



Manual 49
Fitbit Procedures
ARIC Visit 11

Version 1.6
November 4, 2025

Table of Contents

0	MANUAL REVISIONS	3
1	OVERVIEW	6
1.1	Study Aims	6
1.2	Background and Rationale.....	6
1.3	Key Measures	6
1.4	Study Participants	6
	Exclusions.....	7
	Participant Reimbursement.....	7
1.5	Equipment, Materials, and Supplies	7
	Forms.....	8
	Scripts.....	8
1.6	Consent Process.....	8
1.7	Overview of Study Procedures	8
2	DETAILED STUDY PROCEDURES.....	9
2.1	Day 1 Visit.....	9
2.2	Scheduling Day 2 Visit.....	9
2.3	Day Before Day 2 Visit	9
2.4	Day 2 Visit.....	13
	Fitbit Charge 6 – Install and Create an Account	13
	Pairing Fitbit Watch to the Phone.....	17
	Fitbit Charge 6 – Set up for Participant Use	19
	Downloading the Gmail App	25
	Manually Connecting Participants to Fitabase	26
2.5	Following Day 2 Visit	30
	Adherence Monitoring and Technology Support.....	30
	Fitbit Satisfaction Follow-Up.....	31
	Fitbit Follow-Up and Implanted Medical Device Alerts.....	32
	Visit 12 Fitbit Device Check.....	32
	Fitbit Results/Notification Questions	32
	Fitbit Replacement	33
	Fitbit Setup with New Phone	36
	Fitbit Return/Recycle	36

3	DATA AND RESULTS TRANSFER.....	41
3.1	Data Download / Results Transfer.....	41
4	TRAINING AND CERTIFICATION.....	41
5	APPENDIX.....	42
5.1	Fitbit Onboarding Checklist	42
5.2	Visit 12 Fitbit Device Check Instructions.....	43

0 MANUAL REVISIONS

Version Number	Date	Author	Section(s)	Description of Update
0.1	Nov. 15, 2023	Erin Spaulding	All	Initial Draft for Visit 11 Fitbit Manual
0.2	Jan. 5, 2024	Erin Spaulding, Seth Martin, Jessica Golbus, Brahmajee Nallamotheu	All; Section 1.4, updated Exclusions and Participant Reimbursement; Section 1.5, scripts added; Section 2.4, Manually Connecting Participants to Fitabase was added; Section 2.4, Fitbit Onboarding Checklist was updated and moved to an Appendix; Sections 2.5, 3, and 4 were updated/added.	Updated draft following CC and coordinators' feedback.
0.3	Jan. 25, 2024	Erin Spaulding	All; Section 2.3, included steps for updating watch before visit. Section 2.4, Setting up a Fitbit Account updated to reflect having to create a study Gmail address for all participants.	Updated draft following CC and field centers' feedback.
0.4	Feb. 22, 2024	Erin Spaulding	Section 1.5, Fitbit App and Watch Education Guides added to Staff Equipment/Supplies; Section 2.4, Manually Connecting Participants to Fitabase updated to reflect masked ARIC ID; Section 2.4, Fitbit Charge 6 – Set up for Participant Use updated to place watch on wrist the participant wants to wear it on long-term; Section 2.4, Fitbit Charge 6 – Install and Create an Account, Downloading the Fitbit App, added step 7; Section 2.4, Tailoring the Fitbit App and Watch – Additional Customizations added step 4 on the Water Lock feature; Section 2.4,	Updated draft following field centers' feedback and pilot.

			Setting Up a Fitbit Account added alternative method of creating Gmail account (via web browser) as an option to circumvent common error message in setup process on phone; Section 2.5, Fitbit Return/Recycle updated to include disconnecting Fitbit Charge 6 by field center computer; Section, 5.1 Appendix updated.	
0.5	April 29, 2024	Erin Spaulding	Section 2.4, Fitbit Charge 6 – Set up for Participant Use, Tailoring the Fitbit App – Device Settings, step 3 (including 3a-3h) added to include MobileTrack. Section 2.4, Manually Connecting Participants to Fitabase, updated Step 17 to include site specific phone numbers. Section 5.1, Fitbit Onboarding Checklist, section on “Follow-up Procedures”, item 4 added.	Updates following the first month of implementation in V11.
0.6	May 21, 2024	Erin Spaulding	Section 2.4, Fitbit Charge 6 – Set up for Participant Use, Tailoring the Fitbit App – Device Settings, step 3 adjusted.	Updated to reflect that MobileTrack should not be set up for participants that share a smartphone.
1.1	August 21, 2024	Erin Spaulding	Section 5.1, Fitbit Onboarding Checklist, section on “Follow-up Procedures”, item 5 added.	Updated to include staff instructions for participants should they get a pacemaker/cardiac defibrillator after being enrolled in the study.
1.2	December 11, 2024	Quinn Lutz	Section 2.5 Following Day 2 Visit “Fitbit Follow-Up and Implanted Medical Device Alerts” added	This newly added section describes procedures to collect the new Fitbit Check-in form.

1.3	April 7, 2025	Quinn Lutz	Section 1.5 Forms “Fitbit Satisfaction Questionnaire (FSQ)” added Section 2.5 Following Day 2 Visit “Fitbit Satisfaction Follow-Up” added	This newly added section describes procedures to collect the new Fitbit Satisfaction Questionnaire form.
1.4	April 22, 2025	Quinn Lutz	Section 2.5 Following Day 2 Visit “Fitbit Satisfaction Follow-Up” updated.	Updated guidelines for when staff may collect an FSQ form.
1.5	August 26, 2025	Quinn Lutz	Section 2.5 Following Day 2 Visit “Visit 12 Fitbit Device Check” added. Appendix 5.2 “Visit 12 Fitbit Device Check Instructions” added.	This section adds information and step by step instructions on how to conduct checks on Fitbit devices during Visit 12.
1.6	November 4, 2025	Erin Spaulding	Appendix 5.2 “Visit 12 Fitbit Device Check Instructions” updated.	This section adds language offering an option to withdraw from Fitbit at Visit 12. It also checks whether FSQ has been completed and if a new band for the Fitbit is needed.

1 OVERVIEW

1.1 STUDY AIMS

Leveraging a long-term wearable (Fitbit Charge 6), the aims of the Fitbit study are to:

- 1) Evaluate technology acceptance in the oldest old.
- 2) Evaluate the relationship between wearable data (heart rate, physical activity, sleep) and cognitive and physical decline and dementia, and how they are impacted by biomarker levels.
- 3) Evaluate the relationship between wearable data (heart rate, physical activity, sleep) and major adverse cardiac events, including all-cause hospitalization; hospitalization for acute myocardial infarction, stroke, or heart failure; all-cause mortality; and cardiovascular mortality.

1.2 BACKGROUND AND RATIONALE

In recent years, there has been a substantial uptake of digital technology, including smartphones and wearables among adults in the United States. Wrist-worn trackers generate large amounts of real-time data, and clinicians are increasingly presented with these data in practice. However, the interpretation of these data (i.e., heart rate, physical activity, and sleep) has been limited by a lack of longitudinal data in large diverse cohorts, particularly among older adults. This protocol will provide some of the first long-term data on heart rate, physical activity, and sleep among older adults.

To fill these gaps, we will provide interested, eligible, and consented participants in ARIC with a Fitbit Charge 6 at Visit 11 (Day 2 if completing over 2 days). The Fitbit Charge 6 is for the participants to keep for their use. Participants will also receive ongoing tech support and monetary compensation. We will collect wearable data from the participants (and compensate them) for as long as they are willing to wear the Fitbit Charge 6, for up to four years. The Fitbit Charge 6 was chosen for its long battery life of seven days, functionality, compatibility with both iOS and Android devices, and early evidence of measurement validity and ease of use among older adults.

1.3 KEY MEASURES

Up to 4 years (or as long as the participant is willing to wear the Fitbit) of data collection on heart rate, physical activity, and sleep.

1.4 STUDY PARTICIPANTS

The Fitbit study protocol will be offered to all participants returning for the Visit 11 examination who own a smartphone capable of running software compatible with a Fitbit Charge 6 (iPhone requires iOS 15.0 or later; Android requires Android 9 or later).

If completing Visit 11 over 2 days, participants will be asked if they own a smartphone on Day 1. If they do own a smartphone and are interested in participating in the Fitbit study, they will be asked to bring their smartphone to Day 2 of the Visit.

Exclusions

- The participant does not own a smartphone.
- The participant owns a smartphone but it is not capable of running software compatible with a Fitbit Charge 6 (iPhone requires iOS 15.0 or later; Android requires Android 9 or later).
- The participant has an implantable medical device such as a pacemaker or cardiac defibrillator. Consumer electronic devices, like the Fitbit, may create magnetic interference with implanted medical devices.

* Participants that already own a Fitbit Watch will be strongly encouraged to upgrade to the Fitbit Charge 6 through this study. However, if they do not wish to upgrade to the Fitbit Charge 6 but still want to participate in the Fitbit study, they can be enrolled using their own Fitbit Watch. If a participant owns an Apple Watch or another type of wearable, they will be offered the Fitbit Charge 6. However, these individuals with another type of wearable that don't want the Fitbit Charge 6 cannot be enrolled in the Fitbit study.

Participant Reimbursement

Participants will be reimbursed \$10 a month for every month they provide Fitbit data (i.e., wear the Fitbit Watch and sync with the Fitbit smartphone application). Participants should be told that we expect them to wear the Fitbit Watch and provide data 80% of days each month (~24 out of 30 days). However, to receive the \$10 a month they only have to wear the Fitbit Watch and provide data for 50% of days each month (~15 out of 30 days). The JHU Wearable team and/or field center staff discretion can be used to determine whether participants made a reasonable effort to meet these expectations for reimbursement. Participants will be sent the appropriate reimbursement every 6 months.

1.5 EQUIPMENT, MATERIALS, AND SUPPLIES

Field Center Equipment and Supplies

- Field Center computer or laptop
- Field Center smartphone or tablet (compatible with Fitbit)
- Staff member Fitbit Charge 5 or 6 and Fitbit app
- Hand sanitizer
- Fitbit App and Watch Education Guides (Checklist and Example Script)
 - o Found at the following location on the ARIC website: Researchers > Cohort Studies > Supporting Documents > Visit 11

Participant's smartphone plus additional equipment and supplies sent home with the participant:

- Fitbit Kit
 - o Fitbit Charge 6

- o Charger
 - o Additional larger wrist band
- Wall adaptor for charger
- Loop wrist band (provided to all participants as option to replace the original band)
- Fitbit Participant Education Packet (StartKit)
 - o Found at the following location on the ARIC website: Researchers > Cohort Studies > Supporting Documents > Visit 11
- Pre-paid mailer to return device

Forms

- Fitbit Initialization Form (FBI)
- Fitbit Support Log (FBT)
- Fitbit Check-In Form (FCN)
- Fitbit Satisfaction Questionnaire (FSQ)
- Paper versions of all forms can be found at the following location on the ARIC website: Researchers > Cohort Studies > Current and Archived Visit Documents > Forms, QxQs, and Code Books

Scripts

- Telephone Script for Fitbit Heart Rate Inquiries
- Telephone Script for Scheduled Fitbit Follow-up Call
- Telephone Script for Fitbit Nonadherence
- All scripts can be found at the following location on the ARIC website: Researchers > Cohort Studies > Current and Archived Visit Documents > Manuals

1.6 CONSENT PROCESS

Consent for the Fitbit protocol is included in the Visit 11 consent. Consented participants will be assessed for eligibility and interest, which is documented in the Fitbit Initialization Form (FBI).

