

Advanced Responsible Conduct of Research for Biomedical Graduate Students

OBGYN 956

Spring 2018

I. Course Information

Instructor Information

Primary Course Instructor: Ian M. Bird, PhD

Office: 7 E. Meriter Hospital, 202 S. Park St, Madison, WI 53715

Office Telephone: 608-417-6252 (use only if an emergency)

E-mail: imbird@wisc.edu (Contact by Email first)

Course Administration

Course Administrator: Shelley Maxted

Office: 1010 McArdle Building, 1400 University Ave; Madison, WI 53706

Office Telephone: 608-263-4825

E-mail: maxted@wisc.edu

Course Time and Location:

Day: Tuesdays **Class Time:** 8:30 a.m. – 10:00 a.m.

Location: Temin Room, McArdle Building, 1400 University Ave.

Course Description

Meets the NIH Institutional Training Grant requirements of instruction in the nine recommended areas of:

- A. Conflict of interest - personal, professional, and financial
- B. Policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- C. Mentor/mentee responsibilities and relationships
- D. Collaborative research including collaborations with industry
- E. Peer review
- F. Data acquisition and laboratory tools; management, sharing and ownership
- G. Research misconduct and policies for handling misconduct
- H. Responsible authorship and publication
- H/I. Rigor & Reproducibility
- I. The scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research for PHD graduate students in the Biological Sciences.

Weekly lectures will be followed by small group discussion of reading assignments of case

studies. Invited guest speakers and faculty will be the primary source of instruction for the first hour of the course.

This course is NOT a repetition of OBGYN 955. This course is designed to provide advanced consideration of these responsible conduct of research topics, and to teach students how to implement and employ best practices in relation to these topics.

Prerequisites

- Completion of a graduate-level basic responsible conduct of research course (OBGYN 955; Pharmacy 800; Nursing 802; Surgical Sciences 812; or Bacteriology 901)

Textbook & Course Materials

Required Text

- *Scientific Integrity*, 3rd Edition. Francis Macrina ISBN:1-55581-318-6
(This book will be loaned to enrolled students for use during the semester)
- *Making the Right Moves: A Practical Guide to Scientific Management for Post-docs and New Faculty*, Howard Hughes Medical Institute. Download the book at:
<http://www.hhmi.org/sites/default/files/Educational%20Materials/Lab%20Management/Making%20the%20Right%20Moves/moves2.pdf>

Recommended Texts & Other Readings

- *On Being a Scientist: A Guide to Responsible Conduct in Research*, 3rd Edition, National Academy of Science. ISBN-10: 0-309-119701-7
- *At the Helm: A Laboratory Navigator*, 2nd Edition, Baker, Kathy, Cold Spring Harbor Press. ISBN: 0879698667
- Other readings will be made available in the MY UW Course site or distributed in class.

Course Structure

The first portion of class will be lecture format on the topic listed in the syllabus by either the instructor indicated or an appropriate invited speaker. The second 45 minutes of class will focus on a discussion of case studies and application of ideas and concepts from the lecture.

II. Course Goals

This course is designed to facilitate the acquisition of knowledge through a sequence of lectures and group discussion on the nine recommended topics in Responsible Conduct of Research established by the National Institutes of Health. Specific course goals are:

1. To provide more advanced career stage-appropriate training in the responsible conduct of biomedical research as Trainees consider Grant Applications
2. To review important concepts and methods of ensuring responsible conduct, and now extend this to include common practices in proposing and reporting responsible conduct in biomedical research

3. Exercises and discussions will be used to assess progress in one's knowledge and understanding of the responsible conduct of biomedical research

III. Student Learning Goals

1. Be knowledgeable of the ethics and philosophies that shape our understandings of the responsible conduct of biomedical research
2. Understand and utilize some best practices in the responsible conduct of biomedical research
3. Be aware of mechanisms and processes available to UW-Madison graduate students to help ensure the practice of the responsible conduct of biomedical research
4. Obtain a more comprehensive understanding of the responsibilities, requirements, monitoring, and reassurances involved in successful contemporary biomedical scientific research and how they are used in planning for or applying for grant support, as well as in reporting the progress made in grant-funded studies

