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Web Capture: Responsible Conduct of Research (RCR)

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Responsible Conduct of Research (RCR)

The National Institutes of Health (NIH) define 'Responsible and Ethical Conduct of Research' as, "the practice of scientific investigation with integrity. . . [involving] the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research."[1]

Standards for the responsible and ethical conduct of research are set forth by federal and state regulations, institutional policies, professional codes of conduct, and personal convictions.[2] At the federal level (Refer to 42 CFR Part 93), the U.S. Department of Health & Human Services Office of Research Integrity (ORI) is vested with the authority to develop policies, procedures, and regulations for the detection, investigation, and prevention of research misconduct. ORI also serves a support role in assisting institutions as they develop individualized RCR training programs. Accordingly, ORI has identified nine core instructional areas:

- Research Misconduct
- Human Subjects
- Animal Welfare
- Conflict of Interest and Commitment
- Data Acquisition, Management, Sharing and Ownership
- Mentor / Trainee Relationships & Responsibilities
- Collaborative Research
- Publication Practices and Responsible Authorship
- Peer Review

Incorporating ORI's principles, the policies and procedures of the University of Maine System and the University of Maine reflect a strong institutional commitment to fostering an environment in which the highest ethical standards in the conduct of research and

other scholarly activities are not only expected, but required. Primary responsibility for maintaining such standards in the pursuit and dissemination of knowledge rests with the faculty, collaborating staff members, and students. Every individual engaged in research and other scholarly activities is expected to be fully aware of the regulations and ethical guidelines governing his/her discipline. Failure to comply can result in penalties ranging from administrative to civil or criminal for both the institution and the individual(s).

Up Next: RCR Training Requirements

Questions about RCR (including questions about federal training requirements or access to the training) may be directed to:

Sandra Cáceres Tijerina
Research Compliance Officer I
sandra.c.tijerina@maine.edu
207.581.1459, 309 Alumni Hall
Cáceres Tijerina Bio

Amanda Ashe, CRA
Director of Research Compliance
amanda.l.ashe@maine.edu
207.581.1480, 310 Alumni Hall
Ashe Bio

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[1] NIH Notice: #NOT-OD-10-010 "Update on the Requirement for Instruction in the Responsible Conduct of Research" [Accessed 9/3/2012]

[2] Steneck, N. ORI Introduction to the Responsible Conduct of Research (Chapter 1). HTML Version, September 2006, updated from Revised Printed Edition, June 2004 [Accessed 9/4/12]

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National Institutes of Health (NIH)

Pursuant to Notice NOT-OD-10-019: "Update on the Requirement for Instruction in the Responsible Conduct of Research", "all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant and dissertation research grant must receive instruction in responsible conduct of research."

National Science Foundation (NSF)

Implementation of Section 7009 of the America COMPETES Act requires 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."

U.S. Department of Agriculture (USDA) National Institute of Food & Agriculture (NIFA)

Requires training in the Responsible Conduct of Research for "program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff participating in the research project" for all awards subject to NIFA Research Terms and Conditions dated February 2013 and after. Full text of the requirement can be found in NIFA's October 2014 Agency-Specific Terms & Conditions (PDF) and NIFA's March 2013 Terms and Conditions, Small Business Innovation Research Grants Program .

University of Maine

Principal Investigators (PI) or Project Directors (PD) are responsible for ensuring that appropriate training occurs early in the first year each subject person receives NSF, NIH, or USDA-NIFA support, and for promptly submitting certification of that training to ORA. Please note: PI and Co-PI on USDA-NIFA awards subject to the training requirement must complete training before ORA will establish the project account.

The University's Responsible & Ethical Conduct of Research plan is outlined below:

- Undergraduates are directed to register for an Undergraduate RCR training workshop (see current Undergraduate RCR training information).
- Graduate students are directed to take INT601 or an approved alternate course (see Graduate School – RCR Training Requirement).
- Post-Doctoral researchers and other subject faculty/staff may take INT-601 or complete Collaborative Institutional Training Initiative's (CITI) 'General RCR Course' (see Instructions for CITI Training [PDF]).

