

## INSTRUCTIONS FOR BHFU INFORMED CONSENT FORM (BICR)

## I. General Instructions

This form is completed by project staff for all participants who have answered BHR4=Yes (participant is eligible for BHFU). These are the participants who will be approached about enrolling in BHFU. For those who consent, complete the form after the initial study informed consent is signed.

## 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

- 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. Only those who have answered "Yes" to Item 4 in the Brain Health Recruitment form should be recorded using this form. Mark item 1 as N if a participant is not interested in enrolling OR the participant has died AFTER being briefed about BHFU (after BHR form is complete) and prior to the BHFU baseline visit.
  - Select A if participant consents: Skip to item 2
  - Select N if participant declines to consent
- 1a. Record the participant's reason for declining consent. Enter 'Participant death' in the instance where a participant has died prior to joining the study. Skip to the end of the form.
- Record the participant's response regarding allowing the ACHIEVE study team members to contact a primary care doctor, physician, clinic, or designated person in the case of an MRI incidental finding. Note: consent is phrased as Yes or No. If the consent response is yes, record as A (agree). If the consent response is no, record as N (not agree) = no on the consent form.
  - Select A if participant agrees
  - Select N if participant does not agree
  - If the participant <u>refuses the MRI</u> during the consent process or if the participant is <u>already</u> <u>known to be ineligible for MRI</u>, mark the field status for item 2 to 'Not Applicable.'
- 3. Record the participant's response regarding allowing the ACHIEVE study team members to collect the participant's social security number to connect with sources of medical information

for the purpose of this study. These sources of medical information may include Medicare claims data and the Social Security Death Index.

- Select A if participant agrees
- Select N if participant does not agree
- 4. Record the participant's response regarding allowing the ACHIEVE study team members to use data about participant's hearing aid provided by the hearing aid manufacturer for the purpose of this study. If the participant does **not** have a hearing aid, leave this item blank and mark item "not applicable."
  - Select A if participant agrees
  - Select N if participant does not agree
- 5. Record the participant's response regarding accepting a tablet provided by the Principal Investigators and ACHIEVE study team. The participant may already have a GrandPad device if enrolled in the Hearing Intervention Follow-Up (HIFU) study. At the end of the HIFU study, the participant may return the GrandPad device to the study team. At that time, the participant should be offered the Lenovo tablet. After the participant is offered the tablet, MODIFY the response to item 5. You may enter a notelog that the tablet was provided to the participant after the initial consent was recorded following the conclusion of the HIFU study.
  - Select A if participant agrees
  - Select N if participant is not interested
  - Select H if the participant already has a device issued by HIFU
- 6. Record the participant's response regarding contact for future research.
  - Select A if participant agrees
  - Select N if participant does not agree
- 7. Record the participant's response indicating if they are enrolling with a spouse or cohabiting partner.
  - Select Y if participant is enrolling with a spouse or cohabiting partner
  - Select N if the participant is not; End form if No
- 8. Record the participant ID for the enrolling spouse or cohabiting partner of the participant.