

## Taking Responsibility for the Responsible Conduct of Research

*A course to guide postdoctoral fellows and junior faculty in mentoring others looking to them for guidance on the ethics and responsibilities of conducting biomedical research*

Classes begin January 9th and will go through March 20th, 2025 (subject to change)

Thursdays, 3:30-5:00 p.m.

**(In-person classes on the Chicago campus - locations listed below)**

### COURSE CO-DIRECTORS:

**Daniel C. Lee, MD:**

Associate Professor of Medicine (Cardiology) and Radiology

**Rick McGee, PhD:**

Professor of Medical Education, Associate Dean for Professional Development

### OTHER PARTICIPATING INSTRUCTORS:

Robert O. Bonow, MD, MS:

Editor in Chief, JAMA Cardiology, Goldberg Distinguished Professor of Cardiology

Mary Kate Clifford:

Analyst, Export Controls & International Compliance

Michael Fiske, PhD:

Invention Manager, Innovation and New Ventures (INVO)

Adam S. Gordon, PhD:

Assistant Professor of Pharmacology

Mohammad Hosseini, PhD:

Assistant Professor of Preventive Medicine

Rebecca Ober, DVM:

Research Assistant Professor of Pathology

Lauran Qualkenbush:

Director, Northwestern University Office for Research Integrity

Luke Rasmussen:

Senior Clinical Research Associate

Emily Updegraff, PhD:

Director of Conflict of Interest

Amy Weber:

Senior Director, Export Controls & International Compliance

Clyde Yancy, MD, MSc:

Vice Dean for Diversity and Inclusion

### DESCRIPTION:

This course has been created for postdoctoral fellows and junior faculty who are recipients of NIH or other training awards that require training in Responsible Conduct of Research. The course will cover the principles and expectations for conducting biomedical research ethically and responsibility but will go one step farther to guide participants in teaching others for whom they are responsible. Each session will be led by one of the course directors and/or guest instructors.

### REQUIREMENTS:

#### Mentor Discussion and Reflection

Each participant is required to have a one-on-one discussion with their mentor or advisor about at least two of the topics covered in this course. Following the discussion, each participant must submit a reflection paper about the conversation.

#### Pre-Session, Online Modules

This course places a heavy emphasis on in-class discussion. To optimize class time for this, five of the course topics (Research Misconduct; Conflicts of Interests; Research with Human Subjects and Materials; Race, Ancestry, and Disparity in Medical Research; Research with Animals) include an online module that must be viewed prior to class. Completion of the modules includes submission of any accompanying evaluation.

#### Pre-Session Questionnaire

Course topics that do not include a pre-session module and evaluation will require the completion of a short pre-session questionnaire, and one class does have a questionnaire in addition to a pre-session module and evaluation. The questionnaires will assist presenters in gauging current knowledge, discovering questions around the topic and guiding the conversation in class.

### Attendance

Attendance is expected at every session. Up to two class days may be missed provided that all class materials (pre-session modules, pre-session surveys, presentation slide-decks and class recording) are reviewed. Absences exceeding two days will require notification of, and approval by, the course directors. All in person classes are in person only.

### Considerations for using the Zoom Platform

It is the expectation that individual cameras will be on during class, although it is understood that at times students will need to mute their camera momentarily to take care of personal or family needs. Feel free to use appropriate digital backgrounds.

Initially, microphones of non-hosts will be muted to ensure sound quality; individuals can unmute to make comments or for breakout sessions. The Zoom chat feature can also be used to ask a question or raise your hand to make a comment.

**All aforementioned requirements must be met in order to receive a course certificate.**

### WEEKLY SCHEDULE:

| Date      | Location                                                                                     | Session & Description                                                                                                                                                                                                                                                                                                                                                    | Instructor                                                                                    | Pre-Session Assignments                             |
|-----------|----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------|-----------------------------------------------------|
| 1/9/2025  | Baldwin Auditorium<br><br>Robert H. Lurie Medical Research Center<br><br>303 E. Superior St. | <b>Research Misconduct</b> – Policies and Responses to Suspected Misconduct • Identifying lines between misconduct, irresponsible conduct, and expected normative practices • Northwestern policies and resources • What to do if you suspect misbehavior or someone comes to YOU with concerns                                                                          | Lauran Qualkenbush<br><br>Introduction s with Dan Lee, MD, Rick McGee, PhD, and Jaime Ziegler | Module: Research Misconduct L. Qualkenbush          |
| 1/16/2025 | Baldwin Auditorium<br><br>Robert H. Lurie Medical Research Center<br><br>303 E. Superior St. | <b>Publication Practices and Responsible Authorship</b> – The range of norms, beliefs and practices among scientists and disciplines on assignment of credit through authorship and acknowledgements • Journal practices requiring explicit statements of contributions of authors • Establishing and communicating your criteria and process for determining authorship | Dan Lee, MD                                                                                   | Questionnaire                                       |
| 1/23/2025 | Baldwin Auditorium<br><br>Robert H. Lurie Medical Research Center<br><br>303 E. Superior St. | <b>Conflicts of Interest</b> – Recognizing, Acknowledging, Managing, Eliminating • Getting beyond naïveté in the ability to avoid unconscious and subtle unintended bias • Federal and Northwestern policies and practices with respect to financial conflicts of interests • Institutional COI • Risks of non-financial COI such as professional and commitment         | Rick McGee, PhD<br><br>Emly Updegraff, PhD                                                    | Module: Financial Conflicts of Interest J. Campbell |

