Cerebral Magnetic Resonance Imaging for Stroke Risk Factors in the Atherosclerosis Risk in Communities (ARIC) Study

I have been invited to participate in a research study on the relationship between risk factors for stroke and the results of a type of brain scan known as magnetic resonance imaging (MRI). About 2000 men and women who are participating in the Atherosclerosis Risk in Communities (ARIC) study will have this procedure.

I understand that the MRI exam involves lying on a table inside of a large scanning device that will take pictures of my head using magnetic fields. The MRI device does not use ionizing radiation (such as x-rays), and is not known to have any significant risks. No blood will be drawn and no dye will be injected into my veins for this procedure. There is no physical pain. The study will require that I remain still for about 20 minutes so that the pictures can be made. Because the MRI machine is noisy, I understand that I must wear ear plugs or earphones. These will reduce any discomfort and any risk to my hearing. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (claustrophobia).

I am not pregnant; have not had prior surgery for an aneurysm (bulging of a large blood vessel due to a weakness of its wall) in my body or head; do not have metal fragments in my eyes, brain or spinal cord; do not have a cardiac pacemaker or a heart valve prothesis; and do not have any internal electrical devices, such as a cackler implant or spinal cord stimulator.

There will be no costs to me as a result of my participation in this study, and I will receive $50.00 (fifty dollars) as monetary compensation for the additional time this exam takes beyond my regular ARIC visit.

I understand that the use of the MRI scan will not replace any other diagnostic procedure which might be of benefit to my health. I am aware that I may refuse to have an MRI, and may withdraw from this study at any time. Neither failure to join or withdrawal from this study will affect the availability of my medical care at Bowman Gray School of Medicine.
The ARIC study does not provide diagnosis, medical advice or treatment to participants. During the course of this study, if an abnormality is found on the MRI scan which requires medical follow-up, my personal physician and I will be informed.

If an injury or illness occurs as a direct result of my participation in this study, Bowman Gray School of Medicine will pay for medical treatment reasonably necessary to treat that injury or illness. No other compensation is available.

This study has been approved by the Institutional Review Board of this institution.

Further information about the study or my participation in it is available from the investigator(s), Dr. Fred Romm or Jeannette Bensen at (919) 777-3040.

I understand that my medical records will be confidential, but that they may be reviewed by representatives of the National Heart, Lung and Blood Institute which has funded this study. I understand that my identity will be kept confidential in any publication or public disclosure of the information resulting from this study.

I have been given the opportunity to ask questions about this procedure and have received answers that I understand. This study has been explained to me to my satisfaction and I agree to participate.

Participant's signature Date

Participant's name

Person informing participant Date

Witness Date

INSTRUCTION FOR AN MRI SCAN

WHAT AN MRI SCAN IS:

THIS EXAMINATION, CALLED AN MRI (MAGNETIC RESONANCE IMAGING) SCAN, USES MAGNETIC AND LOW ENERGY RADIO WAVES TO PRODUCE A SERIES OF PICTURES OF YOUR HEAD. IT DOES NOT USE ANY X-RAYS, RADIOACTIVE MATERIALS OR ANY FORM OF IONIZING RADIATION. IT, TO THE BEST OF OUR KNOWLEDGE, PRODUCES NO HARMFUL SIDE EFFECTS OR UNPLEASANT SENSATIONS. IT WILL BE ADMINISTERED BY A TECHNOLOGIST TRAINED IN ITS USE.

PREPARATION:

NO PREPARATION IS NECESSARY TO PERFORM AN MRI SCAN. THE EXAM IS NOT AFFECTED BY ANYTHING YOU MAY HAVE EATEN, DRUNK OR ANY MEDICATION YOU MAY HAVE TAKEN.

PRECAUTIONS:

THE PRESENCE OF ANY METALLIC OBJECTS EITHER ON YOUR PERSON, CLOTHING OR IN YOUR BODY MAY INTERFERE WITH THE SCAN. BEFORE THE SCAN IS DONE, THE TECHNOLOGIST WILL ASK YOU TO REMOVE ALL JEWELRY, WATCHES, HAIRPINS, (GLASSES, WALLETS AND THE LIKE, AND CHANGE INTO HOSPITAL GOWNS. IMPORTANT: IF YOU HAVE UNDERGONE SURGERY ON YOUR HEAD OR BRAIN FOR WHICH INTERNAL METAL CLIPS MAY HAVE BEEN LEFT IN PLACE, PLEASE TELL THE TECHNOLOGIST ABOUT THIS BEFORE GETTING ON THE SCANNING TABLE. ALSO, PLEASE TELL THE TECHNOLOGIST IF YOU HAVE A CARDIAC PACEMAKER OR ARTIFICIAL METALLIC JOINT.

