**Responsible Conduct of Research**

Mount Sinai has a strong commitment to providing excellent and ongoing instruction in the Responsible Conduct of Research (RCR) for all students, postdocs and faculty involved in biomedical research. The RCR curricula at Mount Sinai have long surpassed the guidelines described in NIH issued NOT-OD-10-019 “Update On The Requirements for Instruction in the Responsible Conduct of Research”. Reginald W. Miller, DVM, DACLAM, was appointed in 2009 as the Mount Sinai Research Integrity Officer in the Office of the Dean. He has overseen a coordinated increase in RCR education at all levels of the institution that adds even greater vitality to a program that has been a long-standing institutional commitment. All trainees will participate fully in these RCR course offerings upon entrance to the training program, and will partake in the bi-annual refresher course required by the school.

**Format:** Two graduate courses in the Responsible Conduct of Research (RCR) are offered annually. One is for PhD and Master’s students, and the other for MD/PhD students; both courses are considered an integral and mandatory constituent of part of the core curricula. There are also condensed courses for postdoctoral trainees and graduate students who have not taken the RCR course for 4 years, which also ensure a more closely matched peer group to facilitate discussions and relevant experience. A key element of the course is elucidation of best practices in research as they related to reproducibility and transparency. These rigorous courses entail a series of presentations in different formats that include presentations by guest speakers. This material is supplemented by additional assigned reading, use of selected videos, and other special materials. Each session includes didactic material and discussions of relevant case studies.

**Subject Matter:** 1) Specific topics for the eight sessions include: (i) Research misconduct: Definitions and related issues; (ii) Laboratory notebooks, experimental design, and data management; (iii) Protection of Human Subjects; (iv) Welfare of Laboratory Animals; (iii) Conflicts of Interest; Intellectual property, (iv) Mentor and Trainee Responsibilities; Collaborative Research; (v) Experimental Design and Data Management Practices; (vi) Publication, Authorship, and Peer Review; (vii) Peer Review, the Grant Process, and Fiduciary Responsibility; (ix) cognitive biases; (x) scientists as ethical members of society. While as indicated above issues related to transparency and reproducibility are discussed and constitute an important and explicit rationale for the course, as consistently explained to the students, Mount Sinai has recently implemented a complementary mandatory course (in the spring, following the mandatory RCR in the fall for all first-year students) that will specifically review issues of experimental design and statistical analysis addressing best practices for reproducible results.

The main resources for these RCR courses are the materials on the NIH Office of Research Integrity (ORI) website, which presents the most recent official NIH positions on most of the issues covered in the course. At the end of the course trainees are required to take and pass (>85% correct answers) an online test produced by the Collaborative Institutional Training Initiative (CITI) to ensure that the trainees meet the broad standards for RCR.
Faculty Participation: Charles Mobbs, PhD, Professor of Neuroscience and Geriatrics, directs the RCR course. Guest lecturers have included the Executive Director and Chair of the IRB, the Chair of the IUCAC, a representative from the Office of Industrial Liaison, and the Mount Sinai Ombudsman. Small group discussion leaders have been knowledgeable faculty at Mount Sinai who serve on a rotating basis.

Duration of Instruction: The Graduate RCR course is now composed of 8 one-hour sessions over the course of eight weeks. The refresher course is composed of 4 one-hour sessions. The first part of each session entails didactic material (e.g., the NIH definition of misconduct, best practices in note-book keeping and data management, the role of the IRB and IUCUC committees, forms of cognitive biases, etc) followed by class discussions of case studies illustrating the complexities and ambiguities in applying these principles to real-life situations. Participation is monitored by sign-in sheets which are maintained by the instructor. Students are allowed to miss up to 2 sessions for reasons approved by the instructor (e.g., illness or other unavoidable conflicts) but must review the material and submit a report indicating such (often the instructor will review the material in a one-on-one basis: failure to attend this mandatory course occurs at a relatively low rate so this is generally feasible). At the end of the course trainees are required to engage in the ORI interactive video (THE LAB) and submit a report indicating decisions made and outcomes.

