

BIMS 7100 / PHS 7840
Research Ethics /
Responsible Conduct of Research (RCR)
Spring 2024
(Version date: 1/8/24)

Course Meetings:

All sessions meet on Tuesday afternoons from 3:30-5:00 PM. **The 2/13 and 4/30 sessions are in-person in the Medical Education Building Learning Studio and the other sessions are on Zoom.**

Course Overview:

This course covers topics in Research Ethics/Responsible Conduct of Research and fulfills the requirements of the NIH RCR Mandate. The course is case-based and practical. The goal is to have course participants grapple with complex RCR issues, especially through cases, and to take away important points from each session as well as where to turn for more information.

The course strives to take a learner-centered approach. Sessions will begin with an overview of the topic at hand. Participants will then go into breakouts for small group discussion of relevant case studies/questions. The whole group will reconvene at the end of the period to share and discuss interesting points that arose in individual small groups. Faculty participate in the course as presenters and to share their perspectives in discussion.

Course Requirements:

-Class Attendance and Participation

- Attendance is required at all sessions. For in-person sessions, students must sign the attendance sheet. For online sessions, students will register for each class and class attendance will be logged.
- If students need to miss a session, they are required to write a 3-page paper that reflects on the topic of that session. **With extremely rare exceptions, any student who misses 2 (or more) sessions will receive an “Unsatisfactory” for the course and will be expected to repeat the course the following year.**
- The paper for a missed session is due in Canvas within a week of the missed session.
- Each student will take a turn serving as weekly discussion leader for their breakout group for which they are also responsible for summarizing key points of their group’s discussion. This summary is due in Canvas within a week of the class session.

***In order to receive a “Satisfactory” grade for the course, students must meet the requirements above. Keep in mind that if you do not meet these requirements and receive an “Unsatisfactory” grade for the course, you will be out of compliance with the NIH RCR Mandate for one year.**

Course Canvas Site:

Case studies/questions and other relevant course materials will be posted to the course Canvas site.

Reference Text:

National Academy of Sciences, National Academy of Engineering, and Institute of Medicine. 2009. *On Being a Scientist: A Guide to Responsible Conduct in Research: Third Edition*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12192>.

Course Schedule*:

February 13th	Course Introduction; What does it mean to be a Responsible Researcher? Jean Eby, ScD, MS, MEd Director of Human Subjects Research Education & Assistant Professor of Public Health Sciences NIH RCR Mandate Janet V. Cross, PhD Associate Dean for Graduate and Medical Scientist Programs & Associate Professor Pathology Safe Research Environments that Promote Diversity, Equity, and Inclusion (d) Tracy Downs, MD Chief Diversity & Community Engagement Officer & Professor of Urology Keith Keene, PhD Director of the Center for Health Equity and Precision Public Health & Professor of Public Health Sciences
February 20th	Research Misconduct (i) David Hudson, PhD Senior Associate Vice President for Research
February 27th	Protection of Human Subjects (b) Jean Eby, ScD, MS, MEd Assistant Professor of Public Health Sciences
March 12th	Welfare of Laboratory Animals (b) Silvia LaRue, BS Director of Institutional Animal Care & Use Committee Safe Laboratory Practices (b) Tom Leonard, PhD Director of Environmental Health and Safety
March 19th	Conflicts of Interest; Conflicts of Commitment; Collaborative Research (a, e) David Hudson, PhD Senior Associate Vice President for Research
March 26th	Mentor/Mentee Responsibilities and Relationships (c) Samuel Lake, PhD Assistant Director of Research Communication, Office of Graduate and Post-Doctoral Affairs Melanie Sinche, MEd, MA Director of Career and Professional Development, Office of Graduate and Post-Doctoral Affairs Phillip Trella, PhD Associate Vice-Provost & Director of the Office of Graduate and Post-Doctoral Affairs
April 9th	Data Acquisition and Analysis (g) Andrea Horne Denton, MILS Research and Data Services Manager Lucy Carr Jones, MS Research Data and Scholarly Communications Librarian
April 16th	Authorship, Publication, and Peer Review (f, j) David Hudson, PhD Senior Associate Vice President for Research Francine Garrett-Bakelman, MD, PhD Assistant Professor of Medicine & Biochemistry and Molecular Genetics
April 23rd	Secure and Ethical Data Use (h) Sarah Ratcliffe, PhD Professor of Biostatistics, Public Health Sciences
April 30th	Social Responsibility in Research (k) Philip Bourne, PhD Founding Dean of the School of Data Science & Professor of Biomedical Engineering

***Note:** Sessions address topics from the NIH RCR Mandate, as indicated by the letters in parentheses above which are linked to the list of RCR topics below.

Course Leader

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RCR Topics:

(from [NOT-OD-22-055: FY 2022 Updated Guidance: Requirement for Instruction in the Responsible Conduct of Research \(nih.gov\)](#))

- 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