



SAINT LOUIS UNIVERSITY

Policy for Responsible Conduct of Research Training for Students, Post-Doctoral Fellows, and Trainees Supported by External Funds

Policy Number: RC002

Version Number: 2.0

Classification: Research Compliance

Effective Date: 07/01/2011

Responsible University Official: Vice President for Research

1.0 INTRODUCTION

An integral part of the Mission of Saint Louis University (hereinafter “SLU”) is to seek excellence in research and ethical conduct. As a Catholic, Jesuit institution, SLU has an obligation to ensure that faculty, staff, and students engaged in all fields of research have a working knowledge of the ethical and responsible conduct of research (RCR). In addition, SLU must comply with federal requirements of agencies such as the National Institutes of Health (NIH) and the National Science Foundation (NSF) that stipulate such training is in place for students, postdoctoral fellows, trainees and associates as a condition of receiving financial support for research.

SLU believes that providing a formal training program in the area of Responsible Conduct of Research will assist in ensuring that the highest level of integrity is maintained not only in research at SLU, but also in the future research of its faculty, staff, trainees, and students in whatever field they may chose. Therefore, SLU has developed this policy and these procedures for instruction in RCR.

2.0 PURPOSE

The Policy and Procedures are intended to assist University administration in ensuring that all graduate and undergraduate students, Postdoctoral Fellows, Associates, and trainees who are supported by grant funds are adequately trained in all areas of responsible conduct of research. This policy is also intended to support institutional compliance with the National Science Foundation regulations contained in Section 7009 of the America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 U.S.C. 18620-1) and the National Institutes of Health regulations contained in NOT-OD-10-019, “Update on the Requirement for Instruction in the Responsible Conduct of Research,” and other relevant government regulations.

3.0 APPLICABILITY

This policy applies to all undergraduate and graduate students, Post doctoral Fellows and Associates, and trainees engaged in research who are supported by National Institutes of Health (NIH) or National Science Foundation (NSF) grant funds.

While this program is mandatory for students, post-doctoral fellows and associates, and trainees supported by NIH and/or NSF grant funding, SLU encourages all students, faculty, staff, and trainees involved in research to participate in the RCR training provided by the University, whether or not they are supported by grant funds

4.0 GOVERNMENT RULES & REGULATIONS

The National Science Foundation (NSF) and the National Institutes of Health (NIH), require institutions seeking NSF and NIH funding for research to maintain a written, enforced policy and a formal training program on responsible conduct of research for graduate and undergraduate students, Postdoctoral Fellows, Associates, and trainees supported by these funding agencies.

5.0 DEFINITIONS

The following definitions apply to the Policy:

5.1 Awarding Agency means the organizational unit of the federal government or other external sponsor that awarded the funds contributing to the subject research or educational activity.

5.2 Responsible Conduct of Research (RCR): 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.

5.3 Research means a systematic investigation designed and conducted to develop or contribute to the body of knowledge. Research includes basic and applied research as well as product development.

5.4 Investigator means the principal investigator, co-investigators, and any other person(s) responsible for the design, conduct, or reporting of research or educational activities funded by a federal government agency or other external sponsor, or proposed for such funding.

5.5 Appointed Official means the University official designated to maintain, develop, coordinate, and oversee the responsible conduct of research training.

5.6 National Science Foundation (NSF) refers to the independent agency of the federal government responsible for the promotion of progress in science and engineering by supporting programs in research and education.

5.7 National Institutes of Health (NIH) refers to the operating division of the U.S. Department of Health and Human Services and any component of NIH to which authority may be delegated.

5.8 Covered Individual refers to graduate and undergraduate students, Postdoctoral Fellows, associates, and trainees who are supported by funds from NIH and/or NSF, or who are engaged in research supported by NIH and/or NSF funding.

6.0 POLICY

6.1 MANDATORY TRAINING TO MEET REQUIREMENTS:

Beginning January 4, 2010, all graduate and undergraduate students, Post Doctoral Fellows, Associates, and trainees supported by research funds from NIH and/or NSF are required to complete online modules at the CITI website (<https://www.citiprogram.org/Default.asp?>) and a minimum of eight (8) hours of in-person instruction on the fundamentals of Responsible Conduct of Research. Training must be completed prior to the end of the grant-funded activity. These modules or classes will cover the following nine instructional areas as designated by the Office of Research Integrity, Department of Health and Human Services: 1) Data Acquisition, Management, Sharing, and Ownership; 2) Conflict of Interest and Commitment; 3) Human Subjects; 4) Animal Welfare; 5) Research Misconduct; 6) Publication Practices and Responsible Authorship; 7) Mentor/Trainee Responsibilities; 8) Peer Review; 9) Collaborative Science.

Attendance at instructional sessions or module completion will be monitored and documentation of participation/completion will be kept by the Office of Responsible Conduct of Research and produced upon request from the sponsor.

For all funding proposals sent to NSF, SLU is required to certify the existence of 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.

For all funding proposals sent to NIH, SLU is required to certify the existence of a plan to provide appropriate training and oversight in the responsible and ethical conduct of research by all individuals supported by any NIH training/research education/fellowship/career award.

