

Questions to Ask Before Volunteering for a Clinical Trial

Thinking about volunteering for a clinical trial? These questions can be asked directly to your doctor or the researcher staff working with the clinical trial.

Tips for asking your doctor or researcher about clinical trials¹:

Plan some questions to ask in advance, but do not hesitate to ask any new questions you think of while you are there.

Consider taking a family member or friend along to any informational appointments for support. They can help you ask important questions, record answers, or translate. If you are not able to bring anyone but still need translation help, ask if Translation Services are provided.

It is important you write or record all the answers to your questions so that you can review them later whenever you want. Ask if you can record what is said (even if you write down answers) through a tape recorder or a recording app on your phone.

Questions to ask your doctor or researcher about:

Design of the Clinical Trial:

What is being studied?

What is the purpose of this clinical trial?

What phase is this clinical trial in and what does that mean?

How many volunteers are taking part in the clinical trial?

How much of my time will the trial take if I decide to join?

Who is sponsoring the clinical trial, and who has reviewed and approved it?

What type of information will be collected?

What will happen to any personal information collected after the study is completed?

What will you do with my test results and medical information?

How often will I have to visit the hospital or clinic?

Has this experimental drug or treatment been tested before in people?

Why do researchers believe this new experimental drug or treatment might be effective? Or why might it not be effective?

Have there been other clinical trials like this one? If yes, what were the results?

Will I know whether or not I am getting the experimental drug or treatment?

What will happen when the clinical trial ends?

Benefits and Risks:

Are there benefits to me by participating? To my community and future generations?

Are there risks to me by participating? To my community and future generations?

Could I experience potential side-effects from the experimental drug or treatment?

How could being in this clinical trial affect my daily life (positive/negative effects)?

Eligibility Requirements:

What are the inclusion criteria for this clinical trial (factors that allow you to participate)?

What are the exclusion criteria for this clinical trial (factors that disqualify you from participating)?

Clinical Trial Participation:

What will I have to do if I join?

How long do I have to decide if I want to join this clinical trial?

If I have questions during and after the clinical trial, whom can I contact?

Who will know that I am participating?

Will my regular doctor be informed that I am participating?

Who will have access to my medical records?

While I am in the clinical trial, can I talk to other clinical trial participants, or can I talk to other people such as family members or friends about the clinical trial?

Is there anything I am not allowed to do while I am in the clinical trial?

Will I be told about the trial results if I participate?

If I benefit from the experimental drug or treatment, will I be allowed to continue receiving it after the clinical trial ends?

If the experimental drug or treatment does not work for me, or if I receive the placebo, what happens next?

Clinical Trial-Related Costs:

Who will pay for the experimental drug or treatment?

Will there be any travel or childcare costs that I need to consider while I am in the clinical trial?

Will I have to pay for anything related to the clinical trial, such as medical tests or drugs? If so, what are the charges likely to be?

What is my health insurance likely to cover?

Who should I talk to from my insurance company or health plan provider about any questions?

Will I be reimbursed for other expenses?

If I get sick from the clinical trial, who will pay for my health expenses?

If I get paid for participating in a clinical trial, is it taxable? If so, what forms do I need and how do I report it?

Your Care:

Will I be able to take my regular medications while in the clinical trial?

What kind of therapies, procedures, and tests will I have during the clinical trial?

Will hospitalization be required?

Who will oversee my medical care during the clinical trial?

Where should I go to receive my medical care?

What type of follow-up care is part of this clinical trial?

What will happen if I experience a side effect?

Will there be any painful or unpleasant drugs or treatments? If so, how long will they last?

What are my options if I am injured during the clinical trial?

Who can I contact in case of an emergency?

Do you provide traditional, religious, or spiritual resources before, during, or after the clinical trial?

Your Rights:

How will my health information be kept private during and after the clinical trial?

Can I leave the clinical trial if I want to?

Participation in all clinical trials is voluntary. You can withdraw and leave a clinical trial at any time, even if the clinical trial is not over.²

If samples are taken from my body (ex. Blood sample, urine, or saliva), will I get them back, or will they be destroyed?

Will my samples be used for secondary research? What happens if I do not consent to this?

Will my data be deidentified? If so, how?

Will my information or data from this clinical trial be used in future case studies? Will you inform me of this?

Resources:

1. Clinical Research Trials and You: Questions and Answers. National Institute of Mental Health Website. <https://www.nimh.nih.gov/health/publications/clinical-research-trials-and-you-questions-and-answers/index.shtml>. Accessed March 15, 2021.
2. Learn about Clinical Studies. U.S. National Library of Medicine Website. <http://clinicaltrials.gov/ct2/about-studies/learn>. Published March 2019. Accessed March 15, 2021.
3. What should I ask the clinical trial doctor? Clinical Trials Website <https://www.clinicaltrials.com/study-participants/questions-to-ask/>. Accessed March 15, 2021.