

Clinical Trials from a Patient's Perspective

Quinton Nez, a 14 year old male, has hypertension (high blood pressure). His family doctor has suggested that he take part in a clinical trial. A clinical trial is a research study designed to test a medication, program or other intervention to see if it has an effect.

Review this information about the clinical trial that Quinton's doctor would like him to participate in:

A Nutrition Intervention to Lower Blood Pressure in Adolescents

<https://clinicaltrials.gov/ct2/show/NCT00431288?term=adolescents+and+nutrition&rank=2>

Before taking part in a clinical trial, teens under the age of 18 are asked for their **assent**. Assent means that they agree to participate in the clinical trial. They may also dissent, which means they do not agree to participate in the clinical trial.

During the assent process:

- The research team will explain the clinical trial using language that Quinton can understand, including what it means to take part and what he can expect to happen.
- The research team may use written forms, videos, graphics, and other visual aids to help explain the clinical trial.
- Quinton will be encouraged to ask questions.

When the research team feels that Quinton has a clear understanding of what the clinical trial involves he will be asked to show assent or dissent by signing a form. Both of Quinton's parents must also sign to give informed consent (permission) for him to participate in the clinical trial.

Your Task: As part of the research team for this clinical trial, you will need to create a research study assent form that will be used to be certain that Quinton understands what participation in the clinical trial means.

Directions:

Use the Research Study Assent Form Template on the following two pages to make a research study assent form for this clinical trial. To be certain that Quinton can read and understand the assent form, it should be written in an easy to read way.

Research Study Assent Form Template

What is a research study?

Research studies help us learn new things. We can test new ideas. First, we ask a question. Then we try to find the answer. This information sheet describes our research and the choice that you have to take part in it. We want you to ask us any questions that you have. You can ask questions any time.

Important things to know

- You get to decide if you want to take part in this study.
- If you don't want to be in the study, you don't have to be.
- It is also OK to say yes and change your mind later. You can stop being in the research at any time. If you want to stop, please tell the research doctors.
- You can ask questions any time. Ask us any questions you have. Take the time you need to make your choice.

Why are we doing this research?

We are doing this research to find out more about: _____

(Explain why you are doing this research)

What would happen if I join this research?

If you decide to be in the research, we would ask you to do the following things: _____

Create a list of items in age appropriate terms. Here are some examples:

- *Blood draws: You may need a needle poke so we could test some of your blood.*
- *Questions: We would ask you to read questions on a piece of paper. Then you would mark your answers on the paper.*
- *Talking: A person on the research team would ask you questions. Then you would say your answers out loud.*
- *Medical records: We will look at your past doctor visits and use information about your care.*
- *Others...please list*

Could bad things happen if I join this research?

Some of the tests might make you uncomfortable or the questions might be hard to answer. We will try to make sure that no bad things happen.

(List possible "bad things" that could occur)

Could the research help me?

(Include the most appropriate statement for your study)

We think being in this research may help you because _____.

Or...

This research will not help you. We do hope to learn something from this research though. And, someday we hope it will help other kids who have _____ like you do.

Modified from: <http://www.seattlechildrens.org/research/support-services/institutional-review-board/forms-and-policies/assent-consent-forms/>