Appendices

Appendices are identified by section number in Manual and are found in the secure section of the ARIC study website under Researchers -> Cohort Studies -> Current and Archived Visit Documents -> Manuals. The Visit Checklists are also found on the ARIC study website under Researchers -> Cohort Studies -> Current and Archived Visit Documents -> Forms, QxQs, and Form Code Books. **NOTE: sites must use the IRB-stamped recruitment materials to send to participants.** Stamped documents include an approval stamp with the JHU logo and approval date. The stamped recruitment materials (Appendix 1) can be found on the ARIC study website under Researchers -> Cohort Studies -> Supporting Documents -> Visit 12.

Appendix 1.A. PROTOTYPE RECRUITMENT LETTER

The ARIC Study / Logo
Street address
Town/city, State, Zip code
Phone, number

Name of ARIC participant
Street address
Town/city, State, Zip code

Dear <title> <name>:

The Atherosclerosis Risk in Communities (ARIC) Study invites you back to the ARIC center for the 12th visit! Your participation in ARIC over the past 38-plus years has changed how doctors treat patients, has improved the health of people around the world, and would not be possible without your many years of partnership with the ARIC study. Your contributions have led to achievements such as:

- The development of new drugs to treat high cholesterol
- Using repeated brain MRI and PET scans, ARIC identified treatable factors that are linked to worsening of disease in blood vessels and Alzheimer pathology in the brain
- Identified proteins that may affect the health of the heart, brain, and walking abilities.
- Used stored **blood** samples to help develop blood tests that identify Alzheimer pathology in the **brain**.

We hope you will continue to join us in the new visit to build upon these and other discoveries in the ARIC study. The next visit will be **shorter** and **simpler**. We will offer assessments you are familiar with, such as blood and urine testing, tests of your memory and thinking abilities, hearing assessments, and how you walk and move. Limited wearable technology may also be available. [*For Jackson site only, add "*Additionally, if you did not receive your echocardiogram (ultrasound) of your heart during visit 11, you will be offered the opportunity to have an echo at visit 12.*"]* We estimate that the visit will take 3-4 hours to complete.

ARIC staff will be contacting you soon to talk about your availability for this new visit. We genuinely appreciate your past ARIC Study participation and hope you will choose to partner with us again for this upcoming visit.

Sincerely,

[Principal Investigator]

Appendix 1.B. VISIT 12 CLINIC RECRUITMENT SCRIPT

Recruitment for Visit 12 may be done in the context of AFU calls or during calls from dedicated recruitment staff. Outcome of the recruitment call should be recorded in the Recruitment Tracking and Scheduling (RTS) form.

Calls from recruiters should begin with a greeting, the caller's name, and where the caller is calling from, e.g., "**Hello, this is [name] from the ARIC Study at the [*location*].**

*If not during an AFU call: (This parenthetical is an option for sites that send letters in advance of the phone call and are not part of AFU calls: "**As we mentioned in the letter we mailed to you**,")* **We are recruiting and scheduling participants to be part of this new visit focused on your memory, physical activity such as walking or exercise, hearing, and how you walk and move."**

If during AFU calls, at the end of the AFU call, continue with the following:

"Next, I want to tell you about the new ARIC visit at the University of [XXX]. As we mentioned in the letter we mailed to you, we are recruiting and scheduling participants to be part of this new visit focused on your memory, physical activity such as walking or exercise, hearing, and how you walk and move."

Then all will continue:

We expect this visit to take about 3 to 4 hours. In addition to routine assessments like checking your blood pressure and testing your blood and urine, we will conduct memory and thinking assessments, and test your hearing, walking, strength and balance. (*Jackson field center only: "***If you did not receive your echocardiogram (ultrasound) of your heart during visit 11, you will have an opportunity to complete the echocardiogram at this visit.") We will share clinical findings with you and, with your permission, with your healthcare provider.**

We can assist with transportation to the clinic visit [through (*list of options provided by the site*)]; [(if applicable) *or we can compensate your travels for the visit*].

****

Next, I would like to schedule your clinic visit. Is there a day or time that would be best for you for coming into our clinic? Our appointment times are at [TIMES].

1. If appointment is scheduled, record the date and time read the following, and skip to 5 (special needs assessment).

We will be mailing a packet of information to you. We also will give you a reminder call the day before your scheduled visit.

1a. If respondent is unable to schedule appointment at this time, indicate on record of calls, specify reason and prospects for recontacting, and skip to CLOSING (section 6).

