PROGRAM FOR RESPONSIBLE CONDUCT OF RESEARCH AT JEFFERSON

This guideline is consistent to Policy 110.22 and the recent directives from the NIH mandate development and implementation of a multipronged approach to Responsible Conduct of Research (RCR) focusing on NIH-supported, graduate student/postdoctoral trainees (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-019.html). Although that directive was specifically earmarked for those supported on NIH training grants, Jefferson has decided to recommend those mandates for all faculty, trainees and staff participating in research. Jefferson requires at least 8 contact hours of RCR training for all individuals involved in applied, basic or clinical research to be satisfied by participation in a combination of options. These include on-line training modules (e.g., Collaborative Institutional Training Initiative Program (CITI) all seven RCR modules (3 hrs) as well as MyLearning modules (3 hrs) are required of all faculty) combined with other modes of training. These additional resources include formal didactic coursework (GC 640 for trainees (11 contact hrs) or faculty development courses for faculty), and suggested interactive videos from Health and Human Services (HHS) (1 hr). Other resources include those on the Jefferson Office of Research Conduct and Compliance (ORCC) website that describe the RCR program at Jefferson (1 hr) and Jefferson's various policies and guidelines on research (e.g., guidelines for authorship, etc. (1 hr)) .

1) **Format:**

   Jefferson offers a variety of approaches to establishing a comprehensive program focusing on RCR. Our program entails both on-line training modules as well as formal didactic course offerings with particular focus on face-to-face discussions with participating faculty based on a case study approach. For trainees, formal didactic training is offered in the Jefferson College of LIfe Sciences (JCLS) course entitled "Teaching the Responsible Conduct of Research through a Case Study Approach" (GC 640).   Jefferson's ORCC also provides the Institutional Research Compliance Organizational Chart depicting the various components/interactions which help facilitate our campus-wide program in RCR including email and phone contacts for all components. A complete listing of key research policies, procedures and guidelines is also included on the site as well as additional resources to help faculty navigate and fulfill important responsibilities for complying with RCR.   Links to a variety of other sites containing information relevant to RCR also are available including two interactive videos from the U.S. Department of Health and Human Services, Office of Research Integrity, as well as down-loadable links to two PDFs ("Introduction to the Responsible Conduct of Research" and "On Being a Scientist: A Guide to Responsible Conduct in Research"). Several on-line training modules also are available and required including the CITI and MyLearning training programs. Finally, Jefferson has an extensive program in faculty development which offers over 30 different courses focused on leadership and professional development of researchers and scholars covering a wide variety of issues relating to RCR.

2) **Subject Matter:** The on-line training consists of seven modules, which Jefferson licenses from the CITI Program encompassing research misconduct, data management, authorship, peer review, mentoring, conflicts of interest, and collaborative research. CITI is nationally as well as internationally recognized as a leading expert in the RCR and is the leading provider of research ethics compliance and professional development education with over one million users worldwide at 2000 participating organizations. In addition, Jefferson requires all faculty to take annual refresher on-line education and knowledge testing using MyLearning training modules in a variety of subjects relating to RCR. These include the following areas over the last 12 months: HIPAA (1 hr), Code of Conduct and Ethical Behavior (1 hr), and OSHA Hazardous Communications and Fire and Life Safety (1 hr). Updates to conflict of interest disclosure forms are required of all faculty annually. Formal lectures in the JCLS course "Teaching The Responsible Conduct of Research Through a Case Study Approach" (GC 640) are given by Jefferson senior faculty and are focused on 1) conducting and reporting research, 2) handling research data, materials and proprietary information, 3) mentoring and laboratory supervision, 4) the peer review process, 5) gene therapy, genetic testing and uses of genetic information, 6) misconduct in research, 7) human subjects/clinical research, 8) animals in research, and 9) conflicts of interest. In addition, the ORCC developed laboratory check-in and check-out forms for new faculty or those describing the RCR program at Jefferson with information about the appropriate offices which have oversight responsibility for the various aspects of research at Jefferson. Our Program in Faculty Development offers a full curriculum for researchers and scholars. Some of the course offerings include the following: 1) The Roadmap to Clinical Research at Jefferson: Part 1: Negotiating the IRB Process, Part 2: Understanding the Clinical Trials Process, Part 3: Destination Data: How to Request and Use Real-World EMR Data for Research and Clinical Insights, Part 4: Clinical Trials: Managing Your Trials in JeffTrials and EPIC; Grant Writing Workshop, etc.

