Responsible Conduct of Research

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Outline

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What is RCR?

Responsible Conduct of Research

• The practice of scientific investigation with integrity
• Involves awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.
• Encompasses the following areas:
  – research misconduct,
  – research with human participants,
  – research involving animals,
  – data acquisition, management, sharing and ownership,
  – mentor/trainee responsibilities,
  – publication practices and responsible authorship,
  – peer review,
  – collaborative science, and
  – conflicts of interests
Why Is Cornell Requiring Compliance?

• The integrity of research conducted at Cornell University is of the utmost importance to the institution as well as to our research sponsors. Cornell is committed to promoting and supporting the ethical and responsible conduct of research across all disciplines.

• Increased public and regulatory scrutiny on the institution’s ability to conduct research with integrity and free from biases (real or perceived), and to prove due diligence in providing education and guidance to researchers to be able to do so.
  – Of particular concern is the proper training in research ethics for students involved in research.

• NSF and NIH implementation of America COMPETES Act 2007, includes requirements for mandatory training in RCR.
• Institutions that apply for funding must describe in the grant proposal a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers participating in the proposed research project.

• All Undergraduate and graduate students and postdoctoral researchers paid (salary and/or stipend) from NSF funds awarded to NEW FULL proposals submitted or due, on or after January 4, 2010, must receive training in the responsible conduct of research.

• Institutions must verify that undergraduates, graduates, and postdoctoral researchers who receive salary or stipend support on the NSF award to conduct research, receive the requisite RCR training.
Do NSF Requirements apply to...

- All current NSF awards? **NO.** Only to those that meet the deadline.
- Sub-awardees? – **YES.** The proposing institution must ensure that these RCR requirements are appropriately addressed in the sub-award instrument. Applies to personnel on flow- thru funding to Cornell.
- NSF S-STEM or Noyce programs? - **NO,** if the stipend is only to enroll in an academic program. If the students also engage in Research, then **YES.**
- Funding amendments/supplements awarded after Jan 4, 2010, on awards for whom proposals were submitted before Jan 4, 2010? - **NO.**
- Conference, symposium, workshop, or travel proposals? – **NO.** Applies only to research grants.
- PIs and other faculty on the applicable awards? – **NO.** Only students and postdocs funded on the award.
- Unfunded (volunteer or course credit) students working on the award? – **NO.** Only paid personnel.
- New students or post docs to applicable awards? **YES-** the RCR requirement applies for the duration of the project.
NSF Requirements specific to training

• What does the training involve?
  – **Training should cover all 9 areas of RCR**
  – No specific format of training identified. Institutions given the flexibility to determine appropriate training
  – Online training can be used to satisfy requirements
  – No specified duration for “refresher” training
  – PIs not required to provide updates on RCR training in Annual reports
  – Training plan is subject to NSF review

• All peers polled, have chosen to use the CITI online training to meet the RCR requirement and supplement with additional training on the discretion of the PI.
• All trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant, effective with all new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2011.

• This Notice applies to the following programs:
  – 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.

• Institutions must describe how the training requirements will be monitored
• **All current NIH awards? NO.** Only to those specific types of awards and those that meet the submission deadlines.

• **Sub-awardees and flow thru?** – YES. The proposing institution must ensure that these RCR requirements are appropriately addressed in the sub-award instrument.

• **Funding amendments/supplements awarded after Jan 25, 2010, on awards for whom proposals were submitted before Jan 25, 2010?** - NO.

• **PIs and other faculty on the applicable awards?** – NO. Only students, fellows and postdocs funded on the award.

• **New students or post docs to applicable awards?** YES- the RCR requirement applies for the duration of the project.
NIH Requirements specific to training

- Training should cover all 9 areas of RCR
- 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.
- Online training only may suffice for certain short term grants
- No specified duration for “refresher” training
- Training plan must be submitted as part of the proposal
- Institutions required to describe a plan to monitor completion of the training

• All peers polled, have chosen to use the CITI online training as mandatory foundational training. All require additional training.
• All required personnel must complete the online Foundational course in RCR from CITI, within 60 days of being named on the award
• The Foundational online training meets the RCR requirement for NSF awards
• The online training must be completed for applicable NIH awards, even though this training alone does not satisfy NIH requirements
• A passing score of 80% is required for the online RCR course
• If an individual does not successfully complete the training by the due date, the NSF or NIH funding source cannot be available for their financial support and the individual's department or college will be required to determine an alternative funding source.
• Facilitate the work required to track, notify, and monitor on-line RCR trainees.
• Develop mechanisms to educate and inform the PIs and Research Administrators about RCR requirements.
• Make available the foundational on-line training and serve as a resource for access and other issues related to the online training.
• Make available other RCR training resources as needed or requested.
• Develop mechanisms to provide updated training information, inform departments of non-compliance and required corrective action.
• Make reasonable enhancements to tracking and monitoring of online foundational training, as required.
Unit Responsibilities

- Review each Solicitation notice to determine if RCR requirements apply
- Review Award distribution notice to determine any deliverables related to the award
- Communicate to the PI and to funded students and post docs, the RCR requirement, and how to complete them
- Monitor compliance using the tools provided by ORIA for the online training
- Take corrective action if individuals do not complete the RCR training requirement.
Resources for Units

- Awards with RCR requirements are marked in the OSP Portal, with the “RCR Deliverable”
- The Deliverable is mentioned in the Award distribution notice
- A daily log of all RCR online training is available on the ORIA/RCR website
- ORIA will send a monthly email with a list of all RCR awards
- ORIA will send a quarterly list of all personnel with incomplete training requirements
- The RCR website has several other training resources available
Resources

Office of Research Integrity (ORI)

Introduction to RCR:  
http://ori.dhhs.gov/education/products/RCRintro/

RCR Educational Resources:  
http://ori.hhs.gov/education/rcr_resources.shtml

The Lab, Interactive Movie http://ori.hhs.gov/TheLab/

NSF RCR Resources:

FAQs: http://www.nsf.gov/bfa/dias/policy/rcr.jsp

NIH RCR Resources:

http://grants.nih.gov/grants/research_integrity/index.htm  
http://grants.nih.gov/training/responsibleconduct.htm  

Materials from other institutions:

Inventory of syllabuses, PowerPoint slides, videos, lecture notes, handouts, and links for use in RCR educational training. Clinical Research Ethics Educational Materials:  
http://www.ctspedia.org/do/view/ResearchEthics/
Full Version of the Interactive Movie, The Lab, Now Available Online:

The long awaited release of "The Lab: Avoiding Research Misconduct" is now available for viewing on the ORI web site, as well as the ORIA website. The video simulation allows users to assume the role of a graduate student, post-doc, research administrator, or PI and make decisions that affect the integrity or research.

The Lab Facilitators Guide: The Lab: Avoiding Research Misconduct is a Virtual Experience Interactive Learning Simulation (VEILS) program. It includes:
- Simulation that includes four playable characters
- Tutorials for each character that describe a step-by-step way to make ethical decisions.

Materials from other institutions: Inventory site of syllabuses, PowerPoint slides, videos, lecture notes, handouts, and links for use in RCR educational training: http://www.ctspedia.org/do/view/ResearchEthics/