Transforming Parkinson's Care in Africa (TraPCAf)

Participant Information Sheet and Consent Form:

Clinical examination and sample collection

Part 1: Participant Information Sheet

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others, but it is up to you to decide whether to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This research is about a condition called Parkinson's disease. Parkinson's disease affects the brain. It involves symptoms such as shaking, slow movement and stiffness that get worse over time. Parkinson's disease can have a big impact on someone's life, and it is important for it to be identified and managed early. Parkinson's disease is diagnosed mainly through clinical examination and ideally by a doctor who specialises in Parkinson's disease, often this is a neurologist. Once someone is diagnosed, they can begin to access treatment and care to manage the symptoms.

This aspect of the study is part of a bigger research study taking place across Africa to understand more about Parkinson's disease. The research, called Transforming Parkinson's Care in Africa (TraPCAf), is funded by the National Institute for Health and Care Research (NIHR) in the UK. This part of the study involves understanding the symptoms people with Parkinson's disease living in Africa experience, and how the disease progresses over time.

This part of the study also involves understanding risk factors for developing Parkinson's disease, for example, whether pesticides or diet have a role in the disease, or certain genes are responsible for the disease. If you consent, you will be asked to provide biological samples (detailed below) and samples of water and soil from near your home.

Why have I been asked to participate?

You are being asked to take part in this research because you have been diagnosed with Parkinson's disease and are under the care of a neurologist who is participating in the wider research study.

What will happen to me if I take part?

You will be invited to a neurology clinic and would have to come into the clinic for the examination and to provide your samples. The researcher will go through some questionnaires about the **symptoms** you experience, for example, about your movement, your memory, how you sleep, or whether you can still smell and taste. If you agree, part of the examination will be **video recorded**. These videos may be used as case studies to present to other researchers at conferences. The researcher will also ask you questions about your diet, and whether you have ever been exposed to pesticides.

If you consent, the researcher will also ask you to provide some **biological** and **environmental samples**. These samples will have different purposes, outlined here:

- **Understanding genetics**: it is possible to know whether individuals have a gene that places them at higher risk of developing Parkinson's disease. We can do this by analysing your blood and saliva. We will ask you to provide a blood sample, which will be taken by the researcher like any other blood test, as well as a sample of saliva, which you can do by spitting into a pot.

  If you agree to your blood and saliva being collected, we will give you another information sheet about how this data will be stored, used and analysed as part of a wider global genetics study called Global Parkinson's Genetics Program (GP2) who the TraPCAf team are collaborating with.

- **Developing a diagnostic test**: currently, there are no easy ways to diagnose Parkinson's disease using a test. We want to see whether we can diagnose Parkinson's disease by collecting and analysing a few samples. First, we will collect a sample of sebum (oil from the upper back) by rubbing a cotton bud on your skin. Then, we will collect a sample of blood plasma from you, this is done the same way as a blood test by the researcher.

- **Environmental risk factors**: we know there are certain things that can put people at greater risk of developing Parkinson's disease. Providing these samples will help us understand these risks better. This will include a stool sample, which you will collect yourself when you go to the toilet (we'll give you some equipment to do this). If it is not possible to do this on the day of the clinic, then we can arrange to pick the sample up from your home at a later date and will arrange to give you contact details so you can let us know when the sample is ready for collection. We'll also ask to take a swab from the inside of your cheek (called a buccal swab) using a cotton bud. These two samples will allow us to look at the bacteria in your digestive system.

  We also want to see whether exposure to pesticides can increase the risk of Parkinson's. If you consent, we will come and collect a sample of soil from near your house, and a sample of water that you drink from (if this is not from mains supply) or used to drink from. This will help us understand if pesticide residues are present in the samples, which could increase the risk of Parkinson's disease. It is also possible to see whether pesticides remain in the body, and we'll ask you to collect a sample of urine to test for pesticides, you'll do this yourself in the toilet at the clinic by urinating in a small pot.

What are the benefits in my taking part?

By taking part in this study, you will play an important role in helping research discover new ways to identify Parkinson's disease that will be used across the world, and hopefully, reduce the risk of others developing the disease. You may also get a better understanding of your condition and the symptoms that you experience.

If you have paid for transport to the clinic, this will be refunded by the research team.

Are there any risks involved?

