The responsible conduct of research is defined as the practice of scientific investigation with integrity. It is an essential component of research training and involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Weill Cornell Medical College (WCMC) is committed to fostering an environment that promotes the responsible conduct of research. Toward that end, WCMC offers a variety of educational programs to provide formal instruction in the responsible conduct of research for all members of the WCMC community.

RCR Training Requirement

The semester long Responsible Conduct of Research course is open to all members of the WCMC, Tri-Institutional (Tri-I), and Clinical and Translational Science Center (CTSC) research communities. Successful completion of the course is required for all trainees, fellows, participants, and scholars receiving support through NIH or NSF Institutional Research Training Grants, Individual Fellowship Awards, Career Development Awards (Institutional and Individual), Research Education Grants, Dissertation Research Grants, or other grant programs with a training component that requires instruction in responsible conduct of research as noted in the Funding Opportunity Announcement. WCMC allows for reciprocity for RCR courses taken at other institutions provided the course has been completed within the previous 4 years, the course content meets the NIH’s requirements, and a transcript or certificate of completion is provided. Requests for reciprocity should be sent to the Course Director. Requirements for ongoing training in RCR are discussed later in this document.

Definitions

NIH and NSF define postdoctoral scholar as follows: An individual who has received a doctoral degree (or equivalent) and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path [http://grants.nih.gov/grants/funding/all_personnel_report_faq.htm#d1]

WCMC defines postdoctoral scholar as follows: “...postdoctoral trainees ... have any of the following titles: Postdoctoral Associate, Fellow or Visiting Fellow. A postdoctoral trainee at the Medical College is an individual who has a terminal degree (Ph.D., M.D., DVM or equivalent) and is appointed for the purpose of training to develop the ability to reason in a scientific manner, formulate hypotheses independently, and to perform independent research, including basic, clinical, translational or behavioral research. An individual engaging in research activities for a year or two as part of a clinical training program is not considered to be a postdoctoral trainee, unless the training is designed to develop the ability to perform independent research.” Definition from section five of the Academic Staff Handbook [http://www.med.cornell.edu/handbook/pdf/Section5_March2010.pdf]

Semester Long Tri-I RCR Course

The cornerstone course in the responsible conduct of research is a comprehensive semester long course, which is offered annually in the fall and is hosted at WCMC. The Responsible Conduct of Research course is directed by the WCMC Assistant Dean for Research Integrity and is taught by members of the faculty from WCMC, as well as The Rockefeller University (RU) and Memorial Sloan Kettering Cancer Center (MSKCC). The course faculty include both junior and senior faculty from these institutions, as well as senior administrators whose responsibilities include research compliance or integrity, all of whom serve as role models in this training. The course content is continuously
updated to ensure that it includes the most current policies and regulations, as well as topical and timely cases in which participants can engage in real time.

The 2014 RCR course includes a number of formats intended to engage participants in a variety of ways:
• Four (4) in person sessions (see details below)
• Four (4) large group discussions
• A comprehensive online course (through the CITI program)
• Interactive web-based videos produced by the federal Office for Research Integrity (note that participants can choose between 2 different scenarios - clinical or basic science), with self-directed small group discussions based on the videos
• A reflective essay that directly addresses one or more of the issues raised in the course

The in person sessions are intended to provide in-depth and focused presentations and discussions by experts on topics of particular interest and importance. The 2014 sessions will be held in Uris Auditorium at 1300 York Avenue:
1. Thursday September 11, 2014 12:15-2:30pm: "The trouble with research misconduct: from identification to response and beyond"
2. Wednesday October 8, 2014 3:00-5:00pm: "IP, startups, and conflicts of interest: understanding and navigating the potential challenges of successful translation"
3. Monday November 24, 2014 2:00-4:00pm: "The costs of clinical trials: investigators, sponsors, and participants"
4. Thursday December 11, 2014 3:00-5:00 pm: "Ethics in the academy: a case based exploration of emerging challenges in the responsible conduct of research"

The 2014 course content includes instruction in all of the following subject areas: conflict of interest (personal, professional, and financial); policies regarding human subjects, live vertebrate animal subjects in research, safe laboratory practices, mentor/mentee responsibilities and relationships, collaborative research including collaborations with industry, peer review, data acquisition and laboratory tools (including management, sharing and ownership), research and scientific misconduct and policies for handling misconduct, responsible authorship and publication, the scientist as a responsible member of society, contemporary ethical issues in biomedical research and the environmental and societal impacts of scientific research.

