

Getting Involved in Parkinson's Research

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Parkinson's
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Are you thinking about participating in a Parkinson's clinical study?

The most important step in deciding to participate in a clinical study is to be knowledgeable about and comfortable with studies you are considering. This guide is designed to assist you in becoming an informed study volunteer by providing answers to common questions such as:

- Why should I consider participating in clinical research?
- What should I do before deciding to participate in a clinical study?
- Where can I learn more about Parkinson's clinical research?

The guide also provides a **comprehensive list of questions to ask the research team** when you meet to discuss participating in a specific clinical study. These questions will inform your conversation and ensure that you begin your experience as both a knowledgeable study volunteer and an active participant in the clinical research process.

Why Should I Participate in Clinical Research?

Help Find New Medications and Therapies

Many people don't realize that the medications that they take today are available only because people volunteered to participate in clinical trials.

By participating in clinical research, you can play a role in finding new medications and non-drug therapies to treat Parkinson's, as well as help further knowledge about the disease. Your participation can help speed up therapy development — a process that can take as long as 15 years. These delays are due in part to low clinical study enrollment. If more people participated in studies, the time it takes for therapies to reach people who need them would be reduced.

Get Access to Top-Quality Medical Attention

Joining a study can give you early access to potentially helpful treatments and drugs that are not yet on the market. And, once involved, you are likely to receive frequent monitoring and medical attention that can improve your understanding of Parkinson's and how it specifically affects you.

Remember that clinical studies do not replace your standard treatment. Your doctor's goal is to treat your condition, while a researcher's goal is to learn about your disease. For example, while your doctor is able to change your treatment to improve your symptoms, it is a researcher's duty to make sure that your study therapy remains constant.

Types of Clinical Research

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

Therapy

Therapy studies are conducted to test the safety and effectiveness of a potential new Parkinson's therapy, both drug or non-drug, or a different way to use an existing therapy.

Diagnostic

Although there is currently no test to confirm a diagnosis of Parkinson's, diagnostic studies are looking for physical indicators, known as biomarkers, that can help diagnose and track the progression of Parkinson's.

Genetic

Genetic studies help in learning how genes affect PD.

Prevention

Prevention studies aim to find ways to prevent someone from developing Parkinson's.

Contribute to the Diversity of Research Participants

People from various backgrounds are needed to participate in clinical research because people can respond differently to therapies, express different symptoms and have a higher or lower risk of developing Parkinson's. Women, people of certain ethnic and cultural backgrounds, and residents of rural areas are especially underrepresented in clinical studies. When there is more diversity among study participants, research will better reflect how a treatment will work for everyone with PD.

Play a Part Even if You Don't Have Parkinson's

There are numerous opportunities for people without Parkinson's to participate in clinical research. Many clinical studies are looking for "healthy controls," individuals whose study response is compared to the response of people with Parkinson's. This helps determine whether or not a therapy works. For example, if you are a family member of a person with Parkinson's, you can participate in studies that examine the role genetics plays in the development of the disease.

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New therapies and a cure for Parkinson's can't be found unless we feel a sense of urgency and give back to the Parkinson's community by getting involved in clinical studies.”

Israel Robledo, research participant

What Should I Do Before Deciding to Participate?

Talk to Those Around You

There are many people who can aid your decision to take part in clinical research, help you to become an informed participant and support you throughout the time you are enrolled in the study. These people include:

- **Your neurologist**

In addition to knowing about Parkinson's studies that are looking for participants in your area, your neurologist can help you to decide what trials are best for you, and those for which you might not qualify. Not all doctors are familiar with clinical trials near them, so it is a good idea to bring information about studies with you to discuss during your medical visit.

- **Your family**

Your participation in a study can affect members of your family. You might need a ride to and from the study center. You might go to them for emotional support. In any case, it is important to involve your family in your decision-making process. You may also choose to bring a care partner with you when meeting with a study coordinator to help you understand the information that is discussed.

- **Your friends in the Parkinson's community**

One of the best ways to learn about clinical studies is to talk with others in the Parkinson's community. Many people familiar with clinical trials learn about them through support groups or other people with Parkinson's. By sharing experiences about study participation, your peers can help shape those trials you may wish to consider.

Informed Consent

Federal guidelines require that you are given complete information about a clinical study before you decide to take part. If you choose to go ahead, a written agreement is required. This process is known as **informed consent**. It ensures that you fully understand the clinical study and your role as a participant.

Informed consent is more than a document that you sign. It is a process that begins when you first learn about the details of a study and continues throughout your participation in a clinical trial. The informed consent document is not a contract — you are free to discontinue any study if you choose.

