RGPEC REPORT IN RESPONSE TO CHARGE S-1508 Responsible Conduct of Research

November 21, 2016

Charge

Investigate and make recommendations on establishment and implementation of a university-wide policy on training and oversight in the responsible conduct of research (RCR) at Rutgers. Where appropriate, make specific recommendations for different training tracks, e.g. NSF- and NIH- compliant programs. Identify gaps in current resources, the intended recipients of RCR training (e.g. graduate students, undergraduate researchers, postdocs, faculty, etc.), the expected costs (if known) and benefits of implementing recommendations, and the unit(s) responsible for implementing and tracking compliance. Report to Senate Executive Committee by December 2016.

About RCR

The responsible and ethical conduct of research is critical for excellence, as well as public trust, in scientific and other scholarly endeavors. Responsible Conduct of Research (RCR) training involves learning topics such as ethical data acquisition, management, sharing and ownership; research misconduct; preventing and managing conflicts of interest; academic integrity, responsible authorship and peer review; and the ethical treatment of human and vertebrate animal subjects; among others. Key funding organizations, such as the National Science Foundation (NSF) and the National Institutes of Health (NIH) have specific and differing requirements for an institution's training on RCR, and training plans are subject to review and audit by these funding organizations. Rutgers does not have a University-wide policy on training for RCR.

Senate Charge: Background and Process

In January 2015, the NSF notified Rutgers Office of Research Regulatory Affairs that a review would be conducted during the same month of the Rutgers RCR training program. In preparation for this visit, Judith Neubauer, Associate Vice President for Research Regulatory Affairs, prepared a report summarizing RCR programs at Rutgers (see Appendix IV). In the course of this work, it was discovered that while numerous courses and workshops are established to address RCR at the various schools within Rutgers, some of the courses were compliant with NIH policies and others with NSF policies, and this level of compliance was not always readily apparent. There is no central repository of information about these programs (such as a website). Furthermore, there is no consistent and readily auditable system for tracking those who have completed RCR training at a University level, even though the Rutgers Division of Contracts and Grants Accounting is responsible to ensure that this requirement has been met.

Christopher Molloy, Senior Vice President for Research and Economic Development, asked the University Senate's Research, and Professional Development Committee (RGPEC) to help address these issues by: 1) investigating the "best practices" for RCR in place at similar Universities, 2) creating a baseline University-wide policy on training and oversight of RCR to improve consistency and compliance with the requirements of major funders which could be made more rigorous within schools as appropriate, 3) considering the need for different "tracks" and whatever flexibility is needed to meet the needs of the various schools, 4) making recommendations for the creation of a central repository of information and other resources relevant to RCR, and 5) develop an effective and efficient means of tracking and communicating what training has been completed and by whom.

Senior Vice President Molloy indicated that RCR was of utmost importance to his office and recommended RGPEC work with Neubauer on an RCR charge. RGPEC agreed to commence work in September, 2015, once

the report for its current pending charge had been delivered and the new 2015/16 Senate membership was in place. After this meeting, Molloy and Neubauer (as his designee) were appointed voting members of RGPEC. (Prior to the Research Office's restructuring, the Vice President for Research and Graduate and Professional Education served as an ex-officio member of RGPEC.)

In August, 2015, incoming and outgoing chairs Tony Tamburello and Jane Otto met with Neubauer to discuss the nature and scope of the work; a charge was drafted and later approved by the University Senate's Executive Committee (October 30, 2015). Tamburello formed an RCR subcommittee in Fall, 2015 (Janet Alder, Judy Neubauer, Tony Tamburello, Jerome Kukor, Jim Oleske, and John Joergensen), with the first order of business an environmental scan of RCR practices at Big Ten Academic Alliance (BTAA) schools, to help identify best practices (see Appendix III, Comparison of RCR Practices in BTAA Institutions). It was agreed that Committee recommendations should be broad-based, with fine-grain details left to the Office of Research and Economic Development (ORED).

As RGPEC developed its best practices and recommendations, Molloy made plans within ORED, which he announced in RGPEC's final meeting of the 2015/16 academic year. Molloy's primary objectives in this area at that time were to create a "one-stop shop" RCR website, and an RCR coordinator FTE position to reside in Neubauer's area; RGPEC recommended the RCR coordinator be at the PhD level and a research scientist. Molloy also agreed with RGPEC that an advisory board should be formed. He further planned to coordinate with the graduate schools to identify RCR resources, develop policies and programs (including online programs) and align programs with those of peer institutions; to develop a survey to identify what programs and training are already in place, and to create a database of resources.

Dr. Molloy then asked RGPEC to assist by drafting the University's RCR policy. This policy would be fairly generic, as it can evolve; it would not require approval by the Board of Governors, but would reside in the University Policy Library. In July, 2016, Otto and Alder convened a small RGPEC task force comprised of key stakeholders and RGPEC members: Jane Otto, Janet Alder (Associate Professor, Dept. of Neuroscience and Cell Biology, and Assistant Dean for Graduate Academic and Student Affairs, Graduate School of Biomedical Sciences), John Joergensen (Senior Associate Dean for Information Services, Law Library), Judy Neubauer, Carol Goldin (Associate Dean for Assessment, Ernest Mario School of Pharmacy), and Nancy Connell (Professor and Director for Research in the Division of Infectious Disease in the Department of Medicine at Rutgers New Jersey Medical School). The charge of this group was to identify exemplary university policies which might form the basis of a Rutgers Policy, and to draft language for a Rutgers University Policy on RCR. The final draft policy document may be found in Appendix I.

Best Practices in RCR Training

Based on its environmental scan and review of many university RCR policies, RGPEC recommends the following best practices: The University should have a University-wide policy on RCR, a dedicated RCR coordinator within the Office of Research and Economic Development, a website dedicated to the topic, and RCR training, minimally targeted at undergraduates, graduate students, postgraduate fellows, faculty, clinical researchers, and staff involved in research. RCR topics should be based on discipline, and should apply to all University individuals involved in research regardless of status (undergraduate students, graduate students, postgraduate fellows, faculty, staff, visiting scientist). RCR training should be offered in different formats to meet the needs of individual academic units and in respect of the funding source. RCR training is currently available at Rutgers from the Collaborative Institutional Training Initiative (CITI, https://orra.rutgers.edu/ritrainingedu); examples of useful CITI modules may be found in Appendix II, Proposed Best Practices in RCR Training. In addition, inperson training will be required in some circumstances.

Responsibilities within the RCR Program

The Advisory Board will review all RCR training materials to maintain a minimum level of competency in RCR, make recommendations for the structure of training for sponsor- and status-specific RCR training to the Associate VP, Research Regulatory Affairs and the RCR coordinator, and set the standards for RCR training in consultation with the Office of Research and Economic Development through the RCR coordinator. Direct responsibility for training is best situated with the individual schools, which may tailor training to meet their needs. The academic units and programs will identify RCR training materials in their disciplines, and each will designate a contact within the unit who will liaise with ORED's RCR coordinator. The RCR coordinator will be responsible for implementing the recommendations of the Advisory Board; provide guidance, support, and resources to the academic units and programs; and will be responsible for ensuring that compliance is tracked through an online system.

Current Status of RCR Planning at Rutgers

- RGPEC has drafted a Rutgers University Policy on RCR
- Chris Molloy has plans to
 - o create an RCR coordinator position
 - o develop a "one-stop shop" RCR website
 - o form an Advisory Board to advise ORED in RCR matters
 - o coordinate with graduate schools to identify RCR resources
 - develop policies and programs (including online programs), aligned with programs with those of peer institutions.
- CITI RCR training is currently available through ORED; there is no need to buy extra modules, only to identify the appropriate modules
- Experienced ORED teams can identify and monitor those required to take the course
- ORED will not take on the training, but it would be overseen by the RCR coordinator
- GSBS already has an exemplary program that should be ramped up to support additional units
- The RCR coordinator would identify required modules by discipline, including disciplines outside the sciences

Therefore, Be It Resolved that the University Senate recommends

- 1. The Office of Research and Economic Development:
 - a. review and finalize RGPEC's draft University Policy on Responsible Conduct of Research, included here as Appendix I;
 - b. create a new position (RCR coordinator) within ORED to
 - develop and administer a "one-stop shop" RCR website, populated with information and contact information for the discipline-, sponsor-, and status-specific RCR training requirements;
 - ii. in consultation with the Senior Vice President for Academic Affairs, identify specific academic units that need to be engaged;
 - iii. in consultation with these academic units, develop and maintain a database of available RCR resources and training materials;
 - iv. provide guidance and resources to assist academic units in identifying RCR training materials and in establishing and implementing RCR programs within the units;
 - v. ensure RCR policies and programs that meet sponsor requirements are established by all academic units across disciplines;
 - vi. ensure that RCR training requirements are communicated to all persons covered by the policy;
 - vii. develop monitoring and tracking mechanisms to ensure training requirements are met by all persons covered by the policy;
 - viii. establish a mechanism for coordinating compliance monitoring with ORED's Grants and Contracts Accounting, to ensure that sponsor requirements are met;
 - ix. monitor individuals' ongoing compliance with RCR training requirements, in coordination with the academic units
 - x. establish a process for evaluating RCR training and requirements
 - xi. implement recommendations of the RCR Advisory Board
 - c. form an advisory board (appointed by the Senior Vice President for Research and Economic Development, with representation from the graduate schools and senior-level faculty currently involved with RCR, from a range of disciplines such as life sciences, physical sciences, social sciences, and arts and humanities) to:
 - i. Set standards for RCR training
 - ii. Review all RCR training materials and programs to ensure that a minimum level of RCR competency is maintained
 - iii. Make recommendations for the structure for RCR training specific to particular sponsors and statuses (e.g., staff, faculty, students, visiting scientists) to the Associate Vice President of Research Regulatory Affairs and the RCR coordinator
 - iv. advise the RCR coordinator on content and processes for RCR training and monitoring;
- 2. The Senior Vice President for Academic Affairs charge all graduate and professional schools, and other academic units as appropriate, with
 - i. designating a contact within the unit to liaise with the RCR coordinator
 - ii. identifying and reporting to the ORED RCR coordinator all RCR resources and training materials currently in use in their areas, including any required CITI modules or other classes, with funding agency-specific requirements in mind if applicable
 - iii. establishing within the academic unit responsibilities for training and training-the-trainers program development and implementation

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APPENDIX I

Draft Rutgers University Policy on Responsible Conduct of Research



UNIVERSITY POLICY

Policy Name:	Responsible Conduct of Research Policy				
Section #:	Section Title:			Formerly Book:	
Approval Authority:	President		Adopted:	Reviewed:	
Responsible Executive:	Senior Vice President for Research and Economic Development		Revised:		
Responsible Office:	Office of Research and Economic Development		Contact:		

1. Policy Statement

The responsible and ethical conduct of research is critical for excellence, as well as public trust, in scientific and other scholarly endeavors. Rutgers, The State University of New Jersey, is committed to a culture of Responsible Conduct of Research (RCR), and therefore provides access to the necessary information, supporting resources, and training to meet expectations about RCR. Undergraduate students, graduate students, postgraduate fellows, faculty, and staff involved in research are required to complete training that is appropriate for their discipline and role they will serve on the project. In addition, individuals must comply with sponsor regulations, whenever such requirements exist.

