Attachment 2: Case Vignettes For Discussion

Case 1: Research involving persons with intellectual impairments

You are conducting a placebo-controlled, randomized study of an investigational drug to determine whether it improves moderate to severe intellectual difficulties in persons with Alzheimer's disease. Because of the severity of their intellectual impairments, subjects will not be able to provide informed consent. The researcher intends to ask subjects' "next of kin" to provide consent. You submit the protocol for review to your IRB and they ask for more information about who will provide consent of behalf of the subjects. Why does the IRB care about this issue?

Case 2A: Administration of experimental drugs to persons with lung cancer

An investigational drug has shown remarkably good results in animal models of lung cancer. Researchers propose to conduct a research study in which the first human administration of the drug is to people with lung cancer who have failed to respond to all standard treatments. The study will enroll 20 subjects; there will be five groups each made up of four persons. Each group will receive a higher dose than the previous group. The goal of the study is to determine the mean tolerated dose (MTD) of the experimental drug (the highest dose that can be given safely to people). Researchers do not expect the people involved in the study to benefit directly (their cancers are not expected to respond but researchers will learn what dose of the drug can be used safely in future research studies)

Case 2B: Administration of experimental drugs to health volunteers

An investigational drug has shown remarkably good results in animal models of lung cancer. Researchers propose to conduct a research study in which the first human administration of the drug is to healthy volunteers aged 21 to 35 years of age. The goal of the study is to determine the mean tolerated dose (MTD) of the experimental drug. The study will enroll 20 subjects; there will be five groups each made up of four persons. Each group will receive a higher dose than the previous group. Researchers will learn what dose of the drug can be used safely in future research studies in people with lung cancer. The volunteers will be given financial remuneration for their participation.

Case 3: Research conducted in the private practice setting

An internist,in a busy private practice, has been contacted by a pharmaceutical company to participate in several research protocols to study new drugs for high blood pressure, obesity and smoking cessation. The research protocols are designed and written by scientists in the pharmaceutical company. For each patient who enrolls into the protocols, the internist will receive $1200.

Case 4: Who is the research subject?

A researcher is studying various emotional, familial and other aspects of being a twin. A 21 year old women and her twin brother enrolled in the study. A questionnaire was sent to the woman at her parents' house where she was living temporarily. She opened the questionnaire and left it on the kitchen table. Her father noticed that there were a number of questions about him which he considered to be about private information (did he have a history of psychiatric disease, did he

have normal genitalia, etc.). He was upset and felt that the researchers should have asked his permission to elicit this private information for research purposes.

Case 5: Research involving healthy children

Childhood diabetes is a growing problem in the United States. In order to learn more about abnormal sugar metabolism, researchers need to study glucose metabolism in normal aged matched children. Therefore, they write a protocol to study healthy children ages 7 to 17 years old. The research consists of the child subjects staying overnight in the hospital, eating a special high protein diet for one week before and while in the hospital, and taking blood samples (less than a teaspoon) every two hours for 24 hours. In order to minimize the number of times the child must have venipuncture, the researchers propose the placement of a small catheter that will remain in the vein for the 24 hour period (the blood will be taken from the vein through this catheter). Researchers do not expect that the child volunteers will benefit directly from research participation but researchers think this information will help them develop better treatments for diabetic children.

Case 6: Phase 1 clinical trial in ALS

An investigational drug has shown good results in animal models. Researchers propose to conduct a Phase I clinical trial in which the first human administration is to persons with moderately severe ALS. The study will enroll 20 subjects; five groups each made up of four persons. Each group will receive a higher dose than the previous group. The goal of the study is to determine the mean tolerated dose (MTD) of the investigational drug.