



<insert local letterhead details>

## INFORMED CONSENT FORM

### STARFISH: STeroid Administration Routes For Idiopathic Sudden sensorineural Hearing loss

Patient trial no.:

Local Principal Investigator:.....

Trial information: ISRCTN no.: 10535105

EudraCT no.: 2022-000085-17

IRAS no.: 1004878

<i>Please initial inside each box</i>	
1	<p>I confirm that I read and understood the Participant Information Sheet, dated ___/___/___ version number __. __ for the STARFISH trial. I had the opportunity to consider the information and ask questions, and have had these answered satisfactorily.</p> <div style="text-align: right;"><input type="checkbox"/></div>
2	<p>I understand that my participation is voluntary and that I am free to withdraw from the trial at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that even if I withdraw from the STARFISH trial, data collected up to my time of withdrawal may still be used.</p> <div style="text-align: right;"><input type="checkbox"/></div>
3	<p>I understand that relevant sections of my medical notes and data collected during the trial may be looked at by individuals from the STARFISH trial research team, representatives of The University of Birmingham, from regulatory authorities, or from the NHS Trust, where this is relevant to my taking part in this research.</p> <div style="text-align: right;"><input type="checkbox"/></div>
4	<p>I have read and understood the information in the Participant Information Sheet and on the trial website about what happens to the personal data collected for this trial.</p> <div style="text-align: right;"><input type="checkbox"/></div>
5	<p>I agree to my GP being informed of my participation in this trial.</p> <div style="text-align: right;"><input type="checkbox"/></div>
6	<p>I understand and acknowledge that data collected that identifies me by name, on the consent form and the participant contact form, will be transferred from where it is collected and stored to the University of Birmingham.</p> <div style="text-align: right;"><input type="checkbox"/></div>
7	<p>I understand that the information collected will be used for medical research and that I will not be identified in any way in the analysis and reporting of the results. I understand that even if I withdraw from the trial, information already collected about me may be included in the final analysis after being anonymised.</p> <div style="text-align: right;"><input type="checkbox"/></div>



8	I agree to take part in the STARFISH trial.	<input type="checkbox"/>
9	<b>Optional:</b> I agree to share my personal data with researchers at The University of Cambridge and Anglia Ruskin University, and to be invited for possible participation in a sudden hearing loss focus group	<input type="checkbox"/>
10	<b>Optional:</b> I understand that the information collected about me may be used to support other related research in the future, and may be shared anonymously with other researchers.	<input type="checkbox"/>
11	<b>Optional:</b> I agree to sharing my contact details with the STARFISH team, and to be contacted by them for up to 5 years after the trial, regarding my participation in the trial, further data collection, and to receive a summary of the trial results.	<input type="checkbox"/>
12	<b>Optional:</b> I agree that information held in my medical notes, or maintained by NHS Digital and other central UK NHS bodies may be used to help contact me or provide information about my health status and medical history after the trial has ended. I agree to share my NHS number for this purpose.	<input type="checkbox"/>
13	<b>Optional:</b> I agree to use the online hearing tests provided by a private company, HearX. I understand that I can opt out of this at any time during the study.	<input type="checkbox"/>
14	<b>Optional:</b> I agree to share the results of my hearing tests, but not my name, with HearX for them to use to develop a new at-home hearing test. I understand that I can opt out of this at any time during the study.	<input type="checkbox"/>

Name of participant

Signature

Date (e.g., 01/Jan/2021)

Name of person taking consent

Signature

Date (e.g., 01/Jan/2021)

**When completed:** Original to be kept in Investigator Site File, one copy for the participant, one copy for BCTU Trial Office, one copy to be filed in medical notes.

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