2. Reason for Policy

This policy articulates the shared commitment of the University and its students, fellows, faculty, and staff involved in research to ethical behavior and fulfillment of the fiduciary duties of public, private or internal funding that are fundamental to the responsibility of serving as principal investigator (PI) or in another role on projects of research and scholarship.

Various government and other agencies set standards and requirements for education and training in the responsible conduct of research. This policy ensures, where applicable, the scope of the University's program for the responsible conduct of research includes such additional requirements.

This policy establishes the expectation for a training program to meet the shared responsibility for the responsible and ethical conduct of research. The policy is intended to be read and interpreted in conformity with existing Rutgers University policies.

3. Who Should Read this Policy

- Undergraduate students, graduate students, postgraduate fellows, clinical researchers, faculty, and staff involved in research
- Deans, directors, chairs, and department heads
- Chancellors and vice presidents

4. Resources

	Animal Welfare Policy Governing the Use of Animals in Research, Teaching, Testing and
Production	
Section 90.2.2	Research Misconduct
Section 90.2.3	Policy for Controlled Substances
Section 90.2.4	Rutgers University Export Control
Section 90.2.5	Investigator Conflict of Interest
Section 90.2.11	Policy for Human Subjects Protection and the Institutional Review Board
[RCR Website	URL TBD]

5. **Definitions**

Postgraduate Fellows

Postdoctoral scholars as well as clinical residents and fellows

Responsible Conduct of Research (RCR)

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 (National Institutes of Health NOT-OD-10-019)

Responsible Conduct of Research (RCR) Website A central clearinghouse of information on Rutgers' RCR program

6. The Policy

Individual departments, schools, and institutes are responsible for determining the training required based on discipline: e.g., social and behavioral sciences, humanities, engineering, life sciences, mathematics and physical sciences. Required topics may include conflict of interest, collaborative research, peer review, research misconduct and policies for handling misconduct, responsible authorship and publication, policies regarding human and animal subjects in research, and safe laboratory practices.

The Principal Investigator/Project Director (PI) is responsible to ensure that all applicable research team members are informed of the requirement and that the requirement has been met by all members, including themselves.

The Office of Research and Economic Development is responsible for providing an RCR website of training materials and informational resources in support of the program; coordinating and facilitating departmental programs; and for monitoring compliance.

RCR training may be offered in different formats and frequency to meet the needs of the individual unit/school and funding source requirements. For example, the academic unit may elect to use online training modules made available by the Office of Research and Economic Development. In other cases, the funder will have its own requirements, e.g. the NIH mandates a minimum of eight hours and a combination of didactic and small-group discussions (e.g. case studies) for graduate students. Furthermore, the NIH mandates training every four years (initial followed by refreshers) and at least one training series per career phase.

APPENDIX II

RGPEC Proposed Best Practices in RCR training

1) Have a policy on RCR.

All 14 colleague CIC institutions have a policy on RCR in one form or another.

2) The RCR policy should be applied University-wide.

13 out of 14 colleague CIC institutions apply RCR policy University-wide.

3) Have a website dedicated to information on RCR at the University.

13 out of 14 colleague CIC institutions have a website dedicated to RCR visible to the public.

- 4) RCR training must at least target undergrads, graduate students, postdocs, faculty and staff involved in research.
 - 9 CIC colleagues specifically mention undergrads
 - 9 graduate students (or pre-docs)
 - 9 post-docs (or post-grad)
 - 7 faculty (6 unspecified, 1 early faculty w/ K awards)
 - 2 staff
 - 1 students (unspecified)
 - 2 anyone involved in a research project
- 5) Determination of topics required for individuals should be based on discipline: e.g., social and behavioral sciences, humanities, engineering, life sciences, mathematics and physical sciences. The required topics should apply to all University individuals involved in research regardless of status. For example, RCR training for all personnel involved in life sciences research should, consistent with NIH minimum guidelines, include:
 - a. conflict of interest personal, professional, and financial
 - b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - c. mentor/mentee responsibilities and relationships
 - d. collaborative research including collaborations with industry
 - e. peer review
 - f. data acquisition and laboratory tools; management, sharing and ownership
 - g. research misconduct and policies for handling misconduct
 - h. responsible authorship and publication
 - i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Other topics may include copyright and plagiarism, intellectual property, fiscal responsibilities, and social/professional responsibilities.

NSF does not require any specific topics and allows for institutions determine the content of RCR training for themselves.

CIC colleagues cite minimum topics to cover in the following frequency:

Responsible authorship/intellectual property: 5 Data acquisition/management/ownership: 4

Mentoring: 3

Research misconduct: 3

Collaborative research/access & sharing: 3

Conflict of interest: 3 Responsible peer review: 2 General research ethics: 2 Ethical treatment of animals: 2

Human subjects: 2

IRB, safety, export control, fiscal responsibilities, social & professional responsibilities: 1

Three CIC colleagues state only that they follow NSF guidelines

Three CIC colleagues state only that they follow NSF and NIH guidelines

One CIC colleague specifies that training is unit-specific

6) RCR training should be offered in different formats to meet the needs of the individual unit/school and in respect of the funding source. For example, a minimum of 8 hours and a combination of didactic and small-group discussions (e.g. case studies) is required for NIH compliance. Furthermore, for NIH, the frequency of training should be every 4 years (initial followed by refresher) and at least once per career phase.

NSF does not require any specific method or frequency of training.

CITI is already used at Rutgers for Human Subjects training. CITI online training modules are available for initial and refresher training and could be used for the didactic portion of the training.

Basic RCR Modules available through CITI:

Authorship (Initial and Refresher)

Collaborative Research (Initial and Refresher)

Conflicts of Interest (Initial and Refresher)

Data Management (Initial and Refresher)

Financial Responsibility (Initial)

Mentoring (Initial and Refresher)

Peer Review (Initial and Refresher)

Plagiarism (Initial)

Research Involving Human Subjects (Initial and Refresher)

Research Misconduct (Initial and Refresher)

Using Animal Subjects in Research (Initial and Refresher)

Additional RCR CITI modules

Environmental and Social Dimensions of Engineering Research

Export Controls and National Security

Research Ethics and Society

At least 10 CIC colleagues offer some form of in-person training, though the formats vary: graduate course for credit, face-to-face discussion with faculty involvement, workshops. Three CIC colleagues specify in-person training is required for graduate students. Eight CIC colleagues specify that training is tailored to the unit/school or funding source. 13 out of 14 colleague CIC institutions offer CITI training, and some require it specifically for those engaging in human subjects research.

7) Standards for RCR training should be determined, supported, and monitored by a specific University office, usually the Office of Research or a division thereof specifically charged with this purpose. This office should provide Train-the-Trainer sessions for schools that need to offer their own courses and should be responsible for ensuring that compliance is tracked through an online system.

13 out of 14 CIC institutions clearly track RCR training, though the process varies:
When specified, at least 7 are tracked by a named office of research (e.g. Office of Research Compliance)
3 others mentioned using an electronic compliance monitoring system (eCompliance, training management system)

1 CIC institution's monitoring was clearly decentralized

APPENDIX III

Comparison of RCR Practices in BTAA Institutions

Michigan State University

Michigan State University has an Office of Regulatory Affairs under the Office of the Vice President for Research and Graduate Studies. The office is headed by J.R. Haywood, Ph.D., Assistant Vice President for Regulatory Affairs (517-432-4500, haywoo12@msu.edu). The office has oversight over research compliance areas (e.g., IACUC, IRB, COI, etc.) as well as providing a website with information for RCR training and requirements for students and postdoctoral fellows (https://ora.msu.edu/RCR).

The website provides information about standards and resources but the responsibility for unit-specific training and tracking of RCR as appropriate for different funding sources is de-centralized to individual departments/units.

From the MSU website (https://ora.msu.edu/RCR):

- The website provides information regarding the different standards for RCR training standards depending on funding source of the grant personnel (NIH, NSF, USDA-NIFA), as well as MSU Policy for graduate students.
- The Office of Regulatory Affairs offers assistance to units and individuals in tracking/ documenting RCR training.
- Training Resources

Depending upon the standard you are trying to meet, you may be required to complete one or more items (CITI RCR Program, Grad School Workshops, Epigeum's Research Integrity course, or Unit-specific assignments (e.g., brownbags, mentor meetings). Individuals are directed to check with their department.

The following is a summary of RCR training standards on the MSU website (which was last updated August 11, 2015):

USDA-NIFA - Funding requires recipients paid from a NIFA project to complete RCR training. The minimum training must include 3 key areas. Several resources meet the requirement:

- Any CITI Program RCR group. The RCR for USDA-NIFA group is recommended.
- USDA-NIFA modified Epigeum Research Integrity online course

NSF - NSF-funded students and post-doc researchers must receive training, but have no required topics, no minimum times, no specific delivery mode. http://www.nsf.gov/bfa/dias/policy/rcr/rcrfaqs.jsp#4

- MSU Policy for NSF-funded student and post-doc researchers requires 5 hours initial and then 3 hours each year after. Academic units may require more frequent training or additional topics. MSU Policy 2009.pdf
- CITI Program RCR courses and Grad School Workshops are both acceptable if they equal the time requirement.

NIH - NIH-funded training grants, fellowships, and career awards, research education, dissertation research, or other grant programs with significant training component require at least 8 hours every 4 years. The same topics and delivery modes are outlined. These grants require training plans during the application/review and require reporting of instruction for each budget period. http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

• A combination of CITI Program RCR courses, Grad School workshops, and other department activities is acceptable if they meet the time requirement.

Purdue University

Purdue University Education Plan to Satisfy the Requirements of NSF's Implementation of Section 7009 of the America COMPETES Act (42 U.S.C. 1862o-1)

Background - Section 7009 of the America COMPETES Act requires that "each institution that applies for financial assistance from the Foundation for science and engineering research or education 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."

NSF's Implementation Plan [74 FR 42126-42128 (August 20, 2009)]:

"Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution's Authorized Organizational Representative certify that the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research. While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review upon request. NSF will formally implement the new RCR requirement via an update to the NSF Proposal and Award Policies and Procedures Guide (PAPPG). It is anticipated that the revisions to the PAPPG will be issued on October 1, 2009. NSF also will modify its standard award conditions to clearly stipulate that institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received RCR training."

