Mississippi State University Responsible Conduct of Research Implementation Plan

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I. Introduction

Responsible Conduct of Research (RCR) is the practice of scientific investigation with integrity. It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research.

The responsible and ethical conduct of research is critical for excellence, as well as public trust, in science and engineering. Consequently, education in the Responsible Conduct of Research (RCR) is considered essential in the preparation of future scientists and engineers.

II. Federal Requirements

National Science Foundation

Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 U.S.C. 1862o–1) requires that "each institution that applies for financial assistance from the National Science Foundation (NSF) for science and engineering research or education describe in its grant proposal 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."

As of January 4, 2010, at the time of an NSF proposal submission, the Principal Investigator (PI) is required to complete a certification that states the Mississippi State University 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.

The language specified below provides NSF's implementation of Section 7009.

a. An institution must have a plan in place 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. As noted in GPG Chapter II.C.1e, institutional certification to this effect is required for each proposal.

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- b. While training plans are not required to be included in proposals submitted to NSF, institutions are advised that they are subject to review, upon request.
- c. An institution must designate one or more persons to oversee compliance with the RCR training requirement.
- d. 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.

National Institutes of Health

Effective January 25, 2010, the revised National Institutes of Health (NIH) policy requires that all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award (individual or institutional), research education grant, and dissertation research grant receive instruction in responsible conduct of research. This policy also applies to any other NIH-funded grant program with a training component that requires instruction in responsible conduct of research as noted in the Funding Opportunity Announcement.

This policy took effect with all new and renewal applications submitted on or after January 25, 2010, and for all continuation (Type 5) applications with deadlines on or after January 1, 2011. 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.

New institutional applications must include a plan for instruction in RCR, addressing the five instructional components outlined in the NIH policy and describing how participation in instruction in RCR will be monitored. Renewal institutional applications must also describe changes in formal instruction over the past project period and plans for the future that address any weaknesses in the current RCR instruction and must name all training faculty who served as course directors, speakers, lecturers, and/or discussion leaders during the past project period.

New individual applications must include a section on instruction in RCR, 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. Plans must document prior RCR participation or instruction 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. 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. Where applicable, renewal individual applications must describe instruction in RCR activities undertaken during the past project period as well as future plans in order to meet the frequency requirement.

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NIH indicates that a plan that employs only online coursework for instruction in RCR will not be considered adequate as the sole means of instruction except in special instances of short-term training 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 R24 programs), or unusual and well-justified circumstances.

The following topics have been incorporated into most acceptable plans for instruction: conflict of interest – personal, professional, and financial; policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices; mentor/mentee responsibilities and relationships; collaborative research including collaborations with industry; peer review; data acquisition and laboratory tools; management, sharing and ownership; research misconduct and policies for handling misconduct; responsible authorship and publication; the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research. Acceptable programs generally involve at least 8 contact hours and be undertaken at least once during each career stage, and at a frequency of no less than once every four years.

<u>US Department of Agriculture – National Institutes of Food and Agriculture</u>

For NIFA awards and all grants subject to the February 2013 NIFA agency-specific Terms and Conditions or any revisions thereafter, the U.S. Department of Agriculture (USDA) National Institute of Food and Agriculture (NIFA) issued the following RCR Training requirement;

"By accepting a NIFA award the grantee assures 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 is subject to NIFA review upon request."

When applying for NIFA funds, the Program Director must assure that the aforementioned individuals receive training and maintain documentation of such training. Documentation of training is subject to review upon request by NIFA.

The terms and conditions apply to all awards (grants, cooperative agreements, and special projects) funded by NIFA *except:* 1) Formula Funded Programs; 2) the 1890 Facilities Program; and 3) the Small Business Innovation Research Program; as well as 4) awards to individuals.