If you have questions regarding this training requirement or CITI training instructions, please contact us about Responsible Conduct of Research (RCR).

Up Next: RCR Resources

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- "Administrators and the Responsible Conduct of Research" (Boston College)
- DHHS Office of Research Integrity (ORI)
- DHHS ORI Publication: "Introduction to the Responsible Conduct of Research"
- DHHS ORI Video Simulation on Research Integrity: "The Lab"
- National Academy Press: "On Being a Scientist: Responsible Conduct in Research", Third Edition
- NIH online training course "Introduction to the Responsible Conduct of Research"
- NSF Responsible Conduct of Research Resources
- Procedure for Approval of Departmental Graduate-Level RCR Courses (PDF)
- RCR Glossary

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Procedure for Approval of Departmental Graduate-Level Responsible Conduct of Research (RCR) Courses

University of Maine
Office of the Vice President for Research and Dean of the Graduate School
Effective July 2014 (*Revised 1/18/2021*)

Background

All students enrolled in masters or doctoral programs with a research component must receive one credit of Responsible Conduct of Research (RCR) training prior to completing the degree, preferably prior to commencing the research. At the advisory committee's or Graduate Coordinator's discretion, this credit may be substituted for one of the 6 required thesis/dissertation credits (XXX 699). Students must take the RCR training before the commencement of the fourth credit of XXX 699.

Graduate students who are not subject to the Graduate School's RCR Training requirement are not required to take RCR training unless supported to conduct research on an award from the National Institutes of Health, National Institutes of Food and Agriculture, or National Science Foundation (see RCR on the ORC website for information on these federal regulations).

Graduate students subject to the RCR training policy and/or federal mandate must enroll in INT 601, or an approved alternate course (see RCR in the UMaine Graduate School). Recognizing the fact that many UMaine colleges require their graduate students to take existing departmental courses with RCR content, the Assistant Vice President for Graduate Studies (AVPGS), through the Office of Research Compliance (ORC), will consider approving such courses as alternates to INT601 in order to minimize student duplication of effort.

The process for gaining approval for alternate courses is outlined below. Questions regarding the RCR graduate training requirement should be directed to Amanda Ashe at amanda.l.ashe@maine.edu or 207-581-1480.

Alternate Course Approval Process

Step 1: The assigned course instructor will have his/her certification in the Responsible Conduct of Research which may be obtained in any of the following ways:

a. Complete a general or discipline-specific RCR course online through the Collaborative Institutional Training Initiative (CITI) and forward the completion certificate to ORC; or

b. Participate in INT601 and forward the completion report to ORC; or

c. Participate in and complete an ORC-approved RCR workshop.

Step 2: The proposing department will submit for approval a new or amended course syllabus incorporating the RCR topics outlined in the Office of Research Integrity publication, *Introduction to the Responsible Conduct of Research,* by Nicholas H. Steneck[1], as follows:

a. RCR – Rules of the Road
b. Research Misconduct
c. The Protection of Human Subjects
d. The Welfare of Laboratory Animals
e. Conflicts of Interest
f. Data Management Practices
g. Mentor and Trainee Responsibilities
h. Collaborative Research
i. Authorship and Publication
j. Peer Review.

This most effectively can be accomplished by incorporating the contents of INT 601 into departmental courses. This also is the preferred method, as the topics, lectures, and assignments in INT 601 are designed to meet federal RCR training requirements and are all available for use and adaptation at UMaine Computing Course Materials (INT 601).

Important: If the syllabus in question is a modification to an existing, previously approved course, the department must submit the original along with the modified syllabus, and provide an explanation of the changes, and the reason for them.

Step 3: ORC will provide a review of the syllabus(i) and advise the department as to whether and what type of revisions are required for the course to meet federal and UMaine RCR training requirements.

