



INSTRUCTIONS FOR THE DISPOSITION (DSPB) FORM

I. General Instructions

The BHFU Disposition Form documents how and when a participant has completed the BHFU 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 Note, contact ARICHELP@unc.edu for instructions on updating the DSPB when a PPT has withdrawn consent and then wishes to return to the study.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form should be started as soon as the site is made aware of a disposition status, especially when the participant has withdrawn consent, discontinued due to an adverse event other than death, or died.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 DSPB3 for more information.

This form is also used to document the date when a tablet is returned to the site. Participants may return the device at any time during the study. Returning the device does not indicate a withdrawal. Participants are not expected or required to return the tablet issued as part of BHFU, but some participants may wish to do so.

II. Detailed Instructions for Each Item

- 0a. Enter the date the DSPB is completed.
- 0b. Enter the staff ID for the person who completed the DSPB.
- 0c. Enter the date the tablet is returned to the clinic, if returned. Leave this item blank if the participant does not return the tablet.

- 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. The ACC Accelerometry data collection has inherent data collection delays and should NOT be used as the final date of disposition. 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.
 - 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 data collected on the PPT, typically the PPT's ANX Year 3 clinic exam date (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 DSPB.

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 DSPB.

When a PPT has completed, withdrawn, or died, the PI needs to review and sign off that the data collection is complete. In order 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 DSPB3. Leave the field blank until the review is **final**. Entering 'No' in DSPB3 will be used as a trigger for the PPT's subject ID to show up on the PI DSPB 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 DSPB 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, DSPB3 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 DSPB3 to 'Yes.' Save and Close the form (bottom right).

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