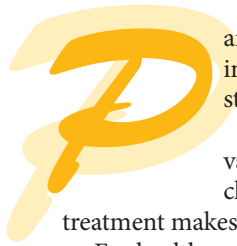


Should I or Shouldn't I? How to Weigh the Risks



Participating in a clinical trial is an intensely personal decision, and the stakes differ for each person.

For those with a serious, advanced stage disease, even a slight chance of getting a more effective treatment makes the decision easy.

For healthy volunteers or people with less critical conditions, potential side effects and other factors need to be balanced against the desire to take part. Most people who consider trials participation do some soul-searching as they weigh the pros and cons.

There are several reasons that people may choose to participate:

To gain access to new treatments

There's the chance that an experimental treatment or a new and better treatment will help your condition improve. Many clinical trials have introduced treatments that were more effective than those that were currently available.

To advance science and help others who have the illness

Helping to develop new treatments that could aid thousands and advance science is a powerful motivation. Many people with this goal are willing to assume some risk because they feel they are contributing toward making the world a better place.

To earn extra money

For some people, the compensation offered is an attractive incentive to participate.

To receive free medical care

The experimental treatment is typically free to the participant. In addition, while volunteers are taking part in the trial, site staff usually monitors their vital signs and pays attention to other symptoms and health factors.

But potential volunteers also have to weigh the risks and balance them against the potential benefits. Some of those negatives include: **You might get a placebo (a pill or treatment that has no effect) instead of the test drug**

Some tests include a control group that gets a placebo—at least for part of the test period—and if so, your disease is not treated during that clinical time frame.

You may be exposed to harmful side effects

Although many volunteers experience no side effects or only minor effects, there are po-



tential risks with an experimental treatment. This factor may weigh especially heavily on healthy volunteers.

A standard treatment is already available

If your current treatment is helping you even slightly, you may feel that's better than trying a new treatment that might not work at all. You'll also probably have to stop taking your current treatment, which could lead to a relapse.

Taking part in a trial may be inconvenient

You may have to get frequent injections or have blood drawn regularly; undergo exams or possibly quit smoking, drinking or other activities that are routine for you.

Visiting the test site, monitoring your physical responses, and keeping a journal, if required, may be burdensome to you.

You may incur unexpected costs

Although in most clinical trials the study drug and the direct cost of care are paid for by the study sponsor, there may other costs associated with the visits, including, but not limited to lodging and transportation costs to visit the test site.

“ I know what I went through with chemotherapy treatment. If I can in any way help someone else not go through that, it can't be anything but good. The trial I'm in is for a possible new treatment for breast cancer and could help millions of people down the road. That in itself outweighs any possible chances of major side effects (for me). ”

Jennie, a subject in a breast cancer relapse prevention trial

How do I decide?

Two key questions can help you make this important decision:

Do I have all of the information that I need to make an informed choice?

It's important to know as much as possible about the treatment and the trial requirements so that you can weigh all the factors. Get information about the trial goals, potential side effects, and what you'll be required to do.

Start by getting information from the research center that will be conducting the trial, but use other information sources as well. Keep in mind the research center may have its own motivations for conducting a trial, and its goals may be different from yours.

Get a second opinion about the trial you're interested in; ask your doctor, other health professionals, family, and friends.

How far am I willing to go?

Only you can answer the question of how hard you're willing to push yourself to get information required and to be willing to comply with the trial requirements. Your motivation to participate will influence how much you're willing to put yourself out.