INSTRUCTIONS FOR THE FITBIT INITIALIZATION FORM (FBI) FORM

I. General Instructions

The Fitbit Initialization Form (FBI) is completed with all participants who are offered the Fitbit Study as a part of ARIC Visit 11. Fitbit is offered on Day 2 of Visit 11 for participants who are completing the visit over two days.

The FBI form should be opened and completed for all participants. If the participant declines participation in the study or is ineligible due to the pacemaker exclusion as indicated in the Participant Snapshot report, you should enter items 0a, 0b, and 0c, then save and close the form.

II. Detailed Instructions for Each Item

0a. Enter the date the form was completed. Since Section D is updated through the course of the study, the completion date should be updated every time this form is updated.

0b. Enter the staff ID of the person who completed this form.

0c. Record if the participant is interested in participating in the Fitbit study. If the participant is interested but ineligible due to the pacemaker exclusion as indicated in the Participant Snapshot report, select No and record this reason in 0c1. If the participant indicates they are not interested in participating, record the reason why not in 0c1. If No is selected, the Fitbit Support Log (FBT) should not be opened.

A. FITBIT EXCLUSION INFORMATION

1-1a. Record whether the participant owns a smartphone. If the participant does not have a smartphone, they are unable to participate in the Fitbit Study due to the necessity of downloading the Fitbit app. The other type of smartphone the participant has is recorded in item 1a1 if the participant does not have an iPhone or Android.

1b. Select whether the participant owns a smartphone that is capable of running software compatible with a Fitbit Charge 6 (iPhone requires iOS 15.0 or later; Android requires Android 9 or later). If No is selected, they are unable to participate in the Fitbit Study.

1c. Record whether the participant consents to receiving text messages about the Fitbit study. Selecting No does not exclude them from participating. Do not enable text messaging in Fitabase for participants who do not consent to receiving text messages that will remind them to sync.

B. FITBIT INITIALIZATION INFORMATION

2-2a. Record the participant’s Google email address and password. Every participant, regardless of whether they already have a personal Google email address, will have a study-related Gmail address created for them. Note, the participant must have a Gmail created for them in order to sign up for a Fitbit account (see MOP Section 2.4, Setting Up a Fitbit Account). Be sure to record the Gmail password the participant creates for their account in item 2a.
3. Record the Fitbit serial number by scanning the barcode directly into CDART. The serial number is 12 characters (letters and numbers) and can be found with the barcode on the bottom of each Fitbit watch box. If you remove the part of the wrist band connected to the bottom of the watch, you can also see where the serial number is located on the watch itself.

3a. The Fitabase participant ID will automatically populate in this field. This is a masked version of the ARIC ID that changes the letter to a number (F=1, J=2, M=3, W= 4) and reverses the numeric portion of the ID. This masked participant ID should be recorded in Fitabase instead of the ARIC participant ID. With both CDART and Fitabase open on the computer, enter this identifier in Fitabase by copying this field from CDART (ctrl + c) and pasting (ctrl + v) into Fitabase. This method is highly preferred over manual entry in order to avoid transcription error.

4. Enter the date that the Fitbit was set up and given to the participant.

5-5a. Record the wrist that the Fitbit watch is worn on, and whether this is the participant’s dominant or non-dominant wrist. Note, it is preferred for the participant to wear it on their non-dominant wrist.

C. AT-HOME TECHNOLOGY SUPPORT INFORMATION

6. Record if the participant needs help when using technology. If the participant frequently needs help or sometimes needs help, proceed to item 6a; otherwise, skip to item 7.

   6a. Record the person who the participant most frequently relies on for help with technology. Only one person may be chosen. If none of the listed people are the person who helps the participant with technology the most, specify the other person in 6a1. You can add a comment to this field in CDART with the individual’s name and phone number if the participant is willing to provide it.

D. FITBIT REPLACEMENTS AND RETURNS

7. Record whether the participant has required a replacement Fitbit device. This could be due to a variety of reasons, including damage to the device, loss of the device, malfunction, etc. If yes is selected, record the replacement Fitbit serial number and the date the participant received the replacement Fitbit in 7a and 7b. The serial number should be scanned into CDART using the barcode scanner to avoid transcription error.

8-11. Record whether the participant has required any additional replacement Fitbit devices. The participant is allowed up to five replacements. Anytime a participant requires a replacement, the serial number of the new device and the date the participant received the device should be recorded.
12. Record if the participant has decided to return their Fitbit device and withdraw from the Fitbit study. If the participant discontinues from the study, the date of the device return should be recorded in 12a.