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

When considering participation in a clinical trial, you should think about the types of studies you are most comfortable with (see page 4). Some studies are as simple as completing a questionnaire, while others can involve more invasive procedures, such as brain surgery. You may also want to take into consideration certain requirements, such as the number of times you must visit the study site, the length of each visit, how long your participation will be needed, etc. Other factors, such as whether you find it easy or difficult to get to and from the study site can also affect how you feel about your study experience, as can the travel reimbursement options that are available.

Keep in mind that you should not feel pressured to participate in a trial that is not a good fit for you and that your complete participation is needed to ensure the study is completed quickly and accurately.

Understand the Risks of Participation

While there are benefits to research participation, it is helpful to keep in mind that the primary goal of a clinical study is to test a scientific idea through experiment. This means that study participation can involve some risk. For example:

- **A study treatment might not work.**
Although many studies do not succeed, unsuccessful studies are important in learning more about Parkinson's.
- **You may not receive the study treatment.**
In some studies, you might be assigned to a group that receives regular care, or even a placebo, for comparison to the group that receives the experimental therapy.
- **You might experience unwanted side effects.**
Side effects can include those that are known, but also potential new ones that might emerge as the therapy is being studied.

Know the Ethical and Safety Regulations

Federal regulations require health care institutions that conduct clinical research to submit studies to what are known as Institutional Review Boards (IRBs). These boards determine that the potential benefits of the research outweigh the risks to participants and that the consent process clearly communicates the study to the participant. If approved, the study is reviewed at least annually by the IRB to ensure that it is conducted safely and ethically.

Be a Partner in the Research Process

When you choose to participate in a clinical study, 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 any concerns you have are addressed. As with any partnership, you have an active role to play, including:

- **Reading all materials provided** about the study and asking questions when information is unclear.
- **Providing a complete medical history** prior to the study and reporting all new illnesses, injuries and medical 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 accurate and honest feedback** to study staff about your response to the treatment.
- **Making every effort to continue until its conclusion**, while understanding that you can withdraw from the study for any reason.

You can also use your own study experience to encourage others with Parkinson's to participate in clinical research. By leading by example, you can introduce new people to clinical research and help move Parkinson's research forward.

Phases of Clinical Research

Clinical studies are conducted and carefully monitored in a series of phases.

Phase I

Tests the 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 therapy being tested and provides preliminary measures of effectiveness.

Phase III

Measures whether the treatment benefits participants, and whether its benefits exceed its risks.

Phase IV

Determines more information about a treatment, including risks, benefits and optimal use, after it has already been approved by the Food and Drug Administration.

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Being actively involved in clinical studies offers the possibility that my children and grandchildren will be free of Parkinson's as we know it.”

Christine Engelhardt, research participant

**Where Can I
Learn More
About
Parkinson's
Research?**

- **PDtrials**

www.PDtrials.org

Find Parkinson's studies that are currently seeking participants and general information about clinical research through this website provided by *PDtrials*, a coalition of Parkinson's organizations led by the Parkinson's Disease Foundation.

- **National Institutes of Health**

www.clinicaltrials.gov

Find federally and privately supported clinical studies conducted in the United States and around the world, as well as detailed descriptions of the clinical research process.

In addition to these resources, Parkinson's Advocates in Research (PAIR), an initiative of the Parkinson's Disease Foundation, has a network of more than 100 people living with Parkinson's from 36 states who bring educated community voices to important issues in Parkinson's clinical research. Research Advocates educate people with Parkinson's about clinical research and study participation as well as work with researchers, government agencies and institutions to inform priorities at each step of the clinical research process.

To learn more about the Parkinson's Advocates in Research program or how to contact a Research Advocate in your area, visit www.pdf.org/PAIR.

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Not all studies I participate in are likely to have the expected results, but even studies that aren't successful contribute to what we know about Parkinson's.”

Don Simmonds, research participant

What Questions Should I Ask About Clinical Studies?

Being an active study participant begins with being an informed participant.

The questions in this section are designed to aid your conversations with researchers and study coordinators when you are thinking about participating in a clinical study. They will help you to learn more about the following topics:

- What you need to know about the study.
- What will be required of you.
- What other treatment options are available.
- What the benefits and risks are.
- How and what expenses will be covered.
- How your health and safety will be monitored and your privacy protected.
- What will happen at the end of the study.
- How post-study information will be made available.