IV. LECTURES

(Discussants at each lecture will be program trainers, in addition to the named presenter)

A. Conflict of Interest

Required Reading: Macrina, Chapter 7

Possible Lecturer: Representatives from WARF

- 1) Refresher: What is conflict of interest
- 2) Advanced Consideration
 - a. Outside Activity Reports
 - b. Clinical trials and participation
 - c. Advising conflicts (industry policies, university policies)
 - d. Employment

Assignment: Review the policies and resources available on UW-Madison's OVCERGE website for Conflict of Interest and Outside Activities Reports

B (1). Human Subjects & Institutional Review Boards (ARROW System)

Required Reading: Macrina, Chapter 5

Possible Lecturer: Offices of IRB or ARROW

- 1) Refresher: Ethics of human subjects research
- 2) Advanced Consideration
 - a. Approval of IRB protocols

- b. How to write protocols and grant sections
- c. Safety monitoring
- d. HIPAA and patient privacy in clinical research
- e. ClinicalTrials.gov and reporting of clinical trials

Assignment: Review your lab's IRB protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research

B (2). Animal Research (RARC) Biosafety (IACUC)

Required Reading: Macrina, Chapter 6

Possible Lecturer: Office of RARC

- 1) Refresher: Animal research
- 2) Advanced Consideration
 - a. Approval of IACUC protocols
 - i. How to write protocols and grant sections
 - ii. Veterinarian involvement
 - b. Show protocols on-line

Assignment: Review your lab's IACUC protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research

B (3). Biosafety (IACUC)

Possible Lecturer: Office of Biosafety

- 1) Refresher: Biosafety policies
- 2) Advanced Consideration
 - a. Approval of Biosafety protocols
 - i. Approvals & Assessments
 - ii. How to formulate and evaluate risks and protections
 - iii. How to write protocols
 - b. Show protocols on-line

Assignment: Review your lab's biosafety protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research

C. Mentor-Mentee Relationships (Focus on the *mentor*)

Required Reading: Macrina, Chapter 3; HHMI, Chapter 5

Possible Lecturer: Experienced mentor or someone from CIMER

- 1) Refresher: Mentor-mentee relationships
- 2) Advanced Consideration of comparison of qualities of mentor/mentee roles and responsibilities
 - a. Boss / Spouse / Friend / Employee exercise
 - b. Qualities of boss-employee vs mentor-friend

- c. How to mentor those in different career stages

D. Collaborative Research

Required Reading: Macrina, Chapter 8; HHMI, Chapters 11 and 12

Possible Lecturer: Experienced Faculty Member or Representative from Office of Industry Partnerships

- 1) Refresher: Collaborative research
- 2) Advanced Consideration
 - a. How does everything fit together
 - b. Advantages of collaborative research
 - c. Potential pitfalls of collaborative research
 - d. Avoiding pitfalls
 - e. New areas to consider (i.e., mandatory data sharing (NIH))

Assignment: Review your lab's collaborative agreements and contracts; Read the relevant sections in your own grant(s) or the grant(s) funding your research

E. Peer Review

Required Reading: Macrina, Chapter 4

Possible Lecturer: Faculty trainers

- 1) Refresher: Grant and journal review process
- 2) Advanced Consideration
 - a. Grant study sections (NIH and NSF)
 - i. Process
 - ii. Conflicts
 - iii. Scores
 - iv. Section D – Program Officer letter
 - b. Mock study session with sample R03 applications (emphasis on scoring)

Assignment: Review the peer review conflict of interest policies for your funding agency. Shortcuts provided for common biomedical funding agencies.

