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# CARDIOVASCULAR HEALTH STUDY

## FIELD CENTER

## MAGNETIC RESONANCE IMAGING

## MANUAL OF OPERATIONS

NOVEMBER 1, 1991

300 finished 4/92? is it worth reporting on them or wait for n = 4,000?

in total n = 5,000 or 4,000

Mag a 0.15 T @ Hagerstown

What information do we have about brainstem strokes eg. localization

MR prescan interviews examinations, are they routine

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## 1. BACKGROUND, RATIONALE & GOALS

The purpose of the CHS MR Reading Center is to perform readings on approximately 4,000 participant MRI exams in the multicenter longitudinal study entitled "Cardiovascular Health Study" (CHS). The CHS is involved with identifying risk factors for heart disease and stroke in persons aged 65 and older. The participants will have the MRI exams at one of four designated CHS Field Centers. The feasibility study consisting of 300 participants will be conducted from November 1, 1991 to end Feb 28, 1992. The main trial consists of 4,000 MRI studies to be completed over a two-year period beginning June 1992. The MRI Reading Center will assist in protocol development for cerebral MRI and will perform interpretations of these images in a standarized and reproducible manner.

During the conduct of CHS, it became clear that stroke detected by clinical examination was too infrequent to permit assessments of some stroke risk factors within the contract period. The NHLBI proposes to improve detection rates for stroke risk factor correlation within the contract period. The NHLBI has added cerebral magnetic resonance imaging (MRI) to the CHS follow-up examination.

### I. Objectives

The first major task will be to implement and supervise an MR Research Design/Feasibility Study for the evaluation of cerebrovascular disease in 330 CHS subjects. Based on the results of this pilot project, a CHS MR Committee, including representatives from the RC, will then finalize the CHS cerebrovascular disease MR Scanning and Analysis Protocol. MR exams, as detailed within this protocol, will then be performed on 4000 CHS participants.

These data will be the basis for testing a number of hypotheses about the relationship between current CHS clinical descriptors of cerebrovascular disease and the criteria of cerebrovascular disease as identified by MR. That is, CHS has identified a number of clinical descriptors of stroke for which data have been obtained. A representative sample of those CHS clinical descriptors is listed below. We propose to measure a number of MR variables of stroke, also listed below, which can be correlated with the CHS clinical parameters.

| CHS Clinical Descriptors of Stroke | MR Variables of Stroke |
|---|---|
| Type of Stroke | |
| Ischemic | Ischemic |
| Major vessel | Major vessel |
| Lacunar | Lacunar |
| Hemorrhagic | Hemorrhagic |
| TIA | SWMD |
| | Number |
| | Size |
| | Location (by same criteria as clinical descriptors) |

The ability to perform these correlations between current CHS measures of cerebrovascular disease and MR measures of cerebrovascular disease is key to our overall goals, which are as follows:

Goals

1. To assess the MR findings associated with various types of clinically apparent cerebrovascular disease including major vessel and lacunar stroke, TIA, dementia and other evidence of cognitive decline.

2. To determine the associations between established and hypothesized cardiovascular risk factors, subclinical evidence of cerebrovascular disease and clinical and MR evidence of cerebrovascular disease including major vessel stroke, lacunar infarction and dementia and other evidence of cognitive decline.

3. To characterize the natural history of MR signal changes in the elderly as a function of clinical and subclinical evidence of cerebrovascular disease, as well as risk factors for the disease.

4. To determine the correlations between MR criteria of cerebrovascular disease and cognitive function.

5. To assess the positive and negative predictive values of MR criteria of cerebrovascular disease to the future incidence of clinical cerebrovascular disease, including consequent cognitive decline and dementia.

## 2. MRI EQUIPMENT

The following are the Field Center MR Instruments to be used in the CHS MR study.

| | |
|---|---|
| 1. Hagerstown | Toshiba 0.35 T |
| 2. Bowman Gray | GE Signa 1.5 T or Picker 1.5 T |
| 3. Sacramento | GE Signa 1.5 T |
| 4. Pittsburgh | GE Signa 1.5 T |

Any changes in imaging equipment at the Field Centers must receive prior approval from both CHS and the MR Reading Center.

## 3. MRI FC PERSONNEL

### A. FC CHS NEURORADIOLOGIST

At each of the four field centers there is a designated neuroradiologist. This person is responsible for the performance of MRI's at his/her CHS Field Center. The CHS neuroradiologist should monitor the study closely to insure adherence to MRI imaging protocol, including proper handling of alerts, and maintenance of appropriate quality control of the CHS studies and MRI imaging equipment. THe CHS MRI neuroradiologists should also supervise the CHS technologist and provide all training needed to perform the imaging protocol.

