

PRVM 853  
RESPONSIBLE CONDUCT OF RESEARCH  
FALL 2017

**INSTRUCTOR:** Christopher Crenner  
**OFFICE HOURS:** By appointment  
**OFFICE LOCATION:** 2026 Robinson / MS 1025  
**TELEPHONE:** (913) 588-7040  
**E-MAIL:** [ccrenner@kumc.edu](mailto:ccrenner@kumc.edu)  
**KU-MPH WEBSITE:** <http://mph.kumc.edu>  
**BLACBOARD:** <http://bb.kumc.edu>

**CREDIT HOURS:** 1

### COURSE DESCRIPTION

The purpose of this course is to engage research trainees in reading about, considering, and discussing the responsible conduct of science. The course is designed as an option for meeting current federal regulations, which require that all NIH training grants provide training in the responsible conduct of research. This course provides a concise overview of key subject areas in the responsible conduct of research. It is designed to make students aware of relevant guidelines, policies and codes relating to ethical research, as well as to provide the skills for identifying and resolving ethical conflicts that may arise in research.

### PREREQUISITES

None

### COURSE GOALS/OBJECTIVES

#### **Course Goals:**

1. Increase knowledge about government laws and regulations, institutional policies, and professional guidelines that govern the conduct of research.
2. Improve abilities for identifying and resolving ethical conflicts.
3. Enhance understanding of the range of accepted practices in research. Some acceptable practices vary according to the norms of specific scientific disciplines and sub-fields, while others are universal.
4. Heighten sensitivity and appreciation for ethical issues associated with contemporary biomedical research.

#### **Course Objectives:**

1. Discuss the principles of bioethics and how these principles should be applied the ethical conduct of scientific research.
2. Determine what conduct falls within the definition of research misconduct.
3. Describe rules and norms for appropriate management of research data.

4. Identify, define and analyze ethical issues concerning animal research subjects.
5. Identify, define and analyze ethical issues concerning human subject research.
6. Identify, define and analyze ethical issues relating to conflicts of interest.
7. Understand criteria for being listed as an author of a paper.
8. Consider the role of mentoring in promoting the responsible conduct of research.
9. Advance an appropriate course of action when encountering scientific misconduct

### **TEXTBOOKS AND MATERIALS**

- Steneck, N.H. ORI Introduction to the Responsible Conduct of Research (Washington, D.C.: U.S. Government Printing Office, 2004). ISBN 0160722853  
 [Available online at: <http://ori.hhs.gov/sites/default/files/rcrintro.pdf>, as a .pdf on the course blackboard site, or in print through Amazon or other booksellers.]
- Cases and supplemental readings available in the “content” section of the course blackboard site.

### **REQUIREMENTS**

#### 1. Case Discussions

The class will meet for two in-person case discussions (attendance is mandatory). The first will launch the course by addressing issues related to data management, research (mis)conduct, mentoring, authorship, and whistleblowing in a case concerning investigations of David Baltimore and Thereza Imanishi-Kari. The second in-person class serves as the course capstone and addresses issues of genetics, testing, and privacy through a case discussion of personal genomic tests offered by the company 23andMe.

Other case discussions (sessions 2 through 12) take place on-line (<https://bb.kumc.edu>). Students must participate in every case discussion by reading assigned materials, reviewing the discussion thread, and posting twice during each weeklong case discussion. In addition, each student will serve as a discussion leader for one case discussion (some discussions may have two discussion leaders, who will share the role). The discussion leader: (1) prepares an initial short summary of the case, including rationale for and against a chosen course of action; (2) posts questions for discussion; (3) participates in the discussion during the week; and (3) submits a final discussion summary once postings conclude.

#### 2. HIPAA Training

Students are expected to have completed HIPAA training through the KUMC online system as well as any additional online training modules (e.g., for human subjects or animal subjects) necessary for their field of scientific research. To access online training,

go to **myKUMC** at: <https://kumed.sharepoint.com/sites/mykumc/compliance/training-program>

## ASSIGNMENTS AND EVALUATION

### **Class Approach**

Class participants are responsible for participating in every discussion throughout the semester by writing and posting a **minimum of two** substantive comments (one may suffice if referencing regulations, legal codes, or broader issues of relevance), and by acting as **discussion leaders** by initiating the on-line forum for a chosen case and submitting a **discussion summary** of that topic after the forum for that week has closed.

