Title: University of New Mexico Certification in the Responsible Conduct of Research	Standard Operating Procedure

OVERVIEW

Creating an environment that promotes and fosters research integrity is critical to achieve excellence in research and maintain public trust in research outcomes at the University of New Mexico (UNM). As our State is home to Native, Indigenous, and other communities that have previously been marginalized or harmed in research, we are committed to including consideration of the health, wellbeing, and respect of all peoples when designing and conducting research. As part of its commitment to support this environment, this standard operating procedure (SOP) establishes guidelines and appropriate standards for training in the Responsible Conduct of Research (RCR) at UNM and complies with regulations from the National Institutes of Health (NIH), National Science Foundation (NSF), and the United States Department of Agriculture's National Institute of Food and Agriculture (USDA NIFA).

Professional excellence in research includes a dedication to integrity. Education in the responsible conduct of research not only meets regulatory standards but also promotes ethical professional values and behaviors. RCR training is encouraged for **all** UNM research faculty, students, staff and postdoctoral fellows, not just those receiving federal funding. The Office of Research Integrity and Compliance (ORIC) of the Office of the Vice President for Research (OVPR) oversee the RCR Certification program for main and branch campus researchers.

UNM RCR Certificate Program

UNM offers certificate programs in RCR education designed to meet the requirements of federal funding agencies such as NIH, NSF, and USDA NIFA. The certificate program consists primarily of a series of workshops, as well as ½ day symposia, designed to cover a broad range of topics under the rubric of RCR. Additional details regarding each certificate can be found below.

The following topics constitute the core subject areas that are covered in RCR instruction:

- Conflict of interest and commitment;
- Responsible authorship and publication;
- Plagiarism;
- Data acquisition, management, ownership, record-keeping, analysis, interpretation, and sharing;
- Peer review;
- Mentor/mentee responsibilities and relationships;
- Research misconduct and questionable research practices;
- Ethical use of human and/or animal subjects in research; *
- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research;
- Collaborative science;
- Civility issues in research environments, including harassment, bullying, and inappropriate behavior;
- Policies regarding laboratory safety, biosafety, and human and animal research subjects

- Scientific rigor and reproducibility.

At UNM, research with humans or animals requires specific training requirements that are additional to and are not satisfied by the RCR training requirements described in this SOP.

Workshop Schedule: https://researchcompliance.unm.edu/research-integrity/responsible-conduct-of-research-certification.html

Training Frequency and Completion Deadline: The NIH and NSF RCR certificate programs must be initiated within 30 days of the investigator's start date and be completed within one calendar year. Students involved in summer research experience or other short-term awards should complete the online training component in the first two weeks of the project/program. Principal Investigators are responsible for ensuring all students and postdocs associated with the relevant award complete the RCR training requirements by the deadline. Individuals should keep documentation of the RCR training they receive, including all workshop and face-to-face discussions with faculty mentors. Individuals involved with long-term projects must take RCR refresher courses every four (4) years. NIH requires completion of RCR at least once per career stage. At this time, NIFA does not provide specific guidance on frequency of instruction, UNM requires that initial training is done before participation or payment from the project and that documentation is available upon request.

Faculty Participation: PIs and other faculty involved in research are expected to have a primary role in providing RCR instruction, which is an integral component of mentoring of students and postdoctoral researchers. Informal discussions of core RCR topics should occur in the context of laboratory interactions and other informal situations throughout the year. For more formal involvement, PIs and other faculty engaged in research are encouraged to serve as discussion leaders, speakers, and lecturers in RCR training sessions. There are also opportunities for PIs to provide training by including RCR content in existing courses, and by incorporating routine discussions of RCR content in the context of everyday encounters such as program meetings, brown-bags, and weekly seminars.

NIH RCR CERTIFICATE

The NIH requires certain proposals and all National Research Service Award applications include a description of the RCR instruction that institutions would provide to trainees. RCR instruction must be provided to all **trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, or dissertation research grant**.[1] In 2022, NIH provided new guidance on the format, frequency, and timing of RCR instruction, as well as additional topics for consideration (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-055.html).

