



INSTRUCTIONS FOR HIFU INFORMED CONSENT FORM (HICR)

I. General Instructions

The form is completed for all Hearing Intervention participants who completed ACHIEVE, including those who enroll in HIFU and those who do not enroll for any reason. See table under item 1a for documenting situations resulting in not enrolling into HIFU. For those who consent, complete the form after the initial study informed consent is signed.

Note, to randomize a participant, the HICR form must be completed, HICR1 must equal A, and the form must be marked COMPLETE and LOCKED in the form grid.

II. Detailed instructions for each item

Enter form information for Participant ID selected from the study ID list:

0a. Enter the date the form was completed.

0b. Enter staff ID of the person who administered the form

A. Consent Status

1. This item should be completed for all participants who completed the ACHIEVE study. For participants recruited to HIFU, record the consent response from the participant after the consent process. This item should be completed for every participant that you approach to join the study. For participants who completed ACHIEVE and were not recruited to HIFU, mark item 1 as N in the case were the time since ACHIEVE Year 3 > 12 months ago, the participant has died, the participant cannot be contacted, or the participant has not been recruited to the study for other reasons.

- Select A if participant was recruited to HIFU and gives consent to enroll, then **Skip to item 2.**
- Select N if 1) participant was recruited to HIFU and refused consent, or 2) participant was not recruited to HIFU due to timing out for enrollment, death, unable to be contacted, or not recruited for other reasons.

1a. Record the participant's reason for declining consent. When a participant has not been recruited to HIFU, record the response as noted in the table, then **Skip to End of Form.**

Reason Not Recruited to HIFU	Text to Add in Item 1a
Participant died prior to being invited to the study	Participant death

Participant withdrew prior to being invited to the study	Participant withdrawn
Participant's ACHIEVE Y3 visit took place over 12 months ago (ACHIEVE Y3 >12 months ago)	Participant missed window for enrollment
Study team was unable to contact participant to invite them to the study	Unable to contact participant
Study team deem the participant is not a good candidate for HIFU (e.g., the participant will be unable to comply with study procedures)	Participant was not invited to enroll

2. Record the participant's response regarding allowing the Principal Investigators and ACHIEVE study team members to make and use audio recordings of participant (or proxy) for the purpose of this study.

- Select A if participant agrees
- Select N if participant does not agree

3. Record the participant's response regarding allowing the Principal Investigators and ACHIEVE study team members to make and use video recordings of participant (or proxy) for the purpose of this study.

- Select A if participant agrees
- Select N if participant does not agree

4. Record the participant's response regarding allowing the Principal Investigators and ACHIEVE study team members to use data about participant's hearing aid provided by the hearing aid manufacturer for the purpose of this study.

- Select A if participant agrees
- Select N if participant does not agree

5. Record the participant's response regarding allowing the Principal Investigators and ACHIEVE study team members to use information about the time spent on different applications on participants tablet device for the purpose of this study.

- Select A if participant agrees
- Select N if participant does not agree