Step 4: Upon preliminary approval, ORC will forward course documents to the Assistant Vice President for Graduate Studies (AVPGS) for final review and approval, as follows:

a) If the course in question is a new course then the syllabus will be submitted to the graduate board for approval.

b) If the course in question is a modified existing course, then the AVPGS shall determine if the changes in the course syllabus are significant enough that the course must be reapproved by the graduate board, or if it is acceptable as proposed.

Step 5: Courses approved as meeting the Graduate School's RCR requirement shall be listed as such in the graduate catalog.

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[1] Available for download at *Introduction to the Responsible Conduct of Research* by Nicholas H. Steneck

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Unless otherwise noted, the definitions below are from ORI Introduction to Responsible Conduct of Research[1].

Animal Welfare

Research, teaching or testing activities using live vertebrate animals must be reviewed and approved by the University's Institutional Animal Care and Use Committee (IACUC). [ORI – Chapter 4]

Conflict of Interest and Commitment

"A divergence between an individual's private interests and his or her professional obligations to the University such that an independent observer might reasonably question whether the individual's professional actions or decisions are determined by considerations of personal gain, financial or otherwise." [UMaine definition[2], see also ORI Chapter 5] See Conflict of Interest for more information.

Collaborative Research

"Research involving more than one investigator working on a common, 'collaborative' project. Special attention should be given to matters such as: establishing roles and responsibilities for each collaborator, developing management plans to address financial and research compliance, establishing criteria to determine authorship, and determining how intellectual property rights and ownership issues will be resolved." [ORI – Chapter 8]

Data Acquisition, Management, Sharing and Ownership

"Accepted practices for acquiring and maintaining research data – researchers should collect, store, protect, and share data, mindful of the need to maintain its integrity, validity, and accuracy. Ownership issues must be considered. Some data must be shared with colleagues; other data must be protected from unapproved use. Some data must be preserved for specified periods of time; some destroyed to protect confidentiality." [ORI – Chapter 6]

Human Subjects

Human subjects are living individuals from whom a researcher obtains data through intervention/interaction with the individual or acquires identifiable private information. Research that uses human subjects must be reviewed and approved by the University's Institutional Review Board for the Protection of Human Subjects (IRB). [ORI – Chapter 3]

Mentor / Trainee Relationships & Responsibilities

"Relationships and responsibilities between researchers and anyone learning to be a researcher (undergraduate and graduate students, and post-doctoral fellows etc.). The keys to a productive mentor-trainee relationship are: a clear understanding of mutual responsibilities, a commitment to maintain a productive and supportive research environment, proper supervision and review, and an understanding that the main purpose of the relationship is to prepare trainees to become successful researchers." [ORI – Chapter 7]

Peer Review

"Evaluation by colleagues with similar knowledge and experience. For peer review to work, it must be: timely, thorough, constructive, free from personal bias, and respectful of the need for confidentiality. Researchers who serve as peer reviewers should be mindful of the public as well as the professional consequences of their evaluations and exercise special care when making these evaluations." [ORI – Chapter 10]

Publication Practices and Responsible Authorship

"Whether structured or informal, controlled or free ranging, responsible publication in research should ideally meet some minimum standards. All forms of publication should present: a full and fair description of the work undertaken, an accurate report of the results, and an honest and open assessment of the findings." With regard to responsible authorship, "authors listed on publications should fairly and accurately represent the person(s) responsible for the work in question." [ORI – Chapter 9]

Research Misconduct

"Fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scholarly community for proposing, conducting, or reporting research and other scholarly activities. It does not include honest error or honest differences in interpretations or judgments of data." [UMaine Definition[3], see also [ORI – Chapter 2] See Research Misconduct for more information.

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[1] Steneck, N. "ORI Introduction to the Responsible Conduct of Research". HTML Version, September 2006, updated from Revised Printed Edition, June 2004 [Accessed 9/4/12]

[2] UMaine "Policies & Procedures for Financial Disclosures and Conflicts of Interest in Extramurally Sponsored Activities" (PDF) [Accessed 9/5/12]

[3] UMaine "Policy & Procedures on Alleged Misconduct in Research and Other Scholarly Activities" [Accessed 9/5/12]

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