PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

All students and basic and clinical research trainees at the University of Rochester (UR) receive multi-faceted training in the methods for enhancing reproducibility and the responsible conduct of research (RCR). We expect integrity and rigor in the practice of scientific investigation and teach these fundamental principles through 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, scientific integrity, rigor & reproducibility, and transparency. We have incorporated these ideals into our various formats of instruction, formal and informal, considering the stage of the trainee's career. Described herein is our model for ***continuing education in the instruction in the responsible conduct of research (RCR)*** using a five-pronged approach. The goal of this model (**Fig 1**) is to ensure ethical and contemporary understanding of how to conduct research.

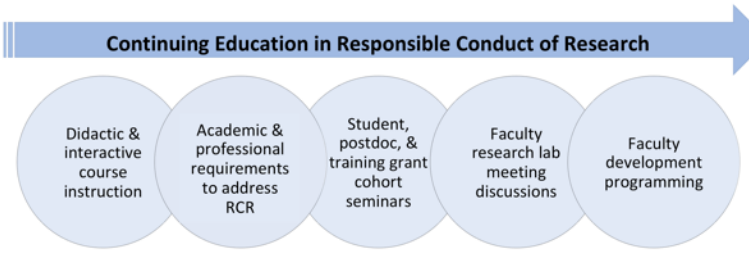

Figure 1. Approach to Instruction in the Responsible Conduct of Research

Didactic and Interactive Course Instruction

Required Courses: All research trainees at the UR involved in research, including predoctoral and postdoctoral trainees, are required to complete and pass the *Ethics and Professional Integrity* Course in the fall of their first year of training. Attendance is mandatory and monitored electronically for lectures (i.e., by scanning ID badges) and by individual sign-in sheets at small group sessions. Attendance at virtual class meetings (due to COVID-19) will be noted using the Zoom registration feature. 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-to-2-page short report on the lecture topic or related case studies. Should a trainee miss two or more sessions, they are required to retake the entire course.

Fall semester - ***Ethics and Professional Integrity in Research – for Biomedical Sciences Students (IND501)*, and *Ethics and Professional Integrity in Research – for Postdoctoral Appointees (IND506)*:** This one-credit course provides 20 hours of face-to-face contact time in both a lecture and small-group format over a 10-week period. The ten, one-hour lectures cover the following core content: mentor-mentee 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 professionalism and diversity, 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, including training faculty in the MSTP. For example, Drs. Brookes, Dewhurst, Lawrence, Palis, and Tropham provided lectures for IND501/506 in 2022.

For the small group sessions, the class splits into small groups of 8-10 learners immediately following the formal lecture. Each group has an assigned faculty facilitator. During the 60-minute session, trainees 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. Among MSTP training faculty, Drs. Grossfield, Mackenzie, Rowe, and Lueck served as small group facilitators for IND501/506 in Fall 2022. 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 continuing education. Participation by these individuals not only serves to further their own ongoing training, but it also helps ensure that fresh and, in some cases, alternative points of view are represented in the small group discussions.

At least **1-2 small group facilitators will be recruited from among the MSTP trainees** (for this purpose, we will reach out to trainees in their 3rd year of graduate training). This will extend and enrich the teaching experience of our Trainees.

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 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 has components

specifically dealing with diversity, interdisciplinary research, and compliance with ethical standards and regulations.

Annual Keynote lecture on Biomedical & Health Science Research Ethics. The Center for Professional Development, named *my*Hub, in the Office of Graduate Education and Postdoctoral Affairs (GEPA) at URSMD hosts an annual lecture featuring a prominent expert in research ethics. All students and postdoctoral appointees are required to attend these lectures. To make sure everyone has access to these lectures, they are streamed live and, with the speaker's approval, video-recorded (and made available online). Recent presenters have included: Dr. Daniel Acuna, Center for Computational and Data Sciences, Syracuse University ("*How to catch a scientific figure falsifier: Analysis and statistical reporting of potential figure element reuse and splicing across millions of images*"), Dr. Elizabeth Bik, Science Consultant, Harbers Bik LLC ("*The Dark Side of Science: Misconduct in Biomedical Research"*), and Dr. David Fajgenbaum, Perelman School of Medicine, University of Pennsylvania ("*From Chasing My Cure to Chasing Our Cures: Lessons Learned as a Physician, Patient, and Researcher"*).

Ongoing Academic and Professional Training in RCR

Formal requirements. GEPA establishes that all trainees must have a formalized component and review of research ethics as part of their academic and professional development.

Graduate Student-Research Advisor Expectations. GEPA has developed "expectations" of learners 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 they 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.

These ***learner expectations state formally that students will participate in RCR training*** and discuss policies on authorship with their advisor before submission. The ***expectations of the research mentors similarly 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 and be attentive to conflicts that may arise.

Animal Training. All trainees working with live vertebrate animals undergo additional training through the Collaborative Institutional Training Initiative (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 CITI *prior* to conducting any human subject research. 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. 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. 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.

Student, Postdoctoral Appointee & Training Grant Cohort Seminars

All graduate programs at the URSMD require a credit-bearing student seminar course that includes all graduate students matriculated in the program, and (in most cases) all postdoctoral trainees (who also present in these seminar courses). ***GEPA has set the requirement that a minimum of at least one seminar per year be dedicated to continued education in research ethics and the responsible conduct of research***. These seminars will include a faculty member from the program or department who will both facilitate and add to the discussion to ensure that diverse perspectives are discussed. This requirement will be part of the course evaluation, thus providing concrete evidence that topics introduced in the didactic learning are contemporaneously discussed. This has the added benefit of ensuring that program faculty experience continuing education in the responsible conduct of research.

A similar approach will be encouraged for all NIH Training Grant programs. Training grant directors are expected to formalize regular meetings with their training cohorts and discuss topics related to research ethics and the

responsible conduct of research at least twice a year. For the MSTP, discussions related to responsible conduct of research are an integral part of the course *Scientific Reasoning in Medicine*.

Faculty Research Lab Meeting Discussions

In addition to the foundational instruction in RCR outlined above, ***URSMD also expects all trainees and faculty to discuss RCR as it relates specifically to their own research projects***. To meet this requirement, the ***URSMD strongly encourages every faculty member to reserve one lab meeting a year, at a minimum, for a discussion of RCR-related topics.***

These settings are more informal than the requirements described above but are integral in assuring that students and postdoctoral appointees are actively incorporating the principles taught in the courses, workshops, and seminars into their own research and ongoing career development.

Faculty Development Programming

All faculty are expected to have continued education in RCR, as follows:

Faculty Participation. Ethical science 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 contributing to course instruction and through continuing education. All faculty will be required to take the institutional RCR course once every 10 years to stay current with best practices and understand cultural changes in conducting research. In addition, faculty will be required to lead small group discussions on RCR once every 3 years.

Faculty Evaluation: All faculty are required to complete an annual self-evaluation on the UR *myPath* portal. Built into this evaluation is a section where faculty are asked to list and summarize the steps they took over the year to continue their training in RCR. Acceptable efforts include course participation, participation as seminar facilitators, and attending training grant and/or departmental retreats/symposia and/or national conferences that include sessions on this topic.