Training in the Responsible Conduct of Research (RCR)

All students and basic and clinical research trainees at the University of Rochester receive multi-faceted training in the responsible conduct of research (RCR). We expect integrity in the practice of scientific investigation and teach it through the promotion of awareness and application of established professional norms and ethical principles related to the performance of scientific research, including basic, clinical, and translational research. There exists a *University Commitment to Ethical Research* and we are proud to have achieved and maintain full accreditation with the Association for the Accreditation of Human Research Protection (AAHRPP). We also recognize the broader concept of responsible conduct and scientific integrity, and we have incorporated these ideals into our various formats of instruction, formal and informal, taking into account the stage of the trainee's career.

Required Course: Ethics and Professional Integrity in Research (lecture and small group exercises)

All research trainees at the University of Rochester involved in research, including predoctoral and postdoctoral trainees, are required to complete and pass the course *Ethics and Professional Integrity in Research*. Two courses are offered annually in parallel in the fall semester: IND501: *Ethics and Professional Integrity in Research – for Biomedical Sciences Students*, and IND506: *Ethics and Professional Integrity in Research – for Postdoctoral Appointees.* Course co-directors for IND501/506 are Robert Freeman, PhD, Professor of Pharmacology & Physiology, and Kelley O'Dongohue, MPH, CIP, Associate Vice President for Human Subject Protection. The one-credit courses provide 20 hours of face-to-face contact time in both a lecture and small-group format over a 10-week period. Attendance is mandatory and monitored electronically for lectures (i.e., by scanning ID badges) and by individual sign-in sheets at small group sessions. Participants who miss or show up late to a lecture or small group session are required to make up the session by writing a 1-2 page short report on the lecture topic or related case studies. Additional information about the course, including a current syllabus, is available here.

The ten, one-hour lectures cover the following core content: mentor-protégé relationships, scientific misconduct, conflicts of interest (personal, institutional, financial), use of human and animal subjects in research, responsible authorship and publication, data sharing and ownership, collaboration and team-science, research rigor and reproducibility, unconscious bias in research, and contemporary ethical issues in research (e.g., human stem cell research). The lectures are taught by prominent faculty and institutional leaders – lecturers in 2017 were Paul Brookes, PhD, Professor of Anesthesiology; John Cullen, PhD, Res. Associate Professor and Director of Diversity and Inclusion for the Clinical and Translational Science Institute; Stephen Dewhurst, PhD, Vice Dean for Research and Professor and Chair, Department of Microbiology & Immunology; Robert Freeman, PhD, Professor of Pharmacology & Physiology; Robert Gross, MD, PhD, Professor of Neurology; Edith Lord, PhD, Senior Associate Dean for Graduate Education & Postdoctoral Affairs and Professor of Microbiology & Immunology; Kelley O'Dongohue, MPH, CIP, Associate Vice President for Human Subject Protection; James Palis, MD, Professor of Pediatrics; David Topham, PhD, Professor of Microbiology & Immunology; and Jeffrey Wyatt, DVM, MPH, Professor and Director, Department of Comparative Medicine.

Immediately following the lecture, the class splits into small groups of 8-10 students, each with a faculty facilitator. During the 60-minute session, students engage in open discussions of 3-4 case studies that provide real-life examples of the topics discussed in the preceding lecture. The small group facilitators, most of whom are mid-to-senior level faculty with extensive experience in basic, clinical and/or translational research, help guide and provide breadth to the discussion and, when appropriate, offer insights from personal experience. In addition to these 'seasoned' facilitators, a smaller group of facilitators are recruited each year from the pool of junior faculty, career development award recipients, and senior postdoctoral fellows and trainees with an interest in RCR education. Participation by these individuals not only serves to further their own ongoing training in RCR, it also helps ensure that fresh and, in some cases, alternative points of view are represented in the small group discussions.

Continuing Education in the Responsible Conduct of Research at URMC

All graduate students, postdoctoral appointees, clinical fellows, and research faculty at the University of Rochester Medical Center involved in research are required to participate in continuing RCR education. This is achieved through a combination of special invited lectures, online courses, skill-building workshops, monthly seminar series, and recruitment to participate as a small group facilitator for the IND501/506 *Ethics and Professional Integrity in Research* courses. A website highlighting RCR continuing education activities is maintained by the Office of Graduate Education and Postdoctoral Affairs: http://www.urmc.rochester.edu/education/graduate/professional-development/research-ethics/continuing-ed.cfm.

Each year, all trainees are required to attend the medical center's Annual Lecture on Biomedical Research Ethics. This lecture series, held continuously since 2011, highlights a different topic in research ethics and professional integrity each year. Invited speakers include leaders and experts on bioethics topics from within the medical center and across the country. A trainee Q&A session with the speaker and an open reception following the lecture provides trainees an opportunity to interact with the speaker. The lectures are streamed live and, with the speaker's approval, videorecorded so that trainees unable to attend can view the lecture in real-time or at a later date. The 7th Annual Lecture on Biomedical Research Ethics, held on Sept 27, 2017 and titled *"Do New Tools Need New Ethics? The Challenge of Governance for Gene Editing in Humans"*, was presented by Dr. Jeffrey Kahn, PhD, MPH, Professor and Director, Berman Institute of Bioethics, Johns Hopkins University. In addition to attending the annual lecture, postdoctoral trainees and fellows who have completed the *Ethics and Professional Integrity in Research* course (or comparable training elsewhere) are encouraged to participate as small group facilitators in the course as part of their ongoing professional development and training. Other activities offered to trainees to further their RCR training include online ethics courses (e.g. Collaborative Institutional Training Initiative (CITI) Program Human Subject Protection and Responsible Conduct of Research courses), skill-building workshops offered by the medical center's Clinical and Translational Science Institute and Office for Human Subject Protection, and the Clinical and Translational Science Institute and Medical Humanities and Bioethics monthly seminar series.

