# CLRE250 Syllabus:

# Online Introduction to Patient Oriented Research

**Overall Course Objective:** To introduce students to the fundamental principles of clinical research study design. Students will learn how to develop high quality research questions, match those questions to the appropriate study design and to write the primary elements of a patient oriented study proposal.

**Primary course text: Brower:** Designing Clinical Research, 5th edition

**Primary course product:** A complete 5 page comparative observational or interventional clinical research protocol synopsis.

**Course components:**

1. Weekly readings
2. Weekly in person lectures, with backup recorded video lectures, with accompanying copies of course powerpoints, in-class quizzes and additional reference material.
3. Approximately every other week student’s will have an assignment that is one component of a clinical study protocol (a total of 3 assignments). They will post the assignment on the Discussion Board for peer review. Each student will perform a minimum of two peer reviews on these assignments before the small group faculty leader provides feedback on the assignments and student discussions.
4. The final project of the course will be the 5 page protocol synopsis developed over the weeks of the course, with evidence of incorporating peer and faculty feedback.
5. A final multiple choice exam administered through Canvas course platform.

**Course expectations and grading**: Students will be responsible for attending the week’s lecture and reviewing the assigned text, powerpoint or other reference materials. In class, as well as through the online Discussion Board (in group or individual posts/messages), the assigned small group faculty leader or the course director can answer student questions about this material. There will be 4 asynchronous assignment posting. These *assignments are due on the Monday at noon PST*. Then students have 5 days to provide their peers with feedback on the assignments. *Each student must perform a minimum of 2 quality peer reviews (2 paragraphs each) by Friday noon PST*. Small group faculty leaders may facilitate this peer discussion. After the peer reviews are complete, faculty will also provide students with critiques of their submissions.

*20% percent of the grade for this course will be derived from the participation in class and on the discussion board.*

*40% of the grade* will come from the the final protocol synopsis and presentation.

The final 40% of the grade will come from a final multiple choice exam on Canvas.

**Assignments:** **Attached to your post you will also submit a running draft of your full protocol to date** (i.e. with both the new and older sections completed).

**Weekly Modules/Lessons**

| **Modules/ Lesson**  **(Date)** | **Topic** | **Learning Objectives** | **Assignment**  *(posts due Mon noon PST)* | **Text Chapers**  **Presenter** |
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| Week 1  7/3/24 | **Course introduction** | - Introductions - Mechanics of the course and using Canvas  - Clinical research overview and “protocol anatomy” | - Post your introduction in your small group on Canvas | Obtain copy of course text and read Chapter 1  Dr. Morris |
| Week 2  7/10/24 | **Research questions, study designs, specific aims and hypotheses formulation** | - How to develop a high quality research question and pick a study design  - Classification of clinical research from case reports to trials  - Writing a background  - Formulating specific objectives from a research question  - Composing a statistically testable hypothesis  and design | Assignment 1: Compose and post post on Discussion Board your research question with i) study objectives, ii) hypotheses | DCR chapters,2, 5, 8, 9, 11  Dr. Ruo |
| Week 3  7/17/24 | **Measurements: Predictors and Outcomes** | - How to select and describe your primary predictor and outcome variables and assess their qualities  - How to evaluate and choose instruments, assays or questionnaires. |  | DCR Chapters  2, , 5, , 8,  Dr. Ruo |
| Week 4  7/24/24 | **Study Populations** | - Understand concepts of the population of interest vs. population studied  - Learn principles of participant selection criteria and generalizability  - Sampling methods  - Key principals of control groups | Assignment 2: Compose and post post on Discussion Board your i) primary and secondary study endpoints (outcome variables) and ii) variables section for your proposal including predictor variables  iii) Study participant section with inclusion and exclusion criteria | DCR Chapter  3, ,  Dr. Graves |
| Week 5  7/31/24 | **Statistical Issues in Clinical Studies** | - Picking a primary statistical model  - Sample Size/ Power  Analysis |  | DCR chapters  5, 6  Dr. Haubrich |
| Week 6  8/7/24 | **Study**  **Implementation** | -Review appropriate clinical study conduct: recruiting, consenting, and assessing participants.  Learn how to longitudinally track, retain, and assess, adherence and outcomes in participants; - Study startup processes, monitoring | Assignment 3: Compose and post primary statistical model including null and alternatives statistical hypotheses selection and sample size calculation. Include analysis section | DCR chapters  15, 18  Dr. Morris |
| Week 7  8/14/24 | **Small Group Presentations** | Present your proposal so far for in person feedback | - | Morris/Graves/Haubrich/Ruo |
| Week 8  8/21/24 | **Complex Study**  **Designs** | - Review advanced clinical trial designs  - Review concept of causation and advanced designs in observational studies. | Revise and update full study protocol synopsis. | DCR chapters  7  Dr. Haubrich |
| Week 9  8/28/24 | **Enhancing Causal Inference** | -Understanding sources of bias, confounding, effect modification and how to address tham  - Review concept of causation and advanced designs in observational studies. | **SUBMIT YOUR FINAL SYNOPOSIS ON CANVAS (Due XXX Noon)** | DCR chapters  10  Dr. Graves |
| Week 10  9/4/24 | **Special lecture: Biomarkers in biomedical research** | - Rigorous definitions of biomarkers in human research  - Study designs for biomarker validation studies, biomarkers as trial outcomes and in epi research designs | **\*\*Course evaluations due XXX Midnight\*\***  **Final exam opens on Canvas Friday XXX at 8 am and closes Thursday XXX Midnight** | DCR chapters  13  Dr. Graves |
| Week 11  9/11/24 |  |  | **Final** |  |