2. If respondent is unwilling to schedule a clinic visit, ask the participant about reasons for not participating:

"Is there a specific reason you are not willing to participate in this ARIC clinic visit"

[Do not read responses unless the participant does not offer a reason]

a. Too busy? Highlight that the participant will receive a number of different tests including hearing, blood pressure measures, physical function tests and memory tests. If still does not agree to complete full exam, see 3 below

b. Exam requires too much time? Highlight that the participant will receive a number of different tests including hearing, blood pressure measures, physical function tests and memory tests. If still does not agree to complete full exam, see 3 below

c. Not interested? Highlight the value of the knowledge that will be gained from the study and that most discoveries in ARIC and other studies like ARIC are only possible through volunteers' years of dedication from volunteers. Some examples from ARIC include:

- The development of new drugs to treat high cholesterol
- Using repeated brain MRI and PET scans, ARIC identified treatable factors that are linked to worsening of disease in blood vessels and Alzheimer pathology in the brain
- Identified proteins that may affect the health of the heart, brain, and walking abilities.
- Used stored **blood** samples to help develop blood tests that identify Alzheimer pathology in the **brain**.

d. Fearful of study procedures? Read the following: **"All the examinations done by ARIC are considered safe. Some tests can cause minor discomfort, but you can always withdraw from the study at any moment without negative consequences. Do you have any additional concerns?"** Answer questions from the participants. If the participant agrees, go back to section 1 and schedule appointment.

e. Fearful of COVID-19 exposure? Assure them that the staff are taking all necessary precautions to keep them safe: masking, social distancing and hand washing. Participants in the clinic will be asked to do the same. Read the following: **"Perhaps you will be more comfortable participating in a few months?"**

f. Because of their, or a family member's, health? See 4 below

g. Unable to travel? See 4 below

h. Distance **"We might schedule the appointment at some other time, before the end of the study, when you are in the area. Do you expect to come back to the area before December 2026?"** If YES, try to schedule a follow-up call closer to the date or schedule visit. If NOT, try to negotiate travel arrangements. Another possibility is a visit to another ARIC field center.

i. They say they are too old to be useful for the study, "you don't need me", or they have done the exams and/or imaging multiple times so "why keep doing it?" **"People are living longer, in part due to medical research. In fact, people 80 years and older are the fastest growing age group. However, people over 65, and especially over 80, make up only a small percent of research study participants. ARIC is the longest-running, most diverse study of older adults in the US. You're an irreplaceable, unique individual, and we very much value your partnership!**

By participating in ARIC, you are helping us to understand changes in the body that come with age, and how scientists can help people age in a healthier way.

j. Another reason? Try to provide a solution to facilitate visit.

3. If participant is unwilling to participate because he or she is too busy or the exam seems too long, we can offer him or her an abbreviated clinic exam that will take approximately half the time:

"We understand that 4 hours is a long visit. Would you be willing to complete an abbreviated clinic visit which will last approximately 1.5- 2 hours?"

If NO, go to section 4.

If YES, offer dates and times, schedule abbreviated clinic exam appointment, read the following and skip to section 5 (Special Needs Assessment).

"We will be mailing a packet of materials to you. We also will give you a reminder call the day before your scheduled visit"

4. If the participant is unable to participate due to illness, residing in a long-term care facility (LTCF), or any inability to come to the clinic, we will offer the opportunity of an abbreviated exam (<2 hours) at the participant's home or nursing home.

"Even if you cannot or prefer not to participate in the clinic exam, we would be happy to come to your home (or current residence [if at LTCF]) and conduct an abbreviated exam there."

If participant does not agree to home visit, go to section 6 (closing).

If the participant agrees to home visit, proceed to schedule an appointment, or make arrangements for a call back to do this. This might involve scheduling a joint appointment with a LAR or proxy:

"We will be mailing a packet of information to you. We also will give you a reminder call the day before your scheduled visit."

5. Special needs assessment and safety screening

At the time of recruitment, it will be necessary to assess the participant's transportation and special needs. Also, if the visit is scheduled soon after the recruitment call (<2 weeks), the Participant Safety Screening (PSA) form could be administered. If the PSA form is not administered during the recruitment call, then it could be administered during the appointment reminder call or at the clinic visit.

5a. If exam is going to be conducted at the field center, read the following:

"To help us prepare for your visit to the ARIC center:"

"Do you need assistance in arranging for transportation?"

If YES, discuss transportation options and arrangements with participant.

"Do you need any kind of assistance reading, hearing questions, walking or in getting on an examination table?"

