PLAN FOR TRAINING IN THE RESPONSIBLE CONDUCT OF RESEARCH AND MENTORING OF GRADUATE STUDENT AND POST-DOCTORAL RESEARCHERS

BACKGROUND

Section 7009 of the America COMPETES Act of 2007 (*America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education and Science*) directed that the National Science Foundation require institutions receiving financial assistance from the Foundation for science and engineering research or education to implement mentoring and training in the responsible and ethical conduct of research for undergraduate and graduate students as well as postdoctoral researchers.

In responding to this requirement, the NSF published a revision to its *NSF Proposal & Award Policies and Procedures Guide* requiring that beginning January 4, 2010, institutions must certify, at the time of proposal submission, it 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 participate in NSF funded projects.

Subsequent to the publication of new requirements by the NSF, the NIH published its own RCR education requirements for institutions receiving funding for training grants through the NIH. These requirements are outlined in NOT-OD-10-019, the NIH *Update on the Requirement for Instruction in the Responsible Conduct of Research.* This notice is applicable to all NIH Institutional Research Training Grants, Individual Fellowship Awards, Career Development Awards (both institutional and individual), Research Education Grants, Dissertation Research Grants and other grant programs with a training component that requires instruction in responsible conduct of research.

PURPOSE

The purpose of this document is to outline a plan for implementing NSF's requirements for providing training to undergraduate and graduate students and postdoctoral researchers in the responsible and ethical conduct of research.

DEFINITION

For the purpose of this Plan, responsible conduct of research is defined as "***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."

POLICY STATEMENT

All East Carolina University (ECU) undergraduate and graduate students as well as postdoctoral scholars who participate in NSF funded research or educational projects must fulfill educational requirements related to the responsible and ethical conduct of research.

All members of the ECU research community, to include students and postdoctoral researchers, are expected to adhere to the highest ethical and professional standards as they pursue research and scholarly activities. In so doing, it requires the vigilance of all members engaged in research and scholarly endeavors to comply with the legal, regulatory, and ethical requirements established by the University, regulatory agencies, funding sources and professional organizations.

The Office of Research Integrity (ORI) in the U.S. Department of Health and Human Services is the federal agency charged with the responsibility of oversight for the responsible conduct of research. The ORI encourages researchers to make a special effort to understand, discuss, and teach others about the responsible conduct of research. It is understood that RCR can be taught and learned in many ways and that standards can vary from discipline to discipline. For this reason, it is the intent of the RCR Education Program at ECU to provide flexibility in its content and delivery methods in such a way that it addresses the specific needs, issues and concerns of various target audiences among numerous disciplines.

RCR CONTENT AREAS

The following are the content areas that comprise the responsible conduct of research:

Research Misconduct
Conflict of Interest and Conflict of Commitment
Human Subjects
Animal Welfare
Data Acquisition, Management, Sharing and Ownership
Publication Practices and Responsible Authorship
Mentor/Trainee Responsibilities
Peer Review
Collaborative Science
Research Ethics and the Role of the Scientist

Difficult Conversations

Training in the content areas related to human subject research, research involving animals, and safe laboratory practices will be conducted and verified in accordance with federal regulatory requirements governing those specific content areas and as specified by institutional policies established by the IRB, IACUC, and other relevant research compliance committees.

BASIC PRINCIPLES AND SUCCESSFUL STRATEGIES

In its *Summary of a Workshop on Ethics Education and Scientific and Engineering Research*, the National Academy of Engineering identified a number of components that characterize successful strategies for ethics and RCR education programs.

In addition, The NIH elucidates in its *Update on the Requirement for Instruction in the Responsible Conduct of Research,* basic principles and key concepts that, based on best practices, are considered components of an effective educational program designed to promote the responsible conduct of research:

ECU endorses these principles and strategies outlined below and they are considered key components for the successful implementation of this Plan.