Animal Training

All trainees working with live vertebrate animals undergo additional training through CITI entitled "Laboratory Animal Welfare" as part of the institutional animal welfare training program through the University Committee on Animal Resources (UCAR). This program stipulates training in animal care and handling that is tailored to specific experimental requirements and vertebrate species.

Human Subjects Training

All trainees conducting human subject research are required to successfully complete (with a score of at least 85%) basic human subjects training through the Collaborative Institutional Training Initiative (CITI) *prior* to conducting any human subject research (see Office for Human Subject Protection [OHSP] Policy 201). The course is completed through CITI's online training platform and completion requirements are based on the risk level of the research being conducted (minimal risk vs. greater than minimal risk). Refresher training is required every 3 years. Additional information regarding the course, including instructions for accessing the course, are available here.

The OHSP Division of Research Education & Training also provides additional, free-of-charge training through their Education & Training Framework. The offerings included within this training framework are meant to build upon the basic human subjects training completed in CITI and cover topics such as review processes and requirements, protocol development and informed consent. Courses are available for research personnel to use as necessary, based upon their research roles. Additional training opportunities are also available through OHSP's 'Achieving High Quality in Clinical Research' seminar series (held approximately once a month during the academic year) and CITI's Good Clinical Practice (GCP) training.

Graduate Student-Research Advisor Expectations

The Office for Graduate Education and Postdoctoral Affairs has developed "expectations" of graduate students and their research advisors. These expectations articulate 15 principles specific to each party that clearly outline their respective rights and responsibilities. Many of these are the professional norms and ethical principles embodied in scientific investigation with integrity. For example, the students' expectations state that he/she will maintain a high level of professionalism, self-motivation, and ethical standards, as well as comply with both the letter and spirit of institutional safe laboratory practices and animal-use and human-research policies. In addition, it states that students will participate in the RCR training programs and discuss policies on authorship with their advisor before submission. The expectations of the research advisors state that the advisor will lead by example and facilitate training in the ethical conduct of research and scientific professionalism, as well as discuss authorship policies regarding papers and be attentive to conflicts that may arise, including intellectual property issues and disclosure policies.

Academic Research Track (Medical Students) and Early Stage Faculty Boot Camp

The Academic Research Track curriculum for year-out medical and nursing students contains lectures pertaining to scientific integrity and professionalism. These include lectures on formulating research questions, measurements, research ethics, mentoring, team-science, authorship/scientific publication, managing innovation, and peer review.

The Early Stage Faculty Boot Camp, co-sponsored by the Clinical and Translational Science Institute and the Office for Faculty Development, is open to all junior faculty intending to pursue a research career (basic science, clinical, translational) – regardless of graduate degree (MD, DO, PhD). In addition to many of the topics above, this weeklong course also includes lectures on the NIH grant process, trial design, and data base management, with concurrent sessions focused on clinical research and on basic science research.

Skill-Building Workshops, Sponsored-Seminars, Courses

Instruction on RCR is also covered in available skill-building workshops, sponsored-seminars, and individual courses. These are open to trainees, research mentors, and other faculty at the University. For example, the individual course PM 419: *Recruitment and Retention of Human Subjects in Clinical Research,* and the *Continuous Learning for Administrators of Sponsored Programs (CLASP)* program are available to all trainees (and required for some training groups) and have components specifically dealing with diversity, interdisciplinary research, and compliance with ethical standards and regulations. In addition, we have a new M.S.program in *Technical Entrepreneurship and Management in Biomanufacturing & Therapeutic Development,* which provides training both in the principles of entrepreneurship and management, and in the techniques and methods used in biomanufacturing and therapeutic development.

Individualized Mentoring

We place a high value on individualized mentoring and role modeling standards of behavior. Faculty members are all highly regarded and respected mentors in their own right, and many have received prior University Mentoring awards. Our program provides support and instruction to faculty in mentor roles and manages a pool of potential mentors based on prior track record, attention to diversity, and funding experience. All faculty are invited to participate in *Mentoring Workshops*, which are offered twice each year by the University's NIH-funded *Broadening Experiences in Scientific Training* (URBEST) program. In addition, all mentors who act as research advisors are required to review the "Expectations of Research Advisors."

Faculty Participation

Responsible conduct of research and scientific integrity begins and ends with our institutional leaders and faculty. Therefore, we expect active and continuous participation not only through serving as positive role models, but also by actively contributing to RCR instruction. Faculty and institutional leaders participate as members of the Mentor Development Core, as lecturers and facilitators of small groups in the *Ethics and Professional Integrity in Research* course, and as lecturers/leaders and participants in skill-building workshops, symposia, and courses such as those described above.