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Enrolling in a Pediatric Clinical Research Study:

An Information Guide for Pre-teens and Teens

An Introduction for Pre-teens and Teens

Everyone knows that kids and grown-ups are different. But how much medicine is right for children and adolescents? It is hard to know because most medicines have not been tested for kids your age. Sometimes kids need the same amount of medicine as adults. For some medicines, taking smaller amounts than grown-ups works better for children. The best way to find out how prescription drugs really work in young people is by testing them in young people. These tests are called pediatric clinical studies.

Pediatric clinical studies for children and adolescents like you are important for several reasons: These studies 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 happen in children and adolescents. These studies can find medicines that work especially well in children and adolescents. Sometimes these studies can identify ways to prevent you from becoming sick in the first place. Often, clinical studies help decide what is the best treatment for the kids participating in the study. And, then doctors know which medicines might be the best for other kids if they have the same illness.

The Clinical Study Team

Pediatric 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 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 legal guardian must give their permission for you to participate in the study. Another term for permission is "informed consent." This means that they agree that you will have the necessary tests, take all the medicines, and understand the good and bad things 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 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 *your* agreement to participate in the study. 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 the study medications that your doctor requested
- Come in for all the office visits
- Complete the medical testing

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

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 who care about you.

Discussing your condition or your participation in a clinical study with your friends is something to think about and discuss with your family. Your medical information and your decisions are very personal. If you and your family agree to share information with others, then your doctors, nurses, and others on the team can help with how to share this information.

Benefits and Risks of Participating

You may get a new, investigational medicine for a disease before it is available to everyone.

Benefits and risks are the good and bad things that might occur during a pediatric clinical study. By participating in the study, you can play a big part in helping scientists find new treatments that may help you and may help other kids in the future who get sick. In other words, you are a key part of a very important scientific process.

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 Things as Fulfilling as Possible

During your participation in the clinical study, allow yourself, your family, and your friends to keep life as fulfilling as possible. Speak to the study team about any activities that you should change or put on hold while in the study. Make sure you discuss if the study will impact your school schedule and other activities. And continue to do the things you enjoy as much as you can while still being safe.

Keeping You Safe

Your doctors and team must follow rules to help make sure you are safe during a pediatric clinical study. Also, there are other scientists or doctors who check for problems that might occur during the study. These people will be able 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. The most important thing is to keep you safe.

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Thank you
for considering a clinical trial