



# Should You Volunteer?

Parkinson's Disease  
Research Studies



Presented by the  
National Parkinson Foundation, Inc.



**If you have Parkinson's disease, you may be asked to volunteer for a research study. Deciding whether or not to sign up is an important decision. Learning about research studies can help you decide if being a volunteer is right for you.**





## What is a research study?

Research studies are done when doctors and scientists want to find new ways of treating an illness. Research studies are often called **clinical trials**. Most Parkinson's studies focus on new medicines. Others focus on treatments such as surgery.

## Why are research studies important?

Research studies are important because they help discover new treatments. They are done to make sure that new medicines are safe and that they work. Research studies couldn't be done without volunteers. **People who volunteer for research studies make new treatments possible.**



# Why should I sign up for a research study?

There are some good reasons to sign up for a research study:

- You may be able to get new treatments before they are available to the public.
- You will receive expert health care, usually at no charge.
- You are helping to find new treatments, which will help others who get Parkinson's.

# What questions should I ask?

Before you decide to sign up, you should learn as much as you can about the research study. You should feel comfortable with the research team so that you can ask questions. Asking these questions will help you learn more about the study.

- Does the study test a new drug or piece of equipment?
- Do I have a chance of getting a pill that isn't the study drug?
- Why is the study being done?
- How long will the study last?
- Where will I have to go for study visits?
- How many visits will I need to make?
- What tests and treatments will I take part in?
- Who will be in charge of my care?
- Are there other treatments that might help?
- What are the risks?
- What are the benefits?
- Who is paying for study treatments?
- What are my rights as a volunteer?
- Will my study information be shared with others?
- Will I have to pay for treatment?

## What are the risks?

There are also risks when you sign up for a research study:

- Some medical tests or side effects may be uncomfortable.
- The treatment may not help your Parkinson's.
- Being a volunteer in a research study can take extra time. For example, you may need to make extra trips to the study office.

## What happens if I decide to volunteer?

If you decide to volunteer, you must sign an **informed consent** form. This form includes answers to all of the questions above. It also lists details such as important phone numbers. You should read the form closely and ask any questions that have not been answered. Once you sign the form, you will be given a copy of it. Then you can begin to take part in the study. **Even though you have signed the consent form, you can decide to stop being in the study at any time.**



### Remember:

- **Only you can decide whether or not to be in a research study.**
- **You can choose to stop being in the study at any time.**
- **Volunteers make new treatments possible.**

## Key terms to know

As you learn about research studies, you may come across words that are not familiar to you. Here is a short list of research study terms and what they mean.

**IRB (Institutional Review Board):** The IRB is a group of doctors, health care professionals, and members of the community. The IRB reviews the study plan and informed consent form to make sure that the safety and rights of the volunteers are protected. Every research study must be approved by an IRB.

**FDA (Food and Drug Administration):** The FDA is the government office that makes sure that all drugs and medical devices are safe and helpful.

**Protocol:** The protocol is the study plan. The protocol describes what types of people can volunteer, how long the study will last, and what will take place during the research study. The protocol is designed to protect the volunteers' safety through out the study.

**Placebo:** A placebo is a pill that doesn't have any medicine in it. It looks like a drug, but causes no changes in the body. Some research studies will compare the new treatment with a placebo.



**Phase of study:** All drugs and treatments go through different phases of research before they are approved. Most studies that you may sign up for will be phase 2 or phase 3 studies.

**Phase 1 study:** Phase 1 studies are usually done with healthy volunteers. The new treatment is tested in a small group of 20-80 people to look for side effects and judge safety.

**Phase 2 study:** Phase 2 studies are done with a larger group of people who have the target illness, such as Parkinson's. The goal of phase 2 research is to test how well the new treatment works, and to gather more information about side effects and safety.

**Phase 3 study:** Phase 3 studies are done with a larger group of at least 500 people. Phase 3 testing compares the new treatment with similar treatments that are already approved.

**Study design:** There are several different designs, or methods, for research studies. Here are three common study designs:

**Placebo-controlled studies** are those in which some people will get a pill without any medicine in it.

**Single-blind, placebo-controlled studies** are those in which either the study patient or the researcher does not know if the patient is receiving actual study drug or placebo.

**Double-blind, placebo-controlled studies** are those in which neither the study patient nor the researcher knows if the patient is getting the study drug or placebo. Double-blind studies are thought to be the best study design.

## Want to know more?

For more information, call the **National Parkinson Foundation** at 1-800-327-4545, or visit the Internet sites listed below.

[www.parkinson.org](http://www.parkinson.org)

The web site of the National Parkinson Foundation includes information about Parkinson's, as well as research updates and referrals to a nationwide network of research centers.

[www.centerwatch.com](http://www.centerwatch.com)

This site provides general information about clinical research, including listings of thousands of active research studies, as well as new drugs in research and those recently approved by the FDA.

[www.clinicaltrials.gov](http://www.clinicaltrials.gov)

Provides easy access to information on clinical trials for a wide range of diseases and conditions. The U.S. National Institutes of Health (NIH), through its National Library of Medicine (NLM), has developed this site in collaboration with all NIH Institutes and the **Food and Drug Administration** (FDA).



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