



# UCC

Coláiste na hOllscoile Corcaigh, Éire  
University College Cork, Ireland

UCC PD STUDY  
EMAIL: PDSTUDY@UCC.IE

## **PARTICIPANT CONSENT FOR PARTICIPATION IN RESEARCH STUDY (Version 2.0 05/01/2024)**

**Study Number (if applicable):**

**Study Title** Tracking Parkinson's Disease (PD) symptoms, medications, and menstruation.

**Name of Chief Investigator:** Prof. Aideen Sullivan

Thank you for considering participating in this research project. The purpose of this document is to explain to you what the study is about and what your participation would involve, so as to enable you to make an informed choice.

### **What is the purpose of this study?**

The purpose of this study is to track Parkinson's Disease (PD) symptoms across the menstrual cycle and medication intake. You have been invited to take part as a woman who may or may not be still menstruating. Should you choose to participate, you will be asked to track your PD symptoms, and your period if you are still menstruating, over 4 months using a digital app called My Moves Matter. You will also be asked to complete an online survey, which will include questions on your demographics, PD symptoms, medication and menstruation symptoms, if any. The survey will take about 20 minutes to complete. At the end of the study, you will be asked to complete an online survey similar to that one that you completed at the beginning of the study. Finally, you will be asked to complete another survey to assess your experience of using a digital app to track your symptoms and period.



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## **Why have I been chosen?**

You have been asked to take part in this research project as you have a diagnosis of Parkinson's disease. You have been invited to take part as a woman who may or may not still be menstruating.

## **How many people will take part in this study?**

We hope to recruit 200 people to take part in this study.

## **Do I have to take part?**

Your participation in this study is completely voluntary.

- If you decide to take part, you will be asked to complete a consent form (at the end of this information leaflet online).
- If you decide to take part, you are free to withdraw at any time without giving a reason and without any disadvantage to your future medical treatment.
- If you decide not to take part, this will not put you at any disadvantage regarding your current treatment.

## **What will happen if I agree to take part?**

- If you agree to take part, you will be asked to take an online survey that you can access through a link to a secure website. You will also be asked to share some of your anonymous data in the My Moves Matter App.
- The surveys will not take more than 20 minutes. You can take breaks while completing the survey, if you need to.
- Questions will be asked regarding your health, medications, PD symptoms, your quality of sleep, your mood and your daily activities and menstrual symptoms, if you have these. You don't need to answer any questions that you feel uncomfortable with.
- All information collected will be anonymous.



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## **What are the possible benefits of taking part?**

You may not receive any benefit from taking part in this study. The information we gather from you and the other participants will help us to understand more about the menstrual symptoms in People with Parkinson's Disease.

## **What are the possible risks of taking part?**

We do not believe that there are any risks of taking part in this study. Participation is voluntary, and it will not affect any future treatment that you might receive for your condition. You may withdraw from the study at any time.

If any concerns are raised for you as a result of taking the survey, please contact your own GP or Neurologist or local Parkinson's association.

## **UCC Clinical Studies Data Protection Notice**

At University College Cork, we treat your privacy seriously. Any data which you provide to the University will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation. This notice sets out details of the information that we collect, how we process it and who we share it with. It also explains your rights under data protection law in relation to our processing of your data.

## **What about confidentiality?**

All information about you will be kept strictly confidential, and any data provided to us during the study will be processed fairly and lawfully. Signing the Informed Consent Form means that your data will be used for the purposes outlined in the Patient information leaflet (PIL). You are entitled to withdraw your consent at any time. All data that are collected during the study are subject to the same regulations as the data collected for your health care.

The results of this study may be published in a medical journal, but it will not be possible to identify you from the publication. We will store the anonymous results of



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the surveys securely for 15 years. Thereafter, they may be stored for a longer time if required by law, or they will be destroyed in line with confidential waste destruction guidelines. Results of the study will be provided to the Clinical Research and Ethics Committee of the Cork Teaching Hospitals (CREC) in compliance with national and international regulations on clinical studies.

### **Who will access my data?**

Your anonymous data will only be accessible to study researchers, quality representatives from the study Sponsor (Monitors and Auditors), and the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC) so that they can check if the study is being conducted to the best standards. Results of the study will be provided to the ethics committee approving the study in compliance with national and international regulations on clinical studies. The anonymous data will be stored on a University College Cork supported cloud storage platform Microsoft Forms, Qualtrics or RedCap. We are also asking for your consent to store the anonymised data in a repository, to allow it to be used to inform subsequent research studies. The information that you provide may contribute to research publications and/or conference presentations and also to newsletters.

### **What if I have a question or Complaint?**

University College Cork (UCC) is the Data Controller for this research project. If you have any complaints in connection with our processing of your personal data, you can contact UCC's Data Protection Officer (DPO): DPO, Information Compliance Section, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork E: [foi@ucc.ie](mailto:foi@ucc.ie) Tel: +353 21 4903949

If you have a question about the survey, please contact the members of the study team who will be happy to answer any questions. The email for the study is [PDSTUDY@ucc.ie](mailto:PDSTUDY@ucc.ie)



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## AGREEMENT TO CONSENT

Please enter your unique code for this study. Your unique code should comprise of the first three digits of your phone number and the last three digits/letters of your post code. Please remember this code, as you will be prompted to enter this code later during the study, specifically when we ask you to complete the follow-up questionnaire and upon entering your data in the My Moves Matter App.

Input anonymous study code: XXX-XXX

The research project has been fully explained to me. All experimental procedures have been identified and no guarantee has been given about the possible results. I have had the opportunity to ask questions concerning all aspects of the project. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I understand that the sponsors and investigators have such insurance as is required by law in the event of injury resulting from this research.

I, the undersigned, hereby consent to participate as a subject in the above-described project conducted online. I have received a copy of this consent form for my records. I understand that if I have any questions concerning this research, I can contact the Chief Investigator listed above. I understand that the study has been approved by the Cork Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact CREC at Lancaster Hall, 6 Little Hanover Street, Cork, 021 4901901 or email [crec@ucc.ie](mailto:crec@ucc.ie).



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I have read and understand the study: yes  no

I agree to participate in this research. I agree to take part in the online surveys and for my anonymized data to be used from the MMM App: yes  no

Do you consent for your anonymised data to be posted on an open repository for sharing and collaborative research? yes  no

I understand that my anonymised data will be stored at UCC for 15 years:  
yes  no

Can you please confirm you are over 18 years of age?

yes  no



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