

If you're thinking of joining a clinical trial, make sure to get the answers to these questions

Many amyloidosis patients each year enroll in clinical trials of experimental drugs and procedures. Some join these studies to advance medicine for future generations, others because they hope to personally benefit from cutting-edge technology before it is available on the market.

So, before you put your health on the line, ask some tough questions:

- ***Does the doctor running your study have a financial stake in the outcome of the clinical trial for which you are being recruited?***

Your clinical trial's doctor may have stock in the company running the trial, or may be an inventor of the drug or device being tested. If the doctor is an inventor, he or she may stand to earn a royalty from sales if the drug is approved. Or the doctor could be a paid consultant or speaker for the company making the experimental medicine or device. Ethics groups recommend that doctors disclose these kinds of potential conflicts, but it isn't required by any law, so you should ask the doctor.

- ***Ask for a copy of the protocol -- the document your trial sponsor gives the doctor that describes in detail the experimental medicine and the study planned.***

Your doctor will give you what is known as a "consent form," a legal document to sign agreeing to participate in the trial. The form contains basic information on the experimental medicine and potential side effects. But doctors participating in clinical trials also have a protocol, a much more detailed document prepared by the sponsor of the trial -- the company or the researcher.

Learning About Trials

Here are some Web sites and tips for finding information on clinical trials

- www.centerwatch.com
A commercial site that lists clinical trials
- www.clinicaltrials.gov
A government site listing clinical trials and offering a guide to participating
- www.acrpnet.org/resources/trial/questions.html
A trade group's Web site offering a guide to participating in clinical trials
- www.nci.nih.gov/clinicaltrials/understanding
A government Web site offering a guide to clinical trials
- Enter the name of the disease or condition you're interested in and the words "clinical trials" into a search engine, such as Google, to find Web sites of patient advocacy groups that share information on clinical trials.

Source: WSJ reporting

If you read the protocol, you will be much better informed about the potential risks and benefits of participating in the study. The protocol may detail the criteria for qualifying for the trial, as well as the criteria for being dropped from the study. It should also tell you the results of previous animal tests and human trials, the number of people expected to enroll and the facility where the trial will be conducted. You can also find the names of the doctors who are the principal investigators for the trial and more detail on side effects and potential benefits.

- ***Is your doctor the principal investigator in the trial? If not, who is the principal investigator?***

If you can't get yourself in a position to be supervised by the principal investigator, you should at least get the name and contact information for this person. Then if you or your treating physician have a question, either of you can contact the principal investigator or his or her core research staff for information.

- ***Ask the doctor which Institutional Review Board is in charge of your trial and who the chairman and members of the board are.***

The protocol, or rules, for your clinical trial had to be approved by a panel made up mostly of medical professionals. This panel is usually called an Institutional Review Board and is charged with monitoring your trial. The IRB, as it is known, may be attached to the hospital or clinic where your trial is being held. Or the IRB could be one of several regional private boards that monitor clinical trials.

It's a good idea to find out the name and credentials of the IRB and the members, or at the very least, the chairman. Then, if you have questions, you can contact the chairman. And you can weigh the credentials of the board members in evaluating whether to participate.

- ***If the experimental drug or procedure helps you, will you be able to continue on the treatment when the trial ends?***

Even if the experimental therapy or device works, it is far from certain that you will be able to continue on the therapy after the trial. In treatments for cancer and AIDS, some companies consider making the treatments available to patients for whom standard therapies have failed. So ask your doctor whether you can continue on the treatment when the trial is finished. The trial's protocol or consent form may tell you about future access to the drug. If it isn't clear, ask your doctor for the phone number for the contact person at the company sponsoring the trial and make the call yourself.

- ***How quickly will you be informed whether you were given the experimental drug, a placebo or some other treatment during the trial?***

When you finish the trial, it could be important to know which therapy you were given, because -- whether it worked well or failed to do so -- it might affect future decisions about your treatment. But don't assume you'll learn what you got as soon as your participation in the clinical trial ends. That's often not the case. Companies often insist on waiting until all patients have finished the trial and the data have been collected and reviewed before disclosing who was on which therapy.

- ***What will happen if something goes wrong? Who will pay?***

This information may be laid out in the "consent form" you are asked to sign. But if it isn't clear, you should ask the doctor to show you where in the consent form or protocol there is information about who pays if your health gets harmed and to interpret it for you. Often, the trial sponsor will pay for your immediate care, and you or your insurer will be expected to cover longer-term costs. Also, remember that you do not give up your ability to file claims in court if your care is mishandled in a clinical trial.

- ***How much will participating in the trial cost?***

Sometimes, it costs nothing to participate in a trial. But it could cost you tens of thousands of dollars. That's because even though companies usually supply the experimental medicines at no cost, you could be charged for tests and procedures that are required by the clinical trial. So be sure to ask the doctor running the trial to detail in advance all of the costs you will be expected to pick up.

- ***How does your doctor answer all of these questions?***

Listen carefully to how your doctor answers your questions. Assess the depth of his or her knowledge of the trial details. Consider his or her willingness to talk to you. It is particularly important when you are taking an untested drug to be supervised by an attentive, caring doctor.