Informed Consent: Your rights are protected.

Choosing to volunteer in a cystic fibrosis study is a personal decision. Through a process called “informed consent” people with CF and their families can find out all the information they need, get answers to their questions and learn key facts about a clinical study.

Clinical trials, the type of quantifiable studies that tests potential drugs and therapies in people with CF, are a major part of CF research. These trials help researchers understand how potential treatments work in people with CF and whether they are safe and effective.

The informed consent conversation can help you better understand the clinical trial if you decide to volunteer. You’re entitled and you’re truly welcome to ask the research team any questions and you can speak directly with the CF clinician.

Your Rights Are Protected

It is your right to know everything about your or your child's role in a clinical trial. To help you make a decision about participating in a CF trial, the research team will first discuss a potential trial with you. If you are interested in receiving more information, the team will give you an informed consent form that explains the clinical trial in greater detail.

Every clinical trial is different. The informed consent form will include information about the specific trial you are considering, including the trial's purpose, how long it will last, and the responsibilities of participants.

The consent form will also explain possible benefits and risks.

A parent or legal guardian will need to give permission for a child under 18 years old to participate in a clinical trial. Children usually must give their own assent as well. The assent form explains the trial in language that is appropriate to your child's age. This clear understanding is important because asking for their assent allows children and adolescents to play a decision-making role in their health care.

Informed consent is more than signing a form. It's a learning process that continues throughout the clinical trial. Occasionally, new information becomes available, or changes are made to the study that may affect your decision to participate. Should this happen it is your right to be notified and you will receive a new informed consent form. If you wish to continue in the trial, you will be asked to review and sign this new form after all your questions are answered.

What to Expect During the Informed Consent Discussion

The leader of the CF research team will start the informed consent discussion by giving you information about the trial and addressing any questions or concerns you have. This team leader will

usually be a principal investigator, usually a CF medical specialist or the trial's research coordinator. A team member on staff who assists in conducting the clinical trial will also join the principal investigator.

Next, the research team will carefully go through the informed consent form with you and explain how the information relates to the clinical trial in which you are interested.

You can take the informed consent form home to give yourself more time to fully consider everything that goes into the clinical trial.

When you feel comfortable that your questions have been answered, the research team will have you sign and date the informed consent form, showing that you fully understand the trial. Your signature indicates that you wish to volunteer or give permission for your child to participate.

And let's reiterate this because it's important - an informed consent form is not a contract. You can stop participating in a clinical trial at any time. If you decide that a particular trial is not a good fit for you or your child, your decision will not affect the care you receive at your CF care centre.

Tips to Help You Prepare

Before the clinical trial begins, you will meet one of the study's investigators or research coordinator to learn more about the trial. Here are some tips to help you prepare:

- Carefully read the information and consent form.
- Write down your questions ahead of time and bring them to the meeting.
- Bring a family member or friend to help you feel more comfortable when talking with the trial doctor or research coordinator. They may ask other questions that will help you as you decide.

The informed consent process will help you judge whether a CF study is right for you or your child. Use these tips to help you begin talking with your CF care team about the clinical trials you are interested in.

Also please remember that the informed consent process will continue when you are enrolled in a clinical trial. The trial team will keep you informed, and you should always feel free to ask questions.