

University Corporation at Monterey Bay's Institutional Plan to Meet the National Science Foundation And National Institutes of Health Educational Requirements for the Responsible Conduct of Research (RCR)

Developed by Grants & Contracts Office CSUMB Academic Senate for Postgraduate Studies and Research and Academic Affairs Deans & Provost December 2009

Background

The responsible and ethical conduct of research (RCR) is critical for excellence, as well as public trust, in research and scholarly activities in disciplines such as humanities, social behavioral science, science and engineering. Consequently, education in RCR is considered essential in the preparation of future scientists and engineers. Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (PL 110-69) 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." (NSF 10-1 January 2010; AAG Section IV B)

In responding to this requirement, the NSF published a revision to the NSF Proposal & Award Policies and Procedures Guide (PAPPG) requiring that beginning January 4, 2010, institutions must certify, at the time of proposal submission, the institution has a plan to provide appropriate training and oversight in the responsible and ethical conduct of research to undergraduate students, graduate students, and postdoctoral researchers who participate in NSF-funded projects.

The National Institutes of Health issued its own revised policy on November 24, 2009. NIH 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 must receive instruction in responsible conduct of research. This policy will take effect with all new and renewal applications submitted on or after January 25, 2010,

Purpose

The purpose of this document is to outline the University Corporation at Monterey Bay's (The Corporation) plan on behalf of the California State University, Monterey Bay (CSUMB) for implementing NSF and NIH requirements for providing training to undergraduate, graduate, and postdoctoral researchers in the responsible and ethical conduct of research.

Responsible Conduct of Research (RCR)

RCR is a widely accepted set of ethical and professional standards for conducting research. The Corporation and CSUMB are committed to maintaining the integrity fundamental to research activities through the responsible and ethical conduct of its faculty, staff, and students.

CSUMB promotes excellence in research and supports scholars from all fields. CSUMB is committed to the highest quality education for students and scholars, and RCR instruction is essential to producing the best scientists and researchers for the future. To further this commitment, The Corporation shall implement an institutional plan for RCR training so that all students and postdoctoral researchers supported by (or volunteering on) NSF and/or NIH sponsored projects can benefit from RCR training.

Institutional Responsibilities

National Science Foundation (NSF):

"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 the NSF PAPPG Chapter II.C.1e, institutional certification to this effect is required for each proposal.

Training plans are not required as part of a proposal submission, but rather as an institutional certification with the proposal submission to NSF. Institutions have been advised by NSF that the plans are subject to review upon request and audits are expected.

"The institution must identify the persons responsible for overseeing compliance with the RCR training requirement and must verify that appropriate training was provided."

"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."

NSF PAPPG "Chapter II.C.1.e, Proposal Certifications, has an entirely new proposal certification added regarding responsible conduct of research. When submitting a proposal to NSF, the Authorized Institutional Representative (AOR) is required to complete a certification 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. 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."

National Institutes of Health (NIH):

Instructional Components:

- Format: 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. 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 (see below), or unusual and well-justified circumstances.
- 2. <u>Subject Matter</u>: 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 policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
 - b. mentor/mentee responsibilities and relationships
 - c. collaborative research including collaborations with industry
 - d. peer review
 - e. data acquisition and laboratory tools; management, sharing and ownership
 - f. research misconduct and policies for handling misconduct
 - g. responsible authorship and publication
 - h. 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 with human subjects, 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. <u>Faculty Participation</u>: 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. <u>Duration of Instruction</u>: 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. <u>Frequency of Instruction</u>: 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.

Institutional RCR Training Plan

The Corporation on behalf of CSUMB will meet the NSF and/or NIH requirements for RCR training by:

Requiring all students and postdoctoral researchers supported by The National Science Foundation to receive and participate in RCR training. The Corporation and CSUMB believe that RCR training can be implemented via many educational avenues and will use a three-phase approach that meets the needs of students and postdoctoral researchers based on the career stage of the individual.

<u>Phase I:</u> All undergraduate students, graduate students, postdoctoral researchers and faculty working or volunteering on a NSF or NIH sponsored project will complete the Collaborative Institutional Training Initiative (CITI) online training (<u>www.citiprogram.org</u>) for RCR based upon their field of research. This training will provide a foundational basis for RCR by encompassing its topical elements. This online training will be completed by all students and faculty assigned to the NSF or NIH grant and will be tracked by Corporation HR in coordination with the PI

<u>Phase II:</u> Students and postdoctoral researchers will be provided opportunities throughout the year to expand their RCR training through interactive events and activities (i.e., workshops, symposia, or classes). Phase II participation will be mandatory for postdoctoral researchers and at Principal Investigator (PI) discretion for undergraduates and graduate students.