Purdue University Training Plan to Satisfy NSF Requirement for Responsible Conduct in Research Education

- 1. Administration The Vice President for Research and Dean of the Graduate School have assigned responsibility to the OVPR Office of Research Administration to coordinate implementation and oversee compliance with the NSF Requirement for RCR Education. Associate Vice President for Research Peter
- Dunn and an Associate Dean of the Graduate School (TBD) will serve as co-chairs of a faculty advisory committee which will periodically review and recommend improvements to this University Responsible Conduct of Research Education Plan. This faculty advisory committee will include representation from the college/school Associate Deans for Graduate Education (Graduate School GEA Committee) and NSF-supported faculty whose projects are subject to the Education Plan.
- 2. Undergraduates Undergraduates to be supported from an NSF project submitted to the sponsor on or after January 4, 2010 must successfully complete online undergraduate core training in the responsible conduct of research (RCR) consisting of online CITI modules on research misconduct, conflict of interest, and data acquisition and management. This requirement must be completed and documentation provided to the hiring department prior to employment. Undergraduates are encouraged to complete the remainder of the CITI online RCR curriculum and to attend seminars/workshops on the responsible conduct of research offered at Purdue University.
- 3. Graduate Students and Postdoctoral Researchers During the first month of support, graduate students and postdoctoral researchers supported by funds from the NSF must successfully complete online graduate core training in RCR. This core training will consist of successful completion of one of the four CITI online RCR courses: Biomedical, Physical Science, Social and Behavioral, or Humanities. Each of these courses consists of modules on research misconduct, conflict of interest, data acquisition and management, responsible authorship, responsible peer review, collaborative research, mentoring, and Purdue University policies and procedures (to be developed). In addition, graduate students and postdoctoral researchers supported by NSF funds are required to engage in additional discussion-based RCR education during the first year of support by NSF funds. The specific method to satisfy this requirement for discussion-based RCR education will be determined by the student's graduate program or

by the postdoctoral researcher's mentor. Graduate programs and postdoctoral mentors, respectively, will be responsible for maintaining auditable documentation of each graduate student's or postdoctoral researcher's completion of discussion-based RCR education.

4. Resources - Information about Purdue courses and workshops addressing the ethical and responsible conduct of research can be found on the Graduate School's Responsible Conduct of Research web site. To access the CITI online courses in the Responsible Conduct of Research referenced in the Purdue RCR Education Plan, please click here.

Recordkeeping Assistance – see RCR Tracking Form 2012:

http://www.purdue.edu/research/docs/pdf/RCR%20Tracking%20Form%202012.pdf

Direction for Online RCR Training – see RCR Quick Reference Card: http://www.purdue.edu/research/docs/pdf/RCR%20Quick%20Reference%20Card.pdf

UW-Madison

National Science Foundation (NSF) Responsible Conduct of Research (RCR) Training Requirement

UW-Madison NSF RCR Policy

The National Science Foundation, by mandate of the United States Congress in the America Competes Act Section 7009, requires all undergraduate students, graduate students and postdoctoral researchers supported by NSF research funding to receive training in Responsible Conduct of Research (RCR). All undergraduate students, graduate students and postdoctoral researchers supported by NSF research funding at the University of Wisconsin-Madison must take the Responsible Conduct of Research course in Learn@UW (course # 2480630). This training is also recommended for those not currently required to complete this course.

If you are working with a student who does not have a NetID, please contact Heather Mc Fadden for assistance. Email: heather.mcfadden@wisc.edu or call 608-890-2468.

This applies to all NSF awards granted for proposals submitted on or after January 4, 2010.

Help desk for UW-Madison NSF RCR training: heather.mcfadden@wisc.edu or 608-890-2468.

Course Registration Information

To register for the course, please use your UW NetID and password to log-in to Learn@UW.

Once logged in, please complete the steps below.

Directions of completing NSF RCR Training:

- 1. Please log-in to Learn@UW (https://learnuw.wisc.edu/).
- 2. Under your "My Course Dashboard" on the right side of the screen, you should see "Direct Access to Desire2Learn." Once you click on this, the self-registration option appears.
- 3. Click on "Self-Registration" and you should see a list of courses.
- 4. Please select "Responsible Conduct of Research (a)".
- 5. Once the next screen appears, please click "Register".
- 6. After registering, you will see the Registration Form. Please click "Submit". The registration summary will take you directly to the course. Please use the "Next" button to advance the training. The course is also viewable from the Learn@UW homepage.

7. Once you have completed all modules, please be sure to complete the RCR certification. Please note there is only one question. Once you have answered the question, please submit the quiz.

Notice of Training

PIs receiving NSF funding for research will be notified of this requirement in the NSF Notice of Award. The Office of Research Policy will also notify the PI and the department of the requirements via email. In addition, individuals who must complete training will be identified via payroll records and notified of their training requirements. Once an individual is notified of the requirement, he or she will have 30 days to complete the training module in Learn@UW.

Subsequent email notices will be sent as reminders to complete training. If the individual does not complete the training within the 30 day window, he or she will be removed from the NSF award and paid with non-sponsored departmental funds.

Look-Up Tools

The Office of the Vice Chancellor for Research and Graduate Education has created look-up tools to assist PIs and RCR Coordinators with tracking online course completion. Please use your UW NetID and password to log-in.

Indiana University

[Most of text below was taken directly from various IU websites]

Indiana University subscribes to the Collaborative Institutional Training Initiative (CITI) for online education and training in RCR.

Vice President for Research has an Office of Research Compliance (ORC). Located within ORC is a Research Integrity Office (RIO). The Research Integrity Office was created in 2014 to provide the university with robust resources devoted to not only research misconduct case adjudication, but also the proactive education and prevention of research misconduct. By housing the educational resources, RCR coordination, and case management under one office within the Office of Research Compliance, we can leverage our existing resources and relationships to best serve the mission of compliance and research integrity at Indiana University. RIO provides extensive informational materials, as well as a detailed website on how IU handles research misconduct.

Vice President for Research, Graduate School, Poynter Center for the Study of Ethics and American Institutions, and Office of Research Ethics, Education and Policy offers a series of RCR workshops on topics such as collaboration and authorship, data ownership, access and sharing, integrity and misconduct, human subjects, and intellectual property. Individuals who complete the series receive a certificate. Participation in workshops is encouraged but not required.

Poynter Center for the Study of Ethics and American Institutions offers 2 online resource projects:

- 1. EthicShare.org is a bioethics community resource developed through a partnership with scholars at the University of Minnesota, Indiana University, Georgetown University, Stanford University, University of Virginia and Mississippi State University. This project has been financially supported by the Andrew W. Mellon Foundation, with additional support from the Council on Library and Information Resources, the National Science Foundation, and the University of Minnesota. The resources on EthicShare have been provided through partnerships with the National Reference Center for Bioethics Literature at Georgetown University, the National Library of Medicine, and the OCLC's WorldCat database.
- 2. <u>Ethics CORE</u>, the Collaborative Online Resource Environment for Ethics and Responsible Conduct of Research Resources, is an interactive online resource funded by the National Science Foundation. Ethics CORE gathers and disseminates ethics resources, including educational curricula and onlines courses, reference materials, scholarly research literature and resources available for use in Responsible Conduct

of Research (RCR) education required by NSF and other funders of research. Co-principal investigators are at the University of Illinois. Ken Pimple, from the Poynter Center, is a senior advisor and blogger.

University of Chicago

[Most of text below was taken directly from various University of Chicago websites]

RCR resources at Chicago are provided through the University Research Administration (URA) Office. Within this office is a section devoted to Responsible Conduct of Research [http://ura.uchicago.edu/page/responsible-conduct-research].

Resources that can be accessed through the URA website include the several IRBs at Chicago, the Institutional Animal Care and Use Committee (IACUC), examples of RCR language that PIs can use in submitting NIH grants, PHS policies on research misconduct, NSF's research misconduct regulation, as well as the University of Chicago's academic fraud policy.

Regarding NSF's Certification Requirement in the Responsible Conduct of Research: Each Division/Unit at the University of Chicago is charged with the responsibility to develop a plan to provide appropriate education and oversight in the responsible and ethical conduct of research to undergraduates, graduate students, and postdoctoral researchers within the Division/Unit who will be supported by NSF to conduct research. The University supports the use of the web based training program of The Collaborative Institutional Training Initiative (CITI Program) to satisfy the RCR education requirement, but advises individuals to check first with their Division/Unit for specific guidance. It is ultimately the responsibility of the Principal Investigator of an NSF-sponsored project to assure compliance with the RCR requirement for all undergraduates, graduate students, and postdoctoral researchers working on his/her project. Division plans have been communicated to the faculty and most have been posted to their websites. For those Units of the University which receive very limited NSF funding, URA will inform the PI at the time of NSF proposal submission that RCR education is required should an award be made, and they will be directed to the appropriate CITI website and RCR program based on their discipline. NSF awardees will also be reminded of the RCR education requirement by email when NSF awards are received. The Associate Vice President for Research Administration will act as primary contact with NSF.

University of Chicago subscribes to the Collaborative Institutional Training Initiative (CITI) for online education and training in RCR.

University of Chicago's Institute for Translational Medicine (ITM) has a requirement that all trainees who receive support from NIH or NSF must complete an in-person RCR course at the start of their training and again every 4 years. This requires 8 hours of in-person training. ITM offers such training via an 8-session course that meets for 90 minutes weekly. The course covers the following topics: Introduction to Scientific Integrity and the Responsible Conduct of Research, Ethics of Clinical Research in Developing Countries, Conflicts of Interest: Research and Industry, Intellectual Property/Patents and Tech Transfer, Mentoring: What Can You Expect?, Ethics of Human Experimentation/IRB, Ethical Treatment of Animals in Research, Ethical Issues in Radiation and Radiation Oncology.

University of Illinois

[Much of the text below is excerpted from an email from Jan Novakofski (Associate Vice Chancellor for Research Compliance and Professor of Animal Sciences, University of Illinois) and 2015/2016 RGPEC chair Tony Tamburello]

I think many of us are still working to find "best practices" and I would be grateful if you share the insights you gain from our CIC colleagues.

Do you have an institution-wide policy on RCR training, and if so, what is it?

We have a University <u>Code of Conduct</u> that covers RCR principles broadly (currently being revised) and a <u>Policy and Procedures on Integrity in Research and Publication</u>. We notify PIs with grants requiring RCR of the training requirements each year, but we do not have specific campus policy focused specifically on RCR training.

Are there different approaches/tracks depending on school or the nature of the research?

Yes. We leave the scope, delivery and training itself to investigators. Some Colleges and Departments have developed guides and/or components, others leave it to individuals.

How is RCR education monitored?

The OVCR has built an online reporting tool to monitor type and completion of training campuswide. We periodically combine the list of PIs that we notified with payroll records to identify individuals that may require training, populate the reporting database, and then remind investigators to update training records.

U of I research training page: http://research.illinois.edu/training

For animal research:

Mandatory Training

All individuals involved in research or teaching activities that use animals must complete the Institutional Animal Care and Use Committee (IACUC) online training module Basic Training Program for Animal Users. The Animal Care and Use Occupational Health and Safety (OHS) Program is also mandatory, and all participants must complete the Animal Care and Use Risk Assessment Form on this site, which is used to evaluate the possible health risks due to animal exposures and occupational hazards. Depending on the project, participants may be required to follow the Division of Research Safety (DRS) Biological Safety Training.