III. RCR Training

<u>Training Required for PRINCIPAL INVESTIGATORS and Co-PIs</u>

The Principal Investigator and co-PIs on covered NSF, NIH, and NIFA proposals shall complete the requirement for RCR training **before** Sponsored Programs Administration will release an award. Training is accomplished through completion of an online course delivered through the myCourses system as well as the online RCR course through CITI website (https://www.citiprogram.org/). It is highly recommended that training is completed soon after a proposal is submitted to minimize delays in awarding. The Principal

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Investigator will receive notification from Sponsored Programs Administration and the Office of Research Compliance regarding this training requirement upon the submission of a proposal.

The online course delivered through the myCourses system takes approximately 15 minutes to complete and is intended to give PIs and co-PIs an overview of their responsibilities in RCR. The online RCR course through the CITI website has discipline-specific courses containing core areas each with foundation text, imbedded case studies, and multiple-choice questions. Individuals are required to complete only the most relevant discipline specific course. Eighty percent (80%) of the questions must be answered correctly in order to pass each module.

Training Required for OTHER PROJECT PERSONNEL:

Other project personnel should complete the RCR training requirement via one of three options listed below:

- 1) CITI online certification in RCR plus attendance at 4 one-hour face-to-face sessions covering ethical issues (8 sessions for NIH projects); or
- 2) Enrollment in an approved 1-hour credit course in Research Ethics plus attendance at 4 one-hour face-to-face sessions covering ethical issues (8 sessions for NIH projects); or
- 3) Enrollment in an approved face-to-face 3-hour credit course in Research Ethics.

The online RCR course through the CITI website has discipline-specific courses containing core areas each with foundation text, imbedded case studies, and multiple-choice questions. Individuals are required to complete only the most relevant discipline specific course. Eighty percent (80%) of the questions must be answered correctly in order to pass each module.

A current schedule of face-to-face sessions can be found on the ORC website (http://orc.msstate.edu/conduct/training/). These sessions are discussions of ethical issues associated with one of the nine core competencies recognized by the Public Health Service (PHS) Policy on Instruction in the Responsible Conduct of Research. These sessions will be facilitated by ethics professionals at MSU.

A listing of all approved 1-hour and 3-hour credit courses can be found on the ORC website. The courses have been determined satisfactory to meet the requirement of a program of study designed to contribute to the knowledge and respect of high ethical standards. A passing grade is required for the course to be counted as RCR training. Anyone wishing to enroll in credit courses should contact the MSU Registrar's Office.

Other project personnel should complete the on-line CITI training component within the first 90 days of appointment to a covered project. The face-to-face training component should be completed within the first 12 months of appointment to a covered project.

Refresher Training

Refresher training is required only for covered NIH projects. NIH states that "[a]cceptable programs generally involve at least 8 contact hours and be undertaken at least once during each career stage, and at a frequency of no less than once every four years".

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IV. Principal Investigator Responsibilities

Compliance with the requirements for providing instruction in RCR is a responsibility of the Principal Investigator (PI). Each solicitation for funding should be reviewed to determine if RCR requirements apply. Each award notice should be reviewed to determine if there are any RCR reporting requirements. The PI should communicate to project personnel, the RCR requirement, and how to complete it. The PI is responsible for monitoring compliance. Documentation of in-person RCR training that has been completed to satisfy the RCR requirement is a responsibility of the PI unless the training is being tracked by ORC (all online training and live sessions sponsored by ORC will be tracked in the ORC database). The PI must take corrective action if individuals do not complete the RCR training requirement within the specified timeframe of training completion.

Willful non-compliance on the part of any project personnel shall result in termination of that person's funding.

V. Additional Resources

National Institute of Health: Training in the Responsible Conduct of Research http://grants.nih.gov/training/responsibleconduct.htm

National Science Foundation: Responsible Conduct of Research http://www.nsf.gov/bfa/dias/policy/rcr.jsp

US Department of Ag, National Institute of Food and Agriculture: Terms and Conditions http://www.nsf.gov/pubs/policydocs/rtc/agencyspecifics/nifa 213.pdf

US Department of Health & Human Services, Office of Research Integrity http://ori.hhs.gov/

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