

Declaration of Clinical Research Rights and Responsibilities for People with Parkinson's Disease

Clinical research is essential to the development of new therapies and treatments for Parkinson's disease. Yet, due to a number of factors, including a lack of awareness and understanding of the research process, only one percent of people with Parkinson's participate. This is far below the number needed, delaying many promising trials.

Those who do participate in clinical studies assume risk to help advance science through research, but are not always fully aware of their rights and responsibilities. To remedy this, the Parkinson's Pipeline Project and other people with Parkinson's developed this Declaration of Clinical Research Rights and Responsibilities with input from the Parkinson's Study Group, and advisement from the Parkinson's Disease Foundation through their People with Parkinson's Clinical Research Advocacy Initiative. The intent of this document is to address the needs of all stakeholders in the clinical trial process by:

- Educating the Parkinson's community about the clinical research process.
- Empowering people with Parkinson's to make informed decisions about their clinical trial participation.
- Increasing participation and improving retention in clinical trials, helping to speed the evaluation and approval of new treatments.
- Providing a roadmap the research team can use to develop and conduct patient-centered clinical research, which goes beyond existing federal regulations governing the informed consent process and adds patient rights that may not currently be common practice.
- Ultimately, inspiring a culture shift where the participant is viewed as a partner, not a passive subject in the clinical research process.

In order to achieve these goals, this document outlines rights and responsibilities for clinical trial participants with Parkinson's disease, including:

- I. The right to receive comprehensive information about a clinical trial prior to enrollment.
- II. The right to receive ongoing comprehensive information throughout their enrollment in a clinical trial.
- III. The right to timely reimbursement for all agreed upon expenses associated with clinical trial participation.
- IV. The right to withdraw from a clinical trial at any time without penalty.
- V. The right to be informed when a sponsor is considering halting or terminating a trial.
- VI. The right to timely post-study information and options for care.
- VII. The right to be assured that participation in clinical research will contribute to the scientific evidence necessary to evaluate new and more effective treatments.

It is assumed that all clinical study information will be communicated verbally and in writing in the primary language of the participant and at an appropriate reading level.

Those rights marked with an asterisk () are based on existing federal regulations governing the informed consent process. Additional rights, not marked by an asterisk, may not currently be common practice, however they should be discussed with trial participants as part of the informed consent process.*

I. Clinical trial participants have the right to receive comprehensive information about a clinical trial prior to enrollment, and should be informed about:

- Potential risks and benefits.*
- Study design, including: purposes and expected outcomes, duration, required medical tests/procedures, and if applicable, the percentage of participants who will receive a placebo.*
- Conditions under which a trial or an individual's trial participation may be terminated without their consent. *
- Other procedures, drugs, devices or treatments that may benefit the participant. *
- How enrollment in a clinical trial could make participants ineligible for some future trials, especially those testing neuroprotective treatments requiring participants who have not previously taken other Parkinson's medications.
- Availability and procedures for obtaining compensation and/or medical treatment necessary due to injury resulting from the clinical trial, and whom to contact.
- Who has access to the data collected and how participant privacy will be protected. *
- Contact information for trial staff responsible for answering questions about the trial. *
- The opportunity to take home, review, and discuss all study information with medical professionals before deciding to enroll in the trial.
- The difference between the roles of doctors as personal physicians and as clinical trial investigators. A personal physician's responsibility is to provide ongoing patient care to maintain the patient's health and well-being. The primary role of the clinical-trial investigator is to advance scientific knowledge regarding the safety and efficacy of the experimental treatment
- Trial staff should evaluate to ensure that participants' fully understand the informed consent document before they sign it.
- The option to have a caregiver, family member, or other trusted person present during discussion and review of clinical trial information.
- How to access published information about the investigational treatment.
- Financial associations between the study sponsor and clinical trial staff, which could lead to a vested interest by the staff in success of the treatment being evaluated, such as employment, consultancies, stock ownership, honoraria, paid expert testimony.

