**Training in the Responsible Conduct of Research**

*NOTE: This information should be customized, revised, and/or condensed as needed for your individual fellowship application. Be sure to follow any specific instructions for your proposal. Document your past RCR instruction, as well as current and/or planned instruction. You should also briefly describe your mentor's role in your RCR instruction. You can’t fit everything in the one page limit for this section of your proposal, so select the activities that are most appropriate for your proposed research training.*

The NIH has stringent guidelines for training in the Responsible Conduct of Research (RCR) and this training plan gives these the highest priority. The University of Florida has taken many steps to ensure that institutional and individual training programs proactively provide both formal and informal training and supervision needed to develop and maintain good RCR practices by trainees and mentors throughout the training period. Multimodal RCR training is provided for all PhD students, regardless of funding source, and emphasizes: (i) training in the protection of the welfare of human subjects through course work, Institutional Review Board visitation and/or service, research team meeting discussions with the mentor, University initiatives, and at trainee meetings and (ii) responsible scientific conduct in the gathering and reporting of scientific data through required course work, research team meetings, discussion with the mentor, and trainee meetings.

**Basic Training.** As a (*PhD student / postdoctoral fellow*) in the *(\_\_\_ PhD program / Dept. of \_\_\_*) in the College of \_\_\_ I participated in the following RCR training activities. (*select those that apply, and indicate dates completed*)

I will continue RCR training during my fellowship by participating in the following activities. (*select those that apply and indicate planned date of training*)

UF requires HIPAA training annually via the online course “HIPAA & Privacy – General Awareness (PRV800)”. *Possible additional online courses, depending on your research roles: “IRB Training (IRB803v)”, “Animal Care Services Orientation (ACS815)”, “Human Subject Payments (RSH320)”, “CTSI Informed Consent Training (CTS800)”, “Identify/Screen Human Subjects (CTS813)”, “Informed Consent Cornerstone (CTS812)”, “PI Responsibility for Informed Consent (CTS801)”, “Roles of Clinical Research Coordinators (CTS805)”, “Financial Conflict of Interest (DSR810)”, “Human Subjects Clinical Research Billing Risks (RBC810)”, “FERPA Basics (PRV802)”, “FERPA for Faculty (PRV803)”, Best Practices in Research Data Management (HSCLBPRD)”, “Good Clinical Practice for Social Behavioral Research (GCP100)”. Search myTraining for other specific training needs.*

My mentor*(s)* and I have read and understand the Belmont Report and 45 CFR 46. The Office of Human Research Protections (OHRP) considers it unethical for anyone involved in human subject research not to have read the Belmont Report, which describes the ethical principles that should be followed by investigators: respect for persons, beneficence and justice. Via Multiple Project Assurance, UF has a contract with OHRP assuring that investigators conducting human research will follow the ethical principles outlined in the Code of Federal Regulations. All trainees must read and be prepared to discuss 45 CFR 46, which describes authority and responsibility of Institutional Review Boards (IRBs) in protecting human subjects.

**Advanced Training.** I *completed/will complete (indicate inclusive dates)* the graduate course “Responsible Conduct of Biomedical Research” (GMS 7877, 1 credit, 24 contact hours), a *required/elective* course in the \_\_\_ curriculum. This course meets all policy requirements for RCR education promulgated by NIH in NOT-OD-10-019 for training at my career stage. The course is designed to introduce key issues in RCR following the research process from inception to planning, conducting, reporting, and reviewing biomedical research, and provides a practical overview of the rules, regulations, and professional practices that define RCR.

Format: This course uses team-based learning (TBL™), a structured small-group teaching method. Eleven 2-hour TBL sessions include ethical decision-making, defining research misconduct, human subjects, animal welfare, conflicts of interest & commitment, data management, mentor-trainee relationships, collaboration, authorship & publication, peer review, and rigor & reproducibility. Each session entails assigned pre- readings, individual and team readiness assurance tests, and application exercises in which student teams practice and discuss making decisions based on research on research scenarios posing real-life ethical dilemmas.

Subject Matter: Session titles include: Intro to RCR & Team-Based Learning; Intro to Ethical Decision-Making; Avoiding Research Misconduct; Welfare of Laboratory Animals; Protection of Human Subjects; Conflicts of Interest & Commitment; Data Management Practices; Mentor & Trainee Responsibilities; Collaborative Research; Authorship & Publication; Peer Review; and Rigor & Reproducibility.

Faculty Participation: This course is taught by faculty members with expertise in RCR topic areas, including ORI-funded research in RCR, IACUC Chair, IRB Members, COI officer, journal editor, etc.

