Responsible Conduct of Research Plan



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Instructions:

As a mission-driven land grant university, The Ohio State University is committed to fostering cutting-edge research. In alignment with the university's shared values, Ohio State is also committed to being a leader in the effort to ensure the highest standards of research integrity, including training in the Responsible Conduct of Research (RCR). Since December 2017, Ohio State has required all faculty, staff and students eligible to conduct research at Ohio State to be trained in RCR.

Applies to:

All faculty, staff including postdoctoral researchers and fellows, students, and trainees eligible to conduct research at Ohio State.

General Principles

Ohio State is committed to ensuring that appropriate RCR training occurs based on federal and university requirements. As such, Ohio State requires all faculty, staff, and students eligible to conduct research at Ohio State to be trained in RCR. All research eligible individuals must take the online Collaborative Institutional Training Institute (CITI) RCR course within 60 days of being assigned to the course. Effective January 1, 2024, online CITI RCR training will be required to be completed every four years.

In addition to the CITI RCR course, all students/trainees engaged in the required NIH grant types (REFER TO OHIO STATE REQUIRED TRAINING MATRIX TABLE) must also complete an approved in-person RCR training provided by the college or grant directors. A list of available university in-person courses is included as Appendix A. Training should occur within one year of assignment to an applicable NIH grant. In Spring 2024, Ohio State Office of Research in collaboration with the Graduate School will be offering an in-person RCR course designed to fulfill NIH requirements (GRDSCH 8000 RCR).

Federal Requirements

RCR training is a federal requirement for researchers funded by National Science Foundation (NSF), National Institutes of Health (NIH) and the United States Department of Agriculture National Institute of Food and Agriculture (USDA NIFA). Ohio State meets these requirements by a combination of online CITI RCR training and in-person RCR courses/workshops offered by Ohio State.

- The 2007 America COMPETES Act includes a <u>requirement</u> that all undergraduate students, graduate students (MA, MS and PhD), and postdoctoral researchers supported by NSF to conduct research receive training in responsible and ethical conduct of research (RECR). The act also requires an institutional plan outlining the appropriate RECR training and tracking. Ohio State meets this requirement via the CITI RCR course.
- The CHIPS and Science Act of 2022 amends the America COMPETES Act to <u>require</u> that faculty and senior personnel paid or supported by NSF funds complete RECR training for grants due or submitted by July 31, 2023. Ohio State meets this requirement via the CITI RCR course.
- NIH requires that all trainees (MA, MS and PhD), postdocs, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant must receive instruction in responsible conduct of research. For the specified award categories, the Principal Investigator (PI) must develop a discipline-specific, tailored plan for RCR training that meets the NIH requirements. Ohio State meets this requirement by having all students/trainees engaged in the required NIH grant types complete CITI training and also complete an approved in-person RCR training. A list of current Ohio State courses is included as Appendix A. Ohio State's Office of Research will be offering an in-person RCR course designed to fulfill NIH requirements (GRDSCH 8000 RCR).
- USDA NIFA mandates that program directors, faculty, undergraduate students, graduate students (MA, MS and PhD), postdoctoral researchers, and any staff participating in NIFA research projects receive appropriate training and oversight in the responsible and ethical conduct of research (RECR). Any award issued after February 1, 2013, must comply with this requirement. Ohio State meets this requirement via the CITI RCR course.

Ohio State Required Training Matrix

Career Stage	Funding Type – All funding (Sponsored, Industry, Internal, Unfunded)	Funding Type – NIH Training and Career Awards
Faculty	CITI RCR	Training faculty may contribute to formal instruction in RCR as discussion leaders, speakers, and/or course direc- tors. Some grant types also require early career faculty to complete 8 hours of in-person RCR training.
Post Doctoral Researchers/Fellows	CITI RCR	In-person course (8 hours minimum)
Graduate Students (Ph.D. and Masters)	CITI RCR	In-person course (8 hours minimum)
Undergraduate Students	CITI RCR	In-person course (8 hours minimum)

Funding Type – NIH Training and Career Awards: Requirement for in-person training in addition to online CITI course and applies to individuals with the following type of NIH awards: D43, D71, F05, F30, F31, F32, F33, F34, F37, F38, K01, K02, K05, K07, K08, K12, K18, K22, K23, K24, K25, K26, K30, K99/R00, KL1, KL2, R25, R36, T15, T32, T34, T35, T36, T37, T90/R90, TL1, and TU2 grants. Available in-person courses list as Appendix A.

