Responsible Conduct of Research Requirements and Resources

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February 22, 2011

Why provide coursework in the responsible conduct of research?

- Practical considerations:
  - NSF and NIH have both mandated that training in responsible conduct of research be provided
  - Increasing incidence of problems with scientific misconduct, authorship disputes, conflict of interest involving graduate students, postdocs, early career researchers

- Educational considerations:
  - Grounding in research ethics an essential part of research training
  - Strong evidence that ethics not learned by "osmosis"

General Considerations

- University-wide one-day workshop on RCR not adequate to meet new requirements
  - Insufficient number of contact hours
  - Format doesn't permit discussion of case studies
  - No discipline-specific content

- Need to design courses that have
  - Substantial contact hours, face-to-face
  - Case study discussion
  - Discipline-specific content

NIH Requirements

- Responsible conduct of research is an essential component of research training and must be an integral part of all research training programs. Its evaluation will impact funding decisions.

- Instruction in responsible conduct of research should be appropriate to the career stage of the individuals receiving training.

- Individual fellowship and career development award recipients are encouraged to assume individual and personal responsibility for their instruction in responsible conduct of research.

- Research faculty should participate in instruction in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.

- Instruction should include face-to-face discussions by course participants and faculty; i.e., on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.

- Instruction in responsible conduct of research must be carefully evaluated in all NIH grant applications for which it is a required component.

What categories of NIH awards are involved?

- All new and renewal applications submitted on or after January 25, 2010
- All continuation (Type 5) applications with deadlines on or after January 1, 2011

- 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

- 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 Format and Content

- Format:
  - Substantial face-to-face interaction
  - Combination of didactic and small-group discussion
  - Participation of research faculty members
  - On-line coursework to be used only as a supplement
  - Online alone is not acceptable

NIH Format and Content

- Content:
  - *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*

NIH Format and Content

- Content:
  - *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

NIH Format and Content

- RCR is applicable to all stages of a researcher's career:
  - Undergraduate, graduate, postdoctoral, faculty
- Senior fellows, career award recipients:
  - Participate as lecturers, discussion leaders
- Training programs: must provide plan for training for all involved participants
- Individual awards: must provide individualized plan
- For more information:

  http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

NSF Requirements

- Section 7009 of the America COMPETES Act

- Education in RCR essential in the preparation of future scientists and engineers

- Applies to all undergraduate, graduate student, and postdoctoral researchers *participating in a project* (whether or not the grant funds them)

- All proposals submitted after January 4, 2010

NSF Requirements

- NSF allows online training; also permits short-term solutions while longer-term solution is being developed

- OSU's short-term solution is CITI (RCR training that is somewhat discipline-specific)

- Two beta sites supported by NSF:
  - Ethics in Science and Engineering National Clearinghouse
    - http://www.umass.edu/sts/digitallibrary/
  - Online Ethics Center Enhancements and America COMPETES
    - http://www.onlineethics.org/CMS/about/UserGuide/18848.aspx

NSF Requirements

- Institution must have plan in place to provide appropriate training and oversight in the responsible and ethical conduct of research. Institutional certification required for each proposal

- Plans subject to review, upon request

- Institution must designate one or more persons to oversee compliance with the RCR training requirement

- Institutions responsible for verifying that individuals have received training

Some Useful Resources

- Resources for Research Ethics Education (RREE) – UC San Diego

  - http://research-ethics.net/

- Columbia University

  – http://ccnmtl.columbia.edu/projects/rcr/index.html

  – http://www.researchethics.cumc.columbia.edu/bio.htm

- Online Ethics Center (NAE)

  – http://www.onlineethics.org/

Example from RREE:
How should case studies be analyzed?

- Who are the affected parties (individuals, institutions, a field, society) in this situation?

- What interest(s) (material, financial, ethical, other) does each party have in the situation? Which interests are in conflict?

- Were the actions taken by each of the affected parties acceptable (ethical, legal, moral, or common sense)? If not, are there circumstances under which those actions would have been acceptable? Who should impose what sanction(s)?

- What other courses of action are open to each of the affected parties? What is the likely outcome of each course of action?

- For each party involved, what course of action would you take, and why?

- What actions could have been taken to avoid the conflict?

- If consensus is not possible, then written or oral summaries should reflect majority and minority opinions.

Columbia University

- Online Courses:
  - Conflicts of Interest
  - Mentoring
  - Responsible Authorship and Peer Review
  - Research Misconduct
  - Collaborative Science
  - Data Acquisition and Management

Columbia University

- Bio and Medical Research Ethics
  - Listing of relevant policies and rules
    - OSTP, DHHS ORI, NIH (OHRP)
    - Nuremberg Code
    - World Medical Assn (Declaration of Helsinki)
    - Belmont Report
    - President's Council on Bioethics
    - National Bioethics Advisory Commission
    - ICH/GCP
    - AAHRPP

Online Ethics Center

- Topics:
  - Environment, Safety, Sustainability
  - Professional Practice
  - Employment and Legal Issues
  - Responsible Research
  - Emerging Technologies
  - Diversity Issues

- Ethics Case Discussion Webforum

Online Ethics Center

- Cases and Scenarios

- Essays, Articles, Student Projects

- Resources

- Ethics Education Library
  - Case Study Collection
  - Examples and Best Practices
  - Syllabi
  - Pedagogical Materials
  - Evaluation and Assessment Methods

What are Ohio State's Goals for RCR?

- An array of courses in RCR across colleges and disciplines

- Coursework for undergraduate and graduate students

- Meaningful conversation on research ethics at the university level
  - Center for Ethics and Human Values Innovation Group