NIH Requirements for Instruction in the Responsible Conduct of Research

NIH OER (Extramural) Nexus podcast (6 minutes of audio) about responsible conduct of research. http://grants.nih.gov/podcasts/All_About_Grants/index.htm

Dr. Rod Ulane, NIH's Research Training Officer, discusses what is required to fulfill the requirement for education in the responsible conduct of research in "Training in the Responsible Conduct of Research." Quote from transcript, “Eight hours, face-to-face, every four years.”


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.

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.

Instructional Components

Format:
- Face-to-face
- Didactic
- Small-group discussions
- Online (may be a component, not sufficient by itself)
- Training others

Subject Matter:
- Conflict of interest – personal, professional, and financial
- Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- Mentor/mentee responsibilities and relationships
- Collaborative research including collaborations with industry
- Peer review
- Data acquisition and laboratory tools; management, sharing and ownership
- Research misconduct and policies for handling misconduct
- Responsible authorship and publication
- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Faculty Participation:
- Serve as course directors, speakers, lecturers, and discussion leader for formal and informal instruction
- Instruction in the course of laboratory interactions or other informal situations

Duration of Instruction:
- At least 8 contact hours
- Semester-long series of seminars/programs may be more effective than single day

Frequency of Instruction:
- At least once at each stage of career (undergraduate, post-baccalaureate, predoctoral, postdoctoral, faculty)
- At least once every 4 years
- Required for K12/KL2
- Senior fellows/career development recipients (F33, K02, K05, K24) may fulfill requirement by teaching or leading discussions
Grant Application Procedures - Individual Applications

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.

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.

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.

Resources

Grant submission template:
UTMB Research Services – click on “RCR Template Language” at: http://research.utmb.edu/AskForFunding/RCR.shtm

Partial Listing of Educational Activities:

UTMB
- Informal training as participant in research project, under guidance of supervisor, includes exposure to IRB and human subject / IACUC and animal protection issues as they arise. In particular...(see grant submission template, RCR Template language).
- TRSP Seminar: Twice monthly; academic advancement, scientific writing and research topics
- ITS Research Ethics Education Resources: http://www.its.utmb.edu/resources/ethics_support/research_ethics_education.html
- UTMB required Training in Scientific Integrity and the Responsible Conduct of Research (online course)
- UTMB Compliance Training for researchers based on UTMB Guidelines for Authorship (online course)
- UTMB required Training regarding the Health Insurance portability and Accountability Act (HIPAA) (online)
- Scientific Writing for Clinical Research
- Formal and Informal Courses in Research Methods and Procedures:
  - Selected GSBS Coursework (as non-degree seeking student) or GSBS Certificate Coursework, including course “Ethics of Scientific Research” (MEHU 6101) http://www.gsbs.utmb.edu/_pdf/GSBSBulletin.pdf
  - ITS course, Clinical Research: Tools & Techniques (also offered for GSBS credit as PHS 6135)
  - Advanced Training Program on the protection of Human Research Participants
  - Navigating the IRB and Investigator Responsibilities
  - CITI Modules (see listing)
  - Research Projects 101
  - Research Financial Grants Management
  - Effort Reporting and ECRT Training
  - Good Laboratory Practices
  - Animal Resource Center Training: see listing at http://research.utmb.edu/arc/arc_train.shtm
  - Other Resources / Presentations available from UTMB Research Services, Research Education
Resources (continued)

Non-UTMB

- ITS Research Ethics Education resources at: http://www.its.utmb.edu/resources/ethics_support/research_ethics_education.html
- NIH Clinical Center online course “Clinical Research Training On-Line Course for Principal Investigators” http://clinicalcenter.nih.gov/training/training/crt.html
- Case Studies from text, “Teaching the Responsible Conduct of Research through a Case Study Approach”
- Intensive off-campus grant writing workshop – many grant writing experiences are offered to early career investigators by federal agencies or at other academic institutions. For example the NIH Clinical Center, Office of Clinical Research Training, and Medical Education (http://www.cc.nih.gov/training/resources/grant_writing.html) contains a comprehensive listing of NIH and other federal resources, including workshops sponsored by the NIH and others
- Bioethics Resources on the Web (click or scroll to “Educational Resources” section) http://bioethics.od.nih.gov/researchethics.html
- NIH Clinical Center, Dept. of Bioethics – Ethical and Regulatory Aspects of Clinical Research http://www.bioethics.nih.gov/hsrc/index.shtml (Videocasts and podcast link for recordings of previous sessions)
- DHHS Office of Research Integrity: “The Lab: Avoiding Research Misconduct” http://ori.hhs.gov/TheLab/
  In “The Lab: Avoiding Research Misconduct,” you become the lead characters in an interactive movie and make decisions about integrity in research that can have long-term consequences. The simulation addresses Responsible Conduct of Research topics such as avoiding research misconduct, mentorship responsibilities, handling of data, responsible authorship, and questionable research practices.

Documentation

Name:
Job Title/Position:

Activity Title: 
Course Director: 
Speaker(s) / Discussion Leader(s):
Date(s):
Beginning and Ending Time(s):
Format:
  [ ] Face-to-face
  [ ] Didactic
  [ ] Small-group discussions
  [ ] Online
  [ ] Training others

Subject Matter:
  [ ] Conflict of interest – personal, professional, and financial
  [ ] Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
  [ ] Mentor/mentee responsibilities and relationships
  [ ] Collaborative research including collaborations with industry
  [ ] Peer review
  [ ] Data acquisition and laboratory tools; management, sharing and ownership
  [ ] Research misconduct and policies for handling misconduct
  [ ] Responsible authorship and publication
  [ ] The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research