How Volunteers Are Protected

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.

Federal agencies inspect individuals and institutions conducting clinical trials.

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.

Also, Some IRBs are accredited, much like hospitals can be accredited, and some research doctors 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.
Your Rights

Any volunteer who gives his or her consent to participate in a clinical trial or who is asked to give his or her consent on behalf of another has the following rights:

1. To be told the purpose of the clinical trial.

2. To be told all the risks, side effects, or discomforts that might be reasonably expected.

3. To be told of any benefits that can be reasonably expected.

4. To be told what will happen in the study and whether any procedures, drugs, or devices are different than those that are used as standard medical treatment.

5. To be told about options available and how they may be better or worse than being in a clinical trial.

For answers to additional questions, visit our web site at www.CISCRP.org or call 1-877-MED-HERO.
6. To be allowed to ask any questions about the trial before giving consent and at any time during the course of the study.

7. To be allowed ample time, without pressure, to decide whether to consent or not to consent to participate.

8. To be told of any medical treatments available if complications occur during the trial.

9. To receive a signed and dated copy of the informed consent form.

10. To refuse to participate, for any reason, before and after the trial has started.

GENERAL RESOURCES

**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

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

**ClinicalTrials.gov**
English & Spanish | www.clinicaltrials.gov | 1-800-411-1222

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

**National Institutes of Health (NIH)** English & Spanish
www.nih.gov | 1-301-496-4000

**ResearchMatch** | www.researchmatch.org

Visit [CISCRP.org](http://CISCRP.org) for more information, including disease and condition specific resources.

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**“Education Before Participation”**

“Participant Bill of Rights” is part of CISCRP’s Education Before Participation resource series. An editorial panel of patients, public and professional representatives has 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 through education and outreach programs. CISCRP services also assist clinical research stakeholders in understanding public and patient attitudes and experiences in research to improve study volunteer participation. CISCRP is neither involved in recruiting patients for clinical trials, nor is it involved in conducting clinical trials.

One Liberty Square, Suite 1100, Boston, MA 02109
Visit www.CISCRP.org or call toll free 1-877-633-4376

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