RESPONSIBLE CONDUCT OF RESEARCH

Course Director: Sara Ackerman, PhD, MPH

Course Manager: Asha Robertson

Course Description:

Responsible Conduct of Research helps people, especially those starting their research careers, learn how to address the ethical issues that inevitably arise in research. It meets the requirements of the National Institutes for Health for trainees to learn about ethical issues in human subjects research and research misconduct. This RCR course was initially developed by Dr. Bernard Lo at UCSF for CTSI.

Course Objectives:

1. Identify common ethical issues that clinical and translational researchers commonly face and the ethical guidelines for addressing these issues.
2. Explain key elements of the federal regulations for research with human subjects.
3. Analyze the ethical issues in a research protocol, identify where it does not meet regulatory and ethical standards, and suggest how to address those problems.
4. Provide constructive feedback on colleagues' ideas regarding ethical issues in research.
5. Describe the ethical guidelines and federal regulations pertaining to research misconduct and conflicts of interest in research.

Faculty:

Course Director

Sara Ackerman, PHD, MPH is an associate professor in the Department of Social and Behavioral Sciences and Institute for Health and Aging at UCSF. She conducts empirical ethics research on emerging genomic technologies and precision medicine initiatives, with a particular focus on populations that have been historically underrepresented in biomedical research. Her current research uses an ethnographic methodology to study the use of exome sequencing for children and pregnant women with a suspected genetic condition. Drawing on her experience in human-centered design, Dr. Ackerman is also developing a novel strategy for communicating aggregate genomics research findings to low-literacy and non-English speaking research participants.

Course Dates: July 19 - September 3, 2021

Course textbook: U.S. Department of Health & Human Services Office of Research Integrity's ORI Introduction to Responsible Conduct of Research

Other course materials:

Other required readings, podcasts, and videos are included with selected modules and can be accessed from the course website. We have also selected supplemental materials for each module that you may wish to review. These recommended resources highlight current topics and controversies.

You may also want to download **45 CFR 46** (The Common Rule and subparts on research with special populations), the federal regulations with which all UCSF research must comply. As specific issues come up in your projects, it is always useful to go back to see what the regulations require.

The website for the **UCSF Institutional Review Board** **(IRB)** gives helpful guidance on how federal regulations are interpreted at UCSF and how to complete IRB applications.

Online Class Discussion:

Your primary responsibility in this course is to **participate actively**. You will be assigned to a small group of about 15-20 fellow students for discussion of a weekly case study. This gives you an opportunity to think through issues raised by current or recent real world cases and to articulate your ideas. You are expected to **POST** an initial response to each case study on the weekly course discussion forum, and then to read the responses of all the students in your small group. To access the discussion blog, click on the "case study" link. Later each week, you will join your fellow students in a live discussion during a one-hour online session (see below). Please adhere to this schedule so that we have adequate time for robust dialogue:

1. **POST** your initial response to the discussion forum by the end of the day on **MONDAY (11:59pm Pacific Time)** each week**.**
2. **DISCUSS** the week's topic and case study with your fellow students during your scheduled small group discussion session.

How the discussion forum will work: You may **Read, Post, and Reply** within your assigned group. You may **Read Only** in other groups if you are interested in seeing the dialogue beyond your own group. The CLE automatically places you in your assigned group – you need do nothing beyond entering the discussion forum. If you would like to enter other groups, you may do so by clicking the drop-down menu at the upper left side of the screen and then click on any group. The faculty and teaching fellows monitor the ongoing dialogue throughout each week and use it in guiding small group discussions in weekly discussion sessions.

Forum Discussion Hints:

We look forward to your thoughtful and significant posts to the forum. Responses that amount to "virtual head-nodding" ("I agree", "Good idea", "Interesting") are nice preambles to your fully developed ideas, but do not count for participation credit.

Your replies might build on, challenge, question, reinforce, debate, probe, appreciate, acknowledge, argue respectfully—in order to advance and stimulate the collective exploration of the case in a compelling manner. Look to add something new or an interesting twist.

Your posts to the forum should be mostly YOUR OWN IDEAS. We are not looking for "correct" or "textbook answers" but rather for critical thinking and weighing of the ethical issues, alternatives, and consequences.

Please think about how your own thinking is developing within each discussion.

- Does the conversation challenge you to reconsider your views?
- Do you have new information that you had not initially considered?
- Did you change your mind?

You are welcome to share helpful materials—articles, news items, online resources, etc.—with proper attribution. The course site allows you to upload files to the discussion and Q&A forums.

Weekly discussion sessions:

Each week (except for week 1), your small group will meet with a Teaching Fellow for a one-hour "sync session," in which you will discuss the readings and case study for the week. **YOU ARE REQUIRED TO ATTEND A DISCUSSION SESSION EACH WEEK.** If an unexpected conflict makes it impossible for you to attend a discussion session, please contact your session leader for help in attending a different session or making up one week's discussion. A make-up assignment to substitute for one—and ONLY one—week's discussion will be allowed in special circumstances. There is no substitute for missing more than one session, and that will result in failure of the course. Live discussion is a requirement of Responsible Conduct of Research training, per NIH guidelines. If you are unable to meet this requirement, please take this course at a later date.

Discussion sessions will be conducted using Zoom. You may log in through an Internet-connected computer that has a microphone, camera and speakers, or is connected to two-way earphones. You may also use the Zoom app on your telephone or tablet to connect to the discussion session.

