5. PLAN FOR INSTRUCTION IN THE RESPONSIBLE CONDUCT OF RESEARCH

OPTION 1 – RCR COURSE CONDUCTED BY COM

Course Director: Wayne McCormack, Ph. D

Informal and formal methods are necessary for effective training in the responsible conduct of research. The example set by the trainee’s mentor is the one most emulated by students and post-docs when they start their own independent careers. Hence, to supplement the formal course work, there will be frequent discussions between the mentor and trainee dealing with specific issues such as conflict of interest, data recording and retention, authorship, professional standards, and codes of conduct.

Along with the informal training, a graduate course entitled “Responsible Conduct of Biomedical Research” (GMS 7003) will be required. This course is offered each spring semester and all first year pre-doctoral and first year post-doctoral trainees take the course. The course provides a practical overview of the rules, regulations, and professional practices that define the responsible conduct of research, and emphasizes case-based discussions in a team setting. As with any formal course, 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.

1. Course Format: The “Responsible Conduct of Biomedical Research” course is directed by Wayne T. McCormack, PhD, director for the UF Clinical & Translational Sciences predoctoral training program and former Associate Dean for Graduate Education (current syllabus available online at http://oge.med.ufl.edu/RCR/). The course was created in 2004 in response to student dissatisfaction with another required lecture-based course, and has evolved into its current format in which 90% of the instructional time is devoted to team-based, active learning activities.

The course begins with a pre-test and concludes with a post-test of ethical decision-making skills, the results of which are coded to maintain student anonymity to the course director, and have no impact on grading. This test is being used both as a research tool in an IRB-approved research study to assess the effectiveness of this RCR training method, and as a learning tool in order to: (1) increase student awareness of the complexity of situations that arise in biomedical research; (2) provide students with an opportunity to apply what they have learned in the course; and (3) provide students with a confidential self-assessment of their decision-making skills.

The first instructional session is a lecture delivered by the course director, which introduces learners to RCR training, research misconduct, the roles of scientists as responsible members of society, and the environmental and societal impacts of scientific research. The lecture also introduces learners to team-based learning™ (TBL, http://www.tblcollaborative.org/), which is used in all subsequent class sessions. TBL is a special form of student-centered learning that 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 application of course concepts. TBL combines the interactivity of small-group collaborative learning with the efficiency of large group teaching, and gives learners experience in working with the uncertainty of complex problems, such as ethical issues encountered in the research environment. The TBL approach also provides advantages of teaching team skills to learners from different ethnic and cultural backgrounds, and is adaptable to learners at different levels, including undergraduate, graduate, postdoctoral, and faculty.

The three phases of TBL are preparation, readiness assurance, and application. In the preparation phase learners must assimilate knowledge outside of class, before each TBL.
session. This course thus requires self-learning, which includes assigned readings from the free on-line textbook "ORI Introduction to the Responsible Conduct of Research" by Nicholas H. Steneck, and videotaped lectures or voice-over PowerPoint presentations posted for students on-line via our course management system. Whenever possible, the faculty members who will be facilitating the TBL sessions have also prepared these lectures. The first in-class activity of each TBL session is the readiness assurance test (RAT) taken by students first individually to hold them accountable for learning, and then within teams, to promote cooperative learning and team-building. RATs consist of ten multiple-choice questions about rules, regulations, and ethical principles relevant to each module, based on the reading assignments and lecture material. Answers are recorded using Scantron forms for the individual RAT and using Immediate Feedback Assessment Technique (IF-AT) “scratch-off” cards (www.epsteineducation.com/home/about/) for the team RAT. The most important part of TBL is the group application exercises, designed to promote deep thinking and content-focused discussion on ethical dilemmas. Key TBL principles followed in the development of these case-based discussions include the use of “4 S’s”: significant problems based on real-life scenarios; having all groups work on the same problems; asking teams to make specific choices in response to very specific questions; and simultaneous reporting from all teams during the class discussion. Within each TBL module students cycle through engaging with course content via self-learning, by working within their team, and working across teams (i.e., whole class), allowing them to learn from each other and develop confidence in their ability to discuss complex issues and work in groups.

2. Course Subject Matter: All topics recommended by NIH notice NOT-OD-10-019 are included in the course.

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<tr>
<th>NIH Topic</th>
<th>Text Chapter</th>
<th>Course Content</th>
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<tbody>
<tr>
<td>i. the scientist as a responsible member of society, contemporary ethical issues in biomedical research, environmental and societal impacts of scientific research</td>
<td>1</td>
<td>Introduction to RCR, Ethical Decision-Making, &amp; TBL (Lecture)</td>
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<tr>
<td>g. research misconduct and policies for handling misconduct</td>
<td>2</td>
<td>Research Misconduct (TBL)</td>
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<td>b. policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices</td>
<td>3</td>
<td>Protection of Human Subjects (TBL)</td>
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<td>f. data acquisition and laboratory tools; management, sharing and ownership</td>
<td>5</td>
<td>Data Management Practices (TBL)</td>
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<tr>
<td>a. conflict of interest – personal, professional, and financial</td>
<td>6</td>
<td>Conflict of Interest (TBL)</td>
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<tr>
<td>c. mentor/mentee responsibilities and relationships</td>
<td>7</td>
<td>Mentor &amp; Trainee Responsibilities (TBL)</td>
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<tr>
<td>d. collaborative research including collaborations with industry</td>
<td>8</td>
<td>Collaborative Research (TBL)</td>
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<tr>
<td>h. responsible authorship and publication</td>
<td>9</td>
<td>Authorship &amp; Publication (TBL)</td>
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<tr>
<td>e. peer review</td>
<td>10</td>
<td>Peer Review (TBL)</td>
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3. Faculty Participation: Training faculty and sponsors/mentors are highly encouraged to contribute both to formal and informal instruction in responsible conduct of research. Informal instruction occurs in the course of laboratory interactions and in other informal situations
throughout the year. The following faculty members are currently involved in teaching the formal RCR course.