<u>Phase III</u>: All students and postdoctoral researchers on NSF or NIH sponsored projects will be provided continuing education in RCR topics specific to their research settings. Such training will be overseen by the PI and will consist of interactive discussions during laboratory meetings, on-line training modules, and/or other similar delivery mechanisms. The goal of Phase III is to bring RCR concepts into the normal daily routine. This Phase III will be documented by the PI and verified by the Dean on an annual basis.

The College Deans and Provost are designated as the units responsible for overseeing institutional compliance with the NSF and NIH RCR educational requirements. The College Deans and Provost, overseeing the compliance with the PI, are also responsible for:

- Providing written summary of the unit's plan for training to accompany the NSF/NIH proposal routing form ("Blue Sheet") during the proposal routing process (see RCR Plan Template);
- Monitoring training activities;
- Verifying with Corporation Human Resources that undergraduate students, graduate students, and postdoctoral researchers supported by NSF or NIH research or educational projects (paid or volunteer basis) have completed training in the responsible and ethical conduct of research for Phase I <u>PRIOR</u> to research commencement;
- Verifying that all postdoctoral researchers have completed Phase II training;
- Ensuring that there is ongoing RCR mentoring in the research setting and maintaining the records of training activities for Phase III of the institutional plan;
- Developing assessment tools to evaluate the implementation plan and effectiveness of RCR training and educational initiatives; and
- Building collaborations with faculty members and units that promote RCR core competencies.

The Grants & Contracts office is the Authorized Organizational Representative (AOR) for certifying that the Institutional RCR Training Plan exists at the time of proposal submission.

The Plan's goals will be to foster and integrate RCR education at the highest standard of ethical and professional conduct for the culturally diverse and multi-disciplinary research community at CSUMB. The plan is intended to provide flexibility in content and delivery and to address the varying needs of different disciplines and career stages. This plan is a living document and as such the Institutional RCR Plan will be regularly assessed and monitored as educational outcomes are evaluated and best practices are increasingly developed to advance RCR education at The Corporation and CSUMB.

RCR Content Areas

- 1. Publication Practices and Responsible Authorship
- 2. Conflicts of Interest
- 3. Data Acquisition, Management, Sharing and Ownership
- 4. Collaborative Research
- 5. Mentor and Trainee Responsibilities
- 6. Peer Review
- 7. Research Misconduct
- 8. Animal Welfare*
- 9. Human Subjects Protection*

Please note:

*Individuals involved in studies of animal or human subjects require additional specific training for certification in these areas as prescribed by federal regulatory requirements and policies of the Institutional Animal Care and Use Committee (IACUC) and Committee for the Protection of Human Subjects (CPHS), respectively, before they can participate in the research.

RCR Resources Available

An abundance of RCR resources exists and many professional societies have adopted policies or best practices that might be usefully considered.

To meet the need for RCR resources, NSF has funded two beta sites to begin to provide an interactive community online resource on ethics education in science and engineering.

Online Ethics Center <u>http://www.onlineethics.org/</u> Ethics in Science and Engineering National Clearing House <u>http://www.umass.edu/sts/digitallibrary/</u>

Many opportunities also exist within colleges and departments for faculty to promote RCR education through activities that already routinely occur in a research or classroom setting:

- Ethics coursework
- Research methods courses
- Informal or formal meetings
- Departmental meetings
- Experiential research programs for graduate and undergraduate students
- Laboratory discussions with research participants
- Orientation sessions for postdoctoral fellows, students, and student assistants
- Departmental activities such as seminar series and discussion groups
- Institution-wide lecture or discussion series
- Professional development programming
- Activities sponsored by graduate student and postdoctoral organizations
- Feature articles on RCR issues in the campus newspaper or departmental newsletter
- Collaboration with graduate program coordinators to promote RCR training

RCR Program Assessment

The Corporation's implementation plans for the RCR educational program will be continually evaluated based on meeting the stated goals of the plan. The goals are intended to be practically focused on skill development coupled with dissemination of shared knowledge and experience. Additional goals of the program are to:

- Serve as a catalyst for questioning decisions, practices, and processes related to the responsible conduct of research with the objective of strengthening individual and group decisions.
- Promote skill development by:
 - Recognizing and defining the ethical issues involved in research and educational training activities
 - Understanding stakeholder perspectives
 - o Identifying conflicting ethical values
 - Revising options, plans, and actions based on lessons learned and best practices of stakeholders and of colleague institutions
 - Engaging in ongoing collaborations with stakeholders to strengthen outreach and increase training capabilities

Annually, the CSUMB Deans and Provost will review the status of the Institutional RCR Training Plan and make modifications with input from the Faculty Postgraduate and Research Committee.