The only minor risk relates to the collection of blood samples, which will involve using a small needle like any other blood test. However, you don't have to do this if you don't want to and can still take part in the other parts of the study. You will be able to ask the researchers about the disease if you have any questions about your symptoms.

What data will be collected?

We will collect data about the symptoms you experience (with part of the examination video recorded, if you agree), biological samples (blood, saliva, stool, urine, sebum and plasma) and environmental samples (soil and water).

If you are interested in providing DNA samples (blood and saliva for genetic analysis), we will give you another information sheet which will outline how these samples will contribute to a wider global study on genetics and Parkinson's disease called the Global Parkinson's Genetics Program (GP2) (www.gp2.org) and you can decide whether you want to consent to this.

Will my participation be confidential?

Your participation will be confidential, and all data collected about you will be confidential. Your data will be anonymised (this means that we will allocate a code to your information, instead of your name, so that no one can identify you). All data will be stored on password protected computers and only members of the clinical and research team will have access to it. The same is true for the GP2 study, and more details about this are in the separate information sheet. The consent form you sign will be locked away in a safe. Data about you will be stored securely for 10 years after the end of the study and then deleted.

Do I have to take part?

Participation in this part of the study is voluntary and you are free to decline to be in this study or change your mind at any point. You do not have to decide now if you want to participate, you can think about it and discuss it with your family. If you have any questions, you can contact the researcher.

If you change your mind about taking part, just let us know. You can withdraw your data and information even after the data has been collected.

What will happen to the results of the research?

The goal of this research is to understand more about Parkinson's disease in Africa, to help develop ways to easily diagnose Parkinson's disease and better understand risk factors for the disease. All the data we collect will be anonymised, stored and analysed by the researchers. This data, along with the data we collect as part of the wider research study, will be published in academic journals and be fed back to policy makers to advocate for better care and support for people with Parkinson's disease.

If you consent to the GP2 aspect of the study, your samples and data will be used to learn about the genetic differences between people with and without disease. More information about this can be found in the GP2 information sheet.

Where can I get more information?

If you want to discuss this study further, please get in touch with the research team:

Contact name:

Phone number:

This study was approved by the Faculty of Medical Sciences Research Ethics Committee, part of Newcastle University's Research Ethics Committee. This committee contains members who are internal

to the Faculty. This study was reviewed by members of the committee, who must provide impartial advice and avoid significant conflicts of interests.

Part 2: Clinical examination and samples consent form

Participant consent

I have been invited to take part in this research study about Parkinson's disease. I have been given and read the information sheet, or the information sheet has been read to me. I have had the opportunity to ask questions about it and any questions have been answered to my satisfaction. I understand my participation is voluntary and I may withdraw (at any time) for any reason without my participation rights being affected. I have consented voluntarily to be a participant in this study and agree for my data to be used for the purpose of this study outlined in the information sheet.

I would like to take part in this study and consent to (initial the boxes):

Clinical examination:

Questionnaires ☐

Video recording ☐

Samples for genetic analysis:

Blood ☐

Saliva ☐

Samples for environmental risk factors:

Stool ☐

Buccal ☐

Urine ☐

Water ☐

Soil ☐

Samples for diagnostic tests:

Sebum ☐

Blood plasma ☐

Name of participant:

Signature/Initials:

Date:

Thumbprint: ☐

I have read the additional information provided to me about the Global Parkinson's Genetics Program (GP2) and consent to (initial the boxes):

My DNA samples being used for the purposes of GP2 ☐

GP2 can contact me about additional data or future research ☐

I consent to being approached by TraPCAf researchers to take part in further studies (initial the boxes):

Interview about my experience with Parkinson's disease ☐

Use of technology for monitoring symptoms ☐

<u>For researcher</u>

To the best of my ability, I have provided the information sheet, and accurately read out the information sheet to the potential participant, if necessary. I have ensured that the participant understands the details of the study. I confirm that the participant was given an opportunity to ask questions about the study, and these were answered correctly to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily. A copy of this Participant Information Sheet has been provided to the participant.

Name of researcher:

Signature:

Date:

For interpreter (if present)

I can confirm that the information I have translated today will not be shared with anyone and the participant will not be made identifiable. I have read the information sheet and confirm that the confidentiality of the participant will be ensured at all times.

Name of interpreter:

Signature:

Date: