



- Responsible Conduct of Research (RCR) Course -

- Information Sheet -

1. Course Description

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.

2. Course Leadership

- RCR Course Director: Mary Simmerling, PhD

Vice President, Quality & Patient Safety, New York Presbyterian Hospital, mcs2006@nyp.org

Assistant Professor of Research Integrity, Department of Medicine, Weill Cornell Medical College

- RCR Course Co-Director: Helene Brazier-Mitouart, PhD

Education Manager, Research Administration Department, Weill Cornell Medical College,
heb2020@med.cornell.edu

3. RCR Course Participants

- The semester long Responsible Conduct of Research (RCR) course is open to all members of the WCMC and Clinical and Translational Science Center (CTSC) research communities (graduate students, post-doctorates, faculty).

- Successful completion of the course is **required** for all trainees, fellows, participants, and scholars* (See definition at the end of the syllabus) receiving support through **NIH** (National Institutes of Health) or **NSF** (National Science Foundation): 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 (FOA). **Instruction must be undertaken at least once during each career stage (graduate students, post-doctorates, faculty), and at a frequency of no less than once every four years.**

- WCMC allows for reciprocity for RCR course taken at other institutions provided that:

1/ the course has been completed within the previous 4 years;

2/ the course content meets the NIH's requirements; and

3/ a transcript or certificate of completion is provided.

Requests for reciprocity should be sent to the Course Co-Director, Helene Brazier-Mitouart at heb2020@med.cornell.edu.

Requirements for ongoing training in RCR are discussed later in this document in the section **8**.

4. RCR Course Topics

The course will cover all of the following subject areas:

I- 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

II- 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

III- Ethical Theory

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

5. RCR Course Requirements

The RCR course includes a number of formats intended to engage participants in a variety of ways. The following components of the course **must be all fulfilled for a successful completion of the RCR course:**

- Four (4) “in person” sessions:** Participants can choose among eight (8) scheduled sessions according to the type of research they are involved with. These “in person” sessions are 2 hours long and are intended to provide in-depth and focused presentations, along with discussions by experts on topics of particular interest and importance.
- Four (4) group discussions:** Participants can choose among eight (8) scheduled discussions. The discussions immediately follow the presentations in the “in person” sessions
- A comprehensive RCR online course through the CITI program** (Collaborative Institutional Training Initiative at the University of Miami) available at <https://www.citiprogram.org/>.
- One interactive research integrity video:** Participants can choose between 2 different scenarios - clinical or basic science. The videos are produced by the Federal Office for Research Integrity (ORI) and consist of self-directed scenarios. The videos are accessible at <http://ori.hhs.gov/THERESEARCHCLINIC> and <http://ori.hhs.gov/THELAB>.
- One small group discussion** based on the video previously chosen. The participants of the

discussion will need to be identified in the appropriate section in the online Canvas Learning Management System. Forum discussions are also available on Canvas, they are highly recommended but not mandatory.

- A reflective essay** that directly addresses one or more of the issues raised in the course- topics will be suggested but participants can also choose their own topic of interest. This written essay must be uploaded to online Canvas Learning Management System.

The WCMC Office of Research Integrity maintains records certifying successful completion of this course.

6. 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.

- i. **The RCR CITI program online** portion of the course is available by registering through the CITI site (Collaborative Institutional Training Initiative) at <https://www.citiprogram.org>. Once the RCR CITI training is completed, participants will receive an official certification by email. **Participants must save that certification and upload it to Canvas.**
 - **In order to register to the CITI training:** On <https://www.citiprogram.org> webpage, click “Register” to access the login page and select “**Weill Cornell Medical College**” as your organization affiliation. When completing the registration process (a couple of steps), make sure you provide **your WCMC email address** as your primary email and **not a private email** (e.g. gmail or hotmail). Please select the “**Responsible Conduct of Research, RCR**” module to begin the online training course. You can select additional optional modules of interest such as Conflict of Interest, Animal Research, US export and/or Biosafety/Biosecurity. If you select these optional modules, you can complete them later on after completion of the RCR course.
- ii. **Interactive research integrity videos:** Based on their research (basic science versus clinical) participants can choose between “The Lab” and “The Research Clinic,” two different interactive videos that explore research misconduct. The videos are accessible at <http://ori.hhs.gov/THELAB> or <http://ori.hhs.gov/THERESEARCHCLINIC>. 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 (RIO), a clinical researcher, an IRB chair (Institutional Review Board)). 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 at least one interactive video either independently or in a small group, and then form small study groups to discuss the issues raised by the video-based simulations. Discussion guide is accessible at <http://ori.hhs.gov/TheLab/TheLabGuide.pdf>.