The portal to access the mandatory programs and forms requires ID authentication. Access is restricted to University of Illinois faculty, students, staff, and authorized guest users. Contact the IACUC or OHS staff to set up a guest account.

The training must be renewed every three years. Risk Assessment Forms must be updated if exposures have changed due to change in research and/or employment.

Participants are strongly encouraged to complete the confidential <u>Health Screening Questionnaire</u>, which will be used to identify potential additional risks. The Animal Care and Use Program medical reviewer will review the form and communicate information directly to the participant.

Contact the IACUC or OHS staff to set up a guest account. For assistance or additional training, contact the IACUC Office at 333-7789 or iacuc@illinois.edu.

Human subjects training:

The University of Illinois at Urbana-Champaign requires that all faculty, staff, students and researchers listed on a IRB protocol to complete required IRB training. The Office for the Protection of Research Subjects provides guidance and instruction on required training:

•Instructions for IRB Training Modules

•NIH Requirements

- NIH has an intramural <u>Web-based training</u> program that is medically oriented but presents basic information on the ethics of human subject research. It provides a certification of completion.
- For subcontracts and consultants, completion of either a training program at their home institution or completion of the UIUC training module will be sufficient. Principal investigators should maintain documentation of completion.
- Other organized educational programs are acceptable to NIH (see their <u>Web site</u>), but it will be the principal investigator's responsibility to maintain documentation of content and completion by all key personnel.
- •Required Training for Investigators

(CITI training)

University of Maryland

Web site for UMD RCR: http://www.umresearch.umd.edu/RCR/

Undergraduates must take a "primer" for NSF funded research.

NSF Plan: Responsible Conduct of Research (RCR) Education Program

Accessed at:

http://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=3&cad=rja&uact=8&ved=0ahUKEwji37 KL3dvJAhXBWz4KHQcbCK0QFggpMAI&url=http%3A%2F%2Fwww.umresearch.umd.edu%2FRCR%2Fdocs%2FRCR_Plan.pdf&usg=AFQjCNHczZ9BWAGQLuurRqlGxpXUZZ7kXw&sig2=2kdzcEMrBU2oCHMd10zUPg

Accessed on: December 14, 2015

I. Background

On August 20, 2009, NSF published a final version of Section 7009 of the COMPETES Act, which requires the implementation of Responsible Conduct of a Research Training Program. "Effective January 4, 2010, NSF will require that, at the time of proposal submission to NSF, a proposing institution's Authorized Organizational Representative certify that the 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." Other key elements of the new requirement include:

- "While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review upon request."
- "...institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received RCR training."
- NSF will leave it up to the institutions to decide the content and delivery method of the training and how the training will be recorded and tracked.

II. Oversight of Training Compliance

Oversight of the Responsible Conduct of Research training is a responsibility shared by the Principal Investigator (PI) and the University, to be coordinated by the Research Compliance Office (RCO) in the Division of Research.

III. Content/Minimum Core Topics

While each discipline and type of research may emphasize different aspects of ethical training, there are core topics essential for all students and postdoctoral researchers including:

- Responsible Peer Review
- Responsible Authorship
- Data Acquisition and Management
- · Conflict of Interest
- Mentoring
- · Research Misconduct
- Collaborative Research

According to federal regulations, investigators conducting human subject research or animal research are already responsible for the training of all members of their research team.

Undergraduate students who are appointed to an NSF-funded project but do not contribute to the design, conduct, or reporting of that project need to be apprised of a responsible conduct of research overview prior to appointment.

Each student and postdoctoral researcher appointed as an hourly employee, graduate assistant, postdoctoral fellow, research associate, or visiting researcher who contributes to the design, conduct, or reporting of an NSF-funded project shall be trained in the responsible conduct of research.

IV. Delivery Methods and Offerings

Online training modules and interactive mentored discussion workshops will be available as effective delivery methods. Options available for meeting the RCR requirement include:

- One-day workshop offered each semester
- Modular workshops covering the core topics (2-3 modules offered each semester)
- · Graduate course for credit
- Collaborative Institutional Training Initiative (CITI) online educational program

V. Tracking

The RCO will maintain a website to include the following:

- NSF RCR Requirements
- UM NSF RCR Plan
- Schedule of RCR Offerings
- Resource Information Guide
- · Contact Information for Assistance

The RCO will contact all NSF PIs and department administrators quarterly to inform them of upcoming scheduled RCR training opportunities.

It is the responsibility of the PI/College/Department to:

- Notify students and postdoctoral researchers of the training requirement when they are appointed.
- Ensure that any NSF supported students and post doctoral researchers complete the training.
- Maintain verification of completion of the training.

VI. Consequences for Non-compliance

Consequences for non-compliance with the NSF RCR training requirement may include:

- Discontinuance from participation on the NSF-funded project.
- Transfer of salary and related expenditures from the NSF account to a departmental account.

[The following is excerpted from an email from Joseph M. (Joe) Smith, CIM, CIP (Manager, Research Compliance Office, University of Maryland College Park) to 2015/16 RGPEC Chair Tony Tamburello]

The RCR page is the extent of our policy currently. The RCR plan can be found in the upper right corner of the screen: http://www.umresearch.umd.edu/RCR/index.html. We have chosen to follow the requirements of NSF and NIH with regard to the training. Currently, the RCR course are completed online through www.citiprogram.org or as part of the semester-long graduate research ethics course that is offered. The day-long in-person trainings began to occur less and less once the online option became available.

RCR Training is tracked on the CITI Website as well as through an internal Excel spreadsheet that we maintain for the in-person classes. Individuals that complete the training can access their completion record/certificate through CITI and provide it whenever it is needed.

NIH states that an online component can supplement the RCR but that in-person training is best. They are a bit more strict. The in-person is offered as a semester-long course for students, fellows, post-docs who need it.

I am copying Bob Dooling (rdooling@umd.edu) on this email. He is one of the professors that teaches this course and may be able to offer some additional details.

University of Nebraska

There is an office of research responsibility which coordinates training and resources for ethics. The vice chancellor for research heads the office. They have a training matrix showing what different categories of students, staff and faculty need to attend, based on the natore of the ir research and the funding source with which they are involved. They break responsible research training down into the following categories:

- Research involving animals
- Research involving human subjects
- · Research safety
- Export Control
- General responsible conduct of research (concluding conflicts of interest).

Information and links to their resources can be found here: http://research.unl.edu/researchresponsibility/

Nebraska makes extensive use of the Collaborative Institutional Training Initiative at the University of Miami (CITI) RCR series to provide training.

Stephen Goddard, Associate Vice Chancellor for Research (goddard@unl.edu).was contacted. He provided the following information concerning verification, monitoring, and compliance practices:

- 1. We receive a report every semester from our Accounting department of PI's who are funded by the NIH, NSF, and USDA/NIFA. We then notify the PI's of the training requirements and give specific deadlines for completion of the appropriate training for them or their team. If the training is not completed within the allotted time-frame, we ask our Accounting department to stop payment to the corresponding person.
- 2. Eventually we plan to move this process so that our electronic database for tracking research funding with Sponsored Programs flags the appropriate projects with NIH, NSF, and USDA/NIFA funding so that it is no longer a manual process and the PI's are automatically notified.
- 3. Our Sponsored Programs and IRB teams are aware of the RCR training requirements and make sure to communicate any projects that may require training with our Research Compliance Services Office as well.
- 4. For projects that require IRB or IACUC protocol approvals, access to research funding is not activated until the protocols are approved. (More compliance in the projection of human and animal research participants than RCR training.)

Ohio State University

OSU has an Office of Responsible Research Practices, which doubles as the institution's IRB. Its website is available here: http://orrp.osu.edu/. It is overseen by a staff of 20, mostly dedicated IRB staff. They have mandatory training and resources separated into the following areas:

- Animal Care and Use
- Biosafety
- Human Subjects

They offer the following services:

- Consultation about when research or instructional activities involving animals, humans, or biohazards require committee approvals;
- Guidance on meeting regulatory, university, and sponsor requirements pertaining to research;
- Assistance with research submissions, reporting, and recordkeeping
- Delivers online and in-person educational programs focusing on ethical research and regulatory requirements for faculty, staff, and students
- Acts as the central resource for research-related questions and concerns for the university and external community
- Maintains the university's federal assurances and executes cooperative research agreements

Individual departments also have their own guidance documents explaining RCR requirements as it applies to the research of that department (See e.g. http://ehe.osu.edu/downloads/research/ehe-rcr-plan.pdf).

Monitoring and Compliance

The IRB is in charge of compliance. In the case of animal protocols, in order to be listed as a member of any research study team, each prospective team member must be registered on OSU's e-protocol system. The e-protocol system will show if a prospective team member has the required certifications. Conflict of interest issues are handled via a mandatory annual disclosure form that must be filed by all people involved in funded studies.

Compliance involving work with human subjects is the responsibility of the Principal Investigator of a study. The PI is required to file plans for RCR compliance with grant applications and insure that all

team members remain in compliance. The University uses the CITI RCR training course from the Collaborative Institutional Training Initiative at the University of Miami as a general training resource for all researchers (See https://www.citiprogram.org/).

As to monitoring and compliance, there is a Study Team Lookup application which allows investigators to see the training and compliance status of team members. They have an extensive listing of resources, including phone numbers, and an online reporting system for the reporting possible ethics or RCR breaches.

Northwestern University

Northwestern University has an Office for Research Integrity that lives within the Research Office along with the IACUC, IRB, Office for Research Development, Office for Sponsored Research etc...

There are 5 staff members including a Director, 2 Senior Compliance Specialists, a Research Training Manager and an Administrative Assistant. An email to Lauran Qualkenbush (lhaney@northwestern.edu) answered questions on implementation which were incorporated below.

There is a website that discusses their RCR requirements and courses for undergrads, graduate students postdocs and faculty/staff http://www.research.northwestern.edu/ori/training/rcr/index.html

On the website is a link to federal requirements for RCR listing NSF and NIH detailed requirements.

Effective Sept 2015, RCR training is managed through a new training management system Learn@Northwestern. NSF RCR is in the first round of roll outs. Their system identifies NSF awards, then who is paid from these awards and depending on their personnel code (student, post doc, etc) and school or program assigns RCR training to their plans, sends an email notification and then the trainees have to register and complete the training. This is how they monitor who has taken the required courses and modules. This learning management system was purchased from Saba and is going to be rolled out university-wide for all training.