NIH certification should aim to cover the majority of the topics listed above. Earning this certificate requires eight (8) contact hours of both formal and informal RCR instruction over the course of a year, which may be fulfilled either through an approved course for academic credit or the workshop-based curriculum described below. Note that online-only instruction of RCR is **not**

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[1] NIH's RCR requirements apply to the following programs: 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, TU2, and U2R. This requirement may also apply to other NIH-funded programs.

acceptable to the NIH. Senior fellows and trainees are encouraged to build upon their research ethics experience by participating as discussion leaders or panelists in the RCR workshop sessions. Interactive learning experiences include case studies, panel presentations, and roundtable exercises.

- Online RCR training through the Collaborative Institutional Training Initiative (CITI) Program (no more than 1 hour of supplemental online instruction in RCR may count toward the certificate)
- Enrollment in HSC BIOM 555, "Problem Based Research Bioethics" (8 hours)
- In-person and online one-hour workshops that combine didactic and small group discussions facilitated by research faculty and administrators; Interactive learning experiences include case studies, panel presentations, and roundtable exercises
- Pre-approved classes (faculty must submit syllabus to ORIC for approval)
- Up to three (3) hours of RCR instruction led and facilitated by faculty mentors on a more informal basis may count toward the certificate if documented and provided to ORIC
- Courses taken at other institutions may meet UNM RCR requirements as approved by ORIC. Evidence of completion and course materials such as a syllabus should be submitted for consideration.
- Certification of attendance at external symposia or workshops emphasizing RCR topics can be considered to meet minimal UNM RCR standards. Contact ORIC for more information on this option.

NSF RCR CERTIFICATE

Institutions applying for NSF financial assistance in science and engineering research or education must certify that they have a plan to provide appropriate RCR training and oversight to **faculty, undergraduates, graduate students, and postdoctoral researchers**. The NSF Proposal & Award Policies & Procedures Guide (PAPPG) describes the requirement to have a training plan in place and for the institution to oversee compliance with the training requirement (https://beta.nsf.gov/policies/pappg/23-1; Part 2, Chapter IX).

UNM requires six (6) hours of RCR in-person instruction to earn this certificate. Four (4) hours must comprise live instructional formats such as workshops, academic course hours, or face-to-face discussions with faculty mentors and peers.

- In-person and online one-hour workshops that combine didactic and small group discussions facilitated by research faculty and administrators. Senior fellows and trainees are encouraged to build upon their research ethics experience by participating as discussion leaders or panelists in the RCR workshop sessions. Interactive learning experiences include case studies, panel presentations, and roundtable exercises
- Online RCR training through the Collaborative Institutional Training Initiative (CITI) Program (no more than 1 hour of supplemental online instruction in RCR may count toward the certificate)
- Up to two (2) hours of RCR instruction led and facilitated by faculty mentors on a more informal basis may count toward the certificate, if documented and provided to ORIC.
- Pre-approved classes (faculty must submit syllabus to ORIC for approval)

- Certification of attendance at external symposia or workshops emphasizing RCR topics can be considered to meet minimal UNM RCR standards. Contact ORIC for more information on this option.

USDA NIFA RCR CERTIFICATE

Grantees accepting a National Institute of Food and Agriculture (NIFA) award must assure that **program directors, faculty, undergraduate students, graduate students, postdoctoral researchers, and any staff** participating in the research project receive appropriate training and oversight in the responsible and ethical conduct of research and that documentation of such training will be maintained. Grantees are advised that the documentation of the training are subject to NIFA review upon request (https://www.nifa.usda.gov/grants/regulations-and-guidelines/research-misconduct/responsible-ethical-conduct-research).

Although the online RCR course available through the Collaborative Institutional Training Initiative (CITI) satisfies the NIFA RCR training requirement, UNM encourages researchers to participate in RCR in-person instruction to round out their experience and knowledge base in RCR topics.

