

Institutional Plan

for Meeting the Educational Requirements for
Responsible Conduct of Research
as Mandated by the National Science Foundation
and Other Federal Agencies

Developed and administered by

The Office of Grant and Research Development

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Responsible Conduct of Research

Background

Research integrity is the foundation of ethical science. Eastern Washington University (EWU) is committed to promoting and fostering the highest ethical standards in the conduct of research and scholarship. These standards are set forth by state and federal regulations, as well as institutional policies.

Responsible Conduct of Research (RCR) is defined by the National Institutes of Health as the practice of scientific investigation with integrity, which involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. RCR is an essential component of research training, and all researchers should assume personal responsibility for instruction in RCR. Active involvement in the issues of responsible conduct of research should occur throughout a scientist's career, and instruction in RCR should therefore be appropriate to the career stage of the individuals receiving training.

Purpose

This document outlines EWU's plan for ensuring that all personnel engaged in research are adequately trained in the basic principles of ethical research and scholarship. This training plan also meets the requirements for providing training in the responsible conduct of research to federally funded research personnel as required by the National Science Foundation (NSF)-The America COMPETES Act (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science, 42 U.S.C 18620-1, Section 7009,); the National Institutes of Health (NIH), NOT-OD-10-019, "Update on the Requirement for Instruction in the Responsible Conduct of Research"; and the National Institute of Food and Agriculture (NIFA), Responsible and Ethical Conduct of Research-sections 2, 3, and 8 of 2 CFR Part 422.

Policy Considerations

The university Ethics in Research policy states the following:

The creation and dissemination of knowledge are primary missions of the university. Accordingly, the university encourages participation in research, scholarship and service activities which contribute to the university's educational, research, and community service mission. In all of these activities, the University endeavors to maintain the highest standards of integrity and ethics.

Faculty, students and staff who direct or participate in research and scholarship must do so with integrity and strict adherence to the ethical standards of this policy and related laws and regulations. (EWU Policy 302-05)

RCR Core Areas

Housed within the Department of Health and Human Services, the Office of Research Integrity (ORI) oversees and directs most Public Health Service research activities on behalf of the Department. The ORI develops policy and implements activities and programs to

teach responsible conduct of research, promote research integrity, prevent research misconduct, and improve the handling of allegations of research misconduct.

While the ORI does not establish how RCR should be taught, it has outlined nine core areas that are fundamental for RCR instruction:

1. Research Misconduct

This core area addresses the importance of establishing procedures for fostering a positive research environment that is free from misconduct, includes procedures for reporting misconduct in research, and assures protections for whistleblowers.

- **Research misconduct** is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.
- Fabrication means making up data or results and recording or reporting them.
- **Falsification** means manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.
- **Plagiarism** is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Research misconduct does not include honest error or differences of opinion.

2. Research Involving Human Subjects

This area of instruction focuses on issues that are relevant to conducting research involving human participants, or subjects, and includes topics such as the definition of human subject research, ethical principles for conducting human subject research, informed consent, confidentiality and privacy of data and patient records, risks and benefits, preparation of a research protocol, institutional review boards, adherence to a study protocol, and special protections for targeted populations.

EWU's Institutional Review Board (IRB) reviews, approves and monitors all research projects that involve human subjects to ensure compliance with all federal and university regulations and policies. All protocols must be approved prior to beginning research.

3. Using Animal Subjects in Research

Training in animal care and use focuses on the responsible conduct of research involving vertebrate animals and includes topics such as the humane treatment of animals, the care and use of animals in research facilities, minimizing pain and distress, and ethical principles for conducting research with vertebrate animals in accordance with all relevant Federal regulations and guidelines.

EWU's Institutional Animal Care and Use Committee (IACUC) reviews, approves and monitors all research projects that involve animals as subjects. Approval must occur prior to beginning any research.

4. Conflict of Interest and Commitment

This training area addresses a range of potential conflict situations that may be encountered in the research environment and outlines strategies that can be used to mitigate the impact of a possible conflict. Conflicts can exist in three critical areas: financial gain, work and time commitments, as well as intellectual and personal matters. If a potential conflict exists,

actions may be needed to ensure that the situation will not interfere with the responsible practice of the research.

