

**Notre Dame of Maryland University
Policy on Responsible Conduct of Research (RCR)**

DRAFT

Background and Intent:

Several federal government agencies making research-related grants to colleges, universities, and other educational entities require that undergraduates, graduate students and post-doctoral researchers must receive training in the Responsible Conduct of Research (RCR). As defined by NIH, RCR entails *“the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles for all activities related to scientific research.”* Every university receiving grant support from the National Science Foundation (NSF) and National Institutes of Health (NIH) is required to have an RCR program in place at the time of proposal submission. Guidance on the requirement for RCR training was provided by NSF and NIH beginning in 2010.

Signed into law in 2007, the **America COMPETES Act**, Section 7009, mandates that the NSF/NIH require applicant institutions in research endeavors to describe *“a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students and postdoctoral researchers participating in the proposed research project.”*

NSF’s implementation of America COMPETES involves the following basic requirements:

- **At the time of proposal submission**, the institution must certify that the institution has a plan to provide appropriate training and oversight in RCR to undergraduates, graduate students, and postdoctoral researchers supported by NSF. (Certification provided by Authorized Organizational Representative – AOR),
- Training plans are not required to be included in the submission to NSF (but are subject to review upon request by NSF),
- An institution must designate one or more persons to oversee compliance with the RCR training requirement, and,
- Institutions are responsible for verifying that undergraduate students, graduate students, and postdoctoral researchers supported by NSF to conduct research have received training in the responsible and ethical conduct of research.
- The policy took effect on Jan. 4, 2010.

NIH’s implementation of America COMPETES involves the following basic requirements:

- NIH requires that 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.
- The policy took effect with all new and renewal applications submitted after Jan. 25, 2010.
- The requirement extends to all continuation applications with deadlines on or after Jan. 1, 2011.

Agency Specific Requirements for RCR:

While the choice and composition of training program has been left to the determination of individual academic institutions, NSF and NIH have provided, within their notices, specific guidance to ensure both effectiveness of the research integrity training program as well as compliance with the federal mandates. NIH guidance can be found in Notice NOT-OD-10-019 available on the NIH.gov website, as well as through NSF via the following link: <https://www.nsf.gov/bfa/dias/policy/rcr.jsp>.

The following reflects agency requirements as set forth by NIH and are reproduced here to provide the basic principles and instructional components upon which NDMU's own RCR Policy and associated training program are based.

Basic Principles

The following principles are based on several key concepts about responsible conduct of research and best practices:

1. Responsible conduct of research is an essential component of research training. Therefore, instruction in responsible conduct of research is an integral part of all research training programs, and its evaluation will impact funding decisions.
2. Active involvement in the issues of responsible conduct of research should occur throughout a scientist's career. Instruction in responsible conduct of research should therefore be appropriate to the career stage of the individuals receiving training.
3. Individuals supported by individual funding opportunities such as fellowships and career development awards are encouraged to assume individual and personal responsibility for their instruction in responsible conduct of research.
4. Research faculty of the institution should participate in instruction in responsible conduct of research in ways that allow them to serve as effective role models for their trainees, fellows, and scholars.
5. Instruction should include face-to-face discussions by course participants and faculty; i.e., on-line instruction may be a component of instruction in responsible conduct of research but is not sufficient to meet the NIH requirement for such instruction, except in special or unusual circumstances.
6. Instruction in responsible conduct of research must be carefully evaluated in all NIH grant applications for which it is a required component.

NIH Programs Affected Under RCR Policy

This Notice applies 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 policy also applies to any other NIH-funded programs supporting research training, career development, or research education that require instruction in responsible conduct of research as stated in the relevant funding opportunity announcements.

Instructional Components

NIH recognizes that instruction in responsible conduct of research occurs formally and informally in educational settings and that informal instruction occurs throughout the research training experience. The guidance provided below is directed at formal instruction in responsible conduct of research. These practices have been incorporated into many of the best regarded programs of instruction in responsible conduct of research.

1. **Format:** While face-to-face in person training will be the primary mode of RCR training, **completion of the necessary online training modules should occur within the first thirty (30) days of the commencement of the grant-funded research activity and should be considered the preliminary step of the complete RCR training.**

While on-line courses can be a valuable supplement to instruction in responsible conduct of research, **online instruction is not considered adequate as the sole means of instruction.**

A plan that employs only online coursework for instruction in responsible conduct of research will not be considered acceptable, except in special instances of short-term training programs, or unusual and well-justified circumstances.

