UNIVERSITY OF Southampton

# Participant Information Sheet

**Study Title**: Integrated bimodal technology outcomes in adult cochlear implant users

**Researcher**: Manal Alfakhri
**ERGO number:** 45969

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 or not 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 study forms part of my PhD study in the Faculty of Engineering and Physical Sciences. The main aim of the study is to investigate the outcomes and experiences of adult cochlear implant users using standard hearing aids versus the new Naida Link hearing aid technology. These outcomes will also be compared with those of adult cochlear implant users who have two implants. The tests used will simulate real-life environments using the Crescent of Sound, a standard test rig at the University of Southampton Auditory Implant Service. The results will contribute to the field by providing information about the benefit of the different technology combinations.

**Why have I been asked to participate?**
You have been asked to take part in the study as you are over the age of 18 years, have a cochlear implant and you have previously agreed to be contacted about research studies you may be eligible to participate in. University of Southampton Auditory Implant Service (USAIS) have identified you as a potential candidate for this study and have sent a letter of invitation on behalf of the researcher. We cannot guarantee a place on the study even if you do express an interest.

**What will happen to me if I take part?**
If you would like to take part, you will need to attend one appointment. In that appointment, you will be asked to undergo four listening tasks:

1- In the first task, you will be asked to listen to different sentences in varying conditions, i.e. competing speech. You will be asked to repeat as many of the words you hear following each sentence
2- In the second task, you will listen to sentences and be asked to determine the direction of the sound.
3- In third task, you will listen to a sound that is moving. You will be asked to say where he sound starts and ends.
4- In the fourth task, will be asked to listen to a series of numbers (digits) via a telephone in different conditions. You will be asked to repeat the digits you hear.

***If you have a cochlear implant and already have received a Naida Link hearing aid:***
In that session, you will be asked to perform the listening tests using your cochlear implant alone, and then with your cochlear implant and Naida Link hearing aid. Testing may last up to 120 minutes (2 hours) and a break will be offered half way through the testing. You may request a break at any other point during testing, if necessary. You will be asked to complete a questionnaire about your experience with the old and new hearing aid technology compared to just your implant alone. This questionnaire will take a maximum of 30 minutes to complete. The total duration of the appointment, including breaks, will be a maximum of 3 hours.

***If you have two cochlear implants:***
In that session, you will be asked to perform the listening tests using one cochlear implant versus two cochlear implants. You will be asked to complete a questionnaire about your experience with one versus two implants. Testing will take a maximum of 90 minutes with a further 30 minutes for questionnaire completion.

**Are there any benefits in my taking part?**
Your participation will enable us to better understand the effectiveness of management options available for individuals with severe to profound sensorineural hearing loss in both ears and potentially guide national guidance and practice.

A reasonable travel expenses will be covered.

**Are there any risks involved?**
There are no anticipated psychological or physical risks involved in this experiment, and your safety will be ensured at all times. Noise levels will be in accordance with The Exposure to Noise at Work Act (2005) and the ISVR human experimentation guidelines (1996) and therefore will not exceed levels heard on a daily basis. However, if you become uncomfortable at any point in the experiment or you wish to stop the experiment, please inform the researcher present.

**What data will be collected?**
Your scores in the listening tasks and in the questionnaire will be collected in a datasheet and will be coded to maintain anonymity. There is no use of personal data and the study results will be stored in a password protected computer at the University of Southampton. In addition, the consent form that you have signed and the questionnaire you have completed will be stored in a securely locked cabinet in the University of Southampton Auditory Implant Service (USAIS). This cabinet is in a clinic room that only authorized people in the University of Southampton Auditory Implant Service (USAIS) have access to. Only the researcher and supervisor will have access to this cabinet.

**Will my participation be confidential?**
Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to anonymised data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your anonymised data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

The research data (the results of the study) that obtained during test sessions will be stored on password protected university computers and used only for the purpose of this study. All files containing any personal data will be made anonymous and kept in compliance with University Data Protection policy. We will have access to your name and cochlear implant processor settings and be able to set up the parameters if you are receiving the new technology. No personal information will however be included in the actual data recorded. Consent forms and questionnaires that completed by the participants will be stored in a securely locked drawer cabinet in the University of Southampton Auditory Implant Service (USAIS). This cabinet is in a clinic room that only authorized people in the University Of Southampton Auditory Implant Service (USAIS) have access to. Only the researcher and supervisors will have access to this cabinet.

**Do I have to take part?**
No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part.

**What happens if I change my mind?**
You have the right to change your mind and withdraw at any time without giving a reason and without your routine care provided by USAIS being affected. However, if you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

**What will happen to the results of the research?**
Your personal details will remain strictly confidential. Research findings made available in the PhD thesis, reports or publications will not include information that can directly identify you without your specific consent. If you interested to know about the results of the study, please contact:

The researcher: Manal Alfakhri (*mna1g13@soton.ac.uk*)
Supervisor: Prof. Nicole Campbell (*n.g.campbell@soton.ac.uk*)
Co- supervisor: Dr. Daniel Rowan (*dr@isvr.soton.ac.uk*)

The results will be sent after the study is completed.

**Where can I get more information?**
If you would like to have any further information regarding this study, please contact:

The researcher: Manal Alfakhri (*mna1g13@soton.ac.uk*)
Supervisor: Prof. Nicole Campbell (*n.g.campbell@soton.ac.uk*)
Co- supervisor: Dr. Daniel Rowan (*dr@isvr.soton.ac.uk*)

**What happens if there is a problem?**
If you have a concern about any aspect of this study, you should speak to the researchers or the supervisors who will do their best to answer your questions.

The researcher: Manal Alfakhri (*mna1g13@soton.ac.uk*)
Supervisor: Prof. Nicole Campbell (*n.g.campbell@soton.ac.uk*)
Co- supervisor: Dr. Daniel Rowan (*dr@isvr.soton.ac.uk*)

If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager (023 8059 5058, rgoinfo@soton.ac.uk).

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

University of Southampton Auditory Implant Service (USAIS) will keep identifiable information about you from this study for three months after the study has finished.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where

you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer (data.protection@soton.ac.uk).

**Thank you.**