Research Compliance: RCR, COI, and Nepotism

Monthly Research Administration Meeting
November 2022

Responsible Conduct of Research (RCR)

The Office of Research Integrity (ORI) oversees and directs Public Health Service (PHS) Responsible Conduct of Research (RCR) on behalf of the Secretary of Health and Human Services (HHS).

RCR encompasses the following 9 areas:

- Research Misconduct
- Protection of Human Subjects
- Animal Welfare
- Conflicts of Interest
- Data Ownership, Collection and Protection

- Mentor/Trainee Responsibilities
- Collaborative Research
- Authorship and Publication
- Peer Review

What is Research Misconduct?

- <u>Research misconduct</u> means fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results.

What is Research Misconduct?

- <u>Fabrication</u> is making up data or results and recording or reporting them.

- Examples of Fabrication:
  - Interviewer completing a questionnaire for a fictitious subject that was never interviewed.
  - Preparing records for follow-up calls or contacts to subjects who were really lost to follow-up.
  - Creating notes for a subject visit that never took place.

data fabrication

What is Research Misconduct?

- <u>Falsification</u> is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

- Examples of Falsification:
  - Back-dating interviews to fit within the timeline provided in protocol.
  - Changing a subject's age in data records by an unimportant amount to fit enrollment criteria.

What is Research Misconduct?

- <u>Plagiarism</u> is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

- Research misconduct <u>does not</u> include honest error or differences of opinion.

How Do You Report Research Misconduct?

- Allegations of research misconduct need to be reported to Dr. Andres Gil, Senior Vice President for Research (SVPR) at gila@fiu.edu or 305-348-0556.

- Allegations can also be reported to the SVPR via the FIU Ethical Panther Hotline at https://compliance.fiu.edu/hotline.

- The FIU Research Misconduct policy # 2370.070 is found at https://policies.fiu.edu/files/733.pdf. Please refer to that policy for more details on the reporting and processing of research misconduct allegations.

Data Ownership, Collection and Protection

- In most cases the institution owns the data, but it can depend on the sponsor or the terms of the agreement/contract.

- The PI is typically the "steward" who collects the data, records the data, stores the data, and disposing of the data.

- Many journals now ask that the raw data be made available in case research findings need to be validated, so researchers need to take appropriate steps to preserve and protect the data.

- All applicable approvals (IRB, etc.) need to be in place prior to collecting data.

Mentor and Trainee Responsibilities

Good mentoring should begin with:

- a clear understanding of mutual responsibilities,

- time and effort commitment,

- maintaining a productive and supportive research environment,

- proper supervision and review, and

- an understanding that the main purpose of the relationship is to prepare trainees to become successful researchers.

Collaborative Research

- Some collaborations simply involve the sharing of resources (e.g., sharing lab equipment, techniques, data, etc.)

- Other collaborations involve assigning specific roles to a research team (recruiter, interviewer, data analyst, etc.)

- Technological advancements have made it even easier to collaborate with other researchers around the globe (REDCap, Microsoft Teams, SharePoint, etc.)

- Many funding agencies now require that a data sharing plan be included as part of the proposal submission

Authorship and Publication

- Authorship norms and conventions can vary depending on many factors including the research discipline.
- Common authorship criteria include whether each person:
  - Made a significant scientific/intellectual contribution;
  - Had a role in writing and/or revising the work;
  - Reviewed the final work product and agreed to be listed on it;
  - Willingness to be held accountable for all (or at least some portion) of the work product.
- If a contribution is very minimal, then it may be more appropriate to "acknowledge" the individual rather than listing them as an author.
- Authorship disputes can often be avoided if the researchers agree on an authorship plan <u>prior</u> to commencing the research project.

What are the NSF RCR Training Requirements?

- <u>NSF Requirement</u>: All undergraduates, graduate students, and postdoctoral researchers who will be supported by NSF to conduct research for more than 120 days need to complete the CITI RCR training.

- Principal Investigators must certify on a per award basis, that all students and postdoctoral scholars supported by the NSF award have completed RCR training.

What are the NIH RCR Training Requirements?

- <u>NIH Requirement</u>: All trainees supported by National Institutes of Health (NIH) Institutional National Research Service Award (NRSA) Research Training Grants (T32, T34) need to complete the CITI RCR Training and also need to attend Continuing Education RCR Training Workshops.

NIH National Institutes of Health

What RCR Training Options Are Available?

- The CITI Program Responsible Conduct of Research (RCR) online training course is available to all FIU faculty, staff, and students.

- Researchers need to complete <u>one</u> of the following CITI RCR Training Courses:
  - Biomedical RCR Course;
  - Social and Behavioral RCR Course;
  - Physical Science RCR Course;
  - Humanities RCR Course;
  - Engineers RCR Course; or
  - Administrators RCR Course

- A training certificate is provided upon completion of the training course and exam.

What RCR Training Options Are Available?

- FIU also provides continuing education RCR workshops for faculty, staff and students.

- The RCR workshops range from core topics to discipline-specific topics. The topics involve case studies and other useful educational information.

- The dates for RCR workshops are announced to the community via email and are also posted on the Office of Research and Economic Development website in advance of an upcoming session.

Conflicts of Interest in Research

- The FIU Conflict of Interest in Research Policy # 2370.005 is found at https://policies.fiu.edu/files/572.pdf.
  - Applies to all FIU faculty, staff and students who wish to engage in research at FIU.

