



MRI RECRUITMENT AND ELIGIBILITY FORM

ID NUMBER:

FORM CODE:

DATE: 11/14/2016
Version 2.0

ADMINISTRATIVE INFORMATION

0a. Completion Date: / /
Month Day Year

0b. Staff ID:

0c. Study: (See QxQ for list of study codes)

0d Would you be interested in participating in this part of this study, as I've described?

Y Yes **GO TO ITEM 1**

N No

0d1. If no, why not? _____ **GO TO CLOSING SCRIPT**

1. Do you have a cardiac pacemaker or a defibrillator?

Y Yes **GO TO ITEM 11**

N No

2. Do you have artificial valves in your heart?

Y Yes

N No **GO TO ITEM 3**

a. MRI examinations are safe for some artificial heart valves, but not for others. Do you have a product card that tells what type of heart valve was implanted?

Y Yes

N No **GO TO ITEM 3**

b. Name of the heart valve on product card

s Starr-Edwards **GO TO ITEM 11**

o Other product

3. Do you have any metal in or near your head, spinal cord, eyes, or in your chest?

Y Yes **GO TO ITEM 11**

N No

4. Do you have any internal electrical devices, such as a cochlear implant, TENS stimulator (for pain), vagal nerve stimulator, brain stimulator, gastric pacemaker, bladder stimulator, or an implanted mechanical pump (such as an insulin pump or pain pump)?

Y Yes **GO TO ITEM 11**

N No

5. Do you weigh more than 350 pounds?

Y Yes **GO TO ITEM 11**

N No

6. Do you have permanent eyeliner?

Y Yes **GO TO ITEM 11**

N No

7. Have you had surgery for an aneurysm?

Y Yes

N No **GO TO ITEM 8**

7a. If yes, in what year? _____

8. Do you have surgically implanted dentures that use magnets?

Y Yes **GO TO ITEM 11**

N No

9. Has a physician told you that you should not have an MRI exam?

Y Yes **COMPLETE 9a, THEN GO TO ITEM 11**

N No

9a. What was the reason your physician told you?

10. Did you in the past or do you currently weld metal?

Y Yes

N No

11. [*For Staff:*] Did participant meet all eligibility criteria?

Y Yes

N No **GO TO CLOSING SCRIPT A**

CLOSING SCRIPT A (If participant does NOT meet all eligibility criteria):

“Unfortunately, we cannot ask you to participate in the MRI component of the study at this time.”

12. [For Staff:] Did participant agree to the study?

Y Yes

N No **COMPLETE 12a, THEN GO TO CLOSING SCRIPT B**

12a. If no, why not? _____

CLOSING SCRIPT B (for participants who decide NOT to participate):

Thank you for your time. → End of Form

13a. MRI Appointment date: //
Month Day Year

13b. MRI Appointment time: :
Hour Min



INSTRUCTIONS FOR THE MRI RECRUITMENT AND ELIGIBILITY FORM (MRE)

I. General Instructions

The MRI Recruitment and Eligibility Form is completed by the staff recruiting for MRI to track and document the status of each Eligible ARIC participant who is invited for the MRI and PET Study.

The form is opened and initiated when the recruitment process begins for a cohort participant. Ultimately, it is to be completed for all ARIC cohort and ACHIEVE participants who are eligible and for whom an attempt to give recruitment materials is made until recruitment goals are met. Only one record per invited participant is expected for this form. The form is NOT completed for participants not invited for MRI (i.e. for those for whom an attempt to give recruitment materials was not made). In cases where the participant could not be reached after numerous attempts or where the participant never explicitly stated whether or not they were interested in the study (item 0d), items 0a and 0b should be completed, and item 0d should be marked missing.

The purpose of the MRE is to allow field centers to track the scheduling status of invited participants, not to identify those who need to be recruited. Participants who are eligible to be recruited are identified using the 'Imaging Recruitment Report' or the ACHIEVE 'Randomization and MRI Status Report' available in CDART.

II. Detailed Instructions for Each Item

0a-0b. Record the completion date and the staff ID in these fields.

0c. Study Code is not required. Please ignore this item. It will not show up as a missing field.

0d. Record the participant's willingness to participate. If they do not wish to participate, record their reasoning in field **0d1**.

If attempts to invite a participant to take part in the MRI study were made, but contact was never established or the participant did not explicitly state whether or not they were interested (e.g., they asked for time to think about it, requested a phone call back, etc.), mark **0d** as missing. A notelog may be added to explain the situation.

1-10. Record the participant's responses to the eligibility questions.

For item 2, the only definite exclusion of heart valve types is the Starr-Edwards valve; other known heart valve types would not be exclusions. If the participant does not have the card for a heart valve, the form can then be completed as if the participant is eligible, but most MRI centers will require that this information be obtained and verified before the actual MRI appointment. Thus, there is a chance that someone will become ineligible despite seeming at the time of form completion to have been eligible.

For participants who answer 'Yes' to item 7 'Have you had surgery for an aneurysm?', assess if the participant had an MRI at Visit 5. Refer to the Recruitment Snapshot

Report in CDART for this information.

Then, if Yes to MRI at Visit 5 and the year recorded in 7a is BEFORE 2011, then the participant is eligible for MRI.

If Yes to MRI at Visit 5 and the year recorded is 2011 or LATER, then you will need to tell the participant that he or she might be eligible for the study, but you need to check with the MRI facility first. In addition, you should also contact the MRI study PI Bruce Wasserman for his input and advice.

If No to MRI at Visit 5, then you will need to tell the ppt that he or she might be eligible for the study, but you need to check with the MRI facility first.

If either of these is the case (no prior research brain MRI or MRI since 2011), ask the participant if he/she has the records of the type of aneurysm clip and record this information. In this event, Staff should proceed to complete the rest of the potential eligibility forms and discuss the other parts of the study, but a final determination about study inclusion likely will not be able to happen until this information is collected and reviewed with the MRI facility. If in doubt, tell the participant you will contact them about the MRI and the remaining parts of the study once the MRI decision is made.

For these participants discussed in item 7, as described above, with placement of an aneurysm clip since the last ARIC-NCS MRI or who did not get an MRI previously through the ARIC study, staff will need to call the MRI facility associated with your field center and verify if the participant is eligible, based on the make and year of placement of the aneurysm clip. If information is not available about the type of aneurysm clip for this group of participants, the participant (if in this category only) should be considered ineligible for MRI.

10. [This question is asked at Washington Co. only. Other sites may leave this item blank.] If the participant answers "yes" to this question, please ask the participant if they have had an MRI either as a research or clinical study since they last welded metal. If the answer is no, this should be considered an exclusion criterion for the MRI.

11. This item is for staff only. The response to #11 should be "no", and closing script A should be read if any of the following are true:

Any of questions 1, 3, 4, 5, 6, 8, OR 9 = yes
2a = no
2b = s (Starr-Edwards)

Then the staff should return to the next text in the recruitment script. If the participant had no affirmative responses to items 1-10, mark "Yes" for 11.

12. Record the participant's agreement to the study here. If they do not agree, record their reasoning in 12a and go to closing script B.

13a-b. These fields are for site staff to record appointment times for future participant MRI visits, for participants who have a "yes" for item 12 only.