

Getting Involved in Research



There is a lot we still don't know about health and Parkinson's disease (PD). Medical research will help us learn more. One way people with PD can help us to better understand the disease is by participating in clinical trials. If you are considering participating in a clinical trial, it is important you learn more about the process and why it's so important.

What is a Clinical Trial?

A clinical trial, also called a clinical study or clinical research, is research conducted with people to answer scientific questions. Clinical trials determine if scientific concepts can be turned into safe and effective therapies that make life better for people with Parkinson's. These trials help researchers and doctors learn what does and does not work in treating diseases like PD. Clinical trials are done for a variety of different therapies, such as nutrition, exercise, devices and drugs. Clinical trials can also observe participants using tests and surveys to better understand PD.

Types of Clinical Research

The purpose of a clinical trial is to test the safety and efficacy of new treatments and to learn more about the disease. Clinical trials help answer specific questions about new treatments by studying their effects in people. The types of research include:

- **Therapeutic.** Tests safety and efficacy of a potential new PD therapy, drug or non-drug or a different way to use an existing therapy.
- **Diagnostic.** Looks for physical indicators or biomarkers, that can help diagnose and track the progression of PD.
- **Genetic.** Helps understand how genes affect PD.
- **Preventive.** Aims to find ways to prevent someone from developing PD.

Phases of Clinical Research For Drug and Device Research

Drugs and devices have to go through a process of clinical trials before the U.S. Food and Drug Administration (FDA) can consider approving a new therapy.

- **Phase I.** Tests potential treatment for the first time in a small group of people to evaluate safety, determine the safe dosage and identify side effects.
- **Phase II.** Further evaluates the safety of the treatment being tested and provides preliminary measures of effectiveness.
- **Phase III.** Determines if the treatment benefits participants and if its benefits outweigh its risks.
- **Phase IV.** After a drug or device is approved, this final phase of research can be conducted. Collects and looks over additional information about a treatment, including risks, benefits and optimal use, after FDA approval.

Why Should I Participate in Clinical Trials?

Your participation in clinical trials can:

- **Help find new Parkinson's medications and therapies.** It can also help speed up the process. The Parkinson's medications people take today could not have happened without clinical trials.
- **Get early access to potentially helpful treatments not yet available.** Keep in mind that this does not replace your typical treatment —

your doctor's goal is to treat your disease, while a researcher's goal is to learn about it.

- **Contribute to the diversity of research participants.** Individuals can respond differently to therapies, have different symptoms and have a higher or lower risk of developing PD. Research will better reflect how a treatment will work for people with Parkinson's when there is more diversity among study participants.
- **Play a part even if you don't have Parkinson's.** Many trials are looking for "healthy controls," or individuals whose study response is compared to that of people with Parkinson's. If you are a family member of someone with Parkinson's, you can participate in trials that look at the role of genetics in the development of the disease.

What Should I Do Before Participating?

Talk to Those Around You

The following people can help you decide whether or not to participate in a clinical trial:

- **Your neurologist.** Can help you decide what trials are best for you. Bring information about studies with you to discuss during your visit.
- **Your family.** Joining a trial can affect members of your family. Involve your family in your decision-making process. You might go to them for emotional support.
- **Your friends in the Parkinson's community.** Many people learn about clinical trials through support groups or other people with PD. Your peers can help you identify trials you may wish to consider.

Informed Consent

It is required that you give informed consent before you decide to take part in a study. This means that you have been given complete information about a clinical trial when you agree to participate. Informed consent makes sure you fully understand the trial and your role in it. It is more than a document you sign — it is a process beginning when you first learn about the study and continuing throughout your participation.

It is not a contract — you are free to stop your participation in a study if you choose.

Decide What Trials You Are Comfortable With and Able to Participate In

Some studies are as simple as filling out a survey, while others can involve procedures. You may want to think about certain requirements, such as the number of times you must visit the study site, the length of each visit, the number and types of tests you will have to do and how long you need to be in the trial. Other factors, such as whether you find it easy or hard to get to and from the study site, can also affect your experience.

Understand the Risks of Participation

Remember that the main goal of a clinical trial is to test a scientific idea through experiment. This means that participation can involve risks:

- **A study treatment might not work.** However, unsuccessful studies are important in learning more about PD.
- **You may not receive the study treatment.** You might be chosen to receive a placebo, like a sugar pill. This lets researchers compare the group that receives the study treatment with a group that does not.
- **You may experience unwanted side effects.** These include those that are known or new ones that might appear as the treatment is being studied.

Know the Ethical and Safety Rules

Healthcare institutions that conduct clinical research are required to submit studies to Institutional Review Boards (IRBs). These groups, made up of other scientists, determine that the potential benefits of the trial outweigh the risks and that the consent process clearly communicates the study guidelines. If approved, the study is reviewed at least once a year by the IRB to make sure it is done safely and ethically.

