

Children's Hospital Program RCR @ BCH

Boston Children's Hospital (BCH) established the RCR @ BCH seminar program to provide education in responsible conduct of research (RCR) and integrity in science as required by NIH. The course is designed to increase investigators' awareness of ethical issues involving normative research practices throughout the course of a career. Trainees, fellows and faculty receiving support through NIH training, career development awards and research education grants are expected to complete course participation (as a participant or as a discussion leader, depending on career stage) no less than once every four years to be in compliance with NIH regulations. The curriculum is routinely updated to ensure compliance with NIH standards.

Course Objectives:

At the end of the course the student will be able to:

- 1) Understand and implement the standards of research integrity.
- 2) Understand and implement the ethical and regulatory requirements for conducting bench, animal, clinical, and public health research.
- 3) Recognize when the standards of research integrity are violated during laboratory practices, publication practices, and other research practices.
- 4) Understand how to comply with ethical and legal requirements in research.

Requirements

- a) Participants must attend all **eight classroom** sessions (over several years), **complete CITI training modules** in order to comply with NIH regulations, and write a **statement** illustrating/demonstrating training in your individual departmental specific program. This includes instruction created by each departmental faculty for the trainees in its own department.
- b) Participants should participate actively in each class by way of reading the suggested materials and constructive contributions to class discussion.
- c) Completion of Research Ethics courses at DFCI, HCSPH are accepted
- d) If a session is missed, it is possible to "make-up" the session in the next calendar year or if completion of the course is urgent by reading and reviewing the material with your lab mentor, with completion conveyed by signed letter to the committee for our records.

Monitoring

Children's Hospital Office of Sponsored Programs (OSP) will maintain records of RCR training progress and completion to ensure compliance with NIH regulations.

- *Attendance is documented by sign-in sheet.*
- *Attendance will not be credited if the participant is over 15 minutes late to class.*
- *Attendance at each session and completion of CITI training is monitored and recorded in CHERP for each individual, and required for NIH Career Development Awards (F-series and K-series).*

Format

RCR @ BCH will offer both discussion-based, hour-long sessions held via classroom discussion and/or via Zoom with relevant literature associated with each seminar topic.

- The overall course is overseen and organized by the Office of Research Affairs and Integrity at BCH with senior-level faculty serving as facilitators, including Diane Bielenberg, PhD (Assistant Professor of Surgery, HMS); Stacy Drury, MD, PhD (Psychiatrist-in-Chief, Department of

Psychiatry and Behavioral Science, Boston Children's Hospital; Chair of Psychiatry, HMS); Jeffrey Dvorin, MD, PhD (Senior Associate Physician in Pediatrics, Division of Infectious Diseases; Associate Professor of Pediatrics, HMS); Margaret Kenna, MD, MPH, FACS, FAAP (Associate, Department of Otolaryngology and Communication Enhancement; Director of Clinical Research, Department of Otolaryngology and Communication Enhancement; Professor of Otolaryngology, HMS); Carla Kim, PhD (Principal Investigator, Stem Cell Program; Professor of Genetics and Pediatrics, HMS); Kristen Leeman, MD (Associate Medical Director, Neonatal Intensive Care Unit (NICU); Program Director, Harvard Neonatal-Perinatal Medicine Fellowship; Director of Quality, Division of Newborn Medicine; Associate Professor of Pediatrics, HMS); Jeffrey Moffitt, PhD, (Assistant Professor, Program in Cellular and Molecular Medicine, Boston Children's Hospital; Assistant Professor, Department of Microbiology, HMS); Lise Nigrovic, MD, MPH (Director, ICCTR Office of Investigator Outreach; Senior Associate Physician in Medicine, Division of Emergency Medicine; Associate Professor in Pediatrics and Emergency Medicine, HMS); Adrienne Randolph, MD, MSc (Senior Associate in Critical Care Medicine, Department of Anesthesiology, Critical Care and Pain Medicine; Professor of Anesthesia, HMS); Matthew Sampson, MD, MS (Attending, Division of Nephrology; Associate Professor of Pediatrics, HMS); Lynn Sleeper, ScD (Scientific Director, Division of Clinical Research; Senior Associate Cardiologist, Cardiology Research; Associate Professor of Pediatrics, HMS); and Michael Lozzi, JD (Conflict of Interest Officer). They modify and determine reading materials and case studies from respected sources as appropriate for each discussion topic. Additional input for sessions is contributed by research support staff including Fariba Houman, PhD (Research Compliance Officer), Kris Bolt (Research Data Management Consultant) and Theresa Applegate (Senior Director, Office of Sponsored Programs).

- BCH will make RCR training accessible through Collaborative Institutional Training Initiative (CITI). CITI online training modules incorporate readings, case studies and quizzes addressing topics in RCR.

This course meets the NIH training requirement for all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant, or dissertation research grant.

Texts and Reading Materials

- a) Required materials:
 - 1) [“On Being a Scientist, A Guide to Responsible Conduct in Research,” 3rd Edition, by National Academy of Sciences, National Academy of Engineering, and Institute of Medicine](#)
 - 2) [ORI Introduction to the Responsible Conduct of Research](#)
- b) Additional reading materials will be posted on the [course website](#).

Subject Matter

Topic	Description
Research Misconduct	including definition of research misconduct and policies for management of misconduct
Data Acquisition	management, sharing and ownership, intellectual property
Collaborative Science	including industry-based collaboration
Mentoring	mentor/mentee responsibilities and relationships
Responsible Authorship	publication practices & responsible authorship
Contemporary Ethics	Contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research
Peer Review	Pros and cons of peer review system
Conflict of Interest	conflict of interest and commitment (personal, professional and financial)