1.7 OVERVIEW OF STUDY PROCEDURES

Participants with a smartphone attending the Visit 11 exam will be invited to participate in the proposed project, which includes wearing the Fitbit Charge 6 and syncing with the Fitbit smartphone application.

Installing and creating a Fitbit account, setting up the Fitbit Watch and smartphone app for participant use, teaching the participants how to use the devices, and registering the participant in Fitabase will take approximately 40 minutes during the visit. Field Center staff will monitor participant adherence on a continuous basis throughout the study via Fitabase.

2 DETAILED STUDY PROCEDURES

The study procedures included below assume the participant is completing the visit over two days. If the participant is completing the visit in one day, the steps in Section 2.3 should be completed the day before the visit. A reminder for the participant to bring their smartphone is included in the visit appointment letter.

2.1 DAY 1 VISIT

Ask participants if they own a smartphone; if yes, introduce them to the Fitbit Study that will be occurring on Day 2 of the exam.

If the participant's smartphone software is not up-to-date, you will need to update the phone's software in the Settings app in order to download the Fitbit app (on Day 2). This will likely be a rare occurrence, but staff should check the software version of the participant's phone at the beginning of the visit on Day 1. This way, if the software needs to be updated it can be done before Day 2.

- iPhone requires iOS 15.0 or later; Android requires Android 9 or later

2.2 SCHEDULING DAY 2 VISIT

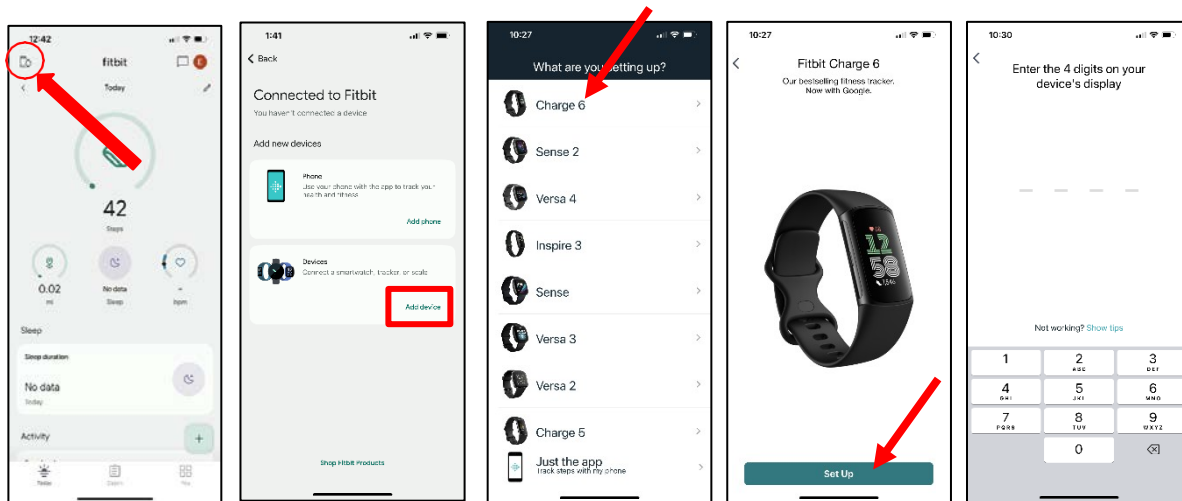
Ask participants if they own a smartphone; if yes, remind them to bring their smartphone to the Visit. Also, ask participants to bring their Apple ID email address and Apple ID password (if they own an iPhone). The protocol can still be completed without this information, as explained below; however, the visit will go faster if they have it on-hand.

2.3 DAY BEFORE DAY 2 VISIT

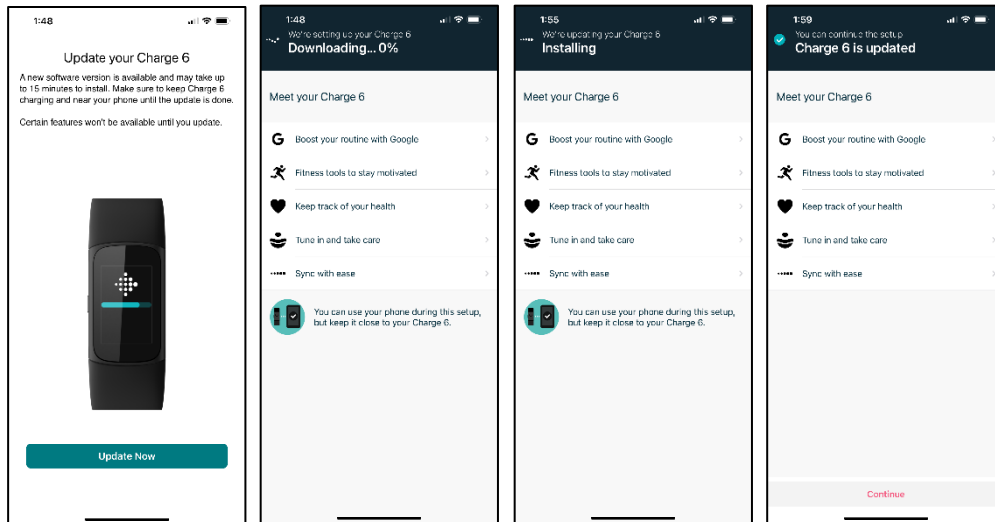
Update the software of the Fitbit Watch that will be given to the participant the next day. You can use a field center smartphone or tablet that has the Fitbit app to do this. This will decrease the amount of time needed to complete the Fitbit protocol during the Day 2 Visit. Another option is to conduct this process during the Day 2 Visit, before the Fitbit onboarding is conducted / while the participant is engaged in other study procedures.

1. Open the Fitbit app, on the field center smartphone/tablet, and on the "Today" screen, go to the "Device Settings" by selecting the icon in the upper left corner
2. Select "Add Device"
3. On the screen, "What are you setting up?"
 - o Select "Charge 6"
4. Select "Set Up"
5. Scroll to the bottom of the page and select "I Agree" to connect the Charge 6 to the Fitbit app

6. On the screen, “Let it charge”
 - o Select “Next”
7. The phone will search for the Fitbit Charge 6 (make sure the Watch is plugged in to charge, as this is required to “find” the watch regardless of its battery percentage)
8. Once the Phone “finds” the Watch, a 4-digit code will appear on the Watch
 - o Enter the 4-digit code into the phone



9. A message will pop up on the phone: “Bluetooth Pairing Request: Charge 6 would like to pair with your phone”
 - o Select “Pair”
10. A message will pop up on the phone: “Allow Charge 6 to Receive Your Notifications: When connected, all notifications you receive on your phone will also be sent to the Charge 6 and may be shown on its display”
 - o Select “Allow”
11. Select “Not Now” when asked about Protecting Your New Device
12. On the screen, “Update your Charge 6”
 - o Select “Update Now”
 - o Wait for the software to be downloaded and installed on the Watch
 - o Once the app says “Charge 6 is updated”, select “Continue”



13. On the screen, “Set up irregular rhythm notifications”
 o Select “Skip”

14. On the screen, “Try it on”
 o Select “Next”

15. On the screen, “Press button to wake”
 o Select “Next”

16. On the screen, “Swipe to navigate”
 o Select “Next”

17. On the screen, “Swipe to go back”
 o Select “Next”

18. On the screen, “Tap 3x to zoom in”
 o Select “Next”

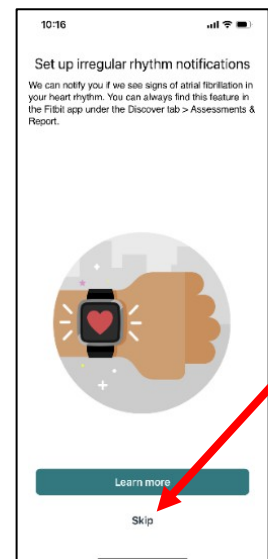
19. On the screen, “Wear & care tips”
 o Select “Next”

20. On the screen, “All Set!”
 o Select “Done”

21. Option to buy Premium will come up on the phone
 o “X” out

22. Go back into the “Device Settings” in the Fitbit app by selecting the icon in the upper left corner

23. Select “Charge 6”



24. Scroll down and select “Remove Charge 6”
25. A notification will pop up, confirm that you want to “Remove This Charge 6” from the field center smartphone or tablet
26. Remove the Fitbit Charge 6 Watch from the Settings app on the field center smartphone or tablet after completing the updating process
 - Open up the smartphone/tablet Settings app
 - Select “Bluetooth”
 - Select “Charge 6”
 - Select “Forget This Device”

2.4 DAY 2 VISIT

After ensuring the participant does not have a pacemaker or other implanted medical device (see Participant Snapshot), complete Section A of the Fitbit Initialization Form (FBI) to determine if the participant meets the other exclusion criteria. Complete Section B and C after the device has been initialized and the Fitbit and Gmail accounts have been created. Note, the Fitbit serial number should be scanned into the FBI form in order to avoid transcription error.

You will be completing the following steps on the participant's phone for them. You should use hand sanitizer before and after completing the following steps.

Fitbit Charge 6 – Install and Create an Account

This section describes how to set up the Fitbit Charge 6, including: charging the Fitbit, downloading the Fitbit app onto the participant's smartphone (iOS or Android), syncing the Fitbit with the app, and creating an account.

Downloading the Fitbit App

- **Steps 4-7 of this section should be completed even if the participant already has the Fitbit app on their phone**

1. Charge the Watch during the initial steps of the setup process.
2. Connect the participant's smartphone to the Field Center's Wi-Fi to speed up app download.
3. Download the Fitbit mobile app onto the participant's smartphone. For iPhones, download the app from the iOS store. For Android phones, download the app from Google Play.



iOS App Store



Google Play



Fitbit: Health
& Fitness

- 3a. Some participants might not have space on their phone to download another app. If this happens, ask them if they are okay with deleting any of the apps on their phone, such as apps for news or games, to make space for the Fitbit app. Delete the suggested apps.
- 3b. For iPhones, you might need to help the participant find/remember their Apple ID and password to download the app from the App Store (if they did not bring the information with them).
 - If a participant does not remember their Apple ID password, you can reset it:
 - i. Open the Settings app
 - ii. Select their "[name]"
 - iii. Select "Sign-In & Security"



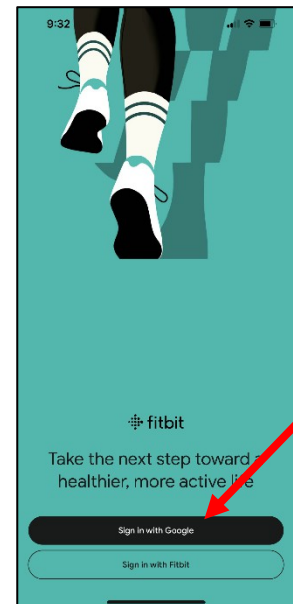
Settings

- iv. Select “Change Password”
 - v. If participants have a numeric passcode on their phone, they will be asked to enter it
 - vi. Enter the new password and verify it
 - o The password must have at least 8 characters, include a number, an uppercase letter, and a lowercase letter
 - vii. Select “Change”
- 4. Change the phone Settings so that the Fitbit app will update automatically when changes are made.
 - Android
 - i. Open the Google Play Store app
 - ii. At the top right, tap the profile icon
 - iii. Select “Manage apps & device”
 - iv. Select “Manage”, then find the Fitbit app
 - v. Tap on the Fitbit app
 - vi. On the page with details about the Fitbit app, in the upper right-hand corner tap the “More” icon
 - vii. Turn on “Enable auto update”
 - iPhone
 - i. Open the Settings app on the phone
 - ii. Scroll down until you see the App Store, tap the “App Store”
 - iii. Turn on “App Updates: Automatically Install New App Updates”
- 5. Make sure the phone Settings allow for use of the Fitbit app on cellular data.
 - Android
 - i. Open the Settings app on the phone
 - ii. Tap "Connections"
 - iii. Tap "Data usage"
 - iv. Tap "Network access"
 - v. In the list of apps, make sure both Mobile Data and Wi-Fi are checked for the Fitbit app
 - iPhone
 - i. Open the Settings app on the phone
 - ii. In the search bar (at the top of the screen), type in “Fitbit”
 - iii. Select “Fitbit”
 - iv. Make sure “Cellular Data” is toggled on for the Fitbit app
- 6. Drag the Fitbit app onto the first “page” of the phone’s home screen in a visible place. Show the participant where the app is located.

