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Joining a Clinical Trial: What to Know Before You Enroll

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As a scientist who has been involved in running clinical trials for the past 30 years, I have seen first-hand how patients have contributed to and benefited from participating in a clinical trial. I am very pleased to have this opportunity to thank all of the many clinical trial participants who have taken part in research over the years.

Because they enrolled in trials, new promising therapies have been understood in terms of safety and efficacy, and new therapies have become available to help others. In fact, clinical trials are vital to the development of new medicines, devices, biological products, and behavioral therapies. And clinical trial findings often lead to new therapies for many people suffering from various illness or conditions now and for generations to come.

Deciding to Enroll in a Trial

Making a decision to join a trial is personal and will likely require input from family, friends, and your doctors. For those of you who are thinking about whether or not to enroll in a study, here are some things to consider before participating.

- Do you feel that you are making the decision to join or not join a trial on your own, without being pressured or too influenced by someone else?

- Does enrolling in the trial offer you a chance at a treatment in the experimental stage that is not available to you otherwise? Is it something you want to explore further as you are considering existing therapies that you are using or those you have not tried yet?
- In order to understand the difference between what is being tested and what may already be available, you may be selected at random to receive either the experimental therapy, or existing therapies you can only get in a trial, or a placebo (e.g., a pill without medicine in it), and not the investigational therapy. This is called randomization. How might you feel about not getting the new therapy that is being tested?
- How would you feel if the experimental therapy does not work or might have serious side effects?
- Is it important to you to participate for others who may face the same disease in the future even if it doesn't benefit you directly? Is this enough for you to balance the inconvenience and potential risks of participating in the specific trial you are considering?
- Do you have the time, energy and commitment to participate in a clinical trial for the length of the trial? Most trials require that you come in for monitoring (such as interviews, blood tests, physical exams). Will you be able to travel to the clinical trial site if necessary?
- Do you trust the institution, doctors, and nurses who will be running the trial? Have they answered your questions? Do you feel like a partner with them in this endeavor?
- Are there any costs associated with trial participation such as the expense to travel to the clinic site? Some clinical trial investigators will cover travel costs but are there other expenses to consider?

The Rule about Informed Consent

The informed consent process offers a great opportunity to ask questions before enrolling. Before agreeing to take part in a trial, you must be informed, to the extent possible, of all the known potential risks of getting (or not getting) the experimental therapy. This is called "informed consent" and is a rule that is governed by trial regulations. In other words, those who are running the study are bound by their code of professional ethics, as well as laws and regulations, to disclose the known risks and benefits before you agree to participate. This means, you should be as informed as possible of the potential good outcomes and the potential negative outcomes that you risk at the time of enrollment.

With informed consent, you get the chance to:

- Hear all about the study from someone involved in running it
- Take some time to express your concerns and consider all your options
- Get answers to any questions you have about the trial, and your condition, explained in a way that you can understand
- Go over all the details of the research as many times as you need, so that you are able to understand what will happen before, during, and after the trial
- Give your voluntary consent to join the trial, decide not to participate in the trial, or decide that you need more time to think about it. The decision is entirely yours
- Learn ways that you can get more information and ask more questions should they come up
- If for any reason you choose not to participate in this clinical trial, you may still consider participating in a different one in the future

Where to Learn More

Your doctor may be an important resource for letting you know where there are open clinical trials and for helping you understand what it takes to participate. He or she may know how you can get in touch with the trial investigators to ask questions and get more information. There may even be open trials at your local hospital, a nearby academic center, or in your community.

There are also advocacy groups that can help you get prepared for the trial experience. The US Food and Drug Administration (FDA) and Center for Information & Study on Clinical Research Participation (CISCRP) are among the organizations that offer information about clinical trial participation.

An Important Decision

After careful thought, you may decide that joining a clinical trial is what you want to do. But you may also decide that it's not the right time or the right choice for you. Some people decide to opt out of a trial after deciding to participate. This is well within your right to do and the trial team will be there to help you during that transition. What's most important is that you are well informed and able to ask questions. Your friends and family can help you meet with the clinical trial team and to weigh the pros and cons about participating.

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