If YES, record the specific need in item 5 of RTS form.

At the discretion of the recruiter, the safety screening could be administered now, and answers recorded in the PSA form. If not administered now, the safety screening can be administered during the reminder call or at the time of the clinic exam. Then, go to CLOSING (6).

5b. If exam is going to be conducted at the participant's home or in a LTCF, read the following:

"To help us prepare for our visit to [your home /residence]:"

"Do you have a quiet room that has a table and at least two chairs that we can meet in?"

“Will there be anyone there with you during our visit?”

If YES:

“How many persons?” “Would that/those person(s) be a spouse?” “Caretaker?” “Your proxy?” “Other?”

If YES, staff should prepare accordingly when scheduling the visit.

“Would any person(s) be dependent upon you for their care?”

If YES to previous question:

“Would someone else be able to provide their care while we are in your home?”

Only if exam is scheduled conducted at the participant’s home ask the following:

“Do you have pets?”

If YES:

“So that we aren’t interrupted, would it be possible to put your pets in another room while we complete the home visit?”

At the discretion of the recruiter, the safety screening could be administered now, and answers recorded in the PSA form. If not administered now, the safety screening can be administered during the reminder call or at the time of the home exam. Then, go to CLOSING (6).

6. Closing

“We want to thank you for your time today. We look forward to talking with you at your next ARIC telephone interview. Good-bye”

Appendix 1.C. PROTOTYPE APPOINTMENT LETTER

Dear [NAME],

Thank you for agreeing to participate in the new exam in the ARIC Study. Your appointment has been scheduled for:

Day_____ Date _____ Time_____

It is expected to take around 3 to 4 hours.

- FASTING IS NOT NEEDED FOR THIS VISIT

You will NOT need to fast for this visit. Please eat breakfast or lunch before your scheduled visit.

- SMOKING AND PHYSICAL ACTIVITY

Please refrain from smoking or vigorous physical activity at least one hour before your appointment

- CLOTHING

You may be asked to remove your upper body clothing (except bras). Please wear loose clothes that are easily removed and comfortable shoes or slippers that are easy to take on and off. Please leave necklaces at home. Also, we suggest you do not use perfume or body lotion.

- GLASSES AND HEARING AIDS

If you normally use glasses for reading, please bring them with you to the clinic. Also, bring your hearing aids, with fresh batteries, if you use them.

- PHYSICIAN CONTACT

Please complete the form on back of the Medications Instructions and bring it with you to the clinic.

- MEDICATIONS

Please be sure to bring your medications in their original containers. You should put these containers in the ARIC medication bag. If you receive medications by injections, infusions, or other ways that do not allow you to have a container, please bring a list with the medication names, doses, and how often you take them.

- TAKE YOUR MEDICATIONS ON THE DAY OF THE ARIC EXAM

If you are taking daily medications, please take them as prescribed by your doctor on the day of your ARIC exam.
If you need to take medications during the day, please remember to bring them with you to the ARIC center and let us know of any that need to be kept refrigerated.

- SMARTPHONE AND FITBIT WATCH

If you were provided a Fitbit watch at your last visit, please bring your smartphone and the Fitbit watch with you to the clinic.

To help you to move through the clinic on schedule, it is important that you be on time for your appointment.

We will give you a reminder call the day before your visit.

If you have any questions or a problem with your appointment, please call the clinic at [PHONE NUMBER] between [7:30 a.m.] and [4:30 p.m.] Monday through Friday.

We look forward to seeing you again.

The ARIC Staff

Appendix 1.D. ARIC MEDICATION INSTRUCTIONS (to be included with the clinic packet)

During your visit to the Clinic, we would like to record any medicines you are taking because they tell us about a person's health and may have effects on the tests which we will perform.

We are interested in ALL medicines that you take for ANY reason, not just heart medicines, now and in the past FOUR WEEKS. We ask you to assemble and bring to the ARIC center all your prescription, over-the-counter, and research medications. This includes medications that are solid or non-solid, that may be swallowed, inhaled, applied to the skin or hair, injected, implanted, or placed in the ears, eyes, nose, mouth, or any other part of the body. If you receive injections or other forms of medications at a clinic or infusion center, please bring the name of the medication and dose if you have it.

- Please use the provided medications bag to bring all medications used in the past four weeks in their original containers, if possible, including: Prescription drugs from your physician or dentist;
- Prescription drugs you may have received from other people, including friends or relatives;
- Non-prescription medicines (over the counter) that you obtained from a drug store, supermarket, by mail, or from the internet, such as aspirin, cold remedies, allergy medications, vitamins, minerals, supplements, or the like.

