Participant Bill of Rights

What you need to know
before participating

How am I protected in a clinical trial?

All clinical trials must follow federal laws and ethical guidelines.

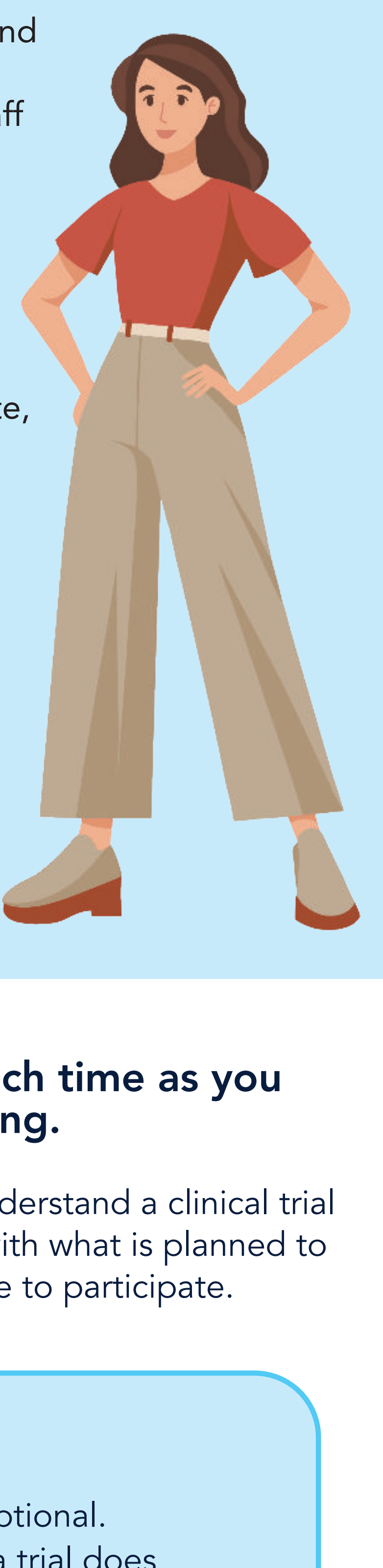
Trials must also be approved by an expert group called an institutional review board (IRB) that helps make sure the trial is fair and as safe as possible, and that any risks to the participants are worth the potential benefits.

Every trial must also have a protocol, which is the overall plan for the trial that includes instructions that the doctors and staff doing the trial must follow. This protocol must be approved by an IRB.

Your Rights

Anyone who is thinking about giving consent to participate in clinical research or giving consent on behalf of someone else has the following rights:

1. To be told the purpose of the clinical trial or study
2. To be told all the potential risks, side effects, or discomforts
3. To be told of any potential benefits
4. To be told what will happen in the trial, including treatments they might get and what procedures might happen
5. To be told if any procedures, treatments, or devices are different than those that are used as standard medical treatment
6. To know how long a trial is expected to last
7. To be told about all options available and how they may be better or worse than being in a clinical trial
8. To receive materials in the language they prefer and to ask for an interpreter
9. To ask any questions about the trial before giving consent and at any time during the trial
10. To be told of any medical treatments available if medical problems occur during the trial
11. To be told about any potential costs or payments
12. To bring a trusted friend or family member to meetings with trial staff
13. To receive a signed and dated copy of the informed consent form
14. To refuse to participate, for any reason and at any time, before and after the trial starts
15. To take their time deciding whether or not to participate



You can take as much time as you need before deciding.

It is very important to understand a clinical trial and to be comfortable with what is planned to happen before you agree to participate.

Remember:

- Being in a trial is optional.
- Agreeing to be in a trial does not take away any of your rights.
- You can stop being in a trial at any time and for any reason.
- You can talk to the trial staff or the IRB anytime you have concerns about being harmed.

For answers to additional questions, visit our website at CISCRP.org or call 1 877 MED HERO.

Additional Resources

Search Clinical Trials
CISCRP's free service designed to help people find clinical trials. Our staff will search clinical trial listings and provide you with the contact information for research studies by email.
searchclinicaltrials.org

CISCRP Education Center
Discover videos, brochures, frequently asked questions, and other information about clinical trials.
ciscrp.org/educationcenter

A panel of patients, professionals, and members of the public reviewed this educational brochure.

CISCRP is an independent non-profit organization dedicated to engaging the public and patients as partners in the clinical research process.

CISCRP does not recruit patients for clinical trials and does not conduct clinical research. CISCRP is also known as the Center for Information and Study on Clinical Research Participation.

Visit www.CISCRP.org or call toll free 1-877-633-4376

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