5. Data Management Practices

This core area examines the use of ethical practices for acquiring, managing, sharing, and maintaining ownership of research data, including intellectual property, as well as maintaining privacy and confidentiality of data, and the storage of such information.

6. Mentor/Trainee Responsibilities

This training area explores the role of the researcher as a teacher, and his or her responsibility as a mentor to undergraduate and graduate students, as well as post-doctoral fellows. Additional topics to be addressed in this core include: handling conflicts between mentors and mentees or trainees, and the role of mentors and trainees in the research relationship.

7. Collaborative Research

This core area addresses the development of responsible collaborations between researchers and the issues that may arise from such endeavors. The development of clear roles and guidelines prior to research beginning can mitigate potential complications. Matters to be addressed include establishing clear roles and relationships for each member in the collaboration, conflict management, developing criteria to determine authorship, determining responsibilities for submitting reports and publications, as well as standards regarding how intellectual property rights and ownership issues will be resolved.

8. Authorship and Publication

This topic emphasizes the purpose and importance of scientific publication, and the responsibilities of the authors. Items of discussion include collaborative work and assigning appropriate credit, acknowledgments, appropriate citations, repetitive publications, fragmentary publication, corrections and retractions, application of discipline-based conventions for deciding upon authors, and author responsibilities.

9. Peer Review

Subject matter for this core area involves the timely review and evaluation of scientific work by one's professional colleagues. In conducting peer review, issues such as offering constructive feedback, non-personal bias, attention and respect for confidentiality, and timeliness should be considered. Additional issues to address include: ethical obligations for reviewers of manuscripts, assessing the quality and appropriateness of research methods, how to judge or evaluate the importance of research, and how to conduct confidential peer reviews in the case of grant proposals, manuscripts for scientific publication and personnel matters.

Adapted from: ORI Introduction to the Responsible Conduct of Research, Nicholas H Steneck PhD. https://ori.hhs.gov/ori-introduction-responsible-conduct-research

Requirements

All federal agencies who sponsor research must have policies and procedures in place that promote a research environment that is free from research misconduct. Several federal

2/21/2019 4

agencies require institutions to have training programs in place to ensure ethical and responsible conduct of research. EWU is compliant with all federal sponsor requirements.

National Science Foundation

The National Science Foundation (NSF), in response to Section 7009 of The America COMPETES Act, requires RCR training for all undergraduate students, graduate students, and postdoctoral researchers supported by NSF research awards. See https://www.nsf.gov/bfa/dias/policy/rcr.jsp.

Consistent with NSF policy the university highly recommends that **all personnel** conducting federally supported research to complete RCR training.

National Institutes of Health

National Institutes of Health (NIH) requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant, or dissertation research grant receive training in RCR. A written training plan is required upon submission. See Policy NOT-OD-10-019: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html.

This regulation applies primarily to research training grants, research education grants, career development awards and fellowships or other grants that have a training component that requires instruction. Review each solicitation to determine if a written training plan is required

EWU highly recommends all faculty and all personnel engaging in federal research projects to participate in RCR training.

USDA/National Institute of Food and Agriculture

USDA National Institute of Food and Agriculture (NIFA) requires that program directors, principal investigators, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in USDA/NIFA funded research projects receive appropriate training and oversight in the responsible and ethical conduct of research, and that documentation of such training be maintained in accordance with sections 2, 3, and 8 of 2 CFR Part 422. See https://nifa.usda.gov/responsible-and-ethical-conduct-research.

Other funding agencies

RCR training may be required by other funding agencies, or for specific funding announcements. The terms and conditions of each award should be reviewed to determine if RCR training is required, and what type of training is acceptable.

Institutional Responsibilities Summary of EWU responsibilities are as follows: NSF:

- a. Have a plan in place to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research.
- b. As noted in <u>Chapter II.C.1e</u>, of the NSF PAPPG, institutional certification is required for each proposal submission.
- c. While training plans are not required to be included in proposals submitted to NSF, they are subject to review upon request.

2/21/2019 5

- d. The institution must designate one or more persons to oversee compliance with the RCR training requirement.
- e. Institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received training in the responsible and ethical conduct of research.

