# LECTURE SCHEDULE

**Course: POR I**

## Course Coordinators/Main Instructors: Dr. Morris

**Quarter: SU22**

**Class Time:** Wednesdays: June 29 - Sept 7, 2022; 4:00pm 6:00pm

**Class Location: University City Center, 6256 Greenwich Dr., Room #111 San Diego, CA 92122 or ZOOM if needed**

| **Lesson**  **(Date)** | **Topic** | **Learning Objectives** |  | **Homework and assignments** | **Speaker** | |
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| **In class Exercises** |
| Lesson 1,  June 29 2022 | **Scientific**  **Principles of**  **POR** | Introduction to course, Overview of clinical research design,  Classification of clinical research from case reports to trials, “protocol anatomy”.  Study types.  Writing a background. | Introduction to Concept  Proposal (CP)  Framework.  Review the CP template in the resources section of Canvas. | Read Hully chapters 1, 2, 5.  Pick a topic of interest that you want to study in a prospective study of human subjects. |  | Morris |
| Lesson 2  July 6 2022 | **Selecting Intervention and Hypothesis**  **Formulation** | Types and characteristics of  research questions, formulating a testable  hypothesis. | Group 1 presentation  of Study idea and design | Read Hulley Chapter 4, 7,10 |  | Ruo/ |
| Lesson 3  Jul 13 2022 | **Selecting and**  **Measuring**  **Outcomes** | How to select and describe your outcomes and assess  their qualities. Choosing Instruments and Questionnaires. Randomization. Blinding. placebos. | Group 2 presentation  of Study Aims and Hypotheses | Read Hulley Chapter 3, 8.  Complete an outcomes section of your concept proposal with discussion of the validity, accuracy, and precision of only your primary outcome measure |  | Ruo |
| Lesson 4  Jul 20 2022 | **Study Populations** | population of interest vs. population studied, generalizability. Study populations, Comparison groups. | Group 3 presentation  of Study Design and Outcomes | Read Hulley Chapter 11, 12  Define study population, inclusion and exclusion |  | Graves |
| Lesson 5  Jul 27 2022 | **Statistical Issues in Clinical Studies** | Sample Size/ Power  Analysis; Randomization Procedures; Analytic  Strategies. | Sample size tutorial | Read Hulley  derive sample size to the primary hypotheses. |  | Morris |
| Lesson 6  Aug 3 2022 | **Study**  **Implementation** | Clinical study conduct: recruiting, consenting, and assessing participants. Longitudinally tracking, retaining, and assessing adherence and outcomes in participants; study start- up and monitoring | Group 4 presentation  of Study Populations | Read Hulley Chapter 9.  Complete section 6.0 for intervention outcome and procedures for your group. Make a schedule of evaluations to include in your CP.  Refine CP. Prepare 10 minute presentation. |  | Morris |
| Lesson 9  Aug 10 2022 | **Q and A** |  | Present to you Project leader group |  |  | MORRIS/ RUO/ GRAVES/ MCCUTHCEON |
| Lesson 7  Aug 17 2022 | **Enhancing Causal Inference** | Understanding sources of bias, confounding, effect modification | Group 5 presentation  On sample size calculations | Chapter 7 Hulley |  | Graves |
| Lesson 8  Aug 24 2022 | **Complex Study**  **Designs** | Crossover and factorial designs, equivalence vs  superiority trials, and adaptive trials | Group 6 presentation  On study procedures | Chapter 6. Build the CP so far and Update based on reviewers.  FINALIZE CP. Prepare 5 minute presentation to present to classs. |  | TBD |
| Lesson 10  Aug 31 2022 | **5 Minute Student Presentations** | **Whole Class Presentations**: Peer Review sessions  with presentation of CP | **Whole Class Presentations**: Peer Review sessions  with presentation of CP | **Complete final exam by Sep 7 4 PM.** |  | Morris/Faculty |
| Lesson 11  Sep 7 2022 | **Final exam Due** | **Whole Class Presentations**: Peer Review sessions  with presentation of CP | **Whole Class Presentations**: Peer Review sessions  with presentation of CP | **Upload final CP to Canvas by Sep 10 midnight** |  | Morris/Faculty |