COMPLIANCE

Principal investigators are responsible for ensuring that individuals supported by NSF, NIH and NIFA funding have satisfactorily completed RCR instruction. This responsibility includes keeping a written record of training (see Training Log template) and submitting information electronically to ORIC (and OSP and the Sponsor, upon request). ***To comply with federal requirements, PIs must send completion certificates to oricgeneral@unm.edu within one year of funding***.

Monitoring Compliance: OSP is responsible for certifying that the RCR training plan is in place at the time of proposal submission and ORIC is responsible for tracking and verifying training hours and providing certificates upon completion of requirements.

Consequences of Noncompliance: Noncompliance with federal requirements for RCR training may result in the forfeiture of research funds and sanctions against future research funding, in addition to any institutional sanctions pursuant to the Student Code of Conduct and relevant UAP and Faculty Handbook policies.

RESOURCES

The following is a list of excellent resources that provide an introduction to the responsible and ethical conduct of research:

National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. (2009). *On Being a Scientist: A Guide to Responsible Conduct in Research* (3rd Edition). The National Academies Press, Washington DC.

National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. (2017). *Fostering Integrity in Research*. Washington, DC: The National Academies Press. https://doi.org/10.17226/21896.

Shamoo, A.E.; Resnik, D.B. (2022). *Responsible Conduct of Research* (4th Edition). Oxford University Press, NY.

CITI Program RCR Course: https://about.citiprogram.org/

NIH Sourcebook on RCR Training: https://oir.nih.gov/sourcebook/ethical-conduct/responsible-conduct-research-training

Online Ethics Center: https://onlineethics.org/research-ethics-resources

Additional resources for research involving humans and/or animal subjects:

Human Subject Research Protections training: https://irb.unm.edu/training/index.html

AALAS on-line training to handle animals: https://hsc.unm.edu/research/compliance/oacc.html. *Note: additional species-specific training is required prior to use of animals in the laboratory.*

DeGrazia, D. Mappes, T.A.; Brand-Ballard, J. (2011). *Biomedical Ethics* (7th Edition). McGraw-Hill, NY.

HHS Office of Research Integrity (ORI) Intro to the RCR: https://ori.hhs.gov/ori-introduction-responsible-conduct-research

The following resources include aspects specific to STEM research:

Martin, M.W.; Schinzinger, R. (2000). *Introduction to Engineering Ethics* (2nd Edition). McGraw-Hill.

Vesilind, P.A.; Gunn, A.S. (2016). *Hold Paramount: The Engineer's Responsibility to Society* (3rd Edition). Cengage Learning, Boston, MA.

Fleddermann, C.B. (2008). *Engineering Ethics* (3rd Edition). Pearson Prentice Hall.

Budinger. T. F.; Budinger, M. D. (2006) *Ethics of Emerging Technologies: Scientific Facts and Moral Challenges*, John Wiley & Sons.

The following resources include aspects specific to research with indigenous people:

https://www.nature.com/articles/d41586-023-02313-1

Emily Carr University in Canada: https://www.ecuad.ca/academics/research-area/research-office/research-ethics-board#in-a-good-way:-principles-guiding-indigenous-research-ethics-at-emily-carr-university

"Supporting Ethical Research Involving American Indian/Alaska Native Populations" OHRP Virtual Workshop. August 26, 2021. https://www.hhs.gov/ohrp/education-and-

outreach/educational-collaboration-with-ohrp/workshops/ohrp-hosted-workshops-aug2021/index.html

https://els2.comotion.uw.edu/product/rethics---research-ethics-training-for-health-in-indigenous-communities

The following resources include case studies and other interactive modalities:

HHS ORI Case Summaries: https://ori.hhs.gov/content/case_summary

HHS ORI Interactive Movie on Research Misconduct: https://ori.hhs.gov/the-lab

Kaebnick, G.E. (2001). *Taking Sides: Clashing Views on Bioethical Issues* (16th Edition). McGraw-Hill Education.