“When I first meet with a study coordinator or researcher, I learn all I can about the study. Research participation is important to me, but it’s especially important that I am an informed participant.”

Linda Morgan, research participant

What do I need to know about the study?

- What is the purpose of the study and why is it important?
- Has it been shown that the experimental treatment being studied may help my condition?
- Has this experimental treatment been studied before? If so, what were the results and how can I get them?
- If this is a placebo-controlled trial, what are my chances of receiving the experimental treatment that is being studied?
- When is the study expected to end?
- Will I be able to receive the experimental treatment when the study ends?
- Will I receive post-study care?
- Who is sponsoring (funding) the study?
- How long has this site been conducting clinical studies? How many are currently underway and how many have been completed?
- Does anyone on the clinical study staff have a financial association (e.g., ownership of stocks, other investments and/or consulting contracts) with the sponsoring company?

What will be required of me?

- How should I prepare for my meetings with the research coordinator or researcher?
- How much of my time will be involved?
- Will I have to travel?
- What types of visits (outpatient, hospitalization, home) will be required and how long will they last?
- How could being in the study affect my daily life?
- What tests will be given before I start the study? Will I get the results of these tests? If so, when will this occur?
- What tests will be given during the study? Will I get the results of these tests? If so, when will this occur?

Are there other treatment options?

- If I don't participate in this study, are there other studies for which I might be eligible?
- Why do researchers believe that the experimental treatment may be better than my current treatment options?
- Is this treatment available outside of this study? If so, how do I get it?

What are the benefits and risks?

- What are the known side effects of the experimental treatment being studied?
- What is likely to happen to my disease symptoms with or without this experimental treatment?
- Will the experimental treatment make me feel uncomfortable or sick? If so, for how long?
- Can I take my prescriptions or over-the-counter medications along with the experimental treatment?
- What is known about the interaction between the medications that I am currently taking and the experimental treatment?
- Will participating in this study prevent me from volunteering for future studies?

How will my expenses be covered?

- Will I have to pay for any part of the study, such as tests to determine eligibility, or the study drug?
- What costs might be covered by my health insurance?
- Who can help answer any questions from my insurance company or health plan?
- Will I be reimbursed for my expenses (travel, meals, overnight stays, caretaker assistance, etc.)?
- How and when will I be reimbursed for expenses that I incur while participating in the study?

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

- Who will provide me with a comprehensive explanation of the information contained within the informed consent form that I am to sign?
- Whom do I contact at the study site if I have questions during the trial?
- How will the study staff work with my physician to keep him or her informed about my care?
- Who is responsible for my care while I am participating in the study?
- What procedures are in place in the event that, due to the progression of my disease, I am no longer able to make decisions for myself with regard to participation in this study?
- How will I be informed of changes to the study and will I be given a new informed consent form to sign?
- If I develop study-related complications during the study, what medical care will I be entitled to, how will this be managed, and what follow-up care will be provided?
- Who has access to the study data collected and how will it be used?
- How and to whom are adverse events reported and how will I be informed?

What happens at the end of the study?

- If I am in a study that uses a placebo, will I be told afterwards whether I received the placebo or the experimental treatment?
- What happens to the information I provided once I stop participating in the study?
- What procedures are in place to notify me if my trial is halted or terminated and how and when will I be advised on what steps to take?
- What is the procedure for withdrawal from the study and can I do so at any time?
- Are there penalties such as being denied future medical treatment if I withdraw from the study?

How will post-study information be made available?

- How will I be notified about side effects, benefits and risks that become known?
- What will be done with the study results after the study is completed?
- Will I receive a copy of the study results? If so, when?
- How will both negative and positive study results be made available to study participants, researchers and the public?
- Will I receive the results of future studies using this treatment?

If you have or believe you have Parkinson's disease, please be aware that this publication is not a substitute for a physician's diagnosis of Parkinson's disease or for a physician's prescription of drugs, treatment or operations for Parkinson's disease.

The section 'What Questions Should I Ask About Clinical Studies?' was based upon the *Declaration of Clinical Research Rights and Responsibilities for People with Parkinson's Disease*, developed by the Parkinson Pipeline Project and PDPlan4Life.

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The Parkinson's Disease Foundation® (PDF®) is a leading national presence in Parkinson's disease research, education and public advocacy. We are working for the nearly one million people in the US living with Parkinson's by funding promising scientific research and supporting people with Parkinson's, their families and care partners through educational programs and services.

Since our founding in 1957, PDF has dedicated over \$85 million to fund the research of leading scientists throughout the world and over \$34 million to support national education and advocacy initiatives.



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