

Informed Consent Concise Summary Examples

Common Rule Changes January 19, 2018

Example #1:

This is a research study to compare two drugs. One drug is a combination drug treatment which means it contains two different drugs combined into one (drug A + drug B). The other drug is a single drug treatment (only drug A). This research is being done to compare the safety of the drugs, how well the drugs are tolerated and how well the drugs work. Drug A is approved to be given as a single drug treatment. Drug B is also approved to be given as a single drug treatment. Giving both drug A and drug B together is considered investigational which means they are not approved to be given together.

If you choose to take part in this research study you will be randomly assigned (this is like a coin flip) to receive either the combination drug treatment or the single drug treatment. These drugs are given by IV infusion at ECU Brody Outpatient Clinic during week 1 of each 3-week cycle. If you have not had bad reactions to the study drugs or disease progression, tests will be performed periodically throughout the study to determine if you may continue in the study.

You will receive the combination drug treatment or the single drug treatment until your disease gets worse or until you can no longer tolerate the side effects of the study drugs or you or your doctor decide to stop treatment for any other reason.

You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last approximately 1-4 hours. The length of time of each visit depends on what is being done on that day.

There are risks to the study drug that are described later in this consent form. Some of the risks include: diarrhea, fatigue, itching, rash, abnormal nerve function in the arms or legs, hair loss, back pain and chills.

If you are interested in learning more about this study, please continue reading the information below.

Example #2:

The purpose of this research study is to determine the effect of treating depression on how one's body responds to stress. People with known depression and who are willing to seek treatment for their depression are being recruited for this study.

Participants will undergo a screening procedure that involves answering a series of questions assessing your mental health and completing surveys about your mental and physical health. You will also have your height, weight, blood pressure and waist circumference measured.

After the screening is complete and if you qualify to take part in the study, you will return to the study site on another day to complete a mental stress test as well as additional surveys. You will be asked to complete two challenging mental tasks while your heart rate and blood pressure are measured. You will be videotaped performing these tasks. Once this study visit is completed you will receive twelve weeks of cognitive behavioral therapy for your depression. At the end of the twelve weeks you will undergo another mental stress test. The research study visits will be conducted at ECU and each visit will take anywhere from 1-2 hours.

People who are depressed are at a greater risk of hurting or killing themselves. This represents one of the greatest risks of this study. Other risks include strong negative emotions that may arise during therapy and the possibility of loss of confidentiality.

If you are interested in learning more about this study, please continue to read below.