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

in adults with severe hearing loss

**Informed Consent Form**

**Version 1.2 14Jan2022**

**Name of Principal Investigator**:

**IRAS Project ID: 297574**

**Participant ID:**

|  |  |
| --- | --- |
|  | **Please initial box** |
|  | I confirm that I have read and understood the Participant Information Sheet, <insert current PIS version number and date > for the COACH trial. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. |  |
|  | I understand that my participation is voluntary and that I am free to withdraw from parts, or all of the trial, without giving any reason, and without my medical care or legal rights being affected. I understand that should I withdraw, then the information already collected will not be erased and that this information may still be used in the trial analyses. |  |
|  | I understand that relevant sections of my medical notes and data collected in the trial may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (NCTU; University of Nottingham), the Sponsor (University of Nottingham), NHS bodies, the trial research group (co-applicants) and regulatory authorities where it is relevant to my taking part in this trial. I give permission for these individuals to have access to these records and for a copy of this signed consent form to be sent to the NCTU.  |  |
|  | I give permission for the NCTU, the Sponsor and the trial research group to collect, store, analyse and publish information obtained from my participation in this trial. I understand that my personal details will be kept confidential and I will not be identifiable in any published information. |  |
|  | I understand that the NCTU and relevant staff at the clinic where I am participating in the trial will have access to my personal details (phone number, email address and postal address) to contact me for the purpose of obtaining follow-up information and sending trial communications. I give my permission for this information to be kept and for these individuals to contact me. |  |
|  |  I agree to the video recording of some of the speech tests as part of the trial procedures. These video recordings will be transferred digitally to NCTU and saved securely and confidentially with the rest of my trial data. The recordings of my speech tests will be assessed by an independent panel for the trial data analysis. |  |
|  | I understand that the information held and maintained by my GP, NHS Digital and other central UK NHS bodies may be used to help contact me or provide information about my health status. |  |
|  | I agree to my GP being informed of my participation in this trial, sent details of the COACH trial and being contacted if further information relating to my health is required for the duration of the trial. |  |
|  | I understand that anonymised information collected about me may be used to support other research in the future and may be shared with other researchers. Anonymised trial data will also be shared with the trial funder (Cochlear Ltd.) at the end of the trial. |  |
|  | I agree to take part in the above trial. |  |

|  |  |
| --- | --- |
|  | **Please initial either box** |
|  | **Optional**  | **Yes** | **No** |
|  | I would be happy for a member of the research team to contact me about taking part in an audio recorded interview on my experience in the COACH trial. |  |  |
|  | Once the trial has ended, I would like to know the results of the trial and agree for my email address, home address or mobile number to be used for sending me the results. |  |  |
|  | I agree to be contacted and informed about future trials. I understand that there is no obligation, and I will just be informed of what the future trials will involve. |  |  |

|  |
| --- |
| ***For telephone consent only****, the person receiving consent should complete this box. When full written informed consent is received at the earliest convenience in person and before randomisation, both the person receiving consent at that time and the participant should complete and sign the section below this box.*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Name of person receiving consent Date Signature(You must be on the delegation log and authorised to perform informed consent) |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of Participant Date Signature

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Name of person receiving consent Date Signature

(You must be on the delegation log and authorised to perform informed consent)

*Original signed ICF to be kept in the Investigator Site File. 4 copies: 1 for participant, 1 for the medical notes and, 1 for the GP and 1 to be sent to NCTU.*