



# MRI EXCLUSION FORM

ID NUMBER:

FORM CODE:

DATE: 06/01/2011  
Version 1.0

## ADMINISTRATIVE INFORMATION

0a. Completion Date: / /   
Month Day Year

0b. Staff ID:

**Instructions:** This MRI Exclusion form is completed at the end of Stage I if the participant is selected for Stage II.

**We would like to make an appointment for you to have a picture taken of your brain using an MRI machine. I will need to ask a few questions to make sure that you don't have any conditions that may interfere with the MRI. If you do not, we will be calling you over the next .... days about scheduling a time for your MRI.**

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

Y	Yes	→ MRI exclusion, go to END
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	→ MRI exclusion, go to END
O	Other product	

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

Y	Yes	→ MRI exclusion, go to END
N	No	

4. Do you 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 an insulin pump or pain pump)?

Y	Yes	→ MRI exclusion, go to END
N	No	

5. Have you had an operation or radiation therapy involving your skull or brain?

Y	Yes	→ MRI exclusion, go to END
N	No	

6. Have you ever had a cyst or tumor (benign or malignant) in the brain?

Y	Yes	→ MRI exclusion, go to END
N	No	

7. Have you ever had excess fluid buildup in the brain?

Y	Yes	→ MRI exclusion, go to END
N	No	

8. Do you weigh more than 350 pounds?

Y	Yes	→ MRI exclusion, go to END
N	No	

9. [*Women only*] Do you have permanent eyeliner?

Y	Yes	→ MRI exclusion, go to END
N	No	

10. Do you have aneurysm clips?

Y	Yes	→ MRI exclusion, go to END
N	No	

11. Do you have dentures that have been surgically implanted with magnets?

Y	Yes	→ MRI exclusion, go to END
N	No	

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

Y	Yes	
N	No	→ Go to closing script for those eligible

12a. What was the reason your physician told you?

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(go to ineligible script)

**END:**

Closing script for those eligible (no "Y" for any question) who agree to participate:

**“Thank you for agreeing to have an MRI. Mr./Ms. (name of ARIC interviewer) will be calling you on ...(approximate day)....at approximately .....(specific time).....to set up your appointment and to answer any questions you may have about the study.”**

Ineligible closing script:

**“Unfortunately, we cannot ask you to participate in the MRI component of the study at this time. You have already made an important contribution to the ARIC study and we thank you for your continued participation in ARIC”.**



## INSTRUCTIONS FOR THE MRI EXCLUSION FORM (MEF) FORM

### I. General Instructions

The MRI Exclusion Form determines the eligibility for the MRI procedure. It is administered by the Stage I examination staff subsequent to the participant having been selected for Stage II and updated by the staff person calling to schedule the MRI. When the MEF is re-administered, update the existing occurrence of the MEF in the data management system. Do not create a new occurrence.

The MRI Exclusion Form must be completed before a participant can be scheduled for the MRI. Participants who agree to participate and don't have a reason for exclusion must be scheduled for the clinic exam within 3 months of the completion of the MRI Exclusion Form. Once past this time window, the participant needs to be questioned again and the form updated for safety reasons.

### II. Detailed Instructions for Each Item

0a. Enter the date on which the participant was seen in the clinic.

0b. The person at the clinic who has completed this form must enter his/her code number in the boxes provided.

Slowly **READ** the following:

***“We would like to make an appointment for you to have a picture taken of your brain using an MRI machine. I will need to ask a few questions to make sure that you don't have any conditions that may interfere with the MRI. If you do not, we will be calling you over the next .... days about scheduling a time for your MRI.”***

1-9. Ask the participant questions 1-9 for exclusion criteria.

**Probe for unknown answers.** If there is any suspicion that any medical and physical exclusions criterion is met, record YES to the exclusion criteria questions, and the participant should be excluded.

As soon as ANY exclusion criterion is met, please read the ineligible closing script (next page of these QxQs).

1. Ask “Do you have a cardiac pacemaker or a defibrillator?” If yes, read the ineligible closing script. Note that this item refers to an implanted pacemaker or an implanted defibrillator.
2. Ask “Do you have artificial valves in your heart?” If yes, read “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?” If yes, request that the participant locate the card so that he/she is able to read the name of the heart valve over the phone when an ARIC staff person calls to schedule the MRI. If the valve is a Starr-Edwards, read the ineligible closing script. If the valve is a different product, proceed with the rest of the exclusion criteria. If the participant does not know the valve type and does not have a product card, read the ineligible closing script.

3. Ask "Do you have any metal in or near your head, spinal cord, eyes, or in your chest?" If the participant asks for clarification, mention that in this case "metal" includes surgical clips, metal wires, implants, fragments resulting from a war injury or work accident, if they are in or near the head, spinal cord, eyes or inside the chest. Stents used in angioplasty are not considered "metal" for purposes of this question.

If the participant answers Yes without asking for clarification, ask about the nature of the metal and its location. If the metal corresponds to any of the items listed above and is located in or near the head, spinal cord, eyes, or inside the chest, read the ineligible closing script.

During this interview you may encounter references to different kinds of surgical interventions and types of metallic devices. The most common of these are addressed below.

