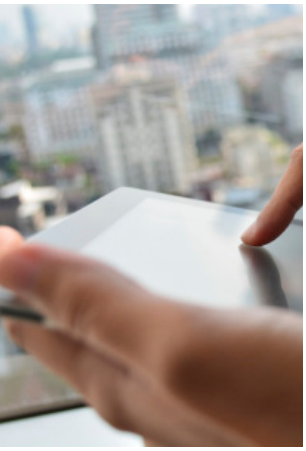
The Cure Parkinson's Trust

Charter for Clinical Trials in Parkinson's

Setting standards of practice for those involved in clinical trials for Parkinson's

POTENTIAL PARKINSON'S STUDY PARTICIPANTS

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:

1. **Read** all available information about the trial so that I fully understand what will be involved *
2. **Understand** any potential risks and benefits of my involvement in this trial as explained to me by the trial coordinators *
3. **Discuss** the pros and cons of the trial with people whose opinion I value before deciding whether or not to volunteer
4. **Carefully read** through the **'Informed Consent'** form and keep a signed copy.
5. **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
6. **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'** *

*The following resources can be downloaded at www.ParkinsonsMovement.com/clinicaltrials: Clinical trials leaflets; Asking questions; Meet the team; Clinical trials Ambassador (coming soon); Top Tips

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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 Parkinson's and wider community – if possible publish results as open access
4. **Use information** collected from above to improve future trials

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