

Responsible Conduct of Research (RCR) Training Plan

Ball State University Office of Research Integrity

Institutional Background

Ball State University (BSU) strongly supports the ethical and responsible conduct of research, regardless of funding status or source. The Institutional Review Board (IRB), the Institutional Animal Care and Use Committee (IACUC), and the Institutional Biosafety Committee (IBC) provide guidance to researchers to ensure all stages of research are conducted to the highest ethical and regulatory standards. Training in the Responsible Conduct of Research (RCR) for projects overseen by the IRB, IACUC, and IBC is available to researchers through BSU's partnership with the Collaborative Institutional Training Initiative (CITI). In addition, the Office of Research Integrity (ORI) provides face-to-face instruction in RCR. This ORI-provided face-to-face RCR training is required of all faculty, staff, and student researchers receiving National Institutes of Health (NIH) or National Science Foundation (NSF) research or educational grants in compliance with federal guidelines.

National Science Foundation Background

The NSF requires institutions applying for, or receiving, NSF funding for research or educational purposes to provide training in the responsible and ethical conduct of research (referred to as RCR for purposes of this plan). Training participation is required for all undergraduate students, graduate students, postdoctoral researchers, faculty, and other senior personnel supported by the proposed research project¹. To ensure compliance with these policies, institutions must have a plan in place for training and oversight of RCR training. ²

The NSF provides guidance on required RCR training content aimed at providing funding recipients with the knowledge and skills necessary to maintain the highest standard of research ethics and integrity. Subject areas on which training must be provided have been outlined in NSF's policy. 3

A list of these training topics can be found in Appendix A.

¹ NSF Proposal & Award Policies & Procedures Guide (PAPPG) (NSF-23-1, Chapter 9.B.2.a): https://new.nsf.gov/policies/pappg/23-1/ch-9-recipient-standards

NSF PAPPG (NSF-23-1, Chapter 2.D.c.1): https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_2.jsp

³ NSF PAPPG (NSF-23-1, Chapter 9.B.1): https://new.nsf.gov/policies/pappg/23-1/ch-9-recipient-standards

National Institutes of Health Background

The NIH requires institutions receiving NIH funding through a research, career development, educational, or dissertation research grant to provide RCR training to all trainees, fellows, participants, and scholars receiving NIH grant-funded support.⁴ These training requirements aim to ensure investigators involved in NIH-funded research are knowledgeable in the ethical considerations and best practices essential for maintaining the highest standards of research conduct.

Requirements for RCR instruction are provided by the NIH and include guidance on the format, frequency, and subject matter of RCR training. Per these requirements, training should include the use of face-to-face instruction that "fosters discussion, active learning, engagement, and interaction among participants." ⁵ Subject matter guidance provided by the NIH includes eleven instructional components to be included in RCR training by the institution.

A list of these training topics can be found in Appendix B.

Institutional Responsibilities

An institution applying for or receiving funding from the NIH or NSF is required to establish an RCR training plan for all faculty, staff, and students receiving grant-funded support. ^{6 7} Institutions are further required to appoint at least one individual responsible for overseeing and verifying compliance with these mandates. ⁸ To assure compliance to funding agencies, the institution must actively track course attendance and engagement in the training program and maintain thorough records of RCR training participation.⁹

Upon submission of a proposal, the institution is responsible for certifying the existence of an RCR training and oversight plan to the proposed funding source. ¹⁰

Ball State University Responsible Conduct of Research (RCR) Training Program

In compliance with NIH and NSF RCR training guidelines, BSU requires the completion of CITI training for those participating in federally funded projects overseen by the IRB, IACUC, and IBC. To meet the face-to-face training requirements of those faculty, students, and staff receiving NIH or NSF-funded support for their research activities, the BSU ORI has established two additional programs: one providing training to faculty and staff, and one providing training to students.

⁴ NIH NOT-OD-10-019: https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

⁵ NIH NOT-OD-22-055: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html

⁶ NIH NOT-OD-10-019: https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

⁷ NSF PAPPG (NSF-23-1, Chapter 9.B.2.a): https://new.nsf.gov/policies/pappg/23-1/ch-9-recipient-standards

⁸ NSF PAPPG (NSF-23-1, Chapter 9.B.2.c): https://new.nsf.gov/policies/pappg/23-1/ch-9-recipient-standards

⁹ NIH NOT-OD-10-019: https://grants.nih.gov/grants/guide/notice-files/not-od-10-019.html

¹⁰ NSF PAPPG (NSF-23-1, Chapter 2.D): https://www.nsf.gov/pubs/policydocs/pappg20_1/pappg_2.jsp

The ORI-provided face-to-face RCR training provides interactive instruction including the use of case studies and practical tasks meant to equip participants with an enhanced understanding of ethical research practices and how to apply them in real-world settings. These additional trainings are meant to compliment required CITI training and are not intended to replace CITI training for those for whom it is required.

Responsible Conduct of Research Faculty and Staff Training Program

Face-to-face training in RCR is provided to faculty and staff researchers receiving NIH or NSF-funded support through BSU's Responsible Conduct of Research Training Program. This training program provides investigators the opportunity to further their understanding of the core values of RCR by working through complex research ethics scenarios in a collaborative learning environment.

