Fall 2014 Course in the Responsible Conduct of Research (RCR)

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Course Description

The responsible conduct of research is the practice of scientific investigation with integrity. Training in this area is an essential component of research training; awareness and application of established professional norms and ethical principles is required in the performance of all activities related to scientific research. Weill Cornell Medical College is committed to fostering an environment that promotes the practice of scientific investigation with integrity. This course is intended to help fulfill that commitment.

Course Participants

The Fall 2014 RCR course is open to all members of the Tri-Institutional (Tri-I) and WCMC Clinical and Translational Science Center (CTSC) 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.

Course Topics

The course will cover all of the following subject areas:

Guidelines Governing Research

- Policies regarding human subjects
- Live vertebrate animal subjects in research
- Safe laboratory practices
- Data acquisition and laboratory tools (including management, sharing and ownership)
- Responsible authorship and publication

Personal, Interpersonal, and Societal Issues

- Conflict of interest (personal, professional, and financial)
- Mentor/mentee responsibilities and relationships
- Collaborative research (including collaborations with industry)
- Peer review
- Research and scientific misconduct and policies for handling misconduct
- The scientist as a responsible member of society

Ethical Theory

- Contemporary ethical issues in biomedical research and the environmental and societal impacts of scientific research

Course Format and Content: Live Sessions, Online Learning, Case Discussion and a Reflective Essay

The course includes a number of formats intended to engage participants in a variety of ways. The Fall 2014 course will include the following:

- Four (4) in person sessions
- Four (4) large group discussions
- A comprehensive online course
- Interactive web-based videos (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

I. Live Sessions

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"

II. Online instruction and small group discussions

Participants are expected to complete an online portion of the course through the CITI program that includes instructional readings and topical case analysis, as well as an interactive video and case discussion.

The CITI program online portion of the course is available by registering through the CITI site at https://www.citiprogram.org/Default.asp. Click “Register” on the login page and select “Weill Cornell Medical College” as your participating institution. After completing the registration process, select the “Responsible Conduct of Research, RCR” option to begin the online course training.

Interactive web-based video: Participants can choose between “The Lab” and “The Research Clinic,” two different interactive videos that explore research misconduct. Through the simulations, participants assume the role of one of a number of key characters (for example, a postdoctoral researcher, a graduate student, a principal investigator, a research integrity officer, a clinical researcher, an IRB chair). In each segment, the selected character will be confronted with choices about how to handle issues related to potential research misconduct. Subsequent segments follow from previous choices the character has made. The videos cover topics relevant to research misconduct such as the handling of data, mentorship, responsible research practices,

responsible authorship, and the protection of research subjects, among others. (Summarized from http://ori.hhs.gov/)

Participants are expected to watch one or both interactive videos independently or in a small group. Participants are also expected to form small study groups to discuss the issues raised by the simulations. Discussion guides will be provided.

III. Reflective Essay Assignment:

Participants are expected to write a 2-page essay about the importance of any of the key topics addressed in the course, or any one of the following topics related to the responsible conduct of research:

1. The current federal regulations governing research misconduct define research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results" (http://ori.hhs.gov/documents/42_cfr_parts_50_and_93_2005.pdf). Do you think this definition is adequate? Discuss why you do or do not believe it should be expanded to include other actions that seriously deviate from accepted scientific practices.

2. The federal Office for Research Integrity provides guidelines on the protection of whistleblowers at http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.shtml As a practical matter, do you think that these guidelines are sufficient to protect whistleblowers? What do you think the challenges of protecting such whistleblowers would be?

3. Persons found guilty of research misconduct often face fairly standard administrative actions that are generally in effect for a period of 3 years. Some examples can be reviewed in the case summaries available at http://ori.hhs.gov/misconduct/cases/ Do you think these kinds of sanctions are sufficient and appropriate? Why or why not?

4. Harvard has been criticized for its handling of the Marc Hauser research misconduct case on a number of fronts. Do you think these criticisms are fair? What if anything do you think could or should have been done differently? Has reviewing the original investigation report documents obtained through The Boston Globe's FOIA request shaped your opinion on this?