NIH:

- a. A plan for instruction on the responsible conduct of research must be included in certain proposals submitted to NIH as indicated in the solicitation. If a training plan is required, a proposal will not be awarded unless an acceptable plan has been submitted.
- b. The instructional plan must include the following components:
 - 1. Format: Substantial face-to-face discussions between individuals in a similar training status, and sponsors, plus a combination of didactic and small-group discussions (e.g. case studies) are highly encouraged. Online course work may not be the sole means of instruction. CITI Training can be a component of the plan but does not fulfill the requirement.
 - 2. **Subject Matter.** Plans must include instruction in the nine core areas of RCR.
 - 3. **Faculty Participation**. Principal Investigators, project directors and other appropriate faculty are highly encouraged to contribute to both formal and informal instruction in RCR, and may contribute to formal instruction as discussion leaders, speakers, lecturers, and/or course directors.
 - 4. **Duration of Instruction**. Most acceptable plans must include at least **eight contact hours of** training. It is suggested that semester-long series is generally more effective than a single seminar or one-day workshop.
 - 5. Frequency of Instruction. Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. Senior fellows may fulfill the requirement for RCR instruction by participating as lecturers and discussion leaders.
 - 6. **Each instructional training plan** should be unique to the intent of the solicitation. *One size does not fit all.*
- c. The institution will submit an annual progress report that will include information describing the nature and extent of participation in RCR training.

USDA/NIFA:

- a. If an application submitted to NIFA results in an award, the Authorized Representative (AR) assures, through acceptance of the award, that the institution will comply with RCR requirements. Award recipients shall, upon request, make available to NIFA the policies, procedures, and documentation to support the conduct of the training.
- b. RCR training is required for program directors, principal investigators, faculty, undergraduate and graduate students, post-doctoral researchers and any other staff participating in a NIFA funded research project.
- c. The general content of the ethics training will at a minimum, emphasize three key areas of research ethics: authorship and plagiarism, data and research integration, and reporting misconduct.
- d. The institution will be responsible for developing its own training system, tailored to their specific needs.

e. It is appropriate to utilize the Collaborative Institutional Training Initiative (CITI) program for RCR (https://www.citiprogram.org/rcrpage.asp). Typically, CITI RCR education addresses the nine core areas of RCR.

EWU Institutional Training Plan

Institutional Certification:

The Executive Director of the Office of Grant and Research Development is the Authorized Organizational Representative (AOR) for certifying that the *Institutional Training Plan* is in place at the time of proposal submission.

Compliance Oversight and Verification:

The Office of Grant and Research Development is the designated unit responsible for overseeing the institutional compliance with RCR requirements.

Training Requirements:

EWU will meet all NSF, NIH and NIFA requirements for RCR training as indicated by each agency's terms and conditions for **research** personnel participating in federally funded research.

Research personnel may be students or nonstudents, paid or unpaid, and participate in either short term or long-term research projects. Research personnel required to participate in training must begin their training prior to working on the research project. Training must be completed within 30 days. Personnel who do not complete the required training in the specified timeframe will be suspended from working on the project until all required training is completed. Upon notification of an award, the principal investigator or project director will be informed of the specific training requirements for his or her research based on the funder's terms and conditions.

RCR training requirements are outlined on the Office of Grant and Research Development website at https://access.ewu.edu/grants/responsible-conduct-of-research-training.

In most circumstances, personnel can satisfy RCR training requirements by completing the appropriate training modules that are offered through the Collaborative Institutional Training Initiative (CITI) by accessing www.citiprogram.org. Certain NIH programs may require additional types of training. (See Institutional Responsibilities: NIH: a-c).

The CITI Program is dedicated to promoting the public's trust in the research enterprise by providing high quality, peer-reviewed, web-based educational courses in research, ethics, regulatory oversight, responsible conduct of research, research administration, and other topics pertinent to the interests of member organizations and individual learners.