- Undergrads supported by NSF awards (as identified from payroll using Learn@Northwestern –this is a limitation of their system since it does not account for undergrads who are doing research for credit) must complete RCR training within 60 d of the salaries being charged to the account. There are 9 online CITI training modules that undergrads are required to do (1.5-2 hr).
- All grad students supported by NSF awards must complete RCR training within one year of salaries being charged. In addition, some programs/departments may require RCR training for all grad students, regardless of funding which the staff acknowledges makes it easier to catch everyone. RCR training is satisfied by completion of instructor-led training courses. There is guidance as to which course is most appropriate.
- All postdocs supported by NSF awards must complete RCR training within one year of salaries being charged. In addition, some schools/departments may require RCR training for all postdocs, regardless of funding which the staff acknowledges makes it easier to catch everyone. RCR training is satisfied by completion of instructor-led training courses and some schools/departments may require web-based CITI training modules. There is guidance as to which course is most appropriate.
- Faculty who receive funding from NIH must receive RCR training. All faculty are encouraged to participate in RCR education. Junior faculty and postdocs who received NIH funding can take the NUCATS Taking Responsibility for Responsible Conduct of Research course.

Along with the tab for Training, there is also a list of University Policies regarding Research misconduct and the procedures and guidelines for handling research misconduct, reporting concerns, resources, research roles, news etc.

Penn State

The Office of Research Protections (ORP) lives within the Office for Research and offers classes in RCR, IRB, IACUC, etc.

For the educational programs there is an Assistant Director, a Research Ethics Educator and an Education Assistant.

The main website that lists education and training resources is http://www.research.psu.edu/training/education-and-training

They have a summary of NSF and NIH requirements and then a statement which can be used for grant proposals about SARI@PSU program and to summarize what is done at Penn State.

SARI@PSU (Scholarship and Research Integrity at PSU) is the portal that offers comprehensive, multilevel education in RCR that is tailored to address the issues of specific disciplines.

- Undergrad researchers are required to take an online CITI course and discussion based activities are optional. The tracking is done by the faculty advisor so they must keep a copy of the certificate on file.
- Graduate students are required to take both the online CITI training and 5 hours of discussion prior to graduation. The graduate programs recommend certain modules and electives and track compliance and report to the ORP annually through the ANGEL system. Colleges must describe and document the specific curriculum to ORP. For the CITI Training that includes: how students will be made aware of the requirement, when students will be expected to complete the requirement and how participation will be monitored. For the discussion based training that includes: type of program to be offered, frequency of offering, RCR topics to be discussed, how the discussion will be facilitated and how the training will meet the needs of students in particular disciplines within the college.
- Postdocs are required to take an online CITI course and discussion based activities are optional. The
 tracking is done by the faculty advisor so they must keep a copy of the certificate on file.
- New full-time faculty are expected to do the online CITI course within 12 months of hire. They also must participate in 2 hours of discussion-based activities plus 1 hour every 3 years. Workshops that are offered by the university as well as at professional conferences can count. Tracking is done by ORP in collaboration with faculty self-reporting into the website and enforcement by colleges. IRB training can count as RCR training.

On their website, for each RCR topic, they offer teaching tools that include background, Penn State policies, federal policies, powerpoints, case studies, online learning tools and articles. They also offer classes, workshops, seminars, online resources and training as well as custom on-request education programs.

University of Michigan

http://research-compliance.umich.edu/responsible-conduct-research-rcr-training

The University of Michigan is committed to fostering an environment of responsible conduct of research.

As such, U-M follows federal, state, and university guidelines regarding Responsible Conduct of Research (RCR) training for principal investigators, key personnel, and students. These guidelines may apply to a specific type of research compliance (e.g., conflict of interest, animal care and use, human subjects protection) or to topics related the proper conduct of research (e.g., authorship).

Recommended RCR components

Format: Face-to-face discussion (e.g., small group, case studies) with faculty participation in the training. Limit

online instruction.

Subject matter: Successful RCR training programs include instruction in:

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

University of Michigan Guidelines

To meet NSF requirements, each U-M school/college has developed a Responsible Conduct of Research training program for undergraduates, graduate students, and postdoctoral researchers. Contact your school/college for information regarding RCR training.

PEERRS

The University's online Program for Education & Evaluation in Responsible Research and Scholarship (PEERRS) offers eLearning courses for investigators and others at U-M to fulfill compliance-specific training regulations, such as that for human subjects protections. PEERRS contains a course called, Research Practice Foundations, which covers many of the recommended RCR topics. Separate courses are available to learn about the policies and guidelines related to:

- Conflicts of Interest
- Human Subjects Protection
- Animal Care & Use

For students and postdoctoral researchers, PEERRS courses may be considered pre-requisites, but are not an equivalent for a U-M school/college RCR training program. PEERRS courses commonly cited as pre-requisites in school/college RCR programs are the Research Practice Foundations and Authorship courses.

PEERRS is the University's online Program for Education & Evaluation in Responsible Research and Scholarship.

U-M Principal Investigators: take applicable PEERRS courses to fulfill RCR and compliance-specific training requirements.

U-M Students & Postdocs: take applicable PEERRS courses upon direction of your school/college.

More information about PEERRS courses here, including a table of who takes what course: http://my.research.umich.edu/peerrs/

Ouestions?

For questions regarding specific RCR training programs, contact the applicable U-M school/college

For questions regarding PEERRS, see http://my.research.umich.edu/peerrs/ or email PEERRS@umich.edu (link sends e-mail).

University of Iowa

http://research.uiowa.edu/researchers/policies-and-compliance/responsible-conduct-research

Overview

In order to meet the institutional obligation to provide RCR training, The University of Iowa has developed a Responsible Conduct of Research Plan under the joint sponsorship and responsibility of the Graduate College and the Office of the Vice President for Research.

RCR Plan (pdf): file:///Users/janeotto/Downloads/ovpr rcr plan sept 15-15.pdf

Responsible Conduct of Research (RCR) Training Process

Our current RCR program focuses on four groups specifically engaged in NIH and/or NSF- funded research or other scholarly creativity involving undergraduates, predocs, postdocs and early career faculty holding NIH K-Awards. For the purposes of RCR education, members of these four groups are designated as trainees.

If the trainee is engaged in research that is funded by NIH, NSF, or NIFA (e.g., investigator initiated, career award, fellowship, or training grant), then the trainee must complete the appropriate RCR program described on page 2 of the RCR plan.

Program	Course Name	Eligibility and Timeframe	Tuition	Notes	
Undergraduate a	Undergraduate and Professional (all AuD, DDS, DNP, MD, MHA, MPH, MSN, PharmD) Degree Students				
Phase 1 online CITI training *	RCR modules according to role in research of trainee	Trainees may complete modules at their own pace, but must complete the entire course RCR course within the first month of research participation.	No cost to trainee	Trainees will access the CITI site through a UI portal designed to track and record their progress. Records of completion will be automatically generated, electronically maintained, and may be transferrable to other institutions.	
* Once logged in, choose Responsible Conduct of Research (CITI) under "Training" Once logged in to the external site, click on "University of Iowa Courses" to expand the menu. Next, click "Add a course or update your learner groups for University of Iowa" Next select "I am required to complete Responsible Conduct of Research (RCR) training" and choose the most appropriate course among the 5 choices provided: Biomedical RCR, Social Sciences RCR, Physical Science RCR, Humanities RCR, Engineers RCR					
Predoctoral (Masters and Doctoral Degree) Students, Postdoctoral Fellows and K-Award Faculty					
Phase 1 Online CITI Training *	RCR modules according to role in research of trainee	Trainees may complete modules at their own pace, but must complete the entire RCR course within the first month on federal funding.	No cost to trainee	Trainees will access the CITI site through a UI portal designed to track and record their progress. Records of completion will be automatically generated, electronically maintained, and	

	may be transferrable to other institutions.
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^{*} Once logged in, choose Responsible Conduct of Research (CITI) under "Training" Once logged in to the external site, click on "University of Iowa Courses" to expand the menu. Next, click "Add a course or update your learner groups for University of Iowa"

Next select "I am required to complete Responsible Conduct of Research (RCR) training" and choose the most appropriate course among the 5 choices provided: Biomedical RCR, Social Sciences RCR, Physical Science RCR, Humanities RCR, Engineers RCR

Phase 2 Faceto-Face Discipline Specific RCR courses

Different course titles in each academic unit.

Open to trainees in specific academic units or by special permission. Offered in either Fall or Spring semesters depending on the academic unit. Trainees must enroll and complete the approved faceto-face RCR course after completion of the Phase 1 CITI training

For graduate students, this course will factor into student registrations and will be subject to the <u>UI Tuition and Mandatory Fees Table</u> in effect at the time.

No cost to postdoctoral or K-Award trainees Course completion will be recorded on the student's transcript and can be reported to other institutions.

Additional Programmatic RCR training

NIH T32 trainees may be required to complete specific T32 RCR training identified by their individual NIH training programs.

Graduate Students and Postdoctoral Researchers

Click here to review the Graduate College's policies and recommendations for all graduate students and postdoctoral researchers involved in federally funded research:

 $\underline{https://www.grad.uiowa.edu/postdoc/responsible-conduct-of-research}$

Frequently Asked Questions (FAQs) and Additional Resources

How do I sign-up for and complete RCR training?

Trainees are required to complete the appropriate RCR program based on their current university position (undergraduate, predoc, postdoc, or K-Award faculty). Details regarding each training plan are available on page 2 of the RCR plan and the RCR Training Summary table above.

Who must receive RCR training?

The National Science Foundation (NSF) expects institutions to be able to verify that those students (undergraduates and graduates) and postdoctoral researchers who receive NSF funds (support from salary and/or stipends to conduct research on NSF grants) will obtain RCR training. However, NSF anticipates that institutions will develop their RCR training programs in a manner that helps prepare the next generation of researchers, including the consideration of risks or other factors associated with student and postdoctoral researcher participation in research.

The National Institutes of Health (NIH) policy 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.

USDA's National Institute of Food and Agriculture (NIFA) has mandated that program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in the research project receive appropriate training and oversight in the responsible and ethical conduct of research.

Does the RCR training plan have to be in place at the time of proposal submission?

