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

**Schedule for FALL-2022**

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, Sep 21 – Dec 7, 2022**

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  9/21/22 | **Introduction to Research Ethics and IRB proposal** | How to prepare an IRB submission |  | Lecture |  | Morris |
| Lesson #2  9/28/22 | Research Ethics - Responsible conduct and misconduct | Issues of identifying and investigating research  misconduct | Begin to prepare your IRB proposal and informed consent documents by reviewing the UCSD IRB documents in CANVAS | Lecture +/- exercises | Readings from UCSD Ethics website  - Reading Assign 1  - Reading Assign 2 | Rothstein |
| Lesson #3  10/5/22 | **Conflict of Interest in Research** |  |  | Lecture +/- exercises |  | Morris |
| Lesson  #4  10/12/22 | **IRB Form and Function** | Practical examples of how human research regulated at the IRB? |  | Lecture +/- exercises |  | Magit |
| Lesson  #5  10/19/22 | **Diversity Equity and Inclusion** | Lecture on being inclusive in research |  | Lecture +/- exercises | - | McCutchan |
| Lesson #6  10/26/22 | **Research Ethics - Responsible conduct and misconduct/ Research**  **Ethics Case 1Discussion 1** | Issues of identifying and investigating research  misconduct | Begin to prepare your IRB proposal and informed consent documents by reviewing the UCSD IRB documents in CANVAS | Lecture +/- exercises | Readings from UCSD Ethics website  - Reading Assign 1  - Reading Assign 2 | Devereaux |
| Lesson 7  11/2/22 | **Emerging Ethical Issues 1: Stem Cell research/ Research**  **Ethics Case Discussion 2** | Changing levels of ethical and regulatory oversight for newly developed technologies |  | Lecture +/- exercises | Lomax et al. Grady et al. | Devereaux |
| Lesson 8  11/9/22 | **Emerging Ethical Issues 2: Ethics of Studying Networks/ End of Life** | ethical and regulatory oversight for challenging topics |  |  |  | Skaathun/Gianella |
| Lesson 9  11/16/22 | **Emerging Ethical Issues 3: TBD** |  | Prepare a 5-minute presentation of your IRB proposal by 12/6/22 **midnight** | Lecture +/- exercises |  | Rothstein |
| Lesson 10  11/31/22 | **Student IRB Presentations** |  | Use peer and faculty feedback to complete your IRB proposal and informed consent documents |  |  | Morris |
| 12/7/22 | **Student IRB Presentations** | Student’s present the highlights of their IRB proposals | Final Exam due by 12/7/22 4 PM PST  Turn in IRB proposal by midnight 12/9/22 |  | none | Morris |