1. The requirement that human subjects must give their informed consent to participate in an experiment can greatly reduce the number of available subjects. In randomized controlled trials of treatments for cancer, for example, patients must agree to be randomly assigned to the standard therapy or to an experimental therapy. The patients who do not wish their treatment to be decided by randomization are dropped from the experiment and given standard therapy. Why is it not correct to keep these patients in the experiment as part of the control group, since the control group also receives the standard therapy? Explain briefly.

2. Some studies find a strong association between liver cancer and smoking. However, alcohol consumption is a confounding variable.

   (a) What does this mean? Explain briefly.

   (b) A newspaper writes an article about the study and titles it “Smoking causes Liver Cancer”. Is their conclusion justified?

3. In each of the following examples, thinking about the situation from the point of view of experimental design, identify the treatment and response variables; specify whether this was a controlled experiment, an observational study, or neither; visualize the raw data (by which I mean: Sketch a data table with rows for subjects and columns for variables, Fill in the blank in the sentence “A row for each ________________,” and (if you know something about the variable(s) in question) fill in some typical data values); Summarize the strength of evidence for the effectiveness of the treatment under study. If there is a weakness in the design, specify the weakness and describe a stronger experimental design for assessing the clinical efficacy of that treatment.

   (a) In the late 1970s in San Francisco, a woman named Dr. Josephine Lo and her associates treated 31 patients suffering from severe headaches resulting from spinal punctures. Conventional treatments did not help. She found that 30 of the 31 patients experienced “complete and permanent relief” after one to five acupuncture treatments.

   (b) One of the leading causes of death in the United States is coronary artery disease, in which the main arteries to the heart break down. The conventional treatment for this disease as of the late 1960s involved drugs and special diets to reduce the
patient’s blood pressure and eliminate fatty deposits in the arteries. Several good studies, involving a few hundred patients, had reported by 1970 that about 68% of patients getting this treatment survived for three years or more.

In 1972, a medical researcher named Daniel Ullyot and his associates introduced a radical new treatment, in which the diseased arteries were replaced by veins transplanted from the patient’s own legs (this procedure is called a coronary artery bypass graft (CABG); and hundreds of thousands of CABGs are now done in the U.S. every year). On December 9, 1975, the San Francisco Chronicle reported preliminary results of Dr. Ullyot’s research: about 100 patients, specially chosen by him, had been treated in the new way by then, and 98% survived three years or more. The Chronicle described these results as “spectacular.”

4. A study of young children found that those with more body fat tended to have more “controlling” mothers; the San Francisco Chronicle (November 9, 1994) concluded that “Parents of Fat Kids Should Lighten Up”.

(a) Was this an observational study or a randomized controlled experiment?

(b) Did the study find an association between mother’s behavior and her child’s level of body fat?

(c) If controlling behavior by the mother causes children to eat more, would that explain an association between controlling behavior by the mother and her child’s level of body fat?

(d) Suppose there is a gene which causes obesity. Would that explain the association?

(e) Can you think of another way to explain the association?

(f) Do the data support the Chronicle’s advice on child-rearing? Discuss briefly.

5. Read the summary (just the first paragraph) of the journal article “What Does Doodling Do?”, attached below.

(a) What is the hypothesis that the researchers are studying?

(b) Are they performing an observational study or a controlled experiment? Explain.

(c) What difficulties do you foresee in performing a blind experiment?

(d) What do the researchers conclude?