Appendix 1.A. PROTOTYPE RECRUITMENT LETTER

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

Name of ARIC participant Street address Town/city, State, Zipcode

Dear <title> <name>:

It has been over 10 years since the Atherosclerosis Risk in Communities (ARIC) Study examined participants recruited in the late 1980s. We are very pleased to be able to now invite you back to the ARIC center for a 5th examination. The focus of this new exam will be on two important areas of health research: the heart and the brain. In this new ARIC exam we will conduct state-of-the-art tests of how well your heart works, and the ways blood flow to the brain sustains memory.

ARIC staff will be calling you within a few days seeking an interview by phone and to determine your availability for this new visit. We ask you, if possible, to have a calendar available to facilitate scheduling of the new visit. If you prefer, feel free to call the ARIC telephone number listed above to ask our study staff any questions in advance, or to mention any concerns that you may have.

We appreciate your past participation in ARIC and hope you will choose to volunteer for this upcoming exam. We look forward to seeing you.

Please note that in the future our staff will be making phone calls to ARIC participants twice a year, to make it easier to remember hospital visits and health events. We hope you will continue to be willing to talk with ARIC staff when they call.

Sincerely,

[Principal Investigator]

Appendix 1.B. VISIT 5 SCHEDULING SCRIPT

(Recruitment for visit 5 will usually be done in the context of AFU calls. Outcome of the recruitment call should be recorded in the Recruitment Tracking and Scheduling (RTS) form. After the corresponding AFU script, continue with the following:)

"Next, I want to tell you about a new ARIC examination at the University of [XXX]. As we mentioned in the letter and DVD we mailed to you, we are now recruiting and scheduling people to be part of this new exam focused on heart disease and memory.

This ARIC clinic visit will be similar to previous visits, and will take place at [LOCATION]. We expect it will take 6 to 7 hours, beginning in the morning. You will need to fast 8 hours unless you have a medical reason to not fast. We will reimburse you for your travel, or we can provide taxi services. In addition, we will give you a monetary compensation of \$[COMPENSATION AMOUNT] you for your participation in this visit. Our appointment times are at [TIMES]. Is there a day or time that would be best for you?"

1. If appointment is scheduled, record the date and time read the following, and skip to **6** (6-item screener).

We will be mailing an instruction brochure to you. We also will give you a reminder call the day before your scheduled visit1a. 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 8).

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 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 an echocardiogram and a comprehensive cognitive assessment. 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 an echocardiogram and a comprehensive cognitive assessment. 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. Try to work out a way that it will work.
- 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 concern?" Answer questions from the participants. If the participant agrees, go back to section 1 and schedule appointment.
- e. Because of their, or a family member's, health? → See 4 below
- f. Unable to travel? → See 4 below
- g. 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

June 2013?" If YES, try to schedule a follow-up call closer to the date or schedule visit. If NOT, try to negotiate travel arrangements. Some field centers have limited funds for airfare. Another possibility is a visit to another ARIC field center.

- h. Another reason? → Try to work out a way that it will work.
- **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 <u>abbreviated clinic exam</u> that will take approximately 3 hours:

"We understand that 6 - 7 hours is a long visit. Would you be willing to complete an abbreviated clinic visit which will last approximately 3 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 **6** (6-Item Screener).

We will be mailing an instruction brochure to you. We also will give you a reminder call the day before your scheduled visit4. 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 (<3 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 5 (phone cognitive assessment).

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 an exam proxy. We will be mailing an instruction brochure to you. We also will give you a reminder call the day before your scheduled visit Go to 6 (6-Item Screener)

5. Telephone Interview Cognitive Status

"We are sorry that you cannot participate in this new exam. However, we would like to ask you just a few additional questions now to assess your memory. These questions will take approximately 10 minutes and will provide us with valuable information in understanding the risk factors for memory decline in the general population. Would you like to complete the questions now or would you rather make an appointment to answer the questions at another time?"

If YES, administer TICS (form TICA) and go to 8 (Closing).

If NO, read the following and go to 8 (Closing):

"We want to thank you for your time today. We look forward to talking with you at your next ARIC telephone interview."

6. 6-item Screener

If the cohort member (1) has agreed to a clinic exam AND there are doubts about his/her capacity to provide informed consent or accurate information, OR (2) has agreed to home/LTCF exam, the recruiter will administer the 6-item Cognitive Screener. The purpose of this screener is to determine whether the participant has the capacity to provide informed consent, which would require recruitment of an exam proxy, and whether he/she has memory problems, which would require the recruitment of an informant.

If 6-item screener is not required, skip to 7 (Safety Screener)

"Before we continue, I would like to ask you some questions that will help us to decide the best way to conduct the new ARIC visit. Specifically, I will ask you to use your memory. I am going to name three objects. Please wait until I say all three words, then repeat them. Remember what they are because I am going to ask you to name them again in a few minutes. Please repeat these words for me: BALL—FLAG—TREE."