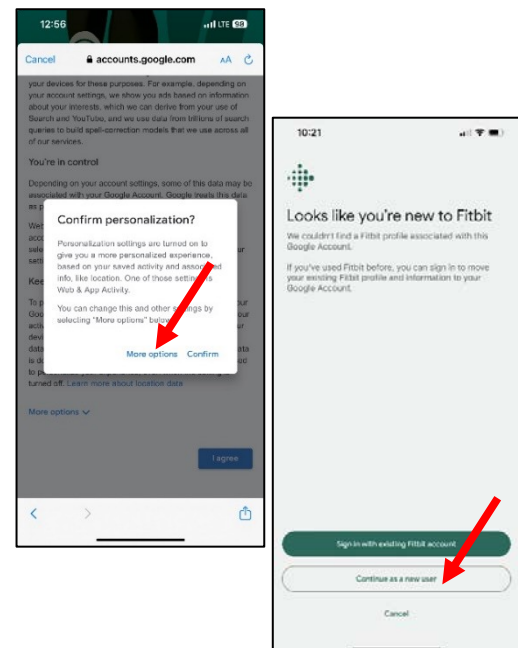
7. If the participant owns their own Fitbit, but they opted to use the Fitbit Charge 6 for the study, remove their other Fitbit Watch from the Settings app on their smartphone
 - Android
 - i. Open the Settings app on the phone
 - ii. Select “Connect devices” or “Device connection”
 - iii. Tap the “gear” icon beside whatever other Fitbit Watch is present
 - iv. Select “Forget”
 - Select “Forget Device” if another menu is displayed
 - iPhone
 - i. Open the Settings app on the phone
 - i. Select “Bluetooth”
 - ii. Select whatever other Fitbit Watch is present
 - iii. Select “Forget This Device”

Setting Up a Fitbit Account

1. Open the Fitbit app
 - A message will pop up on the phone: “Fitbit Would Like to Use Bluetooth: The Fitbit app needs to sync with your device to store your steps, sleep or weight.”
 - o Select “OK”
2. Select “Sign in with Google”
3. Select “Add an account”
4. A message will pop up on the phone: “Fitbit Wants to Use google.com to Sign In: This allows the app and website to share information about you.”
 - o Select “Continue”
5. Select “Create account” on the lower left-hand side
 - o Select “For my personal use”
6. Enter the participant’s first name (do not enter the participant’s last name)
7. Enter the following for the participant’s birthday:
 - o Month: January
 - o Day: 01
 - o Year: [year the participant was born]
8. Enter the participant’s gender, selecting from the following:
 - o Female, Male, Rather not say, Custom
 - o Select “Next”



9. Select “Create your own Gmail address”
 - o You can use letters, numbers and periods
 - o **Each participant (regardless of whether they already have a Gmail address), will have an ARIC study Gmail address created for them for the Fitbit study.**
 - Minneapolis site: aricstudy.m.###@gmail.com
 - Jackson site: aricstudy.j.###@gmail.com
 - Forsyth County site: aricstudy.f.###@gmail.com
 - Washington County site: aricstudy.w.###@gmail.com
 - o Create an ARIC study Gmail address for each participant, replacing “###” in the email address with “001” for the first enrolled participant. Continue this for the second participant (“002”), and so on and so forth.
10. Create a strong password with a mix of letters, numbers, and symbols
 - o The participant can create their own password
 - o **Write the participant’s Gmail address and password down for them on the StartKit**
 - o **Enter the participant’s Gmail address and password into the FBI form**
11. A message will pop up asking if you would like to save this password to your iCloud Keychain to use across apps and websites on all your devices, select “Not Now”
 - o This message will only pop-up for iPhone users
12. Confirm you’re not a robot via a text verification code sent to the participant’s phone. Enter their mobile phone number, then select “Next”
 - o Enter the 6-digit verification code to confirm you received the text message, then select “Next”
13. When asked to add a recovery email, select “Skip”
14. When asked to add a phone number, scroll to the bottom and select “Skip” on the left-hand side
15. On the screen, “Review your account info”
 - o Select “Next”
16. On the screen, “Privacy and Terms”
 - o Scroll to the bottom and select “I agree”
17. A message will pop up: “Confirm personalization?”
 - o Select “More Options”
 - o Under Web & App Activity, select:
 - “Don’t save my Web & App Activity in my Google Account”
 - “Show me ads that aren’t personalized”
 - “Don’t save my YouTube History in my Google Account”
 - o Select “I agree”



18. On the screen, “Looks like you’re new to Fitbit”
 - o Select “Continue as new user”
19. On the screen, “Understand your privacy on Fitbit”
 - o Scroll to the bottom and consent to the two conditions by checking off the two bubbles next to the statements
 - o Select “Agree and continue”
20. Enter the participants weight (lbs.), height (ft. and in.), and sex (female or male). Participant’s height from records, weight from their current visit, and sex will be self-reported.
 - o Select “Save & continue”
21. On the screen, “Fitbit is ready to use”
 - o Select “Continue”
22. On the screen, “Help build new products and advance health research”
 - o Select “No thanks”
23. On the screen, “Email and notification preferences”
 - o Under Email notifications, turn off “News and Updates” and “Research Invites”
 - o Under Push notifications, turn off “Research Invites”
 - o Select “Save and continue”

ALTERNATIVELY, you can create their ARIC study Gmail address through a web browser on a field center computer/laptop using the following link:

<https://accounts.google.com/v3/signin/identifier?continue=https://mail.google.com/mail/&service=mail&theme=glif&flowName=GlifWebSignIn&flowEntry=ServiceLogin>

You can use this web browser method if you are getting an error message when trying to setup the participant’s Gmail/Fitbit account on their phone.

- o Complete steps 5-17 listed above (some of the steps you won’t be asked to complete as they are specific to creating an account on a phone)
- o After Step 17 is complete, open up the Fitbit app on the participant’s smartphone
- o Select “Sign in with Google”
- o Select “Add an account”
- o Sign in with the newly created Gmail address and password
- o Select “Continue as [participant’s name]”
- o Continue with steps 18-23 listed above

Pairing Fitbit Watch to the Phone

1. On the screen, “What would you like to do?”
 - o Select “Add device”

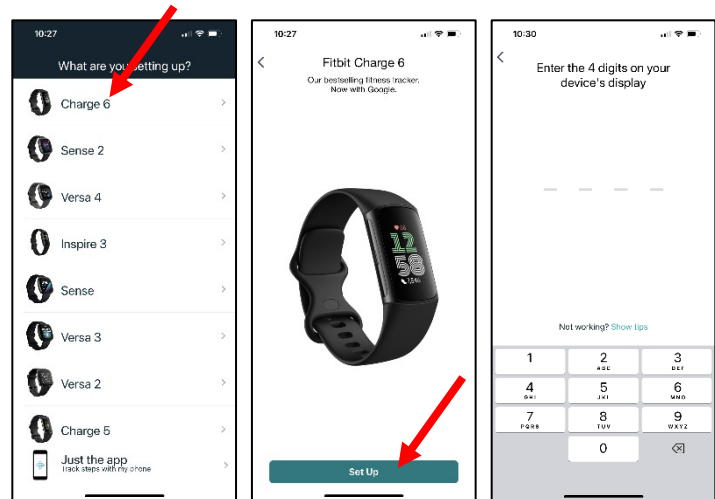
2. On the screen, “What are you setting up?”
o Select “Charge 6”

3. Select “Set Up”

4. Scroll to the bottom of the page and select “I Agree” to connect the Charge 6 to the Fitbit app

5. On the screen, “Let it charge”
o Select “Next”

6. The phone will search for the Fitbit Charge 6 (make sure the Watch is plugged in to charge, as this is required to “find” the watch regardless of its battery percentage)



7. Once the Phone “finds” the Watch, a 4-digit code will appear on the Watch
o Enter the 4-digit code into the phone

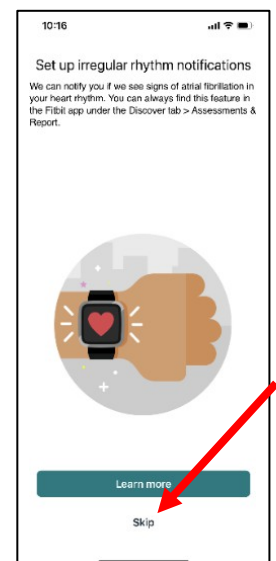
8. A message will pop up on the phone: “Bluetooth Pairing Request: Charge 6 would like to pair with your phone”
o Select “Pair”

9. A message will pop up on the phone: “Allow Charge 6 to Receive Your Notifications: When connected, all notifications you receive on your phone will also be sent to the Charge 6 and may be shown on its display”
o Select “Allow”

10. Select “Not Now” when asked about Protecting Your New Device

11. On the screen, “Set up irregular rhythm notifications”
o Select “Skip”
o **DO NOT enable this for participants**

12. Demonstrate to the participant how to charge the Watch, how to wear the Watch correctly, and provide them with a Loop band (to replace the original band)
o Select “Next”
o Remove the old band and put on the new one
o If the participant has a spouse also being enrolled in the Fitbit study, try to provide them with different colored wrist bands
o If the participant is choosing to wear the Fitbit on their non-dominant wrist long-term, and they are also choosing to use the Leap and WatchPat devices, make sure the band is long enough for the Fitbit to be placed a bit further up the arm when wearing all three devices simultaneously.



13. On the screen, “Allow Fitbit to Use Your Location?”
 - o Select “Don’t Allow”
14. On the screen, “Press button to wake”
 - o Select “Next”
15. On the screen, “Swipe to navigate”
 - o Select “Next”
16. On the screen, “Swipe to go back”
 - o Select “Next”
17. On the screen, “Tap 3x to zoom in”
 - o Select “Next”
 - o You can turn on Magnify in device settings at a later point if the participant wants the feature
18. On the screen, “Wear & care tips”
 - o Select “Next”
19. On the screen, “All Set!”
 - o Select “Done”
20. Option to buy Premium will come up on the phone
 - o “X” out, we are not setting up Premium memberships for the participants

Fitbit Charge 6 – Set up for Participant Use

This section describes how to prepare the Fitbit Charge 6 for participant use, focusing on app and Watch features related to physical activity, heart rate, and sleep.

