

Recruitment Instructions for Imaging studies: PET, Sleep, MRI

Overview:

This document will describe the process by which recruitment scripts are selected given participants' eligibility for the various imaging ancillary studies. This document does not apply to recruitment or recruitment scripts for other ancillary studies beyond ARIC-PET, ARIC Sleep-PET, or the Wasserman MRI ancillary study.

ARIC-PET takes place at Washington County, Forsyth County, and Jackson, ARIC Sleep-PET at Washington County only, and the MRI study is at all four ARIC sites. Therefore, there are 3 potential imaging studies for Washington County, 2 for Forsyth and Jackson, and 1 for Minnesota.

There are 6 different recruitment scripts, depending on which of the 3 imaging studies participants are eligible for. It is important to note that a participant may be eligible for 2 or 3 studies, but depending on which part he/ she agrees to, they may not end up being included in all studies. The purpose of these different scripts is to allow one single script, and one single consent form, regardless of whether the participant is agreeing to 1, 2 or 3 studies.

As of 4/1/2017, unless otherwise specified, participants eligible only for Sleep and MRI will not be approached for inclusion in the Sleep study, but will only be approached for the MRI study.

Based on the DMS V6/V7 ancillary studies report (shown below), staff will be able to determine, therefore, which recruitment script should be used. The report can be run by selecting the boxes for PET, Sleep, and Vascular MRI. Attention should be paid to the columns labeled: MRI, Sleep, and PET. If "Eligible:No" is listed OR if nothing is listed (or if N/A is listed), the participant should be considered ineligible for that particular study. Recruitment scripts are selected based on the table below the screen shot from the report. For example, in the report screen shot below, (left-hand side with identifying information removed for this manual), the third listed participant (red box) will be contacted with Script F. *Please note: there is no specific script for participants only eligible for MRI and Sleep- these participants will be given the same script as participants only eligible for MRI (Script F).* For the fourth and seventh listed participant as shown (yellow box), Script A will be used. The blue box is used to give an example of someone in whom Script E should be used.

V6 appt Date	V6 Date	V5 MRI Date	PWV	MRI	Sleep	PET	eyeDOC	ICT Status
Jan 18, 2017	Jan 18, 2017			Eligible: No	Eligible: No		Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2
		May 17, 2012		Eligible: Yes	Eligible: Yes		Eligible: Yes	2
				Eligible: No	Eligible: Yes		Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2
				Eligible: No	Eligible: Yes		Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2
		Oct 23, 2013		Eligible: Yes	Eligible: No	Eligible: Yes	Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2
				Eligible: No	Eligible: No		Eligible: Yes	2

	MRI	Sleep	PET
Script A	no	yes	no
Script B	No	yes	yes
Script C	yes	yes	yes
Script D	No	no	yes
Script E	Yes	no	yes
Script F	yes	no	no
Script F	yes	(yes)	no

Once the appropriate script based on eligibility is selected, the specific QXQ for that script should be used.

ARIC imaging studies Script E:

	Sleep-PET	ARIC-PET	MRI Wasserman
Script A	yes	no	no
Script B	yes	yes	No
Script C	yes	yes	yes
Script D	no	yes	No
Script E	no	yes	Yes
Script F	no	no	yes

Hello, Mr./Mrs. _____, this is _____ from the ARIC Study at Johns Hopkins.

First, I would like to thank you again for your involvement in the ARIC study and for your most recent visit to the clinic. In addition, I would like to thank you specifically for your involvement in some of our prior brain imaging studies, through the main ARIC study and through the ARIC-PET study.

We are contacting all people who were in the ARIC-PET study before about another visit for this study. Is this a good time to discuss this additional study?

(If no, ask for another good time to call back; if yes, proceed with script)

(If yes:)

We will be collecting information about you during this phone call. Your taking part in this phone call is completely voluntary.

Your information collected on this call will only be seen by researchers at Johns Hopkins. We try to make sure that the information we collect from you is kept private and used only for the research study we are discussing. If you do not agree to continue the phone call, it will not affect your care at any of your local hospitals or at Johns Hopkins.

