

**Responsible Conduct in Biological and Medical Sciences Research
Oncology 715
University of Wisconsin-Madison**

Instructors: Prof. Janet Mertz and Prof. Shigeki Miyamoto
Course Director: Shigeki Miyamoto (smiyamot@wisc.edu; office hours by appointment)
Credits: 1 (by Traditional Carnegie Definition)
Instructional Mode: In-Person
Prerequisites: graduate student standing or above; auditors welcome
When: Thursdays 3:00 p.m. to 5:00 p.m.; first half of the semester
First class meeting: January 26, 2023
Where: WIMR 2 Room 6571

Description: The objective of this course is to teach graduate students, postdoctoral fellows, and medical residents about ethical issues in biological and medical sciences research and how to go about trying to resolve them when they occur. The course is organized around assigned readings/activities and short lectures followed by small group, roundtable discussions of Case Studies in which we consider contemporary ethical issues in biomedical research commonly faced by researchers. All of the topics required by the NIH for Responsible Conduct of Research (RCR) are covered in an integrated manner during the seven 2-hour-long class sessions. These RCR topics include the following:

- (a) conflict of interest – personal, professional, and financial – and conflict of commitment, in allocating time, effort, or other research resources
- (b) policies regarding human subjects, live vertebrate animal subjects in research, and safe laboratory practices
- (c) mentor/mentee responsibilities and relationships
- (d) safe research environments (e.g., those that promote inclusion and are free of sexual, racial, ethnic, disability and other forms of discriminatory harassment)
- (e) collaborative research, including collaborations with industry and investigators and institutions in other countries
- (f) peer review, including the responsibility for maintaining confidentiality and security in peer review
- (g) data acquisition and analysis; laboratory tools (e.g., tools for analyzing data and creating or working with digital images); recordkeeping practices, including methods such as electronic laboratory notebooks
- (h) secure and ethical data use; data confidentiality, management, sharing, and ownership;
- (i) research misconduct and policies for handling misconduct
- (j) responsible authorship and publication
- (k) the scientist as a responsible member of society, contemporary ethical issues in biomedical research, and the environmental and societal impacts of scientific research

Prior to each class meeting, students are expected to complete 2- to 3-hours-worth of assigned readings and other activities related to the focus topics for that week (e.g., watching YouTube videos and documentaries, viewing PowerPoint presentations, taking Implicit Association Tests) and then to prepare in writing their analysis of each of the Case Studies to be discussed that week.

During the first 30- to 45-minutes of class, the instructors will provide brief lectures or discussion related to the focus topics and answer students' questions related to the assigned readings/activities. Most of the remainder of each 2-hour session will consist of student-led, small group, roundtable discussions of the assigned Case Studies designed to enable practice in developing well-reasoned, morally based solutions to ethical dilemmas commonly encountered in biomedical research with guidance by faculty discussants.

Class Format: After an introduction by faculty to the topics of focus for the afternoon, we break out into randomly assigned small groups in which we compare how each of us might deal with the issues raised by the Case Studies. For each session, one of the students in each group takes on the role of 'facilitator'; that person's role is to ensure that the discussion keeps on track, that all aspects of the issues are fully discussed, and that all members of the group are provided opportunities to express their views. Another group member serves as "note taker"; she/he/they is responsible for briefly summarizing the findings from the group when the class reconvenes as a whole in WIMR 2 room 6571 for the last 10 minutes of class. These roles rotate each week among the students so that everyone has an opportunity to serve as either a facilitator or note taker. The faculty discussants (which include the course instructors, faculty associated with the Cancer Biology Training Grant (CMTG) and Cancer Biology Graduate Program (CBGP) on a rotating basis, faculty enrolled in the course as a requirement for an MPH degree or NIH grant, and guest lecturers) will contribute to the discussion with the goal of priming discussion of other viewpoints, providing additional information related to the topics, answering students' questions, and bringing up related issues that arise during discussion of the cases. The credit load standards for this course are met by an expectation of a total of 45 hours of student engagement with the course learning activities, which include doing the assigned readings/activities, writing up and submitting assignments related to the Case Studies, and regularly attending the lectures and group discussions. Auditors are welcome to attend, but are required to complete the same course requirements as students taking the course for credit; upon completion of the course, they can request a certificate of completion.