- RCR is an essential component of research training
- RCR education is mandatory for all students (undergraduate and graduate) and post-doctoral scholars supported by NSF, NIH, and NIFA awards
- RCR education is required for any faculty supported by a NIFA award
- RCR education is required for all personnel, at every career stage, supported by NIH funded awards for
  - ➤ training grants
  - ➤ fellowships,
  - ➤ career development
  - ➤ research education,
  - ➤ dissertation research
  - ➤ others with a training component requiring RCR instruction
- RCR education will encourage the active participation of faculty in ways that allow them to serve as effective role models
- RCR education programs will be conducted on a recurring basis and in formats that allow active (face-to-face) interaction of students and post-doctoral researchers with faculty mentors and trainers

- The RCR education program will provide discipline-specific training to address the needs of investigators in their specific fields of research
- RCR training requires active involvement throughout a scientist's career and should be appropriate to the career stage
- Individuals should assume personal responsibility for their instruction in RCR

CONSIDERATIONS IN DEVELOPING THE PLAN

The following Plan was developed with the requirements of NSF, NIH, NIFA and best practices in mind, as well as local considerations. In developing the plan for implementation, the following considerations were determined to be relevant factors:

- What strategies will be used for implementation?
- What content and delivery methods will be used?
- Is there a need for content development or implementation of other pedagogical methods to meet requirements?
- Who will be responsible for the various components of the institutional RCR Education Program?
- What institutional policy, guidelines, and procedures will facilitate implementation of the plan?
- What resources are available to support implementation of the plan and are they sufficient?
- Who will provide institutional oversight and verification that requirements are met?
- How will completion of training be reported?
- How will the overall efficacy of the RCR education program be evaluated?

PLAN FOR IMPLEMENTATION

Goal: Implement a plan for compliance with RCR training requirements that meets federal funding agency requirements

Requirements:

- **NSF**. NSF requires certification that the institution has developed a plan to provide training and oversight in the responsible conduct of research (RCR) at the time of proposal submission

- **NIH**. NIH has published different requirements for institutional applications and individual applications.

o **Institutional Applications**. Requires that new and renewal applications include a plan for instruction in the responsible conduct of research. The plan must address the five instructional components and describe how instruction will be monitored. Renewal applications must also describe any changes in formal instruction that have occurred over the last project period and plans for the future that address any weaknesses in current RCR instruction.

o **Individual Applications**.

Effective Date: January 4, 2010

Target Audience: Undergraduate/graduate students and post-doctoral scholars working on projects funded in whole or in part by NSF research and education grants. Undergraduate and graduate students, postdoctoral scholars/fellows and faculty members funded in whole or in part from an institutional or individual NIH training grant.

Delivery Methods

Various combinations and modes of instruction will be available for completion of training requirements to afford maximum flexibility in meeting the needs of a broad range of stakeholders. In this sense, the program will be customized and appropriate for the target audience. For example, the requirements for a post-doctoral researcher in engineering are different than those of an undergraduate student in psychology. The Office of Research Integrity and Compliance, in consultation with the RCR Education Steering Committee, will establish and communicate minimum training standards for each target audience (undergraduates, graduate students, post-doctoral researchers/fellows and faculty).

Post-doctoral researcher mentoring plan

Each proposal that requests NSF or NIH funding to support **postdoctoral scholars/fellows** must include, as a supplementary document, a description of the mentoring activities that will be provided for such individuals. In no more than one page, the mentoring plan must describe the mentoring that will be provided to all postdoctoral researchers supported by the project, irrespective of whether they reside at the submitting organization, any sub-awardee organization, or at any organization participating in a simultaneously submitted collaborative project.

Particularly with respect to post-doctoral researchers, mentoring may consist of informal or formal meetings to discuss topics related but not limited to: career counseling, training in the preparation of grant proposals, publication and presentations, improving teaching

and mentoring skills, reconciling dual roles as mentor/mentee, effective collaboration with investigators from diverse backgrounds and disciplinary areas, implications of temporary appointments on data and project ownership, and responsible professional practices.

Faculty mentors are to provide Individual Development Plans to post-doctoral fellows that, identifies both professional development needs and career objectives. The Federation of American Societies of Experimental Biology (FASEB) has developed a useful tool called myIDP, for executing the IDP process for both graduate students and post-doctoral scholars.   The research and career progress of post-doctoral fellows is to be formally documented in an annual review and will serve as a useful performance evaluation tool.