**On-line discussions** will proceed as follows:

1. Each week, the assigned **discussion leader** will select one case for blackboard discussion (for some weeks, only one case is available; for others, there is a choice from up to three posted cases).
2. The **discussion leader** will write and post a concise summary of the case that identifies key information and the major ethical issue(s). In addition, the discussion leader will pose a maximum of two questions to start the discussion. The discussion leader's posting to the blackboard forum for the specific module must take place by Monday morning as indicated in the course schedule.
3. **All course participants** contribute two (or more) discussion postings during the week, either responding to previous comments or raising new substantive points.
4. The **discussion leader** should plan for at least one new question to post mid-week (typically Wednesday afternoon / evening) to keep discussion lively.
5. Once the discussion has concluded (the forum will close on Friday at 6 p.m.), the **discussion leader** writes a summary of that week's forum. The summary should be a brief statement (no more than 500 words) of the main issues and points of dissention raised in the forum. It should be submitted to the professor as an attachment to an email by Monday morning.

Credit for the course requires completion of all course assignments, including demonstrating understanding of the readings through your roles as discussion leader and participant.

## Class Participation

The class is built around active participation in two live class sessions and 11 online (blackboard) discussions. Discussions are not a primary source of factual information, which participants are expected to obtain from the text and through independent research. Discussions instead are intended to advance understanding of issues and situations in research conduct as participants reference their interests, experiences, and knowledge of real-life cases. Perspectives gained from your own research experiences are welcomed.

Discussions will be **asynchronous**. Participants can log on anytime they choose. However, the forum will stall if we are waiting for responses from lagging participants. To minimize this problem, participants are required to log on at least every second day.

Compose postings to the forum, case summaries, discussion questions, and the final discussion summary (when acting as discussion leader) with care so they foster dialogue and interactive learning. Write your contributions first in a word processing program and then copy them onto blackboard. **Proofread and revise prior to posting.**

Remember to be courteous. There are ways to politely disagree with others and I expect you to use these methods rather than impolite or disrespectful methods.

Posts such as “yes,” “no,” or “I agree” do not count as contributions. Instead, write a short paragraph about why you do or do not agree. Cite sources to support your arguments when applicable.

## Blackboard Navigation

Using the main navigation window (on the left side of the *blackboard* course site):

- the **Syllabus & Supplemental Materials** section holds materials of use throughout the course (new materials may be added on occasion);
- the **Content** section contains folders for each course module. In each folder, you will find the reading assignment (either pages from the *Scientific Integrity* text or other readings), and short cases for discussion.
- the **Discussion** section is where the **Forum** is located, with threads for each week’s topic. You can also link to the discussion forum from the content folders.

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- the **Discussion Summary** section is where each week's discussion leader will submit the final discussion summary for evaluation / review.

### **Evaluation**

**100% of the grade is based on participation in the in-class and on-line case discussions, including writing the case summary and final discussion summary when acting as discussion leader.** Participation involves reading assigned materials and posts from other students, and writing a minimum of two substantive postings for each of the weekly on-line discussion sessions.

