The University of Queensland, Queensland Brain Institute
Asia-Pacific Centre for Neuromodulation

Participant Information Sheet and Consent Form

Quantitative Analysis of Movement Disorders' Symptoms: A Longitudinal Study

Coordinating Principal Investigators/ Principal Investigators	Professor Pankaj Sah
Associate Investigator(s)	Dr François Windels, Dr Andrea Giorni, Dr John Morris, Ms Samra Naz
Location	Queensland Brain Institute, UQ.

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in the research project, "Quantitative analysis of Movement Disorders 'symptoms: a longitudinal study". This research project aims at providing a comprehensive, quantitative account of the motor abilities of individuals with movement disorders. The information we acquire may help us understand more about the causes of movement disorders and the quantitative assessment of their symptoms will support more accurate diagnosis of movement-related diseases. This can be helpful in providing more specific treatment in future. The study also focuses on the effect of movement disorders on an individual's quality of life and how it can be improved.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to the tests and research described.
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Aim of research:

The goal of this research is to provide a quantitative assessment of movement disorder by performing standard tasks. A comparison of the results with age-matched healthy controls will provide a better understanding of the difference between the two groups.

Who has initiated the research and participation:

This research has been initiated by Professor Pankaj Sah.

Who is conducting the research:

This research is being conducted by researchers from the Queensland Brain Institute at the University of Queensland.

3 What does participation in this research involve?

This research project involves collecting information from people aged 35 to 75. We are interested in people with movement disorders (e.g. Parkinson's Disease, Dystonia, Essential tremor or Multiple system atrophy) but we also welcome participation from people with no movement disorder, in the same age range, in order to have an age matched control group.
To be able to make the necessary measurements we will need you to attend 1.5–2 hour visits at Queensland Brain Institute on the University of Queensland St. Lucia Campus. You will be asked to perform tasks like writing on graphics tablets, building small part assemblies using a pegboard and calling out some sentences for voice recording. We will take audio and video recordings while you are performing the tasks as part of the research. You will also be asked to fill out some standardized questionnaires about cognition, mood, handedness, sleep, pain and quality of life in general (see list attached). Some of these forms may be mailed to you before the visit to make sure you have all the time you need to fill them and keep the visit duration to a minimum. We will also record your weight at each visit, this is necessary to normalize medication dosage between participants and control for potential weight loss or gain over the duration of the study.
Results from these visits will be used to assign participants to the appropriate groups with matching conditions, symptom categories and demographic details. We will send you a letter confirming your enrolment in the study. If we cannot assign you in one the group making our cohort this will be confirmed to you in writing and your personal details and results will be deleted from our database.

For control participants, there will be two subsequent sessions, with a 3-4 month interval, to test the consistency of the results. In total, control participants will be asked to attend 3 visits over a year.
Participants with movement disorder will have 2 visits in the first 3 months after their enrolment and remain involved in the research for up to 3 years with only one session every 10-12 months. In total they will have to attend no more than 5 times over 3 years.
We are also interested in looking into your medical history in order to see the effect of medication on your performance in the tasks. You will be asked to bring a copy of your medical record on your first visit. If not all documents are available we will discuss with you the opportunity to contact the doctor you nominate to have access to your medical record.
If you agree to participate in this research project, please sign the accompanying consent form. By signing and returning the consent form you are agreeing to identify yourself to the researchers in the study.

Additional costs & reimbursement:

You will be provided free parking at UQ and a travel allowance of $20 per visit.

4 Other relevant information about the research project

The data collection and analysis will be conducted at the Queensland Brain Institute, University of Queensland. Your safety and well-being during your visit at the Queensland Brain Institute is important to us. If you experience fatigue or distress during your visit don't hesitate to inform the research team and they will take appropriate actions to make sure you feel comfortable.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. The data collected up to this point in the study will remain as part of the data and no further data will be collected.

6 What are the possible benefits of taking part?

There will be no direct benefit to you from your participation in this research. The study will promote the clinical assessment of symptoms of movement disorder to improve diagnosis.
The non-identifiable data collected and the results will be published in scientific reports and presented at national and international conferences in order to contribute to the continual improvement of patients undergoing movement disorder treatment.

7 What are the possible risks and disadvantages of taking part?

Findings from this research will contribute in building diagnostic tools and will ultimately help in improving treatment for movement disorder. This research project is not expected to carry any risks to you. During assessment, the researchers will record activity from certain groups of muscles. To do so they will place sterile single use sticky pads (6 to 12) on the skin. These electrodes are commonly used in hospitals and present no known risk.

8 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team and return the withdrawal of consent form attached. If you do withdraw your consent during the research project, you should be aware that the data collected by the researcher up to the time you withdraw will form part of the research project results and cannot be withdrawn.

9 What happens when the research project ends?

The data collection of all participants is expected to cease in July 2024. After this date, the researchers will analyse the data, write up the study, present the data at conferences and publish the findings in journals. Your data will be stored on a secured server at The University of Queensland and kept for seven years after publication for legal purposes.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project.

Any information obtained in connection with this research project that can identify you will remain confidential. Your information will only be used for the purposes of this research project and it will only be disclosed with your permission, except as required by law. If you give us your permission by signing the consent form, we will make the information non-identifiable and will study the results of this research. We will publish the results arising from this research in scientific journals and at national and international conferences. You will not be identified individually in any such publications. Only the combined results of all participants will be published.

The data for this project will be stored at The University of Queensland in a locked filing cabinet and password protected files. From completion of the project, information will be stored for 7 years as recommended by the National Health and Medical Research Council (NHMRC) regulations or as required by law.

Your health records and any information obtained during the research project are subject to inspection for the purpose of this study. This review may be done by named researchers in this project, relevant to this Participant Information Sheet, or as required by law.

11 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of experts called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Uniting Care Health HREC and UQ HREC.

13 Further information and who to contact

This study adheres to the Guidelines of the ethical review process of The University of Queensland and the National Statement on Ethical Conduct in Human Research. If you have any questions or would like to speak to a researcher regarding the project, please do not hesitate to contact Dr Francois Windels at the details below.

Researcher contact person

Name	Dr Francois Windels
Position	Senior Research Fellow
Telephone	04 3642-8774
Email	f.windels@uq.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	Reviewing officer
HREC Executive Officer	LNR Human Ethics Coordinator
Telephone	+617 3365 3924 / +617 3443 1656
Email	humanethics@research.uq.edu.au

Consent Form - *Adult providing own consent*

Title	Quantitative Analysis of Movement Disorders' Symptoms: A Longitudinal Study
Coordinating Principal Investigator/ Principal Investigator	Professor Pankaj Sah
Associate Investigator(s)	Dr Francois Windels, Dr Andrea Giorni, Dr John Morris, Ms Samra Naz
Location	Queensland Brain Institute, Saint Lucia, UQ.

Declaration by Participant

- I have read the Participant Information Sheet or someone has read it to me in a language that I understand.
- I understand the purposes and procedures of the research described in the project.
- I have had an opportunity to ask questions and I am satisfied with the answers I have received.
- I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.
- I understand that I will be given a signed copy of this document to keep.
- I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information, including personal information, to the University of Queensland concerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.
- I agree that the data collected in this study will be made non-identifiable and that non-identifiable data may be transferred outside of Australia and shared with collaborators.
- I understand that confidentiality and anonymity will be maintained and it will not be possible to identify me in any publications.

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Consent for future studies

☐ Please tick if you agree to be contacted in the future by the University of Queensland researchers who would like to invite you to participate in follow up studies to this project, or in future studies of a similar nature.

Form for Withdrawal of Participation - *Adult providing own consent*

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Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect me in any way.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.