

DESIGNING CLINICAL RESEARCH (1 month)

ASSIGNMENT # THREE

Due: Monday August 8th at DCR Small Group Section

Written Assignment Due Electronically: August 11th, 2016 at NOON

In Assignment Three, you will continue to add sections to your protocol and condense those portions you completed in the first two assignments. Again, please be prepared to discuss this assignment during your small group session this week and to submit this assignment electronically to your small group leader by NOON on Thursday to receive comments that will be useful for you to incorporate into your final protocol.

To Do:

I. Read DCR Chapters 7, 8, and either 12, 13 or 18 (depending on which is most relevant for you; see below). If you are doing a study of a diagnostic test, Chapters 1 and 5 of Evidence-Based Diagnosis (EBD) should also be helpful.

II. Compose parts of your protocol

- A. Protocol:** Your one page outline should include the research question, and it should concisely present the relevant sections that you completed for the first assignment. Chapter 19 is a great summary of preparing a protocol. No need to hand this overall outline this week. This is just to help you begin to assemble what will be a 5-page protocol due at the end of the class. **Note that we will soon post examples of final research protocols in the syllabus under the Wednesday, August 24th session.**
- B. Design:** Here is an additional section that you should produce for your protocol. The design can usually be described in a paragraph, amplifying on terms such as cross-sectional, cohort, and randomized blinded trial by giving more information on timing of visits, measurements, treatments, etc. A schematic diagram with a horizontal time sequence is sometimes useful. Please be prepared to describe your study design to your colleagues in the small group session.
- C. Statistics:** Based on your reading and the statistics lecture (Wednesday's talk), identify the appropriate statistical test that you will use in your analysis. Imagine the anticipated result of your study when it is completed and write 1-2 sentences that might be included in the "Results" section of an abstract when your study is published, including an interpretation of the main result. Discuss the internal validity of your proposed study. Discuss the generalizability of your proposed study.

Objectives for section:

After this session, you should:

- 1. Have a clear, detailed understanding of *exactly* how at least one predictor and one outcome variable for their study will be (or was) measured or be aware that they do not have such an understanding and have a plan to acquire it**
- 2. Have experience providing tips to colleagues**
- 3. Be able to list and explain the advantages and disadvantages of basic observational study designs, including case-control, cross-sectional and cohort studies**