

Plan for Instruction in the Responsible Conduct of Research

The NIH has stringent guidelines for training in the Responsible Conduct of Research (RCR) and the UF (name of training program) program give these the highest priority. Analysis of findings of misconduct by the Office of Research Integrity (ORI) reveals that about half of all findings are due to misconduct by trainees. We have taken many steps to ensure that our program will proactively provide training and supervision needed to avoid such unfortunate losses to the research enterprise, and build RCR and research ethics into our culture of research training involving trainees and mentors throughout the training period. Collaborating faculty have a strong commitment to RCR education and track record for best practices in research, including ... [examples in other proposals include the development of the Mentor Academy (Fillingim), NIH T32 and Career Development RCR guidelines (Cottler), and a novel team-based learning (TBL) curriculum for didactic RCR training (McCormack, see below for details)]. The UF Mentor Academy is designed to provide training to mentors in how to optimize the mentor-mentee relationship and promote the highest integrity in research. All mentors are encouraged to participate in the MA in order to become optimal RCR role models.

Format. We are committed to providing excellent, multimodal RCR training to all trainees. RCR instruction will emphasize: (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. Excellence in RCR training will be accomplished for all trainees through the following mechanisms.

Didactic Instruction

Online Training: UF requires HIPAA training annually (“HIPAA & Privacy – Research”). In addition, the online courses “IRB01 Mandatory Local Training” and “Animal Awareness Seminar” will be required of all trainees. Based on relevance to individual trainees’ research and roles, additional online training is available for “Human Subject Payments,” “Administrators and RCR,” “CTSI Informed Consent Training,” “PI Responsibility for Informed Consent,” “Study Coordinator Roles in Research,” “Financial Conflict of Interest,” “Billing for Device Studies,” “FERPA Basics,” and “FERPA for Faculty.”

Required reading for all trainees and mentors available online includes 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.

Novel Team-Based Learning RCR Curriculum. Typical research ethics or responsible conduct of research (RCR) training methods may not provide adequate training in ethical decision-making (EDM) according to recent research in the field. Dr. McCormack has led an educational research project funded by the Office of Research Integrity showing that team-based learning (TBL) provides the necessary student engagement to have a more positive impact on EDM than traditional lecture, online, and/or small group teaching methods. TBL uses individual work, group work, and immediate feedback to motivate students to hold each other accountable for coming to class prepared, actively engaging in discussion, and focusing on the application of course concepts. The TBL RCR curriculum has incorporated the “So Far No Objections” (SFNO) moral method of decision-making to provide both a clear framework within which to assess ethical dilemmas and concrete steps to guide learners in resolving them. This TBL RCR curriculum has less negative impact on ethical decision-making than traditional RCR training, and students make more ethical decisions related to data management. Pre/post-test gains were observed in five of seven meta-cognitive reasoning strategies, suggesting that TBL instruction supports students’ abilities to recognize circumstances, question judgment, manage emotions, anticipate consequences, and analyze personal motivations. Social & behavioral responses after TBL than traditional RCR training, and students’ decisions reflect less retaliation, avoidance of responsibility, and selfishness. TBL provides continual feedback about both student performance in terms of knowledge acquisition and strategies involved in ethical decision-making. Improved learner engagement and satisfaction with RCR and ethics training may help future researchers overcome the notion that such training is simply a requirement that must be endured, and help support the development of a culture of ethics and research

integrity.

The TBL curriculum is implemented in “Responsible Conduct of Biomedical Research” (GMS 7877, 1 credit, 21 contact hours), a required course in the TL1 curriculum. K Scholars may audit this course to certify their RCR training. 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. Ten 2-hour sessions include ethical decision-making, defining research misconduct, human subjects, animal welfare, conflicts of interest & commitment, data management, mentor-trainee relationships, collaboration & team science, authorship & publication, and peer review. Each session entails assigned pre-readings, individual and team readiness assurance tests, and application exercises in which teams will apply the SFNO moral method of decision-making to research scenarios (most involving research trainees) that pose real-life ethical dilemmas. Learners will make decisions via intra-team and inter-team discussions.

The following faculty have recently served as discussion facilitators:

Wayne T. McCormack, PhD, Professor, Pathology, Immunology & Laboratory Medicine, College of Medicine; TL1 Director

William L. Allen, JD, MDiv, Associate Professor, Family Health & Community Medicine; Program in Bioethics, Law and Medical Professionalism; UF Health Shands Hospital Ethics Consult Service

Michael Katovich, PhD, Professor Emeritus, Pharmacodynamics, College of Pharmacy; IACUC Chair

Catherine W. Striley, PhD, MSW, ACSW, MPE, Research Associate Professor, Epidemiology, Colleges of Public Health & Health Professions and Medicine

Michael Scian, MBA, JD, Assistant Director of Compliance, UF Office of Research

Roger Fillingim, PhD, Professor, Community Dentistry, College of Dentistry; Director, Mentor Academy