NIH: <http://grants.nih.gov/grants/peer/reviewer_guidelines.htm>

NSF: <https://www.nsf.gov/pubs/gpg/nsf04_23/appb.jsp>

USDA: <<https://www.ams.usda.gov/sites/default/files/media/FMPPConflictofInterest.pdf>>

EPA: <https://www.epa.gov/sites/production/files/2016-03/documents/epa_peer_review_handbook_4th_edition.pdf>

F. Data Acquisition, Management, Sharing, Ownership

Required Reading: Macrina, Chapter 9; HHMI, Chapter 8

Possible Lecturer: Someone from IT or Program trainers

- 1) Refresher: Data

- 2) Advanced Consideration
 - a. Best practices for data acquisition
 - b. Best practices for data security
 - c. Ensuring rigor and reproducibility
 - d. Responsible use of and practices for public databases
 - e. “Big data” and resources for analysis

Assignment: Review your lab’s data sharing plan(s); Read the relevant sections in your own grant(s) or the grant(s) funding your research

G. Research Misconduct and How to Handle

Required Reading: Macrina, Chapter 1

Possible Lecturer: Senior Faculty or Support offices experienced in handling misconduct

- 1) Refresher: Research misconduct
- 2) Advanced Consideration
 - a. Review of campus safeguards
 - b. “The Lab” simulation, utilizing senior roles and new perspectives

H. Responsible Authorship

Required Reading: Macrina, Chapter 4; HHMI Chapter 10

Possible Lecturer: Faculty Trainers

1. Refresher: Authorship
2. Advanced Consideration
 - a. Thesis and copyright
 - b. Appropriate authorship guidelines
 - c. Traditional Journals vs Direct Publishing/Open Source Journals

H & I. Rigor and Reproducibility

Required Reading: NIH Site <https://grants.nih.gov/reproducibility/index.htm>

Possible Lecturer: Faculty Trainers

1. Refresher: Principles of Rigor and Reproducibility
2. Advanced Consideration
 - a. Addressing Scientific Premise.
 - b. Addressing Scientific Rigor
 - c. Inclusion of sex as a variable
 - d. Validation of Chemicals and Biological Agents- are the reagents what you think they are? Assay specificity?

I. The Scientist & Society

Required Reading: None - Current Affairs and Open Group Discussion

Possible Lecturer: Faculty Trainers

- a. Public perception of research
- b. Causes and consequences of sensationalizing data
- c. Connecting with science and society
- d. Social media interactions
- e. Crowd-funding and direct publishing

Lecture Schedule

<i>Date</i>	<i>Course Topics</i>	<i>Instructor</i>	<i>Discussants</i>	<i>Reading Assignment</i>
2/06/2018	Conflict of Interest	Kurt McMillen, Kurt Zimmerman	Ian Bird	M: Ch. 7
2/13/2018	Mentor/Mentee Relationships	Ian Bird	Amy Trentham Dietz, Will Ricke	M: Ch. 3 HHMI: Ch. 5
2/20/2018	Biosafety	Tara Schnell	Nancy Keller, Ted Golos	
2/27/2018	Vertebrate Animals	Ricki Colman	Nader Sheibani	M: Ch. 6
3/6/2018	Data Acquisition, Management, Sharing, Ownership	Kristen Malecki	Vijay Setaluri	M: Ch. 9 HHMI: Ch. 8
3/13/2018	Human Subjects	Chanel Tyler	Naomi Chesler, Ian Bird	M: Ch. 5
3/20/2018	Scientist and Society	Jo Handelsman	Joan Jorgensen, Ian Bird	M: Ch. 2
3/27/2018	Spring Recess			
4/3/2018	Rigor & Reproducibility	Donata Oertel	Jyoti Watters, Bo Liu	
4/10/2018	Research Misconduct	Brian Fox	Jon Audhya, Jon Matsumura	M: Ch. 1, Ch. 11, Appendix VI
4/17/2018	Authorship & Peer Review	Manish Patankar	Dale Bjorling, Ian Bird	M: Ch. 4
4/24/2018	Collaborative Research	Manish Patankar	Linda Schuler, Bill Murphy	

V. Grading Policy

Graded Course Activities

Points	Description
45 points	Attendance
45 points	Participation
90 points =100%	

Attendance, Participation and Absence Policy

This course is scheduled to meet 1 day per week for 90 minutes each session and weekly attendance will be taken. Topics in this course have the potential to generate and stimulate a robust discussion with many diverse points of view; you the student will benefit from active participation in large and small group discussion as in many situations there are no clear cut answers to the situations in the case studies. On occasion, additional readings are assigned to follow selected topics to help students see regulatory documents and policies in action; these additional readings are estimated to take 60 minutes per assignment.