Wayne T. McCormack, PhD  
Director, Clinical & Translational Sciences Program  
Former Associate Dean for Graduate Education  
Associate Professor, Pathology, Immunology & Lab. Medicine

William L. Allen, JD, MDiv  
Director, Program in Bioethics, Law and Medical Professionalism  
Associate Professor, Community Health & Family Medicine

William Buhi, PhD  
Chair, UF Institutional Animal Care & Use Committee (IACUC)  
Professor Emeritus, Obstetrics and Gynecology

Ammon B. Peck, PhD  
Former Co-Chair, UF Institutional Review Board (IRB)  
Professor, Pathology, Immunology & Laboratory Medicine

Colin Sumners, PhD  
Former Associate Dean for Graduate Education  
Professor, Physiology & Functional Genomics

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

4. Duration of Instruction: The “Responsible Conduct of Biomedical Research” course meets weekly for twelve weeks as a semester-long course, and entails 2 hours of pre- and post-testing plus 2 contact hours of lecture and 18 contact hours of team-based learning activities.

5. Frequency of Instruction: The “Responsible Conduct of Biomedical Research” course is required for all first-year students in the College of Medicine Interdisciplinary Program in Biomedical Sciences, and is available to all UF graduate students, meeting the NIH recommendation that initial instruction during predoctoral training occurs as early as possible in graduate school. The course is also available to postdoctoral fellows and junior faculty supported by training grants, fellowships, or career development awards. Trainees supported by this training grant who have not already taken this course during their current stage of training will be required to do so. In order to meet the frequency of training requirement of no less than once every four years, a “refresher” course is under development for trainees who do not complete doctoral studies within four years of taking this course.

Additional training:
For Research Involving Human Subjects:
- NIH or CITI certification in Research/Good Clinical Practice
- 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.

For Research Involving Laboratory Animals:
- IACUC “Animal Awareness Seminar” (attended by IDP students as part of the course “Essentials of Graduate Research and Professional Development”, GMS 6003).
Before trainees are permitted to have animal contact, they will be required to complete:
- Health Risk Assessment Form for the EHS Animal Contact Program at the UF.
- Online course “Working with the UF IACUC” 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".

OPTION 2 – RCR COURSE CONDUCTED BY CVM
Course Director: Maureen Long, Ph.D

Informal and formal methods are necessary for effective training in the responsible conduct of research. The example set by the trainee’s mentor is the one most emulated by students and post-docs when they start their own independent careers. Hence, to supplement the formal course work, there will be frequent discussions between the mentor and trainee dealing with specific issues such as conflict of interest, data recording and retention, authorship, professional standards, and codes of conduct.

Along with the informal training, a graduate course entitled “Issues in the Responsible Conduct of Research” (VME 6767) will be required. This course is offered each spring semester and is open to all UF graduate students and post-doctoral fellows.

1. **Course Format**: The course syllabus is based on the recommendations of National Institutes of Health and the National Science Foundation. Course subject matter covers scientific misconduct, safety, data management and bias, human and animal subjects, conflicts of interest, professionalism and peer review. Consistent with the recommendations, the course is a combination of lecture, discussion, case study and group exercises. Attendance is required.

2. **Course Subject Matter**

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<tr>
<th>Lecture #</th>
<th>Subject</th>
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<tr>
<td>1</td>
<td>Introduction, Class Organization &amp; Case Study</td>
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<td>2</td>
<td>Scientific Misconduct Exercise in Class</td>
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<td>3</td>
<td>Scientific Misconduct</td>
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<td>4</td>
<td>Scientific Misconduct On-Data Mismanagement-Figures</td>
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<td>5</td>
<td>Data Management and Mismanagement</td>
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<td>6</td>
<td>Plagiarism: Plagiarism Assignment</td>
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<td>7</td>
<td>The Ethics of Experimental Subjects: Animals</td>
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<td>8</td>
<td>The Ethics of Experimental Subjects: Human</td>
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<td>9</td>
<td>Conflict of Interest</td>
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<td>10</td>
<td>Case Studies I</td>
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<td>11</td>
<td>Peer Review of Grants and Publications</td>
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<td>12</td>
<td>Case Studies II</td>
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<td>13</td>
<td>Conflicts and Professionalism</td>
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<td>Group Exercise: Role Playing</td>
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<td>15</td>
<td>Group Presentations</td>
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3. Faculty Participation: The course is directed by Dr. Maureen Long, DVM, Ph.D, from the Department of Infectious Diseases and Pathology in the College of Veterinary Medicine.

4. Duration of Instruction: The “Issues in the Responsible Conduct of Research” course meets weekly for fifteen weeks as a semester-long course.

5. Frequency of Instruction: The “Issues in the Responsible Conduct of Research” is available to all UF graduate students, and has been attended by students in multiple disciplines including Public Health, students in the Pharm D program and Rehabilitation Sciences. The course is also available to postdoctoral fellows and junior faculty supported by training grants, fellowships, or career development awards. A number of the students participating in the course are involved in human clinical trials.

Additional training:
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