### B. QUALIFICATIONS FOR FC MRI TECHNOLOGISTS

Field Center MRI technologists should have appropriate knowledge of cross-sectional anatomy, physiology, and pathologic processes with emphasis on neurologic imaging. The preferred level of education is completion of a two year AMA approved program for diagnostic imaging and a minimum of 3 to 6 months MRI experience. The technologist should have a basic knowledge of MRI and/or knowledge of computer software applications, multi-format cameras, processors and video recording devices.

In addition to the above education and MRI experience, the CHS MRI technologist must have a complete understanding of the MRI CHS Imaging Protocol. This requires training to identify the anatomical location of the AC/PC Line and implementation of the CHS MRI pulse sequences. The MRI technologist should also be trained and competent to recognize a CHS alert.

## 4. PARTICIPANT PRELIMINARIES

### A. CONTACTING PARTICIPANT

Lists of participant ID numbers for the initial sample of cases and controls will be sent from the CC to the FC. The FC will then begin to contact cases to invite them to participate in the MRI pilot study. The two controls who are matched to an individual case should not be contacted until the case has completed his/her MRI scan.

The initial contact for the MRI study will consist of a telephone call from the FC to the participant. The interviewer will first ask a series of questions to determine whether the participant is eligible for an MRI. (See Attachment 1, MRI Exclusion Questionnaire) If a participant answers "Yes" to one or more of questions 2-5 on the Exclusion questionnaire, the participant is not eligible for an MRI. The participant will be thanked and the interview ended.

If the participant is eligible for MRI, the interviewer will give a brief explanation of MRI and then invite the participant to enter the MRI study (see Attachment 2, script). If the participant is willing, the interviewer will then give a more complete explanation of the MRI procedure. The interviewer will instruct the participant that there are no requirements to abstain from food or drink prior to the MRI scan, but that the participant should avoid wearing jewelry or metal objects. In addition, the participant may invite a family member or friend to be present during the exam. To further increase participation, interviewers may set appointments for the participant to view a demonstration of the equipment and scanning.

Educating the participant regarding the MRI exam during this initial telephone call should expedite the process for the MR technologist at the time of the study.

After the telephone call has been completed, the Data Manager will enter the MRI Exclusion Questionnaire into the computer. This will be e-mailed to the CC each week with the regular weekly data transmission. The Field Center will mail an Appointment Form (Attachment 3) to the participant containing information about the MRI appointment and procedure.

Scheduling -- During the feasibility study 300 cases must be scanned and sent to the MRI RC. This requires accrual of 75 participants from each FC. Potential conflicts in scanning time may arise at the FC, and it is suggested that these exams be evenly spaced over the 4 month trial.

## B. DAY OF MRI APPOINTMENT

At the beginning of the participant's MRI appointment, the participant will meet with a FC CHS technician. The technician will review the Informed Consent with the participant (Attachment 4), and his/her signature will be obtained. The MRI Pre-exam Interview and Examination (Attachment 5) will also be completed, and the exclusion questions will be asked again. After completion of these procedures, the CHS technician will escort the participant to the MRI imaging area for the actual scan.

## C. PARTICIPANT PREPARATION AND INSTRUCTIONS

The MRI technologist should again explain the procedure for the study and answer any questions. The participant should be instructed to remove any metalic objects, including jewelry, dentures, hearing aids, hairpins, etc. and secure all items in the patients locker. The technologist should explain to the participant that the exam will take approximately 30 minutes. The participant should be instructed that there are microphones to communicate with the technologist and that the exam may be stopped at any time. The participant should be told that movement, and/or speaking during the exam will cause the images to be less than optimal, and if at all possible to refrain from such activity during the scan. Prior to bringing the participant into the scan room, the technologist should be certain that all equipment necessary for the exam is readily available. The technologist should escort the participant into the scanning room and offer assistance getting on to the scanning table. The participant should be instructed that the table will be moved. After the participant is comfortably positioned on the table, the technologist should explain that positioning aids will be placed along the sides of the head to help them hold still, and a helmet-like apparatus will be placed about their head. The longitudinal localizing light should align the mid-sagittal plane. The participant will be asked to close their eyes to align the transverse light. This light should be aligned along the lids of the eyes. Remind the participant to refrain from movement during the exam, adjust the head coil, advance the participant into the magnet and enter all the necessary information into the system.

## 5. SCANNING OF THE CHS MRI PARTICIPANT

### A. MRI SCANNING PROTOCOL

The MRI scanning protocol should be followed absolutely. If the FC needs to revise the protocol due to modifications in equipment or software, the revised protocol must be approved by the MRC PI prior to scanning a CHS participant.

