

Considering Clinical Trials

Clinical trials are research studies that may help improve outcomes (results) for patients. They may also offer treatment options that are not widely available yet. Clinical trials may also help doctors make important discoveries.

THIS FACT SHEET TELLS YOU:

- What clinical trials are
- Your rights and safety in a clinical trial
- Resources to find a clinical trial and help pay for costs

WHAT IS A CLINICAL TRIAL?

A clinical trial is a way to gather information about:

- How well a new treatment or test works
- How well a new treatment works compared to an old one
- What the side effects are and how to manage them
- How well you can do your daily tasks during or after treatment (quality of life)

When a medicine or treatment is part of a clinical trial it doesn't always mean it's unproven or has never been tested, but in some cases that may be true.

Clinical trials may:

- See if a known medicine used to treat one disease works well to treat another
- Study the safety and side effects of a new graft-versus-host disease (GVHD) treatment
- Compare 2 different but well-known ways to do transplant
- Find out if genetic testing can help doctors decide the best way to treat disease

ARE CLINICAL TRIALS SAFE?

All clinical trials in the U.S. must follow strict rules to keep patients safe. They're all checked by the Office for Human Research Protections (OHRP). Sometimes they're also checked by the Food and Drug Administration (FDA).

An Institutional Review Board (IRB) at each hospital or clinic watches each clinical trial closely. The IRB reviews the trial to make sure that it's ethical (the expected benefit outweighs the potential risks) and that the people who join the trial are protected.

Researchers report to the OHRP, FDA, IRB and Data and Safety Monitoring Board (DSMB) throughout the trial. The trial can be shut down at any time to protect the people in it. They will stop the trial if any unexpected risks are found, such as dangerous side effects.

The FDA and the OHRP also make sure patients understand what will happen in a clinical trial and give informed consent before starting.

Joining a clinical trial is never required. If you're uncomfortable joining one, tell your doctor. Your doctor and health care team will take good care of you whether or not you decide to participate in a clinical trial.

FIND A CLINICAL TRIAL

Your transplant doctor can tell you if you're eligible to join a clinical trial at your hospital.

The **Jason Carter Clinical Trials Program** offered by Be The Match® can also help you find a trial. This **free** program provides one-on-one support and a simple web-based search tool.

- **Call:** 1 (888) 814-8610
- **Email:** ClinicalTrials@jcctp.org
- **Visit:** JCCTP.org

JOINING A CLINICAL TRIAL

For any clinical trial, you will have an informed consent meeting with the study doctor or nurse. Informed consent means that you have been told about and understand the risks and benefits of the trial before you agree to be in it. You will never be part of a clinical trial without your signed agreement to participate.

If you'd like to join a clinical trial, your doctor or research nurse will tell you:

- What they are trying to learn (purpose of the study)
- What the treatment and tests are
- The risks and benefits to you
- Other treatment options available to you
- Your rights as a patient

Make sure you ask questions so you understand the clinical trial process. Ask which treatments in the clinical trial are standard and which parts are new and unproven.

PAYING FOR CLINICAL TRIALS

If you participate in an approved clinical trial, the law requires most insurance companies to pay for costs related to your regular care (patient care costs). These costs include your regular visits to the doctor, hospital stays, X-rays and lab tests.

Your insurance may not cover costs specific to the clinical trial. These may include the cost of the study drug, additional X-rays and lab tests done only for the study.

The financial coordinator at your hospital or clinic can help you figure out what costs your insurance will cover and which ones they don't. They can also help you find financial aid grants to help with the costs.

TRAVEL COSTS

You may have to travel to a different hospital or clinic to join a clinical trial. If you're concerned about the cost of travel to join a trial, you may qualify for financial assistance from the Drs. Jeffrey and Isabel Chell Clinical Trials Travel Grant. You can learn more about the grant at JCCTP.org.

RESOURCES TO LEARN MORE

Be The Match has a variety of free resources to help you. Visit BeTheMatch.org/request and choose the resources that best meet your needs.



AT EVERY STEP, WE'RE **HERE TO HELP**

Be The Match has a team dedicated to providing information and support to you before, during, and after transplant. You can contact our Patient Support Center to ask questions you may have about transplant, request professional or peer support, or receive free patient education materials.

CALL: **1 (888) 999-6743** | EMAIL: patientinfo@nmdp.org | WEB: BeTheMatch.org/one-on-one



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Every individual's medical situation, transplant experience, and recovery is unique. You should always consult with your own transplant team or family doctor regarding your situation. This information is not intended to replace, and should not replace, a doctor's medical judgment or advice.