#### Surgical interventions and types of metallic devices.

Metallic Sutures. Metal fragments in the lungs or around the heart exclude a person from doing an MRI for this study. By contrast, wire sutures or staples in the chest wall or breastbone as used during surgery such as a coronary bypass graft, do not exclude a person from an MRI exam for this study. These metallic sutures are also called "manubrial sutures" or "sternal sutures" and are MRI-safe. The answer should be marked as "NO" and a notelog entered explaining the type of metal. The MRI technologist should be informed if a participant has such sutures or staples, since they should explain to the participant that these sutures could occasionally heat up during the MRI exam. If that is the case the participant should alert the technologist that he/she feels this sensation in their chest wall.

Aortic Aneurysms. Aortic aneurysms (or ballooning of the aorta), whether abdominal or thoracic are not a reason for exclusion from MRI. Aortic aneurysm repairs are grafts that are sutured to the artery walls; no metal clips are used for this, nor any metallic sutures. The answer should be marked as "NO."

By contrast, repairs to an aneurysm in the brain **always** are exclusions for MRI. These are usually "clipped" at the base with metal, and there is no safe way to determine whether the clips used are ferromagnetic or safe for an MRI. Thus, any aneurysm repair in the head is a MRI exclusion as a matter of safety, even if the surgeon has used non-ferromagnetic clips. Aneurysms of the aorta on the other hand, repaired or otherwise, are safe for an MRI exam, whether they are in the abdomen or in the chest.

Metal in Bones. Metal screws, rods, or plates are often used in orthopedic surgery. These are securely anchored in the bony structures and considered to be safe for an MRI exam. The answer should be marked as "NO" and a notelog entered explaining the type of metal. Feel free to consult with the local radiologist or PI if you have a question whether such metal could distort the carotid artery images or otherwise cause a problem. It is important to note that the term "spinal cord" refers to the nerves (soft tissue) inside the spinal canal and not to the vertebrae or bones that make up the spine.

Angioplasty or Stenting. Having had a balloon angioplasty of the coronary (heart) or carotid (neck) arteries - with or without stents placed to open the arteries – or a wire mesh placed in a vein is not a reason for exclusion from MRI.

Coronary Bypass Surgery. Having had a coronary bypass operation does not automatically exclude a person from having an MRI exam but we must take precautions to avoid placing the participant at risk if they take part in this study. Although we do not ask about coronary bypass operation, participants are likely to bring this up. If the participant mentions having had a coronary artery bypass (graft) operation (CABG), let the participant know that a coronary bypass surgery is not by itself a reason to be excluded from an MRI exam and ask if a physician has told this person that s/he should not have an MRI exam. If that is the case we will not invite this person to have an MRI, regardless of the reason for such a statement by the physician. In sum: if a participant reports having had a CABG operation mention the following:

***“Having had a coronary bypass operation is not a reason to be excluded from an MRI exam unless a physician has indicated that an MRI exam should not be done. Has a physician told you that you should not have an MRI exam?”***

If the person being interviewed has had coronary bypass surgery and is unsure whether s/he can have an MRI exam and seems concerned about the safety of the MRI, suggest that s/he contact his/her personal physician or cardiologist to find out if an MRI exam can be done in their case.

For the interviewer’s information: During coronary bypass surgery “pacer wires” or “lead wires” are commonly placed between the chest wall and the heart. These are almost invariably removed shortly after surgery, but sometimes left in place by the surgeon. These wires are not visible but the participant’s physician may know that s/he has them inside their chest, and can determine this from a chest X ray (these are typically taken after coronary bypass surgery). Having these wires in place does exclude a person from an MRI exam. ARIC staff can learn more about the risks associated with an MRI exam at [www.mrisafety.com](http://www.mrisafety.com) or [www.imrser.org](http://www.imrser.org). ARIC study personnel should keep in mind that these websites consider safety from the perspective of clinical studies that have a medical indication for an MRI examination. Because our MRI exams are done for research purposes, our exclusion standards are more stringent since an MRI exam is not considered to offer a benefit to the study participant and must not expose the participant to more than minimal risk.

4. Ask “Do you have any internal electrical devices, such as a cochlear implant, a TENS stimulator (for pain), or an implanted mechanical pump?” If yes, read the ineligible closing script.
5. Ask “Have you had an operation or radiation therapy involving your skull or brain?” If yes, read the ineligible closing script.
6. Ask “Have you ever had a cyst or tumor (benign or malignant) in the brain?” If yes, read the ineligible closing script.
7. Ask “Have you ever had excess fluid buildup in the brain?” If yes, read the ineligible closing script.
8. Ask “Do you weigh more than 350 pounds?” If yes, read the ineligible closing script.
9. Ask this only of women and enter “N” for men: “Do you have permanent eyeliner?” If yes, read the ineligible closing script.

Note: This question refers to a cosmetic tattoo applied to the eyelids, which can cause discomfort during an MRI examination.

If the participant passes all criteria (eligible) and agrees to have an MRI, **READ** the eligible and agrees to participate closing scripts. Otherwise, READ the ineligible closing scripts.

Note: Eligibility determined here expires within 3 months. If a clinic exam is not scheduled within 3 months, the MRI Exclusion Form must be re-administered for safety reasons. If this occurs, the date of form collection should be changed and exclusions updated if necessary.

Closing script for those eligible who agree to participate:

***“Thank you for agreeing to have an MRI. Mr./Ms. (name of ARIC interviewer) will be calling you on ...(approximate day)....at approximately .....(specific time).....to set up your appointment and to answer any questions you may have about the study.”***

Ineligible closing script:

***“Unfortunately, we cannot ask you to participate in the MRI component of the study at this time. You have already made an important contribution to the ARIC study and we thank you for your continued participation in ARIC”.***