(Interviewer may repeat names 3 times if necessary but repetition not scored.)

Did patient correctly repeat all three words? Yes No					
Incorrect Correct					
1.	"What year is this?"	0	1		
2.	"What month is this?"	0	1		
3.	"What is the day of the week?"	0		1	
"What were the three objects I asked you to remember?"					
4.	BALL	0	1		
5.	FLAG	0	1		
6	TRFF	0	1		

Record answers to the 6-item screener in form RTS. If score <2 in questions 1-3, recruitment of a proxy is required. If score <2 in memory questions (questions 4-6), recruitment of an informant is required.

If recruitment of an exam proxy is necessary, request contact information for the proxy, include it in Contact Information Update (CIU) form, ask the ARIC participant to communicate this information to his/her proxy, and perform proxy recruitment a few days after the participant recruitment.

"We think that it might be helpful to have someone [come with you to the clinic/be with you while we visit you at home]. This person could assist you in making decisions about participation in the study. Do you agree to have someone [coming with you to the clinic/being with you during the exam]?"

If YES:

"This person should be someone who can provide consent for your participation in case you do not feel comfortable providing this consent without additional advice. Who would this person be?"

Record name, address, phone number.

"We ask you to tell [PROXY'S NAME] about your decision. In the next few days we will also contact [HIM/HER] to provide information about the exam."

If NO:

Point out that having a trusted someone would help to make decisions about participation in the study. If the participant still does not agree, move forward with scheduling unless there are serious concerns about the ability of the participant to make informed decisions about participation. Consult your supervisor or ARIC Principal Investigator if need be.

7. 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.

7a. 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** (8).

7b. 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?"

"Would any person(s) be dependent upon you for your 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** (8).

8. Closing

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

Appendix 1.C. PROTOTYPE APPOINTMENT LETTER

Dear [NAME],		
Thank you for agre- been scheduled for	•	exam in the ARIC Study. Your appointment has
Day	Date	Time
It is expected to tak	e 6-7 hours.	
[If the participant ac	greed to use his/her own car, n	no need to include the following]
• •	up at your home at approximate at the following instructions of	tely and will return you to your home afte carefully:

FASTING

You should fast for 8 hours before your appointment time. A snack will be provided during your visit. Please drink several extra glasses of water on the night before your exam. This will make obtaining your blood and urine samples easier. Also, please drink a glass or two of water first thing in the morning of your visit; however, please drink it very SLOWLY to avoid gulping and getting air in your stomach, which could interfere with our ultrasound test.

SMOKING AND PHYSICAL ACTIVITY

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

CLOTHING

Please be prepared to change into a hospital gown after your arrival and bring or wear comfortable shoes or slippers that are easy to take on and off. Please wear loose fitting underwear and leave necklaces at home. Also, we suggest you do not use perfume or body lotion.

MEDICATIONS

Please be sure to bring your medications in their <u>original</u> containers. You should put these containers in the ARIC medication bag.

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.

DOCUMENTS

Please bring your Medicare card to the examination. As you know, ARIC is identifying medical events in its participants, and the Medicare number helps ARIC obtain health care information. Your Medicare number and any information obtained are treated with the utmost confidentiality.

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

If you have any question 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, now or in the FOUR WEEKS before your visits to the ARIC clinic, not just in heart medicines. 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

The best way to get this information is for you to bring in the provided medications bag the containers of any medicine used in the four weeks before your visit, 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.

In order 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 with results of your tests	if you would like us to. Will you please fill out
the information below and bring it with you to the clini	c so that we will not have to take time during
the clinic visit to look up the information?	
YOUR DOCTOR'S / CLINIC NAME	_

YOUR DOCTOR'S / CLINIC NAME						
STREET ADDRESS						
CITY	STATE	ZIP CODE				

TELEPHONE NUMBER

Appendix 1.E. CLINIC APPOINTMENT REMINDER

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.

"In addition, for this visit, we ask you to fast prior to the exam unless you are unable due to medical reasons. Do you take insulin or other medication for diabetes or have any other reason that you cannot fast for 8 hours?"

If YES: "We would like for you to fast for 8 hours before the visit, <u>unless</u> your doctor has prescribed a bedtime snack, and come to the clinic without taking your morning insulin or other diabetes medication. Once we have completed the procedures that require fasting, we will give you breakfast at the clinic, and you can take your diabetes medication. Fasting means nothing by mouth but water and essential medications. We do encourage you to drink water, but in small sips. Avoiding large gulps and air in the stomach is important to obtain adequate results in some of the tests. If you have any concerns about fasting or your diabetes medication, we encourage you to contact your physician." Go to 2.

If NO: "Since your appointment is at [TIME], you should begin fasting the night before at [TIME]. Fasting means nothing by mouth but water and essential medications. We do encourage you to drink water, but in small sips. Avoiding large gulps and air in the stomach is important to obtain adequate results in some of the tests. You will be given a snack and lunch at the clinic." Go to 2.

