

DESIGNING CLINICAL RESEARCH (1 month)
ASSIGNMENT # TWO
Due: August 7th at DCR Small Group Section
Written Assignment Due Electronically: August 8th, 2017 at NOON

In Assignment Two, you will compose the first portions of your protocol. Please be prepared to discuss the content of this assignment with your small group on Monday, August 7th. Please submit this assignment electronically to your small group leader by NOON on Tuesday, August 8th to receive comments that will be useful for you to incorporate into your final protocol.

To do:

I. Read Chapters 3 and 4 of DCR.

II. Watch Tom Newman's presentation "How do we know what we know?" by clicking on the link on the course website. This presentation will help reinforce our systematic approach to designing (and critically appraising) a research study.

III. Compose parts of your protocol

(Bring this to class today and email to your section leader by noon on Tuesday.)

- A. Research question.** State the research question that you are interested in pursuing in the form that we have discussed in lecture and small group.
- B. Significance.** Use PubMed to do a computerized literature search, and word-process a "Significance" section for your research question with an adequate set of references (preferably inserted with EndNote or equivalent software). The ideal length for a significance section in a five page protocol is a half page, but it should be no longer than one page.
- C. Study subjects:** Describe the subjects that you intend to study. Provide a more in-depth discussion than will be included in the final protocol (about $\frac{3}{4}$ page) that includes:
 - a. A description of the target and accessible populations. Specify and justify the selection criteria.
 - b. A description of how the study subjects will be sampled from the accessible population.
 - c. A description of how you plan to **recruit** potential subjects identified by your sampling process.
 - d. If you are doing a longitudinal study, a description of how you plan to **retain** potential subjects identified by your sampling process.
- D. Primary Variables:** List the predictor and outcome variables for this research question. Although you may have several predictors and outcomes, you will soon need to determine which are primary as we move to the sample size calculations later in the course.

For the primary predictor and outcome, include a detailed description of how the variable will be measured. Propose and discuss strategies to reduce random and systematic error in your measurements.

Objectives:

After this session, you should:

- 1. Know the names and something else about the section leader and each of the other participants**
- 2. Be able to summarize your study plan on a 1-page standard outline**
- 3. Be able to explain the difference between Target population, Accessible population, and Sample**
- 4. Write out concrete inclusion and exclusion criteria for your study**
- 5. Understand the rationale and tradeoffs for sampling decisions for your own study and at least 2 other studies in the group**