

# SHOULD I PARTICIPATE?

Make an informed decision about clinical trial participation



## About Clinical Trials

### What is a clinical trial?

A clinical trial is a research study involving human volunteers that tries to answer a specific health question. Clinical trials closely monitor people's progress as they take part in the study of an investigational drug, device or method of treatment that has not been approved by the FDA.

Carefully conducted clinical trials are the safest and fastest way to find treatments that work.

A clinical trial is conducted according to a plan called a **protocol**, which describes the types of patients who may enter the trial and the schedules of tests and procedures.

Each person participating in the clinical trial must agree, in writing, to follow the protocol—this is called giving **informed consent**. It is important for volunteers to fully understand all of the information in the protocol before providing informed consent.

Also, participating in a clinical trial is voluntary. Participants may choose to stop participating for any reason, at any time.

### Why are clinical trials conducted?

Clinical trials study potentially new or improved treatment options. They are conducted to determine:

- If a new drug or device is safe and effective for people to use.
- How the potentially new treatment compares to existing treatments.
- Different ways to use existing treatments so they will be more effective, easier to use, or have fewer side effects.
- How to best use the treatment in a different population, such as children, in whom the treatment was not previously tested.

### What are some possible benefits of my participation?

The investigational treatment studied in a clinical trial may or may not benefit you personally. The benefits of participating in a clinical trial include:

- Gaining access to cutting-edge research.
- Receiving expert medical care for the condition being studied, since doctors conducting clinical trials are often specialists in the disease areas being studied.
- Helping patients like you by contributing to medical research and treatment advances.

### What are some possible risks of my participation?

There may be some risks associated with participating. Possible risks of participating include:

- Clinical trials study investigational treatments, therefore some information about the treatments are unknown.
- The investigational treatment you receive may not be effective, or may cause unpleasant, serious or even life-threatening side effects.
- Participating in a clinical trial may require a big time commitment.

# How Volunteers Are Protected

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To protect the rights and welfare of clinical trial participants, US federal agencies, including the **Food and Drug Administration (FDA)** and the **National Institutes of Health (NIH)**, oversee much of the medical research in the US.

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**Federal agencies** inspect individuals and institutions conducting clinical trials.

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**Institutional Review Boards (IRBs)** oversee the centers where clinical trials take place. IRBs review and approve protocols to make sure that clinical trials are ethical and that volunteers' rights are protected. They, too, are inspected by federal agencies.

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Also, **Some IRBs** are accredited, much like hospitals can be accredited, and some research doctors and staff are certified as research professionals.

## What to Ask Before Participating in a Clinical Trial

- What is the main purpose of this clinical trial?
  - Does the clinical trial involve a placebo or a treatment that is already on the market?
  - How will the treatment be given to me?
  - How long is the clinical trial going to last and what will I be asked to do as a participant?
  - What has been learned about the treatment used in the clinical trial and have any results been published?
  - Do I have to pay for any part of the clinical trial? Will my insurance cover these costs?
  - Is there any reimbursement for travel or other costs?
  - Will I be able to see my own doctor?
  - What will happen if I am injured during the clinical trial?
  - If the treatment works for me, can I keep using it after the clinical trial?
  - Can anyone find out if I'm participating in the clinical trial?
  - Will I receive any follow-up care after the clinical trial has ended?
  - What will happen to my medical care if I stop participating in the clinical trial?
  - What is the research experience of the doctor and clinical trial staff?
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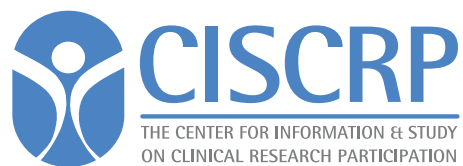
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CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process through education and outreach programs. CISCRP services also assist clinical research stakeholders in understanding public and patient attitudes & experiences in research to improve patient satisfaction. *CISCRP is not involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.*

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