Draft / Proposed Epi and Biostats Comprehensive Examination

(Proposed August 2000, *Not* Yet Adopted)

The goal of this comprehensive exam project is to demonstrate your understanding of the materials covered in HS161, HS167, and HS267. You will do this by documenting a protocol for a modest public health study. The study may a simple survey, cohort study, case-control study, or trial. It should have modest goals but be well focused, and should address an area that interests you. The study can be descriptive or inferential (or both), and entail some degree of quantification or testing. Your study protocol should include the following components:

1. **Research question and hypothesis**. Describe the problem that motivated the study. What question will be examined? What parameter will be estimated? What hypothesis will be tested (if any)?

2. **Target population**. What person, place, and time factors define the target population? How will this population be sampled?

3. **Independent variable**. What is the independent variable (explanatory factor, "exposure," "treatment") and how will it be measured? Does the study include a control group? If there is no active control group, will there a comparison be made to an external reference group or hypothetical norm, or will the study remain strictly descriptive?

4. **Dependent variable (study outcome)**. How will the dependent variable (outcome, "disease") be defined and measured? Will data come from abstracting existing records, from a survey questionnaire, by a direct exam, by collecting biospecimens, by environmental sampling, or by some other means? Will the outcome be validated?

5. **Extraneous variables (potential confounders)**. Will potential confounders be considered? If so how will they be measured and how will they be dealt with during analysis (e.g., matching, stratified analysis)?

6. **Type of study (design features)**. Will the study be experimental or observational? If it is experimental, describe the method of randomization that will be used. Also describe potential blinding methods and ethical concerns. If the study is observational, will it be a cross-sectional study, cohort study, or case-control study?

7. **Data Analysis**. What descriptive methods (summary statistics, frequency analyses, and graphs) will be used? What inferential methods (confidence intervals and tests) will be used? What are the planned analyses?

8. **Sample size requirements**. How many subjects will be studied? Complete preliminary sample size calculations. Justify your assumptions.

9. **Study limitations**. Consider possible sources of bias. List potential limits in the generalizability of results.

Hand in:

(A) A concise write-up of the protocol: The write-up should be no more than a couple of pages long. It should be numbered with the 9-point scheme shown above. Click here to see an evolved example done by former student Matt Staley. (Yours need not be as long or as involved.)

(B) A copy of the data collection form you will use to collect data. Your data collection form include no more than 10 variables: the independent variable, the dependent variable, about 4 potential confounders and several study subject identifiers (e.g., name).

(C) Skeletal computer files intended for data collection and documentation. For example, if you are using Epi6, hand in your QES file, [empty] REC file, and DD file. If you are using Epi Info 2000, hand in your MDB file and DD file. If you are using other software for data collection and management, please see Dr. Gerstman.