FOR PARTICIPANTS AND FAMILIES

Understanding Clinical Trials: A Plain-Language Guide for Participants and Families

What a clinical trial is, what consent means, and the rights you keep the whole way through.

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> **Please read this first.** This guide is for learning only. It is not medical advice. It does not help you find or join a study, and it does not tell you whether to take part. For decisions about your health or a specific study, talk with your own doctor and the study team.

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1. What a clinical trial is

A clinical trial is a planned research study with people. It is designed to answer one clear question that no one knows the answer to yet.

A trial is research, not routine care. Its purpose is to find an answer.

Every trial has a written plan, called the protocol. It says what the study is asking, who can take part, what happens at each visit, and how the results will be judged.

An independent ethics committee, sometimes called an IRB, reviews the study to help protect the people who take part.

Many studies of new treatments move through steps called phases. Early phases mostly look at safety and dose in a small number of people. Later phases include more people and compare the new treatment with a current treatment or a placebo.

The phase describes the stage of the research. It does not tell you whether a study is right for you.

2. Informed consent

Informed consent is a conversation, not just a form. The form is a record that the conversation happened. The real thing is the understanding you build with the study team, before you decide and all the way through the study.

Before you decide, the team should explain:

- why the study is being done and what it is trying to find out
- what would happen to you, and for how long
- the possible risks and discomforts
- the possible benefits, if any
- other choices you have if you do not take part
- how your information is kept private
- who to contact with questions, and about your rights
- that taking part is your choice, and you can stop at any time

The team should use plain words, in a language you understand. You can ask them to slow down, repeat, or explain in a different way.

You do not have to decide the same day. You can take the form home, read it slowly, and talk it over with your family or your own doctor.

If something important changes during the study, the team should tell you and ask again whether you still want to take part.

When the participant is a child, the parent or guardian gives permission. The child is also asked, in words that suit their age, whether they agree. This is called assent.

3. Randomization and placebo

Randomization means a computer decides, by chance, which group each person joins. It is like flipping a coin. This keeps the groups alike, so the comparison is fair.

A placebo looks like the treatment but has no active medicine in it. Comparing the two helps show whether the treatment itself makes a difference.

Many studies are blinded. That means you, and sometimes the team, do not know which group you are in, so that expectations do not affect the results. You can ask the team whether, and when, you will be told which group you were in.

You cannot choose your group. That is the point of randomization. But you can always choose whether to take part at all.

Ethics rules limit when a placebo may be used. The consent should explain what each group receives and the chance of being placed in each group. Ask the team to explain every group until it is clear.

4. Risks and benefits

Any study can carry some risk. Some risks are known before the study starts. Others may not be known yet. The consent process should explain the risks that can reasonably be expected, and may also tell you that some risks are not yet known.

A study may or may not help you. Some studies are not expected to help the people in them directly. If so, the consent should say so.

An adverse event is any unwanted change in your health during a study, big or small, whether or not the study caused it. Tell the study team about it, even small things. Working out the cause is their job, not yours.

If you ever think it is a medical emergency, get urgent medical help first. Then tell the study team as soon as you can.

Ask what taking part would cost you, before you agree. Ask about travel and time too. You are entitled to a clear answer in writing.

5. Your rights

- Taking part is your choice. No one should pressure you.
- You can say no. You can also say yes and later change your mind.
- You can leave at any time, for any reason, and you do not have to explain why.
- Saying no, or leaving, should not change the usual medical care you receive.

- You can ask questions at any time, as many times as you need.
- Your information is kept private. In research records your name is usually replaced with a code. You can ask what is collected, why, and who may see it.
- You can raise a concern with the study team, or with the ethics committee that reviewed the study.
- You can ask how and when the results of the study will be shared.

6. Questions to ask

It helps to write your questions down and bring them. You can bring a family member or friend for support. There are no wrong questions.

- Why is this study being done, and what is it trying to find out?
- What would happen to me, and how long would it last?
- Where would I need to go, and how often?
- What are the possible risks or side effects?
- What are the possible benefits, if any?
- What other choices do I have if I do not take part?
- Would I get a placebo? What does each group receive?
- Will taking part cost me anything? Is travel covered?
- Who do I call if I feel unwell or have a question, including outside visit hours?
- What happens if I decide to stop? Will my usual care change?
- Who can I talk to if I have a concern about how I am treated?
- How and when will I hear about the results?

7. Who to contact with concerns

- The study coordinator is usually your first contact for day-to-day questions.
- The investigator is the doctor or researcher responsible for the study at that site and for your safety in it.

- The ethics committee (IRB) is independent of the study team. If you have a concern about your rights or safety, you can ask the team for its contact details. They are often printed on the consent form.
- Your own doctor is the right person for decisions about your health.

Study coordinator name and phone	Phone for problems outside visit hours
Ethics committee (IRB) contact	My own doctor

About this guide

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