Post-doctoral scholars/fellows and faculty may also be credited with RCR training by completing the Train-the-Trainer Course and facilitating an educational session as part of the ECU centralized RCR training program or at the departmental level.

Mentorship in RCR will be augmented by the availability of web-based instructional modules as well as more formal methods of instruction such as credit or non-credit courses, seminars, workshops, lectures, etc.

Other Training Options: Principal Investigators may select a number of options to ensure completion of training requirements.   ORIC has developed a matrix made available on the Website that displays acceptable training options for each target audience.

- Web-based. Supplemental training is available and consists of completing on-line modules developed by the Collaborative Institutional Training Initiative (CITI). A certificate of completion is generated for each individual successfully completing the on-line training and reports of completion are generated by CITI to ORIC. CITI is designed to be discipline specific and may be fully customized for a particular research community (biomedical, social behavioral, physical sciences, humanities). Please note that the completion of RCR training through CITI only is not recognized as sufficient in meeting the RCR training requirements of NIH.

  An alternative on-line tutorial developed by ORIC will be used for undergraduates participating in a short-term project (i.e. summer internship).

- Formal instruction. The primary method of instruction in RCR will be by formal face-to-face instruction consisting of a minimum of eight contact hours. Formal RCR instruction is offered by ORIC for postdoctoral scholars in an RCR course held twice annually. ORIC will also provide a Train-the-Trainer RCR Course and ethics instruction to certify post-doctoral scholars as RCR instructors at the departmental level. Schools, departments and institutes are encouraged to offer decentralized

training designed to meet the specific needs of the students assigned to projects under the supervision of their faculty.

Responsibilities under the Plan

Responsibility for compliance rests primarily with principal investigators. Accordingly, principal investigators will:

- Identify all members of the research team upon notification of an NSF or NIH funded award
- File an RCR training plan with ORIC for each applicable audience (undergraduate/graduate students and postdoctoral researchers/fellows and faculty) participating in projects that are funded in whole or in part by an NSF or NIH award
- Upon confirmation of receipt of NSF or NIH funding, confirm or report changes in membership of the research team in RAMSeS
- Schedule and monitor completion of RCR training for required students/post-doctoral researchers or fellows/faculty
- Report completion of RCR training to ORIC
- Engage in compacts with post-doctoral appointees that outline the commitments of both the PI and the post-doctoral appointee relative to the post-doctoral appointee-mentor relationship
- Complete an Individual Development Plan (IDP) and Annual Review for post-doctoral fellows

Research, Economic Development and Engagement (REDE) is the division within the institution responsible for:

- Designating an Authorized Organizational Representative who will certify the existence of an institutional plan for RCR education on NSF proposals
- Developing and allocating sufficient resources necessary to conduct and report completion of training
- Delegating authority and responsibility for monitoring training and compliance with RCR requirements to ORIC

ORIC is responsible for:

- Monitoring RCR training activities
- Verifying compliance with NSF, NIH, and NIFA RCR training requirements
- Establishing and providing administrative support to the RCR Education Steering Committee

- Coordinating reviews and certification of RCR curricula developed by ECU departments, schools or institutes
- Developing an assessment tool or tools for the evaluation of the effectiveness of RCR training and educational activities
- Building collaborations with departments that promote faculty involvement in the program

The RCR Education Steering Committee is responsible for:

- Providing institutional leadership for implementing and evaluating the RCR Education Program
- Assisting in the development and review of RCR educational resources
- Serving as a liaison between the ORIC and Schools/ Departments/Institutes for implementation and conduct of the RCR Education Program
- Developing minimum standards of RCR training for each target group
- Recommend implementation of policies that promote the institutional goals of the RCR education program

Institutional policy, guidelines and procedures

The development of institutional policy, guidelines and procedures relevant to RCR practices and the RCR Education Program underscores its legitimacy as an institutional priority and advances the responsible and ethical conduct of research within the ECU community.