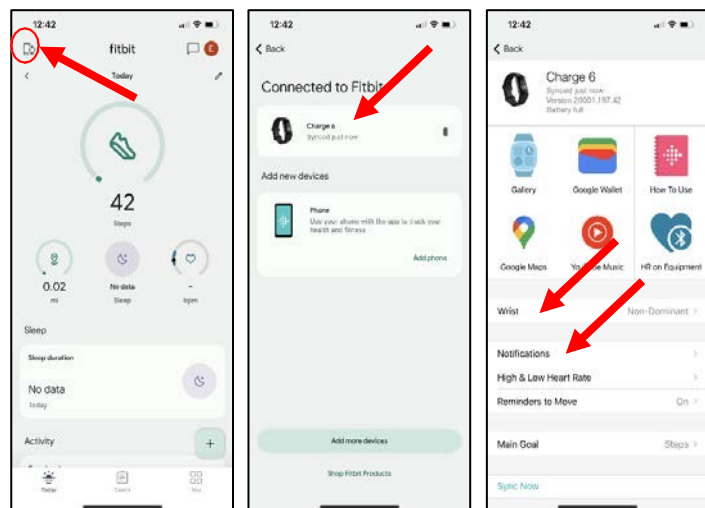
Tailoring the Fitbit App – Device Settings

1. Go to the “Device Settings” by selecting the icon in the upper left corner

2. Select “Charge 6”

- 2a. Select “Wrist”

- i. Select either “Dominant” or “Non-Dominant” by asking the participant whether the watch is on their dominant or non-dominant arm. **Place the watch on whatever wrist the participant wants to wear it on long-term**, to minimize switching during the study.



2b. Select “Notifications”

- i. Ask the participant if they want to receive notifications on their Watch for calls, text messages, and calendar events. Toggle “off” if they do not want them.

3. Select “Add phone” (**SKIP this step and go directly to step 4, if participants share a smartphone; i.e., a spouse pair shares a phone and you are creating a Fitbit account for both of them on the same phone/app**)

- i. You are adding their phone as a device to the Fitbit app, so that if they take off the Fitbit Watch for a bit, but they are carrying their phone, their steps will still be collected.

3a. On the screen, “Take charge of your health right from your phone”

- i. Select “Continue”

3b. On the screen, “Use your phone to track metrics with Fitbit”

- i. Select “I agree”
- ii. **For Androids**, a box will pop up asking “Allow Fitbit to access your physical activity?”
 - a. Select “Allow”

3c. **For iPhones**, on the screen, “Connect Fitbit to Apple Health to track steps”

- i. Select “Continue”

3d. **For iPhones**, on the screen, Health: “Fitbit” would like to access and update your Health data

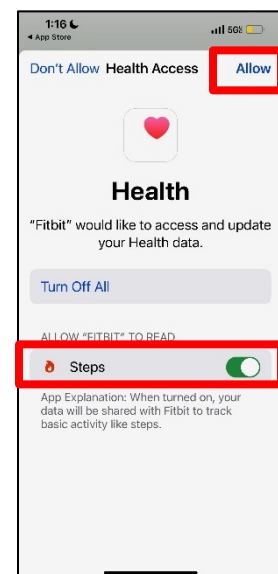
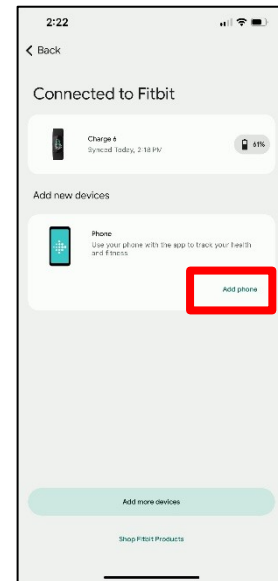
- i. Toggle/Turn on Steps
- ii. Select “Allow” in the upper right-hand corner

3e. **For Androids**, on the screen, “Get more from your data with Health Connect”

- i. Select “Not now” in the bottom right-hand corner

3f. On the screen, “You’re ready to go”

- i. Select “Done”



3g. Option to buy Premium will come up on the phone

i. “X” out, we are not setting up Premium memberships for the participants

3h. On the screen, “Connected to Fitbit”, you should now see that both their Charge 6 and Phone are connected as devices

4. Go back to the “Today” screen

5. Go to the “Account Settings” by selecting the icon in the upper right corner

6. Select “Fitbit Settings”

5a. Select “Activity & Wellness”

i. Select “Daily Activity”

o Change the daily Steps goal to 4,500

- According to Visit 6 ARIC data, older adults that

walked ~4,500 steps per day had a 77% lower observed risk of experiencing a cardiovascular event.

o Change the daily distance goal to 2 miles

- There are about 2,100 steps in a mile

o Daily steps and distance goals can also be adjusted later per participant preference

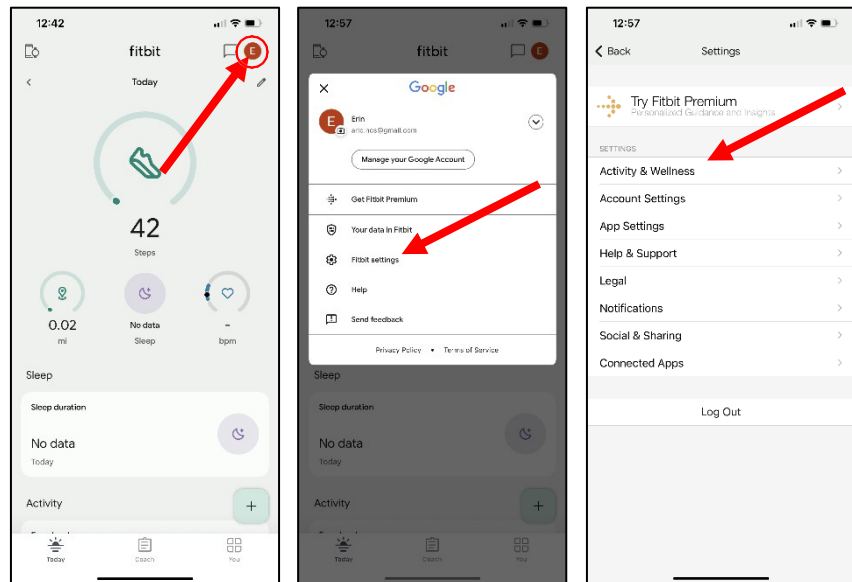
ii. Select “Sleep”

o Change “Sleep Sensitivity” to “Sensitive”

- You may not be able to change the sleep sensitivity for Android devices here, an alternative method is provided in the next step (Step 5b).

5b. For Android devices only: Select “App Settings”

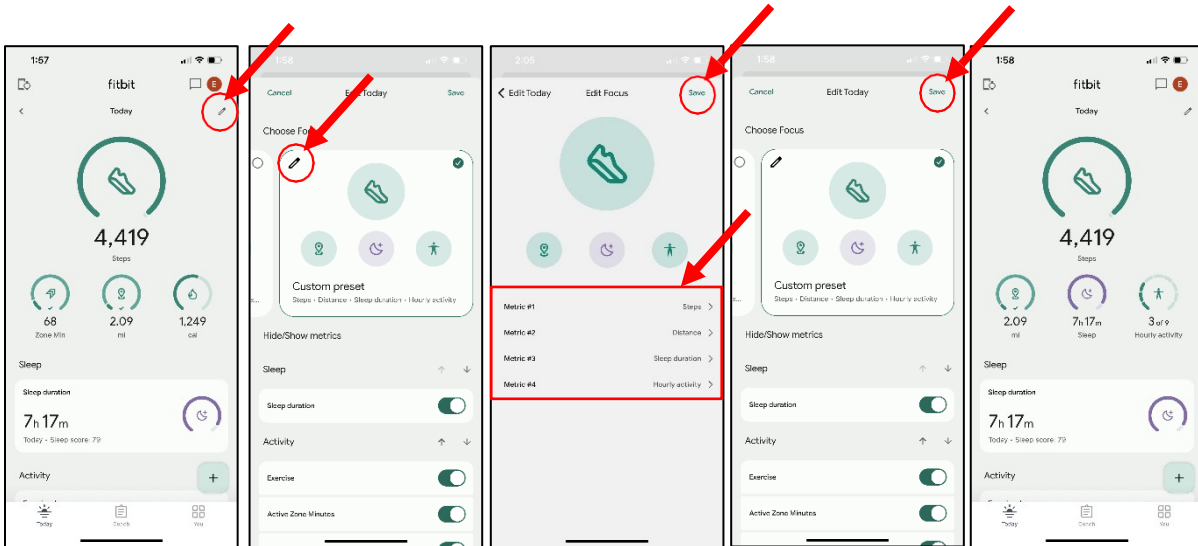
i. Change “Sleep Sensitivity” to “Sensitive”



Tailoring the Fitbit App – Today Screen

There are 3 tabs along the bottom of the app screen (Today, Coach, and You). **Participant use will be focused on the Today screen.**

1. Go to the Today screen by selecting the “Today” icon  in the bottom left corner
2. Choose the Spotlight Stats for the Today screen
 - 2a. Select the “pencil” in the upper right corner
 - 2b. Under “Choose Focus”, swipe to the left until you see the focus “Custom preset”, select the “pencil” in the upper left corner of “Custom preset”
 - 2c. Update the four metrics to: Steps, Distance, Sleep duration, and Hourly activity
 - 2d. Select “Save,” in the upper right corner of the Edit Focus screen
 - o Steps, Distance, Sleep Duration, and Hourly Activity will now be emphasized on the Today Screen
3. Remove certain features from the Today Screen to simplify the interface and keep the focus on the study outcomes (physical activity, heart rate, and sleep)
 - 3a. Under Hide/Show metrics
 - i. Turn On/Show: Sleep Duration, Exercise, Active Zone Minutes, Steps, Hourly Activity, Distance, Energy Burned, Health Metrics, and Heart
 - ii. Turn Off/Hide: Menstrual Health, Weight, Glucose, Mindful Days, Stress Management Score, Food, and Water
 - o Some of these features can be kept if the participant wants them. However, make sure to tell the participant that they would be tracking these metrics manually for their own interest. It’s not a requirement of the study.
 - 3b. Select “Save,” in the upper right corner



At this point, you should educate the participant on how to use the Fitbit smartphone app and Watch. Focus the education on how to monitor physical activity, sleep, and heart rate. You can use the participant’s educational packet (StartKit) as well as the Fitbit App and Watch Education Checklist and Example Script to guide this education. You should pull up the Fitbit app on your own smartphone to educate the participant on how the app looks once real data starts coming through. After educating the participant on the app and Watch, return to this MOP and continue with the subsequent sections.

