



## INSTRUCTIONS FOR ANCILLARY INTERACTION FORM (ASI)

### I. General Instructions

The Ancillary Study Interaction form collects objective information regarding unplanned interactions following each *new* issue with a participant's hearing aids. This form will track all interactions associated with the issue until the issue is resolved. For HIFU participants this form will be entered into CDART in the ANX Unscheduled Visits form group. For Successful Aging Extended Follow-up participants ASI will be entered in ACHIEVE Unscheduled Visits form group.

### II. Detailed instructions for each item

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

0a. Enter the date the form was completed. **Enter the date the first interaction started.** This should be the same date as the first unplanned interaction.

0b. Enter staff ID for the person who completed this form.

### Administrative information

The Audiologist will begin this form when interacting (via unplanned visit, telephone call, or email) with a participant experiencing a new issue (see description in QxQ) with their hearing device(s). This form will track all interactions related to the issue until it is resolved.

### A. Event: Hearing Program Issue

1. Select the reason(s) for the unplanned visit/telephone call (items 1a-1l).

If the reason for the unplanned event was due to mailing HAT to participant record "Yes" to item 1h "HAT not functioning" and enter a notelog describing the interaction, ex: HAT mailed for dispensing/pairing.

If the reason for the unplanned event was due to a device upgrade, use the following guidance:

- 1a – Select this if the hearing aid is not functioning, stock is depleted and device cannot be sent for repair.
- 1c – Select this if the patient requires a different style device (ITC).
- 1e – Select this if the hearing aid is no longer functioning due to water damage, and if your stock is depleted and device cannot be sent for repair.
- 1f – Select this if the hearing aid was lost and your stock is depleted.
- 1h – Select this if the hearing assistive technology is not functioning, stock is depleted and device cannot be sent for repair.

- 1i - Select this if the hearing assistive technology was lost and your stock is depleted.
- 111 – Select “other” if any of the following are reasons for the upgrade appointment:
  - If there is a decrease in hearing and/or speech in noise ability and the participant would benefit from the upgraded processing features within the upgraded devices.
  - If there is a change in dexterity or vision and the participant would benefit from features within the upgraded devices (automatic on/off, use of application for manual controls)
  - If the participants re-locate and require remote audiology services through the upgraded device’s telehealth platform. (Note: This can only be completed after completion of HIFU visits)
- Note: 1b, 1d, 1g, 1j, and 1k are not an applicable selection for upgrades.

A notelog may be completed explaining other issues associated with the interactions.

111. Specify other if applicable.

## B. Interactions

Fill out the interaction section for each interaction associated with the issue identified in the previous section in items 2 – 26, for each provide the following:

- A. Date of unplanned visit/telephone call
- B. Start time of visit/telephone call (hh:mm)  
Note: If an HICF/SICF CRF is also completed, please replicate the time stamp on both the HICF/SICF and ASI.
- C. End time of visit/telephone call (hh:mm)  
Note: If an HICF/SICF CRF is also completed, please replicate the time stamp on both the HICF/SICF and ASI.
- D. Type of Interaction Code
  - a. In-person Visit other than scheduled visit
  - b. Video Call (Remote Support Session, GrandPad Session)
  - c. Telephone (no video)
  - d. Curb-side interaction, drop-off, pick-up
  - e. Asynchronous Support (Email, Application-based messaging, Postal mail service)
  - f. Home visit

If the reason for the unplanned event was due to mailing HAT to participant record E - Asynchronous Support (Email, Application-based messaging, Postal mail service, for the type of interaction

- E. If H/SICF was completed, enter the occurrence number for the H/SICF. If there was no H/SICF completed, enter “0”.

## C. Resolution

27. Was the issue resolved?

- This response should be set to “no” when the form is first opened, and should remain “no” for each additional interaction until the issue is resolved and the form is completed.
- If the issue is resolved, select Yes and continue to question 28.

28. What action(s) was/were taken to resolve the issue?

- a. Hearing aid replacement device provided
  - *Example: Poor EAA results, rechargeable battery replacement, damaged hearing aid, participant provided with loaner or stock hearing aids and their original hearing aids sent for repair, or participant received an upgraded device.*
- b. HAT replacement device provided
  - *Example: Broken HAT replaced and original sent for repair, participant needed different HAT due to changing needs or inability to use, or participant received an upgraded hearing aid requiring an upgraded HAT.*
  - *If the reason for the unplanned event was because the HAT was mailed to the participant then record “HAT replacement provided” as the action taken to resolve the issue and enter a notelog describing the interaction, ex: HAT mailed for dispensing/pairing.*
- c. Counseling and/or reinstruction
  - *Example: Questions about -- hearing loss, when to wear hearing aids, insertion/removal, charging, remote control/manual program use, HAT/Bluetooth pairing or use, smartphone app, participant reaches out to share general comments.*
- d. Study staff repairs
  - *Example: Any of the following when performed by an audiologist or trained study staff -- receiver replacement or wax protection replacement, reprogramming needed due to dissatisfaction with sound quality, volume, or feedback. Adjustments to acoustic coupling needed due to poor fit. Custom earpiece fitting or replacement.*
- e. Participant self-repair
  - *Example: Participant replaces receiver, wax trap, dome while supported by the audiologist via verbal or written instructions.*
- f. Supplies provided
  - *Example: New charging case or cable, wax protection, desiccant, etc. provided to participant*
- g. Other
  - If selected, continue to question 28g1.

28g1. Specify other.