

5. PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

Informal and formal training are necessary for effective education in the responsible conduct of research (RCR). One of most effective ways of accomplishing this training is through the example set by a Trainee's Mentor and/or Co-Mentor and via a close relationship between Trainee and Mentors. Therefore, in addition to formal training, there will be frequent one-on-one discussions between the Mentors and Trainee dealing with issues such as conflict of interest, data recording and retention, authorship, professional standards, and codes of conduct. Formal training will include the required graduate course "Responsible Conduct of Biomedical Research" (GMS 7003). This course is offered each spring semester and all first-year Pre- and Postdoctoral Trainees take the course. The course provides a practical overview of the rules, regulations, and professional practices that define the responsible conduct of research. The coverage is not exhaustive and leaves room for continued reading and discussion with the student's mentor, in the laboratory and classroom, at professional meetings, and in any setting where researchers gather to discuss their work.

The course meets weekly for 12 weeks (22 contact hours total). Sessions 1 & 12 are 1-hour sessions during which learners take a pre-test and post-test of ethical decision-making before and after the RCR training experience. All other sessions are 2 hours each. Session 2 is an introductory lecture/discussion about why we do RCR training, an overview of the ethical decision-making framework used in the course, and an introduction to team-based learning (TBL). Sessions 3-11 are conducted using TBL, a student-centered small group teaching method that dramatically shifts the focus of classroom time from conveying course concepts by lecture to application of course concepts by student teams through problem-solving and decision-making. The nine TBL sessions focus on the following subjects: Research Misconduct; Welfare of Laboratory Animals; Protection of Human Subjects; Data Management Practices; Conflicts of Interest; Mentor & Trainee Responsibilities; Collaborative Research; Authorship; and Peer Review. The course is letter-graded, based on individual and team readiness assurance test scores. Learning resources include nine locally produced, 20-50 minute online lectures (History of Research Ethics; IACUC & Animal Research; Protection of Human Subjects; Mentor & Trainee Responsibilities and Collaborative Research; Conflicts of Interest; Intellectual Property; Data Management Practices; Ownership of Biological Materials; and Authorship & Publication and Peer Review), and the online textbook "ORI Introduction to the Responsible Conduct of Research" by Nicholas H. Steneck, which features case studies, text-box inserts, discussion questions, and electronic and printed resources.

The faculty members are Wayne T. McCormack, PhD (Course Director, former Associate Dean for Graduate Education); William L. Allen, JD, MDiv (Director, Program in Bioethics, Law & Medical Professionalism); William Buhi, PhD (IACUC Chair); Ammon B. Peck, PhD (Associate Dean for Research & Graduate Studies, College of Veterinary Medicine, and former IRB Co-Chair); Colin Sumners, PhD (former Associate Dean for Graduate Education and Director, Junior Honors Medical Program); and Bruce Goldberger, PhD (Editor-in-Chief, Journal of Analytical Toxicology). In order to meet the frequency of training requirement, a "refresher" course is under development for Trainees who do not complete doctoral studies within four years of taking this course.

Trainees who participate in research involving human subjects are also required to take the following additional training:

- NIH or CITI certification in Research/Good Clinical Practice
- UF IRB required training: including the Belmont Report, 45 CFR 46 in Code of Federal Regulations, IRB Policies & Procedures, and Researcher Responsibilities
- UF HIPAA for Researchers training, updated yearly
- UF RAC/ CTC required training for any study staff member with face-to-face contact with the subject or with responsibilities for tracking sponsor paid billing vs. standard of care
- Participation in the regular IRB Education and Training sessions

Additionally, all study staff will attend initial training regarding specifics of the study conducted by the PI, sub-investigators and study coordinator.

Trainees who participate in research with vertebrate animals are also required to take the following additional training:

- "Animal Awareness Seminar" (online).
- Health Risk Assessment Form for the UF EHS Animal Contact Program.
- "Working with the UF IACUC" (online) with a passing of 85% and re-examination every three years.

Trainees who working with mouse breeding colonies, outside of Animal Care Services, must take and pass "Mouse Breeding Colony Management". All individuals breeding genetically engineered mice, outside of Animal Care Services, are required to take "Genetically Engineered Mice: Approaches for Evaluating the Phenotype" AND "Genetically Engineered Mice: Overview of Transgenesis and Conditional Control".