CYSTIC FIBROSIS FOUNDATION
ADDING TOMORROWS

Informed Consent

Get key facts about volunteering for a CF clinical trial.

The informed consent conversation will help you better understand the clinical trial and your role as a CF clinical trial volunteer. Feel free at any time to ask the research team questions or request to speak directly with the CF doctor.

Clinical trials that test potential drugs and therapies in people with cystic fibrosis 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.

Choosing to volunteer in a CF clinical trial is a personal decision, and people often have questions about what they can expect. 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 trial.

This guide explains the informed consent process to help you begin the conversation with your CF care team about taking part in a clinical trial.

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 clinical 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 the trial volunteer. 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 must also give their own **assent.** The assent form will explain the trial in language that is appropriate to the child's age. Giving 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 clinical trial 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 (or **principal investigator,** usually a CF doctor) or the trial's **research coordinator** will start the informed consent discussion by giving you information about the trial and addressing any questions or concerns you have. Next, the research team will carefully go through the Informed Consent Form with you and explain how the information relates to the clinical trial you are interested in.

You can take the Informed Consent Form home with you to give yourself more time to read about and consider the clinical trial.

I AM THE KEY

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BETHESDA, MD 20814

When you are ready and 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.

Remember: 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 center.

Tips to Help You Prepare

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

- Write down your questions ahead of time and bring them to the meeting. See some suggestions below.
- Bring a family member or friend to help you feel more comfortable when talking with the CF doctor or research coordinator. They may ask other questions that will help you as you decide.
- Bring a recording device or use your cell phone to record the conversation so you can listen to it later.

Start the Conversation

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

Remember: 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.

Questions to Ask the CF Research Team

- What is the purpose of the clinical trial?
- Why do researchers think that this particular CF drug or treatment might work?
- Who will be in charge of my or my child's care?
- Will the trial benefit me or others? What kinds of tests are involved?
- Do I need to stop any of my current CF medications?
- How do the possible risks, side effects and benefits compare with my current treatment?
- Will I be paid for my participation in the clinical trial and/or travel expenses?
- Will results of the clinical trial be given to me and, if so, when?
- Who should I communicate with during the trial: the research team, my CF care team or both?

Learn More

Cystic Fibrosis Foundation

- Hear from researchers and study volunteers about participating in a CF clinical trial: **www.cff.org/LivingWithCF/Webcasts/ArchivedWebcasts/Research**
- Read frequently asked questions about clinical trials: **www.cff.org/research/ClinicalResearch/FAQs**

National Institutes of Health

- Search for clinical trials: **www.clinicaltrials.gov**
- Learn more about children and clinical research: **www.nhlbi.nih.gov/childrenandclinicalstudies**

"We decided to enroll our daughter in a CF clinical trial after our doctors and nurses explained what to expect on a daily and monthly basis."

— Tracy, mother of Quinn, 11, who has CF