Bruce Goldberger, PhD, Professor, Pathology, Immunology & Laboratory Medicine, College of Medicine; Editor-in-Chief, Journal of Analytical Toxicology

Ann Progulsk-Fox, PhD, Professor, Oral Biology, College of Dentistry

Charles Wood, PhD, Professor & Chair, Physiology & Functional Genomics, College of Medicine

Ammon B. Peck, PhD, Assoc Dean of Research & Graduate Studies, Past IRB Co-Chair

Gary D. Wimsett, Jr, JD, Director of Compliance and Conflicts of Interest, UF Office of Research

Colin Sumners, PhD, Professor, Physiology & Functional Genomics, College of Medicine

(Note: other courses that meet all NIH RCR training guidelines may be substituted for GMS 7877)

New Graduate Course. “Ensuring Rigor and Reproducibility in Clinical and Translational Research” is a new graduate course (1 credit hour) piloted in Summer 2018. It is taught in an online synchronous format by Matthew J. Gurka, PhD, Professor, and François Modave, PhD, Associate Professor, Health Outcomes & Biomedical Informatics, College of Medicine. The course introduces the principles and practices required to conduct rigorous and reproducible research across the translational spectrum. Students learn best practices, including 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.

Additional Graduate Courses. “Ethical and Policy Issues in Clinical Research” (GMS 6931, 2 credits) is directed by Dr. Bill Allen, Program in Bioethics, Law and Medical Professionalism, and 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. “Ethics in Genetics” (GMS6221, 1 credit), is taught by Dr. Bill Allen, Program in Bioethics, Law and Medical Professionalism, an expert in ethical issues in genetics. This course focuses on presentation and critical discussion of relevant topics pertaining to ethics, science policy, and translation in genetics research. “Ethics in Population Science” (PHC 7427, 2 credits) is taught by Dr. Catherine Woodstock Striley, Dept. of Epidemiology. Designed for students enrolled in research intensive graduate programs, the course combines didactics with case studies and web-based teaching tools to cover federally mandated RCR topics: 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. A “Current Topics in Research Ethics” refresher

course will be available for trainees remaining for more than four years in a single stage of training, e.g., 5th year PhD students. Discussion topics will include relevant current local and national events, recent ORI research misconduct findings, and the collaborative development of new real-life research scenarios for courses and workshops by trainee teams.

SEMINARS AND SMALL GROUP MEETINGS

Mentoring. Trainees meet on a regular basis with their mentors. A compilation of RCR discussion topics for lab meetings will be provided to all mentors. Trainees are also required to have regular mentoring team meetings to review progress and set goals. RCR issues are to be reviewed and documented in these meetings.

ORI Casebook Discussions. Mentors will be charged with conducting small group discussions with trainees in informal and/or semi-formal settings such as lab meetings, using case scenarios from “The ORI Casebook: Stories about Researchers Worth Discussing” (downloadable from the DHHS Office of Research Integrity website) to prompt discussion. The Casebook provides case studies, role plays, and reflection questions relevant to all RCR training topics, which are based on real-life challenging situations encountered in the research setting. Trainees are thus provided with continued ways of being engaged in face-to-face discussion and debate after more formal didactic training. An accompanying Casebook Instructors’ Manual is available as a reference for mentors who wish to review pedagogical reflections and logistic tips from research ethics experts, which may help them to use the Casebook most effectively to guide trainees in RCR best practices.

EXPERIENTIAL TRAINING

IRB & IACUC Protocols. In the development of their research projects, trainees will either submit their own protocols during the course of their training and/or assist with submission of a mentor’s protocol if they are listed among the project key personnel, providing another opportunity to learn more about protection of human and non-human research participants. As part of this experience, trainees will attend relevant IRB/IACUC meetings at which these research protocols are being reviewed, in order to better understand the IRB & IACUC review processes.

Faculty Participation. Faculty members are specifically involved as instructors/leaders of the formal classes, seminars, and workshops. Most importantly, faculty members serve as mentors and mentoring team members during the ad-hoc one-on-one mentoring components of the research training, and will be specifically charged with conducting continual periodic discussion in informal/semi-formal settings such as lab meetings using the ORI Casebook, as described above. Continual RCR training will therefore occur through faculty/student discussions.

Duration of Instruction. Online coursework consists of approximately 2-3 hours annually. The formal coursework (GMS 7877) involves 21 contact hours. RCR topics will be included in at least four contact hours during journal clubs and seminars. RCR certification via postdoc and faculty workshops will entail 15 contact hours. Additional instruction will be ongoing. Mentoring meetings will entail at least 3-4 contact hours annually, plus much more, undocumented, in weekly sessions with the primary mentor and/or other mentoring team members.

Frequency of Instruction. Instruction is ongoing. Formal courses are intensive semester-long courses which will be taken early in training. Additional discussions intended to inculcate a culture of RCR and research ethics will be ongoing, including lab meetings, ORI Casebook discussions, informal and formal mentoring meetings, journal clubs and seminars.