Policy for the Responsible Conduct of Research (RCR)

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Spring 2010

Why the Push from Federal Sponsors?

Table 9: Research Misconduct Activity, 1993-2008

Year*	Institution Reporting Activity	New Allegations
2007	130	183
2006	111	151
2005	113	137
2004	101	120
2003	106	136
2002	99	163
2001	78	127
2000	82	103
1999	72	89
1998	67	69
1997	73	92
1996	88	127
1995	96	104
1994	79	89
1993	73	86

* The year 2007 is a record of what institutions submitted in their 2008 Annual Report.

"130 institutions reported 183 new or continuing research misconduct activity in their 2007 Annual Report on Possible Research Misconduct"

"This is a 15% increase over 2006 and is almost 2x more activity than in 1993."

http://ori.dhhs.gov/documents/annual_reports/ori_annual_report_2008.pdf

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SBU RCR Policy

- GENERAL POLICY:
  - Adheres to professional practices that comprise scholarly and research integrity and fosters, actively endorses, and participates in the instruction in RCR for all faculty, students and staff, regardless of status, discipline, or source of funding.

- APPLICABILITY:
  - This policy is applicable to all SBU undergraduates, graduate students, post-docs, residents/fellows, and faculty.

SBU RCR Policy

- TIMELINE FOR TRAINING:
  - One year of either the effective date of this policy (1/4/2010), or the date of grant application submission, whichever comes first for:
    - all undergraduate and graduate students, post-docs supported by NSF.
    - for trainees, fellows, participants, and scholars supported through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant.

  - Any students not covered above must complete training described in this policy as a requirement toward their involvement in research activities at SBU.

  - Current faculty who are supported by NSF or NIH grants to which RCR requirements apply must complete training within one year of either the effective date of this policy (1/4/2010), or the date of grant application submission, whichever comes first.

  - Current faculty not covered in category above must complete training within 1 year of the effective date of this policy (1/4/10). Future hires must complete training within 1 year of hiring date.

SBU RCR Policy

- **TRAINING REQUIREMENTS:**
  - If the learner is:
    - An individual who will only be involved in research for a limited amount of time, (e.g., an undergraduate involved in a summer REU -Research Experiences for Undergraduates- program, etc.)

      Or

    - A faculty member

  - successful completion of Phase 1 will serve to meet the RCR requirement. Non-faculty must obtain approval from their department or school of a request and justification for waiver of Phase 2 requirement

  - With the exception of the above, the following format (Phase 1, 2 and 3) is expected and will also be supplemented via informal instruction by active mentoring throughout the individual's educational and research training experience

SBU RCR Policy

- TRAINING REQUIREMENTS:
  - Phase 1: Online instruction
  - Undergraduates:
    - Required review of an introduction to RCR, at: http://ori.dhhs.gov/education/products/RCRintro/
    - Selection of 3 topics to examine in-depth (not to include animal or human research modules) in a relevant RCR module discipline set (i.e., biomedical, social behavioral, physical science, humanities, engineering) within the web-based Collaborative Institutional Training Initiative (CITI)
    - A passing grade of 80% must be achieved on the quizzes taken at the end of these modules.
    - Notification of successful completion of on-line training will be provided by e-mail to the undergraduate, and to the office of Research Development and Assessment.

  - Graduate students, postdocs, fellows, faculty:
    - Completion of the relevant RCR module discipline set (i.e., biomedical, social behavioral, physical science, humanities, engineering) within CITI
    - A passing grade of 80% must be achieved on the quizzes taken at the end of these modules.
    - Notification of successful completion of on-line training will be provided by e-mail to the undergraduate, and to the office of Research Development and Assessment.

SBU RCR Policy

- TRAINING REQUIREMENTS:
  - Phase 2: Discipline-specific, credit-earning curriculum to be integrated into the coursework within each department/school
  - Minimum requirement to satisfy this phase: 8 contact hours per learner at intervals no less than once every 4 years.

  - Curriculum content must include training in:
    - conflict of interest – personal, professional, and financial
    - human subjects, live vertebrate animal subjects in research, and safe laboratory practices (general; formal training and certification is required, outside of the RCR instructional program, in order to do research involving human or animal subjects etc)
    - mentor/mentee responsibilities and relationships
    - research involving collaborations, internal and external to the University
    - peer review
    - data acquisition and laboratory tools; management, sharing and ownership
    - scientific misconduct (fabrication, falsification, and plagiarism) 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

SBU RCR Policy

- TRAINING REQUIREMENTS:
  - Course/other model should include the following components:
    - 25-30 minute lectures to introduce the topic,

    - coupled with

    - 60-90 minute small group break-out sessions headed by faculty, with goal of active participation by learner in applying the principles outlined in the lecture to relevant case studies. Examinations will be required for quantitative assessments. Attendance and participation is required at all sessions.

    - Faculty from the school/department, or other applicable individuals with expertise in the content being addressed may teach the lectures or lead the break-out sessions.

    - A passing grade of 80% constitutes successful completion of Phase 2 training (if a formal course is set up).

SBU RCR Policy

- TRAINING REQUIREMENTS:
  - Phase 3: RCR Recertification
    - All individuals conducting research must recertify in RCR no less than once every four years, with a minimum of 8 contact hours.