Training for faculty and staff researchers is offered each semester as an in-person seminar. Training must be completed by the end of the semester following the semester during which funding is made available for the project.

A list of learning sessions provided during this training can be found in Appendix C.

Responsible Conduct of Research Student Training Program

Face-to-face training in RCR is provided to student researchers receiving NIH or NSF-funded support through BSU's Responsible Conduct of Research Student Training Program. ¹¹ This program is designed to familiarize student researchers with the core values of RCR. Instruction is provided using a multi-modal approach including interactive face-to-face instruction, online learning modules, and the consideration of case studies.

The RCR Student Training Program will be piloted throughout the 2023-2024 academic year. Between September 2023 and April 2024, participants will participate in 10 separate 1-hour inperson training sessions. Additional interactive learning activities will be posted to the RCR Student Training Program Canvas Community. Active participation in Canvas activities and attendance at face-to-face training is required for a trainee to receive credit for each training module.

A list of topics covered in this training can be found in Appendix D.

Compliance Monitoring

To ensure compliance with NIH and NSF RCR training requirements, BSU provides oversight of training through program offices operating under the Office of Research. The ORI, in collaboration with Sponsored Projects Administration (SPA), identifies projects with RCR

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¹¹ Responsible Conduct of Research Student Training Program: www.bsu.edu/rcrtraining

training requirements, informs investigators of these requirements, and provides program oversight and verification of training completion.

BSU's Responsible Conduct of Research Officer (RCRO) receives funded research reports from SPA regularly and reviews the projects to identify Principal Investigators (PIs) for whom participation in face-to-face RCR training is required. Once identified, the RCRO informs the PI in writing of the training requirements. *It is the responsibility of the PI to provide the RCRO with contact information for any staff or students supported by the grant*.

Completion of required CITI training is documented within CITI and verified by the IRB, IBC, and IACUC at the time of project proposal submission. *PI's are required to ensure that all research team members have completed all required trainings, including applicable RCR training.*

Oversight of required RCR training is provided by the RCRO who reports compliance to SPA. Certification of the existence of an RCR training plan at the time of proposal submission is provided by SPA.

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Appendix A

NSF Training Requirements

The NSF requires training provided by an institution applying for, or receiving, NSF funding includes, but may not be limited to, training in:

- 1) Conducting peer review to the highest ethical standards;
- 2) Diligently protecting proprietary information and intellectual property from disclosure;
- 3) Mentorship, and;
- 4) Treating students and colleagues fairly and with respect.

Source: NSF PAPPG (NSF-23-1, Chapter 9.B.1)

Appendix B

NIH Training Requirements

The NIH requires training provided by an institution receiving NIH-funded support to minimally include training in the following RCR core principles:

- 1) Conflicts of interest personal, professional, and financial and conflict of commitment, in allocating time, effort, or other research resources.
- 2) Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices.
- 3) Mentor/mentee responsibilities and relationships.
- 4) Safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability, and other forms of discriminatory harassment).
- 5) Collaborative research, including collaborations with industry investigators and institutions in other countries.
- 6) Peer review, including the responsibility for maintaining confidentiality and security in peer review
- 7) 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.
- 8) Secure and ethical data use; data confidentiality, management, sharing, and ownership
- 9) Research misconduct and policies for handling misconduct.
- 10) Responsible authorship and publication.
- 11) The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research.

Source: NIH NOT-OD-22-055

Appendix C

Responsible Conduct of Research Training Program (Faculty and Staff) Training Requirements

Learning sessions provided during the RCR Training Program include:

- Overview of RCR: COI/COC; responsible research practices involving animals, humans, and biological hazards; responsible authorship and publication; collaborative research; and research misconduct;
- 2) Conducting peer review to the highest ethical standards;
- 3) Diligently protecting proprietary information and intellectual property from disclosure:
- 4) Mentorship, and;
- 5) Treating students and colleagues fairly and with respect.

Source: Ball State University Responsible Conduct of Research Program

Appendix D

Responsible Conduct of Research Student Training Program Training Requirements

Topics covered during each training module throughout the RCR Student Training Program

Include:

- 1) Introduction to Responsible Conduct of Research, Conflicts of Interest, and Conflicts of Commitment
- 2) Responsible Research Practices and Policies: Students will have the opportunity to choose from one of two trainings related to their field of study
 - The Use of Human Subjects in Research
 - The Use of Animals and Biological Hazards in Research
- 3) Mentor and Mentee Responsibilities and Relationships
- 4) Safe and Inclusive Research Environment Free from Discrimination
- 5) Responsible Authorship and Publication
- 6) Collaborative Research
- 7) Peer Review
- 8) Responsible Data Practices: Data Acquisition, Data Analysis, Record-Keeping Practices, and the Secure and Ethical Use of Data
- 9) Research Misconduct
- 10) The Scientist as a Responsible Member of Society and Contemporary Issues

Source: Ball State University Responsible Conduct of Research Student Training Program