Be a Partner in the Research Process

When you participate in a clinical trial, you become a partner in the research process. As a partner, you should feel that your time with the study team is valued, your questions are



answered and your concerns are addressed. As a participant, you have an active role to play, including:

- Reading all study materials and asking questions when information is unclear.
- Providing a complete medical history before the study and reporting all new illnesses, injuries and procedures that occur during the study.
- Making no changes to the study treatment plan or to your medications before talking to the study staff.
- Providing honest feedback to study staff about your treatment response.
- Making every effort to continue until its conclusion, while understanding you can withdraw for any reason.

Sharing your experience can encourage others with PD to participate in trials and help move PD research forward.

Common Myths About Research

MYTH: People who participate in trials are treated like "guinea pigs."

FACT: Participants in clinical trials are active partners in the study. You should ask the research team questions and be engaged in the process. A team of professionals monitor a study for safety. Good study sites strive to make visits as easy and comfortable as possible.

MYTH: I will not benefit from participating in research, especially if I get a placebo.

FACT: Even if you receive a placebo, being in a clinical trial means you will get to spend more time with PD experts. Your health will be followed more closely and you may get access to cutting edge technology and therapies.

MYTH: I will have to give up my usual treatments to take part in a trial.

FACT: Many trials allow you to continue your regular treatment regimen or start new treatments during the trial. Talk to the study

team about what treatments you can and cannot use in the trial, before deciding to participate. Often times, you won't need to change your treatments for exercise, nutrition or observational trials. If a trial does require delaying treatment or altering your current treatment, talk to your doctor.

What Questions Should I Ask About Clinical Trials?

Being an informed participant begins with knowing what questions to ask.

The below questions are meant to guide your conversations with researchers and study staff when you are thinking about participating in a clinical trial.

What do I need to know about the trial?

- What is the purpose and importance of this trial?
- If this is a placebo-controlled trial, what are my chances of getting the study treatment?
- How long has this site been doing clinical trials?

What will be required of me?

- How should I prepare for my meetings with the researcher or study staff?
- How much of my time will be involved with the trial?
- What types of visits are required and how long will they last?

Are there other options?

- If I don't participate in this trial, are there other ones I may be eligible for?
- Will this trial prevent me from volunteering in future trials?
- Why do researchers believe the study treatment may be better than my current options?

What are the benefits and risks?

- What might happen to my disease symptoms with or without this study treatment?
- Will the study treatment make me feel uncomfortable or sick? If so, for how long?



- Can I take my prescriptions or over-the-counter medications with the study treatment?

How will my expenses be covered?

- Will I have to pay for any part of the trial?
- What costs might be covered by my health insurance?
- Will I be reimbursed for my expenses (travel, meals, hotel, etc.)? If so, how and when?

How will my health and safety be monitored and my privacy protected?

- Who will give me a detailed explanation of the information in the informed consent form or answer any questions I have during the trial?
- If I develop trial-related complications, what medical care will I get?
- Who has access to the study data collected and how will it be used?

What happens at the end of the trial?

- If I am in a trial that uses a placebo, will I be told afterwards if I received the placebo or the study treatment?
- What procedures are in place to notify me if my trial is halted or terminated early?
- How will trial results be made available to me, other participants, researchers and the public?

Where Can I Learn More About Parkinson's Research?

Connect with Parkinson's Foundation Research Advocates

Though the Parkinson's Advocates in Research (PAIR) program, people with Parkinson's and care partners are involved in creating and running clinical trials. These research advocates are a national network who together are committed to advancing PD research. Research advocates partner with the scientific community, bringing the PD perspective to new treatment development ensuring research meets the needs and priorities of the Parkinson's community. It also makes research more efficient and effective. Interested in becoming a research advocate or speaking to one? Please call 1-800-4PD-INFO (473-4636) or visit Parkinson.org/PAIR.

Parkinson's Foundation Research

Our **Parkinson's Outcomes Project** is the largest-ever clinical study of Parkinson's disease with more than 12,000 participants. Through this groundbreaking initiative, Parkinson's Foundation Centers of Excellence track and monitor their care of people with Parkinson's over time.

Our unique study evaluates a wide range of Parkinson's factors including:

- Most effective Parkinson's treatments
- Therapy benefits
- Best candidates for each treatment
- Various exercise program benefits
- Caregiver impacts

Research has shown that the better we manage Parkinson's today, the better life will be tomorrow. Learn more about the Parkinson's Outcomes Project at Parkinson.org/Outcomes.

PD GENERation

Parkinson's Foundation PD GENERation is the first national Parkinson's study to offer genetic testing plus counseling for Parkinson's-related genes through medical professionals. The goal is to track the genetic makeup of 15,000 people with Parkinson's across approximately 50 sites in the U.S. For more information, email Genetics@Parkinson.org or visit Parkinson.org/GeneticsInitiative.

Search for Parkinson's Studies Online

To find open and enrolling clinical trials in the U.S. and around the world, visit www.clinicaltrials.gov. National Institutes of Health (NIH) Clinical Research Trials and You, www.nih.gov/health/clinicaltrials, is an online resource to help people learn more about clinical trials, why they matter and how to participate.

Call our Helpline 1-800-4PD-INFO (473-4636) or visit Parkinson.org/Research to learn more about ongoing Parkinson's research.