  - Training Certification
    - After successful completion of the course, the departmental/school RCR coordinator will enter the requisite information into the centralized web-based RCR database (maintained by the office of Research Development and Assessment) that also houses the Phase 1 (CITI online training) certifications.

Additional tools that may be used for RCR training

- Face to Face: research methods courses /seminars including case studies
- Departmental faculty meetings/journal clubs
- Training sessions offered by Institutional Review Boards, Institutional Animal Care and Use Committees, and Institutional Biosafety Committees
- Experiential research programs for graduate and undergraduate students—laboratory rotations
- Orientation sessions for new faculty, postdoctoral fellows and graduate and undergraduate students
- Training sessions for new department chairs
- Institution-wide lectures or discussion series
- Activities sponsored by graduate student and postdoc organizations
- Feature articles on RCR issues on VPR web site
- Communications in VPR Research News
- Collaboration with graduate program coordinators to promote RCR training
- Responsible and ethical conduct of research blogs

RCR Responsibilities

- Colleges/Schools/Departments/PIs
  - RCR training program methods
  - RCR training program content for each "group"
  - Department by department RCR training programs
  - Follow through to ensure RCR trainee Certification/Recertification

- Research Office
  - Educating faculty and researchers about SBU RCR Policy
  - Record keeping and coordination of electronic materials
  - Database of "certified" trainees
  - Verification of certification with PIs/Departments
  - 1 year window for training to occur before payments are discontinued
  - Assurances to federal government
  - Audit of charges to sponsored awards

SBU RCR Policy Summary

- **Everyone conducting research** must have 8 contact hours of RCR training no less than every 4 years.

- **NSF requires** (at the time of proposal submission) the university to have an RCR policy and a plan to provide RCR training and oversight to undergrads, grads, and post-docs supported by the grant - training has to be completed within the first year of the period of performance.

- **NIH requires** investigators to describe a **training plan** (comprised of instructional components including format, subject matter, faculty participation, duration of instruction, and frequency of instruction) and **how participation in RCR will be monitored** in every proposal application to which RCR requirements apply for trainees, fellows, participants and scholars. the training plan. Reporting/certifying that this has been completed occurs with submission of the continuation app/progress report.

Possible Federal Actions for Non-compliance with RCR

- **Institutional**
  - Letter of Reprimand
  - Disallowance of costs
  - Fines/restitution
  - Federal-wide debarment

- **PI specific**
  - Ban from serving as reviewer
  - Mandatory ethics training

RCR Resources

- http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html
- http://grants.nih.gov/training/extramural.htm
- http://bioethics.od.nih.gov/researchethics.html
- The National Academy Press has just published the 3rd. edition of the classic, On Being a Scientist, and is available online at http://books.nap.edu/catalog.php?record_id=12192.
- NSF Federal Register Notice on RCR Implementation: Federal Register Notice of August 20, 2009 (Volume 74, Number 160)
- NPA RCR Toolkit: http://www.nationalpostdoc.org/rcr-toolkit
- ORI's RCR Education Materials Clearinghouse http://ori.dhhs.gov/education/products/
- National Academy of Engineering Workshop Report: Ethics Education and Scientific and Engineering Research: What's Been Learned? What Should be Done? http://www.nap.edu/catalog.php?record_id=12695
- Collaborative Institutional Training Initiative (CITI), www.CITI.org

- http://www.stonybrook.edu/research/orc/rcr/index.shtml

Mandate from Federal Sponsors

- National Science Foundation (NSF) –Section 7009 America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act
  - *"Each institution that applies for financial assistance from the Foundation for science and engineering research or education must describe in its 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."*

- Proposal and Award Policies and Procedures Guide (PAPPG)
  - Effective January 4, 2010 authorized signatory must certify with every proposal that institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research
    - Standard award conditions - Institution responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received RCR training

    - Training must occur within period of performance, typically 1 year (exception: summer REU, training must occur in 3 summer months)

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Mandate from Federal Sponsors

- ## National Institutes of Health
  - ### Grant Proposal Guide (GPG)
    - 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 must receive instruction in RCR.

    - Effective for new and renewal applications submitted on or after January 25, 2010, and for all non-competing continuations (Type 5) applications with deadlines on or after January 1, 2011.

    - applies to: 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 RCR per relevant funding opportunity announcement

Mandate from Federal Sponsors

- National Institutes of Health
  - Guidance for training (NOT-OD-10-019*)
    - Format:
      - Substantial face-to-face discussions - a combination of didactic and small-group discussions (e.g. case studies)
      - Participation of research training faculty members in instruction in responsible conduct of research are highly encouraged.
      - While on-line courses can be a valuable supplement to instruction in responsible conduct of research, online instruction is not considered adequate as the sole means of instruction.

    - 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

Mandate from Federal Sponsors

- ## National Institutes of Health
  - Guidance for training (NOT-OD-10-019*)
    - Faculty Participation:
      - Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research.

    - Duration of Instruction:
      - Instruction should involve substantive contact hours between the trainees/fellows/scholars/participants and the participating faculty.
      - Acceptable programs generally involve at least eight contact hours.

    - Frequency of Instruction:
      - Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels.
      - Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years.

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