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An Introduction to Clinical Trials for Providers

Clinical Trial Guidelines for Health Care Providers

Clinical research supports the National Institute of Health's mission to enhance health, lengthen life, and reduce the burdens of illness and disability. Only through clinical trials can we gain insights and answers about the safety and effectiveness of drugs and therapies. The challenge to create successful clinical trials lies in recruiting participants.

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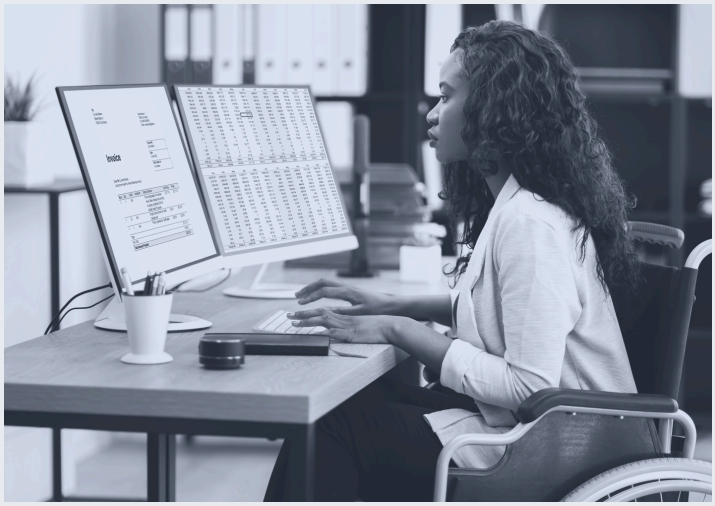
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Importance of Clinical Research Awareness

The first step in tackling this challenge is regularly getting the public to think about participating in clinical research. General awareness may help advance the diagnosis, and treatment of disease, as well as prevention in some cases. It is never too early to consider participation whether or not someone ultimately chooses to join a study.



The ethics of promoting greater awareness of clinical research must be considered carefully. The focus of any campaign should be to advocate for patients to consider participation, rather than to encourage participation. Providing resources to help individuals make informed decisions about research involvement promotes understanding of the true benefits and risks of participation. It also increases awareness about the importance of clinical research. (Alvins, 2007)

The Role of the National Institutes of Health

Clinical research is vital to the National Institutes of Health (NIH) mission of enhancing health, lengthening life, and reducing the burdens of illness and disability. For instance, through clinical research we gain insights and answers about the safety and effectiveness of drugs and other therapies. Groundbreaking scientific advances in the present and the past were possible only because of the participation of clinical research volunteers, both healthy and ill. Clinical research requires complex and rigorous testing in collaboration with communities that are affected by the disease. As NIH-supported clinical research opens new doors to advancing prevention, treatments, and cures for disease and disability, clinical trial volunteer participants are essential to this progress.

When given information about clinical research, survey respondents affirmed its importance:

- 32% of American adults indicate they would be very willing to participate in a (cancer) clinical trial if asked.
- 28% indicated they would consider it, but hold some reservations. (Comis, 2003)
- Focus groups with the public and caregivers found that many lacked familiarity with clinical trials and were unaware of opportunities for participation by healthy volunteers. They generally expressed negative attitudes about participation. These attitudes significantly changed after learning more about clinical trials. (NIH CRA Focus Groups, 2011)

Learning About and Participating in Clinical Research

In two separate studies, the Internet and general media were identified as the primary sources for learning about clinical trials (ACRP, 2009; Taylor, 2004). Those who participated in clinical research increasingly cited the "information [they] read, saw, or had heard" about the study as being a major influence on their decision to participate (28% in 2001 versus 41% in 2004). (Taylor, 2004)

Health care providers play an important role in raising awareness about the option of clinical trial participation. By having a focused conversation about treatment options including clinical trials, a patient can be made aware of, and invited to enroll in a clinical research study.

- 77% of patients who participate in a trial learned about it from their health care provider.
- 32% of patients who participated in clinical trials reported that their health care providers took the time to explain the trial clearly
- In a 2005 survey of nearly 2,000 cancer patients, 73% of those who joined a clinical trial said they did so because of their health care provider's awareness of clinical trials.
- Participating patients were more likely to have first learned about clinical trials through a doctor, have had a doctor explain the pros and cons of participation, and found an appropriate trial with the help of their health care provider. (Comis, 2009)

OPPORTUNITIES FOR EDUCATION AND AWARENESS

Clinical trials are essential for identifying and characterizing interventions to prevent, diagnose, and treat disease. Educational efforts aimed at the public and health care providers raise awareness of the concept of clinical research and the important role it plays in improving health and quality of life. Prior knowledge of clinical research helps patients consider a clinical trial as an option at the time treatment decisions are being made. Poor accrual rates to clinical trials can be addressed through increased awareness of the benefits of clinical research.