7. Reflective Essay Assignment

Participants are expected to write an **original 2-page essay** as a personal reflection either on the importance of one of the topics of interest addressed in the course, or on one of the following topics related to the responsible conduct of research. Please note that all essays will be subject to plagiarism software.

- i. 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.
- ii. The federal Office for Research Integrity provides guidelines on the protection of whistleblowers at http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.html. 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?
- iii. 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?
- iv. 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?

8. On going RCR Training

Because instruction in the responsible conduct of research should occur throughout a scientist's career and be appropriate to the career stage, WCMC **requires** ongoing training **at least every 4 years**. In order to meet ongoing training needs, WCMC **requires** the successful completion of the CITI RCR Refresher Course during the 5th year and at least every 4 years thereafter the first completion of the RCR training. This refresher is accessible at <https://www.citiprogram.org/> under request to the RCR course director.

9. Supplemental Courses related to the topic of Responsible Conduct of Research

- i. 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**" (ESLI course) 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. This course is at the CTSC.
- ii. WCMC also 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.

- iii. 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). 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.
- iv. WCMC requires that specific training in the responsible conduct of research that is relevant to the research performed, be completed by all researchers engaged in any of the following activities:
 - **Human subjects:** http://researchintegrity.weill.cornell.edu/institutional_review_board/irb_human_subjects_training_requirements.html
 - **Human Embryonic Stem Cells hESC and Human Pluripotent Stem Cells hPSC:** <http://trisci.org/trainingintro.html>
 - **Animal subjects:** http://intranet.med.cornell.edu/research/rarc/edu_tra/training.html
 - **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.

- v. 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.

10. 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 regulations, College and other applicable requirements, and the Research Integrity Policy.

11. Additional Information

Please contact:

- **RCR Course Director:** Mary Simmerling, PhD
Vice President, Quality & Patient Safety, New York Presbyterian Hospital, mcs2006@nyp.org
Assistant Professor of Research Integrity, Department of Medicine, Weil Cornell Medical College

- **RCR Course Co-Director:** Helene Brazier-Mitouart, PhD
Education Manager, Research Administration Department, Weill Cornell Medical College,
heb2020@med.cornell.edu

12. Definitions

- Postdoctoral scholar:

- *For NIH and NSF:* 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 at:
http://grants.nih.gov/grants/funding/all_personnel_report_faq.htm#d1
- *For WCMC:* "... 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."

13. Acronyms

CITI	Collaborative Institutional Training Initiative
CTSC	Clinical and Translational Science Center
DVM	Diploma in Veterinary Medicine
ESLI	Ethical, Social, and Legal Issues of Responsible Clinical Research
FOA	Funding Opportunity Announcement
FOIA	Freedom of Information Act
hESC	Human Embryonic Stem Cells
HIPAA	Health Insurance Portability and Accountability Act
hPSC	Human Pluripotent Stem Cells
IRB	Institutional Review Board
MD	Doctor of Medicine
NIH	National Institutes of Health
NSF	National Science Foundation
ORI	Office of Research Integrity
PhD	Doctor of Philosophy
RCR	Responsible Conduct of Research
RIO	Research Integrity Officer
WCMC	Weill Cornell Medical College



- Responsible Conduct of Research (RCR) - Fall 2015 Course -

- Syllabus -

1. RCR Course Requirements

The Fall 2015 RCR course includes a number of formats intended to engage participants in a variety of ways. The following components of the course **must all be fulfilled for a successful completion of the RCR course (see the section below for specific details related to each requirement)**:

- Four (4) “in person” sessions:** Participants can choose among eight (8) scheduled sessions according to the type of research they are involved with. These “in person” sessions are intended to provide in-depth and focused presentations, along with discussions by experts on topics of particular interest and importance (See schedule below).
- Four (4) group discussions:** Participants can choose among eight (8) scheduled discussions. The discussions immediately follow the presentations in the “in person” sessions (See schedule below).
- A comprehensive RCR online course through the CITI program** (Collaborative Institutional Training Initiative at the University of Miami) available at <https://www.citiprogram.org/>. The completion is required by **December 31, 2015** and the **obtained certification must be uploaded to Canvas**.
- One interactive research integrity video:** Participants can choose between 2 different scenarios - clinical or basic science. The videos are produced by the Federal Office for Research Integrity and consist of self-directed scenarios. They are accessible at <http://ori.hhs.gov/THERESEARCHCLINIC> and <http://ori.hhs.gov/THELAB>.
- One small group discussion** based on the video(s) previously chosen. **The participants of the discussion will need to be identified in the online Canvas System.** The completion is required by **December 31, 2015**.
- A reflective essay** that directly addresses one or more of the issues raised in the course- topics will be suggested but participants can also choose their own topic of interest. This written essay is due by **December 31, 2015 and must be uploaded to Canvas**.

