What should I know before joining a clinical trial?

Deciding to take part in a clinical trial is an important decision, and it is yours to make. Before enrolling in a clinical trial, you should learn as much as possible about the trial and meet with the research staff to address all of your questions and concerns.

Accordion:
What is informed consent?

Informed consent is the process of learning about a clinical trial before deciding whether or not to participate. To help someone decide whether or not to participate, the doctors and nurses involved in the trial are required to explain the details of the study.

There is a written document called the “informed consent form”. This is also called the “ICF”. This form includes details about the study including the purpose, risks and potential benefits, duration, required procedures, and important contact information.

If you are considering participating in a trial, you can ask the doctors and nurses any questions about the trial until you feel comfortable about joining. You can also talk with family, friends, or your personal doctor before you choose to participate.

You decide whether or not to sign the form and participate in the trial and no one should pressure or influence your decision in any way. Parents or guardians sign the form and decide whether or not children can participate in a trial.

Informed consent is not a contract and the participant may withdraw from the trial at any time and for any reason.

Do clinical trial participants have specific rights and responsibilities?

Yes, all people who participate in clinical trials have specific rights and responsibilities. The doctors and nurses involved in the study are required to make sure people know these rights and responsibilities before deciding whether or not to participate in a trial.

All clinical trial participants have the right to:

- Clearly understand the risks, possible benefits, tests that will be done, and other information about the trial that is in the consent form
- Receive a signed and dated copy of the informed consent form
Ask the doctors and nurses any questions about the trial at any time
Leave the trial at any time and for any reason
Ask to receive the results of the trial after it is done

All clinical trial participants have the responsibility to:

- Provide truthful answers to the questions that the doctors and nurses ask
- Follow the rules of the clinical trial that are explained in informed consent

What are the benefits and risks of participating in a clinical trial?

Potential benefits of participation may include:

- Playing an active role in one's own health care
- To have the possibility of getting access to new research treatments before they are widely available
- Helping others by contributing to medical research

Potential risks of participation may include:

- The possibility of unpleasant, serious, or even life-threatening side effects
- The treatment may not be effective
- The protocol may require a great deal of time and effort, including trips to the study site, hospital stays, or complex dosage requirements

Before enrolling in a clinical trial, be sure to discuss all of your questions with the research team, including questions about the potential benefits and risks of the trial.

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