



INSTRUCTIONS FOR BHFU EXTENSION INFORMED CONSENT FORM (BICRX)

I. General Instructions

This form is completed by project staff for any participant who has completed BHFU. These are the participants who will be approached about enrolling in BHFU Extension. 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

1. **This item is not asked of the participant.** Indicate if the participant is going to be invited to join BHFU Extension by the Principal Investigators and/or research staff. This item should be completed for every BHFU participant who completed or is anticipated to complete their Year 3 BHFU visit. Mark item 1 as N if the PI/research staff deem the participant is not a good candidate for BHFU Extension (e.g., the participant will be unable to comply with study procedures).

- Select Y if the participant will be invited: **Skip to item 2**
- Select N if the participant is not invited or cannot be invited

1a. Provide the rationale for declining the invitation to the participant.

- Select A if the participant is deceased following the completion of BHFU; **End form, not eligible**
- Select B if the participant is not interested in future ACHIEVE ANX studies; **End form, not eligible**
- Select C if the participant is unable to comply with site procedures; **End form, not eligible**
- Select D if the participant is planning to relocate after BHFU **End form, not eligible**
- Select E if there is insufficient time remaining in study to complete additional visit **End form, not eligible**
- Select F if the participant is unable to be reached **End form, not eligible**
- Select G if there is another reason why a participant will not be invited to enroll in BHFU Extension

1b. If other reason is selected that prevents the participant from being invited to enroll in BHFU Extension, please specify in the space provided and **close the form; not eligible.**

2. 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. Mark item 2 as N if a participant is not interested in enrolling.

- Select A if participant consents: Skip to item 3
- Select N if participant declines to consent

2a. Record the participant's reason for declining consent. Close the form.

3. 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

4. Record the participant ID for the enrolling spouse or cohabiting partner of the participant.