

Responsible Conduct of Research

March – May 2011
Cambridge Campus

Instructor Information

Instructors: Mark Barnes, JD, LL.M., and Delia Wolf, MD, JD

Instructors' Title: Delia: Assistant Professor, Health Policy and Management, HSPH
Mark: Chief Research Compliance Officer and Senior Advisor to the Provost, Harvard University; Lecturer on Law, HLS,

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Office Hours: By appointment

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Holyoke Center, Room 635, Cambridge Campus (Mark)

Texts and Reading Materials

- a) Required text book:
- 1) “*On Being a Scientist, A Guide to Responsible Conduct in Research*,” 3rd Edition, by National Academy of Sciences, National Academy of Engineering, and Institute of Medicine
http://www.nap.edu/openbook.php?record_id=12192&page=8
 - 2) ORI Introduction to the Responsible Conduct of Research
<http://ori.dhhs.gov/documents/rcrintro.pdf>
- b) Additional reading materials will be posted on the course website.

Course Objectives:

At the end of the course the student will be able to:

- 1) Describe the concepts of research misconduct and research integrity.
- 2) Describe basic ethical and regulatory requirements for conducting bench, animal, clinical, and public health research and apply them to research practice.
- 3) Recognize when laboratory practices, publication practices, and other research practices deviate from legal, ethical, or regulatory requirements.
- 4) Describe practices that promote compliance with ethical and legal requirements for the responsible conduct of research.

Outcome Measures

- a) Class participation – Class participation consists of attending a minimum of six lectures, preparation, and constructive contributions to class discussion
- b) Case studies – students are expected to submit their written answers to all 12 cases during the 8-week period.

Grading

Pass/Fail

Additional Information

This course will meet the NIH training requirement for all trainees, fellows, participants, and scholars receiving support through any NIH training, career development award, research education grant, or dissertation research grant. Harvard graduate students, post-doctoral fellows, and junior faculty members will be allowed to audit the course, but are expected to attend a minimum of six lectures, participate in class discussions, and complete all written case study assignments.

Session by Session Detail

Date	Topic	Instructor
Week 1	<ul style="list-style-type: none">• Introduction to the responsible conduct of research• Scientist as a responsible member of the society – ethical issues in biomedical and public health research• Mentor-mentee relationship and their responsibilities• Grant writing, budgeting and adequate allocation of resources• Cases 1 & 2 will be distributed	M. Barnes
Week 2	<ul style="list-style-type: none">• Cases 1 & 2 assignment due• Regulations and guidelines governing research involving human subjects• Financial and non-financial conflict of interest• Cases 3 & 4 will be distributed	D. Wolf
Week 3	<ul style="list-style-type: none">• Cases 3 & 4 assignment due• Peer review• Responsible authorship and publication• Cases 5 & 6 will be distributed	M. Barnes
Week 4	<ul style="list-style-type: none">• Cases 5 & 6 assignment due• Ownership of data and biological samples• Research misconduct• Cases 7 & 8 will be distributed	D. Wolf

Week 5	<ul style="list-style-type: none"> • Cases 7 & 8 assignment due • Regulations and guidelines governing research involving live vertebrate animal subjects • Mistakes and negligence • Cases 9 & 10 will be distributed 	M. Barnes
Week 6	<ul style="list-style-type: none"> • Cases 9 & 10 assignment due • Data acquisition, selection and management • Sharing of research results • Responding to suspected violations of professional standards • Cases 11 & 12 will be distributed 	D. Wolf
Week 7	<ul style="list-style-type: none"> • Cases 11 & 12 assignment due • Intellectual property • Safe laboratory practice • Export control 	M. Barnes
Week 8 10/22	<ul style="list-style-type: none"> • Collaborative research including collaborations with industry • RCR Q & A 	D. Wolf

Course Evaluations

Completion of the evaluation is a requirement for the course. Student grades will not be available until an evaluation is completed.