GMS 7003 – Responsible Conduct of Biomedical Research

Spring 2017 – This course meets on Tuesdays at 3:30-5:30 pm in room LG-110AB.

Tentative Schedule:

- Jan 10 – Intro to RCR & Team-Based Learning
- Jan 17 – Intro to Ethical Decision-Making
- Jan 24 – Research Misconduct
- Jan 31 – Welfare of Laboratory Animals
- Feb 7 – Protection of Human Subjects
- Feb 14 – Conflicts of Interest & Commitment
- Feb 21 – Data Management Practices
- Feb 28 – No class
- Mar 7 – No class – UF Spring Break
- Mar 14 – Mentor & Trainee Responsibilities
- Mar 21 – Collaborative Research
- Mar 28 – Authorship
- Apr 4 – Peer Review
- Apr 11 – No class
- Apr 18 – No class

Course Director: Wayne T. McCormack, PhD  (e-mail mccormac@ufl.edu; phone 294-8334; office CG-72K)

This course is required for all COM BMS doctoral students. It 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.

This course is open to graduate students in other graduate programs, and postdoctoral fellows and junior faculty members who must complete RCR training to fulfill fellowship or training grant requirements are also welcome to participate. 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.

Textbook: 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. The text is available on-line (Table of Contents), but please note that some sections are out-of-date due to changes in government regulations. For the most up-to-date information for this course, please use only the links provided in the Resources section of the course eLearning site.

Lectures: PowerPoint presentations and/or videotaped lectures are available on-line at the course eLearning site. Log in using your Gatorlink username and password. Click on “Documents” to see folders for each session. Click on the folder to see contents (arrow head will point down).

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 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 eLearning web site)
2. read the assigned chapter of “ORI Introduction to the Responsible Conduct of Research” (use links at the course eLearning 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 – Individual Readiness Assurance Test
3:45 – Team Readiness Assurance Test
4:00 – Team Application Exercise – Team discussion of case studies and questions, followed by class discussion
5:30 – Adjourn
Readiness Assurance Tests will consist of 10 multiple-choice questions based on the assigned reading and seminar content (closed book). Individual Readiness Assurance Tests will be completed individually, and answers will be collected using an audience response system with assigned “clickers” that 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 TWO sets of question in the assigned reading chapter: (1) the case study questions; and (2) the discussion questions at the end of the chapter. Links to the case studies are in the right margin of the introduction page for each chapter (labeled either “Short Case” or “Case Study”), under the cartoon. 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.

**Acknowledgements:** Some course materials used in the TBL sessions are adapted from the following sources.


Online Research Ethics Course, Practical Ethics Center, University of Montana. [http://ori.dhhs.gov/education/products/montana_round1/research_ethics.html](http://ori.dhhs.gov/education/products/montana_round1/research_ethics.html)

Online Ethics Center for Engineering and Science, Case Western Reserve University. [http://onlineethics.org](http://onlineethics.org)