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 **are highly encouraged.**

2. **Subject Matter:** While there are no specific curricular requirements for instruction in responsible conduct of research, the following topics have been incorporated into most acceptable plans for such instruction:
 - a) conflict of interest – personal, professional, and financial
 - b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - c) mentor/mentee responsibilities and relationships

- d) collaborative research including collaborations with industry
- e) peer review
- f) data acquisition and laboratory tools; management, sharing and ownership
- g) research misconduct and policies for handling misconduct
- h) responsible authorship and publication
- i) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

While courses related to professional ethics, ethical issues in clinical research, or research involving vertebrate animals may form a part of instruction in responsible conduct of research, they generally are not sufficient to cover all of the above topics.

3. **Faculty Participation:** Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations throughout the year. Training faculty may contribute to formal instruction in responsible conduct of research as discussion leaders, speakers, lecturers, and/or course directors. Rotation of training faculty as course directors, instructors, and/or discussion leaders may be a useful way to achieve the ideal of full faculty participation in formal responsible conduct of research courses over a period of time.
4. **Duration of Instruction:** Instruction should involve **substantive contact hours** between the trainees/fellows/scholars/participants and the participating faculty. **Acceptable programs generally involve at least eight contact hours.** A semester-long series of seminars/programs may be more effective than a single seminar or one-day workshop because it is expected that topics will then be considered in sufficient depth, learning will be better consolidated, and the subject matter will be synthesized within a broader conceptual framework.
5. **Frequency of Instruction:** Reflection on responsible conduct of research should recur throughout a scientist's career: at the undergraduate, post-baccalaureate, predoctoral, postdoctoral, and faculty levels. Institutional training programs and individual fellows/scholars are strongly encouraged to consider how to optimize instruction in responsible conduct of research for the particular career stage(s) of the individual(s) involved. **Instruction must be undertaken at least once during each career stage, and at a frequency of no less than once every four years. It is highly encouraged that initial instruction during predoctoral training occurs as early as possible in graduate school. Individuals at the**

early career investigator level (including mentored K awardees and K12 scholars) must receive instruction in responsible conduct of research at least once during this career stage. Senior fellows and career award recipients (including F33, K02, K05, and K24 awardees) may fulfill the requirement for instruction in responsible conduct of research by participating as lecturers and discussion leaders. To meet the above requirements, instruction in responsible conduct of research may take place, in appropriate circumstances, in a year when the trainee, fellow or career award recipient is not actually supported by an NIH grant. This instruction can be documented as described below.

Special Considerations by Type of Award

Institutional training and institutional career development programs (for example, T15, T32, T34, T90/R90, TL1, K12, or K30 programs): Institutional programs are encouraged to provide instruction in responsible conduct of research for all individuals associated with the program of training regardless of their source of support.

Short-term training and research education programs (for example, T35 and R25 programs lasting six or fewer months, short-term trainees supported on T15, T32 and T34 programs, and short-term participants in R25 programs): The NIH recognizes that the duration of an institutional training or research education program should be considered in the design, implementation, and review of plans for instruction in responsible conduct of research. The duration of such instruction within short-term institutional programs should be appropriate for the total duration of the program and should be justified in the application. This is an instance where on-line instruction could be appropriate. Such programs may also use innovative strategies to incorporate instruction in responsible conduct of research and to relate instruction in responsible conduct of research to the scientific focus of the short-term program.

Individual awards: In keeping with the individual nature of these programs, fellows and scholars, along with their institutions and sponsors/mentors, are encouraged to tailor instruction in responsible conduct of research to the needs of the individual. Thus, instruction may go beyond formal institutional courses and provide opportunities for the individual to develop their own scholarly understanding of the ethical issues associated with their research activities and their impact on society. An individualized plan would also be appropriate in the rare instance where an institution does not have an established formal mechanism for such instruction.

Application Procedures for NIH Applications to Above Referenced Programs

1. Institutional Applications

- a) **New (Type 1) applications** must include a plan for instruction in responsible conduct of research. In addition to addressing the five instructional components, the plan must describe how participation in instruction in responsible conduct of research will be monitored.

- b) **Renewal (Type 2) applications** must, in addition, describe changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current instruction in responsible conduct of research. All training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period must be named in the application

2. Individual Applications

- a) **New (Type 1) applications** must include a section on instruction in responsible conduct of research, appropriate to the career stage of the applicant (instruction for applicants in the early stages of their careers; participation as course directors, lecturers, or discussion leaders for applicants in middle or senior stages of their careers), as part of the Research Training Plan or Candidate Information and Career Development Plan. This section will document prior participation or instruction in responsible conduct of research during the applicant's current career stage (including the date instruction was last completed) and propose plans to either receive instruction in responsible conduct of research or participate as a course lecturer, etc., depending on the applicant's career stage. Such plans must address the five instructional components outlined above. The plan may include career stage-appropriate, individualized instruction or independent scholarly activities that will enhance the applicant's understanding of ethical issues related to their specific research activities and the societal impact of that research. The role of the sponsor/mentor in instruction in responsible conduct of research must be described.

