

## Responsible Conduct in Research

The Beth Israel Deaconess Medical Center (BIDMC) is a major teaching hospital of Harvard Medical School and receives \$225M of both public and private funding for research directed at studies of human disease. As part of its research mission to understand and improve treatments of disease, BIDMC understands that the institution and its researchers have a responsibility to abide by the laws and regulations that govern federally funded research. As such, BIDMC is committed to the education and training of faculty in the responsible stewardship of federal funds.

Protection of human research subjects through education of research faculty and staff is one key to excellence in research. Towards that end, and in order to comply with the federal education mandate, the core of the RCR training for BIDMC is a research education program offered through the Collaborative IRB Training Initiative (CITI).

Once the CITI exam component is completed, BIDMC will provide a series of 4 to 5, two-hour case-based workshops. Workshop cases are currently being prepared and are likely to cover the suggested subject matter listed in the NIH guidance document:

- a. Conflict of Interest – personal, professional and financial
- b. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- c. Mentor/mentee responsibilities and relationships
- d. Collaborative research including collaborations with industry
- e. Peer review
- f. Data acquisition and laboratory tools; management, sharing and ownership
- g. Research misconduct and policies for handling misconduct
- h. Responsible authorship and publication
- i. The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

The ethical use of animals in research, through the education of faculty and staff working with animals, is another key to excellence in research. Towards that end, and in order to comply with federal mandates, the core of this portion of the RCR training again involves the education program offered through the CITI program. All BIDMC personnel working with animals must complete two or more modules depending on the type of work being performed:

- a. For mouse and rat protocols the required CITI modules are “Working with the IACUC”, “Working with Mice”, and “Working with Rats”
- b. For rodent protocols the BIDMC carbon dioxide euthanasia of rodents on-line training is required
- c. When applicable, the BIDMC Animal Biosafety Training and on-line quiz must be completed

- d. When applicable, the BIDMC Animal Research Facility (ARF) Rodent Survival Surgery Training and on-line quiz must be completed

In addition to the on-line modules, face-to-face training is provided in three required sessions:

1. A tour of the animal facility that the researcher will be working in, scheduled by the facilities CLS Management
2. An overview lecture on the facility
3. ARF Overview Training, which is provided by the BIDMC's veterinarian responsible for the care of animals at all animal facilities, Dr. Barbara Garibaldi

Suggestions for Faculty/Mentor Involvement:

- a. Individual lectures in the responsible conduct of research
- b. Informational meetings held on various RCR related topics such as data management, expectations regarding publications/authorship, etc.

In addition to the above core courses that are offered at BIDMC, the following courses are available:

- a. Introduction to Laboratory Research (at neighboring Brigham and Women's Hospital)
- b. The Program in Clinical Effectiveness, which includes classes on Decision Analysis, Current Issues in Health Policy, Medical Informatics, Health Care Ethics, and other topics (through Harvard Medical School)
- c. The FASEB Grantsmanship Training Program
- d. The Jackson Laboratory Annual Short Course on Medical and Experimental Mammalian Genetics
- e. The Division of Medical Ethics within Harvard Medical School will host 1 hour courses for 5-6 sessions. The course is designed to run as a graduate-style seminar. It is purposefully not a list of "dos and don'ts". Instead, this course is meant to provide an opportunity to openly and critically reflect and discuss what responsibility and integrity should mean to the professional scientific community.

Currently, there is a RCR subcommittee at the Harvard Catalyst Program. As this program matures, there may be additional opportunities for RCR training offered to BIDMC staff.