



Is a Clinical Study Right for your Patient?




Print PDF of
this page




Download
PDF Reader

 = glossary definition

Why Patients don't Participate in Clinical Studies

Participation in a *clinical trial*  may afford access to the latest investigational therapies in a closely monitored setting, and yet only a small proportion of eligible patients enroll in clinical trials each year. There has been research into why people do or do not participate in clinical research. The findings are as varied as the participants themselves, however some reasons include¹ :

- Patients may not know about a clinical trial for which they might be eligible.
- Poor understanding of clinical trial concepts such as randomization or *placebo* .
- Parents may refuse to enroll their child in a trial because of anxiety about “experimentation” or exposing their child to additional procedures.
- Parental belief that their child’s regular doctor would not want them to participate may cause some parents to decline participation.

Perceived Risks in Referring Patients to Clinical Studies

Caldwell et al (2002) discuss perceived risks and gains for pediatricians in their article, “*Pediatricians’ attitudes toward randomized controlled trials involving children*”². Perceived risks may influence whether the healthcare provider will refer a patient for study participation and may include:

- Discomfort with counseling patients about details of unfamiliar trials.
- Caregivers may feel a conflict with their role as patient advocate when a child is selected into a placebo arm of a trial or for a certain treatment that the caregiver perceives to be less effective.
- Speaking with a patient about a trial, seeking more information and cooperating with a treatment protocol may be time-consuming.
- Inadequate communication from the investigators about trial progress, patient follow-up, treatment protocol adherence or study closure may negatively influence future decisions to refer a patient.
- Caregivers must balance their own attitudes about a trial, what they sense parent’s views to be and the perceived risks and benefits in the decision-making process.
- There may be concerns about losing a patient permanently to the care of the individuals conducting a study.

Perceived Benefits in Referring Patients to Clinical Studies

Perceived gains may include:

- Increased professional interaction with specialists from different fields.
- Improved care for patients that may include thorough follow-up, special attention and parental access to information and extra resources.
- Satisfaction from contributing to scientific advancement and future patient benefits.
- Early awareness and access to clinical research findings with the ability to change clinical practice based on appropriately studied interventions or medications.

When Your Patient Asks about a Clinical Study

You may be aware of clinical studies that are open for patient enrollment or your patient may want to discuss with you whether they should participate in a particular clinical study or not. If you feel a clinical study may be an appropriate option for a patient, you can follow the steps below to find the best study and to refer the patient:

Step 1: Access clinical study information.

This website can give you important information about [current PHN studies](#), inclusion and exclusion criteria, study procedures, patient time commitment and contact information. You will also find patient brochures for each study that outline the study purpose and procedures and can be printed and given to the patient.


Another way to identify an appropriate study is to utilize the information at ClinicalTrials.gov and place a key word in the search box. Summaries of the studies include study objectives, eligibility criteria, and contact information for the study's investigators.

Step 2: Call the [principal investigator](#)  or [research coordinator](#) .

After reviewing the information, you may want to contact the principal investigator or research coordinator to further discuss eligibility and protocol requirements. You might be asked to provide specific medical information or test results to determine eligibility


Step 3: Talk to your patient about the study.


Inform your patient about the study and, if he or she is interested in participating, provide the patient with the study team's contact information. Someone from the study team will discuss the details of the study, such as time commitments, potential side effects, and other information needed to make an informed decision. If the patient lives a distance from the study site, travel arrangements will be discussed as well as what is paid for by the study.

Frequent communication with the study team is important for maintaining the high level of care for a patient enrolled in a study. Feel free to contact the research team at any time with questions or concerns that you may have about your patient or the study in which she or he is enrolled. It is especially important to share information about hospitalizations, visits to the ER or physicians office. Any [adverse event](#)  or side effect (whether you think it is related to the drug or intervention or not) should be reported to the study team. In addition, the study team will want to know how to contact you and inform you of events that occur during the course of the study.

¹ Llewellyn-Thomas, H.A., McGreal, M. J., Thiel, E., Fine, S. and Erlichman, C. Patients' willingness to enter clinical trials: Measuring the association with perceived benefit and preference for decision participation, *Social Science & Medicine*, 32(1): 35-42

² Caldwell, P., Butow, P., and Craig, J. (2002). Pediatricians' attitudes toward randomized controlled trials involving children. *Journal of Pediatrics*, 141(6):798-803.

 [How Studies are Created and Monitored](#)

[How To Refer a Patient For a Study](#) 

Adjust Text



Department of Health and Human Services



National Institutes of Health



National Heart, Lung, and Blood Institute