- b) **Where applicable, renewal (Type 2) applications** must describe instruction in responsible conduct of research activities undertaken during the past project period as well as future plans in order to meet the frequency requirement as outlined above in Instructional Components.

Applications lacking a plan for instruction in responsible conduct of research will be considered incomplete and may be delayed in the review process or not reviewed.

Compliance

NIH policy requires participation in and successful completion of instruction in responsible conduct of research by individuals supported by any NIH training/research education/fellowship/career award. It is expected that course attendance is monitored and that a certificate or documentation of participation is available upon course completion. NIH does not require certification of compliance or submission of documentation, but expects institutions to maintain records sufficient to demonstrate that NIH-supported trainees, fellows, and scholars have received the required instruction.

NDMU Responsible Conduct of Research Training Program

NDMU's implementation of the requirements for responsible conduct of research involve both online training modules and in-person training components.

- All undergraduate and graduate students supported in any part by a grant from the NSF or the NIH are required to complete both an online training program and in-person training.
- Likewise, all faculty members serving as Principle Investigators (PIs) or co-Principle Investigators (co-PIs) on research grants through the NSF and the NIH are required to complete both online and in-person training. PIs/co-PIs on NSF or NIH research grants involving students are expected to conduct, oversee, and certify the training of their student-researchers.
- On any grant where a trainee is PI, the named faculty mentor on the grant is responsible to conduct, oversee, and certify the trainee's compliance with the RCR training requirements.
- On any grant where a trainee is PI and there is **no** named faculty mentor, the PI's Department Chair is responsible to conduct, oversee, and certify the trainee's compliance with the RCR training requirement.

In-Person Training

Components of in-person RCR training should: promote discussion on ethics and research integrity, provide practical and relevant examples of correct and incorrect conduct of research for students and faculty to review, allow a forum for student/faculty input on issues surrounding research integrity, present NDMU's mission and culture as they intersect with research and academic integrity, and provide review and training in NDMU's research policies and procedures.

- **Acceptable training resources for in-person RCR training may include:**
 - Printed selections from: <http://ori.hhs.gov/images/ddblock/rcrintro.pdf> (ORI Introduction to the Responsible Conduct of Research by Nicholas Steneck), <http://www.nap.edu/catalog/4917/on-being-a-scientist-responsible-conduct-in-research-second-edition> (On Being a Scientist - Responsible Conduct in Research, Second Edition, Institute of Medicine), <http://www.nap.edu/read/2091/chapter/1> (Responsible Science: Ensuring the Integrity of the Research Process, V. II, National Academy of Sciences).
 - Review and discussion of NDMU policies on financial conflict of interest, policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices, mentor/mentee responsibilities and relationships,

research misconduct and policies for handling misconduct, and/or responsible authorship and publication.

- Presentations or panels from field experts or scholars with participation from students and faculty involved in research, lecture series/workshops, laboratory rotations, or other curriculum.
- Informal opportunities should also be considered which could include: faculty meetings, academic clubs, lunch-and-learn sessions between students and faculty, laboratory courses. **Such opportunities should be well-defined, cataloged, and approved in advance through the relevant Academic Dean and the VPAA.**
- In order to meet the minimum mandate for in-person RCR training as required by NIH-guidelines, in-person RCR training must consist of at least:
 - Eight (8) hours over the course of four (4) years or, alternatively,
 - Two (2) hours annually over the course of four (4) years.
 - Should the student's term at NDMU be shorter than 4 years, the in-person RCR training must be completed and certified prior to her or his departure from NDMU.

Online Training Modules

The approved, online training module for RCR training at NDMU is:

http://ori.hhs.gov/education/products/montana_round1/research_ethics.html

(Online Research Ethics Course developed through the Practical Ethics Center at the University of Montana with Office of Research Integrity (ORI))

Do we have CITI online training currently available?