Tailoring the Fitbit App and Watch – Additional Customizations

1. Changing Text Size in the Fitbit App

- Ask the participant if they would like you to enlarge the font size in the Fitbit app
- You can skip this step if they are happy with the current font size

1a. iPhone

- Open the Settings app
- Select “Display & Brightness”
- Select “Text Size”
- Drag the slider to select the desired font size
- Confirm the new text size in the app is appropriate for the participant

1b. Android (11 and Older)

- i. Open the Settings app
- ii. Select “Display”
- iii. Select the option “Font Size” (may be called “Font and Screen Zoom” in some phones)
- iv. Depending on the phone: drag the slider to select the desired font size OR select from small, medium, or large fonts
- v. Confirm the new text size in the app is appropriate for the participant

2. Enabling the Magnify Feature on the Fitbit Charge 6

- Ask the participant if they would like you to enable a feature that allows them to magnify the font size on the Watch
- You can skip this step if they are happy with the current font size or don’t like the magnify feature

2a. Scroll down on the Fitbit Charge 6 Watch screen until you see “Settings”



2b. Select “Settings”

2c. Scroll up until you see “Magnify Settings”

2d. Select “Magnify Settings”

2e. Make sure the feature is turned/toggled on

3. Enabling Sleep Mode on the Fitbit Charge 6

- Ask the participant if they would like you to enable a feature that will stop them from receiving notifications on the Watch while they sleep as well as make sure the Watch doesn’t light up at night while they are sleeping
- You can skip this step if they don’t need this feature

3a. Scroll down on the Fitbit Charge 6 Watch screen until you see “Settings”



3b. Select “Settings”

3c. Select “Quiet Modes”

3d. Scroll down and select “Sleep Mode”

3e. Select/Turn on “Schedule”

3f. Select “Interval”

3g. Set the times for roughly when they go to bed and wake up every day so they do not receive notifications on the Watch or have the Watch light up during this time

4. Enabling Water Lock on the Fitbit Charge 6

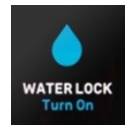
- Ask the participant if they swim regularly as a form of physical activity. If yes, demonstrate to them how to enable/disable the Water Lock feature when they are swimming.
- There is no setup required for using this feature, you just need to demonstrate to the participant how to use the Water Lock feature every time they want to go swimming.
- You can skip this step if they don’t need this feature

The participant should complete steps 4a-4b before going swimming:

4a. Scroll down on the Fitbit Charge 6 Watch screen until you see “Water Lock: Turn on”

4b. Select “Water Lock: Turn on”

4c. When you see “To lock: Firmly double tap”, double tap on the Watch screen very forcefully



4d. You will get a message that the Watch is locked

The participant should complete steps 4e-4f after going swimming:

4e. After swimming session is complete, make sure the Watch is dried off completely

4f. To disable the Water Lock feature, double tap on the Watch screen very forcefully

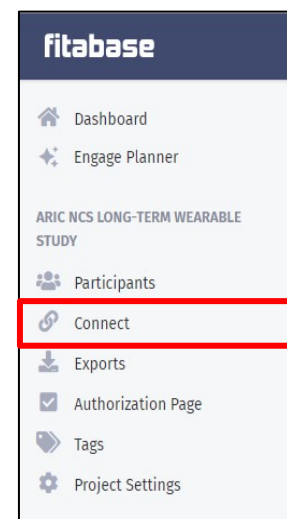
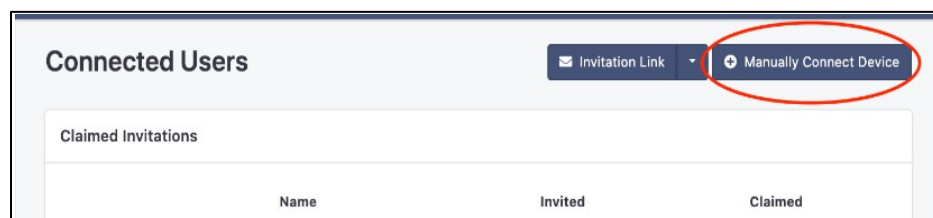
Downloading the Gmail App

1. Download the Gmail mobile app onto the participant’s smartphone. For iPhones, download the app from the iOS store. For Android phones, download the app from Google Play.
 - Some participants, especially if they own an Android, may already have the Gmail mobile app already installed on their phone. If this is the case, you will just need to add another email account to the app.
2. Drag the Gmail app onto the first “page” of the phone’s home screen in a visible place next to the Fitbit app. Show the participant where the app is located.

3. Open the app, then select “Sign in”
4. Under “Set up Email”, select “Google”
5. A message will pop-up: “Gmail Wants to Use google.com to Sign In”, select “Continue”
6. Enter in the participant’s Google Email, then select “Next”
7. Enter in the participant’s Gmail password, then select “Next”
8. On the screen “Google 2-Step Verification”, select “Try another way”
9. Select “Get a verification code at (****) *** - **XX”
 - Make sure that is the participant’s phone number
10. Enter the 6-digit verification code, then select “Next”
11. A message will pop-up: “Google would like to Send You Notifications”, select “Allow”
12. The participant can now open the Gmail app to see their weekly feedback emails from Fitbit

Manually Connecting Participants to Fitabase

1. Using a Field Center computer, sign in to your personal staff member account on Fitabase
2. Navigate to the Connect page by using the dashboard menu link
3. Select “Manually Connect Device”



4. On the Manually Connect Device screen, **enter the Fitabase participant ID** (instead of First Name), and **Gmail address** used to sign in with Fitbit. The Fitabase participant ID will be populated in the FBI form. 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. 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.

5. In the Syncing section, specify the observation window through which data will be collected

- a. Start date: date of enrollment
- b. End date: 4 years from the date of enrollment

6. Click “Save Changes”

7. Click on “Connect a Fitbit to this user”

8. Select, “Continue with Google”

9. Select, “Use another account”

10. Enter the participant’s Gmail address, then select “Next”

11. Enter the participant’s Gmail address password, then select “Next”

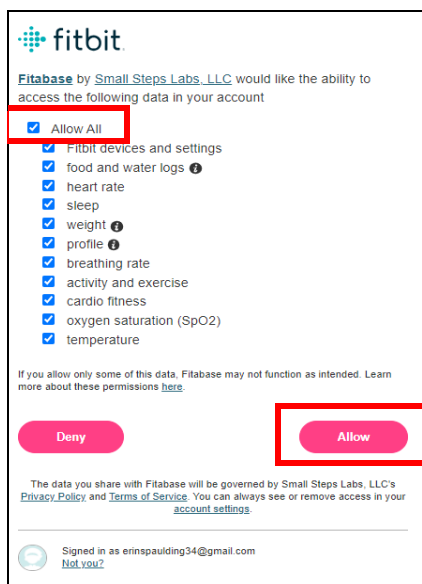
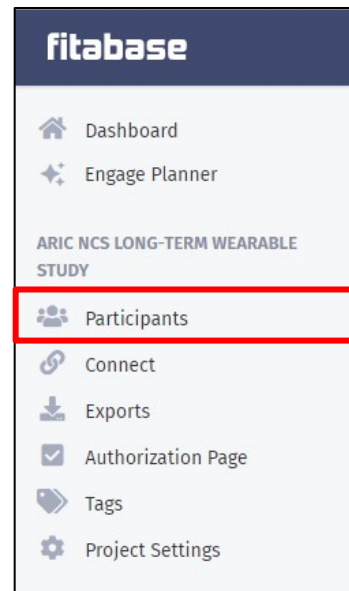
- a. The participant’s Gmail address and password were written on their StartKit as well as in the FBI form. You can refer back to either their StartKit or the FBI form for their Gmail address and password.

12. Select, “Allow All” and then “Allow”

13. Navigate to the Participants page by using the dashboard menu link

14. Once you connect a user/account, it will show up on this screen (see next page for screenshot). If a device had been connected, the device name will be shown.

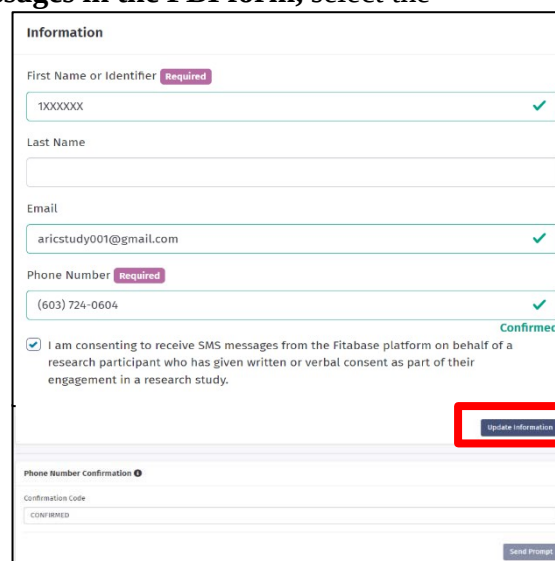
- a. You may also see a message “No Device Sync Yet”, open the participant’s Fitbit app and have them sync. Once the participant syncs, information on their last sync will become available.

A screenshot of a Fitbit permission screen. At the top, it says "fitbit" and "Fitabase by Small Steps Labs, LLC would like the ability to access the following data in your account". Below this is a list of permissions with checkboxes: "Allow All" (checked), "Fitbit devices and settings", "food and water logs", "heart rate", "sleep", "weight", "profile", "breathing rate", "activity and exercise", "cardio fitness", "oxygen saturation (SpO2)", and "temperature". At the bottom, there are "Deny" and "Allow" buttons. A red box highlights the "Allow All" checkbox and the "Allow" button.A screenshot of the Fitabase dashboard. It has a dark blue header with the "fitabase" logo. Below the header is a sidebar menu with options: "Dashboard", "Engage Planner", "Participants" (highlighted with a red box), "Connect", "Exports", "Authorization Page", "Tags", and "Project Settings". The main content area shows "ARIC NCS LONG-TERM WEARABLE STUDY" and a "Connect" button.A screenshot of the "ARIC NCS Long-Term Wearable Study" participants list. The header shows "Collecting Data(3)", "Not Collecting Data(0)", and "All(3)". Below is a search bar and a table with columns "Name", "Tags", and "Last Sync". The first row is highlighted with a red box and contains the following data: Name: "1XXXXXX", Tags: "Steps Intensity Calories Sleep Heart Rate", Last Sync: "28 minutes ago" (with a "more sync events" link), "fitbit" (with a "Charge 6" link), "MobileTrack", and "Messages".

If the participant consented to receiving text messages in the FBI form, select the participant’s identifier and continue with step s 15-19.

15. Under the Information section, enter the participant’s phone number and select the box to agree to: “I am consenting to receive SMS messages from the Fitabase platform on behalf of a research participant who has given written or verbal consent as part of their engagement in a research study.”

- a. Select “Update Information”

A screenshot of the "Information" form in the Fitabase platform. It has fields for "First Name or Identifier" (required, with value "1XXXXXX"), "Last Name", "Email" (with value "aricstudy001@gmail.com"), and "Phone Number" (required, with value "(603) 724-0604"). Below these fields is a checkbox labeled "I am consenting to receive SMS messages from the Fitabase platform on behalf of a research participant who has given written or verbal consent as part of their engagement in a research study." which is checked. At the bottom right, there is a "Update Information" button highlighted with a red box. Below the form is a "Phone Number Confirmation" section with a "Confirmation Code" field and a "Send Prompt" button.

