



## Consultee Information Sheet

Version 3.4 02/02/2017

### Title of research study:

### Care of Late Stage Parkinsonism (CLaSP Study)

### Name of Lead Researcher: Prof Anette Schrag

Your relative is being invited to take part in a research study. This leaflet explains why the research is being done and what taking part will involve. Please read the following information carefully and discuss it with others if you wish. You can then talk to the researchers before you decide whether to go ahead. Thank you for taking the time to read this.

#### ***What is the study about?***

The aim of this study is to determine the needs of those who have had Parkinsonism for a number of years, and their carers. We are interested in how needs are currently met in different European countries, and how care could be improved. We suspect that there are unmet needs and that these can be addressed better. We will therefore assess the problems and needs of those who have had Parkinsonism for a number of years, and their carers, through examination and questions, and by looking at existing health care databases. We will also study the effect of a specialist clinician making an assessment and treatment recommendations compared to those who receive their normal care.

In addition, we are collecting saliva samples in order to allow genetic analysis by ourselves or our collaborators in future studies that are approved by a Research Ethics Committee. These samples will help us study markers that could help in the future diagnosis of Parkinson's disease or in monitoring how the condition progresses.

#### ***Why has your relative been invited?***

Your relative has been invited because he or she has had Parkinson's disease or Parkinsonism for at least seven years. We are writing to everyone who has been diagnosed for that length of time as everyone has different experiences of Parkinson's. We are particularly looking for people whose health, movement and daily life have been significantly affected after this length of time with the condition.

#### ***What does taking part involve?***

- Someone from the research team will talk to you and your relative about the study. If you and your relative agree to take part the researcher will also ask them a few questions to assess their memory and understanding and physical ability.
- A member of the research team will contact you to make an appointment for an assessment. The assessment can be in your relative's home or in a hospital clinic, if you prefer.

- The appointment will involve an assessment of their movements as well as answering questions about their health, memory, circumstances, the health care received and previous treatments, as well as questions about their general needs. The researcher will ask you if they may video or audiotape some of their movements and replies in the interview. They will also take your relative's or friend's lying and standing blood pressure.
- The researcher will also ask for a saliva sample. If this is not possible at the first face-to-face assessment the researchers will post a sample kit with full instructions on how to use it.
- The assessment should take approximately 2 hours, but this can be carried out in two appointments if you and your relative prefer.
- The researcher will ask you, a carer, relative or friend, if applicable, to complete a questionnaire about the usual activities and behaviour of the person who has Parkinson's, and ask questions about their needs and health care received.
- They will also ask your relative's health care provider or member of staff about their medical problems and treatments.
- After the assessment the researcher will discuss the findings with a specialist in movement disorders who will also watch the video made of movements and the replies given to the questionnaires.
- If you agree, and they are eligible, your relative may then be given the opportunity to participate in the open trial. This would mean that they will either receive their normal care, or the research doctor will contact your primary care physician to inform them about the assessment results, and make recommendations about possible changes to treatment and care. During this time there would be access to a helpline. Your relative will be offered up to 3 further assessments, and the last two can be in person or via telephone.
- We do not know whether having a specialist assessment in this way in addition to normal care will make a difference to health for those who have had Parkinsonism for a number of years. To find this out one quarter of participants will continue with their usual care and three quarters of participants will receive a closer review of treatment.
- The choice of which group your relative will be in is completely random. You and their doctor will know which group he or she are in but not all of the researchers will necessarily know. Whichever group they are in a letter with the assessment results will be sent to their GP.
- The researchers would like to carry out semi-structured interviews with a number of participants and carers. This would take the form of an interview about the needs, experiences and health-care support of those who have had Parkinson's for a number of years. The option of taking part in this aspect of the study will be discussed at the assessment.
- Confidentiality is very important to us. The information given to us during this study will be used in strict confidence by the people working on the study. Personal information will not be released under any circumstances, other than to their health care team. However, we will share data with the researchers from other countries to enable comparisons to be made between health care systems; but this will not be personal details that could identify your relative.

***What are the possible risks of being in the study?***

The study will require a commitment in time and they may find the assessment lengthy. However, there will be breaks and they can ask to stop the assessments at any point.

### ***How does this study benefit my relative?***

The care of those with Parkinson's disease can often become difficult as the disease progresses. This is partly due to difficulty accessing health care services and the complexities of the disease. This study aims to establish the best ways to improve care in Parkinson's. This will be done by providing information about met and unmet needs, and the current management and availability of health care resources. Although taking part may not directly benefit you or your relative at the time, the study findings will provide international guidelines that will benefit those with Parkinsonism and their carers.

Similarly, whilst providing a saliva sample will not benefit you directly the information we obtain from it may mean we learn more about Parkinson's. We hope this might help to treat people better in the future.