WHAT HAPPENS DURING AN MRI SCAN:

AFTER YOU HAVE CHANGED INTO HOSPITAL GOWNS AND REMOVED ALL METAL OBJECTS, THE TECHNOLOGIST WILL POSITION YOU ON A SPECIAL TABLE. YOUR HEAD WILL BE PLACED IN A Padded PLASTIC CRADLE OR ON A PILLOW, AND THE TABLE WILL THEN SLIDE INTO THE SCANNER. IT WILL SEEM AS THOUGH YOU ARE BEING ROLLED INTO A LONG TUNNEL.

OUTSIDE THE SCANNER TUNNEL SURROUNDING YOUR HEAD AND BODY, THERE IS A LARGE MAGNET WITH A RADIO TRANSMITTER AND RECEIVER. INFORMATION FROM THESE INSTRUMENTS IS ACCUMULATED AND FED INTO A COMPUTER. THE COMPUTER THEN PRODUCES A SERIES OF PICTURES OF YOUR HEAD.

WHILE THE MACHINE IS TAKING YOUR PICTURES, YOU WILL HEAR REPEATING, LOUD THUMPING NOISES COMING FROM THE WALLS OF THE SCANNER. THEREFORE EARPLUGS WILL BE PROVIDED. ANY MOVEMENT, ESPECIALLY OF YOUR HEAD OR BACK (EVEN MOVING YOUR JAW TO TALK) DURING THIS TIME WILL SERIOUSLY BLUR THE PICTURES. DURING THE SCANNING, YOU SHOULD BREATHE QUIETLY AND NORMALLY BUT OTHERWISE REFRAIN FROM ANY MOVEMENT, COUGHING OR WIGGLING. WHEN THE THUMPING NOISE STOPS, THE PICTURES WILL BE PROCESSING AND YOU MAY RELAX FOR A FEW MINUTES, BUT YOU MUST REFRAIN FROM CHANGING YOUR POSITION OR MOVING ABOUT. THE ENTIRE EXAM ORDINARILY TAKES APPROXIMATELY 25 MINUTES.
### Atherosclerosis Risk in Communities (ARIC) MRI Procedure Form

**ID NUMBER:** 

**CONTACT YEAR:** 

**FORM CODE:** MPR  

**VERSION:** A 04-06-93

**LAST NAME:** 

**INITIALS:** 

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**INSTRUCTIONS:** This form should be completed on paper during the participant's visit. ID Number, Contact Year, and Name must be entered above. Whenever numerical responses are required, enter the number so that the last digit appears in the rightmost box. Enter leading zeroes where necessary to fill all boxes. If a number is entered incorrectly, mark through the incorrect entry with an "X". Code the correct entry clearly above the incorrect entry. For "multiple choice" and "yes/no" type questions, circle the letter corresponding to the most appropriate response. If a letter is circled incorrectly, mark through it with an "X" and circle the correct response.

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<table>
<thead>
<tr>
<th>Status of MRI procedure:</th>
<th>3.a. Reason for incomplete MRI:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Go to Item 3b.</td>
<td>Completed C</td>
</tr>
<tr>
<td>Attempted, incomplete I</td>
<td></td>
</tr>
<tr>
<td>Not attempted N</td>
<td></td>
</tr>
<tr>
<td>Go to Item 3a.</td>
<td>Claustrophobia C</td>
</tr>
<tr>
<td>Other (Specify) D</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Specify: ____________________________</td>
</tr>
</tbody>
</table>

2. The reason MRI was not attempted:  

<table>
<thead>
<tr>
<th>No show</th>
<th>Rescheduled</th>
<th>Refused to sign informed consent form</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>B</td>
<td>C</td>
</tr>
</tbody>
</table>

Refused for other reasons (specify) E 

Specify: ____________________________

3. Date MRI attempted or completed:  

<table>
<thead>
<tr>
<th>M</th>
<th>M</th>
<th>D</th>
<th>D</th>
<th>Y</th>
<th>Y</th>
</tr>
</thead>
</table>

GO TO ITEM 7, SCREEN 2.

