# CAREGIVER INFORMATION SHEET

## Cannabidiol for Parkinson's Disease Psychosis (CAN-PDP): PHASE II

We would like to invite you to take part in our research study as a partner, relative, friend or caregiver of a person who has consented to participate in the above research study. Before you agree to participate, we want you to understand why the research is being done and what it would involve for you. Please feel free to talk with family and friends about the study if you wish. Please ask a member of the study team if there is anything that is not clear or if you would like more information. Take your time to decide whether or not you wish to take part. If you decide to take part, you may keep this information sheet.

**What is the purpose of the study?**
Parkinson's disease psychosis is a symptom of Parkinson's disease that causes patients to experience hallucinations and/or delusions. More than half of all patients with Parkinson's disease eventually develop these symptoms over the course of their disease. These problems can be difficult to manage and can impact quality of life. Currently, existing medications to treat these symptoms are either not very effective or have significant side effects.

This is a research study to test an investigational medicine called cannabidiol (CBD). Previous studies not only suggest that CBD may be useful in treating psychosis, they also suggest that it is safe to use in older adults.

The purpose of this trial is to look at how safe and well CBD works in patients with Parkinson's disease psychosis, and how well it is tolerated. The investigational medicine is not expected to modify the progression of Parkinson's disease.

**Why have I been chosen?**
You are a partner, relative, friend or caregiver of a person who is taking part in a research study of a medicine called cannabidiol (CBD). It is important that you know the participant well and see them on a weekly basis.

**Do I have to take part?**
Your participation is entirely voluntary. If you agree to participate, you will always remain free to withdraw at any time without giving a reason. If you decide not to take part, the main participant can identify an alternative person to assist them in the study.

**What will happen to me if I take part?**
The main participant will be in this study for approximately 16 weeks. You will be required to be involved in the study for the duration of the study. During the initial screening visit you will be required to sign a consent form.

If you are the nominated partner, relative, friend or caregiver for a participant in the study, you will be asked to:

• Attend study visits with the participant:

The participant will be asked to attend 6 study visits over a period of 16-18 weeks, which can take place either at home or in a clinical setting. The majority of study visits will last approximately 2-4 hours. Your presence might be needed for the entire duration of visits..

• Give information and fill out questionnaires during the study visits about the participant, including information about the participant's memory, behavioural and psychological symptoms, quality of life and daily functional skills. To minimise the length of time taken for face-to-face visits, we will aim to conduct the majority of these questionnaires remotely (i.e. over the telephone, videocall or email) where this is feasible

• Tell the study team at every visit if the participant shows or tells you about any unexpected or unusual symptoms, behaviour, physical changes, or other changes, or suffers from any sickness or health problems (side effects or any adverse experience to the study medicine).

**How will we use information about you?**

We will need to use information from you for this research project. We will keep all information about you safe and secure.

KCL/ SLaM is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. KCL/ SLaM will keep identifiable information about you for a minimum of 25 years after the study has finished.

The NHS participating Trust will use your name, NHS number and/ or date of birth and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from KCL/ SLaM and regulatory organisations may look at your research records to check the accuracy of the research study. The NHS Trust will pass these details to KCL/ SLaM along with the information collected from you and your medical records. The only people in KCL/ SLaM who will have access to information that identifies you will be people who need to contact you for trial monitoring purposes or audit the data collection process.

People who do not need to know who you are (for example, the people who analyse the information) will not be able to see your name or contact details. Your data will have a code number instead.

**What are your choices about how your information is used?**

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

**Where can you find out more about how your information is used?**

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by ringing us on 07936545178
- by contacting King's College London's Data Protection Officer, Mr Albert Chan at info-compliance@kcl.ac.uk

**Can I withdraw from the study?**
You can withdraw from the study at any point, without having to give a reason, via the contact details given at the end of this document. If you decide to withdraw from the study, anonymised information collected from you up until the point you withdraw may still be used, but you can request that your personal details (e.g. contact details) are not stored. However, for legal purposes, we are required to store your full name and a copy of your consent form.

**What will happen to the results of the research study?**
When we have collected all the results for this study we will analyse them and then publish and present the results. If you wish we can send you a copy of the published results. You will not be identified in any publication or presentation.

**What are the possible benefits of taking part?**
You will not receive any direct benefit by taking part in this study. Participation may or may not help the study participant. Results from this study may benefit others in the future.

**Are there risks to you in this study?**
There are no anticipated physical risks to you if you are in this study. There may be a risk of loss of confidentiality of information that you provide. You will read more about the protection of your information later in this information sheet. Please ask the study team if you would like to know more about how your information will be protected while you are in this study.

Filling out the questionnaires could cause you to feel uncomfortable or upset. Please tell the study team if this happens. You do not need to answer any questions you do not wish to.

**What if there is a problem?**
Although we have no specific complaints procedure for this project, in the unlikely event that you are harmed due to our negligence, you are encouraged to approach us on the contact details below. You may also contact the NHS Patient Advice and Liaison Service (PALS) for independent advice. South London and Maudsley (SLaM) NHS Foundation Trust PALS can be contacted on free-phone 0800 731 2864 or by email at pals@slam.nhs.uk. Alternatively, you can dial NHS 111 to find the nearest PALS.

**Who is funding the research?**
Parkinson's UK is funding this research.

**Who has reviewed the research?**
The London Hampstead Research Ethics Committee (REC) and Medicines and Healthcare products Regulatory Agency (MHRA) have authorised this Clinical Trial.

**Will I be paid for my participation in this study?**
If travelling separately from the main participant, we are happy to refund any travel expenses you incur in order to attend the research visits. We ask that you keep your receipts.

**Contact for Further Information**
If you wish to participate, you will be asked to sign a consent form. You can keep the information sheet for your records.

Thank you for reading this and for your interest in the study.

For further information, please contact:

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