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| 1/30/2025 | <p><b>Simpson-Querrey Auditorium</b></p> <p>Louis A. Simpson and Kimberly K. Querrey<br/>           Biomedical Research Center</p> <p>303 E. Superior St.</p> | <p><b>Mentoring</b> – Core principles of teaching and learning through mentors • Responsibilities when mentoring others • Helping others deal with the lack of consensus across the community on some practices • Individual Development Plans</p> <p>• Clarifying expectations</p>                                                                                                                                                                       | <p><b>Rick McGee, PhD</b></p>                                                             | Questionnaire                                                                                                      |
| 2/6/2025  | <p><b>Daniel Hale Williams Auditorium</b></p> <p>McGaw Medical Center</p> <p>240 E. Huron St.</p>                                                             | <p><b>IP and Commercialization, and Export Controls and International Collaborations</b> – Role of the university tech transfer office • The institution's challenge to balance commercial opportunity and its traditional teaching/research mission • Ethical and compliance aspects of conducting research with international collaborators • Details of international compliance, research security, malign foreign influence, and export controls</p> | <p><b>Michael Fiske, PhD</b></p> <p><b>Amy Weber</b></p> <p><b>Mary Kate Clifford</b></p> | Questionnaire                                                                                                      |
| 2/13/2025 | <p><b>Daniel Hale Williams Auditorium</b></p> <p>McGaw Medical Center</p> <p>240 E. Huron St.</p>                                                             | <p><b>Research with Human Subjects and Materials</b> – Beyond the basics to reality • Balancing potential conflicts between protecting subjects and accomplishing vital research</p>                                                                                                                                                                                                                                                                      | <p><b>Dan Lee, MD</b></p>                                                                 | <p><b>Module: Human Subjects Protections</b></p> <p>E. Yates</p>                                                   |
| 2/20/2025 | <p><b>Baldwin Auditorium</b></p> <p>Robert H. Lurie Medical Research Center</p> <p>303 E. Superior St.</p>                                                    | <p><b>Race, Ancestry, and Disparity in Medical Research</b> – Defining and describing disparities • Understanding historical origins of race and scientific racism • Differentiating race, ancestry, and genetic variation • Identifying and mitigating structural racism and bias in research</p>                                                                                                                                                        | <p><b>Adam Gordon, PhD</b></p> <p><b>Clyde Yancy, MD, MSc</b></p>                         | <p>Questionnaire</p> <p><b>Module: Human Subject Issues in Genetic Research and Biobanking</b></p> <p>M. Smith</p> |
| 2/27/2025 | <p>Online via Zoom</p>                                                                                                                                        | <p><b>Data Acquisition, Management, Sharing, and Ownership &amp; Reproducible Research</b> – Expected practices and policies of journals, sponsors, and institutions • Tools for reproducibility in research</p>                                                                                                                                                                                                                                          | <p><b>Rick McGee, PhD</b></p> <p><b>Luke Rasmussen</b></p>                                | Questionnaire                                                                                                      |

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| <b>3/6/2025</b>  | <b>Daniel Hale Williams Auditorium</b><br><br><b>McGaw Medical Center</b><br><br><b>240 E. Huron St.</b>          | <b>Peer Review</b> – What really are the instructions and expectations for journal and NIH peer reviewers? • Inclusion of graduate students and postdocs in peer review processes • Teaching others the high bar for respect of intellectual property revealed to peer reviewers | <b>Dan Lee, MD</b><br><br><b>Robert O. Bonow, MD, MS</b>    | <b>Questionnaire</b>                                                 |
| <b>3/13/2025</b> | <b>Online via Zoom</b>                                                                                            | <b>Research with Animals</b> – Going beyond the web-based training to real-life considerations of using animals in research • Practical applications for seeking approval to use animals in your research • Supervising and training others to work with animals in research     | <b>Rebecca Ober, DVM</b>                                    | <b>Module: Animals in Biomedical Research</b><br><b>M. Kozlowski</b> |
| <b>3/20/2025</b> | <b>Baldwin Auditorium</b><br><br><b>Robert H. Lurie Medical Research Center</b><br><br><b>303 E. Superior St.</b> | <b>Case Studies</b> – Analysis and discussion of selected recent topics in responsible and ethical research                                                                                                                                                                      | <b>Mohammad Hosseini, PhD</b><br><br><b>Rick McGee, PhD</b> | <b>Questionnaire</b>                                                 |