To be sure you have included everything, think about the past few weeks when you were ill, when you visited a physician or dentist and might have been given medication.

We ask that you bring the containers so that we can copy information from the label. If you don't have the container, please bring the prescription or any other information that has the name of the drugs. Even if you only have loose pills or capsules, please bring them to the clinic so that we can identify them.

At the clinic we will handle all your medicines and containers very carefully and will return them in the same bag before you leave. Like all other information we collect, your use of medicines will be kept in strict confidence.

We will provide your doctor(s) with results of your tests if you would like us to. To save time at your clinic visit, we ask you to please fill out the information below and bring it with you to the clinic.

Primary doctor:

_____

YOUR DOCTOR'S / CLINIC NAME

_____

STREET ADDRESS

_____

CITY STATE ZIP CODE

_____

TELEPHONE NUMBER

Appendix 1.E. CLINIC APPOINTMENT REMINDER

If talking with LAR/proxy instead of participant, adapt as needed.

1. Opening and instructions about fasting:

"Hi, this is __(NAME)__, with the ARIC study at [INSTITUTION]. May I please speak with [Participant's Name]? I am calling to remind you of your clinic appointment on [DATE] at [TIME]. We look forward to seeing you tomorrow. Also, we would also like to remind you about some additional items that were included in the information package we sent you."

Go over the different items in the appointment letter, including transportation arrangements, if any were done, length of exam, need to bring glasses, comfortable clothing, physician information, and need to avoid smoking and vigorous physical activity.

2. Request to bring smartphone and Fitbit watch, if provided a Fitbit watch at Visit 11 (see Visit 12 snapshot report, to determine if participant is a current Fitbit wearer; if not, go to **3**).

"You were provided a Fitbit watch at your last visit. Please bring your smartphone and the watch with you to this upcoming clinic visit."

3. Reminder about need to bring medicines

"We will ask you about your use of medicines, vitamins or supplements. This includes all medicines such as prescription drugs from all doctors, prescription drugs you may have received from other people, such as friends or relatives, over the counter medications, such as medicines for colds, vitamins, minerals, or other supplements. ARIC is interested in medications that are solid or non-solid, that may be swallowed, inhaled, applied to the skin or hair, injected, implanted, or placed in the ears, eyes, nose, mouth, or any other part of the body.

We ask that you bring the containers so that we can copy information from the labels. Please bring in the bottles of any medication you have taken in the PAST FOUR WEEKS. If you do not have the container, please bring the prescription or the loose pills or capsules. If you receive injections or other forms of medications at a clinic or infusion center, please bring the name of the medication and dose if you have it. **A bag to carry your medications was included in the packet that was mailed to you. Do you have any questions about this or any other aspect of your clinic visit?"**

If questions, address them. Then, go to **5** (Closing).

4. Patient Safety Screening

If not administered during the recruitment call, the safety screening could be administered during this call (PSA form).

5. Closing

"We look forward to seeing you on [day of visit]

Appendix 1.F. HOME APPOINTMENT REMINDER

If talking with LAR/proxy instead of participant, adapt as needed.

1. Opening and instructions about fasting:

“Hi, this is __[NAME]_, with the ARIC study at [INSTITUTION]. May I speak with [Participant’s name]? I am calling you to remind you of your visit on [DATE] at [TIME]. We look forward to seeing you tomorrow.”

Go over the different items in the appointment letter, including length of exam, need to have a table and two chairs, comfortable clothing, need to have readily available physician information, and need to avoid smoking and vigorous physical activity.

2. Request to have smartphone and Fitbit watch ready, if provided a Fitbit watch at Visit 11 (see Visit 12 snapshot report, to determine if the participant is a current Fitbit wearer; if not, go to **3**).

“You were provided a Fitbit watch at your last visit. Please have your smartphone and the watch available for this upcoming visit.”

3. ONLY for individuals at nursing homes, read the following paragraph. Adapt as needed if arrangements are being made with nursing home staff:

Read the following to ALL (home or nursing home):

“We will ask you about your use of medicines, vitamins or supplements. This includes all medicines, such as prescription drugs from all doctors, prescription drugs you may have received from other people, such as friends or relatives, over the counter medications, such as medicines for colds, vitamins, minerals. We ask that you have the containers available so that we can copy information from the labels. If you don’t have the container, please show us the prescription or the loose pills or capsules. If you receive injections or other forms of medications at a clinic or infusion center, please bring the name of the medication and dose if you have it. **A bag to put them in is in the packet that was mailed to you. Do you have any questions?”**

If questions, address them. Participants in nursing homes or assisted living facilities most likely will not have their own medication. In that case, it will be necessary to obtain this information from the caregivers at the facility.