- **Step 1: File a Disclosure**

  - HR Outside Activity/Conflict of Interest Form via web portal at Working at FIU - FIU Human Resources

  - Disclosures are required from "Investigators" defined as anyone responsible for the design, conduct or reporting of research.

  - Investigators must report their Significant Financial Interests and those of their spouse and dependent children.

Conflicts of Interest in Research

- **Step 2: Complete the CITI Online COI Training Course**

  - Investigators must complete training on the COI in Research policy
  - Required prior to engaging in any sponsored research
  - Valid for 4 years
  - Online COI training is available at the following webpage: Conflict of Interest Online Training - Research (fiu.edu)

Conflicts of Interest in Research

- **Step 3: Determine if you need a Monitoring Plan**

    - Florida Law
        o Prohibits FIU to enter into an agreement with an entity in which FIU employee, his/her spouse and/or dependent children has interest.
        o Requires that FIU make a determination that the outside activity or financial interest does not affect the integrity of FIU.
        o Requires that an employee who fails to disclose any OA or financial interest "*shall be suspended without pay pending the outcome of an investigation which shall not exceed 60 days. Upon conclusion of the investigation, the university or entity may terminate the contract of the employee.*"

Conflicts of Interest in Research

- **Step 3: Determine if you need a Monitoring Plan (Continued)**

    - Federal law requires that financial conflicts of interest (FCOI) in federally funded research be identified and managed by the University (if they can be managed)
        - An FCOI exists when the Investigator's SFIs is/are:
            1) "Related to" the subject research project
            2) Could directly and significantly affect the design, conduct or reporting of the subject research.

Conflicts of Interest in Research Committee (COI-RC)

- **Step 4: File a Monitoring Plan & Exemption Disclosure Form**

  - What is a Monitoring Plan?
    - A document that sets forth the conditions to manage conflicts of interest so that the research or contract may proceed.

  - COI Research Committee (COI-RC)
    - Charged with reviewing instances of potential or actual financial conflicts of interest in research and for developing and reviewing monitoring plans to manage the conflicts that are capable of being managed.

Conflicts of Interest in Research Committee (COI-RC)

- **Step 5: Monitoring Plan Process**

  o *Admin Review*: The completed Monitoring Plan and the Exemption Request, if applicable, will be reviewed by the Office of Research Integrity to ensure that all required information is provided.

  o *COI-RC Review*: The Committee will review the Monitoring Plan and the Exemption Request, if applicable, prior to the meeting.

  o *COI-RC Meeting*: The Members will meet to determine if the conflict may be managed and if so, shall recommend the conditions to be included in the Monitoring Plan to manage the conflict.

Conflicts of Interest in Research Committee (COI-RC)

- **Step 5: Monitoring Plan Process (Continuation)**

  - The following steps are only required if you have a Request for Exemption:

    o **First Level Approval:** SVPR Review and Approval

    o **Office of General Counsel (OGC) Review:** OGC will review prior to sending it to the President

    o **Second Level Approval:** FIU President Review and Approval.

    o **Third Level Approval**: FIU Board of Trustees Chair Review and Approval.*

* *No agreement between FIU and the company can be executed until the request for exemption form is executed by all approval levels. Execution date will be the date the BOT Chair signs off.*

Resources on COI Requirements

- Questions about the disclosure of research activities on the ROA/COI form should be directed to Dr. William Anderson, Associate Vice President for Research.

- Questions about disclosing COIs associated with sponsored research projects should be directed to Pre-Award.
  - https://research.fiu.edu/coi/disclosure/

- Questions about the COI Monitoring Plan and Exemption process should be directed to ORI.
  - https://research.fiu.edu/coi/implementing-monitoring-plan/

Award Action Report of Conflict of Interests of Employees Engaged in Sponsored Research Activities Form

- Updated certification allows for form to be used for the life of the project

- An updated form is required when:
  - There is a new outside activity requiring prior approval
  - There is new Significant Financial Interest

- Award Modifications
  - HR Outside Activity Form must be up to date
  - Research questions must be answered and approved
  - FCOI CITI training must be up to date
  - New personnel (FIU employees or anyone deemed investigator) must complete ORED form/HR OA form/Citi training

Conflict of Interest Forms

- ORED FCOI FORM
  - [Award Action Report of Conflict of Interests of Employees Engaged in Sponsored Research Activities](#)

- HR Conflict of Interest Form
  - https://myhr.fiu.edu/

- Paper Conflict of Interest Form*
  - [FCOI Adjunct Faculty or Student Disclosure Form](#)

*To be used when a non-FIU employee is considered an investigator

*The term **"Investigator"** is defined to encompass individuals "responsible for the design, conduct or reporting of the project.*

Nepotism in Research

- PI must state on the Electronic Proposal Routing Approval Form (ePRAF) if any personnel to be working on the sponsored project is/are related to the PI or to each other or to any other University employee(s).

- The Nepotism Disclosure Form found on the HR Forms Library must be completed explaining the nepotism relationship as it pertains to the sponsored project, and the project staffing must be approved by ORED and HR.

- The FIU Nepotism in Research policy # 2320.060 is found at https://policies.fiu.edu/files/258.pdf.

Do Not Hesitate…

- To Ask Questions
- To Raise Concerns
- To Provide Feedback