GMS 7877: Responsible Conduct of Biomedical Research Tuesdays, 3:30-5:30 pm, Learning Studio 125 Harrell Medical Education Building

Date	Session	Instructors
Jan 9	Intro to RCR & Team-Based Learning	Wayne T. McCormack, PhD
Jan 16	1 - Intro to Ethical Decision-Making	William L. Allen, JD, MDiv & WTM
Jan 23	2 - Avoiding Research Misconduct	William L. Allen, JD, MDiv & WTM
Jan 30	3 - Welfare of Laboratory Animals	Kerri O'Malley, PhD & WTM
Feb 6	4 - Protection of Human Subjects	Catherine Striley, PhD, MSW & WTM
Feb 13	5 - Conflicts of Interest & Commitment	Amber Moore, MPA, Lana Kaufman, JD, MEd & WTM
Feb 20	6 - Data Management Practices	William L. Allen, JD, MDiv & WTM
Feb 27	7 - Rigor & Reproducibility	Malu Tansey, PhD & WTM
Mar 5	8 - Collaborative Research	Catherine Striley, PhD, MSW & WTM
Mar 12	No Class – Spring Break	
Mar 19	9 - Safe Research Environments	Malu Tansey, PhD & WTM
Mar 26	10 - Mentor & Trainee Responsibilities	Roger Fillingim, PhD & WTM
Apr 2	No Class	
Apr 9	11 - Authorship & Publication	Timothy Garrett, PhD & WTM
Apr 16	12 - Peer Review	Timothy Garrett, PhD & WTM

Course Director: Wayne T. McCormack, PhD, mccormac@ufl.edu, office phone 352-294-8334, room CG-72K

This course is offered **in-person only**, and is intended for COM Biomedical Sciences PhD students and MD-PhD students. This course is also open to other graduate students, postdoctoral fellows and junior faculty members who must complete RCR training to fulfill fellowship or training grant requirements. The course is designed to introduce key issues in the responsible conduct of research (RCR), following the research process from inception to planning, conducting, reporting, and reviewing biomedical research. The course seeks to provide 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 other setting where researchers gather to discuss their work. Please contact Dr. McCormack for more information.

Attendance: Unexcused absences will lower your grade as described below. If you will miss any sessions due to professional travel or illness, please contact Dr. McCormack and see below for instructions about a make-up assignment. **You must arrive on time!** The first in class activity is a graded individual readiness assurance test.

Preparation Materials: Each session will include pre-class preparation assignments, which will be detailed in Canvas. These assignments will typically consist of readings from an online textbook and other sources, and PowerPoint presentations and/or videotaped lectures, all of which will be posted in Canvas. The textbook "ORI Introduction to the Responsible Conduct of Research" by Nicholas H. Steneck (Department of Health & Human Services) features case studies, text-box inserts, discussion questions, and electronic and printed resources.

Grading: Letter grade (90, A; 85, A-; 80, B+; 75, B; 70, B-; 65, C+; 60, C; 55, C-; 50, D). On a 100 point scale, grading for students registered for credit will be based on both individual and team assessments during team-based learning sessions (90 points total; relative weighting to be determined by student vote) and completion of the

ethical decision-making pre-test and post-test (5 points each). Unexcused absences will result in a score of 0 and will lower your grade (see Make-Up Assignments below).

Academic Honesty: Please do not seek material from students from previous years for this course. Doing so constitutes academic dishonesty, and will result in automatic failure for this course.

Reading Assignments: Please read the assigned chapters and view the on-line lectures before each session. Each team-based learning (TBL) session begins with a quiz (readiness assurance test) about the reading material content, which you will take individually and counts toward your grade. Assigned readings associated with each seminar include case scenarios and discussion questions dealing with the relevant ethical issues. Please think about how you would answer these questions before each team-based learning session, as your team will be discussing similar scenarios in some detail.

Preparation for Team-Based Learning Sessions: Small groups will be set up using the team-based learning format. Team assignments will be posted on the door, and you will work with the same team for the duration of the course. Your assignments before each team-based learning session are to:

- 1. view the relevant PowerPoint and/or videotaped lecture (links at course web site)
- 2. read the assigned chapter of "ORI Introduction to the Responsible Conduct of Research" (links above and at course web site)
- 3. familiarize yourself with the main points of the assigned chapter, and
- 4. think about how you would answer the case study and discussion questions in the assigned chapter. Session schedule:
 - 3:30 Arrive and login to Canvas
 - 3:35 Individual Readiness Assurance Test (Canvas)
 - 3:50 Team Readiness Assurance Test
 - 4:05 Intra-Team Application Exercise Team discussion of case studies and questions
 - 4:45 Inter-Team Class Discussion of Case Studies
 - 5:30 Adjourn

Readiness Assurance Tests will consist of up to multiple-choice questions based on the assigned reading and seminar content (closed book). Individual Readiness Assurance Tests must be completed individually, and answers will be recorded electronically (clickers will be provided). Team Readiness Assurance Tests will consist of the same questions as the Individual Readiness Assurance Test, and team answers will be recorded on scratch-off cards that will be provided.

Make-Up Assignments: If you miss a session due to illness or professional travel, please contact me as soon as possible (preferably in advance for travel). Please submit via e-mail, preferably in advance of your trip or within a week if absent due to illness, brief written answers to each of the discussion questions and case study questions in the assigned chapter for reading. Links to the case studies are in the right margin of the introduction page for each chapter (labeled either "Short Case" or "Case Study"). Discussion questions may be found at the "Questions" link in the left margin. I don't expect you to write extensively on each question, but enough to demonstrate that you have read the material and have thought about the issues in the context of responsible conduct of research.

Accommodations for Students with Disabilities: Students with disabilities requesting accommodations should first register with the Disability Resource Center (352-392-8565, https://disability.ufl.edu) by providing appropriate documentation. Once registered, students will receive an accommodation letter which must be presented to the instructor when requesting accommodations. Students with disabilities should follow this procedure as early as possible in the semester.

Counseling and Student Health: Students may occasionally have personal issues that arise in the course of pursuing higher education or that may interfere with their academic performance. If you find yourself facing problems affecting your coursework, you are encouraged to talk with an instructor and to seek confidential assistance at the UF Counseling & Wellness Center, 352-392-1575, http://www.counseling.ufl.edu (see also link therein for Emergency Assistance). Crisis intervention is always available 24/7 from the Alachua County Crisis Center at (352) 264-6789. Do not wait until you reach a crisis to come in and talk with us. We have helped many

students through stressful situations impacting their academic performance. You are not alone, so do not be afraid to ask for assistance.

Course Evaluation: Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at https://gatorevals.aa.ufl.edu/students/. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via https://ufl.bluera.com/ufl/. Summaries of course evaluation results are available to students at https://gatorevals.aa.ufl.edu/public-results/.