16. Under the Phone Number Confirmation section, select “Send Prompt”
 - a. This will send a text message to the participant’s phone
 - b. Respond to the text message on the participant’s phone with the confirmation code in Fitabase
 - c. Refresh the Fitbit webpage to verify that the participant’s phone number has been confirmed
17. Add the following as a contact in the participant’s phone. All Fitabase text messages will come from this site-specific phone number.
 - a. Minneapolis, MN: ARIC Fitbit Study, (844) 585-0892
 - b. Jackson, MS: ARIC Fitbit Study, (877) 842-6979
 - c. Forsyth County, NC: ARIC Fitbit Study, (833) 535-0046
 - d. Washington County, MD: ARIC Fitbit Study, (833) 306-1853
18. Under Participant Details, select “Messaging Settings”
19. Enter Messaging Dates (dates between which participants will receive text messages from the study reminding them to sync)
 - a. Start date: date of enrollment
 - b. End date: 4 years from the date of enrollment
 - c. Select “Update Information”

The Fitbit Onboarding Checklist, found in Appendix 5.1, can be used to confirm that all the onboarding steps have been completed / to guide the process.

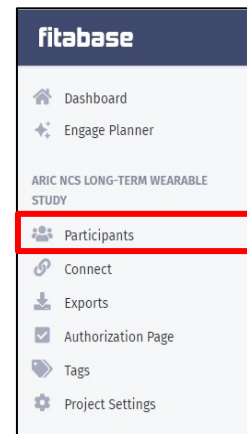
2.5 FOLLOWING DAY 2 VISIT

Adherence Monitoring and Technology Support

Scheduled Touch-Points

7 days following their Day 2 visit, call each participant to see if they are having any issues with the Fitbit or if they have any questions. Use the “Telephone Script for Scheduled Fitbit Follow-up Call” to guide the conversation.

1. In Fitabase, navigate to the Participants page by using the dashboard menu link.
2. Find the participant in Fitabase and check when their last sync was. This information will be used in the scheduled phone call.
3. Document the phone call in the Fitbit Support Log (FBT).



If participants are having significant problems that can’t be answered by staff over the phone, the field center staff will ask the JHU wearable team to call the participant to troubleshoot. If the JHU wearable team is unable to resolve the problem, they will let the field center staff know that a home-visit is required. In that case, the staff member should bring a replacement Fitbit device on the home-visit in case the problem can’t be fixed.

As Needed Touch-Points

- A text message will be sent directly to each participant’s phone, if they agreed to receive text messages, if they haven’t synced in the past 5 days. This text message will thank them for their continued involvement in the study, remind them to sync, and refer them to the StartKit if they need a reminder on how to sync.
- Participants may call the field center with questions about the Fitbit. Staff should attempt to answer these questions. It is helpful to have the Fitbit app open on your personal smartphone when trying to answer participant questions / guide them to the correct feature. However, if the staff are unable to answer the question or solve an issue that a participant is having then the JHU wearable team will be asked to call the participant to resolve the issue. Either the staff or the JHU Wearable team can also send the participant a Zoom link via text message or

email to facilitate troubleshooting. These contacts with the participant will be documented in the Fitbit Support Log (FBT) by the field center staff.

- Staff will review Fitabase at least 2-3 times a week, for participants at their field center who have not synced / provided Fitbit data in the past 2 weeks.
 - In Fitabase, navigate to the Participants page by using the dashboard menu link
 - Filter by last sync, so that participants who have gone the longest without syncing are at the top of the participant list
 - Call the participants that day who have not synced in the past 14 days
 - Use the “Telephone Script for Fitbit Nonadherence” to guide the conversation
 - Document the call in the Fitbit Support Log (FBT)

Fitbit Satisfaction Follow-Up

Three to six months following Fitbit Study enrollment, clinic staff will call the participant to complete the Fitbit Satisfaction Questionnaire (FSQ). The purpose of this form is to assess the participant’s overall satisfaction with their experience wearing the Fitbit device, whether they are currently enrolled in the study or have previously withdrawn. While 3-6 months after enrollment is the standard time period to collect this form, any time after the 3-month mark is permissible.

Fitbit Satisfaction Scheduling Report

The Fitbit Satisfaction Scheduling Report is available in CDART to support data collection of the Fitbit Satisfaction Questionnaire. The Fitbit Satisfaction Scheduling Report displays participant enrollment dates, FSQ eligibility, and contact information. This report can be run through the CDART main menu and will be used by site staff to determine whether participants are eligible to have an FSQ form collected.

Implementation of the Fitbit Satisfaction Questionnaire (FSQ) Form

	Ideal Collection Window	Special Cases/Notes
Participants who are currently enrolled in the Fitbit Study	3-6 months after enrollment in order to ensure there is enough time for participants to get acclimated to their device and work out any technological issues with the Fitbit Support Team.	The survey may be collected at any point after the participant has been enrolled for 3 or more months. The FSQ form collection should not align with Fitbit adherence or technology support calls, unless the participant chooses to withdraw while on the call. Staff may collect this form during calls with participants asking general questions

		about the study as long as these occur after 3 months of enrollment in the Fitbit Study.
Participants who are currently withdrawing from the Fitbit Study	At the time of study withdrawal.	For participants who withdraw after the FSQ form is implemented, field center staff should only collect this form at the time of withdrawal if it has not been previously collected.
Participants who have previously withdrawn from the Fitbit Study	At the earliest possible opportunity.	

Fitbit Follow-Up and Implanted Medical Device Alerts

During annual and semi-annual follow-up calls, staff will complete the Fitbit Check-in (FCN) form to assess whether a participant wearing a Fitbit has received a pacemaker since the previous contact point. If a participant is known to be wearing an ARIC Fitbit, the Annual Participant Tracing Sheet will indicate that the FCN form should be collected. Like the Medical Conditions Update form (MCU), the same occurrence of the FCN should be updated during each check-in call until the Tracing sheet indicates that the FCN form no longer should be collected or the participant indicates that they have received a pacemaker.

A “Yes” response to question 1 of the FCN form indicates the participant has received a pacemaker or cardiac defibrillator since the last follow-up call and will trigger an alert in the Visit 11 Alerts Report on CDART. To resolve this alert, clinic staff will send the Implanted Medical Device Letter for Fitbit to the participant to request the return of their Fitbit device. This letter can be found and downloaded from the ARIC website under **Researchers > Supporting Documents > Visit 11/NCS**. Staff should download the template, fill in the participant’s information where appropriate, then print and send the letter to the participant. Once this letter has been sent, the alert should be recorded and resolved using the RARX form within the usual alerts reporting time frame. Only one alert will ever be triggered for Fitbit, and once the alert has been resolved, no additional action is needed by clinic or follow-up staff.

Visit 12 Fitbit Device Check

If a participant continues to be enrolled in the Fitbit Study at the time of their ARIC Visit 12, field center staff should conduct checks on the participant’s Fitbit device to ensure that it is working properly. Steps for these checks can be **found in Appendix 5.2**.

Fitbit Results/Notification Questions

If participants call with questions about their Fitbit results, do not provide any clinical advice about what these data mean. You can direct participants to these results in Fitbit if they are having trouble finding them or you can reiterate interpretation that is already provided in Fitbit. For example, if a participant were to tell you they received a sleep score of 80 the night before,

you could tell them Fitbit interprets this as a “Good” sleep score. Document the phone call in the Fitbit Support Log (FBT).

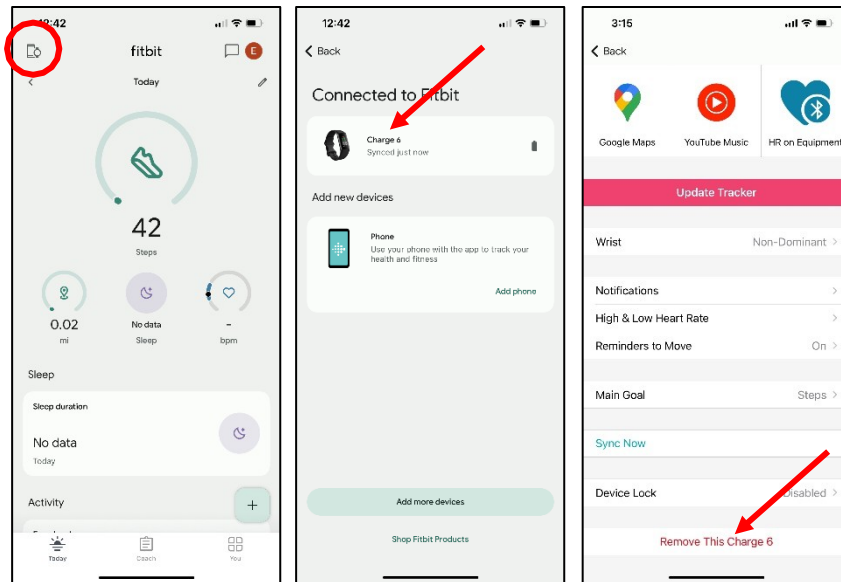
If participants call with inquiries about low or high heart rate notifications from Fitbit, refer to the script “Telephone Script for Fitbit Heart Rate Inquiries” on how to respond. Document the phone call in the Fitbit Support Log (FBT).

Fitbit Replacement

Participants can receive up to 5 replacement Fitbit Watches throughout their enrollment in the study due to loss of, damage to, malfunction of, or battery loss of the original device (or prior replacement). Participants are eligible to receive a replacement Fitbit Watch if they (1) wore the previous Watch for more than half the time they had it (e.g., at least 3 out of 6 months), or (2) they didn’t wear the previous Watch for more than half the time they had it but they make a strong case that they are going to wear it in the future. Staff discretion can be used when deciding who is eligible to receive a replacement Fitbit. There should be no evidence that the participant gave their Fitbit Watch to someone else. Participants are not allowed to gift their Fitbit to someone else and then ask for a replacement. In instances when the Watch was damaged, malfunctioned, or the battery died, participants will be asked to return the device when receiving a new one. Fitbit replacement (including Watch, charger, and band if needed) can occur at the field center or via a home visit, depending on participant preference. If the participant just needs a new charger or Watch band, they can pick it up at the field center or it can be mailed to the participant’s home, depending on their preference. All Fitbit Watch replacements should be documented in the Fitbit Initialization Form (FBI) in Section D.

To link a new Fitbit to the participant’s Fitbit app, first, remove the current Fitbit Watch from the participant’s Fitbit app:

1. Open the participant’s Fitbit app on their phone.
2. On the Today screen, tap the device icon in the upper left-hand corner.
3. Select “Charge 6”.
4. Scroll down and select “Remove This Charge 6”.
5. A reminder will pop up to sync the Watch one last time, select “Remove This Charge 6”.
 - a. If the Watch is broken you most likely won’t be able to complete the syncing process.

