CLINICAL TRIALS HELP US FIND CURES

WHO WE ARE

The Mended Hearts, Inc. (MHI) is the largest cardiovascular disease peer support non-profit organization in the United States. With its three main programs, Mended Hearts®, Mended *Little* Hearts® and Young Mended Hearts®, MHI provides hope and support to patients with cardiovascular disease across the lifespan.

Our volunteers inspire, educate, and empower hundreds of thousands of patients and family members each year. When you need us the most, we are there.

The Mended Hearts, Inc.

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CLINICAL TRIALS

WHAT DO I NEED TO KNOW ABOUT PARTICIPATING IN A CLINICAL TRIAL?

LEADING THE WAY

Advancing Innovation Through Clinical Trial Education

The Mended Hearts, Inc.

THINGS TO KNOW

If you have agreed to participate in a clinical trial, you are helping advance research and find cures for people living with cardiovascular disease. Thank you!

However, before you get started, be sure you know what to expect and what your rights and responsibilities are. This guide will help you be prepared.

INFORMED CONSENT

Most studies have consent forms that describe the study, the goal of the research, what is involved, and who to contact with questions, concerns or if you want to stop participating. Be sure someone from the clinical trial research team goes over the form in detail so you understand and can get your questions answered. Informed consent can only happen when you **fully understand and agree**.

RANDOMIZATION

In many clinical trials, participants will be put into groups to compare them. This is called randomization. Sometimes one group will get a new procedure, device or drug and others will get the existing one or "**standard of care**." Other times a group, called the "**control group**," will get a **placebo**—a harmless drug, device or procedure—and they do not know if it is the real one or not during the study. In randomization many times no one knows which group the participants are in until after the trial, including the researchers.

LENGTH OF TRIAL

Be sure you know how long the study lasts. Some have different phases with different requirements at each phase.

TESTS AND PROCEDURES

Be sure you understand what tests and procedures are required during the clinical trial and where and when they will be done. Some studies require more involved tests, like blood tests, echocardiograms, EKGs, MRIs, CT scans, etc. that may require hospitalization. Others require the participant to answer certain questions and speak with someone on the research team. Ask questions until you fully understand what tests and procedures you will need to have.

TRAVEL

Some clinical trials require travel for tests and procedures. Ask:

- What travel is required?
- Can I have the tests or procedures near me?
- How often will I travel?
- How long will I need to stay?
- What costs are involved?
- What is reimbursed?

COSTS

There is no cost to participate in most clinical trials, and some expenses may even be reimbursed. Also, patients do not pay for trial medication, devices or other treatment. Ask about costs.

REPORTING

Most people want to know the results of the trial they participate in. Result reporting may be affected by:

- enrollment is slower than anticipated
- need for more data analysis or information
- FDA approval of drug, device or procedure is pending

Be sure to ask how and when you can get information on the clinical trial results.

RESEARCH TEAM

- **Who is the principal investigator leading the clinical trial?**
- **Who is the trial coordinator?**
- **Who do I contact if I have questions or concerns?**
- **What is the name of the hospital, clinic or practice where the trial takes place?**

If you have an emergency relating to the trial, please call 911.

PARTICIPATION

In a survey by National Institutes of Health about clinical trial awareness:

85%
didn't know a clinical trial was an option at diagnosis

75%
would have been willing to enroll, if available

MORE INFORMATION CAN BE FOUND AT: CLINICALTRIALS.GOV