Audit and verification of compliance

Periodic compliance audits will be conducted by Internal Audit.   Information on salary paid to research staff from NSF and NIH funds will be extracted from databases maintained by grants accounting on a quarterly basis and compared to RCR training information reported in RAMSeS to ensure all personnel required to complete RCR training have done so or are in the cue for doing so.

Training previously completed at other institutions

Personnel who have documented completion of RCR training at another institution may be considered to have met ECU training requirements. RCR training completed at another institution will be evaluated on a case-by-case basis and predicated on the equivalency of that institution's RCR education program to that of ECU's.

RCR Resources

ORIC will be responsible for developing and coordinating institutional RCR educational resources. Resources that will be made available include:

- Case studies. A catalog of case studies for use in formal instruction will be made available on the ORIC RCR website.
- Videos. ORC will maintain a library of videos to complement formal RCR instruction.
- RCR training on demand. ORIC will provide formal instruction to various audiences upon request.
- Centralized Post-doctoral Scholar RCR training. A course specifically designed for post-doctoral scholars will be held twice a year during the Spring and Fall semesters. The course will be scheduled as five weekly sessions of two hours each and be based on interactive dialogue and case study review with faculty facilitators.
- Train-the-Trainer RCR Course. ORIC will provide a course designed to qualify post-doctoral instructors of RCR at the departmental level.

Departments may develop discipline-specific ethics and RCR training appropriate for each target audience. Schools, Departments and Institutes with NSF research/education awards an/or NIH training grants, may develop and submit these additional RCR training options to the RCR Education Steering Committee for peer review and certification. In so doing, the following must be submitted for review:

- A course syllabus
- Identification of an instructor
- Target audience eligible to attend

Program Assessment

Overall efficacy of the RCR Education Program will be evaluated based on meeting the goals and objectives of the program outlined below. These goals are more practically focused on skill development rather than knowledge (as articulated in the NAE's Summary of a Workshop on Ethics Education and Scientific and Engineering Research). The goals of the RCR Education program are to:

- Serve as a catalyst for the questioning of decisions, practices and processes related to the responsible conduct of research with the objective of arriving at better informed decisions
- Promote skill development by:
  - ➢ Recognizing and defining ethical issues
  - ➢ Identifying relevant stakeholders and socio-technical systems
  - ➢ Collecting relevant data about stakeholders and systems
  - ➢ Understanding relevant stakeholder perspectives
  - ➢ Identifying value conflicts

> ➢ Constructing viable alternative courses of action or solutions and identifying constraints
> ➢ Assessing alternatives in terms of consequences, public defensibility, institutional barriers, etc.
> ➢ Engaging in reasoned dialogue or negotiations
> ➢ Revising options, plans or actions
> ➢ Collecting relevant data about stakeholders and systems

This concept of skills development is consistent with the guidelines developed by the AAMC concerning the student-mentor relationship as outlined in their *Compact Between Biomedical Graduate Students and Their Research Advisors*. This compact outlines core tenets of pre-doctoral training and includes the following:

- Institutional Commitment
- Program Commitment
- Quality Mentoring
- Providing Skills Sets and Counseling that Supports a Broad Range of Career Choices

These core tenets are supported in principal and practice by ECU through implementation of this plan.   Although the AAMC document is intended for use by advisors and students within the biomedical community, its concepts have broad application across disciplines.

In addition to the compact that the AAMC developed for pre-doctoral students and their advisors, the AAMC also developed a *Compact Between Postdoctoral Appointees and Their Mentors* which outlines similar tenets as follows:

- Institutional Commitment
- Quality Postdoctoral Training
- Importance of Mentoring in Postdoctoral Training
- Foster Breadth and Flexibility in Career Choices

The AAMC *Compact Between Postdoctoral Appointees and Their Mentors* underscores the importance and value of mentoring in postdoctoral training: "Effective mentoring is critical for postdoctoral training and requires that the primary mentor dedicate substantial time to ensure personal and professional development. A good mentor builds a relationship with the trainee that is characterized by mutual respect and understanding. Attributes of a good mentor include being approachable, available, and willing to share his/her knowledge; listening effectively; providing encouragement and constructive criticism; and offering

expertise and guidance." ECU supports this philosophy; it is the principle upon which program success will be measured.