**The COACH Trial:** **Co**mp**a**ring **c**ochlear implants with **h**earing aids

in adults with severe hearing loss

**Recruitment Intervention Participant Information Sheet**

Version 1.2 20Dec2021

IRAS Project ID: **297574**

We would like to **audio-record the conversations** you have with your audiologist or ENT surgeon about the COACH trial. This is to help us understand how this research trial and the treatments are explained to potential participants and if there are any improvements we can make to this.

**The recording of your recruitment conversation is optional. Please read the following information to help decide whether you agree to have your conversation audio-recorded or not.**

**Why do we want to record your recruitment conversation?**

* We would like to find out how people who have expressed an interest in the COACH trial have the trial explained to them. This will help us to:
	+ Check the information is explained well
	+ Help us improve recruitment conversations with potential participants in the future.

**What would we like you to do?**

* If you agree to have your conversation recorded, we will ask you to sign a recruitment intervention consent form before you start talking to the audiologist/ENT surgeon about the COACH trial. This will cover any subsequent discussions that you may have with health or trial staff about participating in the COACH trial too unless you change your mind.
* Agreeing to have your conversation recorded does not commit you to taking part in the COACH trial.
* If you do not agree to the recording, then your conversation will not be recorded. This will not affect your legal rights, medical care, or participation in the COACH trial.

**What will happen afterwards?**

* Researchers from the University of Nottingham will listen to the recording of your conversation and will provide feedback to the audiologist/ENT surgeon and the local trial team about what went well and what (if anything) could be improved for future conversations about participation in the COACH trial.

**What will happen with the recordings?**

* Any personal information that you provide in the audio-recordings will be handled in the **strictest confidence,** stored by the University of Nottingham, and used in compliance with the relevant current data protection laws, Data Protection Act 2018, and General Data Protection Regulation (GDPR) 2016.
* Data (recordings) will be captured on an encrypted audio-recorder, labelled with a reference number (as opposed to your name or any personal information), and held on a password protected computer.
* Data will be transferred securely and shared between members of the trial team from the University of Nottingham, and their authorised representatives for transcription (i.e., creating a word for word written account of the recording).
* Recordings will be transcribed in full or in part as soon as possible after they have been received. Any recordings and transcripts sent to and from a university approved external transcription company (Clayton Research Support) will adhere to the secure transfer of recordings/transcripts procedure specified by the university.
* Transcripts will be anonymised so that you cannot be identified.
* Recordings and anonymised transcripts will be securely held by the University Nottingham for at least seven years after the COACH trial has closed and may be used for training, teaching, research and publication purposes in COACH and future studies. Any quotes used will be anonymised so that you cannot be identified.

**Your choices about how your information is used:**

* You may change your mind about having conversations about participation in the COACH trial recorded at any time without it affecting your legal rights, medical care, or participation in the COACH trial. Although any data collected before withdrawal may be retained and used anonymously in a way that will not identify you.
* Anonymised transcripts of audio-recordings may be made available to other researchers outside of the COACH trial team who secure the necessary approvals appropriate for a controlled level of access. Data from the anonymised transcripts may be used for purposes not related to this trial, but it will not be possible to identify you from them.

**If you wish to find out more information about how your information is used:**

For more information on how your information will be stored, please read the details on the final page. For more information on how the University of Nottingham processes personal data can be found on the university’s web pages here: <https://www.nottingham.ac.uk/utilities/privacy/privacy.aspx>

**Who to contact for further information:**

If you want to talk to someone about the audio-recording of consultations as part of the COACH trial, please contact:

**COACH trial team**
Nottingham Clinical Trials Unit
Phone: XXXX XXXXXXXX

Email: COACH@nottingham.ac.uk

This request to record your conversation is part of the COACH trial which is looking at whether a cochlear implant or hearing aids are better at improving speech understanding for adults with severe hearing loss. The COACH trial is being carried out by and sponsored by the University of Nottingham and is funded by an independent research grant from Cochlear Ltd. The COACH trial protocol has been approved by the South West – Frenchay Research Ethics Committee, IRAS number 297574.

**Additional information on how your information will be stored**

We will follow ethical and legal practice and all information about you will be handled in confidence.

If you join the study, we will use information collected from you during the course of the research. This information will be kept **strictly confidential**, stored in a secure and locked office, and on a password protected database at the University of Nottingham. Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (named above) is the Data Custodian (manages access to the data). This means we are responsible for looking after your information and using it properly. Your rights to access, change or move your information are limited as we need to manage your information in specific ways to comply with certain laws and for the research to be reliable and accurate. To safeguard your rights we will use the minimum personally – identifiable information possible.

You can find out more about how we use your information and to read our privacy notice at:

<https://www.nottingham.ac.uk/utilities/privacy.aspx>.

The data collected for the study will be looked at and stored by authorised persons from the University of Nottingham who are organising the research. They may also be looked at by authorised people from regulatory organisations to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

Your contact information will be kept by the University of Nottingham for up to 7 years after the end of the study so that we are able to contact you about the findings of the study and possible follow-up studies (unless you advise us that you do not wish to be contacted). This information will be kept separately from the research data collected and only those who need to will have access to it. All other data (research data) will be kept securely for 7 years. After this time your data will be disposed of securely. During this time all precautions will be taken by all those involved to maintain your confidentiality, only members of the research team given permission by the data custodian will have access to your personal data.

In accordance with the University of Nottingham’s, the Government’s and our funders’ policies we may share our research data with researchers in other Universities and organisations, including those in other countries, for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified) but if we need to share identifiable information we will seek your consent for this and ensure it is secure. You will be made aware then if the data is to be shared with countries whose data protection laws differ to those of the UK and how we will protect your confidentiality.