<https://www.citiprogram.org/index.cfm?pageID=265>

- Students and faculty as described above are expected to complete the components of the online, RCR training modules **within the first thirty (30) days of beginning work** on an NSF or NIH-funded research program as outlined in this Policy.
- Satisfactory completion of the online modules will represent a score of **70% or greater** and/or the achievement of a certificate from the online training provider.
- Once completed, students must sign and submit an RCR Training Certification Form to their PI along with copies of the applicable achievement certificates. The PI will sign the certification form and submit the original to the Vice President for Academic Affairs (VPAA) and provide copies to the relevant Academic Dean and to the Office of Corporate, Foundation, and Government Grants (OCFGG).

- For faculty required to complete RCR training, PI's are required to submit their Certification Form and applicable achievement certificates to their Department Chair and/or Academic Dean who will sign and submit to the VPAA and OCFGG.

Compliance Oversight and Responsibility

As required under NSF implementation of America COMPETES, an institution must designate one or more persons to oversee compliance with the RCR training requirement. At NDMU, the Vice President for Academic Affairs (VPAA) oversees compliance with the RCR Policy. The VPAA is assisted in this oversight by the university's Academic Deans, the Office of the Associate Vice President for Academic Affairs (OAVPAA), and the OCFGG.

- The VPAA's Office, through the Dean, will notify the Principal Investigator of the requirement for the documentation of the RCR training.
- The PI is responsible for providing the VPAA, Dean, and OCFGG with all relevant information (e.g., employee names and start dates) and documentation when requested, including copies of all signed certification forms.
- The Dean will track and record names, start dates, and RCR training completion dates of all affected students and faculty when payroll authorizations are processed. Copies of certifications for all students and faculty who successfully complete RCR training will be retained in a dedicated RCR file for at least three years after completion of the project.
- Certifications will be kept on file in the Office of the VPAA, Dean, and the OCFGG.

Noncompliance with NDMU RCR Policies

Faculty and/or student-researchers failing to complete RCR training in a timely manner may be subject the following penalties: (1) removal from the applicable research project, (2) withholding of applicable grant-funding until training is completed, and (3) withholding of other non-RCR related grant funding.

- Students and faculty will be provided with reminders to complete the applicable RCR training
- Should students and faculty not begin, show progress towards completion, or complete the RCR training within the specified timeframe (in-person training of 8 hours over 4 years or 2 hours annually over 4 years; online modules within the first 30 days of the funded-research), the VPAA and Academic Dean will require a meeting with the PI and, if applicable, student-researchers to inform them of the consequences of non-compliance. A further meeting within 30 days should be conducted to determine if progress on RCR training is being made.

Record-Keeping and Training Repository

Documentation of the completion of required RCR training is kept by the Office of the VPAA, the Dean, and the Office of Corporate, Foundation and Government Grants for at least 3 years following the completion of the research project.

The Office of the AVPAA will act as a repository for training materials and information on accepted-RCR training (e.g. printed materials, videos, online training modules, speaker contact information). Such materials will be made available to faculty and students to assist in meeting the training requirements for RCR.

Renewal Training and Review of RCR Policy

NDMU requires that all faculty and students **previously engaged** in research activities with funding from the NSF or the NIH renew their RCR training **at least every four years**, regardless of their **current** participation in an NSF or NIH-funded research project.

The RCR Policy for NDMU will undergo an annual review by the VPAA, AVPAA, Academic Deans, and the Director of Corporate, Foundation, and Government Grants. Such a review will determine if policy adjustments are needed for NDMU to remain in compliance with federal mandates.

RCR Training Certification Form

Role on Project: Trainee/Student PI/co-PI Academic Dean

Project Name or Grant Number: _____

Principal Investigator (PI)/Co-PI Name: _____

PI/co-PI Employment Start Date on Sponsored Project: _____

Trainee/Student Name: _____

Trainee/Student Employment Start Date on Sponsored Project: _____

As the trainee/student on this sponsored project requiring RCR training, I acknowledge that I have successfully completed an approved training course on the Responsible Conduct of Research.

As the PI on this sponsored project requiring RCR training, I acknowledge that the Trainee/Student named above has successfully completed an approved training course on the Responsible Conduct of Research.

As the Academic Dean of the department involving the sponsored project, I acknowledge that the PI/co-PI named above has successfully completed an approved training course on the Responsible Conduct of Research.

Student/Trainee	PI/co-PI	Academic Dean
Signature/Date	Signature/Date	Signature/Date

Please submit this original signed certificate of RCR completion to the VPAA and a copy of the signed certificate to each of the following: Academic Dean and the Office of Corporate, Foundation and Government Grants.

Please attach copies of any training certificates from online training courses.

Should you have any questions regarding RCR compliance, please contact the Office of the Vice President for Academic Affairs, 410-532-5321.