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Title: NIH Responsible Conduct of Research (RCR) Training Plan

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Signature:

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# 1. Purpose

On November 24, 2009, the National Institutes of Health (NIH) released a notice updating information on the requirement for instruction in the responsible conduct of research. NIH requires for trainees, fellows, participants, and scholars hired on certain grants to be trained in Responsible Conduct of Research. The Office of Research & Graduate Studies requires that all trainees, fellows, participants, and scholars hired on NIH training grants to be trained in Responsible Conduct of Research.

Principal investigators can use or adapt this training plan for use in any grants they apply for. If funded, principal investigators will abide by the NIH training plans submitted with their grants.

# 2. Scope

This SOP covers the administrative notification and tracking of Responsible Conduct of Research (RCR) training for training grants only.

This SOP does not describe the training sessions.

### 3. Responsibilities

- 3.1. The Office of Sponsored Programs (OSP) Proposal Administrator(s) is responsible for:
  - 3.1.1. Notifying the Principal Investigator (PI) during the Pre-Award process of the need for RCR training in the event of funding, unless a training plan has already been included as part of the proposal.
- 3.2. The Office of Sponsored Programs (OSP) Project Administrator(s) is responsible for:
  - 3.2.1. Notifying the Associate Director of Research Compliance (ADRC) of all funded NIH training projects.
  - 3.2.2. Notifying the PI that any trainees on their grants will need to participate in RCR training once funding has been received.

- 3.3. ADRC is responsible for:
  - 3.3.1. Assisting in the coordination of RCR training held by the Office of Research and Graduate Studies.
  - 3.3.2. Monitoring training progress and notifying PIs when trainings are due for individuals on their grants.
  - 3.3.3. Reviewing Hiring proposals for new positions on grants.
  - 3.3.4. Notify the Project Administrator of the completion of trainings.
- 3.4. Principal Investigator is responsible for:
  - 3.4.1. Ensuring that trainees are aware of and attend RCR trainings
  - 3.4.2. Corresponding with OSP and the ADRC regarding training completion.
  - 3.4.3. Documenting all in-person training sessions.
  - 3.4.4. Providing copies of all training documentation to OSP and the ADRC.
  - 3.4.5. Notifying the ADRC of all non-paid personnel added to the training program.
  - 3.4.6. Notifying the ADRC and OSP of any changes in personnel career stages.

### 4. Reference Documents

4.1. CITI RCR Training Instructions

http://www.pvamu.edu/research/office-of-research-compliance/responsible-conduct-of-research/

4.2. NIH Policy

The full notice can be viewed at the following link: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

4.3. NIH Notice: Update on the Requirement for Instruction in the Responsible Conduct of Research

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html

4.4. NIH Notice: Modification of PAR-10-206: NCRR Science Education Partnership Award (SEPA) (R25):

http://grants.nih.gov/grants/guide/notice-files/NOT-RR-11-005.html

### 5. Procedure

- 5.1. Notification
  - 5.1.1. Pre-Award Notification:

- 5.1.1.1. At the time of receipt of a NIH proposal from a Principal Investigator (PI), the Proposal Administrator will review guidelines for relevant NIH programs to see if it requires NIH RCR training.
- 5.1.1.2. If the NIH RCR training is not required, the Proposal Administrator will move forward with submitting the proposal.
- 5.1.1.3. If NIH RCR training is required, the Proposal Administrator will check the proposal for a Responsible Conduct of Research (RCR) Training Plan.
  - 5.1.1.3.1. If an NIH RCR Training plan is included, the Proposal Administrator will move forward with submitting the proposal.
  - 5.1.1.3.2. If the NIH RCR Training is not included, the Proposal Administrator will notify the PI that an NIH RCR Training plan is required for the grant if funded. After notifying the PI, the Proposal Administrator will move forward with the proposal submission process.
    - 5.1.1.3.2.1. If the proposal submission requires that the NIH RCR training plan be included at the time of proposal submission, the Proposal Administrator will direct the PI to ADRC. (Refer to section 5.2. Training Plan)

#### 5.1.2. Post Award Notification

- 5.1.2.1. Once the Project Administrator has received notification that a proposal has been funded by NIH, the project administrator will notify the ADRC via email of the receipt of the funded project. The email will include the name of the PI, personnel listed on the project, and the project number.
- 5.1.2.2. The Project Administrator will contact the PI of their funding status, and their responsibility to ensure that all personnel on their grant completes the required RCR training.
- 5.1.2.3. The ADRC will contact the PI to reiterate their responsibilities regarding RCR training and documentation of the training.
- 5.1.2.4. The ADRC will work with the PI to schedule the appropriate training sessions that are needed by the Office of Research, Innovation and Sponsored Programs.
- 5.1.2.5. The ADRC will monitor training completion for personnel by contacting the PI once a month for an update on completion.
  - 5.1.2.5.1. If training sessions have been completed, and the ADRC does not have a copy of the training documentation, the documents will be requested from the PI.

