INSTRUCTIONS FOR THE FITBIT CHECK-IN FORM (12/11/2024) (FCN, VERSION 1, 12/11/2024)

I. General Instructions

The FCN is collected for all ARIC participants wearing a Fitbit. The FCN is a single question form designed to ascertain whether a participant has had a pacemaker or cardiac defibrillator implanted since the last point of contact.

The FDA guidance for Fitbit exclusions is focused on pacemakers and defibrillators because of the risk of the Fitbit interfering with their therapeutic life-saving functions. Participants may have many different implantable medical devices, which cannot be specifically called out in this QxQ. Staff should focus on ascertaining pacemaker or defibrillator use. Specific FAQ device inclusion/ exclusion and rational is included below:

- An implantable loop recorder does not have any therapeutic function like a pacemaker or defibrillator. Participants with this device do not need to be excluded. Any electrical interference from the Fitbit should have minimal impact on the diagnostic value of the loop recorder, which collects information over a long period of time.

The Annual and Semi-Annual Tracing Sheet will indicate whether the FCN form should be collected. The tracing sheets consider Fitbit wear status and previous indication of pacemaker/ cardiac defibrillator wear to determine whether this form should be collected. If the participant is wearing a Fitbit (i.e., has not yet withdrawn from the Fitbit study), and has not previously reported pacemaker or cardiac defibrillator wear, then the FCN should be collected.

Like the Medical Conditions Update form, the same occurrence of the Fitbit Check-in form should be used for each time this question is asked. The form will stop being updated when the participant reports having a pacemaker or cardiac defibrillator, either at a visit on the Participant Safety Screener (PSA) or on the FCN form, or if the participant withdraws from the Fitbit study.

If the participant responds “Yes” to item 1 of this form, this will trigger an alert in the Visit 11 Alerts Report. Clinic staff will resolve the alert by sending the participant the Implanted Medical Device Letter for Fitbit to the participant requesting the return of their Fitbit device. This letter is found on the ARIC website under Researchers > Supporting Documents > Visit 11/NCS. Once an alert has been triggered and resolved by sending the letter to the participant, it should be reported in the Results and Alerts Reporting Form (RARX).

II. Detailed Instructions for Each Item

0a. Enter the date on which the Fitbit Check-in form was completed. This date should be updated each time this form is collected during a follow-up call.

0b. The follow-up interviewer who has most recently collected the information enters their code number in the boxes provided.

1. Respond “Yes” if the participant reports having a pacemaker or cardiac defibrillator. This will trigger an alert for the ARIC clinic staff to send the participant the Implanted Medical Device Letter. If the participant does not report having a pacemaker or cardiac defibrillator, respond “No”.