INSTRUCTIONS FOR
RESULTS AND ALERT REPORTING FORM
(RARX)

I. General Instructions

The results and alerts reporting form is designed to track the date when participants were notified of any alert value as well as track when study results were reported to participants.

Notifications of alert values can occur under different circumstances:

- While the participant is at the field center (e.g., blood pressure, depression and otoscopy).
- Urgent, or expedited, alerts may be communicated to the field center from a central reading center (e.g., the iRhythms ZioPatch Reading Center) when time is of the essence and waiting for the results to be reported to the ARIC CC is not timely enough
- Alerts that are processed through the ARIC CC from a reading center or lab will show up in the 'Alerts report' on CDART until the RAR form indicates that the alert has been reported.

The alerts reports should be run **daily** by the data manager. All new alerts that show up in the report should be processed and resolved in a timely manner. Sometimes a phone call to the participant is the mechanism for reporting. Other times mailing the Summary of Results reports that includes the alert value(s) is the appropriate mechanism. In other instances, the proxy or even the physician, when the participant is unreachable, is the person notified.

The visit 'Alerts Report' and ancillary studies 'Alerts Report' in CDART will list all unreported alerts, and the corresponding alert code for each one. Data managers will also have the ability to run the Alerts Report for all alerts (resolved or not) for a given participant, in case they want to see when alert values were reported to the participant.

Field center staff are responsible for notifying the participant and, as determined from the participant's informed consent, the participant's physician. (Notification of alerts requires that the field center staff member review the instructions for reporting study results provided by the participant in his/her informed consent.) The level of the alert determines the length of time allowed to notify the participant and/or their physician – specific timelines for specific alerts are given in Manual 2. If the participant and/or physician could not be contacted within the time frame specified for an alert value, the Field Center PI must be notified on the day of expiration of that notification time window.

Some study participants do not identify a personal physician or another provider of medical care. Field centers keep a list of local physicians whom participants can call. The local medical society is typically a good source for such a list and one that is acceptable to practitioners in the community.

This form may be accessed more than once, since alert value information may be obtained from the central laboratories or the study reading centers at different times. Similarly, it is possible that notification may take place on a different date than the date of receipt of the alert notification at the field center. Only one occurrence of this form is allowed, so updates are made to a single record in CDART.

The study participant does not need to be present when this form is completed. The information required is gathered at the time of the study visit or after laboratory tests have been completed or the results of other components processed by reading centers.

Alerts will continue to appear in the CDART Alerts Report until the participant and/or physician is notified and the notification details (Alert Code and Date Participant Notified) are entered in this form. Consequently, field center staff should make every effort to notify participants and/or physicians as soon as possible.

The RARX form can also be used to track Alerts and Results for the ARIC Generation 2 study. This form is the same in the ARIC cohort study and the ARIC Generation 2 study. When tracking alerts and results at the ARIC Generation 2 study visit 1, please log alerts and results under "Visit 10" when given the option. This form was purposely built to be flexible to the type of results provided at each visit, so not all result options listed in the form will apply for ARIC Generation 2.

II. Detailed Instructions for Each Item

The RARX is organized into seven sections:

A: **Administrative Items** – This sections contains information on the most recent date of completion and the staff ID.

B: **Visit 9 Exit Interview** – alerts and reporting. This section denotes alerts that are known in real-time as data are collected during the visit. If there is an alert value for blood pressure or depression, the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES). The Alert Report should be run at the end of the visit. These alerts are reported to the participant while still present. The date the participant is notified is recorded. Most often this will be the date of the visit, but the system will allow for later dates.

C: **Visit 10 Exit Interview** – alerts and reporting. This section denotes alerts that are known in real-time as data are collected during the visit. If there is an alert value for blood pressure or depression, the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES). The Alert Report should be run at the end of the visit. These alerts are reported to the participant while still present. The date the participant is notified is recorded. Most often this will be the date of the visit, but the system will allow for later dates.

D: **Visit 11 Exit Interview** – alerts and reporting. This section denotes alerts that are known in real-time as data are collected during the visit. If there is an alert value for blood pressure or depression, the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES). The Alert Report should be run at the end of the visit. These alerts are reported to the participant while still present. The date the participant is notified is recorded. Most often this will be the date of the visit, but the system will allow for later dates.

E: **Visit 12 Exit Interview** – alerts and reporting. This section denotes alerts that are known in real-time as data are collected during the visit. If there is an alert value for blood pressure or depression, the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES). The Alert Report should be run at the end of the visit. These alerts are reported to the participant while still present. The date the participant is notified is recorded. Most often this will be the date of the visit, but the system will allow for later dates.

F: **Alerts** – select from the Alert and Visit Codes found in the drop-down lists. This section allows for entry of alert codes, visit codes, and date participant is notified of alert.

Alert Codes:

Highlighted alert codes must be visit specific

CAC - CT: Alert from CT scan reading center

ECH - Echo: Alert from Echocardiography Alerts Notification Form (ECA)

LGU - Lab: Glucose

LSC - Lab: Serum Creatinine

LTG - Lab: Triglycerides

LAC - Lab: Albumin: creatinine ratio

LGF - Lab: eGFR

LSP - Lab: Serum potassium

LHG - Lab: Hemoglobin

MRL - MRI: Alert from local radiologist

MRB - MRI: Alert from brain MRI reading center

MRV - MRI: Alert from vascular MRI reading center

Z1a - Ziopatch/ePatch: Wide QRS tachycardia >120 for >30 secs

Z1b - Ziopatch/ePatch: Complete heart block

Z1c - Ziopatch/ePatch: 2nd degree AV Block, Mobitz II

Z1d - Ziopatch/ePatch: Pause > 6 seconds

Z1e - Ziopatch/ePatch: Bradycardia 30 seconds

Z1f - Ziopatch/ePatch: Afib with average HR 180 bpm for 60 seconds

Z1g - Ziopatch/ePatch: Narrow QRS tachycardia >180 bpm for 60 seconds

Z1h - Ziopatch/ePatch: Other alert

FRA - Falls risk

Visit Codes:

Visit 9

Visit 10

Visit 11

Visit 12

G: **Results** – Whenever possible, it is preferable (mainly from an operational standpoint) to send the Summary of Results one time with complete results. This means ensuring that all of the lab values are available, the ePatch results are available, and other visit information is available and complete in the Summary of Results report. This section includes the type of result, visit number, and date sent to the participant.

Because there may be additional studies that are added after the start of the visit, the date that each set of results is reported to the participant must be recorded. Often, this will be the same date; which is the date the full report is available and compiled.

Type of Results:

Highlighted result codes must be visit specific

A - Diabetes Lab

B - Accelerometer

C - Ziopatch / ePatch

D - Lipid Lab

E - MRI

F - PET

G - Gait Mat

H – CT

I - Echo

J - PYP

K - OH

L - ABPM

M - CGM

N - Audiology

O - Peripheral Neuropathy

P - Neurocognitive

Q - HBPM

R - Physical Function

S – Sleep

T – Mini Nutritional Assessment

Visit Codes:

Visit 9

Visit 10

Visit 11

Visit 12