**Information for the participant**

**and informed consent form for Informal Caregivers**

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| **Title of the study:** Co-design of an electronic diary (eDiary) application for patientswithParkinson’s disease (PD)  **Acronym:** MyPD  **Sponsor of the study:** University of Luxembourg (UNILU)  **Chief Scientific and Medical Investigator of the study:**  Prof. Dr. med. Jochen KLUCKEN  Luxembourg Centre for Systems Biomedicine University of Luxembourg Campus Belval, Biotech II-Annex 6, avenue du Swing L-4367 Belvaux, Luxembourg  Tel: +352 46 66 44 6399  Email: jochen.klucken@uni.lu  **Study assistant:**  Name: Marijus Giraitis, clinician-scientist  Contact details: marijus.giraitis@ext.uni.lu  Telephone: **+**352 621 519 122 |

# INTRODUCTION

You are invited to take part in a co-design study entitled “MyPD”. The purpose of this document is to provide you with information on the study to help you decide if you would like to take part. Your participation is entirely voluntary. If you decide to take part, you may withdraw at any time without giving any reason. This study has received a favourable opinion from the National Research Ethics Committee on 01/03/2024. The ethics favourable opinion should not be taken as an incentive to participate in this study.

# WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to co-design an electronic patient diary application (MyPD) as a digital support to Parkinson’s disease (PD) patients in self-management and with health knowledge. In this study we will collect information on the current status of self-management and health knowledge in PD.

Co-design is an approach that actively involves users of technology in the development of this one – from the idea to the implementation of the technology in daily life. Involvement of the users in the co-design of the technology ensures addressing user needs and the acceptance and application of the technology by its users.

Parkinson’s disease (PD) is a complex disease with a variety of care needs. Management of PD requires active involvement of various healthcare professionals (e.g. neurologists, physiotherapists, nurses etc.), informal caregivers (e.g. friends, family members) and people with PD themselves. In this study, we aim to include the perspectives of the people involved in PD care to understand self-management and health knowledge in PD in everyday life. This information will allow guiding the development of the technology (MyPD) better fitting the needs and providing optimal support.

You have been proposed to participate in this study because you are an adult informal caregiver supporting PD patients on daily basis (e.g. family member, partner, friend)

# HOW WILL THE STUDY BE CONDUCTED?

The study consists of 3 steps, a survey, interview and focus groups (workshops). You may choose to participate in one or more steps according to your preference and availability.

* **Step 1 – Survey** - 200-300 PD patients and 200-300 informal caregivers
* **Step 2 – Interviews** - 10-12 PD patients and 5-7 informal caregivers
* **Step 3 – Focus groups** -up to 10-12 participants per mixed focus group (PD patients, informal caregivers and HCPs)

Before consenting, you will be informed about the study and its course. We will provide you with the participant information sheet and give you sufficient time to ask questions about the study. If you decide to participate in the study, you will be asked to sign 2 copies of the Informed Consent Form (ICF), one copy will be kept by the study team and the other will be given to you for your records. If you choose to sign digital ICF, a tokenized link will be sent to your email so that you can access the electronic Ethical Information Notice, Informed Consent Form, and Data Protection Notice, in the language of your preference (English, French or German). After signing the electronic ICF, you will be able to download a copy of this document and an electronic copy will be sent to the study team who will contact you back to on-board you on to the study. Signed electronic ICF will be kept in secure server hosted by UNILU. After signing the ICF, you can choose the step(s) of the study in which you are interested to participate. More details are given in the following sections.

**STEP 1 – Survey**

If you consent to participate in STEP 1, a member of study team will explain you the procedure of filling in the survey. You may select to complete the survey either in **digital** or **paper** format.

If you choose to fill in a **digital** survey, please note the following;

1. You do not need to download any application to fill out the survey. No account, login or password needs to be created and you are expected to complete the survey once.
2. You will indicate if you are a PD patient or informal caregiver so that you are provided with the respective token. You will be assigned a unique study ID allowing the separation of your personal data from the survey data. The study team will provide you a unique token and the link to the online survey. The token is needed to access the survey. The token allows the linking of the survey filled by you to your unique study ID.
3. You can open the link in your web browser and enter your token. Information about the survey will appear. Once you have read this, you can start filling the survey.
4. Upon completion of the survey, you will be asked to indicate if you are interested to participate in other study steps (interviews or focus groups). If you wish to participate one/ or the other/or both steps, the study team will contact you accordingly.

If you choose to fill in a paper survey – a member of study team will provide you with a paper version with a unique study ID number, for you to fill in. Questions on digital and paper surveys are identical.

No personal information (name, address or telephone number) will appear on the digital or the paper survey. The survey is thus, only collected with a specific study ID.

The purpose of the survey is to collect information about health knowledge in PD, caregiver burden and involvement in PD patients care. You will be asked question about your socio-demographic information (such as age, education, living arrangement) and your perspective in supporting PD patients in daily life, referred as caregiver burden and caregiver involvement (e.g. believes, motivation and challenges in helping PD patients) and health knowledge. Filling the survey takes approximately 40 min.

**STEP 2 – Interviews**

If you consent to participate in STEP 2, a member of study team will explain the procedure for participating in individual interviews which will be conducted face-to-face. The purpose of individual interviews is to further explore caregiver burden, involvement and health knowledge domains in PD, and collect more precise information on how technology (such as eDiary) can support it.

