An Introduction for Pre-teens and Teens

Everyone knows that kids and grownups are different. Adults are bigger, of course, so when they get sick they 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 kids your age. Sometimes taking smaller amounts of medicine than grown-ups works pretty well for children. But they 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 pediatric clinical studies.

Pediatric clinical studies for children and adolescents like you are important for several reasons:

- They can find out how much medicine you need so you do not receive too much (which can make you sick) or too little (which will not help you get better)
- Pediatric clinical studies can discover new drugs to treat illnesses that develop primarily in children and adolescents
- These studies can find medicines that work especially well in children and adolescents in the future
- They can identify ways to prevent you from becoming sick in the first place
The Clinical Study Team

Pediatric clinical studies are run by a group of doctors, nurses, and other people ("men and women in white coats") 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 medication, 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

Before beginning a pediatric clinical study, your parents or caregivers must give their informed consent. This means that they agree that you will have the necessary tests, take all of the medicines, and understand the good and bad things (the benefits and risks) that can happen in a study.

*The reason your parents or caregivers must give informed consent is to help protect your rights as a participant in a pediatric clinical study.*

Remember to talk with your parents or caregivers. Express any concerns or fears you may have with them. If you have any questions about the informed consent or the study itself, ask the clinical study team. They will be happy to answer all of your questions before you and your parents or caregivers agree to participate.
Understanding Assent

In some pediatric clinical studies, it is necessary for participants to give their assent. Assent is the child’s or adolescent’s affirmative 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.

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

If you and your parents or caregivers decide to participate, you will be asked to:

- Take all of the study medications that your doctor requested
- Come in for all of the office visits
- Complete the medical testing

Also, there may be other activities that are specific to the study.

Keeping You Safe

Governmental organizations around the world have established rules to help make sure you are safe during a pediatric 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 help minimize the risks during the study.
Benefits and Risks of Participating

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

- Getting an investigational medication for your illness that is not yet available to others
- Actively helping yourself get well

At the same time, there is a possibility that something bad might happen. The study medications you take may make you feel sick. These feelings are called side effects. And sometimes the new study drug might not work very well.

*Keep in mind that by participating in the study, you can play a big part in helping scientists find new drugs, vaccines, and other medical therapies that may help kids in the future who get sick. In other words, you are a key part of a very important scientific process.*
What Questions Should I Ask?

Here is a list of questions you may wish to ask the clinical study team. They will be happy to discuss them with you and your parents or caregivers.

- Why is the clinical study being done?
- How long will the study last?
- What will I have to do?
- What are the possible side effects of the study drug?
- What tests will I have?
- Will they 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?
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 treatment can add another level of concern for you as well as for the people you care about. 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 more deeply understand 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. As you talk with them, you may want to write down the questions that come up so that you can discuss them with the clinical study team.
If you decide to talk with your friends about your decision to participate in a clinical study, you may want to consider the following:

**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 also may 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 listen to music with you. Remember, allowing others to help lets them know they are useful—and an important part of your life.
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 always did with you—like sending e-mails, hanging out after school, going to the movies—without feeling guilty. People of all ages tend to find it beneficial to stick to a routine.