Best Practices in Responsible Conduct of Research (RCR)

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Learning Objectives

- Understand background and history for current regulations and practices in responsible conduct of research
- Review required components of RCR
- Identify low-cost, existing opportunities
- Explore available external training options
- Determine pros and cons of developing own training programs
- Take home relevant resources for implementing RCR

Basic Sources of RCR

- Professional codes of behavior and ethics in academic fields
- Journal publication policies
- Agency review policies and practices
- Government regulations
- Institutional policies
- Personal convictions and values

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Starting point: RCR Components

- Human subjects
- Animal subjects
- Research misconduct
- Conflict of interest
- Training/mentoring of graduate students and other new scientists
- Data sources, recording, protection, management, storage, sharing
- Research collaboration: internal, external, international
- Reporting and reviewing of research

RCR: Brief History

- 1966 Animal Welfare Act
- 1974 National Research Act created National Commission for Protection of Human Subjects
- o 1979 Belmont Report
- o 1985 Health Research Extension Act
- o 1989 NIH Training Grant Requirement in RCR
- 1989 Office of Scientific Integrity and Office of Scientific Integrity Review—which led to
- o 1992 Office of Research Integrity
- 1991 Common Rule for Protection of Human Subjects in Research
- 1995 NSF and NIH guidelines for conflict of interest
- o 1996 Guide for Care and Use of Laboratory Animals
- 2000 Federal Policy on Research Misconduct
- 2002 PHS Policy on Humane Care and Use of Laboratory Animals

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Institutional Best Practices: NIGMS

- o Topics of instruction:
 - Conflict of interest
 - Data sharing
 - Responsible authorship and publication
 - Policies for handling misconduct
 - Policies regarding the use of human and animal subjects
 - Data management

Institutional Best Practices: NIGMS

- Peer review
 - o Practices and responsibilities
- Mentor/trainee responsibilities
 - o Mutual responsibility between both sides
 - Difference between mentoring, training and advising
 - Post-docs
 - Graduate students
 - Undergraduate students
- Collaborative science
 - Internal and external
 - o Issues and problems

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Institutional Best Practices: NIGMS

- Format of instruction
 - Combination of didactic (lecture) and small group discussion (i.e., case studies)
 - Faculty participation in research training
 - On-line courses as adjuncts to supplement in-person RCR instruction
 - On-line not adequate as only source

Institutional Best Practices: NIGMS

- o Compliance
 - Trainee attendance
 - Required
 - Monitored
 - Certification or documentation upon completion
 - Opportunity for refresher training

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Institutional Best Practices: NIGMS

- Opportunities for continuing instruction
 - Predoctoral training (usually offered early in program)
 - Additional RCR instruction offered later in training or throughout
 - Postdoctoral training may build on earlier predoctoral RCR experiences

Institutional Best Practices: NIGMS

- Individual mentoring
 - One on one contact with mentors and advisors throughout training
 - Individual study assignments on RCR
 - As research involvement changes, opportunities to repeat or revisit RCR training, especially for postdocs

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Institutional Best Practices: NIGMS

- Duration of instruction
 - Substantive contact hours
 - One-time exposure inadequate and lacking sufficient depth
 - Series of programs or seminars
 - Learning over longer periods
 - Linking individual programs to broader picture
 - o Allowing time to apply classroom learning

Low-Cost Best Practices for RCR

- Research methods courses
- Department faculty meeting
- IRB, IACUC, Institutional Biosafety Committee training sessions
- Experiential/hands-on research programs for undergrad and grad students
- Orientation sessions for new faculty, postdocs, graduate students and graduate assistants

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Low-Cost Best Practices for RCR

- Training sessions for new department chairs
- Meetings or luncheons for new faculty hosted by university officials
- Departmental activities such as seminar series, dissertation groups
- Institution-wide lecture or discussion series
- Professional development programming offered by graduate school

Low-Cost Best Practices for RCR

- Activities sponsored by graduate student or postdoc groups
- Feature articles on RCR in campus newspapers and web sites
- Collaboration with graduate program coordinators across campus to promote RCR training
- Regular RCR communication from chief research officer to campus community

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Sharing of Best Practices

- o What is your institution doing?
- o What successes have you had?
- What great materials have you developed or found?
- o Who's in charge?
- How extensive/intensive is your program?
- What feedback have you received?

Useful Resources

- On Being a Scientist: A Guide to the Responsible Conduct of Research, 3rd edition, National Academies Press, 2009
- Introduction to the Responsible Conduct of Research, ORI, 2007
- Office of Research Integrity
 - http://ori.dhhs.gov

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Parting Thoughts

- RCR sets minimal standards, not best practices.
- Your own institution and culture should influence your approach to RCR.
- Consider annual review and upgrades of your RCR materials and practices.
- Reflect on our discussion, examples and ideas.
- Decide what your own best practices can and should be.
- Keep in mind your worst-case scenario.



For Questions and Follow-up

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