A Note about Privacy and Confidentiality:
You are strongly encouraged to express your ideas, opinions, and beliefs within the Responsible Conduct of Research discussion forums and in the discussion sessions. In order to protect your ability to express yourself authentically and honestly, we ask that the dialogue be confined to this course site. ***Keep this space safe for dialogue: do not share specific things said by other students outside of this course.*** *While you may discuss general themes with others beyond this course, we ask that you protect the privacy and confidentiality of all members of this course by adhering to strict non-attribution practice. Only people officially enrolled in this course may access the course site and content.*

STUDENT INSTRUCTONS
For each Module: 1. **READ** Required Reading Assignments 2. **VIEW** Lecture Videos 3. **COMPLETE** Assignments

COURSE SCHEDULE 2021

MODULE 1: July 19 - 23

Course Introduction (NO discussion session this week)

Objectives:

1. Obtain access to required course materials.
2. Fulfill basic human subjects training requirements for researchers.
3. Familiarize yourself with and introduce yourself to the course, the instructors, and your fellow students.

Assignments:

Review the syllabus, the course site and expectations for the course. (myaccess login required)

Select your preferred discussion section time on the course site. *You must attend the same section unless special arrangements have been made with your group leader.* ***Due July 23.***

Complete the following by the end of the day on **MONDAY (11:59pm Pacific Time)**:

- ***Complete*** your Learner Contract.
- ***Meet*** your Course Director and Teaching Fellows: read bios, watch welcome videos
- ***Watch*** videos
- ***Post*** your introduction to the Module 1 discussion forum
- ***Complete*** the CITI Human Subjects Protection Training. This online module is required for key personnel in any study protocol submitted to the IRB at UCSF. It provides an overview of the federal regulations and UCSF policies that govern human subjects research. You will be asked to designate the type of research you are doing and will be directed to the appropriate modules. See the UCSF IRB page on CITI training for full instructions on registering and completing CITI training. If you are not from UCSF, register through your own institution and complete the modules your IRB requires. *Note: If you have completed the CITI Human Subjects Protection Training online course within the past three years and you are not embarking on a new study, you are excused from this activity.*
- ***Complete*** the Research Aspects of HIPAA online tutorial. *Note: If you have previously completed this tutorial, you are excused from taking it now*.

MODULE 2: July 26-30

Overview of Clinical Research Regulations

Objectives:

1. Identify the key features of the federal regulations for human subjects research.
2. Identify the types of research that are subject to the Common Rule.
3. List six criteria that must be satisfied for IRB approval prior to a study.
4. Describe how you would evaluate and optimize risks and benefits for a study in your research area.
5. Identify five important ways to discuss benefits and risks with study participants.

NOTE: From this week forward, you must post a response to the online discussion forum **EACH WEEK** by midnight Monday, and attend the live online discussion session **EACH WEEK**. Log onto the course website to access the readings, case studies, videos, discussion forums and link to your weekly live discussion session.

Assignments:

Complete the following by Monday 11:59pm Pacific Time:

- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your first weekly online discussion at scheduled time

MODULE 3: August 2 - 6

Informed Consent and Related Issues

Objectives:

1. Define informed consent.
2. List six information elements researchers must disclose to participants.
3. Describe at least three examples of vulnerable populations or participants.
4. Define the HIPAA Health Privacy Rule.
5. Discuss an ethical rationale for exceptions to consent.

Assignments:

Complete the following by Monday 11:59pm Pacific Time:

- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your weekly online discussion at scheduled time

MODULE 4: August 9 - 13

Conflicts of Interest and Reproducibility

Objectives:

1. Define conflicts of interest.
2. Discuss the association between conflicts of interest and bias in research projects.
3. Discuss how and under what circumstances disclosure, management, and prohibition are appropriate responses to conflicts of interest.
4. List some strategies to reduce bias in research and enhance reproducibility.

Assignments:

Complete the following by Monday 11:59pm Pacific Time:

- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your weekly online discussion at scheduled time

MODULE 5: August 16 - 20
Authorship and Research Misconduct

Objectives:
1. Describe the purpose of authorship.
2. Explain how disputes over authorship might be resolved.
3. Discuss ways that community-based research can share authorship and knowledge dissemination.
4. Define the federal standards for research misconduct.
5. Describe at least three warning signs of research misconduct.

Assignments:
Complete the following by Monday 11:59pm Pacific Time:
- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your weekly online discussion at scheduled time

MODULE 6: August 23 - 27
Research Ethics in Big Data and Precision Medicine

Objectives:
1. Discuss potential ethical opportunities and challenges in "precision medicine" and data sharing.
2. Discuss authors' ethical obligations regarding sharing research materials and data.
3. Discuss the issues of balancing consent and governance in Big Data research.
4. Describe the Ten Simple Rules regarding responsible conduct of research in Big Data research.
5. Discuss researchers' ethical obligations regarding the return of results to participants.

Assignments:
Complete the following by Monday 11:59pm Pacific Time:
- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your weekly online discussion at scheduled time

MODULE 7: August 31 – September 4
Ensuring Equitable Benefit from Medical Research

Objectives:
1. Describe how biomedical research and new medical technologies can mitigate or exacerbate systemic health disparities.
2. Discuss scientists' ethical obligations regarding the distribution of benefit from research.
3. Discuss issues related to the provision of background and ancillary care and access to the study intervention after a trial.

Assignments:

Complete the following by Monday 11:59pm Pacific Time:

- ***Read*** textbook and all required readings
- ***Watch videos***
- ***Post*** a response to this week's Case Study

Attend your weekly online discussion at scheduled time

COURSE EVALUATION

Please take a few minutes to fill out the course evaluation. As we strive to improve our online educational program, we need and value your input. Many of the changes in our program have been ones suggested by prior trainees. *The content of your course evaluation is anonymous, but the system will record that you completed it.*