

Key Questions to Ask Before Participating in a Clinical Trial

1. What is the main purpose of this study?
2. Does the study involve a placebo or a treatment that is already on the market?
3. How will the treatment be given to me?
4. How long is the study going to last and what will I be asked to do as a participant?
5. What has been learned about the study treatment and are any study results published?
6. Do I have to pay for any part of the study? Will my insurance cover these costs?
7. Is there any reimbursement for travel costs?
8. Will I be able to see my own doctor?
9. If the treatment works for me, can I keep using it after the study?
10. Can anyone find out whether I'm participating in the clinical trial?
11. Will I receive any follow-up care after the study has ended?
12. What will happen to my medical care if I stop participating in the study?
13. Does the physician/investigator have any financial or special interest in the clinical study?
14. What are the credentials and research experience of the physician and study staff?



Resources

General

CISCRP - a non profit dedicated to educating and informing the public about clinical research participation.
www.ciscrp.org • 1-877 MED HERO

Search Clinical Trials - Public service that compiles clinical trial listings from multiple sources. You can also request a free search for clinical trials in your area.
www.searchclinicaltrials.org • 1-877 MED HERO

Acurian - Clinical research information
www.acurian.com • 1-866-566-5966

CenterWatch - Clinical research information & Listing service
www.centerwatch.com • 1-866-219-3440

PhRMA Clinical Study Results Database
www.clinicalstudyresults.org

Government

AIDS Clinical Trials Information Service - English and Spanish
www.aidsinfo.nih.gov • 1-800-448-0440

ClinicalTrials.gov - English and Spanish
www.clinicaltrials.gov • 1-800-411-1222

Food and Drug Administration (FDA)
www.fda.gov • 1-888-INFO-FDA (1-888-463-6332)

Healthfinder - English and Spanish
www.healthfinder.gov

The National Cancer Institute (NCI) - English and Spanish
www.cancer.gov • 1-800-4-CANCER

National Institutes of Health (NIH) - English and Spanish
www.nih.gov • 1-301-496-4000

Disease specific

American Cancer Society (ACS) - English and Spanish
www.cancer.org • 1-800-227-2345

American Diabetes Association - English and Spanish
www.diabetes.org • 1-800-342-2383

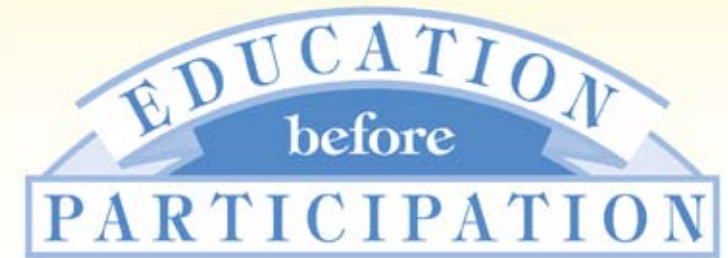
American Lung Association - English and Spanish
www.lungusa.org • 1-800-586-4872

Alzheimer's Association
www.alz.org • 1-800-272-3900

Arthritis Foundation
www.arthritis.org • 1-800-283-7800

National Multiple Sclerosis Society - English and Spanish
www.nationalmssociety.org • 1-800-344-4867

Parkinson's Disease Foundation
www.pdf.org • 1-800-457-6676



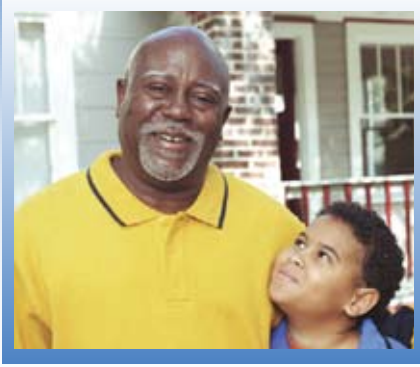
Helping you make an informed decision about clinical research participation.



CISCRP is an independent non-profit organization founded for the purpose of educating the public, patients, media, and policy makers in order to promote greater understanding and awareness of clinical research participation and the role it plays in public health.



1-877-MED HERO • www.ciscrp.org



How Volunteers are Protected

- To protect the rights and welfare of clinical research participants, U.S. Federal Agencies including the Food and Drug Administration (FDA) & the National Institutes of Health (NIH) oversee much of the medical research in the U.S.
- Institutional Review Boards (IRBs) oversee the centers where clinical research studies are conducted. IRBs review and approve study protocols to ensure that a clinical trial is ethical and that volunteers' rights are protected.
- A participant in a clinical trial has access to the IRB that is overseeing the research and access to a volunteer advocate, the physician and staff conducting the trial.
- Federal agencies inspect individuals and institutions conducting research. They also inspect IRBs.
- Some IRBs are accredited much like hospitals can be "accredited" and some research investigators and staff are "certified" as research professionals.

CISCRP is not involved in recruiting patients for clinical trials nor is it involved in conducting clinical trials.

About Clinical Trials

What are clinical trials?

- A research study involving human volunteers to answer specific health questions.
- Carefully conducted clinical trials are the safest and fastest way to find treatment that work in people and new ways to improve health.
- Clinical trials are conducted according to a plan called a protocol.
- A protocol describes what types of patients may enter the study; schedules of tests and procedures, drugs, dosages, and length of study, as well as outcomes that will be measured.
- Each person participating in the study must agree to follow the protocol.

Why are clinical trials conducted?

- To see if a new drug or device is safe and effective for people to use.
- To compare existing treatments to determine which is better.
- To study different ways to use standard (approved) treatments, so they will be more effective, easier to use, and/or decrease side effects.
- To learn how to best use the treatment in a different population, such as children, in whom the treatment was not previously tested.

What are some of the possible benefits of my participation?

- Gain access to potentially new research treatments.
- Receive expert medical care for the condition being studied, since investigators are often specialists in the disease area being studied.
- Help others by contributing to medical research and treatment advances.

What are some of the possible risks of my participation?

- There may be unpleasant, serious, or even life-threatening side effects resulting from the treatment.
- The treatment may not be effective.
- Participation in the trial may be demanding and time consuming.

For answers to additional questions, visit our Web site at www.MedHero.org or call 1-877 MED HERO.



CISCRP – helping you to make an informed choice.