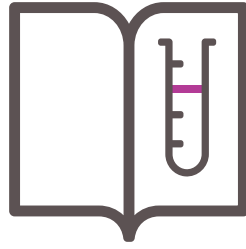




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# Enrolling in a Paediatric Clinical Study

An Information Guide for Pre-teens and Teens



## An Introduction for Pre-teens and Teens

Everyone knows that children and adults are different. Adults may be bigger, of course, so when they get sick they may need more medicine. But how much medicine is right for children and adolescents? It is hard to know because most medicines have not been tested on children your age.

Sometimes taking smaller amounts of medicine than grown-ups works pretty well for children. But children are still growing and their bodies are different. That is why the best way to find out how prescription drugs really work in *young people* is by testing them on *young people*. These tests are called **paediatric clinical studies or trials**.

Paediatric clinical studies for adolescents like you are important for several reasons:

- They can find out how much of the study drug you need so you do not receive too much (which can make you sick) or too little (which will not help you get better)
- Paediatric clinical studies may discover new drugs to treat illnesses in children and adolescents
- These studies may find study drugs that work especially well in children and adolescents

## The Clinical Study Team

Paediatric clinical studies are run by a group of doctors, nurses and other people who make up the clinical study team.

The clinical study team makes sure the study is right for you, performs medical tests, gives you the study drug, checks how well you are doing and makes certain the study is going smoothly and safely.

If at any time you have a question about the study, ask a member of the clinical study team for assistance. They will be happy to help you.



# Giving Informed Consent

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The Informed Consent Form (ICF) is a document intended to help your parents or caregivers understand a specific clinical study. This document guides them through what can be expected in the clinical study before anyone makes a decision about whether you will take part.

Your parents or caregivers can take as long as they need to read the ICF and make a decision. If they, together with you, decide to take part in the clinical study, your parents or caregivers will then be asked to sign the ICF to provide their informed consent. This means that they agree that you will have the necessary tests and take all the study drugs, and that you understand the good and bad things (the **benefits** and **risks**) that can happen in a study.



*The law requires that your parents or caregivers must give informed consent to protect your rights and ensure your safety as a patient in a paediatric clinical study. Please note that 16 to 17-year-olds do not need the parental consent that 12 to 15-year-olds do.*

Remember to talk to your parents or caregivers about any concerns or fears you may have. If you have any questions about the informed consent or the study itself, ask the clinical study team. If you would like the opportunity to read the informed consent, ask the clinical study team and it will be made available to you. They will be happy to answer all of your questions.



# Understanding Assent

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In some paediatric clinical studies, it is necessary for participants to give their **assent**. Assent is the child's or adolescent's agreement to participate in the study.

Depending on your age and the type of study being conducted, you may be asked to provide assent in addition to your parent's or caregiver's informed consent. This means that you will be asked to show your willingness to be in the study – and that you are not participating against your will because a parent, caregiver or member of the clinical study team wants you to. Please note that 16 to 17-year-olds do not need the parental consent that 12 to 15-year-olds do.

**Remember, it is important that you understand the procedures and are willing to take the study drug and take the tests, and that you understand the risks and benefits of a paediatric clinical study. Always discuss any concerns you might have with your parent, caregiver or member of the clinical study team.**



## During the Study

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After you enrol in a study, you will be asked to:



Take all of the study drugs that your doctor has requested

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Come to the study centre for all the office visits

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Complete the medical testing

There may also be other activities that are specific to the study.

## Keeping You Safe

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Government organisations around the world have established rules to make sure you are safe during a clinical study. These groups are made up of people who know a great deal about clinical studies and medical research. In addition, there are other scientists or doctors who check for problems that might occur during the study. These people have the power to stop the study if it is not going as planned. The purpose of these rules and regular supervision is to reduce the risks during the study.



*93% of clinical study participants said they would take part in another study and recommend participating to people they know.<sup>1</sup>*

## Benefits and Risks of Participating

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**Benefits and risks** are the good and bad things that might occur during a clinical study. Some of the good things are:



Information learned from this study may help other children in the future who get sick

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It can actively help you get well

At the same time, there is a possibility that something bad might happen. The study drugs you take may make you feel sick. These feelings are called **side effects**. And sometimes the study drug might not work very well. Ask your study doctor to explain known and potential side effects to you.



# Which Questions Should I Ask?

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Here is a list of some questions you and your parents or caregivers may wish to ask the clinical study team.

- Why is the clinical study being done?
- How long will the study last?
- What will I have to do?
- Will the study drugs make me feel sick?
- Will the study drugs help me get well?
- Which tests will I have?
- Will the tests or procedures hurt, and if so, for how long?
- Who will take care of me?
- Will participating in the study mean I will miss school?
- Can I talk to other people in the study?
- Can my friends come with me to my study visits?
- What is a 'placebo'? And will I receive it?
- What does 'randomisation' mean?



*Thank you for considering a clinical study.  
Advances come from working together.*



# Discussing the Clinical Study with Your Friends

Being diagnosed with any medical condition can be overwhelming. Participating in a clinical study as a part of your medical care can add another level of concern for you as well as for the people who care about you. Most likely, your family will be almost as involved in the clinical study as you are. But discussing your condition or your participation in a clinical study with your friends is a different matter.

It is up to you to decide whether or not you want to tell your friends about your participation in a clinical study. Most people need and want to talk to their friends when they find themselves in this kind of situation. Sometimes, telling those close to you helps you understand more deeply what is happening. Some people find that by talking to others, they begin to solve problems and think about other issues as their friends ask questions. When you talk to them, you may want to write down the questions that come up so that you can discuss them with the clinical study team.



*The following points may help you prepare for discussions with friends.*

### **Understand your feelings:**

Think about how much information you want to share. You may decide to explain what a clinical study is and why you are participating. It is normal for your friends to have a lot of questions – and you can answer them if you are comfortable doing so.

You may also choose to talk about the clinical study with only one or two close friends. It might be tiring to explain the details to a lot of different people. You should also know what you do *not* want to discuss with your friends – things that are too personal to talk about with anyone besides your family or doctor. Think about an appropriate response when asked questions you do not feel comfortable answering.

### **Allow your friends to help:**

When you tell others that you have a medical condition and that you are participating in a clinical study, they will probably ask, “How can I help?”. You may want your privacy, but keep in mind that your friends care about you and really do want to help. It is okay to allow others to help you – even if it is just to listen, to come with you to an appointment, or even just to relax or to do a fun activity with you.

### **Keep things as normal as possible:**

During your participation in the clinical study, allow yourself, your family and your friends to keep life as normal as possible.

Encourage your friends to keep doing the things they have always done with you – like sending messages and hanging out. People of all ages find it helpful to stick to a routine.

