# Plain Language Statement

Faculty of Medicine, Dentistry and Health Sciences

**Project:** Investigation into consumer views receiving deep brain stimulation: views of patients, previous and prospective recipients and carers.

**Project Supervisor:** Professor Nick Opie
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**Additional Researchers:**

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## Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research.

Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about.

Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time.

## What is this research about?

This research project is exploring the views of participants with or without a movement disorder disease on Deep Brain Stimulation (DBS) therapy.

The purpose of this research is to help us better understand what is important to end-users in their everyday life when using DBS technologies. It may guide the development of technology effectively to meet end-user needs appropriately.

This study aims to recruit up to 20 people per group, consisting of

1. Patients considering DBS therapy
2. Patients receiving DBS therapy

3. Patients that have received DBS therapy in the past
4. Carers and/or relatives of the above groups.

You will be participating in a scientific research project. Participants will be invited to take part in semi-structured interviews. Participants will be interviewed via telephone, secure online platform, face to face interview, or in a in a group setting, which will be audio recorded and transcribed. It is important that you do not suffer from memory problems, so you can recall events that may be important during the interview.

The interviewer will follow an interview guide, to maintain focus during the interview. This method is designed to facilitate focus on participants.

## What will I be asked to do?

Should you agree to participate you will be asked to sign a consent form. By signing the consent form, you're telling us that:

1. you have understood what you have read,
2. consent to take part in the research project,
3. consent to the use of your personal and health information as described,
4. consent to the methods that are described.

The interview is expected to take approximately 1 hour. You will be asked to participate in this study, either via telephone, secure online platform, face to face or group interview. The interview group will be kept small, approximately 3 to 5 participants.

You can choose the method of interview, according to your preference. If you do not wish to continue the interview before completion, you may indicate your wishes to the researcher and the interview will be stopped. The study can be terminated at any time at your convenience for any reason.

Information collected will include:

1. Your name and contact details (for purposes of arranging the interview)
2. Gender and age
3. Medical diagnosis (type of movement disorder)
4. Status of DBS therapy (proposed, current, past)

All information gathered will be anonymised by using unique participant numbers.

The interview will be recorded using a Dictaphone, exclusively used for this study.

## What are the possible benefits?

The main goal of this research is to gain scientific information. We cannot guarantee or promise that you will receive any benefit from this research.

However, the results arising from this research may indirectly help people and their relatives/carers living with a movement disorder in the future.

## What are the possible risks?

There are no serious risks foreseen in this study.

During the initial information giving session the researcher will look out for memory problems, which may mean that you will not be able to take part in the study.

A minor risk is fatigue. Should you feel tired, you are free to stop the interview at any point. You are free to withdraw from the interview altogether if required.

## Do I have to take part?

No. Participation is completely voluntary. You are able to withdraw at any time.

Should you wish to withdraw from the study during the interview, you are free to do so. Any data and information collected from you up to this point will be included in the study.

If you do not wish for your data to be included, you can advise the researcher.

## Will I hear about the results of this project?

The information gathered will be analysed by professional researchers to answer the research question. Any formal reports or academic publications arising from this data would be made available to you at your request.

## What will happen to information about me?

By signing the consent form, you consent to the collection of personal and medical information as described above, about you, for this research project.

Any information obtained in connection with this research project that can identify you will be anonymised. Any information on paper will be kept in locked cabinets at a secure University of Melbourne building and electronic data, including recordings, will be kept in a password protected electronic database on an encrypted cloud server.

Only researchers involved in this project can access this information.

Any information obtained during this research project about you are subject to inspection (for the purpose of verifying the procedures on the data) by the relevant authorities and authorised representatives of the institution relevant to this Participant Information and the Consent Form or as required by law.

By signing the consent form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this project will be published and or presented in a variety of forums. It is also anticipated that the information gathered in this study may be used in future research. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

In accordance with the relevant Australian and/or Victorian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team.

You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored.

It will be disclosed only with your permission, or as required by law. The information and data collected for this research project will be confidentially destroyed five years after the last publication, in line with the University of Melbourne policy and procedures.

Data from this project may be used in the future for secondary analysis or presentations on consumer needs related to device development. You will not be able to be identified from the information retained or presented.

## Is there any potential conflict of interest?

The conduct of this study may lead to discoveries that may be of commercial value to the company developing the new DBS device. There will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal benefit from your involvement in this research project, other than ordinary wages.

## Who is funding this project?

The project is funded by Ultra Bionics Pty Ltd, an Australian Start-up company developing the novel device.

Participants will receive reimbursement for incurred travel costs and a shopping (Coles) voucher for their participation. These costs are funded by Ultra Bionics Pty Ltd.

## Where can I get further information?

If you would like more information about the project, please contact the researchers:
Name: Christin Mathew
Position: Researcher
Telephone: 0480 556 824

## Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne Project ID 34843.

If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au.

All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.