Frequency of Instruction: Mount Sinai is committed to recurring and ongoing instruction in RCR for all students, postdocs and faculty. All first year PhD and MD/PhD graduate students, along with all new trainees, participate in the mandatory graduate course in RCR, and are required to take the refresher course after 4 years of training. All trainees are required to take the biannual refresher RCR course in order to maintain the NIH mandated instruction in RCR every 4 years. Because our RCR courses are continually updated, with variation in lectures, case studies, and group discussions to reflect important issues and current cases, our RCR course is a valuable and fresh learning experience each time it is taken throughout a scientific career.

Other RCR training and resources at Mount Sinai: Furthermore, it is recognized that proper instruction in RCR requires an ongoing dialogue about these important issues that is not satisfied by recurring course work. Informal instruction in RCR occurs normally in the course of laboratory instructions and mentor/trainee interactions and other informal situations during training. In addition, Mount Sinai has had an ongoing program in bioethics since 1980, under the direction of Rosamond Rhodes, PhD, Professor of Medical Education and Director of Bioethics Education at The Icahn School of Medicine. The Bioethics program includes several semester long courses offered to trainees. Trainees will participate in ethics seminars and luncheons which have been ongoing at Mount Sinai for many years as an integral part of our training program, as follows:

- Attendance at the monthly Mount Sinai Center-Wide Ethics Luncheons convened by Dr. Rosamond Rhodes. At each luncheon, a guest speaker presents a case that poses an ethical dilemma. Faculty, trainees, students, and other medical professionals participate in stimulating conversation and debate on issues confronted in clinical practice and
research. Recent focuses of discussions have been transplant tourism, end-of-life
decision making, and surrogate decision making. These luncheons have always had a
significant proportion of sessions discussing issues in Human Genetics, partly because
Kurt Hirschhorn, MD, a medical geneticist and member of our executive faculty
committee, founded these luncheons in 1970. We anticipate that the advent of
translational genomics research will generate even more ethical discussion sessions of
great interest to our trainees.

- Attendance at Research Ethics Seminar Series Course Directors: Karin Meyers, MA and
  Rosamond Rhodes, PhD. This semester-long seminar, offered as part of the Clinical
Research Education Program, addresses the key issues related the use of human
subjects in biomedical research. It involves seminar discussion, extensive reading, and a
research paper. Topics include: the evolution of clinical trial oversight, informed consent,
assent, assessment of risks and benefits, research design, research with minors and
other vulnerable subjects, inducements for research subjects, conflict of interest,
payments for researchers, confidentiality, privacy, scientific fraud, authorship, attribution,
and whistle blowing. This is a graduate-level seminar attended by students in the MS
degree programs in Clinical Research and in Genetic Counseling, the Certificate in
Clinical Research program, and the medical and graduate students. Dr. Rhodes also will
be available to consult with trainees on ethical issues and to mentor them.

Furthermore, ethical consultation services are available on a per need basis to all members of
Mount Sinai including trainees, as follows:

- The Clinical Ethics Consultation Committee of the Medical Board of the Mount Sinai
  Hospital is available for consultation and guidance on ethical issues concerning patient
care and treatment (Ian Holzman, MD, Richard Stein, MD, Rosamond Rhodes, PhD).
  Kurt Hirschhorn, MD, a member of our executive faculty committee, founded this
committee in 1970 and was chairman for 30 years.

- The Research Ethics Consult Service helps clinical and translational investigators to
  identify bioethical issues in their research proposals and helps them design their studies
and carry out their research to meet the highest ethical standards. Members of the
Consult Service are available for consultation and guidance on ethical issues concerning
the conduct of human subject research. Nada Gligorov, PhD, Rosamond Rhodes, PhD,
and Glenn Martin, MD, CIP, who teach research ethics at Icahn School of Medicine and
in the Mount Sinai Bioethics program, provide this consultation service. Dr. Rhodes has
a particular academic interest and expertise in the bioethical issues associated with
genetics and genomics. Researchers may consult the service directly or through referral
by a department chair, the IRB, or any one of the other consultation services.

- Institutional Animal Care and Use Committee (IACUC) is available for consultation and
guidance on ethical issues concerning the use of animals in research. Consultation is
available during the study design process and during the conduct of research. The
IACUC Chair is Giorgio Martinelli, PhD.

For more information: