



INSTRUCTIONS FOR INFORMED CONSENT ADDENDUM FORM (AICR)

I. General Instructions

The AICR form tracks consent for participants who completed ACHIEVE regarding additional ACHIEVE follow-up data being added to their ACHIEVE research study record (information related to the delivery of hearing aids and the hearing program and two additional follow-up visits). The form is expected for all Successful Aging participants who have completed the ACHIEVE study.

Site staff contact the participant to see if they are interested in the additional ACHIEVE follow-up. The form is completed by project staff immediately after a participant has had the opportunity to be consented for additional follow-up OR when the participant was unable to be contacted due to death or lost to follow-up. The AICR form will also be used to note when a participant does not agree to get fitted for hearing aids. See AICR item #1 for those detailed instructions.

II. Detailed instructions for each item

0a. Enter the date the form was completed. If a participant was unable to be contacted despite multiple attempts, enter the date when the site decides to not continue trying. Complete the BHR to note the site will not be attempting to enroll the participant in BHFU.

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

1. Record the consent response from the participant or proxy regarding allowing information related to the delivery of hearing aids and the hearing program to be included as part of research study record.

- Select A if participant consents
- Select N if participant declines to consent
 - Any previously entered SICF and ASI forms should be deleted for this participant.
- Select N if participant dies **prior** to being fitted for hearing aids
 - Enter a notelog that states “death” or “died”.
- Leave the field blank and set the field status to “Not Applicable” if the participant did not receive hearing aids.
- Leave the field blank and the field status to “Missing” if the AICR was unable to be completed due to lost contact or death **after** hearing aids were fitted.
 - Washington County received a waiver to allow the study to keep the associated SICF/ASI forms

- For participants at the Forsyth, Jackson, or Minneapolis field centers, any previously entered SICF and ASI forms should be deleted.

2. Record the participant's response about agreeing to participate in the extended follow-up visit(s) with the additional data collection. If a participant does not agree to participate add a notelog stating the reason. In order to keep the reasons consistent in the notelogs please use one of the following reasons: death, not interested, other.

Mark this item as N if a participant dies after their completing ACHIEVE and prior to being fitted for hearing aids, then enter a notelog that states “died” or “death.”

- Select A if participant agrees
- Select N if participant does not agree or if the participant dies after completing ACHIEVE and before being fitted with hearing aids (enter a notelog that states “died” or “death” in this case).

3. Record the participant's response about agreeing to allow the Principal Investigators and ACHIEVE study team members to use data about the hearing aid provided by the hearing aid manufacturer for study-related purposes.

- Select A if participant agrees
- Select N if participant does not agree or if the participant dies after completing ACHIEVE and before being fitted with hearing aids (enter a notelog that states “died” or “death” in this case).