

CONCISE SUMMARY EXAMPLE 1

A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of a Drug in Adult Subjects with Acute Spinal Cord Injury

You are being asked to join a research study. The research is for people who have just had a spinal cord injury. Before you consider the research, you should be aware of the following information:

- Research is voluntary. You do not have to be in this study.
- You will get standard medical care for your spinal cord injury even if you decide not to join the study.
- This study uses an investigational drug. The drug is not approved by the U.S. Food and Drug Administration.
- Researchers hope the study drug will help repair some of the nerve damage, but they do not know if the drug works yet. They are doing the study to find out if the drug works.
- This is the first time the drug has been tried in people with spinal cord injuries.
- This study uses a **placebo**. The placebo is sterile water, and it does not have any medication in it.
- If you join the study, you might not get the drug. You have a 50/50 chance of getting the drug and a 50/50 chance of getting the placebo.
- Everyone in the study gets standard medical treatment for spinal cord injury, in addition to getting the study drug or the placebo.
- The study lasts about 26 weeks. If you sign up now, you can still take yourself out of the study later on.
- You might benefit from being in the study, but there is no guarantee of benefit.
- The drug has some risks. The risks are explained later in this document.
- Please be sure all your questions are answered before you decide to be in the study.
- If you think you want to be in the study, you should read the rest of this document and discuss it with the study team. The document explains what will happen to people in the study.

Subject's initials confirming discussion

CONCISE SUMMARY EXAMPLE 2

Research Study Title: A Randomized Trial of Continuous Positive Airway Pressure (CPAP) for Sleep Apnea in Pregnancy (SLEEP)

Sponsor: This research is being funded by <<Sponsor Name>>.

STUDY SUMMARY

We have summarized the key information about this research study at the beginning of this consent document. More complete details are included following this summary.

We invite you to take part in a research study because you have mild or moderate sleep apnea. Sleep apnea is a common sleep disorder in which you have one or more pauses in breathing or shallow breaths while you sleep. It is your choice whether to be in the study.

The purpose of the study is to find out if treating sleep apnea will affect certain disorders that happen during pregnancy and other complications during pregnancy. The study will last throughout your pregnancy and will finish after delivery of your baby. Everyone in the study will answer questionnaires and have blood taken at study visits. You will either be assigned to a treatment group that uses a CPAP machine or another group that gets advice about getting good sleep. What group you will be in is decided by chance, like flipping a coin. We will be following-up with you by phone, text messages or e-mail in between study visits. After you deliver your baby, we'll ask to take a tissue sample from the placenta. The procedures will be described in more detail later in this document.

There are some risks and discomforts from the blood draw and if you use the CPAP machine. There is a risk of loss of confidentiality. All the risks will be described in more detail later in this document. You may benefit from being in the study, but there is no guarantee of benefits. You might help others in the future by being in this research study.

You can get standard care for your pregnancy or sleep apnea even if you decide not to be in this study.

You may take this document home to read or to discuss with your family members or doctor before deciding to take part in this research study. Please take your time and read this information carefully. You should ask the research staff if you have any questions about this study, or if there is anything you do not understand. If you decide to take part in the study, you will be asked to sign this form.

CONCISE SUMMARY EXAMPLE 3

Your child is being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you will allow your child to take part in this research study.

Your child's participation is voluntary, which means that you are free to decide whether to allow your child to be in this study. The purpose of the study is to evaluate the safety of the study drug being tested, <<Study Drug A>> plus <<Study Drug B>> when compared to <<Study Drug C>> in individuals with a complicated intra-abdominal infection. We are asking you to allow your child to participate in this study because s/he has a complicated intra-abdominal infection. This study is being conducted by <<Sponsor Name>>. The sponsor is paying for the University of Utah to conduct this study.

This is a Phase 2 study which means it is done on a larger number of human subjects to see if a new drug is safe. They are also done to find out if the drug works and does what it is supposed to do.

<<Study Drug A>> is an approved drug available by prescription for use in adult patients with complicated intra-abdominal infection (in combination with <<Study Drug B>>) and for complicated urinary tract infections, including kidney infections but is not approved for use in patients less than 18 years of age yet. <<Study Drug C>> is an approved drug available by prescription in children and adults for treatment of different types of infections.

About 120 patients will be in the study. Your child will be in the study about 5-7 weeks. Your child will be screened to find out if they should be in the study. There will be a review of your child's medical record and a physical exam. Blood will be drawn from your child and some blood tests will be done. Your child will be randomized to receive one of the two treatments and your child will be given the drug through an IV. The study procedures will be explained in detail later in this document.

There are known side-effects that may occur as a result of the drugs used in this study. The study team does not know all the effects that the study drug may have on your child. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life threatening. There is also the risk of an allergic reaction to the drugs. The risks are explained in detail later in this document.

There are no direct benefits to your child from your taking part in this study. The information we get from this study may help us treat future patients. We hope that this study will help your child, however, this cannot be guaranteed.

You may choose not to allow your child to participate in this study. If you do not want to take part in the study, there are other choices such as other approved antibiotics for intra-abdominal infections. You may discuss these options with your child's doctor.

CONCISE SUMMARY EXAMPLE 4

You are being asked to take part in a research study. Participation in this study is voluntary.

Many of the youth who have contact with the juvenile justice system will go on to be resilient and lead productive lives. But some youth will return to detention—what explains the different outcomes for these youth? Researchers at the University of Utah are conducting a research study to begin to answer this question called the ***Adolescents Coping with Experiences Study (ACES)***, which has been funded by the National Institute of Justice. The purpose of this study is to test theories about how the kinds of stress youth experience in their lives, and how youth's emotional, cognitive, and interpersonal styles of coping with stress, might help us understand why some youth will return to detention and others will not over the course of the next three years.

We would like you to complete surveys and we will measure your natural body responses. The full explanation of what we are asking you to do is described below in this consent document in the “Study Procedure” section.

Risks of participating are small. However, it is possible that you or your caregiver may feel upset thinking about or talking about stressful life experiences or behaviors. These risks are similar to those experienced when discussing personal information with others. If you or your caregiver feels upset from this experience, you/your child can tell the researcher, and he/she will tell you about resources available to help.

There are no direct benefits for taking part in this study. We hope the information we get from this study may help us learn how to keep youth from re-entering detention centers in the future.

Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you would like to participate in this study and whether you will allow your child to take part in this study.