Course participants are graded based on class attendance and participation and completion of the required online course materials. The WCMC Office of Research Integrity maintains records certifying successful completion of this course and issues certificates of completion at the end of the course.

Ongoing RCR Training

Because instruction in the responsible conduct of research should occur throughout a scientist’s career and be appropriate to their career stage, WCMC requires ongoing training at least every 4 years. In order to meet ongoing training needs, WCMC offers a number of standing short courses, workshops, seminars, and lectures that address the responsible conduct of research. These offerings are intended to sustain an environment that fosters the intellectual challenge and spirit of inquiry appropriate to a community of scholars, including the practice of scientific investigation with integrity. Trainees, fellows, participants, and scholars receiving support through any federal funding must include in their applications or reports a description of any of these RCR activities in which they have participated as an instructor, mentor, participant, or trainee.

An annual short course for the K-30 Masters and Certificate Program in Clinical Research entitled "Ethical, Social, and Legal Issues of Responsible Clinical Research," gives participants the opportunity to participate in a small group setting with lecturers whose expertise includes a variety of
topics within the penumbra of the responsible conduct of research. The Office of Research Integrity and Assurance maintains records of completion of the K-30 course.

Throughout the academic year, WCMC organizes and hosts workshops on research integrity and compliance that include expert lectures on a wide range of timely issues (e.g., research integrity, financial conflicts of interest, lab safety, bioterrorism, drug accountability, and research involving human and animal subjects). The WCMC Assistant Dean for Research Integrity also organizes, leads, and participates in educational programs in the responsible conduct of research that are specifically tailored to the interests and needs of specific individuals or groups (e.g., graduate classes, departments, centers, and labs). These programs include Grand Rounds, lab-based trainings, and workshops. Importantly, these educational programs engage students and researchers at every level of their career and are conducted in a setting that allows for interactive small group discussions.

WCMC requires that specific training in the responsible conduct of research be completed by all researchers engaged in any of the following activities: human subjects and http://researchintegrity.weill.cornell.edu/institutional_review_board/irb_human_subjects_training_requirements.html; human embryonic stem cells and hPS (http://trisci.org/trainingintro.html); animal subjects http://intranet.med.cornell.edu/research/rarc/edu_tra/training.html; and recombinant DNA, transgenic animals, biological hazards, and radioactive materials (http://weill.cornell.edu/ehs/training.htm). These training courses are offered on an ongoing basis and recertification is required at periods as determined by the particular program area. The individual administrative units that require the training maintain certification of completion of these trainings. WCMC also provides training through the CITI program on the following topics: Biosafety, Conflicts of Interest, Good Clinical Practice, HIPAA, Export Control, Human Gene Transfer Trials, Research Involving Human Subjects, and Research Involving Animals. The CITI courses can be accessed by registering through the CITI website at https://www.citiprogram.org/Default.asp (click “Register” on the login page and select “Weill Cornell Medical College” as the participating institution). After completing the registration process, select the appropriate course option to begin the online training.

Informal RCR Instruction

In addition to the formal instruction in the responsible conduct of research described above, informal instruction occurs through training and mentoring in research labs and other settings that offer unique opportunities for junior and senior faculty to engage with trainees and students in hands-on learning environments. Trainees, fellows, participants, and scholars receiving support through any federal funding must include in their applications or reports a description of any of these RCR activities in which they have participated as an instructor, mentor, participant, or trainee.

Evaluation and Monitoring

The University Audit Office conducts periodic auditing of the Responsible Conduct of Research program, including the evaluation and monitoring of required formal training and educational programs, their compliance with federal, College, and other applicable requirements, and the Research Integrity Policy.

For additional information, or to request instruction in the responsible conduct of research, please contact Mary Simmerling, Assistant Dean for Research Integrity at mcs2006@med.cornell.edu.