**Participant Information Sheet**

**Study Title:** Getting ready for cochlear implant assessment - online tools at home

**Researchers:** Helen Cullington, Padraig Kitterick, Magdalena Margol-Gromada

**ERGO number: 28011** **IRAS number: 233693**

**Please read this information carefully before deciding to take part in this project. It is up to you to decide whether or not to take part. If you are happy to take part, you will be asked to sign a consent form.**

**What is the research about?**

This is a research project funded by the Ida Institute. We want to try online tools made by the Ida Institute for people who have been referred for cochlear implant assessment. The online tools aim to help people prepare for their first appointment at the cochlear implant centre. We want to see how much they help to improve the person’s preparation and involvement in the appointment. We also want to see whether using the tools improves how ‘person-centred’ the appointment is.

**Why have I been asked to take part?**

You have been invited to take part because you are an adult who has been referred to the cochlear implant centre for cochlear implantation assessment.

**Do I have to take part?**

No. Taking part or not will not affect your clinical care in any way and is entirely up to you.

**What will happen to me if I take part in the project?**

The people that choose to take part will be asked to sign a consent form and fill in some data online. After this you will be split into two groups using a random allocation:

Group 1 will follow the usual care pathway and will not be given access to the online tools. **We ask that you do not try to access the Ida Institute tools until after your communications appointment**, when you will be free to do so. We may collect geographical data from the Ida Institute so we know how many people in your area use the tools. Being in the control group is equally important to being in Group 2.

Group 2 will be given access to the online tools and you will be asked to use the online tools at some point before the first appointment, as often as you wish to. You will be asked to email the results of the online tools to the cochlear implant centre. We will also ask you for feedback about how you found using the online tools.

Both groups will be asked to fill in a questionnaire about how confident you feel to look after your health and cochlear implant before and after your first appointment. For both groups, your first appointment at the implant centre will be video recorded for us to analyse.

If you choose to take part in the project, you will be sorted into one of the groups randomly; this means that neither the researchers nor you can choose which group you are in. Whichever group you are sorted in to, you can stop taking part in the project at any point for any reason.

**Are there any benefits in my taking part?**

There may not be any direct benefits to you if you take part. However, it may enable us to improve our service for people with hearing impairment in the future. If you are in the telemedicine group, you may enjoy using the new tools and find them useful.

**Are there any risks involved?**

There are no significant risks involved in this research project.

**Will my participation be confidential?**

Information collected about you (age, gender, highest level of qualification and duration of deafness) will be kept in a password-protected computer and only be used for the purpose of this research. You will be given a unique identifier (a code) when you join the study, for example IDA001. We will store your results using this code- not your name. The list of who is each code name will be kept in a password-protected computer file separate from the study results and destroyed one year after the research project ends. The data of the research will be kept for at least 10 years and will be used for presentations, articles and publications around the world; we will not share it with anyone outside the research team. Your name will not be used at any point. We may publish quotes that you say about the project or remote care; we will never use your name or any other identifying details.

We will video your appointment at the centre. We will then transcribe it (we will send it away for someone to write down what was said). We will make sure any names used are removed from the transcription. When we have finished analysing the videos, we will destroy them.

**What happens if I change my mind?**

It is totally up to you whether you take part or not. **Whether you take part or not will not affect your clinical care in any way.** We will include the data we have collected from you so far, unless you say you don’t want that. You are free to withdraw at any point without telling us why.

**Where can I get more information?**

**Dr Helen Cullington** *(Research Coordinator, University of Southampton Auditory Implant Service)*

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Telephone: 02380 592310

**What happens if something goes wrong?**

In the unlikely case of concern or complaint, you should contact the Research Governance Office:

**Research Governance Office**

George Thomas Building 37

Room 4079

University of Southampton

Highfield

Southampton SO17 1BJ

[rgoinfo@soton.ac.uk](mailto:rgoinfo@soton.ac.uk)

Telephone: 02380 595058

**Patient Advice and Liaison Services (PALS)**

Southampton General Hospital

Tremona Road

Southampton

Hampshire

SO16 6YD

[patientsupportservices@uhs.nhs.uk](mailto:patientsupportservices@uhs.nhs.uk)

Telephone: 023 8120 8498

**Who has reviewed this study?**

All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been given a favourable opinion by the University of Southampton Faculty of Engineering and the Environment Faculty Ethics Committee (ERGO 28011) and National Research Ethics Committee (IRAS project ID 233693).

***Please note that the researcher or others persons involved in the study will not deal with complaints.***