Assigned Readings/Activities: At least six days before each class meeting, the Course Director will post on the Oncology 715 course web site within Canvas the assigned Readings/Activities and Case Studies to be completed prior to that week's class meeting. Most of these Readings and Activities will be accessible via the links provided. For some of them, there will be attachments containing pdf, ppt, or MS Word files. In addition, you should plan to familiarize yourself over the course of the half-semester with the contents of the book entitled, *On Being a Scientist: A Guide to Responsible Conduct in Research*, 3rd edition, National Academy Press, Washington DC, 2009 located at: http://www.nap.edu/openbook.php?record_id=12192&page=1 and with the UW-Madison research-related materials located at: <https://kb.wisc.edu/gsaminkb/page.php?id=33279>

For students interested in a more comprehensive background and up-to-date analysis of the materials to be presented in this course, we recommend the book by F. L. Macrina entitled, *Scientific Integrity: Text and Cases in Responsible Conduct of Research*, 4th edition, ASM Press, Washington, DC. One can borrow it briefly from Professors Mertz or Miyamoto or purchase it for ~\$50.

Course Learning Outcomes: The students are expected to become proficient in the Federal, State of Wisconsin, and UW-Madison rules and regulations relevant to the performance of research in the biological and medical sciences. They are also expected to become knowledgeable in applying ethical reasoning to help in the resolution of ethical dilemmas that sometime arise during the performance of biomedical research.

Course Grade will be S/U. You are expected to attend **all** classes, to turn in all written assignments via Canvas **before** each class begins, and to actively participate in the discussions to receive an S grade. Written assignments consisting of a few lines of text without substantive content are unacceptable. Remember to include at the top of the first page your name and which week's assignment it is. If you are unable to attend a class because of illness or a **significant** scheduling conflict (*e.g.*, attendance at a scientific conference), please email the course director with your reason for absence and submit your written responses to the homework assignment when able to do so. Classroom discussions are an important component of this course. Thus, one should try to avoid missing a class. If you already know that you will likely need to miss class more than once, you should arrange to take a different ethics course or wait until spring 2024 to take this one.

SPRING 2023 LECTURE SCHEDULE (subject to change)*

(Primary focus topics for each week correspond to NIH RCR topics listed above by letter. Other RCR topics also included each week integrated within the Case Studies along with the primary ones.)

Week #1 – January 26 Focus: **Responsible Authorship & Publication (j)**
Peer Review (f)

Lecturers: Professors Janet Mertz and Rob Kalejta[#]

Case Study Leaders: Professors Mertz, Miyamoto, Rob Kalejta[#], Kinjal Majumder[#], and faculty enrolled in course

Week #2 – February 2 Focus: **Conflicts of Interest (a)**
Research Misconduct & Policies for Handling Misconduct (i)

Lecturer: Sam Leinweber, JD

Case Study Leaders: Professors Mertz, Miyamoto, Leinweber, Aussie Suzuki[#], and faculty enrolled in course

Week #3 – February 9 Focus: **Policies Regarding Human & Vertebrate Animal Subjects in Research and Safe Laboratory Practices (b)**

Lecturers: Professors Mark Burkard[#] and Richard Hallberg[#]

Case Study Leaders: Professors Miyamoto, Burkard[#], Hallberg[#], and faculty enrolled in course

Week #4 – February 16 Focus: **Collaborative Research (e)**
Scientist as a Responsible Member of Society, Contemporary Ethical Issues in Biomedical Research, & Environmental & Societal Impacts of Scientific Research (k)

Lecturers: Professors Jing Zhang[#] and Bill Sugden[#]

Case Study Leaders: Professors Mertz, Miyamoto, Zhang[#], Sugden[#], and faculty enrolled in course

**Week #5 - February 23 Focus: Data Acquisition, Analysis, Recordkeeping Practices (g)
Secure & Ethical Data Use, Including Confidentiality, Management,
Sharing & Ownership (h)**

Lecturers: Professors Kirk Hogan, Shigeki Miyamoto

Case Study Leaders: Professors Mertz, Miyamoto, Hogan, Jane Churpek[#], and faculty enrolled in course

**Week #6 – March 2 Focus: Promoting Inclusive and Safe Research Environments (d)
Mentor/Mentee Responsibilities & Relationships (c)**

Lecturers: Professors Janet Mertz and Elaine Alarid[#]

Case Study Leaders: Professors Mertz, Miyamoto, Elaine Alarid[#], Huy Dinh[#], and faculty enrolled in course

Week #7 - March 9 Focus: “The Wisconsin Cystic Fibrosis Newborn Screening Study” (a, b, e - k)

Lecturer: Professor Norman Fost, MD, MPH

This lecture/discussion brings together with a real-life UW case much of what we learned throughout the course.

* The lecture portion of these 2-hour class sessions are held in WIMR tower II room 6571; they last 30- to 45-minutes. The breakout small group discussions of case studies are held in WIMR 2 rooms (6471 and 6571) and WIMR 1 rooms (6001A and 6001B) until we reconvene as a whole class again in WIMR 2 room 6571 for the last 10 minutes for summary discussion.

[#] These Cancer Biology Graduate Program/Cancer Biology Training Program faculty will be replaced by other faculty on an annual basis to include all of the faculty trainers in the course over a several-year period.