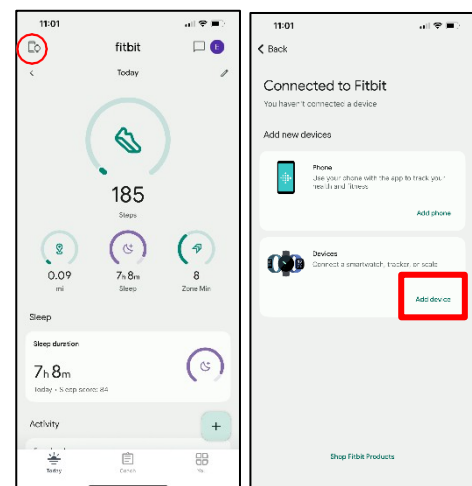


6. Remove their current Fitbit Watch from the Settings app on their smartphone

- Android
 - i. Open the Settings app on the phone
 - ii. Select “Connect devices” or “Device connection”
 - iii. Tap the “gear” icon beside the Fitbit Charge 6
 - iv. Select “Forget”
 - Select “Forget Device” if another menu is displayed
- iPhone
 - i. Open the Settings app on the phone
 - iv. Select “Bluetooth”
 - v. Select the Fitbit Charge 6
 - vi. Select “Forget This Device”

Second, connect a new Fitbit Watch to the participant’s Fitbit app:

7. On the Today screen, tap the device icon in the upper left-hand corner.
8. On the screen, “Connected to Fitbit”
 - a. Select, “Add device”
9. On the screen, “What are you setting up?”
 - a. Select “Charge 6”
10. Select “Set Up”
11. Scroll to the bottom of the page and select “I Agree” to connect the Charge 6 to the Fitbit app



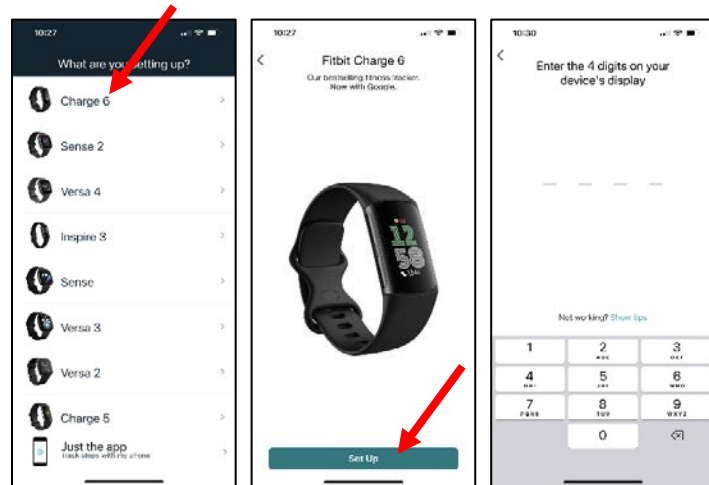
12. On the screen, “Let it charge”

- a. Select “Next”

13. The phone will search for the Fitbit Charge 6 (make sure the Watch is plugged in to charge, as this is required to “find” the watch regardless of its battery percentage)

14. Once the Phone “finds” the Watch, a 4-digit code will appear on the Watch

- o Enter the 4-digit code into the phone



15. On the screen, “Set up irregular rhythm notifications”

- o Select “Skip”
- o DO NOT enable this for participants

16. Demonstrate to the participant how to wear the Watch correctly and provide them with a new Loop wrist band (if they lost the previous one) or transfer the old Loop wrist band to the new Watch (if they still have it)

- o Select “Next”

17. On the screen, “Allow Fitbit to Use Your Location?”

- o Select “Don’t Allow”

18. On the screen, “Press button to wake”

- o Select “Next”

19. On the screen, “Swipe to navigate”

- o Select “Next”

20. On the screen, “Swipe to go back”

- o Select “Next”

21. On the screen, “Tap 3x to zoom in”

- o Select “Next”
- o You can turn on Magnify in device settings later if the participant wants this feature

22. On the screen, “Wear & care tips”

- o Select “Next”

23. On the screen, “All Set!”

- o Select “Done”
24. Option to buy Premium will come up on the phone
- o “X” out, we are not setting up Premium memberships for the participants
25. Sync the participant’s new Watch to their Fitbit app
26. Log into Fitabase and make sure information on their most recent sync is present

Fitbit Setup with New Phone

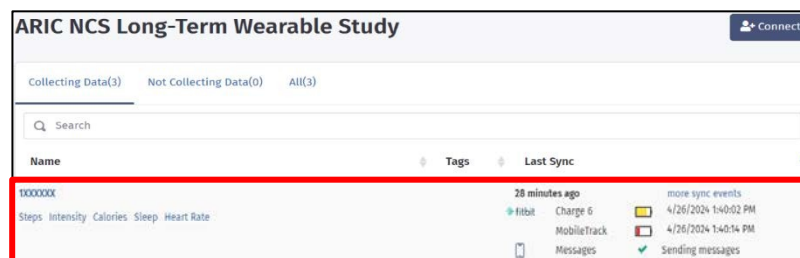
If a participant buys a new phone over the course of the study, a staff member can help them re-setup their Fitbit with the new device. Set-up can be conducted either at the field center or via a home visit, depending on participant preference. Set-up will include repeat of the following aspects in Section 2.4 of this Manual: “Fitbit Charge 6 – Install and Create an Account”, “Pairing Fitbit Watch to the Phone”, “Fitbit Charge 6 – Set up for Participant use”, and “Downloading the Gmail App”. No changes need to be made within Fitabase; however, once the set-up is complete, sync the Watch to the Fitbit app and make sure the most recent sync shows up in Fitabase.

- Make sure to use the participant’s original study related Gmail address when resetting up the Fitbit app.

Fitbit Return/Recycle

If a participant decides to return their Fitbit Watch and disengage from the study, this should be recorded in Section D of the FBI form. The Fitbit can then be recycled for another participant using the following steps:

1. Sync the Watch to the participant’s Fitbit smartphone app one last time to make sure their most recent data is captured in Fitabase. Check their data in Fitabase to make sure it synced properly.
 - a. If the participant returns the Watch by mail, you will be unable to complete this step. However, in the StartKit, participants are reminded to sync one last time before mailing the Watch back.



2. Then select the participant’s identifier in Fitabase, then under Participant Details select “Syncing”

3. Under Activity/Sleep, change the “end date” to today’s date (i.e., the date you are removing the Fitbit Watch from their account). Then select, “Update Sync Dates”.
 - a. This will stop data from being collected in Fitabase for this participant moving forward.

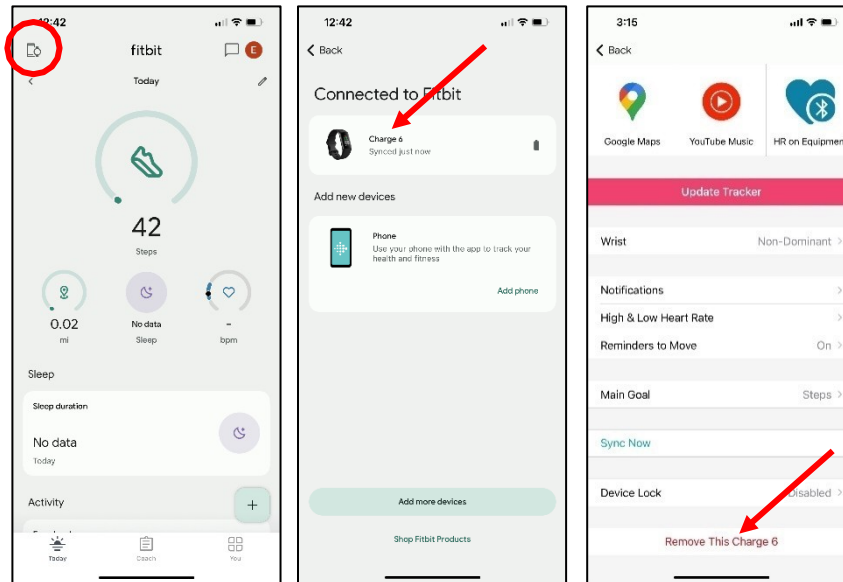
4. Under Participant Details, select “Messaging Settings”, then change the “end date” to today’s date (i.e., the date you are removing the Fitbit Watch from their account). Then select, “Update Information”.
 - a. This will stop the participant from receiving text message reminders to sync from Fitabase moving forward.
5. Scroll down on the Fitbit Charge 6 Watch screen until you see “Settings”.

Select “Settings”



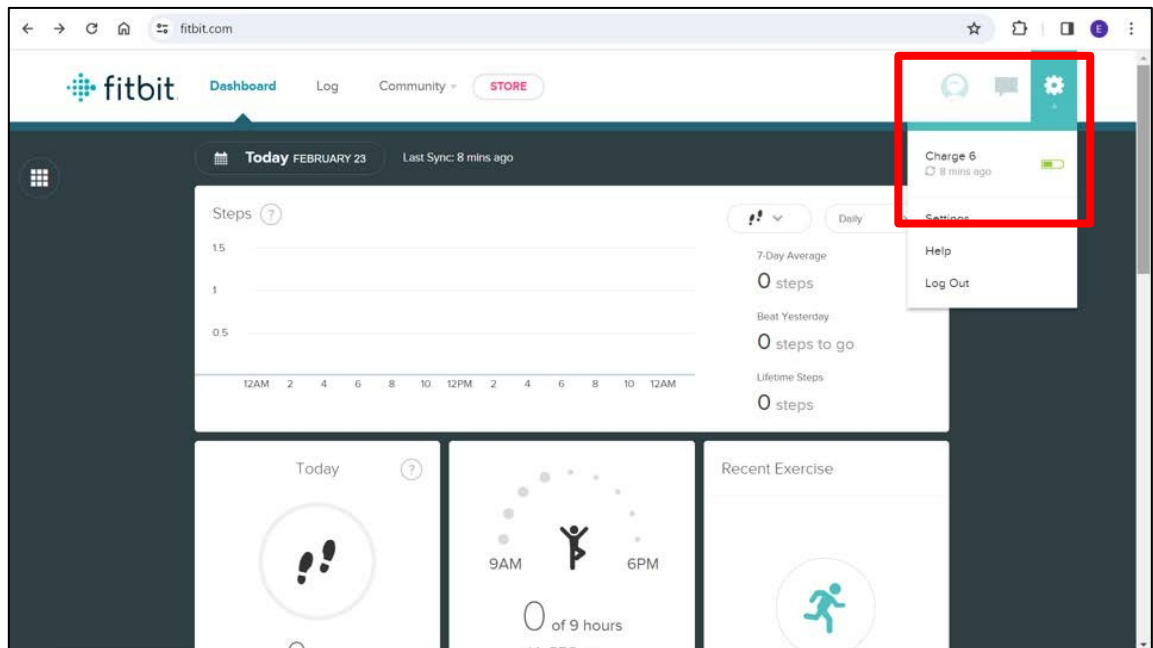
- a.
 - b. Scroll up on the screen, then select “Device Info”
 - c. Scroll up on the screen, then select “Clear User Data”
 - d. You will see a message: “Clear Data? This clears your data and disconnects the device from your phone. Any unsynced data will be lost.”
 - i. Press and hold the blue “Hold 3 sec” button for three seconds before releasing
 - e. The Fitbit Charge 6 will vibrate and the Fitbit logo will be displayed on the screen
6. If the participant is returning their Watch in-person: Open the participant’s Fitbit app on their phone.
 - a. On the Today screen, tap the device icon in the upper left-hand corner
 - b. Select “Charge 6”
 - c. Scroll down and select “Remove This Charge 6”

- d. A reminder will pop up to sync the Watch one last time, select “Remove This Charge 6”