### **GRADING SCALE**

A = 90% - 100%

B = 80% - 89.9%

C = 70% - 79.9%

D = 60% - 69.9%

F = 59.9% and below

## COURSE OUTLINE

Module & Topic	Discussion Period (begin Monday, 9:00am; conclude Friday, 8:00pm)	Reading Assignments (all readings are available on the course blackboard site)	Summary Due
1. Introduction	<b>In-person class</b> Monday, Aug 28, 8:00 am 4004J Robinson	<ul style="list-style-type: none"> <li>David Baltimore case</li> </ul>	Prof. Crenner will post summary
2. Research Conduct	Tuesday, Sep 5 → Friday Sep 8	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 2-29</li> <li>Case selected by discussion leader</li> </ul>	Monday, Sep 11 9 am
3. Data Management	Monday, Sep 11 → Friday, Sep 15	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 87-101</li> <li>Case selected by discussion leader</li> </ul>	Monday, Sep 18 9 am
4. Animal Subjects	Monday, Sep 18 → Friday, Sep 22	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 51-63</li> <li>Case selected by discussion leader</li> </ul>	Monday, Sep 25 9 am
5. Human Subjects	Monday, Sep 25 → Friday, Sep 29	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 35-47</li> <li>Henrietta Lacks case</li> </ul>	Monday, Oct 2 9 am
6. Conflicts of Interest	Monday, Oct 2 → Friday, Oct 6	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 67-81</li> <li>Case selected by discussion leader</li> </ul>	Monday, Oct 9 9 am
7. Authorship	Monday, Oct 9 → Friday, Oct 13	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 130-145</li> <li>Case selected by discussion leader</li> </ul>	Sunday, Oct 15 Midnight
8. Peer Review	Monday, Oct 23 → Friday, Oct 27	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 147-157</li> <li>James Lloyd case</li> </ul>	Monday, Oct 30 9 am
9. Publication	Monday, Oct 30 → Friday, Nov 3	<ul style="list-style-type: none"> <li>Self-plagiarism readings (Bird, The Lancet, Chalmers)</li> <li>Danish Cohort Study case</li> </ul>	Monday, Nov 6 9 am
10. Collaboration	Monday, Nov 6 → Friday, Nov 10	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 117-127;</li> <li>Case selected by discussion leader</li> </ul>	Monday, Nov 13 9 am
11. Mentoring	Monday, Nov 13 → Friday, Nov 17	<ul style="list-style-type: none"> <li>Steneck, <i>Intro to RCR</i>, 103-115;</li> <li>Selman Waksman case</li> </ul>	Monday, Nov 20 9 am
12. Whistle Blowing	Monday, Nov 27 → Friday, Dec 1	<ul style="list-style-type: none"> <li><i>KU Whistleblower Policy</i></li> <li>D. Jackson, "Whistleblowers?"</li> <li>Nancy Olivieri case</li> </ul>	Monday, Dec 4 9 am
13. Conclusion: TBA	<b>In-person class</b> Monday, Dec 4, 8:00 am 4004J Robinson	<ul style="list-style-type: none"> <li>23andMe case in course content</li> </ul>	Prof. Crenner will post summary

## COMPETENCIES

The following Public Health core competencies are addressed in **PRVM 853 RESPONSIBLE CONDUCT OF RESEARCH**

### MPH CORE COMPETENCIES

<b>DOMAIN 1: COMMUNICATION</b>	
<b>Competency</b>	<b>Learning Activity</b>
1. Apply effective written and oral skills to communicating with different audiences in the context of professional and public health activities.	Written summaries of cases with discussion opening, response to peers, and written discussion summaries.
<b>DOMAIN 2: PROFESSIONALISM</b>	
<b>Competency</b>	<b>Learning Activity</b>
2. Demonstrate compassion, integrity, honesty, and respect for others.	In-class and online discussion with required and monitored participation.

## CONFIDENTIALITY

Students should not expect that all work they produce in an MPH course is confidential. The KU-MPH program may review course deliverables such as papers, projects, on-line discussion postings and the like with persons other than fellow students in the course and the course instructor. While administering the program, students' work may be shown to KU-MPH faculty and staff, or other faculty and accrediting bodies such as the Council on Education in Public Health. Examples of students' work and performance may be used to market the KU-MPH program and KU School of Medicine, and during efforts to secure grant funding to support the KU-MPH program and related faculty research and service projects. Therefore, students should not include in their course assignments any sensitive personal information that they wish to keep confidential. Students wishing to discuss a confidential issue with a classmate or the instructor should use telephone calls or personal e-mails for this purpose.

## ADDITIONAL NOTES

This syllabus is subject to change by the instructor. Any changes will be announced.