Yes, a RCR training plan must be in place at the time of proposal submission. Additional details regarding NIH proposals are available here: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

Additional Resources

UI Implementation of Responsible Conduct of Research Requirements," presented 12/01/2010 at the Research Administrator's Meeting. (See link at http://research.uiowa.edu/researchers/policies-and-compliance/responsible-conduct-research#FAQs)

RCR References and Web sites

The AAAS references and online resources on the Responsible Conduct of Research

NSF Federal Register Notice on RCR Implementation: Federal Register Notice of August 20, 2009 (Volume 74, Number 160)

ORI's RCR Education Materials Clearinghouse

National Academy of Engineering Workshop Report: Ethics Education and Scientific and Engineering Research: What's Been Learned? What Should be Done? (2009)

Collaborative Institutional Training Initiative, University of Miami, CITI Responsible Conduct of Research Program Extensive on-line RCR courses provide a significant source of instructional material

Steneck, N.H. (2004) ORI Introduction to the Responsible Conduct of Research An introduction to RCR, with a useful list of resources in its bibliography

Poynter Center for the Study of Ethics and American Institutions, Indiana University. Resources for Teaching Research Ethics

Board on Health Sciences Policy and Institute of Medicine (2002) Integrity in Scientific Research: Creating an Environment That Promotes Responsible Conduct. Washington, DC: National Academies Press. Focuses on research integrity in the biomedical sciences. Note in particular Chapter 5: "Promoting Integrity in Research through Education" which contains advice on how to teach RCR and how it should be integrated with the teaching of basic research skills

Fischer, B.A. and Zigmond, M.J. (2001) "Promoting Responsible Conduct in Research Through "Survival Skills" Workshops: Some Mentoring is Best Done in a Crowd." Science and Engineering Ethics 7(4): 563-87. Addresses the efficacy of "survival skill"-types of programs for teaching graduate student

Korenman, S.G. and Shipp, A., eds. (1994) Teaching the Responsible Conduct of Research Through a Case Study Approach: A Handbook for Instructors. Washington, DC: Association of American Medical Colleges. Guidance and useful case studies for teaching RCR

Contact Information

Questions and comments on the overall RCR Plan or the CITI online training may be directed to: Richard Hichwa, Senior Associate Vice President for Research, 319-335-2106

Questions on the formal course requirements may be directed to: Shelly Campo, Administrative Fellow, Course Director, Principles of Scholarly Integrity, 319-335-2136

University of Minnesota

The University of Minnesota has an RCR program for all students and employees and a University Policy Education in the Responsible Conduct of Sponsored Research and Grants Management" (see attached copy of the policy). Organizationally, there is an Office of Research Education & Oversight (http://research.umm.edu/reo/) within the Office of the Vice President for Research (OVPR) under the directed by **Sarah Waldemar** (612-624-8349; s-wolg@umn.edu). The office has oversight over research compliance areas (e.g., IACUC, IRB, COI, etc.) as well as providing a website with information for the RCR CORE Curriculum with training requirements for faculty, students, and postdoctoral fellows (http://research.umn.edu/reo/education/core.html).

From the University of Minnesota Policy (https://policy.umn.edu/research/responsibleconduct):

- Faculty, staff, and students who participate in research and scholarship projects are required to complete training that is appropriate for the role they will serve on the project and meets sponsor regulations. Sponsor regulations, University policies, and the supervisors of staff and students will determine the appropriate level of training.
- The OVPR has the responsibility to ensure that PIs, investigators, and their staff and students have access to the necessary information and supporting resources to meet RCR.
- Research funding is not released until faculty and staff complete RCR education requirements.

- The OVPR is responsible for establishing and maintaining an RCR program; consulting with faculty, administrative, and/or research staff for guidance on the content and delivery the RCR program; and track and maintain information on participation in RCR and NSF/USDA-NIFA education activities and assess the ongoing effectiveness of the research education program.
- The College/Unit Research Dean (or equivalent) is responsible for ensuring faculty, staff, and students complete research education requirements and providing advice and guidance for RCR.
- Department heads are responsible for ensuring faculty, staff, and students complete research education requirements and monitoring completion of requirements by research staff and students.
- PIs and Faculty must complete the RCR training and ensure that staff and students complete research education requirements appropriate for the role.

From the U Minn RCR website (http://research.umn.edu/reo/education/core.html):

- Completion of RCR core curriculum is required to become eligible as a principal investigator.
- The RCR core curriculum version is based on discipline or type of research: RCR Core—Arts & Humanities; RCR Core—Biomedical Sciences; RCR Core—Engineering & Technology; RCR Core—Natural & Physical Sciences; RCR Core—Social & Behavioral Sciences.
- The website provides information regarding "Sponsor Requirements" for the different standards for RCR training standards depending on funding source of the grant personnel (NIH, NSF, USDA-NIFA).
- The website provides language for inclusion in NIH grants: "The RCR core curriculum includes basic principles that are based on key concepts and best practices of research integrity. It is an online workshop. The core curriculum can be completed in 6-8 hours. The workshops were developed by national and international subject matter experts and University of Minnesota faculty members. The workshops include interactive materials, video presentations, and review of case studies. They address the following ethical topics: Social and Professional Responsibilities, Reporting Misconduct, Mentoring, Authorship, Plagiarism, Peer Review, Fiscal Responsibilities, Intellectual Property, and Research Data Management."

ADMINISTRATIVE POLICY: Education in the Responsible Conduct of Sponsored Research and Grants Management

Responsible University Officer: Vice President for Research

Policy Owner: Director - Research Compliance Office

Policy Contact: David March

POLICY STATEMENT

Faculty, staff, and students who serve in various capacities on research and scholarship projects are required to complete training that is appropriate for the role they will serve on the project and meets sponsor regulations. Sponsor regulations, University policies, and the supervisors of staff and students will determine the appropriate level of training. The Office of the Vice President for Research has the responsibility to ensure that PIs, investigators, and their staff and students have access to the necessary information and supporting resources to meet expectations about the responsible conduct of research.

Research funding from internal and external sources will not be released for faculty and staff who fail to complete research education requirements. Other policies address requirements related to research and may impose additional consequences for non-compliance.

REASON FOR POLICY

This policy implements the principal investigator and researcher eligibility requirements contained in Board of Regents Policy: Submitting and Accepting Sponsored Projects and Board of Regents Policy: Code of Conduct, and establishes the expectation for a training program to meet the shared responsibility for the responsible and ethical conduct of research.

This policy also articulates the shared commitment of the University and its faculty, staff, and students to ethical behavior and fulfillment of the fiduciary duties of public funding that are fundamental to the responsibility of serving as principal investigator (PI) or in another role on projects of research and scholarship.

In addition, various government and other agencies set standards and requirements for education and training in the responsible conduct of research. This policy ensures, where applicable, the scope of the University's program for the responsible conduct of research includes such additional requirements.

PROCEDURES

Education Requirements for PI Eligibility

Research Ethics Training Requirement for NSF and USDA-NIFA

FORMS/INSTRUCTIONS

http://www.research.umn.edu/reo/education/documents/NSFRequirementCompletionForm.docx

APPENDICES

There are no appendices associated with this policy.

FREQUENTLY ASKED QUESTIONS

There is no FAQ associated with this policy.

ADDITIONAL CONTACTS

Primary Contact(s) David March; 612-624-1229; march016@umn.edu

Other Contact: REO Helpline; 612-625-9057; ovprreo@umn.edu

DEFINITIONS

Principal Investigator (PI): The individual or individuals primarily responsible for and in charge of a sponsored project.

Responsible Conduct of Research (RCR): Term used in many contexts; in general, the rules, regulations and best practices used to guide research and scholarly activities to produce results that are honest, accurate, efficient and objective. The University also uses this term to define the expectations included in Subd7, Board of Regents Policy: Code of Conduct, and to describe its education program.

RESPONSIBILITIES

Office of Vice President for Research

- Ensure establishment and maintenance of a program to address the education needs for responsible conduct of research for faculty and investigators involved in externally and internally funded research and scholarship;
- Consult with faculty, administrative, and/or research staff for guidance on the content and delivery of the educational materials and other program requirements;
- Publicize the research education program to all faculty, staff, and students; and

• Track and maintain information on participation in RCR and NSF/USDA-NIFA education activities and assess the ongoing effectiveness of the research education program.

Associate Dean for Research or equivalent for College or Unit

- Ensure faculty, staff, and students complete research education requirements appropriate for their role on the project and/or required by the sponsor or the University;
- Publicize the research education program to faculty, staff, and students in college or unit; and
- Provide advice and guidance for research education program, as needed.

Department Heads

- Ensure faculty, staff, and students complete research education requirements appropriate for their role on the project and/or required by the sponsor or the University;
- Publicize the research education program to faculty, staff, and students in department; and
- Monitor completion of requirements by research staff and students, as needed.

PIs and Faculty

- Complete the University's responsible conduct of research requirement (RCR);
- Be aware of appropriate training and/or required training requirements for staff and students working on project; and
- Ensure staff and students complete research education requirements appropriate for the role they will have on the project and/or as required by the sponsor or the University.

Research staff and students

- Be aware of research education requirements appropriate for the role they will have on the project and/or as required by the sponsor or the University; and
- Complete research education requirements appropriate for the role they will have on the project and/or as required by the sponsor or the University.

RELATED INFORMATION

Related Policies

- Board of Regents Policy: Submitting and Accepting Sponsored Projects
- Board of Regents Policy: Code of Conduct

HISTORY

Amended: April 2014 - Comprehensive Review, Minor Revision. Eliminated both (annual and every three years) Responsible Conduct of Research (RCR) continuing education requirements; eliminated Administrative Procedure: Requesting A Time Extension for RCR Completion; added Administrative Procedure: Research Ethics Training Requirement for NSF and USDA-NIFA.

Effective: June 2010

ADMINISTRATIVE PROCEDURE: Education Requirements for PI Eligibility

Related Policy: Education in the Responsible Conduct of Sponsored Research and Grants Management

To be eligible to serve as a PI, the University of Minnesota responsible conduct of research (RCR) curriculum must be completed. It is recommended that new faculty and researchers complete the following within their first

90 days at the University:

• Responsible Conduct of Research (RCR) Core; (details available: http://research.umn.edu/reo/education/core.html)

Completion of research education requirements is tracked electronically. When a proposal for funding is submitted or an award is received, completion records are verified to ensure the PI has completed the RCR core curriculum. If not, an email reminder about the requirement is sent to the PI. Submission of the proposal is not delayed, but set up of the award account is delayed if the requirement is not completed at the time of the award.

Depending on the nature of the research/investigation, additional training in one or more of the following may be required:

- o Conflicts of Interest (details available: http://www.compliance.umn.edu/conflictHome.htm)
- o Human subjects protection (details available: http://www.research.umn.edu/irb/training.html)
- o Sponsor-Investigator on Drug or Devices studies (details available: http://www.research.umn.edu/irb/training.html)
- o Protecting animal subjects (details available: http://www.research.umn.edu/iacuc/index.cfm)
- o HIPAA (details available: http://www.ahc.umn.edu/privacy/home.html)
- o Environmental health and safety (details available: http://www.dehs.umn.edu/)

ADMINISTRATIVE PROCEDURE: Research Ethics Training Requirement for NSF and USDA-NIFA

Related Policy: Education in the Responsible Conduct of Sponsored Research and Grants Management

The National Science Foundation (NSF) and the National Institute of Food and Agriculture (NIFA), U.S. Department of Agriculture (USDA) require institutions to provide appropriate training and oversight in the responsible and ethical conduct of research to everyone who participates in or conducts research supported by funding from these agencies, including undergraduate and graduate students, postdoctoral fellows and staff. Institutions are required to detail their plans to meet this requirement, and document completion of the training.