Responsibility

Principal Investigators (PI) are responsible for ensuring that everyone in their research group has completed CITI training and if listed on an applicable grant, the appropriate in-person training. The PI is also responsible for ensuring that course attendance is monitored, and training records are maintained to document that all NIH or NSF supported trainees, fellows, and scholars received the required instruction. The PI must also comply with the specific reporting requirements in continuation applications. The instructional plan should include coursework with significant face-to-face interaction and participation by research faculty members. Analysis of relevant case studies is recommended. While on-line instruction may be used as a component of the training program, it is not sufficient to meet the NIH requirement for RCR instruction, except in special or unusual circumstances.

PI's may want to use the online CITI RCR training course as part of instructional plan. All the NIH required subject areas are addressed in the CITI RCR coursework. If used, the most relevant, discipline-specific CITI RCR course (Biomedical Research, Social and Behavioral Research, Physical Science, Humanities, or Engineering) should be specified. The CITI RCR course also offers online case studies that can be used for face-to-face discussion. Please note CITI alone is not sufficient to meet <u>NIH requirements</u>.

Compliance Actions

For all faculty, staff and students eligible to conduct research who do not complete the CITI RCR training within 60 days of appointment to an NIH, NSF, or USDA NIFA award, continued access to certain university systems and processes related to research will be suspended until RCR training is completed. This includes, but is not limited to, submission of IBC, IRB, and IACUC protocols and amendments; new project award set-up; project amendment processing; and access to certain internal funding programs.

Tracking

Upon CITI RCR course completion, a copy of the completion certificate will be available in CITI to print and retain for a researcher's records. The CITI system keeps track of all completion data, and completion status is provided nightly to Ohio State. Ohio State offers several inperson academic courses, including GRDSCH 8000, which meet NIH training requirements. Applicable trainees' completion or course status is provided nightly to the Office of Research through the University's Reporting and Analytics Environment. This information is used by automated processes to verify RCR completion and to set the appropriate status within the Office of Research Training Database. A list of these courses can be found in Appendix A.

Subject Topics for In-Person Courses

Courses should aim to include the following topics.

- a. conflict of interest personal, professional, and financial and conflict of commitment, in allocating time, effort, or other research resources
- b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- c. mentor/mentee responsibilities and relationships

- d. safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
- e. collaborative research, including collaborations with industry and investigators and institutions in other countries
- f. peer review, including the responsibility for maintaining confidentiality and security in peer review
- g. data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
- h. secure and ethical data use; data confidentiality, management, sharing, and ownership
- i. iresearch misconduct and policies for handling misconduct
- j. responsible authorship and publication
- k. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Considerations for In-Person RCR Course Instructors/NIH Trainee Grant PIs

Principal Investigator (PI) must develop a discipline-specific, tailored plan for RCR training that meets the NIH requirements. The instructional plan is evaluated as a component of the NIH funding proposal and applications lacking an RCR instructional plan may be delayed in the review process or not reviewed. NIH has provided a sample NIH RCR training plan template here: <u>sample NIH RCR training plan template</u>

OHIO STATE meets NIH RCR requirements by having all students/trainees engaged in the required NIH grant types complete CITI training and also complete an approved in-person RCR training provided by the college or grant directors. A list of current Ohio State courses and workshops is included as Appendix A. Ohio State's Office of Research also has developed an in-person RCR course designed to fulfill NIH requirements (GRADSCH 8000). This 1-credit hour in-person course is open to all graduate students, postdoctoral fellows, and Ohio State staff members. Postdoctoral fellows may enroll by the graduate non-degree mechanism to allow for tuition coverage. GRADSCH 8000 RCR will utilize the flipped classroom model and will provide content and case studies for students to complete before class. The pre-course content will be provided from subject matter experts from the Office of Research, while in-person discussions are facilitated by Ohio State faculty and trainee grant directors on a rotating basis based on expertise.