Duration of Instruction: This course meets over the course of one semester and has a total of 24 contact hours, including one introductory 2-hour session of lecture/discussion, and eleven 2-hour TBL sessions.

I *completed/will complete (indicate inclusive dates)* the graduate course “Ethical and Policy Issues in Clinical Research (GMS 6931, 2 credits, 30 contact hours), a *required/elective* course in the \_\_\_ curriculum. This course covers ethical and policy issues relating to conduct of clinical research and provides a basic understanding of regulations governing research on human subjects and an introduction to the topic of research with animals. In addition to didactic training, case-based presentations and discussions are used to facilitate active learning.

I *completed/will complete (indicate inclusive dates)* the graduate course “Ensuring Rigor and Reproducibility in Clinical and Translational Research (GMS 6848, 1 credit, online), a *required/elective* course in the \_\_\_ curriculum. This course covers best principles and practices required to conduct rigorous and reproducible research across the translational spectrum. Topics include sound study planning and design, consideration of all relevant biomedical variables, sound data management practices, statistical considerations and techniques, and transparency in reporting research results.

I *completed/will complete (indicate inclusive dates)* the graduate course “Ethics in Genetics (GMS 6221, 1 credit), a *required/elective* course in the \_\_\_ curriculum. This course involves presentations and critical discussion of relevant topics pertaining to ethics, policy and translation in genetics research.

I *completed/will complete (indicate inclusive dates)* the graduate course “Ethics in Population Science (PHC 7427, 2 credits), a *required/elective* course in the \_\_\_ curriculum. This course covers federally mandated topics in the Responsible Conduct of Research: Data Acquisition, Management, Sharing, Ownership; Conflict of Interest/Commitment; Human Subjects; Animal Welfare; Research Misconduct; Publication Practices and Responsible Authorship; Mentor/ Trainee Responsibilities; Peer Review; and Collaborative Science.

**Mentor Participation.** In my mentor Dr. \_\_\_’s lab, I am receiving training in the responsible conduct of research through individual meetings with my mentor and collaborators (Drs. \_\_\_) on a (*weekly, biweekly, monthly*) basis *(mention any special training your mentors have had in RCR)*. Additionally, the members of the lab have group meetings, which provide consistent forums to discuss experimental rigor and reproducibility and to evaluate and critique experimental data. These discussions also offer the opportunity to address ethical issues such as responsible authorship, sharing of data and reagents, and data management. We are also provided informal instruction from various faculty and scientists in the responsible conduct of research in laboratory interactions and other situations. *(Possible additional details for this section are shown below)*

R4I@UF “Case of the Month” Discussions. Our lab conducts small group discussions during lab meetings on a monthly basis using case scenarios provided at a new UF-based website called “Responsible Rigorous Reproducible Research Integrity at UF”. Case scenarios include a series of topics in all domains of responsible conduct of research and research rigor & reproducibility, based in part on “The ORI Casebook: Stories about Researchers Worth Discussing”.

(*Department/center/institute*) seminar presenters are encouraged to incorporate research ethics issues encountered in their research, including discussion of ethical dilemmas involving IRB policies, authorship guidelines, conflicts of interest, mentoring, and/or responsible reporting of research findings.

Our (*weekly/monthly) (Dept. of Pathology Works in Progress / Dept. of Epidemiology All Hands / lab / other*) meetings include an “ethical moment” discussion that highlights a timely issue related to authorship, data management, data analysis, conflicts of interest, research funding, or other matters that affect research integrity.

I am required by the \_\_\_ program to have at least (*weekly, biweekly, monthly*) meetings with my mentors to review progress and set goals. RCR issues are reviewed and documented in these meetings.

In the development of my dissertation research project, I (*prepared and submitted my own protocol / will prepare and submit my own protocol / assisted or will assist in the preparation and submission of my mentor’s protocol*) for the *Institutional Review Board (IRB) / Institutional Animal Care & Use Committee (IACUC)* to learn more about protection of human and non-human research participants. As part of this experience, I *attended/will attend (indicate dates)* the *IRB/IACUC* meeting at which the protocol *is/was* reviewed, in order to better understand the *IRB/IACUC* review processes.

**Frequency of Instruction.** RCR instruction is embedded throughout my research training. Most RCR training requirements *have been/will* be met in my basic and advanced training as described above. Additional RCR training and practice with my mentor has been and will continue to be ongoing throughout the *(number)* years of my *predoctoral/postdoctoral* training program.

*(If you or your lab have other activities that you believe would be of interest to and benefit other students and/or postdocs, please share them with Dr. McCormack so they can be included in this document. Thank you.)*