The University of Minnesota meets this requirement with the following procedures:

1. Background

Three main topics were selected as the primary focus for this training to support the idea that students involved in research will likely become the next generation of researchers and scholars, and that this training should create a foundation for their future research and investigation. While each discipline and type of research may drive different kinds of ethical training, there is a core set of topics that training for any student researcher should address to create a foundation for their future research and investigation:

- Authorship & Plagiarism roles and responsibilities of being an author; how different disciplines approach co-authorship; how to define, identify, and avoid the many forms plagiarism can take
- Data/Research Integrity how to collect, store, protect, and share data in ways that protect the validity and accuracy of the research and scholarship
- Reporting Misconduct responsibilities of student researchers for identifying and reporting misconduct; University resources for reporting and for self-protection

Oversight and tracking of the training is a responsibility shared by the PI and the University, to be coordinated by the Office of the Vice President for Research (OVPR), Research Compliance Office (RCO). PIs and their academic units will be responsible for identifying current courses and activities that

meet the requirement and encourage the development of new courses and activities. OVPR will provide infrastructure to identify and notify students who need the training and maintain completion records.

2. Structure for Training

Format: In-person training is the best format to facilitate discussion and in-depth consideration of these topics. However, online training is the more realistic option, given existing resources. The online training must incorporate some sort of interactive element, such as synchronous or asynchronous online chats or discussions, or the ability to assess understanding.

Length of training: The minimum topics must be addressed in a substantive way. While no minimum time is dictated, experience indicates that at least 2 hours are needed to cover this material.

Due dates: Students must be enrolled in a semester-long course or have completed this training activity within 30 days after they begin to be funded by the project. If enrolled in a course that extends beyond 30-day deadline, successful completion of course will be verified.

Other training: The research ethics training will not substitute for other coursework that must be completed because of the nature of the research being conducted, e.g., human subjects' protection, animal subjects' protection, lab safety, etc.

3. Options for completing training requirement

OVPR maintains a list of courses, seminars and activities approved to meet the NSF and USDA-NIFA research ethics training requirement, at http://www.research.umn.edu/reo/education/funded.html

Postdoctoral Researchers:

Postdoctoral researchers can complete the Collaborative IRB Training Initiative (CITI) Responsible Conduct of Research curriculum (see approved course list for details). Postdoctoral researchers who plan to apply for funding as a University of Minnesota principal investigator (PI) must complete the University's Responsible Conduct of Research (RCR) core curriculum. For details, see http://www.research.umn.edu/reo/education/core.html

Graduate and Undergraduate Students:

Students complete the requirement in one of the following ways:

- Complete a course or seminar that has been approved to meet the requirement and submit the signed Completion Form to ovprreo@umn.edu;
- Complete the Collaborative IRB Training Initiative (CITI) Responsible Conduct of Research curriculum (see approved course list for details); or
- Complete some other unit/department-developed course or activity that has been approved to meet the requirement and submit the signed Completion Form to ovprreo@umn.edu.

4. Approval process for courses, seminars, and other activities

The Associate Dean for Research or equivalent for each college or academic unit serves as a clearinghouse to identify and approve courses, seminars, and other activities that meet this requirement. RCO publishes and maintains the list with information from the academic units.

5. Notification

Reports will be generated to identify the students, postdocs and staff who are being paid from these sponsored projects, based on UMN payroll records for the appropriate employee categories. An automated e-mail will be sent to the individuals who have not yet completed the required training, based on this report. A copy of the email will also be sent to the PI on the project and to the Resource Responsibility Center (RRC) Manager

assigned to the unit. The email will contain information about the requirement, the options and deadline for completing it, and the consequences for failure to do so.

6. Oversight and tracking of requirement

Oversight and tracking of this research ethics training requirement is a responsibility shared between PIs, departments, and OVPR/RCO. Completion of for-credit courses and the CITI RCR curriculum will be tracked electronically. If students complete non-credit seminars or activities, the coordinating department or program must submit a list of participants to RCO, or the individual student must submit a Completion Form to RCO. All data entry of completed courses or activities is done by RCO staff.

7. Failure to complete training

If the requirement has not been met at the 30-day deadline, a final reminder email will be sent to the student, PI, RRC Manager, and to the Associate Dean for Research or equivalent for the collegiate unit. If the training is not completed after this final reminder, RCO will work with Sponsored Financial Reporting (SFR) to remove the individual's salary and fringe benefits charged to the project to a departmental non-sponsored default account until the requirement has been met.

APPENDIX IV

Summary of Rutgers RCR programs prepared for 2015 NSF site visit by Judith Neubauer
Associate VP for Research Regulatory Affairs
Office of the Vice President for Research & Economic Development

Rutgers University's Responsible Conduct of Research Programs

The ethical conduct of research is a core value for all of the research conducted at Rutgers University. In addition to the Responsible Conduct of Research programs offered by the Rutgers Graduate Schools, Rutgers has several research policies and mandatory training requirements governing the various facets of ethical conduct of research. It starts with the Rutgers Academic Integrity Policy (Appendix 1; http://www.academicintegrity.rutgers.edu/academicintegrity-policy) which serves as a foundation for all aspects of academic integrity including responsible conduct of research for all undergraduate, graduate and postdoctoral trainees. The essentials of the Academic Integrity Policy are discussed at all new student orientations and workshops in the Fall semester. The Academic Integrity Policy is a prominent section of the "Scarlet Guide: A Resource for Getting Started at Rutgers University" which is tailored for each of the Schools at Rutgers (see Appendix 2 for an example). In addition, Rutgers has specific policies and training requirements that govern ethical research conduct for all investigators including the Rutgers Investigator Conflict of Interest Policy (Appendix 3, http://policies.rutgers.edu/9025-currentpdf), Rutgers Research Misconduct Policy (Appendix 4; http://policies.rutgers.edu/9022-currentpdf), and Rutgers Export Control Policy (Appendix 5; https://ored.rutgers.edu/sites/ored.rutgers.edu/files/7-1-13_Rutgers_Export_Control_Policy.pdf). In addition, there are policies and guidance for research when the research involves human subjects, animals, controlled substances, biohazards or stem cells: the Rutgers Policy for Human Subjects Protection and the Institutional Review Board (Appendix 6; http://policies.rutgers.edu/90211-currentpdf) which is supplemented with multiple policies and guidance for human subject research (https://orra.rutgers.edu/irb-guidance-2) and mandatory training required with completion of the CITI Human Subject Protections Course; the Rutgers Animal Welfare Policy Governing the Use of Animals in Research, Teaching, Testing and Production governs the ethical use of Animals in Research (**Appendix 7**; https://orra.rutgers.edu/rutgers-university-animal-welfare-policy-0) with mandatory training requirements for use of animals in research (https://orra.rutgers.edu/animal-orientation-training); the Rutgers Controlled Substances Policy (Appendix 8; http://policies.rutgers.edu/9023currentpdf) provides ethical oversight of controlled substances used in research, the Biosafety, Radiation and Laboratory Safety policies (see http://ored.rutgers.edu/content/biosafety-radiationand-laboratory-safety) provide for ethical use of biohazards, pathogens and radiation in research; and policies, guidance and training are provided to assure ethics of stem cell research http://stemcellcourse.org/EthicsinhESCResearch.php. Finally, Rutgers has contracted with the Collaborative Institutional Training Initiative (CITI) to provide online educational modules including Responsible Conduct of Research (RCR).

To meet the January 4, 2010 mandate of the National Science Foundation (NSF) that every institution receiving NSF funds implement training for the Responsible Conduct of Research (RCR) for all trainees supported with NSF funds, the Rutgers University Office of Research and Sponsored Programs, which is responsible for all pre-award submission of grants and contracts, informs the principal investigators of NSF grants of the requirement either formally (**Appendix 9**) or informally and assists them in identifying an appropriate Responsible Conduct of Research program. These RCR programs are offered by the Rutgers Graduate Schools (Graduate School of Biomedical Sciences–New Brunswick, Graduate School of Biomedical Sciences–Newark, Graduate School-New Brunswick and Graduate School-Newark) each of which offers programs as described below.

I. Rutgers Biomedical Health Sciences (RBHS)

A. RBHS New Brunswick:

RCR plan: The Rutgers University Graduate School of Biomedical Sciences (GSBS) at Robert Wood Johnson Medical School offers an annual Ethical Scientific Conduct course (http://rwjms.rutgers.edu/education/gsbs/current/ethics.html) for the purposes of Responsible Conduct of Research (RCR) training (GSBS Course # IDST 5000; Rutgers GS Course # 16:115:556). The *duration* of the course is for one semester and participants are required to attend a minimum of eleven, one-hour weekly meetings. The subject matter of the course addresses the following topics: Mentor-Mentee Responsibilities and Relationships; Plagiarism, Academic Rules and Copyright; Data Acquisition and Laboratory Tools: management, sharing and ownership; Research Misconduct and Policies for Handling Misconduct; Responsible Authorship and Publication; Conflict of Interest - personal, professional, and financial; Scientist as Responsible Member of Society; Collaborative Research in Academia and Industry; Peer Review; Policies for Animal Subjects in Research; Policies for Human Subjects in Research; Contemporary Ethical Issues in Biomedical Research and the Environmental and Societal Impacts of Scientific Research; Intellectual Property and Technology Transfer. The format of the course is weekly meetings conducted as a large group lecture for 25 min followed by small group (~10 students/group) discussion of cases for 25 min. Faculty participation includes both the large group lecture conducted by an expert in the field who is affiliated with Rutgers University and the small groups facilitated by Rutgers faculty actively conducting research who represent each of our 9 joint graduate programs. The large lectures can have assistance as necessary from regulatory experts from the schools and are video captured to allow for review. Graduate students register and receive one credit for completion of the requirements. To allow for additional frequency of instruction fellows and others are provided a certificate of completion after attendance at a minimum of eleven meetings. F33 and K award recipients at Rutgers can either take the class themselves and/or lead small group sessions. Initial training is required for all first year graduate students and postdoctoral fellows on training grants who have not completed a course in RCR in graduate school. RCR training is required at least once per education stage and no less than once every 4 years. To this end, refresher training is required for all fifth year graduate students and postdoctoral fellows on training grants who have completed a course in RCR in graduate school. Refresher training consists of 8 hours of small group case discussion lead by faculty.

Number of participants:

	Year	GSBS New Brunswick	GSBS New Brunswick
		Students	Postdoctoral Fellows
2010		64	0
2011		57	0
2012		67	0
2013		63	3
2014		58	2

The RCR course is mandatory for all graduate students. A small number of postdocs have attended the course.

Description of materials that are provided to participants: Materials consist of powerpoint lectures, case studies, relevant journal articles and written assignment questions. Some of the cases for the course come from:

Korenman, SG and Shipp, AC, Eds. <u>Teaching Responsible Conduct of Research Through A Case Study Approach: A Handbook for Instructors.</u> Washington, DC: Association of American Medical Colleges, 1994.

National Academy of Sciences, National Academy of Engineering, Institute of Medicine *On Being a Scientist: A Guide to Responsible Conduct in Research, Third Edition.* Washington, DC: The National Academy Press, 2009.

