

Drew University

Responsible Conduct of Research Policy

Effective January 1, 2015

Background and Purpose

United States government granting agencies, including the National Institutes of Health (NIH) and others, have established research training requirements for grant recipients to ensure that government-funded research is conducted in a responsible and ethical manner. Additionally, under the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science (COMPETES) Act of 2007, Section 7009, the National Science Foundation (NSF) and other government agencies require each institution applying for funding in science and engineering research or education to certify that the applying institution has a plan for appropriate training and oversight in the responsible and ethical conduct of research by undergraduates, graduate students, and postdoctoral researchers who will be supported by government funding.

Beginning with proposals submitted (or due) on or after January 4, 2010, institutions must certify at the time of submission that the institution has a plan to provide to undergraduates, graduate students, and postdoctoral researchers supported by government funding appropriate training and oversight in the responsible and ethical conduct of research, referred to as RCR.

The purpose of this document is to outline and update Drew University's policy and program for compliance with the RCR requirement. While the intent of this plan is to provide information sufficient to comply with the minimum RCR requirements, departments, programs and project directors are strongly encouraged to provide additional training and guidance that goes beyond these minimum requirements as appropriate.

Guidelines

It is the policy of Drew University that all scholarly activities, including research, must be carried out with honesty, accuracy, efficiency and objectivity. All members of the Drew research community – students, faculty and staff - are expected to adhere to the highest ethical and professional standards as they pursue their research activities. All research involving human subjects must also seek and receive approval from Drew's Institutional Research Board (IRB) before any research is conducted. Please contact Dr. Kate Ott, Chair, Drew IRB for additional information. All research involving living animals must also seek and receive approval from Drew's Institutional Animal Care and Use Committee (IACUC) before any research is conducted Dr. Graham Cousens, Chair, Drew IACUC, for additional information. It is expected that all participants engaged in research endeavors will comply with the legal,

regulatory, and ethical requirements established by the University, regulatory agencies, funding sources and professional organizations.

All Drew University faculty who apply for NSF, NIH and other U.S. government grants that include funding for student research must agree, in writing and prior to proposal submission, that they will comply with the training requirements for the responsible conduct of research (RCR) as described herein if their proposal is funded.¹ Further, all Drew University students who participate in government-funded research must fulfill specific educational requirements related to RCR. Recognizing that specific training needs will vary across disciplines and depending upon the particular research being pursued, this policy intentionally allows for flexibility in both content and delivery method, relying on the discretion of the project director to determine the most appropriate option(s). It should also be noted that different governmental agencies have different standards that must be met. For example, NIH requirements are substantially different from NSF requirements. Please contact Dr. Jessica Lakin, Associate Dean of the College and RCR Compliance Officer, if you have any questions related to specific RCR training requirements.

Fulfilling RCR Training Requirements

All students wishing to participate in government-funded research projects must, at a minimum, successfully complete the CITI (Collaborative Institutional Training Initiative) online training program, to which Drew subscribes. CITI is a consortium of educational institutions that offers web-based training in RCR (and other research-related compliance areas) based at the University of Miami. CITI is used by millions of learners at thousands of subscribing academic institutions, government agencies, and commercial organizations for research training. Students and faculty may access the CITI online course here: <u>https://www.citiprogram.org/</u>. This online training should be renewed every three years. Students funded by NIH grants must also participate in an intensive face-to-face RCR training program.²

In view of the fact that research training (both content and delivery method) for an undergraduate student in neuroscience, for example, will likely be different than that for an M.A.T. student pursuing certification to teach biology, various additional modes of instruction may also be used to supplement the CITI online training program. In this sense, the RCR training program may be customized as appropriate and necessary for the field, the research, and the particular granting agency.³ Depending upon the discipline and the research itself, topics to be covered by the training may include:

- Data Acquisition, Management, Sharing and Ownership
- Publication Practices and Responsible Authorship

¹ This is accomplished via Drew University's Grant Proposal Processing Form, available from the Associate Director of Foundation and Government Relations.

² See: <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html</u>

³ Online training alone would not satisfy the mandates for NIH, for example, which require substantial face-to-face discussions among the participating trainees/fellows/scholars/participants; a combination of didactic and small-group discussions (e.g. case studies); and participation of research training faculty members in instruction in responsible conduct of research. NIH's policy is available at: <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html</u>.