6.2 ALTERNATE MEANS OF MEETING RCR REQUIREMENTS:

6.2.1 Other RCR programs conducted at the University may be deemed sufficient to comply with the NIH, NSF, and University requirements. Those programs must have a minimum of eight (8) hours of contact instruction and must cover the nine (9) areas of RCR listed above. Academic units that offer such programs must petition the Division of Research Administration to obtain certification that the proposed course of instruction meets federal standards. The Vice President for Research will make the final determination as to whether a particular program meets the requirements of the federal agencies. If a program is determined to meet the RCR requirements, the academic unit responsible for the program must provide the following information to the Manager of Responsible Conduct of Research:

1. A syllabus of the entire course, with dates and times of meetings
2. Names of discussion leaders, lecturers, guest speakers
3. The department responsible for the course
4. A list of students attending the program
5. A list of students successfully completing the program

6.2.2 For trainees whose programs are short-term (e.g., summer programs or programs for less than one academic year), successfully completing the CITI modules on RCR will be considered meeting the requirements. CITI modules must be completed prior to the end of the short-term program.

7.0 RESPONSIBILITIES

7.1 University Responsibilities

The University has the following responsibilities under this Policy:

1. Informing each Covered Individual of this Policy and reporting obligations under this policy, including relevant time frames.
2. Identifying and approving the Appointed Official, who is responsible for identifying Covered Individuals and communicating this policy.
3. Ensuring that all Covered Individuals receiving support from the Awarding Agency comply with federal requirements.
4. Certifying to the Awarding Agency that the University has a responsible conduct of research program, and a system for identifying individuals required to complete the program.
5. Maintaining records of all Covered Individuals who have completed the responsible conduct of research program, and producing records upon request from federal sponsors.
6. Overseeing the establishment of adequate enforcement mechanisms to promote conformance with this Policy and sanctions, as appropriate, against individuals who fail to comply with this Policy.

7.2 Investigator Responsibilities

Investigators have the following responsibilities under this Policy:

1. Identifying all Covered Individuals required to complete the responsible conduct of research program as required by the Awarding Agency and notifying Appointed Official of Covered Individuals.
2. Notifying Covered Individuals of this policy, the procedures, and requirements herein and following up with Covered Individuals to ensure that they have completed the program according to the required timeline.
3. Failure to accept these responsibilities will result in prohibiting the Covered Individual from activities on the specified grant and may result in penalties for the Investigator.

7.3 Covered Individual Responsibilities

Covered Individuals have the following responsibilities under this Policy:

1. Completing the required responsible conduct of research modules/classes as specified in Section 6.0 of this Policy.
2. Confirming with Appointed Official that completion documentation has been received.
3. Failure to accept these responsibilities will result in termination of the Covered Individual's activities on the specific research project.

8.0 PROCEDURES FOR COMPLETION OF RESPONSIBLE CONDUCT OF RESEARCH MODULE

Each graduate or undergraduate student, Postdoctoral Fellow, Associate or trainee receiving support from grant funding must begin the University-sanctioned Responsible Conduct of Research program within ninety (90) days of the start of such support. The University Appointed Official, with the help of the Investigator, department of Human Resources, and the Office of Sponsored Programs, will identify all Covered Individuals. Identified students and trainees are required to complete the University of Miami CITI training modules: Responsible Conduct of Research, Human Subjects, and Animal Welfare. The CITI training can be accessed at: <http://www.citiprogram.org/>.

As Covered Individuals complete the mandatory modules, CITI will notify the Appointed Official via email that modules have been completed. The Appointed Official will maintain records of modules completed by each Covered Individual.

Covered Individuals are also required to take a series of University endorsed courses, as listed on the Responsible Conduct of Research website, <http://www.slu.edu/x25238.xml>. A minimum of eight (8) hours of face-to-face instruction is required.

9.0 SANCTIONS FOR NON-COMPLIANCE

Individuals are expected to comply fully with this Policy. Covered Individuals who fail to complete the required RCR modules or face-to-face instruction will be prohibited from further activities on the research project and will have research support revoked. Any federal funds expended for support of such individuals will be removed from grant funds and will be charged to an appropriate department fund.

Investigators who do not comply with this policy may be disciplined according to University Policy.

10.0 RECORD RETENTION

The Appointed Official will maintain records of all Covered Individuals and all completed RCR modules or classes in connection with all Awarding Agency-funded research for at least three years from the date of submission of final reports or, where applicable, from other dates specified in award documents.

11.0 REFERENCES

America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act (42 U.S.C. 18620-1).

Update on the Requirement for Instruction in the Responsible Conduct of Research, NOT-OD-10-019, Release Date: November 24, 2009.

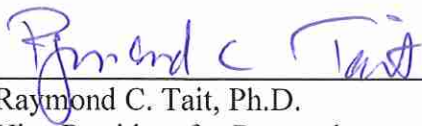
Responsible Conduct of Research Education (RCR), Office of Research Integrity, U.S. Department of Health and Human Services; <http://ori.dhhs.gov/education/>.

APPROVAL SIGNATURES

This policy has been prepared by:

Carole Knight, PhD, Associate Vice Provost for Research

This policy was approved by:



Raymond C. Tait, Ph.D.
Vice President for Research
Saint Louis University

Date: 06/27/2011

REVISION HISTORY		
EFFECTIVE DATE	REVISION NUMBER	MODIFICATION
January 4, 2010	1.0	New Policy
July 1, 2011	2.0	Policy Revision