



RESULTS AND ALERT REPORTING FORM

ID NUMBER:

FORM CODE:

DATE: 10/23/2017
Version 2.0

Instructions: The purpose of this form is to acknowledge receipt of and document notification of local and central alerts that occur as a result of the exam visit, as well as document distribution of results to the participant. Listings of alerts are available in the Alerts Report in CDART.

A. VISIT EXIT INTERVIEW

1. Were there any alert notifications at the time of the visit? Yes
No **GO TO ITEM 6**
2. Seated blood pressure alert: date notified / /
Month Day Year
3. CES-D Depression alert: date notified / /
Month Day Year
4. Otoscopy alert: date notified / /
Month Day Year
5. Falls risk alert: date notified / /
Month Day Year
6. Was a copy of the Exit Interview results report provided to the participant? Yes
No
7. Date the Exit Interview results report was provided: / /
Month Day Year
8. Date neurocognitive status letter sent to the participant: / /
Month Day Year

B. EXTERNAL ALERTS (see RAR QxQ for list of ALERT CODES)

9. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	9a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
10. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	10a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
11. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	11a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
12. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	12a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
13. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	13a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
14. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	14a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
15. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	15a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
16. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	16a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
17. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	17a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
18. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	18a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
19. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	19a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
20. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	20a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year
21. Alert code:	<input type="text"/> <input type="text"/> <input type="text"/>	21a. Date notified:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			Month	Day	Year

C. RESULTS REPORTING

22. Date diabetes lab results report sent to the participant:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year
23. Date accelerometer letter sent to the participant:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year
24. Date Ziopatch results sent to the participant:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year
25. Date Lipid results sent to the participant:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year
26. Date Pulse Wave Velocity results sent to the participant:	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> /	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	Month	Day	Year

27. Date MRI results sent to the participant:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			

28. Date PET results sent to the participant:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			

29. Date CT scan results sent to the participant:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			

30. Date Echo results sent to the participant:

<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	/	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Month			Day			Year			



INSTRUCTIONS FOR RESULTS AND ALERT REPORTING FORM (RAR7)

ALERT CODES:

Lab	LGU	Glucose
	LSC	Serum Creatinine
	LTG	Triglycerides
	LAC	Albumin:creatinine ratio
	LGF	eGFR
	LSP	Serum potassium
	LHG	Hemoglobin
Ziopatch	Z1a	Wide QRS tachycardia >120 for >30 secs
	Z1b	Complete heart block
	Z1c	2 nd degree AV Block, Mobitz II
	Z1d	Pause > 6 seconds
	Z1e	Bradycardia <40 bpm for > 30 seconds
	Z1f	Afib with average HR <40bpm or >180 bpm for 60 seconds
	Z1g	Narrow QRS tachycardia >180 bpm for 60 seconds
MRI	MRL	Alert from local radiologist
	MRB	Alert from brain MRI reading center
	MRV	Alert from vascular MRI reading center
CT Scan	CAC	Alert from CT scan reading center
Echo	ECH	Alert from Echocardiography Alerts Notification Form (ECA)

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 Alert Report 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 report 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 'V6 Alerts Report' and the '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 MOP 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.

II. Detailed Instructions for Each Item

The RAR is organized into three sections:

A: Visit 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, depression or excessive ear wax, the alert will show up in the Alert Report once the values have been keyed into CDART (SBP, CES, AUD). The Alert Report should be run at the end of the visit. These alerts will also be displayed in the Participant Preparation Report. These alerts 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.

B: External Alerts - see the Alert Codes table at the top of this QxQ for a list of the possible alert triggers at Visit 7.

C: Results Reporting – 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 Ziopatch results are available, and other visit information is available and complete in the Summary of Results report.

Because there may be additional ancillary studies that are added after the start of Visit7, 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. It is possible new data could be submitted and results would therefore be updated. In that case, the Results Status

report will highlight any results for which the date they were submitted to CDART is after the date the results were sent to the participant as entered into this form. When that happens, site staff must confirm the results. If the results have changed, the updated results need to be sent to the participant and the date sent must be updated to reflect the date the updated results were mailed to the participant. If the results have not changed, and they are identical to the results that were previously sent to the participant, the results do not need to be re-sent. Site staff should update the date sent to indicate the date they confirmed the results. In both cases, the date will confirm the participant received accurate, up-to-date results. Note that when results are updated in CDART, previous results reports cannot be retrieved. Sites should save printed or electronic pdf documents of results sent to participants.