If a LAR, proxy or informant will be present, according to results from the recruitment call, read the following:

“In our initial call, you mentioned that [LAR/PROXY/INFORMANT NAME] will also be present during our visit. Is this still the case?”

Keep track of LAR/proxy/informant availability.

5. Closing

“We look forward to seeing you on [DATE].”

Appendix 1.G. LAR/PROXY/INFORMANT RECRUITMENT

Information collected as part of this call is collected in the Recruitment Tracking and Scheduling (RTS) Form, for those circumstances in which a LAR or proxy is required to accompany the participant to the visit.

1. "Hi, may I talk with [LAR/PROXY'S NAME]? My name is [NAME] and I am with the ARIC Study, a clinical research study being conducted by [INSTITUTION]. The study aims to understand the health of the heart and the brain. I am contacting you on behalf of [Mr./Ms.] [PARTICIPANT'S NAME], who has been a participant of the ARIC study for over 30 years. [HE/SHE] provided your name as a proxy/Legally Authorized Representative, who might help [HIM/HER] to make decisions about study participation. Is this a good moment to talk with you?"

If NO:

"When would be a good time to call you back?"

Record and reschedule call. Go to **CLOSING**.

If YES:

2. "[Mr./Ms.] [PARTICIPANT'S NAME] has shown interest in being involved in a new exam as part of the ARIC study. [HE/SHE] has agreed to [come to our clinic/have us go to his/her residence or care facility] for this exam on [DATE/TIME]. However, [HE/SHE] may need help to make decisions about participation. Would you be willing to help in this role?"

If YES:

"We will mail you information about the ARIC exam and information on the date and time of the visit. You might want to contact [Mr./Ms.] [PARTICIPANT'S NAME] to coordinate the exam with [HIM/HER]. Do you have any questions?"

2a. If YES, address questions, and then go to **CLOSING**. If NO, go to **CLOSING**.

If NO:

"Is there a specific reason you are not willing to participate as a proxy in this ARIC visit?"

[Do not read responses unless the participant does not offer a reason]

a. *Too busy?* → Highlight that the time commitment will be limited to this exam and the importance of the knowledge to be gained from this research.

b. *Not interested?* → Point out the interest of the ARIC participant and the important role the proxy plays. Use the script from the letter to highlight research discoveries from the participant's longstanding participation in ARIC. "Thank you for your longstanding participation in the ARIC study. Your role in the study led to accomplishments such as:

- The development of new drugs to treat high cholesterol
- Using repeated brain MRI and PET scans, ARIC identified treatable factors that are linked to worsening of disease in blood vessels and Alzheimer pathology in the brain
- Identified proteins that may affect the health of the heart, brain, and walking abilities.
- Used stored **blood** samples to help develop blood tests that identify Alzheimer pathology in the **brain**."

c. *Unable to travel? Distance?* → Explain that arrangements have been made with the study participant to facilitate transportation to the field center.

d. *Not an adequate proxy* → Ask about other person who could be a better proxy for the participant.

e. *Another reason?* → Try to work out a way that it will work.

If need be, consult with your supervisor.

3. Closing

“I would like to thank you again for your time. Good-bye.”

Appendix 1.H. NAME AND CONTACT INFORMATION FOR SCHEDULING OF ARIC PARTICIPANTS IN ALTERNATE FIELD CENTERS

Forsyth County

Catrina McDaniel

PP I 1st floor Suite 101
1920 W 1st St.
Winston Salem, NC 27104

Phone: 336-716-9020. Email: cmcdanie@wakehealth.edu

Jackson

Stacee Naylor

University of Mississippi Medical Center
Office Annex II
2500 North State St.
Jackson, MS 39213

Phone: 601-984-6649. Email: sbnaylor@umc.edu

Minnesota

Kathryn Hiolski

University of Minnesota
Epidemiology Clinical Research Center
1100 Washington Ave. South Suite 201
Minneapolis, MN 55415

