

PRE-TRIAL



As a potential volunteer for a clinical trial in Parkinson's, I understand that, at any stage, I have a choice whether to be involved in a trial or not. In making my decision on whether to volunteer for a particular trial, I am prepared to:

Read all available information about the trial so that I fully understand what will be involved *

Understand any potential risks and benefits of my involvement in this trial as explained to me by the trial coordinators *

Discuss the pros and cons of the trial with people whose opinion I value before deciding whether or not to volunteer

Carefully read through the 'Informed Consent' form and keep a signed copy

Choose to participate only when I am satisfied that the purpose of this study is important to me, and when I have established what it involves and what I might expect

Commit to taking part in the trial until its completion whilst being aware that I can withdraw if I choose

DURING TRIAL



I should:

1. Talk to the research team...
 - if I have questions or concerns
 - if I experience changes to symptoms or side effects
 - if there is an emergency
 - about my appointment or any visits to the trial centre*
2. Be aware of what experiences might occur and know to whom and how to report them if they happen

POST-TRIAL



It will help future studies if I communicate with the trial team to:

1. Share my opinion of the trial and the quality of care at the trial centre
2. Speak openly about how the trial affected me positively or negatively
3. Make suggestions on how the trial might have been improved
4. Consider becoming a 'Clinical Trials Ambassador' *

*Denotes where further resources can be downloaded at www.ParkinsonsMovement.com/charter

Developed by people with Parkinson's and clinicians with particular thanks to Dr. Camille Carroll (Plymouth University, UK), Parkinson's UK, European Parkinson's Disease Association, The Cure Parkinson's Trust, The National Parkinson Foundation (Miami, US), Prof. Michael Schwarzschild (Harvard and Parkinson Study Group, US), Van Andel Research Institute (Grand Rapids, US), Prof. Bastiaan Bloem (Parkinson Centre, Nijmegen, Netherlands), Dr. Michael Okun (University of Florida, US), Dr. Joseph Jankovic (Baylor College of Medicine, Houston, US), Dr. Tom Foltynie and Prof. Huw Morris (University College London, UK), Prof. Roger Barker (Brain Repair Centre, Cambridge, UK)

CLINICIANS/RESEARCHERS

PRE-TRIAL



As researchers, we understand we are responsible for designing and delivering ethical studies that are of relevance to patients. We aim to ensure participants' safety and to protect their rights and dignity.

We strive to:

1. **Communicate effectively** with all participants and wider stakeholders which will involve:
 - identifying individuals to be responsible for communication*
 - producing information about the trial which is accessible and easy to understand *
 - providing ample opportunity to address participants' concerns or questions about the study
 - involving patient advocates and prospective participants in all aspects of study design and conduct as appropriate
2. **Be transparent and clear** in what we hope to achieve from the study, its potential, the risks and benefits
3. **Ensure all appropriate approvals and safeguards** are in place prior to the start of the study*

DURING TRIAL



We should:

1. **Listen carefully** to participants' concerns and address unforeseen issues rapidly as they arise
2. **Employ and continuously re-evaluate** the practices used in this trial, to ensure the optimum care of participants
3. **Communicate effectively** and keep trial participants informed, motivated and supported
4. **Use data collected during the trial** to re-assess the design and validity of the study and its potential value in future research

POST-TRIAL



We should:

1. **Create** a project debrief for all participants using a range of media and collect feedback from patients on their trial experience (good and bad)
2. **Disseminate** lessons learnt to the wider Parkinson's community – best practice should evolve
3. **Communicate** the results of the trial to the Parkinson's and wider communities – if possible publish results as open access
4. **Use information** collected from above to improve future trials

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