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. Since the previous award, the RCR curricula at Mount Sinai has been considerably expanded, and now surpasses the guidelines described in NIH issued NOT-OD-10-019 “Update On The Requirement For Instruction In The Responsible Conduct Of Research”. Reginald W. Miller, D.V.M., 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: The graduate course in the Responsible Conduct of Research (RCR) is offered annually to each incoming class of Ph.D. and M.D./Ph.D. students as an integral part of their core curricula. Trainees from this program will participate in this mandatory graduate course. Qualified trainees must participate in a biannual refresher course offered specifically for postdoctoral trainees and junior faculty, which also ensures a more closely matched peer group to facilitate discussions and relevant experience. This rigorous 16-hour (8 x 2 hour sessions) RCR course encompasses a series of presentations in different formats that include presentations by guest speakers, panels of faculty members and videos. This material is supplemented by additional assigned reading, use of selected videos, and other special materials. Each session has an hour devoted to small group discussion of specific pre-assigned case studies with a faculty mentor. These discussions are followed by a full class wrap-up in which the groups compare notes on their conclusions, insights and remaining questions. Each trainee is required to submit a report discussing the assigned case study each week, and at the end of the course is required to submit a real-life case study of an ethical research dilemma encountered by the trainee, and an analysis of the resolution of the dilemma.

Subject Matter: 1) Specific topics for the eight two hour classroom sessions include: (i) Conflicts of Interest; Intellectual property, (ii) Protection of Human Subjects; (iii) Welfare of Laboratory Animals; (iv) Mentor and Trainee Responsibilities; Collaborative Research; (v) Research Misconduct; (vi) Experimental Design and Data Management Practices; (vii) Publication, Authorship, and Peer Review; (viii) Peer Review, the Grant Process, and Fiduciary Responsibility. The main resources for this course 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, Ph.D., Professor of Neuroscience and Geriatrics, directs the RCR course. Guest lecturers have included the Executive Director and Chair of the IRB (Jeff Silverstein, MD, CIP), the Chairman of our IUCAC (Giorgio Martinelli, DSc, PhD), a representative from the Office of Industrial Liaison (Rajesh Udupa, Ph.D.), and the Mount Sinai Ombudsperson (Barry Stimmel, MD). Small group discussion leaders are knowledgeable faculty at Mount Sinai who serve on a rotating basis, and research mentors from this training program will be included as small group discussion leaders.

Duration of Instruction: The Graduate RCR course is composed of 8 two hour sessions over the course of eight weeks. The refresher course is composed of 4 two hour sessions. The first
hour of each session is lecture format or faculty panel discussion, followed by a second hour with faculty mentors in small group discussions of a preassigned case relevant to the lecture topic. These discussions are followed by a full class wrap-up in which the groups compare notes on their conclusions, insights and remaining questions. Each trainee is required to submit a report discussing the assigned case study each week, and at the end of the course is required to submit a real-life case study of an ethical research dilemma encountered by the trainee, and an analysis of the resolution of the dilemma.

**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 2-4 years of training. All postdocs and junior faculty, including the trainees in this program, 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, Ph.D., 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 Dr. 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.

Each trainee will complete mandatory online training programs on HIPAA regulations, and an on-line course of instruction developed by the National Cancer Institute designed to educate investigators in the ethical conduct of research. This course is designed around the NIH Handbook, "Human Participant Protections-Education for Research Teams" and covers issues of scientific integrity, mentoring, scientific record keeping, authorship, peer review, the use of animals in biomedical research, institutional review boards, ownership of data and intellectual property, conflict of interest, scientific misconduct and new topics of great importance such as use of human fetal tissue and stem cells in research and clinical research in developing countries. Upon successful completion of this course, each fellow will obtain a certificate. 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). Dr. 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.

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