Phone: 612-624-8914. Fax: 612-626-6983. Email: hiols001@umn.edu

Washington County

Melissa Minotti

The Johns Hopkins University
1100 Dual Highway
Hagerstown, MD 21740

Phone: (301) 791-1847. Fax: (301) 791-3541. Email: mminott@jhu.edu

Appendix 2: PROTOTYPE COVER LETTERS AND INSTRUCTIONS FOR REPORTING OF STUDY RESULTS

A. Reporting of ARIC Study Results and Alert Notifications – ARIC-NCS Visits 8-12

Overview

a. Retrieve the template cover letters from the ARIC study website and store them in a folder on your computer, so you can access them to generate alert letters and ARIC results cover letters to participants and their physicians. An overview table listing these 11 template letters is shown below and is included on the website with the letters.

b. Check the data management system (CDART) daily for alert reports, and look regularly at the *Results Status Report* to see what results are due and available for your participants.

c. Print the participant's report of results from CDART. This may be accessed via the *Summary of Results Report*.

d. Select the appropriate template letter (see table below).

e. CDART does not track who the results should be reported to, but the Alerts Report indicates whether or not the ppt. has given permission to release results. The CIU has a field for request to send results to physician (Q27) and if so, the physician's address.

f. Merge the names and addresses of the MD and participant into the template cover letters. Use the *Results Address Labels Report* for participant addresses.

g. When all results are available to report for a participant, or delays require sending a partial report, check CIU Q27-29 to see who (participant, MD, LAR, proxy, etc.) should get the report of ARIC results.

Alert Reporting

1. Check daily for alerts.

2. Select the appropriate notification letter (e.g., MD designated, referral at the time of the exam visit, after the exam visit).

3. For each alert, look up the script in the results report or Table 20.2 of MOP 2 that describes the alert. This information needs to be included in the alert notification letter or conveyed by phone.

4. Consider whether this alert might already be known and might not need to be treated as an alert (e.g., longstanding atrial fibrillation on treatment need not be an alert).

5. Determine from the Alerts Report or CIU Q27-29 to whom the participant wanted results sent.

6. Discuss items 3-4 with your field center MD or clinician, per local protocol. Determine whether the alert reporting should be done by letter or whether a phone call is needed. You may bypass field center MD consultation if rules are set up with the MD on how to handle various alerts.

7. Generate and send alert letters or make phone calls followed by letter.

8. Record this action on the RAR form.

Results Reporting

1. Print the participant's report of results from CDART. This may be accessed via the *Summary of Results Report*.

2. Check on the Alerts Report whether the ppt. has given permission to release results. The CIU has a field for request to send results to physician (Q27) and if so, the physician's address.

3. Check whether any results in this report are abnormal (abnormal values are listed in Table 20.2 in MOP 2).

4. Select the appropriate cover letter (e.g., participant, physician, are any results in this report abnormal, was an alert referred previously?).

5. Merge the names and addresses of the MD and participant into the template cover letters (see Overview).

6. Edit the letters as needed (e.g., explain why some results are missing; point out any special instructions; if applicable, explain to participant which MD got letter, etc.).

7. Have someone review the letters and reports to make sure there aren't errors.

8. Print and send the appropriate letters, envelopes, and reports.

9. Archive PDFs of letters, being certain to use the participant ID in naming the PDFs.

10. If only partial results were sent, repeat the process after the remaining results are available.

11. Record these actions on the RAR form.

Template Letters to Report Alert Results – ARIC-NCS Visits

Alerts	To ARIC Participant	MD Designated	Consider: Phone call and/or letter?
		No MD Designated	Consider: Phone call and/or letter?
	To Provider of Care	Referral at Visit	--
		Referral after Visit	--

Template Letters to Report Study Results – ARIC-NCS Visit

Results	To Participant	Normal Results	MD Designated	--
			No MD Designated	--
		Abnormal Results	MD Designated	--
			No MD Designated	Phone call?
	To Provider of Care	Normal Results	--	--
		Abnormal Results	No Previous Alert	--
			Previous Alert	--

B. MD Letter: Alert Referral at Clinic Visit

[Date]

[MD Name]
[Address]

RE: [Participant Name]
[Date of Birth]

Dear Dr. [MD Name]:

We saw your patient, [Participant Name], in the [ARIC Generation 2/ARIC] Study center on [Date]. During the course of our evaluation, the following problems were identified which we believe need attention:

[Insert alert report]

The [ARIC Generation 2/ARIC] Study does not provide diagnoses, medical advice, or treatment. We have recommended to [Participant Name] that [he/she] contact you as soon as possible to determine how to follow-up on these results.

Should you have any questions, please feel free to contact us at xxx-xxx-xxxx. A full report with results of our tests will be forwarded when available.