2. Times, dates, and locations for the “in person” sessions

Session #1: 09/17/15 **Topic:** “The Trouble with Research Misconduct: from Identification to Response and Beyond.”

Panelists: Jamie Kalven; Ivan Oransky, MD; Donald Palmer, PhD; Charles Graybow; Harold Garner, PhD and Adam Marcus, MA.

Location: Hunter College, Kaye Playhouse **4 pm-6:30 pm**

<u>Session #2: 10/9/15</u>	Topic: “Burnout: an Historical Exploration of the Cases, Costs, and Causes of Burnout.” Presenter: Marco Viniegra, PhD. Location: WCMC, Uris Auditorium	10 am-12 pm
<u>Session #3: 11/6/15</u>	Topic: “Lab Safety and Biosafety: Being Safe and Staying Safe.” Presenter: Erik Talley. Location: WCMC, Uris Auditorium	10 am-12 pm
<u>Session #4: 11/13/15</u>	Topic: “Privacy, Security, and Confidentiality: What they Mean and Why they Matter.” Panelists: Brian Tschinkel, Christy O'Connor and Susanna Partrick. Location: WCMC, Uris Auditorium	10 am-12 pm
<u>Session #5: 11/13/15</u>	Topic: “Understanding and Complying with the NIH’s Requirements for Sponsored Research and Training.” Panelists: Michelle Lewis and Stephen Hunt. Location: WCMC, Uris Auditorium	3 pm-5 pm
<u>Session #6: 11/20/15</u>	Topic: “Ethical Standards in the Pharmaceutical Industry: Could Rating Help?” Presenter: Jennifer E. Miller, PhD. Location: WCMC, Uris Auditorium	3 pm-5 pm
<u>Session #7: 12/11/15</u>	Topic: “The Role of Institutional Review Boards (IRBs) in Overseeing Research Involving Human Participants.” Panelists: Margaret Polaneczky, MD; Sunday Clark, DO; Rosemary Kramer, PhD and Milda Plioplys. Location: WCMC, Uris Auditorium	10 am-12 pm
<u>Session #8: 12/11/15</u>	Topic: "Ethics in the Academy: a Case Based Exploration of Emerging Challenges in the Responsible Conduct of Research." Panelists: Susan Pannullo, MD; Steve Gross, PhD; David Christini, PhD; Margaret Polaneczky, MD; Margaret Ross, MD, PhD; Sunday Clark, DO; James Kahn, Esq; Roni Foster, DO; Alicia Lewis, MA; John Rodgers, John Leonard, MD and Thomas Blair, MDA. Location: WCMC, Uris Auditorium	3 pm-5 pm

3. 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.

- i. **The CITI program** online portion of the course is available by registering through the CITI site at <https://www.citiprogram.org>. See the instructions on the Information sheet of the RCR course. Once the RCR CITI training is completed, participants will receive an official certification. Participants **must save that certification and upload it to Canvas**.

- ii.* **Interactive research integrity videos:** Participants can choose between “The Lab” and “The Research Clinic,” two different interactive videos that explore research misconduct at <http://ori.hhs.gov/THELAB> or <http://ori.hhs.gov/THERESEARCHCLINIC>. 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 (RIO), a clinical researcher, an IRB chair (Institutional Review Board)). 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 and then form small study groups to discuss the issues raised by the simulations. Discussion guide is accessible at <http://ori.hhs.gov/TheLab/TheLabGuide.pdf>.

4. Reflective Essay Assignment

Participants are expected to write **an original 2-page essay** as a **personal reflection** on the importance of any of the topics of interest addressed in the course, or of the following topics related to the responsible conduct of research. No plagiarism will be accepted. Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

- i. 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.
- ii. The federal Office for Research Integrity provides guidelines on the protection of whistleblowers at http://ori.hhs.gov/misconduct/Guidelines_Whistleblower.html. 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?
- iii. 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?
- iv. 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?

5. Course Registration

The semester long Responsible Conduct of Research (RCR) course is open to all members of the WCMC and Clinical and Translational Science Center (CTSC) research communities. Participants can register for the course by registering at [RCR Registration](#) (also available at

<https://docs.google.com/forms/d/1oDylVy8zxejoaGjW9656E470KMayrECyjtUFGGILPB8/viewform>).