We are contacting people who are part of the ARIC and ARIC-PET study. To remind you, the ARIC study and the brain MRI study in ARIC, both of which you participated in, allowed us to study how risk factors for vascular disease, such as high blood pressure and smoking, might be associated with changes in your brain or blood vessels. The ARIC-PET study, which you also participated in, is being done to understand how these same risk factors might be associated with memory problems and changes that might contribute to Alzheimer's Disease. We are very appreciative of the time you have already spent being a part of these earlier ARIC research studies, and we think we can learn even more about how risk factors for vascular disease affect the brain, the brain blood vessels, and memory by repeating MRI and PET scans in people who were in these previous studies, which will allow us to study change in the brain and brain blood vessels.

In this study, we are asking approximately 315 people from three of the ARIC sites who were in ARIC-PET if they will come see us again for two types of brain imaging: a brain MRI and a special kind of brain imaging called a PET (positron emission tomography) scan. These are exactly the same as the brain MRI that you had previously in ARIC, and the PET scan you had previously in ARIC-PET. We're asking ARIC participants to have this scan to help us understand more about how risk factors for vascular disease might

be associated with memory problems and with changes in blood vessels in the brain. May I tell you more about this?

(if no, record response on ancillary study contact form, and read closing script A)

Closing Script A:

Thank you for your time, and we hope you will continue to participate in ARIC studies in the future. We will continue to keep your information private to the extent possible by applicable law. (also ask if contact on another day would be preferable, or determine reasons for refusal).

(if yes:)

As part of this study, there are two short imaging visits, both scheduled on days convenient for you.

First, I would like to describe the brain PET scan. This is a special kind of CT scan that uses a special radioactive injection, and then takes pictures of it in the brain to see if there is buildup of the protein that we think might cause Alzheimer's disease, just like you had before in the ARIC-PET study. If you are willing to participate in the study, we would ask you to meet us at the same PET imaging facility where you went for the prior study, where (I/ a member of our staff) would tell you about the study again, and you would undergo the PET scan. The staff at the imaging facility would put an IV in a vein in your arm, and then take special pictures. The procedure would take about an hour, with less than half of that time taking the pictures.

There are a few risks associated with having the PET scan, and we'd like you to know about them before you decide whether or not you want to participate. For instance, you will be exposed to radiation—it is a little more radiation than if you had a CT scan of your head. The injection, which is called Florbetapir F18, was approved by the Food and Drug Administration. It is used at very small doses, and has been used in thousands of people in ongoing studies with minimal side effects. Some of these side effects have included shoulder pain, nausea and anxiety, as well as headache in a small proportion of participants. None of these were deemed to be medically significant to the doctors involved in the studies done with Florbetapir.

You will be compensated \$75 for your involvement in the PET scan part of the study.

(Complete PET exclusion form, including scheduling date/ time of appointment if they agree.)

(Read the following script to everyone:)

In addition, we would like you to get a brain MRI scan, which is a kind of brain imaging that uses magnets to take pictures of your brain. You would need to lie still on your back for about an hour. Our staff would meet you at the facility for the MRI scan, which is the same place where you had a brain MRI scan before. The whole visit would take between one and a half and two hours. There are some risks associated with the brain MRI scan. If you have metal in your body, the magnets used for the MRI scan can cause problems with that metal; some of the questions we asked you earlier in this call were to make sure you don't have any metal that would be problematic. Other people report that the MRI scan makes them claustrophobic. You will be compensated between \$75 and \$100 for your involvement in the MRI part of the study, depending on how long of an MRI scan we need to do.

*(Complete MEF form, including scheduling date/ time of appointment if they agree)
(If refused both PET and MRI, read Closing Script A, above)*

(If agreed to either PET or MRI or both PET and MRI, read Closing Script B:)

Closing Script B:

Thank you.

We will send you a letter to confirm your involvement in the study and to send you directions of where your appointment(s) will be. We will also send you a copy of the consent form that you should review (but don't sign) before your visit. We will need you to sign another one for the whole study when you come to the imaging facility. We will continue to keep your information private to the extent possible by applicable law.