



INSTRUCTIONS FOR HIFU RANDOMIZATION FORM (RANH)

I. General Instructions

Complete this form to randomize a participant or cohabiting partner pair on the day of their study visit. Like ACHIEVE randomization, partner pairs are randomized from the same RANH form, however, unlike ACHIEVE randomization, only ONE RANH form from the partner pair needs to be completed. No forms need to be locked to complete the HIFU randomization, also a change from the ACHIEVE process. All ACHIEVE participants from the Hearing Intervention arm are invited to enroll in HIFU. HIFU-consented participants can be randomized by following the steps in the RANH form.

- Invite only ACHIEVE hearing arm participants to HIFU.
- Interested ACHIEVE participants will be consented. Complete the HICR in CDART for those who agree to participate.
- To randomize partner pairs, both participants of the pair must be present, and both must be eligible (Hearing arm and HIFU-consented).
- Complete and save the HICR form(s) **BEFORE** starting the RANH form. **For partner pairs, the HICR form must be completed for each participant before starting the RANH form.**

II. Detailed instructions for each item

0a. Enter the date the form was completed.

0b. Enter staff ID of the person who administered the form. The staff ID must be entered in the form to randomize. If left blank, an error message is returned.

A. Inclusion and Exclusion Criteria

1. Record if the participant is enrolling with a spouse or cohabiting partner pair.

- Select "Yes" if participant is enrolling with a spouse or cohabiting partner pair
- Select "No" if participant is enrolling singly

Note: If the participant enrolled with a partner as part of ACHIEVE and is no longer enrolling with that partner or any other partner, select 0 (No).

If "Yes" is selected in item 1, both participants must have been in the ACHIEVE hearing aid treatment assignment group.

1a. Record the partner participant ID if applicable. Be extra careful to enter the partner participant ID without error; copy-paste where you can. If the partner ID is not a valid ACHIEVE ID, the eligibility check report in section B will return an error.

Enrolling with a partner is a special randomization case. However, unlike in ACHIEVE, the randomization form for HIFU (RANH) does NOT need to be completed for both participants. Choose one participant within the partner pair to use for the RANH form and both partners will be randomized from that form. Completing the partner's RANH form is not necessary; leave it empty in the form grid.

Note: Review the ACHIEVE HIFU Randomization Training Slides on the study website in case of other questions. Navigate to the Ancillary Studies->ACHIEVE->Training.
(<https://www2.csc.unc.edu/aric/training-achieve>)

B. Eligibility Determination

Verify the items 0a, 0b, 1, and 1a (if applicable) are data entered. Check that item 2 is either blank OR “No”. SAVE form.

Follow the directions on the screen for running the eligibility check application for the participant. The eligibility check application will open in a new tab. The messages returned in the eligibility check application give instructions for data checking and/or eligibility.

Resolve any errors generated in the eligibility check application before proceeding to section C. Some errors may not be able to be resolved which would indicate that the participant or pair is ineligible to participate in HIFU. If this happens, click Save and Close at the bottom of the form and do not attempt to randomize the participant or partner pair. If you believe that the participant or partner pair is eligible and an error is incorrectly being generated, contact ARICHELP@unc.edu..

C. Randomization

2. Confirm eligibility criteria are met, items 0a, 0b, and 1 are data entered, and you are ready to assign an intervention.

- Select “No” as a safeguard for time to verify all randomizing information OR if unable to complete intervention assignment at this time. If item 2 is set to “No” the randomization application will not run. If you select “No”, because the eligibility report indicates the participant(s) are ineligible, click Save and Close the form. Do not assign a GrandPad; do not answer questions in section D.

Select “Yes” if confirming eligibility criteria are met after running the eligibility report in section B.

For the randomization application to run, the participant(s) is eligible as determined by the eligibility report, item 2 is set to “Yes” and the user clicks Save and Reload at the bottom of the form. **Click Save and Reload one time only.** A successful randomization will display the result of the randomization, including the treatment intervention group in item 3.

Rarely, the user may experience a brief delay when the application is working to verify the eligibility data and then write the randomization record to the randomization table. Clicking Save and Reload more than once during this brief delay may write more than 1 record to the randomization table. Contact ARICHELP@unc.edu if you suspect this rare situation may have occurred and pause subsequent randomizations until receiving guidance from the CC.

NOTE: If you have answered “Yes” to item 2 and have already Saved and Reloaded the RANH form, the participant(s) is(are) randomized. They are formally enrolled in HIFU. Changing item 2 to “No” will not unenroll the participant(s). A query will be generated for RANH item 2 set to “No” and the participant has been randomized.

If after you select “Yes” on item 2, you realize that the participant is not eligible, verify that treatment was NOT assigned in item 3. If there is a sentence that reads “The subject/ cohabiting pair has been assigned to <TREATMENT>.” in item 3, this indicates that a treatment was assigned. If treatment was assigned, contact the ARICHELP@unc.edu.

If the participant decides that they do not want to participate in the study any time (including immediately after clicking “Save and Reload” after selecting “Yes” to item 2) after the treatment is assigned, you must follow the steps for withdrawing the participant from the study.

3. Review the treatment assignment or error. If a treatment is assigned without error, proceed to section D. If the participant or cohabiting partner pair could not be randomized due to error, STOP the randomization and contact ARICHELP@unc.edu for guidance on proceeding with the randomization.

D. GrandPad Assignment

4. Record only if the participant was successfully randomized.

- Select “Yes” if GrandPad accepted.
- Select “No” if GrandPad not accepted. Save and close the form.

5. Record GrandPad subscription ID.

For assistance finding the GrandPad subscription ID, please reference the ACHIEVE-HIFU Manual of Operations.

6. Record only if the participant was successfully randomized and item 1 equal to “Yes”

- Select “Yes” if partner accepted a GrandPad.
- Select “No” if partner did not accept a GrandPad. Save and close the form.

7. Record partner GrandPad subscription ID.

For assistance finding the GrandPad subscription ID, please reference the ACHIEVE-HIFU Manual of Operations.

If you encounter any problems during the randomization process, please contact ARICHELP@unc.edu.