



INSTRUCTIONS FOR THE DISPOSITION (DSPH) FORM

I. General Instructions

The DSPH Disposition Form documents how and when a participant has completed the HIFU study. Complete the form for study participants (PPT) to document their final status in the study. Note: contact ARICHELP@unc.edu for instructions on updating the DSPH when a PPT has withdrawn consent and then wishes to return to the study.

The data entry on this form should be started as soon as the site is made aware of a disposition status, especially when the participant has withdrawn consent, discontinued due to an adverse event other than death, or has died. In that instance, complete date, staff code, and questions 1 through 2. Question 3 should remain blank until the site has completed all data entry. See instructions for DSPH3 for more information.

This form is also used to document the date when a GrandPad device is returned to the site. Participants may return the device at any time during the study. Returning the device does not indicate a withdrawal.

Note: If participant is *also* enrolled in BHFU, the DSPB Disposition Form must be completed in addition to the DSPH.

II. Detailed Instructions for Each Item

- 0a. Enter the date the DSPH is completed.
- 0b. Enter the staff ID for the person who completed the DSPH.
- 0c. Enter the date the GrandPad device is returned to the clinic. The GrandPad device may be returned to the site prior to completion of the study by the participant. If the GrandPad is not returned to the site:
 - 1. leave the date field blank,
 - 2. set the field status to missing, and
 - 3. document the reason the GrandPad is not returned in a Notelog. If the reason the device is not returned to the site because the participant died, the GrandPad was lost, or the participant decided to keep the GrandPad, please use the following specific Notelog language in the table. Otherwise, specify "Other" in the notelog. When adding information to notelogs, omit participant-identifying content.

Situation	Notelog
Participant died before returning GrandPad	Participant died
Participant lost GrandPad and device cannot be recovered	GrandPad lost
Participant chose to keep their GrandPad and pay for their own subscription	Participant kept Grandpad and started own subscription

- 1. Enter the date of disposition. The date is the last day of participation in the study or the last day of most data collection. See additional notes under item 2 regarding dates.

Only record the date in this field after all items from the completion list described under item 2 have been completed.

2. Choose one disposition category. If a HIFU participant misses their ANX Year 2 visit and they are enrolled in BHFU, we will not consider them lost to follow-up in HIFU; enter the DSPH item 2 as *Completed the study* (DSPH2="E"). If a HIFU participant misses their ANX Year 2 visit and they were not enrolled in BHFU, we will consider them lost to follow-up in HIFU; enter DSPH item 2 as *Participant lost to follow-up* (DSPH2="B").

A=Withdrew consent

- If a PPT withdraws consent, the date of disposition is the date the PPT notifies the site of their intention to discontinue. Examples: the date from a letter of withdrawal notification, or the date the PPT telephones or emails the site to inform them of the withdrawal.

B=Participant lost to follow-up

- The date of disposition for a PPT lost to follow-up is the last date of contact with the PPT.

C=Death

- The date of disposition for a PPT who dies is the date of death. Deaths are also recorded on the AER form in the ANX Adverse Events form group.

D=Discontinued study due to adverse event other than death

- The date of disposition for a PPT who discontinues due to an adverse event is the later of the 2 dates, adverse event date when no additional data is collected from the PPT, or the last date that data is collected on the PPT. Adverse events are also recorded on the AER form in the ANX Adverse Events form group.

E=Completed study

- Most PPTs will be categorized as completing the study. The date of disposition is the last day of HIFU data collected on the PPT (not the date the accelerometer is returned to the site). Only complete this field after all items from the completion list have been addressed:
 - Complete the data entry for all outstanding accelerometry forms and upload the data. If it has been more than 10 days since the last visit and you have not received the accelerometer and log, please contact the participant.
 - If relevant, complete all Informant Interviews and enter data into CDART.
 - Resolve all queries returned from the CDART Form Data Queries Report.
 - Resolve all missing fields returned from the CDART Missing Fields by ID and Form Group reports.
 - Resolve any outstanding manual queries that have been assigned by reviewers.

- Enter a Missed Ancillary Data Collection Form (MDCX) in the ANX Administrative Forms group if any of the expected forms were not collected.
 - Set missing forms from partial visits to Permanently Missing in the CDART form grid.
- 2a. If option 'C' is selected, enter the date of the participant's death. All deaths must be recorded on the AER form in addition to the DSPH.
- 2b. If option 'C' is selected, enter the cause of the participant's death.
- 2c. If option 'D' is selected, enter the date of the participant's adverse event. All adverse events must be recorded on the AER form in addition to the DSPH.

When a PPT has completed, withdrawn, or died, the PI needs to review and sign off that the data collection is complete. To close out the data collection for a PPT, the study site staff should:

- a. Carefully review all data collected up through the disposition date.
 - b. Run all query reports to look for missing fields and missing forms. Mark any uncollectable, but expected, forms as permanently missing on the form grid.
 - c. Verify all data has been entered into CDART.
 - d. Complete the Missed Data Collection form to enter reasons for missed forms or missed visits.
3. When all data has been entered and reviewed, the site will enter 'No' for DSPH3. Leave the field blank until the review is **final**. Entering 'No' in DSPH3 will be used as a trigger for the PPT's subject ID to show up on the PI ANX Sign-off Report in CDART. Sites will have access to this report so they can confirm that a PPT's data collection is final and available for the PI to review.

The principal investigator will run the PI ANX Sign-Off report periodically to be informed of needed data reviews from PPTs who have come to the end of the study. This includes PPTs who have died or withdrawn. If questions arise from the PI data review, DSPH3 will remain 'No' and the PI will notify the site about their concerns. The site should address the concerns and notify the PI when the data has been updated or an explanation has been provided to the PI. If satisfied with the data review, the PI updates DSPH3 to 'Yes.' Save and Close the form (bottom right).

PI only: Lock the form in the form grid by clicking the LOCK icon.