Murphy, T.F. (2004). *Case Studies in Biomedical Research Ethics.* The MIT Press, Cambridge, MA; 2004

DOCUMENT REVIEWED AND ACCEPTED:

Approved:

Ellen R. Fisher

Ellen R. Fisher (Aug 14, 2023 15:07 MDT)

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APPENDIX A: TEMPLATES FOR FEDERAL PROPOSALS

National Science Foundation Proposals

At the time of proposal submission, an authorized organizational representative (AOR) must certify that UNM has a plan in place to provide RCR training. In the narrative of the proposal, the PI should reference this SOP, the personnel that will require the training, and the PI's planned retention of training records. **NOTE: It is the PI's responsibility to maintain RCR training records in compliance with the sponsor's requirements.** This SOP does not have to be included with the proposal submission but must be provided to NSF upon request.

The following recommended text should be included in the NSF proposal:

Faculty, undergraduates, graduate students, and postdoctoral researchers will complete training in accordance with the University of New Mexico (UNM) Instruction in the Responsible Conduct of Research Standard Operating Procedure and will receive a certificate of completion. Acceptable RCR content includes, but is not limited to:

- Conflict of interest and commitment
- Authorship and publication
- Plagiarism
- Data acquisition, management, ownership, and sharing
- Peer review
- Mentoring
- Research misconduct
- Ethical use of human and/or animal subjects in research, as appropriate

Template for National Institutes of Health Proposals (Training Grant, Career, or National Service Research Award Applications)

In all instances, an RCR training plan must be included within the body of the proposal submission. The RCR plans submitted in proposals will be evaluated and rated "Acceptable" or "Unacceptable" but they will not be a factor in determining the impact/priority score of the proposal. However, no proposal with an unacceptable RCR plan will be funded.

In addition to the subject matter required by the NSF (listed above), the NIH requires training in the following subject areas:

- The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research;
- Collaborative science;
- Civility issues in research environments, including harassment, bullying, and inappropriate behavior;
- Policies regarding laboratory safety, biosafety, and human and animal research subjects
- Scientific rigor and reproducibility.

New applications to NIH for individual awards must include:

1. A section on RCR instruction appropriate to the career stage of the applicant (see Timing and Frequency of Instruction below);
2. Documentation of prior participation or instruction in RCR during the applicant's previous career stage; and
3. The role of the applicant's mentor in the RCR training.

Renewal applications for individual awards must describe RCR instruction undertaken during the past project period as well as future plans to meet the frequency requirements. Renewal applications must also include:

1. Any changes in the formal RCR instruction offered over the past project period;
2. Plans that address any weaknesses in the current RCR instruction; and
3. The names of all faculty who served as course directors, speakers, lecturers, or discussion leaders during the past project period.

Below is sample template language:

The University of New Mexico (UNM) requires that all researchers complete training modules as required for all compliance units. In addition to these baseline compliance requirements, I have created a plan for ongoing instruction in the Responsible Conduct of Research (RCR) for my research program. Through the course of this [*state type of grant*], I will meet NIH's RCR requirements in the following ways:

Include the title of the course, subject matter covered in the course, format (discussion or lecture etc.) name and experience of the faculty member or members who participate, how often the course meets and number of contact hours and credits, and who the target audience is or the time point at which you are taking or have taken the course. Also, explain how the course will meet your training needs with respect to the subject matter suggestions from NIH (e.g. mentoring, authorship, being a responsible member of society). This section shows how your plan is tailored to you.

Although formal instruction will lay the basis for meeting the requirements for my students, I will also take part in ongoing informal instruction through [*weekly or biweekly or monthly*] lab meetings, journal club, and one-on-one conversations with my students. I have an open-door policy and encourage trainees to speak with me to discuss issues as they arise, including but not limited to conflict of interest, research misconduct, data management, records, intellectual property, issues of social responsibility, and responsible authorship and publication.

Template for National Institute of Food and Agriculture Proposals

If a proposal to NIFA results in an award, the AOR assures, through acceptance of the award, that the institution will comply with all requirements. Award recipients must provide NIFA the policies, procedures, and documentation to support the conduct of the training, upon request.