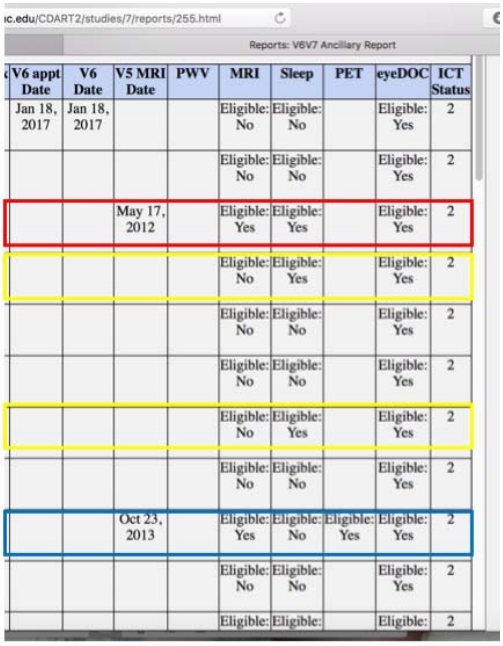
Recruitment Instructions for Imaging studies: PET, Sleep, MRI

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.


ic.edu/CDART2/studies/7/reports/255.html

Reports: V6V7 Ancillary Report

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:	Eligible:		Eligible:	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 A (WASHINGTON ONLY):

	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.

I am calling because there is another study that we would like to discuss with you. 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 study, and were also part of the Sleep Heart Health Study a number of years ago. We are working on a research study to learn more about how sleep and problems with sleep might be associated with memory problems.

In this study, we are asking approximately 200 people from the Washington County ARIC site who were in ARIC and in the Sleep Heart Health Study if they will come see us for a brief set of visits to undergo two types of brain imaging: a brain MRI and a special kind of brain imaging called a PET (positron emission tomography) scan. We would also like to repeat a sleep study, in your home, to evaluate how you are sleeping. We will also ask you some questions about your sleep and may ask you to fill out a sleep diary. We're asking ARIC participants to have this scan to help us understand more about how sleep patterns and sleep disturbances might be associated with memory problems. May I tell you more about this?

(if no, 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, read on:)*
As part of this study, there are two short imaging visits and a sleep study at your house, all scheduled on days convenient for you. The imaging visits include a brain MRI scan and a brain PET scan. If you are eligible in all parts of the study, and agree to participate, you will be compensated $200 for involvement in the MRI, PET and sleep part of the study.

First, 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 a half hour. Our staff would meet you at the facility for the MRI scan. The whole visit would take one to one and a half 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.

Before I go on to tell you more about the study, I would like to ask a few questions to be sure you would be eligible for this study.

(Read this script if they had exclusions in MRE or refused to participate)
Closing script B:
We will not be able to enroll you in this new study because of one of the responses you gave us. The personal health information that you have given us in this phone call will be kept in locked file cabinets and in password protected computer files. We will continue to keep your information private to the extent possible by applicable law. Thank you for your time and we hope that you will continue to participate in ARIC studies in the future.
(and then end script)

(Or, if no exclusions and no refusals):
In addition, on another day, we would like to get a 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. If you are willing to participate in the study, we would ask you to meet us at a PET imaging facility, 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. Now I will ask you some more questions to make sure that you are eligible for this part of the study.

(Please complete PRE form in CDART, but do not complete date/ time of appointment yet)
(Read Closing script B, above, if they had exclusions in PRE PET exclusion form or refused to participate).
(If No PRE PET exclusions, continue:)

In addition to these brain scans, similar to what you had done when you were in the Sleep Heart Health Study, we would like to schedule you for a sleep study, which can be done at your convenience in your home, or in a hotel if you would prefer that. Our staff will come to your home about an hour and a half before your usual bedtime, and connect the sleep study equipment, which will be very similar to what you wore when you had sleep studies as part of the Sleep Heart Health Study, many years ago. They would apply several electrodes (sensors) using sticky tape or paste to your scalp, face, chest, legs, and stomach that will monitor your sleep and breathing patterns. You would wear a nasal cannula (a flexible plastic tube with two prongs at the end) and a thermistor (thin wires with two small wire prongs) under your nose. You would also wear a sticky clip on your finger to measure your oxygen levels and heart activity, and two devices, called actigraphs, on your wrist. Actigraphs look like wristwatches and record movement. The main risk associated with having a sleep study done in your house is that this may disrupt your usual nighttime routine by having to be hooked up for the sleep study.

The next parts of the study are optional. This means that you can still be in the study I just described without agreeing to wear the devices I will describe in a moment. Remember that a moment ago, I mentioned that you would wear two actigraphs during the sleep study. They're similar to wristwatches, but they measure movement. In the optional part of the study, you would also wear these two devices outside of the sleep study.

One of the devices is called a Fitbit Charge HR which is for longer-term activity monitoring. The Fitbit provides detailed information on the number of steps you have taken and measures your heart rate. It also can tell you the time. You will be given instructions on how to charge the device every five days, or as needed, and to sync the device daily with your smartphone or your computer. You will be asked to wear the Fitbit for a period of 6 months. You would leave the Fitbit on all the time, except when you are bathing or swimming.

The other device is called Actigraph GT9X which is used for short-term monitoring (seven days and nights). There will be up to three different times during the study when you will be asked to wear the Actigraph. The first time will be at the time of MRI visit in this study. After that you will be asked to begin wearing the Actigraph at the time of your Sleep Study, and at your PET scan. Each time you will be asked to wear the Actigraph for seven (7) days and nights and to mail it back in between. The Actigraph is designed to be worn at all times during each of the seven day periods and removed only for bathing or swimming. You would be asked to complete a sleep diary, providing information about when you went to bed and got up for the day, when you napped and if you removed the device.

If you agree to participate, we will go over all of this information with you again in person and give you an opportunity to ask any questions that you may have. We will send you a copy of a consent form that you can look over at home before we review it in person with you. This form will provide you with even more details about what is known about the imaging agent, Florbetapir, and the MRI and PET scan and sleep study. We will ask you to sign a consent form before participating in the study. A few months after the study we will let you know if there were any abnormalities on your brain MRI scan or as part of your sleep study. If we find anything more urgent on your brain MRI or as part of your sleep study, we will let you know right away.

There is no benefit to you as a participant in this study, however your participation may help others in the future.

There is no cost to you for participating. As I mentioned before, you will be compensated $200 for involvement in the MRI, PET and sleep part of the study.

Also, if you participate in the optional part of the study with the activity watches, you could be given an additional $20.00 each time you wear the Actigraph for a maximum of $60.00, and if you complete the optional part of the study that uses the Fitbit, you will be able to keep the Fitbit when the study is over.

Do you have any questions?
(Go to SRE form, and complete)
(If response to "are you interested in participating in the study" is no, read Closing Script C)
Closing Script C:
We will not be able to enroll you in this new study because of one of the responses you gave us. 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.

(If response to "are you interested…" is yes, complete date/ time scheduling on Sleep form as well as MEF form and PET exclusion form"., then read Closing Script D below)

Closing Script D:
Thank you. We will send you a letter to confirm your involvement with details about the time of our visit; we will need to come to your house to get you set up for your sleep study several hours before your regular bedtime, and you will need to stay home for the evening after our visit. 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 we see you for the sleep study. We will continue to keep your information private to the extent possible by applicable law.

We will also send you a letter to confirm your involvement and to send you directions to the imaging facilities where the MRI and PET scans will take place. 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 MRI facility. We will continue to keep your information private to the extent possible by applicable law.

If you have any further questions about the study, please call _____/ARIC Study at _____.