Sincerely,

_____

Principal Investigator

/xx

C. MD Letter: Alert Referral After the Exam Visit

[Date]

[MD Name]
[Address]

RE: [Participant Name]
[Date of Birth]

Dear Dr. [MD Name]:

We saw your patient, [Participant Name], in the [ARIC Generation 2/ARIC] Study center on [Date]. We have since received some results on your patient from our central laboratories. They include a finding which we believe needs attention.

[Insert alert report]

The [ARIC Generation 2/ARIC Study] does not provide diagnoses, medical advice, or treatment. We have recommended to [Participant Name] that [he/she] contact you as soon as possible to determine how to follow-up on these results.

Should you have any questions, please feel free to contact us at xxx-xxx-xxxx. A full report with results of our tests will be forwarded when available.

Sincerely,

_____

Principal Investigator

/xx

D. Alert – Participant: MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

We have identified a result that seems abnormal that should be reviewed by a physician to be confirmed or studied further. This result is as follows:

[insert from alert report]

We encourage you to consult your physician or usual source of medical care, as soon as possible about this [result/these results]. Since you authorized us to share your study results with your physician we are sending a copy of this letter to the provider of medical care you designated

[Our staff will continue to call you twice every year to stay in touch. (ARIC only)] Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

E. Alert – Participant: No MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

We have identified a result that seems abnormal that should be reviewed by a physician to be confirmed or studied further. This result is as follows:

[insert from alert report]

During your [ARIC Generation 2/ARIC] Study visit you indicated that we should send these results to you. We encourage you to consult your physician or usual source of medical care, as soon as possible about this [result/these results].

[Our staff will continue to call you twice every year to stay in touch. (*ARIC only*)] Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

F. Physician: Abnormal Results, No Previous Alert Reported

[Date]

[MD Name]
[Address]

RE: [Participant Name]
[Date of Birth]

Dear Dr. [MD Name]:

[Participant Name], a patient of yours, is a participant in the [ARIC Generation 2/ARIC] Study and was seen at our Field Center on [Date]. Attached to this letter is a report of the results of this examination. We have indicated on the report the results we consider to be outside the normal range.

The [ARIC Generation 2/ARIC] Study routinely offers to send all clinically relevant data to the participant's physician. Your patient has indicated that we should send these results to you. We also mailed a letter to your patient to report that one or more abnormal findings were noted during the [ARIC Generation 2/ARIC] Study examination and reported to you. We have also suggested that your patient contact you to determine if these findings need further study.

The [ARIC Generation 2/ARIC] Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that requires diagnostic confirmation or possible treatment, the study participant is referred to his/her usual source of medical care.

Thank you for your cooperation.

Sincerely,

_____

Principal Investigator

/xx

Attachment

G. Physician: Abnormal Results, Previous Alert Reported

[Date]

[MD Name]
[Address]

RE: [Participant Name]
[Date of Birth]

Dear Dr. [MD Name]:

[Participant Name], a patient of yours, is a participant in the [ARIC Generation 2/ARIC] Study and was seen at our Field Center on [Date]. Attached to this letter is our final report of the results of this examination. We have indicated on the report the results we consider to be outside the normal range.

The [ARIC Generation 2/ARIC] Study routinely offers to send all clinically relevant data to the participant's physician. Your patient has indicated that we should send these results to you, and we have already reported to you about [the previous referral]. We are now sending a final report indicating possible abnormal findings to your patient, reminding him/her to contact you if he/she has not already done so.

The [ARIC Generation 2/ARIC] Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that requires diagnostic confirmation or possible treatment, the study participant is referred to his/her usual source of medical care.

Thank you for your cooperation.

Sincerely,

_____

Principal Investigator

/xx
Attachment

H. Physician: Normal Results

[Date]

[MD Name]
[Address]

RE: [Participant Name]
[Date of Birth]

Dear Dr. [MD Name]:

[Participant Name], a patient of yours, is a participant in the [ARIC Generation 2/ARIC] Study and was seen at our Field Center on [Date]. Attached to this letter is a report of the results of this examination.

The [ARIC Generation 2/ARIC] Study routinely offers to send all clinically relevant data to the participant's physician. Your patient has indicated that we should send these results to you. We also mailed a letter to your patient to report that no abnormalities were found for any items covered by the ARIC Study examination, and that the enclosed results were sent to you.