These materials are designed and regularly updated to:

- Enhance the knowledge and professionalism of investigators, staff, and students conducting research in the United States and internationally
- Educate members, administrators, and leadership of ethics committees that review and oversee research

 Promote ethical research at organizations through the education of research administrators and organizational leadership

To access Collaborative Institutional Training Initiative (CITI) training modules:

- If you have an existing account, log on <u>https://support.citiprogram.org/customer/en/portal/articles/2736167-login-registration-changes-on-new-citi-program-website#read</u>
- If you are new to CITI, access the site at <u>www.citiprogram.org</u> click on **Register**
 - a. Select EWU from the Participating Institutions drop down menu
 - b. Create user name and password
- 3. Select appropriate user group and course(s)
- 4. Complete the course(s)
- 5. When the course is completed, a copy of the certificate will be forwarded to the Office of Grant and Research Development. Print out a copy of the certificate for your records and provide a copy to the Principal Investigator or Project Director. Training certificates are valid for three years.

The CITI program's RCR training contains a series of content specific course designed modules. All individuals who are required to take RCR training must complete the following basic modules:

- 1. Introduction to RCR
- 2. Authorship
- 3. Collaborative Research
- 4. Conflicts of Interest
- 5. Data Management
- 6. Mentoring
- 7. Peer Review
- 8. Plagiarism
- 9. Research Misconduct

In addition to modules 1-9, based on individual research projects, participants will choose the appropriate module(s):

- Research Involving Human Subjects
- Using Animals in Research

Additional Modules of interest are available but not required:

- Export Controls and National Security
- Research, Ethics and Society
- Environmental and Social Dimensions of Engineering Research
- Reproducibility of Research Results
- Communicating with the Public
- Presentation of Research Findings

RCR training **DOES NOT** satisfy other mandated training areas that are covered under certain regulatory requirements such as Conflict of Interest, Human Subjects Protections, or Animal Care and Use training.

The principal investigator or project director (PI/PD) is responsible for ongoing RCR mentoring of students and other personnel who are working on their research project. In addition, the PI/PD is also responsible for ensuring that all personnel participate in CITI training within 30 days of employment on the research project and for keeping accurate records of RCR training in their files.

Additional Considerations:

- Principal investigators, project directors or participants who are funded by certain programs from the NIH must develop a RCR training plan that meets the requirements set forth in <u>NOT-OD-10-019</u> for their specific research project. These plans are required upon submission.
- 2. If a subaward arrangement will be implemented for a funded research project, the Office of Grant and Research Development will inform the subrecipient of the appropriate requirements for training.
- 3. The Office of Grant and Research Development will maintain certificates of participation in accordance to the record retention schedule of the state of Washington and the federal government.
- 4. Certificates of participation are valid for three years from completion. The Office of Grant and Research Development OGRD will monitor certificate renewals or if additional training is necessary and inform the appropriate personnel of any additional requirements.

Ongoing Considerations:

The primary purpose of the Office of Grant and Research Development's *Responsible Conduct of Research* plan is to foster and promote RCR education to ensure a high level of ethical and professional conduct at EWU as research and other sponsored projects are undertaken. To this end, the Office of Grant and Research Development will seek collaborative opportunities to promote RCR education with colleges, units, and departments, to continue to identify RCR resources and best practices that may be useful in fulfilling and improving RCR education at EWU.

RCR Requirements by Funding Source:

FUNDING SOURCE	National Institutes of Health Research Grants	National Institutes of Health Training Grants per NOT-OD-10-019	National Science Foundation	USDA/National Institute of Food and Agriculture
WHO MUST COMPLETE TRAINING	EWU highly recommends all personnel including faculty engaging in research projects	Undergraduate students, graduate students, post doc's, researchers, all other participants	Undergraduates, graduate students, postdoctoral researchers must complete RCR training	EWU highly recommends all personnel including faculty engaging in research project
			EWU highly recommends all personnel including faculty engaging in research projects	
FREQUENCY	EWU requires certificate of participation valid for three years	Not less than every four years	EWU requires certificate of participation valid for three years	EWU requires certificate of participation valid for three years
ADDITIONAL TRAINING	None	At least eight contact hours CITI training does not satisfy this requirement	None	None
INSTITUTIONAL TRAINING PLAN REQUIRED	No	Yes	Yes	Yes
PERSONAL TRAINING PLAN REQUIRED	No	Yes upon submission	No	No