIFA grants subject to NIFA Feb. 2013 (and subsequent) Terms and Conditions that contain the RCR training requirement. At this time, trainees can use the online RCR instructional modules produced by the Univ. of New Hampshire http://www.unh.edu/research/usda-nifa-rcr-training-requirement

What must be included in training? Various formats should be used.
- Face-to-face discussions about issues in RCR with mentor
- Online courses (such as CITI)
- Formal coursework (for-credit classes)
- Seminars (esp. semester-long) and workshops
- Participation as instructor

Instructional Plan (included in grant applications and progress reports)

Your plan must address the following five instructional components.
1. Format

    o Trainees, fellows, scholars, and participants should engage in substantial face-to-face discussions.

    o You should have research training faculty lead formal instruction, when possible.

    o On-line courses can supplement instruction but cannot be the sole means of instruction except in special instances of short-term training programs or unusual and well-justified circumstances.

2. Subject Matter—incorporate the following topics for instruction.

    o Conflict of interest—personal, professional, and financial.

    o Policies regarding human subjects and live vertebrate animal subjects in research, and safe laboratory practices.

    o Mentor and mentee responsibilities and relationships.

    o Collaborative research including collaborations with industry.

    o Peer review.

    o Data acquisition and laboratory tools; management, sharing and ownership.

    o Research misconduct and policies for handling misconduct.

    o Responsible authorship and publication.

    o The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research.

3. Faculty Participation

- Training faculty and sponsors or mentors are highly encouraged to contribute to both formal and informal instruction.
- In formal instruction (classes, seminars, workshops), training faculty may serve as discussion leaders, speakers, lecturers, or course directors.

4. Duration of Instruction

- Instruction generally <u>involves at least eight contact hours</u> between the trainees, fellows, scholars, or participants and the participating faculty.
- A semester-long series of seminars or programs may be more effective than a single seminar or one-day workshop.

5. Frequency of Instruction

- Instruction must be undertaken at least once during each career stage and no less than once every four years.
- Initial instruction during predoctoral training should occur as early as possible in graduate school. If you are at an early career investigator level (including mentored K awardees and K12 scholars), you must receive instruction at least once during this career stage.
- Senior fellows and career award recipients may fulfill the requirement for instruction by participating as lecturers and discussion leaders.

Individual Applications

- As part of your Research Training Plan or Candidate Information and Career Development Plan, you must include a section on instruction in responsible conduct of research that is appropriate to your career stage (e.g., instruction if you are in the early stage of your career; participation as a course director, lecturer, or discussion leader if you are in the middle or senior stage of your career).
  - Plan must address the five components listed above.
  - Document your participation or instruction in research during your current career stage.
  - Plan may also include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance your understanding of ethical issues related to your specific research activities and the societal impact of your research.
  - Describe the role your sponsor or mentor will play.

Resources Offered though the Office of Research Risks Protection or the Office of Research
Online: Human Participants in Research http://orrp.osu.edu/irb/investigator-guidance/human-participants-in-research/
RCR workshop materials
- Office of Research Introduction
http://research.osu.edu/files/2011/03/RCR-Requirements-and-Resources-Presentation1.pdf
- RCR Basic Principles
http://research.osu.edu/files/2011/03/RCR-Basic-Principles.pdf

RCR Courses offered at OSU for credit

1) Pharmacol 7510 Professional and Ethical Issues in Biomedical Science SP2015
2) Vision Sci 7960 Ethics in Biomedical Science AU2014
3) Biomed Eng 6983 Research Ethics AU2014
4) Pharmacy 8520 Research Ethics Maymester 2015 (need to confirm)

- Other Resources (websites)
  http://research.osu.edu/files/2011/03/RCR-Resources.pdf