Macrina, FL Scientific Integrity, 3rd Edition. Washington, DC: ASM Press, 2005.

Another resource is "*The Lab, Avoiding Research Misconduct*" prepared by the Office of Research Integrity of the Department of Health and Human Services which is an interactive movie that allows the viewer to choose the outcome of the film based on ethical decisions facing the four characters. The movie can be accessed online at http://ori.hhs.gov/TheLab.

For refresher training, cases are taken from The Office of Research Integrity http://ori.hhs.gov/rcr-casebook-stories-about-researchers-worth-discussing.

Financial and staffing resources available to the program: There is a course director whose salary is supported in part by GSBS at RWJMS. There are also two administrative assistants at GSBS at RWJMS who help with room scheduling, course website maintenance and attendance records.

B. RBHS GSBS Newark:

RCR plan: The Rutgers University Graduate School of Biomedical Sciences (GSBS) on the Newark campus at New Jersey Medical School offers an annual Responsible Conduct of Research course (GSBS Course #GSND 5001) which is mandatory for all PhD students. **Format:** The course is designed as an introduction to graduate level ethics and the responsible conduct of research. GSBS Newark recognizes the importance of training in and analysis of the "practice of scientific investigation with integrity" and strives to address application of ethical principles to all aspects of the scientific enterprise. The classes are a combination of lectures and group discussions of case studies. In some cases, small groups are formed; in others, the entire class engages in the discussion. There is no on-line component to this course. There is no assigned text, but each student is provided with copies of the lecture slides and case studies. Case studies are based on those found in the texts listed below. Attendance is recorded for every class: make-up essays are required for more than 2 missed classes. If a student misses four classes, s/he is must repeat the course the following year. Subject Matter: The topics that are covered every year are Dual Use Research, Human Experimentation, Biosafety and the IBC, Stem Cell Ethics, Misconduct/fraud, Publications, Biomedical Ethics, Patent/ Copyrights, Funding/ Peer Review, Interpersonal Relationships, Animals in Research. Faculty participation: Training faculty are identified from among the graduate school faculty and chosen for their ability to lead discussions, to engage the students' interest, and their knowledge of the issue. In the case of compliance and regulatory issues (IRB, IBC and IACUC, for example) the lecturers represent those specific research cores and offices and have

first-hand experience. *Duration of instruction:* the course meets 11 times for 1.5 hours (16.5 hrs total). *Frequency of instruction:* the course is required once per career stage, and meets in the spring semester of PhD candidates' second year.

Number of participants:

Year	GSBS
	students
2010	33
2011	44
2012	82
2013	46
2014	37
2015	44

The RCR course is mandatory for all graduate students. A small number of postdocs have attended the course *ad hoc*; no formal mechanism for recording their attendance exists.

Description of materials that are provided to participants:

Texts (serving as sources of case studies and material for faculty):

Biomedical Ethics by David Degrazia, Thomas A. Mappes and Jeffrey Brand-Ballard, McGraw-Hill, 2011.

Scientific teaching, by Jo Handelsman, Sarah Miller and Christine Pfund, Freeman and Co. 2007

On Being a Scientist: Third Edition, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine, 2009.

General Resources available on the Office of Research Integrity website at http://ori.hhs.gov/education/

Other original documents including as examples:

The Belmont Report, 1979 (http://www.hhs.gov/ohrp/policy/belmont.html)

Ethics and Clinical Research by Henry K. Beecher, 1966, New England Journal of Medicine 274:367-372.

Links to Federal Guidelines for Human Subjects Protection

(http://www.hhs.gov/ohrp/humansubjects/index.html)

<u>Key Action Items for the Stem Cell Field: Looking Ahead to 2014</u>, Stem Cells and Development, Paul S. Knoepfler, 2013.

Financial and staffing resources available to the program: The class is team taught, and there is no remuneration for faculty. The Course Coordinator is responsible for all documentation, distribution/copying of materials, and communications with students.

II. Rutgers University

A. Rutgers Graduate School New Brunswick

RCR plan: The Rutgers University Graduate School on the New Brunswick campus (GS-NB) offers an annual Professional Development & Future Faculty Training program http://gsnb.rutgers.edu/ProfDev which includes a Responsible and Ethical Research course (GS #16:486:501) that is available to all graduate students. The Course consists of 3 sessions (2.5 hours each). Topics include Research misconduct (Fabrication; falsification; plagiarism) with real-world examples (e.g., Mark Hauser at Harvard; examples posted on ORI website), Management of data and results (i.e., how to avoid "questionable research practices"), Responsible authorship (who is an author; who isn't; responsibilities of authors), Responsible peer review practices (responsibilities of authors; reviewers and editors; how to deal with manuscript reviews; issues of confidentiality), Responsibilities of mentors and mentees, Conflict of interest (including university/industry collaborations). The course is run as a discussion. The main theme is how students can become better communicators and decisionmakers; how to become less reluctant to ask difficult questions; how to be aware of responsibilities and how to be aware of rights; when and how to raise questions and problems. Students who want "lecture" type material can complete the Collaborative Institutional Training Initiative (CITI) Responsible Conduct of Research programs website. The course uses case studies (some from the NAS book; some written by the course director; some from other sources) which students discuss in small groups and then report back to the group as a whole. There is lots of discussion where students raise questions about their own experiences. The course director also raises questions and issues based on her experience for years as a mentor, scientist, training grant PI, journal editor, grant panel member. Open discussion is encouraged in an interdisciplinary forum for participants to share experiences, and ask questions.

Number of participants:

	Year	GS New Brunswick	
		Students	
2010		**	
2011		**	
2012		60	
2013		60	
2014		60	

^{**}In 2010 and 2011 students participated in RCR training in the Ethical Scientific Conduct course (GS Course # 16:115:556 offered by GSBH at the Robert Wood Johnson Medical School (see above section **I.A.**).

Description of materials that are provided to participants:

RCR topics are the standard RCR topics taken from the standard sources:

On Being a Scientist: Third Edition, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. 2009.

ORI Introduction to the Responsible Conduct of Research, Revised Edition, 2007 by Nicholas H. Steneck.

General Resources available on the Office of Research Integrity website at http://ori.hhs.gov/education/

The Graduate School-New Brunswick hosts a website (http://gsnb.rutgers.edu/RCR) with links to online resources, sample RCR Workshop materials and Publications of interests.

Financial and staffing resources available to the program: The Course Coordinator is responsible for all documentation, distribution/copying of materials, and communications with students.

B. Rutgers GS Newark

RCR plan: The Rutgers University Graduate School in Newark (GS-Newark) requires all students and postdoctoral fellows supported on NSF and NIH grants to complete a program in RCR (http://gsn.newark.rutgers.edu/responsible-conduct-of-research). The RCR program is a combination of completing the online CITI course in RCR and workshops sponsored by GS-Newark. Completion of four modules is required to complete the program (Research misconduct, Data acquisition and management, Responsible authorship, Conflict of interest). NSF or NIH funded students and postdoctoral researchers are required to take a workshop that will provide an opportunity for discussion of case studies and decision-making skills. The workshop topics include: Research Misconduct; Management of Data and Responsible Authorship; Mentoring and Peer Review; and Collaboration and Conflict of Interest. The workshop is offered as a three-day series of presentations and discussions just prior to the beginning of the Fall semester each year.

Number of participants:

Year	GS Newark
	Students
2010	88
2011	
2012	22
2013	17
2014	73

Description of materials that are provided to participants:

Rutgers University Academic Integrity Policy

(http://www.academicintegrity.rutgers.edu/academic-integrity-policy) and other resources used in the Fall student orientations workshops to disseminate the essentials of the Academic Integrity Policy

(http://gsn.newark.rutgers.edu/sites/default/files/files/RU_Academic_Integrity_Policy.pdf)

Online training provided by the Collaborative Institutional Training Initiative (CITI) Responsible Conduct of Research.

In addition, other resources used in workshops include:

General Readings:

On Being a Scientist: Third Edition, Committee on Science, Engineering, and Public Policy, National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. ORI Introduction to the Responsible Conduct of Research, Revised Edition, 2007 by Nicholas H. Steneck

Collaborative Research: Avoiding Pitfalls and Sharing Credit by Kenneth D. Pimple, http://gsn.newark.rutgers.edu/sites/default/files/files/Collaborative Research.pdf

The Perverse Effects of Competition on Scientists' Work and Relationships by Melissa S. Anderson, Emily A. Ronning, Raymond De Vries, and Brian C. Martinson, Sci. Eng. Ethics, 2007, 13:437-461. (http://gsn.newark.rutgers.edu/sites/default/files/files/Competition.pdf) Honor in Science, Sigma Xi, The Scientific Research Society, Research Triangle Park, North Carolina, 2000. (http://gsn.newark.rutgers.edu/sites/default/files/files/Honor-in-Science.pdf)

Resources for discussion topics on:

Biomedical Research Integrity Cases - University of Washington Biomedical Research Integrity Cases https://ori.hhs.gov/education/products/burke_washington/burke.pdf
Ethical Dilemmas in Research Integrity by Janet Brigham, Arthur B. Chausmer, Kendall S. Fraiser, Claire E. Gutkin, Gailen D. Marshall, Shawn Spilman and Harry W. Tyrer, 2004, ORI, HHS.

Moral Reasoning in Scientific Research: Cases for Teaching and Assessment, Developed by Muriel J. Bebeau, Kenneth D. Pimple, Karen M. T. Muskavitch, Sandra L. Borden, and David H. Smith, Indiana University, 1995.

(http://gsn.newark.rutgers.edu/sites/default/files/files/moral_reasoning_cases.pdf)

Research Ethics Mentoring Vignettes: Discussion Guide, Anderson & Bjork, Syracuse University Graduate School.

(http://gsn.newark.rutgers.edu/sites/default/files/files/syracuse_video_guide.pdf)

Powerpoint slide presentations on:

"The Responsible Conduct of Research: Research Misconduct" presented by Claudia Farber Assistant Dean, GSNB and Eileen Kowler Professor, Associate Dean, GSNB (http://gsn.newark.rutgers.edu/sites/default/files/files/Research_Misconduct.pdf).

"Conflicts of Interest Conflict of Commitment Collaborative Work" presented by Claudia Farber Assistant Dean, GSNB and Eileen Kowler Professor, Associate Dean, GSNB (http://gsn.newark.rutgers.edu/sites/default/files/files/conflicts_talk.pdf).

"Data management and Responsible authorship" presented by Claudia Farber Assistant Dean, GSNB and Eileen Kowler Professor, Associate Dean, GSNB (http://gsn.newark.rutgers.edu/sites/default/files/files/Data_authorship%282%29.pdf).

"Peer Review and Mentorship" presented by Claudia Farber Assistant Dean, GSNB and Eileen Kowler Professor, Associate Dean, GSNB (http://gsn.newark.rutgers.edu/sites/default/files/files/mentoring_peerreview.pdf).

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