Case 1:
Informed Consent

You are a researcher working with a team developing a new drug that shows promise in reducing tumor loads in animals with experimental hematological malignancies. The drug has the side effect of nausea, based on data from preliminary human subject safety (Phase 1) trials. About 60% of patients experience nausea and a small percent suffer severe vomiting. Additionally, some peripheral nerve dysfunction was noted in experimental animals exposed to the drug, and in the phase 1 human subject studies about 10% of subjects reported mild tingling sensations in hands or feet. The plan is now to test the drug in patients who have failed conventional therapy for certain leukemias; the goal of the trial is to determine whether reductions in tumor load similar to those observed in experimental animals will occur. In the doses used in this trial, the drug is unlikely to change life expectancy of these terminal patients.
You are charged with developing:

11. an appropriate consent form for use in this trial
12. a plan for recruitment of subjects.

- What are the key elements you must include in order to guarantee informed consent?
- What are your considerations regarding who you want to recruit and how you plan to recruit them?
- If you are going to offer an incentive to participants, how will you determine whether or not the incentive is appropriate and not unintentionally coercive?

Case 1: Variations
Informed Consent

The following variations in this case can be used to further explore the issues.

- What if it were a study focusing on teenagers?
- What if you wanted to include a colleague in the study, who will recruit patients from a clinic?
- Would you develop the consent form or recruitment plan differently for a study of participants in a weight loss clinic who would be receiving free care and a new obesity drug?
- Do your responses change if a certain racial or ethnic group were the subjects of study?
- What if you wanted to retain blood or tissue samples for future studies?