The [ARIC Generation 2/ARIC] Study examination procedures are designed exclusively for epidemiologic research. Our study procedures do not substitute for a clinical examination, nor does the study provide any diagnosis or treatment. If a condition or laboratory test result is found that requires diagnostic confirmation or possible treatment, the study participant is referred to his/her usual source of medical care.

Thank you for your cooperation.

Sincerely,

_____

Principal Investigator

/xx
Attachment

I. Participant: Normal Results, MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. Because the [ARIC Generation 2/ARIC] Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. As you instructed us to do during your [ARIC Generation 2/ARIC] Study visit we sent a copy of these results to [your provider of medical care / to Dr. Name]. We encourage you to review these results with your physician or usual source of medical care at the next convenient opportunity.

Our staff will continue to call you twice every year to stay in touch. Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

J. Participant: Abnormal Results, MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. We have identified the results which are possibly abnormal. In most instances such a result does not mean that a medical problem exists. However, we believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

Because the [ARIC Generation 2/ARIC] Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. As you instructed us to do during your [ARIC Generation 2/ARIC] Study visit we sent a copy of these results to [your provider of medical care / to Dr. Name]. We encourage you to consult your physician or usual source of medical care, to review those results that we have highlighted for verification.

Our staff will continue to call you twice every year to stay in touch. Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

K. Participant: Abnormal Results, No MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. We have identified the results which are possibly abnormal. In most instances such a result does not mean that a medical problem exists. However, we believe that the enclosed report should be reviewed by a physician to determine whether these results should be confirmed or studied further.

Because the [ARIC Generation 2/ARIC] Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. During your [ARIC Generation 2/ARIC] Study visit you indicated that we should send these results to you. We encourage you to consult your physician or usual source of medical care, to alert them to those results that we have highlighted for verification.

Our staff will continue to call you twice every year to stay in touch. Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

L. Participant: Normal Results, No MD Designated

[Date]

[Participant Name]

[Address]

Dear [Mr./Mrs. Participant Name]:

Thank you for taking part in the [ARIC Generation 2/ARIC] Study examination at our Field Center. We appreciate your willingness to join us in this important study.

The results of your examination are summarized on the attached sheet. Because the [ARIC Generation 2/ARIC] Study does not provide any clinical diagnosis or treatment, we offer to send all relevant information to participants' usual sources of medical care. During your [ARIC Generation 2/ARIC] Study visit you indicated that we should send these results to you. We encourage you to share these results with your physician or usual source of medical care at the next convenient opportunity.

Our staff will continue to call you twice every year to stay in touch. Thank you again for being a member of the [ARIC Generation 2/ARIC] Study.

Sincerely,

_____

Principal Investigator

/xx

Attachment

Appendix 3.A: Template – CES-D Alert Letter – Physician

<**Date**>

Dear <**Name, provider of medical care**>

On <**visit exam date**> your patient, <**Name, [ARIC Generation 2/ARIC] visit participant**> participated in an examination of the [Atherosclerosis Risk in Communities (ARIC) Generation 2/Atherosclerosis Risk in Communities (ARIC)] Study. Depressive symptoms were assessed during this comprehensive exam, using the Center for Epidemiologic Studies Depression Scale (CES-D) Short Form.

As you know the CES-D is not a diagnostic tool but can be used as a screening test to identify individuals at risk for clinical depression. In elderly participants, especially those with multiple comorbidities, some positive responses are expected.

Your patient had a CES-D score ≥ 9, suggesting probable Major Depression. At that time we recommended that your patient make an appointment with you for clinical follow-up and asked for authorization to contact you with this letter.

Please feel free to contact me if additional information is needed.

Sincerely,

<**ARIC Study Manager**>

c.c. <Name, ARIC visit participant>, <ARIC Principal Investigator>

Appendix 3.B: Template – CES-D Alert Letter – Participant

<**Date**>

Dear <**Name, ARIC Participant**>

In the course of your [ARIC Generation 2/ARIC] visit interviews we assessed depressive symptoms using a questionnaire called the Center for Epidemiologic Studies Depression Scale (CES-D) Short Form. We found that your score in answering these questions is 9 or greater, suggesting that you may have major depression. We recommend that you make an appointment with your provider of medical care for a clinical follow-up of this result.

We have prepared a letter for your provider of medical care, indicating that we recommended this clinical referral. Following your instructions we will mail this letter to your physician or provide it to you.

Please don't hesitate to contact your [ARIC Generation 2/ARIC] Center for questions or additional information.

Thank you for being part of [ARIC Generation 2/ARIC].

Sincerely,

<**ARIC Study Manager**>

c.c. <ARIC Principal Investigator>