UCSD CREST POR II (Patient Oriented Research II – Ethics and Regulation of Human Research)

**Schedule for Spring-2024**

Course Director

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Objectives: This CREST module will help your acquire the following knowledge and skills:

a. Identify the three major ethical principles that guide research involving human participants

b. Understand the ethical, legal, and regulatory framework for issues of scientific integrity and misconduct

c. Apply a framework to guide the analysis of case studies that depict ethical and regulatory dimensions of research

d Identify how various biases and conflicts of interest can influence research integrity

e. Identify and discuss ethical and regulatory challenges associated with emerging biotechnologies

f. Identify relevant regulatory requirements for conducting clinical research

g. Describe responsibilities for safety monitoring and functions of a data and safety monitoring board (DSMB)

h. Develop and orally present for peer review an IRB application which is submitted to the faculty as a document at the end of the course. (This application can be based on the student’s CREST POR I Concept Proposal or an alternative study. (This study need not be interventional, but must involve prospective research on living human subjects for which informed consent is obtained.)

**Course Content and Schedule**

**Wed, 4:00-6:00 pm, 4/3/24 – 6/12/24**

UCSD Extension, UCC, 6256 Greenwich Dr.,

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| **Lesson / Date** | **Topic** | **Content** | **Homework to be completed before class** | **Exercise in class** | **Reading**  **Assignment**  **for this lecture** | **Faculty** |
| Lesson #1  4/3/24 | **Introduction to Ethics and IRB proposal** | How to prepare an IRB submission | Review templates for IRB proposal and informed consent document in CANVAS | Lecture +/- exercises |  | Morris |
| Lesson #2  4/10/24 | **The Importance of Research Ethics** | Basics of research ethics |  | Lecture +/- exercises |  | Rothstein |
| Lesson #3  4/17/24 | **Student Ethics Cases** |  | Discuss an ethical dilemma you have faced in clinical research/research/clinical care | Class Discussion |  | Morris |
| Lesson  #4  4/24/24 | **IRB Form and Function** | Practical examples of how human research regulated at the IRB? |  | Lecture +/- exercises |  | Magit |
| Lesson  #5  5/1/24 | **Diversity Equity and Inclusion** | Lecture on being inclusive in research |  | Lecture +/- exercises |  | Dube |
| Lesson #6  5/8/24 | **Student IRB Presentations** | Student’s present the highlights of their IRB proposals | Do an oral 3-minute presentation of your proposed IRB study submission |  |  | Morris |
| Lesson 7  5/15/24 | **Responsible conduct and misconduct** | Issues of identifying and investigating research  misconduct | Work on your IRB proposal and informed consent documents | Lecture +/- exercises | - Readings | Devereaux |
| Lesson 8  5/22/24 | **Emerging Issues in Research Ethics** | Changing levels of ethical and regulatory oversight for newly developed technologies | complete your IRB proposal and informed consent documents | Lecture +/- exercises |  | Devereaux |
| Lesson 9  5/29/24 | **Emerging Ethical Issues: International Research/ Ethics Cases** |  | Turn in IRB | Lecture +/- exercises |  | Rothstein |
| Lesson 10  6/5/24 | **Conflict of Interest** |  | Final exam week | Course Reflection |  | Morris |
| Last day  6/12/24 | **Emerging Issues in Research Ethics: Studying Networks/ End of Life** | ethical and regulatory oversight for challenging topics |  | ZOOM lectures |  | Skaathun/Gianella |
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