One of the principal challenges of recruiting participants is the lack of awareness and education about clinical trials, availability, and how to participate.

- Just 14% of respondents in a 2017 ResearchAmerica! national public opinion survey said that they or someone in their families had participated in clinical research.
- 94% in a 2010 ResearchAmerica! Survey said their doctor had never suggested participating in a clinical research study. In a 2006 Research!America nationwide survey of approximately 1,000 adults:
- 40% perceived only some value, no value, or didn't know the value of a clinical trial.
- Among cancer patients, 80% did not consider the possibility of participating in a treatment clinical trial because they were unaware that this was an option. (Zon, 2008)

OPPORTUNITIES FOR EDUCATION AND AWARENESS

There have always been barriers to recruiting volunteers for clinical research studies. Through the efforts of the NIH, challenges such as language differences, low literacy, and mistrust are being addressed. Recent NIH research suggests that individual indifference and/or negative attitudes toward participation in clinical trials change for the better through education and discussion (NIH Clinical Trials Messaging Focus Group Testing Report, 2011).

Despite low participation rates in clinical trials, patients who do participate report that they are satisfied with the care they receive. The 2000 survey of public attitudes found that patients who did participate in clinical trials found the experience to be positive, that they were treated with respect, and that they learned more about their illness and its treatment. Three out of four said they would recommend clinical trials to others. (Comis, 2000)
Talking with prospective participants about enrollment in a clinical trial is not always easy and there are few evidence-based strategies to help us.

Fortunately, an NCI-funded research team (Eric Kodish, MD, PI)* has pioneered an approach in pediatric oncology that can be applied to a broader range of populations and disease areas.

Their research provides practical advice for improving these conversations. It stresses the importance of a sequenced approach: a patient's understanding of the disease, followed by discussion of current standard treatment, and finally the possibility of a clinical trial.

All of these steps have been incorporated into the following modified checklist that supports understanding and encourages questions.

COMMUNICATION TECHNIQUES

When speaking with potential participants, consider the following:

- **Provide an empowering environment by inviting the prospective participant to select who will attend this discussion.**
- **Increase your prospective participant's ability to focus on the discussion by holding the meeting in a private location without interruptions.**
- **Communicate respect and the importance of this meeting by acknowledging trauma of diagnosis (if appropriate) and empathizing with emotional reactions.**
- **Simplify information by avoiding medical jargon and a laundry list of medications and side effects. Summarize often, and repeat important points.**
- **Provide a pen and paper to take notes and write down questions, invite them to make comments or ask questions at any time, and encourage them to share their thoughts and feelings. Tell them that all questions are good questions.**
- **Stress the importance of information-seeking and elicit questions in an open-ended manner. ("What questions do you have?")**
- **Avoid interrupting.**
- **Check that questions were answered to your patients' satisfaction.**
- **Talk about how disease treatments have improved over time due to clinical research and participation of patients in clinical trials.**
- **Avoid pushing the recommendation of clinical trial, but if asked, respond accordingly.**

IMPROVING DISCLOSURE TO INCREASE POTENTIAL PARTICIPANT UNDERSTANDING

When speaking with potential participants, consider the following:

- Follow the sequence of 1) explain disease, 2) describe current best proven treatment, and 3) present option of the clinical trial. Assure that the potential participant has good comprehension of each step before moving to the next one.
- Break the informed consent conference into two separate meetings if your patient would prefer this or if you think two sessions would help enhance understanding.
- Use the consent document as a communication tool by providing copies, encouraging reading, and referring to sections of the document during the conference.
- Discuss treatment options outside of the clinical trial and explain how the study differs from current standard treatment.
- Explain at least three times that trial participation is voluntary.
- Explain the right to withdraw at any time.
-

For randomized trials, use examples to clarify the randomization process and avoid potentially misleading descriptions (for instance, a computer randomly assigns alternative treatments). Use a diagram to show differences among the randomization groups of the trial.

Discuss any potential conflict of interest you may have as an investigator.

Be prepared to give an answer if the prospective participant asks if you personally would enroll in the trial, or if you would advise one of your family members to enroll.

HOW TO REFER YOUR PATIENT

Contact the trial team directly. The clinical trial summary should include the phone number of a person or an office that you can contact for more information.

You do not need to talk to the lead researcher (called the "protocol chair" or "principal investigator") at this time, even if his or her name is given along with the telephone number. Instead, call the number and ask to speak with the "trial coordinator," the "referral coordinator," or the "protocol assistant."

This person can answer your initial questions about the study and how to refer. It is this person's job to decide whether your patient is likely to be eligible to join the trial.

The final decision will probably not be made until your patient has a visit with a doctor who is taking part in the trial.

RESOURCES

- Promotional Materials | National Institutes of Health (NIH)
- Talking to Your Patient About a Clinical Trial
- How to Refer Your Patient

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