INSTRUCTIONS FOR THE ECG PATCH SENSOR INITIALIZATION (EIO) FORM

I. General Instructions

The ECG Patch Sensor Initialization Form is administered by ARIC field center staff for all participants. It is recommended that the EIO form is filled out directly before the ECG Patch is placed on the participant. For information on completing this form in the case of ineligibility or participant refusal, please follow the instructions in the "Logging Device Exclusions in CDART" table (ARIC Website > Researchers > Cohort Studies > Supporting Documents > Visit 11/NCS). This form asks whether the participant meets any of the exclusion criteria that would exclude the participant from the ECG Patch protocol. The form also records the ECG Patch sensor serial number and sensor application date to be able to track the sensor back to the correct participant. Finally, the form asks whether the ECG Patch applied to the participant was an ePatch or ZioPatch device.

Only one occurrence is allowed in the EIO form. If the participant meets any of the temporary exclusion criteria (air travel or imaging appointments in the next 14 days), the ECG Patch sensor should not be applied to the participant and the EIO form should be saved and closed before starting Part B. For each future recruitment attempt until the sensor can be applied on the participant, **the same occurrence of the EIO form should be overwritten with updated information**.

Before starting the EIO form, ensure that the participant is eligible for the ECG Patch protocol and has agreed to participate and is able to mail or otherwise return the ECG Patch sensor back to the clinic. History of adhesive allergy and indication that the participant wears an implantable medical device can be verified by viewing the Participant Snapshot report.

For the ARIC Cohort study, participation in CGM is *not* required for participation in the ECG patch protocol. For the ARIC Generation 2 study, participants must simultaneously wear CGM to participate in the ECG patch protocol. Two eligibility questions are asked on both the EIO and CGMR forms (EIO1a/CGMR1 and EIO1b/CGMR2). When a participant receives both CGM and ECG patch on the same day, the participant should only be asked these questions once, but both questions should be filled out on both forms.

If the participant is eligible but declines participation in the study, is ineligible due to the medical device or adhesive allergy exclusions, or is temporarily excluded due to travel or imaging appointments, you should enter items 0a, 0b, 0c, and 0c1, then save and close the form. The EIO form should be opened and completed for all participants in the ARIC Generation 2 study.

II. Detailed Instructions for Each Item

0a. Enter the date the form was completed.

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

0c. If the participant is interested in participating in accelerometry, mark "Yes". Otherwise, see instructions in the "Logging Device Exclusions in CDART" table (ARIC Website > Researchers > Cohort Studies > Supporting Documents > Visit 11/NCS) to assist with completing this field.

0c1. If the participant indicates that they are not interested in participating in the ECG Patch

ancillary study, record the reason why not. Save and close the form after completing this item.

A. Sensor Exclusion Information

1a. Record whether the participant indicates they have an MRI scan, CT scan, X-ray, or diathermy treatment scheduled in the next 14 days.

1b. Record whether the participant indicates they plan to travel by air in the next 14 days.

1c. Record whether the participant indicates they have an implanted neurostimulator device.

1d. Record whether the participant meets eligibility criteria to wear the ECG patch. A participant is eligible to wear the ZioPatch if the answer to questions 1a, 1b, and 1c are all "No" and the participant does not have a history of adhesive allergy and the participant does not have an implanted cardiac device listed in the Participant Snapshot report. If the participant has a history of adhesive allergy or an implanted cardiac device, or if “Yes” is marked for 1a, 1b, or 1c, the answer to 1d should be “No.” If 1d is marked “No”, save and close the form.

B. Sensor Initialization Information

If the participant is eligible to complete the ECG patch protocol, record the ECG Patch Sensor Initialization Information in items 2 and 3.

2. Record the sensor serial number. This 10-digit number can be found on the back of the Zio XT Monitor and on the Skin Prep & Placement Kit package.

3. Record the date that the sensor was applied to the participant.

4. Record whether the participant received a BioTel ePatch device or a Zio XT Monitor device.