3) **Faculty Participation:** Many of our faculty contribute to informal as well as formal instruction in RCR. Informal instruction occurs daily and continuously by faculty trainers/mentors in their respective laboratories throughout the trainees graduate and/or post-doctoral fellowship experiences. Formal participation involves rotating faculty instructors teaching in our required one-credit course (GC640) entitled "Research Ethics: The Responsible Conduct of Research" which is taken by all pre-doctoral trainees in the first year of matriculation. The course is directed by members of the graduate faculty assisted by university administrators responsible for oversight in the relevant areas under discussion. Post-doctoral trainees also participate in the course which is offered twice each year. Our program in continuing faculty development is organized by The Vice Provost for Faculty Affairs who is also Vice Dean for Faculty Affairs and Professional Development. The organizing committee consists of faculty at various stages in their careers and relevant administrators who help select faculty experts who then organize and present a wide array of formal courses dealing with various aspects of RCR.

4) **Duration of Instruction:** CITI = 3 hrs; MyLearning modules = 3 hrs; formal lectures/case studies in GC640 course = 11 hrs; human/animal and laboratory safety education = 3 hrs; plus

continuous informal mentoring in RCR in all research laboratories in addition to suggested reading materials = 3 hrs

5) **Frequency of Instruction:** CITI certification is required for all faculty once every 4 years; IRB and IACUC continuing protocol reviews for research involving humans or animals, respectively, are mandated annually. A variety of different MyLearning modules are required annually for faculty; formal lectures are provided for all predoctoral trainees in the required 1-credit GC 640 course in which postdoctoral trainees also participate. Additional training for postdoctoral trainees in RCR occurs through new employee orientation and ongoing required training sessions presented by the Office of Research Administration. Refresher training is required for trainees beyond their 4th year since their last formal RCR training was provided. CITI certification is required now as refresher training for all trainees. For the faulty, Faculty development courses are provided throughout the year with multiple offerings in a variety of RCR areas. Finally, ongoing mentorship and training in RCR occurs continuously during the trainees' laboratory experience and through presentations by the ORCC at the SKMC Executive Council, Provost Council and Departmental faculty meetings.

6) **Reporting and Documentation:** The Office of Research Conduct and Compliance assigns which on-line modules from CITI are required for each participant. The CITI software program then records which on-line modules were taken by faculty members and trainees, so that an electronic record of participation is available. A similar electronic record is available for the various required modules using MyLearning. Pre- and postdoctoral trainees are required to take the GC640 1-credit course with follow up refresher training beyond their 4th year of study since their last formal RCR training was completed. JCLS tracks and records participation in the course. Continual informal RCR sessions occur during the careers of trainees, and faculty laboratory mentors track and report those activities as required in PHS 2590 and by NIH policy. All scholars and faculty are required to sign confidentiality agreements upon enrollment with required annual updates, at the latest, documenting any changes since the initial filing.

7) **RCR Requirements for:**

    A. **All Faculty involved in applied, basic or clinical research**- CITI certification every four years and a variety of annual MyLearning modules are required as well as familiarity with RCR program at Jefferson.

    B. **Graduate Students and Postdoctoral Fellows**- GC640 course and recertification with CITI modules after 4 years since taking the course are required as well as familiarity with RCR program at Jefferson.

    C. **Research Staff and Visiting Scientists**- CITI certification required every four years and familiarity with RCR program at Jefferson is highly recommended.