



INSTRUCTIONS FOR THE TELEPHONE SCREENING FORM (TSF)

I. General Instructions

The Telephone Screening Form is recorded to determine the participant eligibility against some of the study inclusion criteria before in-person screening visit. This is the very first data entry form of the ACHIEVE visit. Complete all questions on the TSF. **Refrain from commenting about a screening candidate's responses, particularly when the answer provided will result in the candidate being ineligible.**

Prior to starting the TSF, study staff should ascertain if the person is an ARIC or de novo participant and check that they are aged between 70-84. If they are age eligible then the TSF should be initiated.

Upon initiating the TSF, study staff should first enter the participant ID number. It is imperative that ARIC participants be screened with their ARIC participant ID. De novo participants get an ACHIEVE ID number. De novo ACHIEVE ID numbers look like ARIC IDs (start with F, J, M or W) but have an '8' as the second character of the ID {e.g., F812345 or J823456 or M834567 or W845678}. For de novo participants: Prior to assigning an ID, study staff should have already confirmed that the person is in the appropriate age range.

It is possible that there are ARIC members in the community who have not recently participated in ARIC, who are interested in ACHIEVE. These participants use their ARIC ID for ACHIEVE.

When asking the participant if he or she has a spouse or partner who might be interested in being screened (TSF12), it is important to find out first if that person is an ARIC participant. If yes, the ARIC ppt ID is recorded in the RSF and screened with the TSF under the ARIC ID. If no, the partner is assigned a de novo ID (use the CDART de novo ID Report to find the next available ID number) and that partner is screened with the TSF under the de novo ID. The de novo participant (and partner if applicable) is also asked some key questions which are recorded in the DEM form (name, address, phone number, education and date of birth).

Recording 'No Interest in ACHIEVE' for ARIC Participants

An ARIC participant who had been identified as ACHIEVE-eligible on the V6V7 Ancillary Study report may not be interested in being screened; they may not want to answer questions on the TSF. In this case, no TSF will be required. Record 'No Interest' in the RSF form. Find the instructions in the RSF QxQ. The TSF form may be marked as Permanently Missing in the form grid for these ARIC Participants.

II. Detailed Instructions for Each Item

- 0a. Enter the date the participant was screened over the phone.
- 0b. Enter the staff ID for the person did the telephone screening.

1 – 10. The interviewer reads the script on the telephone call. Enter the answer given by the participant for each response.

Script: *“I am going to ask you some questions about yourself. For each question, please let me know if your answer is “Yes” or “No””*

2. This question asks if the participant lives at home. Note: If the person indicates that they live in a nursing home then the ‘No’ option should be selected. A nursing home is not considered living at home.

4. This question asks if the participant intends to stay in the area for the duration of the study and whether they have any health issues that would prevent them from participating for the duration of the study. If the participant is not planning to stay in the area for the next 3 years then they are not eligible. Exception: For individuals who live elsewhere for part of the year (i.e. snowbirds) but could attend all visits it is okay to include them (i.e. they are eligible) as they are intending to maintain their residency in the field site area. If the participant identifies any health issues that they think would prevent them from participating in the study for the next three years then they are not eligible. If the participant is unsure whether a health condition would prevent them from participating ask the participant to describe their concerns so that you may help them determine their response. If in doubt, check with the site PI.

6. This question asks if they are willing to wear hearing aids on a regular basis. A regular basis means daily or near daily. If they are not willing to wear hearing aids on a regular basis then they are not eligible for the study.

7. This question is specifically asking about hearing aids. This question is not asking about assistive listening devices. If assistive listening devices have been used within the past one year this is okay and does not affect eligibility. If a participant states that they bought a device from a drug store rather than seeing a hearing professional that is not a hearing aid and would not impact eligibility. If hearing aids have been used within the past one year then the participant is not eligible. There is one exception to this rule: If the participant states that they tried a hearing aid out but did not end up buying it, then they are still eligible for ACHIEVE.

8. This question is designed to eliminate individuals who had a very early onset hearing loss that affected them their whole lives (as opposed to older adults with primarily age-related hearing loss in later life). If there is uncertainty, further questioning of the participant may be helpful to clarify if any hearing problems have been noticed since childhood (if so the participant would be ineligible) or if any hearing problems appeared later in life (if so the participant is still eligible). If further questioning does not clarify the situation then the more conservative response of ‘Yes’ should be selected.

9. This question asks about other studies that the participant may be involved in.
- If they are participating in studies of an **intervention** for cognition, thinking, memory or hearing then they are not eligible.
 - If they are participating in **observational studies** where cognition/thinking/memory is assessed then they are not eligible.
 - Participation in ARIC is okay and does not impact eligibility.
 - If the participant indicates that they are involved in a study ask them to name/describe the study so that you can help them determine if it is an intervention study. If in doubt check with the site PI.

10. Special equipment excludes routine equipment such as canes, walkers, and grab bars. If they use a leg brace that is over-the-counter or temporary then the participant is allowed to participate. If the leg brace is more permanent (medically necessary), then their limited mobility would make it difficult for them to participate in ACHIEVE. A wheelchair is considered special equipment. If you are unsure whether an item constitutes 'special equipment' contact the ACHIEVE recruitment committee (Nick: nreed9@jhmi.edu) and ARICHELP (arichelp@unc.edu). Staff can begin the question by saying:

"I am now going to ask you about difficulty in doing certain tasks by yourself, that is without the help from another person or special equipment. Special equipment would include things like a wheelchair or a permanent medically necessary leg brace but it would not include canes, walkers or grab bars."

11. This field is a script that CDART runs, using the information in items 1 through 10. It returns a value of either 'Yes' or 'No' [or 'missing'] for eligibility. If an item in 1 through 10 is left blank, and other items are eligible, the script will return a 'null' value as the script cannot evaluate missing data. If a 'missing' value is returned, review responses 1 through 10 for any missing values and, if necessary, repeat the question.

12. Ask the participant if s/he lives with a spouse or partner who might be interested in participating.

Participants who are ineligible based on the TSF are considered complete. No further data collection is needed on those participants. For participants who are eligible, the Demographics Form (DEM) needs to be initiated to gather the following information:

- Question 7 (first name)
- Question 8 (last name)
- Question 9 (date of birth)
- Question 14 (education)
- Question 16 (current address)
- Question 17 (home phone number)
- Question 18 (cell phone number)
- Question 19 (current email address)

- Question 20 (best contact method)

See the DEM QxQ for more information.

If the participant indicated that they had a spouse or partner who might be interested in participating, if that partner is available to be screened over the phone right then, go ahead and get the partner's information (determine if s/he is an ARIC participant and assign the appropriate ID) and then ask the screening questions over the phone with that partner under the appropriate ID.

Eligible participants are then invited to an in-person screening visit. If the eligible participant is willing to set up a screening appointment at the end of the call, say,

"You may be eligible for our trial. We would like to invite you to a screening visit. Can we go ahead and schedule that with you today?"

The Recruitment Tracking and Scheduling Form (RSF) then needs to be initiated. See the RSF QxQ for further information.

If the candidate is a screen failure, use the following script to inform them that they are not eligible:

"Thank you for your consideration and time. Unfortunately, you did not meet all of the criteria needed to take part in the ACHIEVE study."

If the candidate is an ARIC participant, add the following:

"Please note that this will not affect your continued involvement with the ARIC study in any way."

Refrain from providing details about the reason(s) the screened candidate is not eligible.