#### 5.1.3. Personnel Addition

- 5.1.3.1. The ADRC will be notified via email from Qualtrics of all proposed positions and hires of personnel from a grant.
- 5.1.3.2. The ADRC will review the *New Hiring Screening* submitted, and contact the PI with the name and position of the new personnel, reminding the PI that the personnel must complete the appropriate RCR training.
- 5.1.3.3. It is the responsibility of the PI to notify the ADRC and OSP of all non-paid personnel that is added to the training program.
- 5.1.3.4. The PI is responsible for notifying the ADRC and OSP of any changes in personnel career stages (e.g. change from undergraduate to post-baccalaureate).

# 5.2. Training Plan

- 5.2.1. Online training alone is not sufficient except for Short-term Training and Research Education Programs (Please refer to section 5.2.6).
- 5.2.2. Training will occur via face-to-face discussions in seminars given by various faculty, staff, and administrators every academic semester. The Office of Research, Innovation, and Sponsored Programs will assist in the coordination. There were will be at least eight contact hours of NIH RCR instruction.
- 5.2.3. NIH RCR training will be recurring throughout the different levels of an individual's career—undergraduate, post-baccalaureate, pre-doctoral, postdoctoral, and faculty levels. Instruction will be taken once during every career stage and at a frequency of no less than once every four years. Instruction in pre-doctoral training will occur as early as possible in graduate school.

# 5.2.4. PI Hosted Training

- 5.2.4.1. The faculty awardees or their appointed faculty associates will give a series of in-lab seminars. These seminars will total up to four hours of inperson training, and will cover the following topics:
  - Mentor/mentee responsibilities and relationships;
  - Collaborative research including collaborations with industry
  - Peer review
  - Data acquisition and laboratory tools; management, sharing and ownership
  - Responsible authorship and publication
  - Other safety courses, such as laboratory safety

- 5.2.4.2. Faculty, staff, and administrators will participate in the training as discussion leaders, course directors, and lecturers. Senior fellows and career award recipients may fulfill their NIH RCR requirement by leading discussions or lecturing.
- 5.2.5. Office of Research, Innovation and Sponsored Programs Hosted Training
  - 5.2.5.1. Research Compliance staff and Research Administration staff will give a series of two-hour seminars. These seminars will be given twice a semester, and will cover the following topics:
    - conflict of interest personal, professional, and financial;
    - policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices;
    - research misconduct and policies for handling misconduct;
    - the scientist as a responsible member of society, contemporary ethical issues in research, and the environmental and societal impacts of scientific research
- 5.2.6. Short-term Training and Research Education Programs
  - 5.2.6.1. In the case of training programs lasting six months or fewer or trainees/participants taking part in programs for six months or fewer, online training will be sufficient.
    - 5.2.6.1.1. Examples of programs where the online training would be sufficient are as follows:
      - T35 and R25 programs lasting six or fewer months
      - short-term trainees supported on T15, T32 and T34 programs
      - short-term participants in R25 programs
  - 5.2.6.2. Online RCR training is available through the <u>Collaborative Institutional</u>
    <u>Training Initiative (CITI)</u>. Please register for the website and affiliate with Prairie View A&M University.
  - 5.2.6.3. Trainees, fellows, participants, and scholars should take the modules in an RCR learner group from their discipline.
  - 5.2.6.4. Once CITI RCR training has been completed, the PI must submit a copy of the training transcript to the ADRC and their assigned OSP Project Administrator for their file.

#### 5.3. Documentation

5.3.1. Face- to- face training

- 5.3.1.1. Attendance at the training will be documented, and upon completion of the course, a certificate with the signature of the lead instructor and the signature of the attendee will be issued.
- 5.3.1.2. The PI will send copies of the participant certificates to OSP and the ADRC to be kept with the award file in OSP, and in the RCR training file with the ADRC.
- 5.3.1.3. The following documentation must be provided to OSP and ADRC for all in lab training:
  - 5.3.1.3.1. Sign-in sheet
    - 5.3.1.3.1.1. Sign in sheet must include the date and time of the training, and sections for the attendees to print and sign their names.
  - 5.3.1.3.2. The training agenda for that session
  - 5.3.1.3.3. Training materials covered

# 6. Revision History

- 2.0 Change the office name from "Research, and Graduate Studies" to "Research, Innovation and Sponsored Programs. Revised Section 5.2 to remove PV Talent review procedures, and replace it with the hiring screening procedures utilizing Qualtrics.
- 1.0 This is an original procedure.

### **Contact Information**

If you have any questions, please contact the Office of Research, Innovation and Sponsored Programs:

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