- Mentor/Trainee Responsibilities
- Peer Review, Problem Selection and Problem Solving
- Collaborative Research
- Time Management and Personal Responsibility
- Research Misconduct and Ethics
- Conflict of Interest and Commitment
- Human Subjects
- Animal Welfare
- Safe Laboratory Practices
- Whistleblowing
- Dispute Resolution
- Appropriate Use of Literature
- Lab Notebooks and Graphical Presentation of Data
- Data Ownership and Inventions
- Posters and Oral Presentations
- Attending Scientific Meetings
- Writing Grant Proposals/Obtaining Funding
- Writing a Research Article
- Legal Issues in Research and Research Misconduct
- Job Skills

Beyond the baseline requirement of successful completion of the online CITI RCR training program, additional RCR training that may be required in specific instances⁴ may include one or more of the following:

- *Appropriate Drew course offerings in research methods.* Students involved in research activities may take a Drew course on research methods in their discipline. Examples of courses (not all of which may be offered in any given semester) are:
 - **o** Research Methods in Psychology (PSYC 211)
 - **o** Sociological Research Methods (SOC 210)
 - o Neuroscience Research Methods (NEUR 210)
 - o Research in Chemistry (CHEM 395)
 - o Research in Biochemistry (BCHM 395)
 - o Molecular and Cellular Biology (BIOL 250)
- *Mentoring activities conducted by supervisory faculty.* One of the hallmarks of a Drew education is the close, mentoring relationship between faculty and students; therefore, faculty mentoring will be a key mechanism for providing supplemental RCR instruction. Drew faculty are aware that their role in mentoring student researchers encompasses teaching students about safe and ethical research practices. Research mentoring at Drew occurs in many settings, both formal and informal. Formal settings in which RCR mentoring may occur include:

⁴ Project directors should consult the RCR Compliance Officer for guidance or clarification on the specific RCR requirements of the granting agency to which they are applying.

- Drew Summer Science Institute (DSSI), during which summer research students conduct research responsibly and safely;
- Research Institute for Scientists Emeriti (RISE), where students engage in research under the mentorship of retired industrial scientists, both during the academic year and during the summer as part of DSSI.

More informal research mentoring may occur during meetings, discussions and demonstrations (one-on-one or in a group setting) about topics related to RCR.

- Drew's Certificate in Research Ethics Program. The Certificate in Research Ethics, based in Drew's Caspersen School of Graduate Studies, develops a specific skill set required by regulation, profession or industry best practice to ensure ethical conduct in medical research or medical and health services. The program is designed for researchers and applied and clinical professionals, as well as students in biomedical sciences and health services. The program design nurtures a humanistic and ethical approach to research, wherein students learn how to apply ethical principles to various research activities and manage conflicts of interest, as well as nurture respectful and culturally appropriate behavior toward research subjects.
- *Guided reading and study.* Project directors may recommend specific RCR resources and case studies to research students that address RCR-related topics they find applicable to their area of research.⁵

Proof of Successful Completion of RCR Training

Before students can engage in U.S. government-funded research, at a minimum, they must be able to demonstrate successful completion of the CITI online RCR training program. In the case of NIH-funded projects, they must also successfully complete the face-to-face training requirement. Project directors may, at their discretion, require evidence of a student's successful completion of additional supplemental training before, during or following participation in research.

Repeat Researchers: Students performing research on subsequent research projects, who previously completed RCR training in conjunction with earlier projects, may be subject to retraining.

• If three years or more has elapsed, RCR training should be repeated.

⁵ The Office of Research Integrity (ORI) in the U.S. Department of Health and Human Services is the federal agency charged with oversight responsibilities for the responsible conduct of research (RCR). The ORI developed a comprehensive text that discusses the essential aspects of an RCR program, which is available for review: <u>http://ori.dhhs.gov/publications/ori_intro_text.shtml</u>. Project directors may recommend other applicable print and/or online resources to augment student RCR training as appropriate.

• If less than three years has elapsed, repeat training is at the discretion of the project director (taking into consideration the length of time that has elapsed since initial training, the extent of training initially completed, the nature of the research, etc.).

Responsibilities under the Plan

Project directors are responsible for ensuring that government-funded students conducting research under their supervision have successfully complied with RCR training requirements and are conducting research within acceptable RCR parameters. Accordingly, project directors will:

- Upon notification of government funding, identify student research team members who are subject to RCR training requirements;
- Offer and monitor completion of adequate and appropriate RCR training for those students requiring training; and
- Maintain records of training experiences (except for CITI courses, documentation of which is automatically recorded online).

The RCR Compliance Officer is responsible for:

- Monitoring the existence and adequacy of RCR training activities;
- Verifying compliance with RCR training requirements as appropriate;
- Ensuring all faculty are aware of their responsibilities under this policy through an active educational and outreach program;
- Assessment, evaluation, and, as appropriate or necessary, modifications to the RCR policy and program; and
- Oversight and maintenance of the Office of RCR Compliance website.

The Director of Corporate, Foundation and Government Relations (CFGR) or, in the absence of a Director of CFGR, the Vice President of University Advancement, is the Authorized Organizational Representative (AOR) who certifies on U.S. government grant proposals the existence of the institutional plan for RCR training.

Questions

Questions regarding RCR compliance requirement should be directed to Drew's RCR Compliance Officer:

Dr. Jessica Lakin Associate Dean, College of Liberal Arts (973) 408- 3263 rcrcompliance@drew.edu