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5. Was oblique axial scan parallel to the AC/PC line? ........... Yes Y  
           No N

6.a. Were any emergent alert conditions noted? .... Yes Y  
           No N

6.b. Specify the alert condition:

6.c. Who was notified of this alert?

6.d. Date of alert notification:

    M M D D Y Y

7. MRI Technologist initials:

8. Date of data collection:

    M M D D Y Y

TO BE COMPLETED BY MRI READING CENTER:

Tape Number:  
Date Received:  
             M M D D Y Y

Date Archived:  
                 M M D D Y Y

Date of dBase Entry:  
                M M D D Y Y

INSTRUCTIONS FOR THE MRI PROCEDURE FORM
MPR, VERSION A: 04-06-93
PREPARED 10-14-93

The MRI Procedure Form (MPR) is completed by the MRI technologist during the course of the MRI scan. The primary purposes of the form are to record whether the scan was completed, document the reasons for not attempting or completing the scan, record the scanning pulse sequence, verify that the oblique axial scan was taken parallel to the AC/PC line, document the presence of any emergent alert conditions, who was notified of this condition and the date of notification.

The questionnaire is completed by the MRI technologist at the MRI center at different stages during the procedure. A form is completed for every participant who is scheduled for an MRI by the field center, regardless of whether the MRI Center Informed Consent document is signed or the scan is initiated and prematurely terminated.

The MRI Procedure Form is collected using the paper version of the form. No questions are read to the participant. If a response needs to be changed after it has been entered, an 'X' is placed over the incorrect numeric or multiple choice response. For numeric entries, the correct response is clearly written above the incorrect entry. For 'multiple choice' and 'yes/no' responses, the correct response is circled. If there is additional information (for which there is no data entry field) that could be of use to staff at the field center or the MRI reading center, write it on the form. This information, however, will not become part of the database.

1. The completion status of the MRI scan is entered once the technologist is certain of its status. This can be done either at the beginning of the procedure and corrected as required at the end of the study or completed at the end of the procedure, at the discretion of the technologist.

   If the scan is not attempted, enter 'N' and the reason for not doing the scan in Item 2.

   If the scan is started and prematurely terminated, enter 'I'. The reason for not completing the scan is entered in Item 3.a and the date on which it was performed is entered in Item 3.b.

   If the scan is started and completed, enter 'C' and the scan date in Item 3.b, leaving the intervening items blank.

2. Item 2 is completed when the scan is not attempted. Several common reasons for not attempting the scan are available as response categories. Select only one. If more than one response category applies, or if there is another reason, select OTHER, and enter the reason in the space provided. Complete the...
administrative data (Items 7 and 8) at the end of the form. Send the form to the ARIC field center.

3a. Enter the reason the scan was not completed, selecting claustrophobia (C) or other (O). If there are multiple reasons, including claustrophobia, select 'C' in preference to the other reasons. If the scan was not completed for a reason other than claustrophobia, select 'O' and enter the reason in the space provided (SPECIFY).

3b. Enter the date on which the scan is performed regardless of whether the scan is terminated prior to completion or the scan is completed, using the standard date format.

When the scan is terminated prior to the collection of any data, leave Items 4-6 blank and go to Item 7. When the scan includes some data, continue with Item 4.

4. Record in the three boxes the sequence in which the scanning pulses are performed. If all series were completed in order, enter 1, 2, 3. If one or more of the series is not completed or one or more of the standard series are repeated, enter 4 in the appropriate box and record the final pulse sequence on the line below.

5. Indicate whether the oblique axial scan was done parallel to the AC/PC line.

6. Record the presence or absence of any emergent alert conditions, as defined in the MRI protocol. If none are present (NO), go to Item 7. If YES, specify the alert condition in Item 6.b, record the name of the neuroradiologist who reviews the possible alert condition, and record the date on which the field center is notified of the alert condition.

If the MRI radiologist does not feel the condition observed on the scan warrants alert status, correct 6.a, 6.b and 6.c.

7. Enter the MRI technologist’s initials.

8. Enter the date on which the form is completed.