### ***Does my relative have to take part?***

Your relative does not have to take part in the study and it is entirely up to them and you whether you would like them to take part or not. You do not have to give a reason if you do not want them to be involved. Whatever you decide will have no effect on the care your relative receives now or in the future. If you agree for your relative to take part but then change your mind you can withdraw them from the study at any time without giving a reason. If you do withdraw them, you can decide whether we can use any information you and your relative have already given us.

### ***Expenses***

If you agree for your relative to take part in this study and you choose to have the assessment done at a hospital clinic we will cover their travel expenses by car or taxi. If you or another relative, friend or carer accompanies them, their travel expenses will also be paid.

### ***Personal information policy***

If you decide for them to take part in the study, all information that you and your relative provide to us and the results of the study will be treated confidentially. Information will be stored securely in locked cabinets and password protected computer systems which can only be accessed by the research team.

The saliva sample will be stored securely within appropriate storage facilities and without any identifying personal details, in accordance with rules by the Human Tissue Authority

We will write to their General Practitioner (GP) with your permission, informing them of your agreement to take part in this study. If your relative is in the treatment arm of the study, a summary with recommendations will be sent to their GP and/or specialist. The NHS is improving the quality of clinical and research standards. This is being achieved through 'clinical governance'. As part of this process, this study may be reviewed by a clinical governance team. Such a team would need to look at your relative's records to make sure that the research was carried out in accordance with proper procedures. If this takes place all information will remain confidential during this process.

### ***What if there are any problems during the study?***

Every care will be taken to ensure that your well-being and safety is not compromised.

If however you have any concerns about the research study you can speak to a member of the research team who will do their best to answer any questions. Contact details are at the end of this information sheet. If you wish to complain, or have any concerns about any aspect of the way you or your relative have been approached or treated by members of staff when your relative participated in the research, National Health Service or University College London (UCL) complaints mechanisms are available to you. Please ask the research team if you would like more information on this. In the unlikely event that your relative is harmed by taking part in this study, compensation may be available to them. If you suspect that the harm is the result of the Sponsor's (UCL) or the hospital's negligence then you may be able to claim compensation; UCL has a special insurance arrangement in place (no-fault compensation). After discussing with the research team, please make the claim in writing to Prof. Anette Schrag who is the Chief Investigator for the research and is based at the UCL Institute of Neurology, who will then pass the claim to the Sponsor's Insurers. You may have to bear the costs of the legal action initially, and you should consult a lawyer about this. NHS Indemnity does not offer no-fault compensation i.e. for non-negligent harm, and NHS bodies are unable to agree in advance to pay compensation for non-negligent harm. All communication will be dealt with in the strictest confidence.

### ***Who is organising and paying for the study?***

The study is funded by the Economic and Social Research Council (ESRC) of the UK, in collaboration with similar funding bodies in other European countries which are also participating in this study.

The research team you will have contact with is mainly based at the University College London.

### ***What will happen next?***

The next step will be a telephone call from one of the researchers. If you are interested in your relative participating in the study, they will arrange to visit your relative at home or see your relative at the hospital if they already have an appointment booked. This will give you a chance to ask any questions before you make a decision about taking part.

If you do decide for your relative to take part you will be given a copy of this information sheet to keep and be asked to sign a consent form.

### ***Who has reviewed the study?***

This study has been reviewed and approved by the NRES Committee London – Camden and Islington.

### ***Further information***

The research team should contact you in the next week or so. If you would like further information

Or contact the head of the research team: Prof. Anette Schrag at University College at

Email: [a.schrag@ucl.ac.uk](mailto:a.schrag@ucl.ac.uk)

Alternatively, you may contact The Dementias and Neurodegeneration Research Network:

General Enquiries, DeNDRoN  
27 Old Gloucester Street, LONDON, WC1N 3AX, C/O Box 81.  
Phone: +44 (0)20 3206 4960, +44 (0)20 3206 4960  
Email: [crndementias@nihr.ac.uk](mailto:crndementias@nihr.ac.uk)

Independent information and advice about taking part in research projects are available from patient advice and liaison Service (PALS) office at the Royal Free NHS Foundation Trust:

Phone: 0207 472 6446 or 0207 472 6447  
24-hour answer phone: 0207 472 6445  
Text: +447860023323 (Deaf, hard of hearing and hearing impaired patients)  
Email: [rf.pals@nhs.net](mailto:rf.pals@nhs.net)

For more information on Parkinson's and how to get involved in other studies, please visit Parkinson's UK's website [www.parkinsons.org.uk](http://www.parkinsons.org.uk) or NIHR website [www.peopleinresearch.org](http://www.peopleinresearch.org) or [www.invo.org.uk](http://www.invo.org.uk)

Thank you again for reading this information.

Prof. Anette Schrag  
Clinical Neuroscience  
UCL Institute of Neurology, Royal Free campus  
Rowland Hill Street  
London NW3 2PF  
[a.schrag@ucl.ac.uk](mailto:a.schrag@ucl.ac.uk)  
020 7794 0500