



Advanced Responsible Conduct of Research for Biomedical Graduate Students

OBS&GYN 956

Spring 2023

I. Course Information

Instructor Information

Primary Course Instructor: Ian M. Bird, PhD

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Course Administration

Teaching Assistant: Robbie Manuel

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Course Time and Location

Day: Tuesdays

Class Time: 8:30 a.m. – 10:00 a.m.

Location: TBD

Instructional Mode

In-Person

Credit Information

1 credit

This class meets for one 90-minute class period each week over 11 weeks during the spring semester and carries the expectation that students will work on course learning activities out of the classroom for every class period. The syllabus includes additional information about meeting times and expectations for student work.

Course Description

Follows course OBGYN 955 (for 1st year Graduate Trainees) to meet the NIH Institutional Training Grant requirements of repeat/further instruction in the nine recommended areas (1) conflict of interest - personal, professional, and financial; (2) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices; (3) mentor/mentee responsibilities and relationships; (4) collaborative research including collaborations with industry; (5) peer review; (6) data acquisition and laboratory tools, and management, sharing and ownership; (7)

research misconduct and policies for handling misconduct; (8) responsible authorship and publication; and (9) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research; as well as rigor and reproducibility. OBGYN 955 provides first year biomedical graduate students with an introductory overview of these topics. OBGYN 956 is designed to provide advanced consideration of these topics to our more experienced students, and to illustrate how to *implement* these responsible conduct and ethical considerations into actual grant- and career-related documents. The course format typically includes lectures by invited guest speakers and faculty, followed by small group discussion of reading assignments of case studies.

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 (OBS&GYN 955; Pharmacy 800; Nursing 802; Surgical Sciences 812; or Microbiology 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, and is available as read-only files on the course's Box folder)
- *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 Box 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

- 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
- 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

- Be knowledgeable of the ethics and philosophies that shape our understandings of the responsible conduct of biomedical research
- Understand and utilize some best practices in the responsible conduct of biomedical research
- Be aware of mechanisms and processes available to UW-Madison graduate students to help ensure the practice of the responsible conduct of biomedical research
- 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

Lecture Schedule

<i>Date</i>	<i>Course Topics</i>	<i>Instructor</i>	<i>Reading Assignment</i>	<i>Assignment Due for this Class Meeting</i>
02/07/23	Mentor/Mentee Relationships	Ian Bird	M: Ch. 3 HHMI: Ch. 5	No assignment
02/14/23	Conflict of Interest	Kurt Zimmerman	M: Ch. 7	Review the policies and resources available on UW-Madison's OVCERGE website for Conflict of Interest and Outside Activities Reports
02/21/23	Collaborative Research	Marina Emborg		Review your lab's collaborative agreements and contracts; Read the relevant sections in your own grant(s) or the grant(s) funding your research
02/28/23	Human Subjects	Aleks Stanic	M: Ch. 5	Review your lab's IRB protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research
03/07/23	Biosafety	Tara Schnell		Review your lab's biosafety protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research
03/14/23	SPRING RECESS, No Class			
03/21/23	Vertebrate Animals	Ricki Colman	M: Ch. 6	Review your lab's IACUC protocols; Read the relevant sections in your own grant(s) or the grant(s) funding your research
03/28/23	Research Misconduct	Brian Fox	M: Ch. 1, Ch. 11, Appendix VI	No assignment
04/04/23	Authorship & Peer Review	Manish Patankar	M: Ch. 4	Review the peer review conflict of interest policies for <u>your</u> 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
04/11/23	Rigor & Reproducibility	Ian Bird		No assignment
04/18/23	Data Acquisition, Management, Sharing, Ownership	Amy Schultz	M: Ch. 9 HHMI: Ch. 8	Review your lab's data sharing plan(s); Read the relevant sections in your own grant(s) or the grant(s) funding your research
04/25/23	Scientist and Society	Jo Handelsman	M: Ch. 2	No assignment

IV. Grading Policy

Graded Course Activities

- Grades are based on attendance and participation
- Grades are not curved

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.

Participation - 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 nine of the eleven class meetings will result in an unsatisfactory grade.

Exams, quizzes, papers & other major graded work

There are no quizzes, papers or exams

Homework & other assignments

The homework will be assigned readings prior to class

Discussion sessions

This course has no discussion sessions

Laboratory sessions

This course has no laboratory sessions

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

V. 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.

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. The only exception to this policy is for clinical or other professional emergencies.

Rules, Rights & Responsibilities

See the Guide's [Rules, Rights and Responsibilities](#)

Academic Integrity

By enrolling in this course, each student assumes the responsibilities of an active participant in UW-Madison's community of scholars in which everyone's academic work and behavior are held to the highest academic integrity standards. Academic misconduct compromises the integrity of the university. Cheating, fabrication, plagiarism, unauthorized collaboration, and helping others commit these acts are examples of academic misconduct, which can result in disciplinary action. This includes but is not limited to failure on the assignment/course, disciplinary probation, or suspension. Substantial or repeated cases of misconduct will be forwarded to the Office of Student Conduct & Community Standards for additional review. For more information, refer to studentconduct.wiscweb.wisc.edu/academic-integrity/.

Accommodations for Students with Disabilities

The University of Wisconsin-Madison supports the right of all enrolled students to a full and equal educational opportunity. The Americans with Disabilities Act (ADA), Wisconsin State Statute (36.12), and UW-Madison policy (Faculty Document 1071) require that students with disabilities be reasonably accommodated in instruction and campus life.

Reasonable accommodations for students with disabilities is a shared faculty and student responsibility. Students are expected to inform faculty of their need for instructional accommodations by the end of the third week of the semester, or as soon as possible after a disability has been incurred or recognized. Faculty will work either directly with the student or in coordination with the McBurney Center to identify and provide reasonable instructional accommodations. Disability information, including instructional accommodations as part of a student's educational record, is confidential and protected under FERPA. <http://mcburney.wisc.edu/facstaffother/faculty/syllabus.php>

Diversity & Inclusion

Diversity is a source of strength, creativity, and innovation for UW-Madison. We value the contributions of each person and respect the profound ways their identity, culture, background, experience, status, abilities, and opinion enrich the university community. We commit ourselves to the pursuit of excellence in teaching, research, outreach, and diversity as inextricably linked goals.

The University of Wisconsin-Madison fulfills its public mission by creating a welcoming and inclusive community for people from every background – people who as students, faculty, and staff serve Wisconsin and the world. <https://diversity.wisc.edu/>