Class Participation Expectations - Students are expected to have completed the required readings prior to the start of each class to refresh their knowledge on the day's concept. These readings are estimated to take 30 to 60 minutes per class. While participants may be passionate about a particular point of view, discussion is expected to remain respectful of all individuals, levels of experience and area of scientific study.

The following guidelines will be used to assess participation for each class meeting.

Satisfactory: Students regularly provide substantive content that help the class as a whole to (1) consider alternative viewpoints; (2) connect ideas and concepts; (3) explore ways to assess and address ethical issues; and (4) apply course themes to real world practice. Students may provide this content by asking and answering questions, reflecting on case studies, and discussing course themes with classmates.

Unsatisfactory: Students rarely or seldom are able to provide substantive content.

Absences - Students are expected to notify the course coordinator by email at least one week in advance of planned absence. Failure to attend at least seven of the nine class meetings will result in an unsatisfactory grade.

Grade Assignment

This course will be graded as satisfactory / unsatisfactory:

Grade	Equivalent Percentage	Performance
Satisfactory	80 – 100%	Excellent Work, Nearly Excellent Work, and Good Work
Unsatisfactory	0 – 79%	Average Work, Below Average Work, and Failing Work

VI. Course Policies

Understand When You May Drop This Course

It is the student's responsibility to understand when they need to consider withdrawing from a course. Refer to the Registrar's website for dates and deadlines for registration and withdrawal.

Inform Your Instructor of Any Accommodations Needed

If you have a documented disability and verification from the McBurney Center, and wish to discuss academic accommodations, please contact your instructor as soon as possible.

Use of Handheld Devices

All handheld devices including but not limited to iPads, smart phones, laptop computers and tablet devices must be turned off during the first hour of the lecture. Devices may be used during the discussion session provided their use is relevant to the task at hand. The instructor reserves the right to temporarily retrieve electronic devices from students as needed.

Commitment to Integrity

The following text is provided by the Graduate School Academic Guidelines access online 8/12/2015 from the following site: <http://grad.wisc.edu/acadpolicy/> (scroll down for "Misconduct, Academic")

Misconduct, Academic

Graduate students should be aware that the university holds graduate students to a high standard of academic integrity and believes that misconduct may warrant university discipline in addition to sanctions imposed by an instructor. Graduate students who have been found by their instructors to commit academic misconduct can expect that the Division of Student Life will consider whether to impose a further disciplinary sanction of university probation, suspension, or expulsion.

Chapter 14 of the University of Wisconsin Administrative Code defines academic misconduct as follows:

Academic misconduct is an act in which a student:

1. seeks to claim credit for the work or efforts of another without authorization or citation;
2. uses unauthorized materials or fabricated data in any academic exercise;
3. forges or falsifies academic documents or records;
4. intentionally impedes or damages the academic work of others;
5. engages in conduct aimed at making false representation of a student's academic performance; or
6. assists other students in any of these acts. UWS 14.03(1)

Examples of academic misconduct include but are not limited to:

1. cutting and pasting text from the Web without quotation marks or proper citation;
2. paraphrasing from the Web without crediting the source;
3. using notes or a programmable calculator in an exam when such use is not allowed;
4. using another person's ideas, words, or research and presenting it as one's own by not properly crediting the originator;
5. stealing examinations or course materials;
6. changing or creating data in a lab experiment;
7. altering a transcript;
8. signing another person's name to an attendance sheet;
9. hiding a book knowing that another student needs it to prepare for an assignment;
10. collaboration that is contrary to the stated rules of the course; or
11. tampering with a lab experiment or computer program of another student.

The full text of the state statute governing academic misconduct, UWS 14, Student Academic Disciplinary Procedures, as well as the UW-campus procedures for implementing the provisions of UWS 14 and general information about academic misconduct, are available at web location http://www.students.wisc.edu/doso/docs/uws_chapter_14.pdf or from the Division of Student Life, 75 Bascom Hall, (608) 263-5700.