

LUMBAR SCENARIO

Learner Instructions

Scenario:

You work for (or with) Dr. Humenay and have been paged by the Emergency Room staff because a potentially eligible research subject has just come in.

You bring an informed consent document and your study supplies to the ER, where you meet S. Pamona, a patient brought in by their daughter due to fever and apparent confusion. The nurse informs you that S. Pamona seems uncomfortable, but is able to pay attention. The nurse also reports that the patient is slow to answer questions, but seems to understand questions and is answering appropriately.

Research Project Summary:

Title: Meningococcal Diagnostic Detection Using N-Transferase

Sponsor: LabCo, Inc

Eligibility: Subjects must be between 18 and 75, with signs and symptoms of possible meningitis, and be scheduled to receive a spinal tap. Subjects must not have any history of spinal cord injury

Procedure: 20cc's of additional spinal fluid will be withdrawn for research purposes during the routine spinal tap. Subjects will be followed for headache for 24 hours. Medical records will be reviewed by the research team for up to one year to determine eventual clinical diagnosis and any additional adverse events. After data is extracted from the medical record and samples, all data will be made anonymous. After data is anonymous, subjects will not be able to withdraw from their samples.

Risks: risk of headache from the spinal tap is increased from 5% to 10%.

Benefits: No direct benefits to subjects, expected benefit to future meningitis patients.

Financial Interests: LabCo, Inc. will provide a bonus payment of \$5,000 to the study budget if recruitment goals are met each quarter.

HEART FAILURE SCENARIO

Learner Instructions

Scenario:

Dr. Smith alerts you that one of her heart failure patients seen at clinic today is being admitted. You bring an informed consent document and your study supplies to the cardiac unit, where you meet S. Jackson, a patient with a history of heart failure who came in to the clinic today with significant shortness of breath. The patient is also worried this latest setback may jeopardize their placement on the transplant list. S. Jackson is alert and oriented, but is uncomfortable with the oxygen tubes and continues to have difficulty breathing.

Research Project Summary:

Title: Sustained Erevase Treatment in Heart Failure

Sponsor: Shire Pharmaceuticals, Inc.

Eligibility: Subjects must be 20 years or older, hospitalized for heart failure, and eligible for transplants. Subjects must not have any contraindication for inotropic agents and must not be pregnant.

Procedure: A physical exam and record review will determine eligibility. Eligible subjects will be randomized to Erevase or placebo, assignment will be double blinded. Erevase is not an FDA-approved treatment for heart failure but has shown promise in animal studies and Phase I/II trials. Erevase or placebo will be administered intravenously through the subject's hospital stay or until treatment discontinuation parameters are met. Subjects will wear a cardiac monitor throughout their hospital stay. Daily physical evaluations and blood samples will be collected, medical records will be followed during and after hospitalization to collect outcome information.

Risks: Erevase side effects include headache, nausea, orthostatic hypotension, weakness, fatigue, malaise, loss of appetite, potassium and sodium depletion, and (rarely) hives. More serious complications include edema, acute renal failure, cardiac irritability, arrhythmias and death. There is also a risk associated with blood draw and IV placement. There is a risk to the fetus if a subject becomes pregnant during the study.

Financial Interests: Shire Pharmaceuticals, Inc. will provide a bonus payment of \$5,000 to the study budget if recruitment goals are met each quarter.

SOCIOBEHAVIORAL SCENARIO

Learner Instructions

Scenario:

You are part of a research team using face-to-face interviews to learn how general individual attitudes and beliefs influence political behavior and opinions. The interview, which you will conduct, takes 20 – 30 minutes to complete. Topic areas for the interview include: demographic items (e.g., age, educational attainment, household income), religious and moral beliefs, current public policy issues such as gun control, taxes, Social Security and abortion, and voting and other political behavior.

For today's interview, you are meeting with S. Benson, a potential volunteer who was randomly selected and determined to be eligible for the study by a short phone interview. Due to the confidential nature of the interview, you must first obtain valid informed consent or refusal from S Benson to fulfill participation requirements. You open your research supplies folder, take out the consent forms, and enter the room.

Research Project Summary:

Title: Annual Political Survey

Sponsor: Federal granting agency

Eligibility: Subjects must be 18 or older, able to participate in a face-to-face interview, answer questions appropriately, and have been previously selected as a potential participant.

Procedure: 20-30 minute in person interview in the subject's home or other location they choose.

Risks: Loss of privacy related to personal religious, moral and political opinions; emotional upset caused by discussion of particular topics.

Benefits: Subjects receive a modest gift certificate to a local grocer.

Financial Interests: Because representational sampling is vital to the ability of the study to draw conclusions, it is very important to get those adults identified for the study to agree to be interviewed.

Financial Interests: The Federal Granting Agency will provide a bonus payment of \$5,000 to the study budget if recruitment goals are met each quarter.