2. 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. 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 4 (Closing).

3. Patient Safety Screening

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

4. Closing

"We look forward to seeing you tomorrow"

Appendix 1.F. HOME APPOINTMENT REMINDER

If talking with 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, need to have readily available physician information, and need to avoid smoking and vigorous physical activity.

"For this visit, we ask you to fast prior to the exam unless you are unable due to medical reasons. Do you take insulin or other medication for diabetes or have any other reason that you cannot fast for 8 hours?"

If YES:

"We would like for you to fast for 8 hours before the visit, <u>unless</u> your doctor has prescribed a bedtime snack, and to not take your morning insulin or other diabetic medication. After we complete the procedures that require fasting, you could have breakfast and take your diabetes medication. Fasting means nothing by mouth but water and essential medications. We do encourage you to drink water. If you have any concerns about fasting or your diabetes medication, we encourage you to contact your physician." Go to 2.

If NO and appointment in the morning:

"Since your appointment is at [TIME], you should begin fasting the night before at [TIME]. Fasting means nothing by mouth but water and essential medications. We do encourage you to drink plenty of water." Go to 2.

If NO and appointment in the afternoon:

"Since your appointment is at [TIME], we understand that it might not be possible to fast for 8 hours. In any case, we would like you to fast after breakfast. Fasting means nothing by mouth but water and essential medications. We do encourage you to drink plenty of water." Go to 2.

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

"We understand that fasting might be difficult in your situation. We encourage you to make arrangements with your caregivers, if possible. We will bring snacks for participants who are fasting."

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

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

Keep track of proxy/informant availability.

4. Closing

"We look forward to seeing you on [DATE]."

Appendix 1.G. PROXY/INFORMANT RECRUITMENT

Information collected as part of this call is collected in the Recruitment Tracking and Scheduling (RTS) Form.

1. "Hi, may I talk with [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 25 years. [HE/SHE] is interested in being involved in a new exam in the study and has provided your name as a proxy, 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.
- 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. SCHEDULING/RECRUITMENT FOR STAGES 2 AND 3

participants. In a few cases, selection to Stage 2 will require contact with an informant. In these cases, participant recruitment to Stages 2 and 3 will be done by phone.					
"Hello Mr./Mrs	My name is	As we explained you at			
the beginning of this visit, some ARIC participants are being selected for a second exam, which					
includes an examination of re	flexes, strength and movement,	an additional interview about your			
health, memory and aging, ar	nd a photograph of the back of yo	our eyes that can detect problems			
such as macular degeneration	n and changes due to diabetes o	or high blood pressure. You have			
been selected for this second	exam.				

Recruitment for Stages 2 and 3 will be done in the clinic at the end of Stage 1 for a majority of

This visit will take about 2 -2 ½ hours to complete. You will not need to fast for this visit but we will ask you to bring with you someone who knows you well. This person could be a spouse, relative, or friend."

If the participant already brought an exam proxy or informant for the clinic exam, this same person could be the informant for Stage 2 (provided that she or he knows the participant well).

"If you agree to participate in this additional exam, I would like to schedule it with you. If you cannot schedule the additional exam now, we can contact you later on the phone at a convenient time for you. Is there a day and time that would be best?"

- 1. If appointment is scheduled, record the date and time and give instructions to participant and tell them that you will be mailing the same instructions to their informant. If participant is unable to schedule appointment at this time because they need to discuss appointment time with the informant, ask participant for a date and time to call to schedule appointment.
- 2. If participant is unwilling to continue to Stages 2 and 3, ask the participant reasons for not participating:

"Is there a specific reason you are not willing to participate in this additional exam?"

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

- a. *Too busy* → This additional exam will be much shorter than the one you just participated. We can schedule it at the most convenient time for you. Additionally, you will benefit from receiving additional exams and a photography of the back of your eyes.
- b. Exam requires too much time → This additional exam is much shorter than the one you just completed. Already devoted 6 hours with Stage 1
- c. Not interested → Try to work out a way that it will work. Highlight importance of the information to be obtained from this study, that the participant will receive additional information about her/his health.
- d. Fearful of study procedures → Components of the second exam do not have any associated risks or discomfort. No blood will be drawn.
- e. Does not wish to bring an informant → Ask whether the informant can be contacted by phone even if he or she does not come to the field center.
- f. Does not have an informant → Ask about anyone, even a neighbor, who might provide some information about the participant.

- g. Distance already travelled for Stage I and cannot come back for Stage II → Try to accommodate the new exam on a date that will work for the study participant (for example, during a future trip to the field center area).
- h. Other list reason → Try to find a way that it will work.
- 3. If the participant agrees, recruitment can be close with the following sentence: "We look forward to seeing you again."

If the participant does not agree to participate: "We understand, and want to give you thanks for your participation in the ARIC study."

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

Forsyth County

Pamela Williams, Project Manager

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