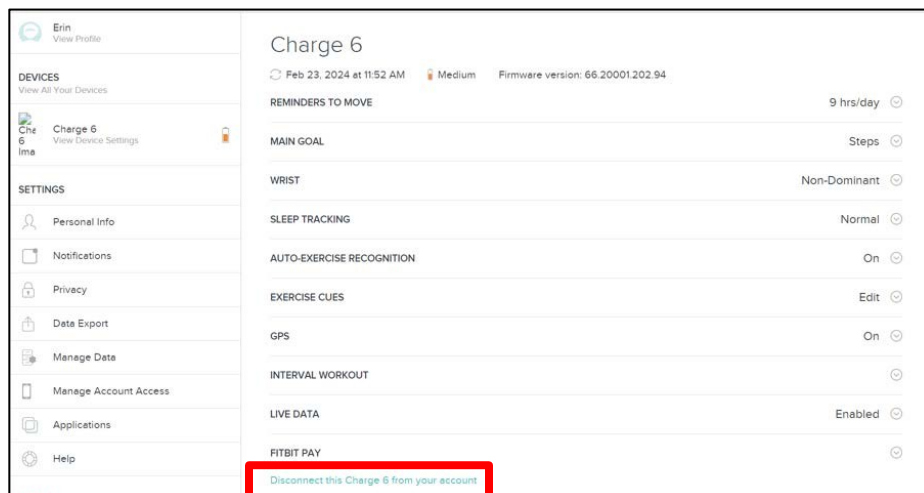


7. If the participant is returning their Watch in-person: Remove the Fitbit Watch from the Settings app on their smartphone
- Android
 - i. Open the Settings app on the phone
 - ii. Select “Connect devices” or “Device connection”
 - iii. Tap the “gear” icon beside the Fitbit Charge 6
 - iv. Select “Forget”
 - Select “Forget Device” if another menu is displayed
 - iPhone
 - i. Open the Settings app on the phone
 - vii. Select “Bluetooth”
 - viii. Select the Fitbit Charge 6
 - ix. Select “Forget This Device”
8. If the participant returned their Watch by mail: Open the participant’s Fitbit account on a field center computer.
- a. Open this link using a web browser on a field center computer:
https://accounts.fitbit.com/login?targetUrl=https%3A%2F%2Fwww.fitbit.com%2Flogin%2Ftransferpage%3Fredirect%3Dhttps%253A%252F%252Fwww.fitbit.com&lcl=en_US
 - b. Select “Continue with Google”
 - c. Select “Use another account”

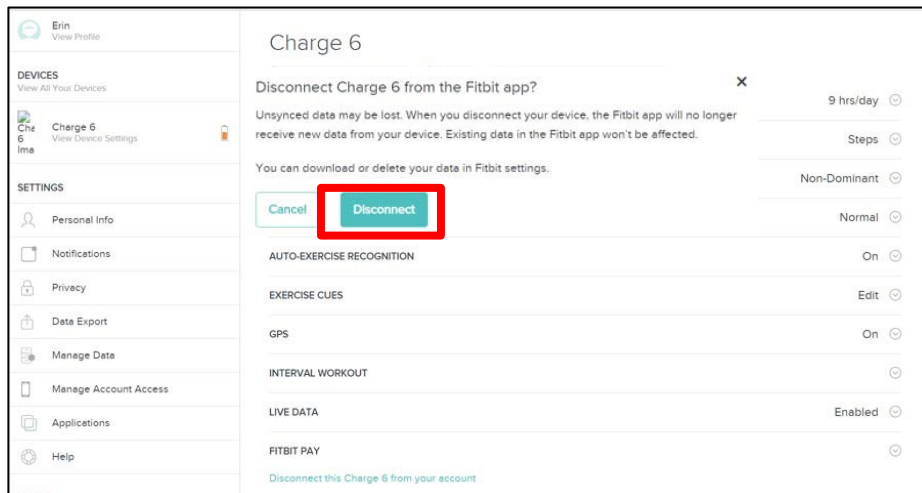
- d. Enter the participant's study Gmail address (obtained from the FBI form), then select "Next"
- e. Enter the participant's study Gmail address password (obtained from the FBI form), then select "Next"
- f. On the participant's Fitbit dashboard, select the "Settings" icon in the upper-right hand corner
- g. Select "Charge 6" from the drop-down menu



- h. Select "Disconnect this Charge 6 from your account" at the bottom of the next screen



- i. A message will appear, confirm you want to disconnect the Charge 6 from the Fitbit app by selecting “Disconnect”



- j. If the device has been disconnected, you will see a message “You don’t have any devices paired to this account.”
 - k. Select “Logout” in the upper right-hand corner
7. The Fitbit Watch can now be given to another participant.

3 DATA AND RESULTS TRANSFER

3.1 DATA DOWNLOAD / RESULTS TRANSFER

Bi-monthly (every 60 days) summary data on Fitbit adherence will be generated by the Johns Hopkins Wearable Team through Fitabase and will be sent to the Coordinating Center. These adherence reports will include data on Fitbit wear time and syncing. All other data (e.g., sleep, activity, heart rate) will be stored in Fitabase and not CDART.

Participants' result reporting will occur directly from Fitbit (data on the Fitbit app as well as weekly summary emails to the participant). No results reporting to the participant will come from CDART.

4 TRAINING AND CERTIFICATION

Prior to conducting the Fitbit protocol at ARIC Visit 11, all current examiners are to be certified by completing the following:

- Attending the in-person Fitbit training delivered by Dr. Spaulding in January 2024 at the local field center, prior to the study start date.
- Review Manual 49 which details the Fitbit protocol, and the participant StartKit.
- Watch a mock visit* conducted by Dr. Spaulding at the in-person training session in January 2024.
- Complete a mock visit* or visit** as overseen by Dr. Spaulding at the in-person training session in January 2024. Each staff member to be certified will complete a mock run through of the procedures.

For new staff hired after the initial in-person training session conducted by Dr. Spaulding, certification procedures will include:

- Review Manual 49 which details the Fitbit protocol, the participant StartKit, and the Fitbit App and Watch Education Guides.
- Watch a visit** conducted by a previously certified examiner.
- Complete a visit** as overseen by a previously certified examiner. Each staff member to be certified will complete a run through of the procedures.

* The mock visit will include completing Section 2.4 of this Manual with a staff member acting as the participant. The Fitbit Onboarding Checklist, **found in Appendix 5.1**, will be used to evaluate and provide feedback on a staff member's performance of the core competencies. Dr. Spaulding or a previously certified examiner can decide whether the staff member needs to be overseen in more than one visit prior to certification.

** The visit will include completing Section 2.4 of this Manual with a pilot volunteer participant or an ARIC participant. The Fitbit Onboarding Checklist, **found in Appendix 5.1**, will be used to evaluate and provide feedback on a staff member's performance of the core competencies. Dr. Spaulding or a previously certified examiner can decide whether the staff member needs to be overseen in more than one visit prior to certification.

5 APPENDIX

5.1 FITBIT ONBOARDING CHECKLIST

Steps	Complete / Incomplete
1. Confirm participant's eligibility using the FBI form and Participant Snapshot	
StartKit	
1. Write down the participant's Google (Gmail) email and password on their StartKit (the Fitbit handout/participant instructions)	
2. Describe how the participant can navigate the StartKit to answer their questions while at home	
3. Make sure the participant leaves with the StartKit	
Fitbit app	
1. Show participant where the Fitbit app is on their phone (put it on the first page)	
2. Have the participant open the Fitbit app themselves	
3. Demonstrate to the participant how to sync and have them demonstrate it back	
4. Describe to the participant that they just need to interact with the "Today" tab in the app	
5. Show the participant how to view their physical activity, heart rate, and sleep metrics in the app (as described in the StartKit and the Fitbit App and Watch Education Guides)	
6. Remind the participant to open the app and sync at least every 5 days	
7. Tell the participant that for the study, they do not need to pay for anything in the app	
Fitbit Watch	
1. Show the participant how to connect the charger to the Watch, indicating the gold prongs and that it is magnetic	
2. Make sure the participant is wearing the watch correctly and that he/she knows how to put it on	
3. Show the participant how to wake-up the watch screen, get back to the main screen, magnify the screen (if the participant requested that feature be enabled), use the water lock feature (if they swim as a regular form of activity), find the battery life, and view their physical activity, heart rate, and sleep metrics (as described in the StartKit and the Fitbit App and Watch Education Guides). Make sure they demonstrate these back to you.	
Gmail app	
1. Show the participant where the Gmail app is on their phone (put it on the first page)	
2. Have the participant open the Gmail app themselves	
3. Have the participant open an email to make sure they will be able to view their weekly feedback emails from Fitbit	
Connecting Participant to Fitabase	
1. Manually connect the participant to Fitabase and set up their phone to receive text messages if they agreed to receiving texts (including adding the phone number, from which they will receive text message reminders to sync, as a contact in their phone)	

2. Open the participant's Fitbit app and sync, to get the first "sync" in Fitabase	
Follow-up Procedures	
1. Tell the participant they will receive text message reminders (if they consented to this) every 5 days reminding them to sync, if they haven't already.	
2. Tell the participant to expect a phone call from the field center staff 7 days following Day 2 of the Visit to make sure everything is going okay with the Fitbit.	
3. Tell the participant we hope they will wear the Watch and provide Fitbit data for about 80% of days each month. However, they will receive \$10 a month if they provide Fitbit data for at least 50% of days each month.	
4. Tell the participant, if they feel well enough, to try to continue wearing and syncing the Watch even if they are hospitalized. (Data from directly before, during, and after hospitalizations will be important to collect if participants are able to provide it.)	
5. Tell the participants that if they get a pacemaker or cardiac defibrillator after being given a Fitbit Charge 6 for this study, to take off the Fitbit Watch and call the field center for further instructions.	

5.2 VISIT 12 FITBIT DEVICE CHECK INSTRUCTIONS

The following steps should be taken to make sure the participant wants to continue with the Fitbit during Visit 12, and if so, that the Fitbit is working properly:

- 1) If not already completed, record participant responses to the Fitbit Satisfaction Questionnaire (FSQ)
- 2) Tell the participant, "Thank you for your invaluable contribution to the Fitbit study! We'd love for you to continue wearing your Fitbit watch to keep supporting our research. However, if you prefer to return it at this time, please let us know."
 - a. If the participant chooses to stop wearing the Fitbit, proceed with the steps in section 2.5, Fitbit Return/Recycle, and withdraw them from the study.
 - b. If the participant chooses to continue wearing the Fitbit, proceed with the subsequent steps.
- 3) Open the Fitbit app on the participant's phone.
- 4) Confirm they are signed into the ARIC study account.
 - a. Select the colored-circle (with a letter in it) in the upper-right-hand corner of the "Today" screen.
 - b. Make sure the email listed at the top of the screen is the ARIC study account; if not, change to the study account.
- 5) Confirm that the Charge 6 is updated and paired to the ARIC study account.
 - a. Select the phone/watch icon in upper-left-hand corner of the "Today" screen.
 - b. Make sure Charge 6 is listed under "Connected to Fitbit"; if not, the watch will need to be re-paired.
 - c. If there is a message under Charge 6 that says "Update available", go through the steps to update the watch software.
- 6) Sync the watch to the Fitbit app and confirm that the watch synced in Fitabase.
- 7) Ask participants who don't have text messaging reminders set up through Fitabase if they would like to start receiving them.
 - a. If they want the text message reminders set up, add this functionality to their account in Fitabase (see MOP for directions on how to do this), and change their answer to question

1c on the FBI form to “yes.”

- 8) Check to see if participants need a new band for the Fitbit Charge 6 watch.