WHO WE ARE
Mended Hearts is the largest cardiovascular peer-to-peer support non-profit organization in the United States. Along with its program, Mended Little Hearts, Mended Hearts is the only organization in the nation that supports cardiovascular disease patients and their families throughout the entire lifespan of the patient.

Our volunteers inspire, educate, and provide hope to hundreds of thousands of patients and family members each year. We are a trusted source of patient and family education on living with heart disease.

CLINICAL TRIALS HELP US FIND CURES

CONTACT US
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What do I need to know about participating in a clinical trial?
In many clinical trials, participants will be put into groups to compare the groups. Sometimes one group will get a new procedure, device or drug and others will get the existing “standard of care.” Other times the other 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. When people are put into groups randomly, this is called “randomization.”

Most studies have consent forms that describe the study, the goal of the research, what is involved for you, and who you can contact with questions, concerns or if you want to stop participating. Usually, someone from the clinical trial research team will go over it in detail as well so you understand and can get your questions answered. When you fully understand and agree to participate, this is called “informed consent.”

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

However, before you get started, be sure to know what to expect and what your rights and responsibilities are.

**TESTS AND PROCEDURES**

Be clear about what tests and procedures are required during the clinical trial and where and when they will need to happen. 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 so 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 do some tests or procedures near me?
- How often will I travel?
- How long will I need to stay?
- What costs are involved?
- What is reimbursed?

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

**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.

**REPORTING**

Most people want to know the results of the trial they participate in. Result reporting may be affected by:
- enrollment slower than anticipated
- need for more data analysis
- more information needed
- FDA approval of drug, device or procedure pending

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

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]