

Problems 1 and 2 are to be answered by e-mail by 5:00 pm on Monday, April 11.

1. Send email to semerson@uw.edu including the following information:
  - a. your name (please let us know what you would like to be called)
  - b. any graduate degrees you have previously earned
  - c. your home department, major within that department, and year of study
  - d. the email address at which you would like to receive all class notices and to communicate with your group (you are responsible for informing us regarding any updates to this address)
  - e. a telephone number through which members of your eventual research team can contact you
  - f. area of clinical experience and/or interest (e.g., cardiovascular diseases, infectious diseases, cancer)
2. Provide ideas for two Phase II or Phase III randomized clinical trials that might be used for a course project in this class. Provide a very brief summary of
  - a. The disease or condition you will be targeting. (You may consider therapeutic, preventive, or diagnostic strategies for the disease.)
  - b. The population you will be targeting. (Very broad characterization of the population is the goal here. You do not yet need full inclusion / exclusion criteria.)
  - c. The treatments, preventive strategies, or screening methods you will be investigating. (We want RCTs, so you need to tell us both the experimental arm and the control arm. It is also okay to compare two or more treatments, preventive strategies, or screening methods that are in current use. Very broad characterization of the treatment arms is adequate.)
  - d. The outcome measure that will be used as the basis of the comparison.

By way of an example, were we to be suggesting a RCT similar to the National Lung Screening Trial (recently completed), we would submit:

- We propose a large scale screening trial to compare two methods for diagnosing lung cancer in a high risk population
- The population will be otherwise healthy individuals with a history of heavy smoking
- The methods being compared are spiral CT and plain chest Xrays used annually for three years.
- The patients will be followed for death from lung cancer.

The course project will be to prepare major parts of a Clinical Trial Protocol:

1. You will work in groups of approximately 4 students. Group assignments will be made by us in order to optimize areas of expertise within each group, though we will solicit your interest in the suggestions that we receive from this homework.
2. In providing ideas for your project, you are encouraged to draw on your own interests and experience. You might also consider perusing the website [clinicaltrials.gov](http://clinicaltrials.gov), which is a registry of clinical trials that are currently being conducted or that have recently been completed.
3. The final written form of your project will be due Wednesday June 1. There will be an oral defense of

the protocol to a Protocol Review Committee that consists of another group. (So your group will also be the Protocol Review Committee for another group's protocol.)

4. The project is 75% of your grade, hence it is extremely important that you not procrastinate. To that end, we will be asking to see a draft of specific portions of your protocol several times during the quarter. Furthermore, on Friday, May 20. we will expect to see a version of your protocol that is approximately three-quarters complete. We will then provide a brief written critique of your draft.
5. A template for a protocol is posted on the website..