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

in adults with severe hearing loss

**Recruitment Intervention Informed Consent Form**

**Version 1.3 14Jan2022**

**Name of Principal Investigator**:

**IRAS Project ID: 297574**

**Participant ID:**

|  |  |  |
| --- | --- | --- |
|  | | **Initial box** |
|  | I confirm I have read and understood the participant information sheet about the recruitment study <inset version and date> and have had the opportunity to ask questions and have had these answered satisfactorily. |  |
|  | I agree to audio-recordings being made of the conversation about COACH trial participation between me and the audiologist/ear, nose and throat (ENT) or other health professionals or trial staff up until the point at which I am randomised into the trial. |  |
|  | I understand the recording of conversations about participation in the COACH trial is voluntary and I am free to withdraw at any time, without giving any reason, and without it affecting my legal rights, medical care, or participation in the COACH trial. I understand that should I withdraw, any information collected so far cannot be erased and that this information may still be used anonymously in the project analysis. |  |
|  | I understand that data collected in the study may be looked at by authorised individuals from the University of Nottingham, the research group and regulatory authorities where it is relevant to my taking part in this study. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. |  |
|  | I understand that anonymised direct quotes from the conversation may be used for training, teaching, research and publication for the COACH trial and future studies. |  |
|  | I agree to anonymised data being made available by controlled access to researchers outside of the COACH trial who secure the necessary approvals and that data may be used for purposes not related to this study, but it will not be possible to identify me from the transcripts. |  |
|  | I agree to take part in the above study. |  |

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

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. 3 copies: 1 for participant, 1 for the medical notes and, and 1 to be sent to the Nottingham Clinical Trials Unit.*