

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 [REDACTED]
- 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