The participant has the responsibility to:

- ✓ Read all materials provided about the trial and treatment being considered and ask questions when information is unclear.

II. Clinical trial participants have a right to receive ongoing comprehensive information throughout their enrollment in a clinical trial. This includes being told about:

- Access, where available, to an ombudsman who can assist with communication between the participant and the research team.
- The opportunity, where available, to create an Advance Directive for medical research and appoint a legally authorized representative to make medical and research decisions if the individual becomes unable to do so.
- The option to consult, at any time, with a personal physician not involved in the study.
- The procedure for reporting and resolving problems with clinical trial staff. Where these issues cannot be resolved on site, a trained patient representative, where available, may be asked to mediate. If mediation fails, participants may request referral to a different trial researcher or site, if available.
- New findings, adverse events, and side effects, as they develop.
- What they can and cannot tell others about the study, and why

The participant has the responsibility to:

- ✓ Become familiar with the trial site staff and their respective responsibilities.
- ✓ Provide a complete medical history prior to the trial, and report all new illnesses, injuries, and medical procedures that occur during the trial.
- ✓ Be available for each required test, procedure and clinical evaluation ..
- ✓ Follow all trial instructions

III. Clinical trial participants have a right to timely reimbursement for all expenses associated with trial participation:

- Non-medical expenses, such as lodging, transportation, and meals, for the participant, and where medically necessary an accompanying caregiver, will be arranged and paid for, in advance when possible, as stipulated in the informed consent.
- All out-of-pocket expenses will be reimbursed in a timely manner, as stipulated in the informed consent.

The participant has the responsibility to:

- ✓ Submit all related personal expense receipts in a timely manner for reimbursement.
- ✓ Contact the designated trial staff member prior to each scheduled appointment regarding any pre-paid expenses.

IV. Clinical trial participants have the right to withdraw from a trial at any time without penalty, and are entitled to receive:

- An explanation of procedures for orderly withdrawal, to include how to transition from trial treatment to previous treatment and any health consequences due to this decision.
- Post-study information (as provided to those who complete the trial) as soon as it is available

The participant has the responsibility to:

- ✓ Refrain from making any changes to treatment plan before talking to the trial staff..
- ✓ Contact the designated trial staff member stating his or her intent to withdraw from the study and why.

V. Clinical trial participants have the right to be informed when a sponsor is considering halting or terminating a trial:

- Trial staff should advise participants of a trial halt, at the same time it is publicly announced, and explain the reason(s) for the halt and how to proceed with remaining trial medications or devices.

VI. Clinical trial participants have the right to post-study information and options for care including:

- Trial results, both positive and negative.
- Information about the conditions under which they may receive post-trial access to the experimental treatment.
- Notification as to whether they received a placebo or the experimental treatment and at what dosage.
- The option for participants in the experimental/treatment group to continue the treatment. Likewise, those who received placebo or low dose treatments, or sham surgery should have the option of receiving the experimental treatment at the full dose , upon conclusion of their trial.
- Results of all tests and procedures and copies of scans, x-rays, MRI's, etc. if requested by the participant.
- Timely updates about all adverse events following trial conclusion.

The participant has the responsibility to:

- ✓ Submit in writing any change of address and/or phone number..

VII. Clinical trial participants have the right to be assured that their participation in clinical research will contribute to the scientific evidence necessary to evaluate new and more effective treatments. To lay the groundwork for this:

- Patient reported outcomes should be collected and considered.

- Study sponsors will be required to list all clinical trials with appropriate registries and make publicly available, in a timely manner, all positive and negative trial results.

The participant has the responsibility to:

- ✓ Provide accurate and honest feedback to trial staff about their response to the treatment..
 - ✓ Use the trial experience, to help encourage greater clinical trial participation in the Parkinson's community.
 - ✓ Make every effort to continue in the trial until its conclusion, recognizing that participant retention is important in obtaining in obtaining useful data.
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Sources consulted:

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