Duration of interview is approximately 60 minutes. Depending on your preferred language, interview can be conducted in either, French, German or English. Interviews will be **audio** **recorded** so that no information provided by you could be missed. After the interview, the audio recording will be transcribed, and the recordings will be deleted one month after transcription.

**STEP 3 – Focus groups (workshops)**

If you consent to participate in STEP 3, a member of study team will explain you the procedure and invite you to join one or more focus groups. Focus groups are small group workshops aiming to collect information on participants’ interest in technology, about their thoughts and ideas on technology. It will be organized face-to-face with an approximate duration of up to 2 h. A maximum of 12 focus groups will be organized. You will have the choice to participate in one or more focus groups (no obligation to participate in all focus groups). Focus groups will be moderated in French, German or English. The language of each focus group will be announced in advance, so you can choose the focus group of your preferred language.

The purpose of focus groups is to jointly define and design the MyPD application developed to support PD patients in self-management and health knowledge.

During the focus groups, we will focus on the following 4 aspects of the concept and configuration of the MyPD:

1. **Content**: the kind of information (e.g. medical, socio-demographic) should be collected by the MyPD
2. **User interfaces**: display and navigation (e.g. visual layout, structure)
3. **User journeys:** everyday life use and needs (e.g. step-by-step plan, on-boarding, frequency, needs for support)
4. **Visualization**: the way the information is provided through the display (e.g. reports generation, additional app features)

During the focus groups, study team may also request you to fill in some questionnaires that will help us to improve the application design and collect your feedback on the focus groups itself. Focus groups will be audio **recorded** to capture the discussion with accuracy and completeness. After the focus group, audio recording will be transcribed onto paper and recordings will be permanently deleted one month after transcription.

# USE OF MY DATA

You are invited to provide your data for the purposes of medical research.

In this study, your data will be collected and analysed for the primary purpose, which is the co-design of an electronic diary (MyPD) application with your feedback on the concept and configuration as explained in previous sections.

# WHAT ARE THE POSSIBLE RISKS?

Although, all data will be collected on the secure database and servers of UNILU, there is a risk associated with data breaches or data loss (for example by hacking). This data breach may include participants' personal data. This risk is small but exists. UNILU has implemented extensive data protection measures to minimize this risk. These measures are explained in the "Confidentiality and protection of personal data" section.

# WHAT ARE THE BENEFITS OF TAKING PART IN THE STUDY?

You will not benefit directly by taking part in this study. Your participation is voluntary. You will receive no form of compensation for your involvement or from any subsequent developments resulting from the study.

However, your participation is highly important to us, as it will help increase current scientific knowledge about self-management and health knowledge in Parkinson’s disease. You will also have a chance to learn about the development of health technologies and how such solutions could support Parkinson’s disease patients in everyday life and people involved in PD care.

# CONFIDENTIALITY AND PROTECTION OF PERSONAL DATA

Your personal data will be treated as strictly confidential. Your data will be pseudonymised, meaning that your name will be replaced by a confidential unique study ID (such as MYPDXXX). This study ID will not directly identify you and will only be used to process your data for scientific purposes. Your identity will never be disclosed in any document produced for the public or for other research institutions. Apart from the study’s investigating doctor and the authorised members of his team working under his responsibility (clinical team), only authorized members of UNILU, who provide IT support services for data storing platforms, could have access to your personal data if needed.

If you consent to take part in the study, the data that could identify you will be stored in accordance with the applicable laws and guidelines. The correspondence table between the participants’ personal data and the study ID (pseudonyms) will be deleted 2 years after the end of the data collection in the study. UNILU will retain your data collected via the online survey, individual interviews and focus groups in a pseudonymized form for 2 years, followed by additional 8 years in an anonymized form for a total retention period of 10 years following the end of the study. Data will be stored within the UNILU secured databases. Audio recordings from the interviews and focus groups will be deleted from the local file within 1 month after the transcription performance. Emails of people contacting us directly will be deleted 6 months after the first contact in case the person does not participate in the study.

You will find detailed information in the document about the data protection provided to you by the study team before consenting to this study.

# COSTS ASSOCIATED WITH YOUR PARTICIPATION

Your participation in the study will not incur any costs for you or your insurance.

# INSURANCE

As a participant in this study, you will have an insurance, which covers any damage caused to your life or health by participating in the interview and/or focus group(s). If needed and if you have questions, a copy of the insurance policy can be provided to you. In the event of a claim, you can contact the principal investigator of the study who will evaluate your request and contact the insurer if needed. Luxembourg law applies to the insurance contract, the insurance claims are enforceable in Luxembourg.

Insurance is acquired by University of Luxembourg for the study and will cover all study-related activities (interviews and focus group) as described in this document, as well as the risk of data breaches for personal information. The insurance will only cover activities carried out at the study site and will not cover any activities or accidents that might occur while arriving at the study center or leaving it.

# YOUR DECISION TO TAKE PART

Your participation in the study is voluntary. If you choose to take part, you may withdraw at any time without giving a reason. Before you take part in the study, you will need to provide your written consent by completing the form below. You will receive your own copy of the document. Should you have any questions about this study, you can contact the scientific PI Prof. Dr. med. Jochen KLUCKEN or a member of the study’s clinical team at any time (see contact details at the beginning of the document).

If you would like further information on the study, please contact:

**For medical-related questions:** **+**352 621 519 122 or marijus.giraitis@ext.uni.lu

**For logistical questions:** **+**352 621 519 122 or marijus.giraitis@ext.uni.lu

**For data protection related questions**: [dpo@uni.lu](mailto:dpo@uni.lu).