Considerations for NSF Funding

NSF requires the university to certify that it has a plan to provide appropriate RECR training and oversight to undergraduates, graduate students, postdoctoral researchers, faculty, and other senior personnel who receive NSF support to conduct research. Certification of University compliance is done by an authorized Ohio State representative as part of the institutional proposal approval process (e.g., when a sponsored program officer submits the proposal in FastLane). Specific instructions are found in Chapter IX.B.1 Responsible and Ethical Conduct of Research (RECR) of the NSF <u>Proposal and Award Policies and Procedures Guide</u>. Expanded NSF guidelines for RECR also require that training cover mentor training and mentorship. CITI modules have been expanded to include mentorship and a list of supplemental mentoring resources available at Ohio State can be found in Appendix B.

All students and postdoctoral researchers supported by NSF sponsored projects must complete the CITI online course in the Responsible Conduct of Research within 60 days of appointment. The PI is responsible for ensuring that all students and postdocs complete the CITI RCR course and begin a dialogue on the responsible conduct of research. The PI is also required to complete the CITI RCR training. PI's should not include any specific information on RCR training within proposals. NSF does not require program details – only the institution's certification that there is a program in place. Training records are subject to monitoring by NSF auditors.

Ohio State designates the Senior Vice President of Research Operations, Office of Research and the Vice President of Research Compliance, Office of Research Compliance, Office of Research and their designated staff to oversee compliance with the RECR training requirement.

Contact <u>rcrinfo@osu.edu</u> with any questions related to RCR.

RCR Resources

- <u>Sample NIH RCR Training Plan template</u> (NIH website scroll toward the bottom of the page)
- U.S. Department of Health & Human Services (Place mouse over "RCR Resources" for a list of resources):
 - <u>RCR Casebook</u> (Case study narratives and facilitator discussion questions)
 - <u>Video Case Studies</u>
 - <u>The Lab</u> (Interactive simulation on research misconduct; learner makes decisions about research integrity throughout the simulation on topics such as research misconduct, mentorship, handling of data, authorship, and research practices)
 - Infographics that can be used to summarize information, for formative assessments, and as artifacts for discussion
 - Avoiding plagiarism
 - Illinois Institute of Technology Ethics Education Library
 - Case study collection
 - Instructional methods and programs
 - Syllabi

- Pedagogical materials
- Evaluation and assessment methods
- American Physiological Society <u>Rigor and Reproducibility Checklist</u>

Appendix A:

OHIO STATE IN-PERSON COURSES (Note these courses have not been formally reviewed or audited for their fulfillment of NIH requirements but course syllabi indicate they would meet NIH requirements for subject area, format, and duration. To get added to this list, course instructors may submit course syllabi to ORC (rcrinfo@osu.edu) for review and endorsement). Ethics courses alone typically are not sufficient to meet RCR requirements.

Undergraduate:

- BIOPHRM 5510 Responsible Conduct in Biomedical Research
- MEDCOLL 5000 Responsible Conduct of Research & Research Ethics

Graduate:

- ANIMSCI 7789 Nutrition Research Ethics
- BIOMEDE 6983 Research Ethics
- BIOPHRM 5510 Responsible Conduct in Biomedical Research
- BIOPHRM 7510 Professional and Ethical Issues in Biomedical Sciences
- BIOPHYS 7600 First-Year Student Orientation
- MCDBIO 7600 First-Year Student Orientation
- MICRBIO 7600 First Year Student Orientation
- MOLGEN 7600 First-Year Student Orientation
- OSBP 7600 First-Year Student Orientation
- PHR 8520 Research Ethics
- VISSCI 7960 Ethics in Biomedical Research
- GRDSCH 8000 Responsible and Ethical Conduct of Research

Appendix B:

- Ohio State Mentoring Initiative
- Center for Clinical and Translational Science (CCTS) <u>Research Mentor Training</u>
- Graduate School <u>Mentoring Workshops</u>