

**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 class meeting: March 21, 2024
Where: WIMR 2 Room 6571

Description: The objective of this course is to teach graduate students, postdoctoral fellows, medical resident fellows, and assistant professors 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 the topics required by the NIH for Responsible Conduct of Research (RCR) are covered in an integrated manner during the six 2-hour-long class sessions. These RCR topics include the following:

- (a) conflicts of interest (personal, professional, and financial) and conflict of commitment (in allocating time, effort, and other research resources)
- (b) policies regarding human and live vertebrate animal subjects in research; 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

The class will also cover some additional topics such as patents that may be particularly relevant to some researchers at UW-Madison.

Prior to each class meeting, students are expected to complete all the required readings and other activities related to the focus topics for that week (e.g., reading articles and other materials with weblinks, watching 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 and discussions related to that week's 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.

Important: The introductory lectures / discussions will not have time to comprehensively cover all the materials being addressed. Consequently, it is important that each student take the necessary time to learn on their own the materials presented in the assigned reading materials, websites, etc. prior to the class. Questions that may arise can then be addressed in class or in the small group discussion sessions.

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 being able to briefly summarize 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 and/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), faculty enrolled in the course, 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 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/gsadminkb/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.

Your written responses to the questions in the Case Studies should be solely your own, *i.e.*, not copied from another current or former student or generated with the help of a Generative Artificial Intelligence system such as ChatGTP.

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 2025 to take this one.

SPRING 2024 LECTURE SCHEDULE

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

Week #1 – March 21 Focus: **Ethical Reasoning; Responsible Authorship & Publication (j); Peer Review (f)**

Lecturers: Professors Janet Mertz and Rob Kalejta

Case Study Leaders: Professors Mertz, Miyamoto, Rob Kalejta, Lixin Rui, and faculty enrolled in course

Week #2 – April 4 Focus: **Policies Regarding Human & Vertebrate Animal Subjects in Research; Safe Laboratory Practices (b)**

Lecturers: Professors Richard Hallberg and Mark Burkard

Case Study Leaders: Professors Mertz, Miyamoto, Hallberg, Wei Xu, and faculty enrolled in course

Week #3 - April 11 Focus: **Patents; Data Acquisition, Analysis, Recordkeeping Practices (g); Secure & Ethical Data Use, Including Confidentiality, Management, Sharing & Ownership (h)**

Lecturers: Professors Kirk Hogan and Shigeki Miyamoto

Case Study Leaders: Professors Mertz, Miyamoto, Hogan, Lixin Rui, and faculty enrolled in course

Week #4 – April 18 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 Kinjal Majumder

Case Study Leaders: Professors Mertz, Miyamoto, Zhang, Kinjal, and faculty enrolled in course

Week #5 – April 25 Focus: **Conflicts of Interest (a); Research Misconduct & Policies for Handling Misconduct (i)**

Lecturer: Sam Leinweber, JD and Shigeki Miyamoto

Case Study Leaders: Professors Mertz, Miyamoto, Leinweber, Huy Dinh, and faculty enrolled in course

Week #6 – May 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, Alarid, Aussie Suzuki, and faculty enrolled in course

* The lecture portion of these 2-hour class sessions are held in WIMR tower 2 room 6571 (the north end conference room); 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.