**Scanning Pulse Sequences**

Scanning pulse sequences should be performed in the following order:

1. Series 1 - T1W Sagittal localizing scan

2. Series 2 - Oblique Axial Spin Density/ T2-weighted images from the vertex to skull base.

3. Series 3 - Oblique Axial T1-weighted images matching slice positions in Series 2.

Upon reviewing scans, if extensive artifacts are evident on images, please repeat the sequence once if possible. Series #2 must be completed for interpretation purposes. If for some reason, series 2 is not completed, do not send this study to the MRI Reading Center. Although it is up to the individual Field Center whether to perform additional sequences, the only information on the magnetic tape sent to the RC should be this CHS protocol. It is also up to the individual Field Center whether they decide to "hard copy" these studies on film. The MRI Reading Center only requires the study on magnetic tape.

**CHS MRI Imaging Protocol**

| | | |
|---|---|---|
| Series 1 | - | Sagittal T1-weighted localizing scan used to identify AC/PC line, TR 500 (400-600), TE 20 (<35), 5 mm, 0 gap, 128 x 256 matrix, 1 nex, images centered to midline. |
| Series 2 | - | Angled (Parallel to AC/PC line) axial spin density SD/T2-weighted scans, TR 3000 (>2500), TE 30,100 (<35/>75), flow comp, 5 mm, 0 gap, 256 x 192 matrix, 1/2 nex, (1 nex on less than 1T scanners), images obtained from vertex to skull base. |
| Series 3 | - | Angled (Parallel to AC/PC line) axial T1- weighted scans TR 500 (400-600), TE 20 (<35), 5 mm, 0 gap, 256 x 192 matrix, 1 nex (2 nex on less than 1T scanners), cover vertex to skull base. The slice positions on series 2 and 3 should match. |

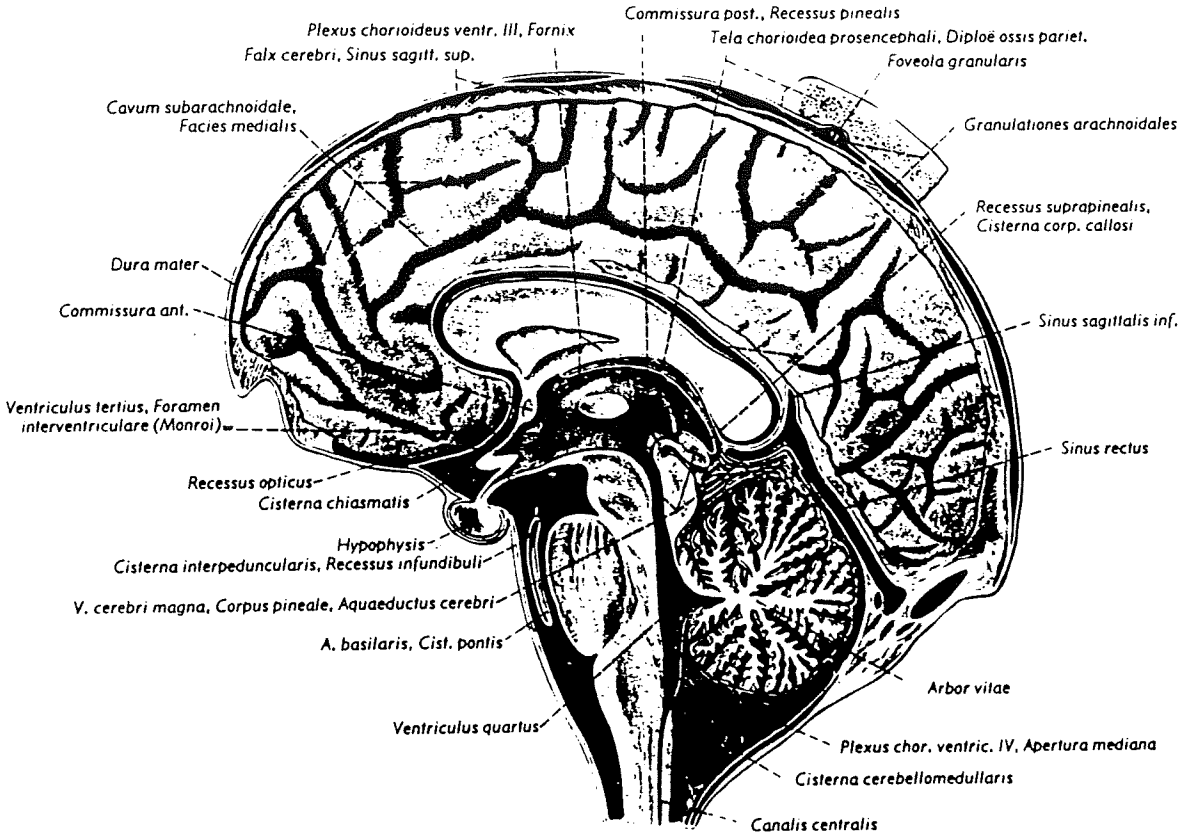
## Localization of AC/PC Line

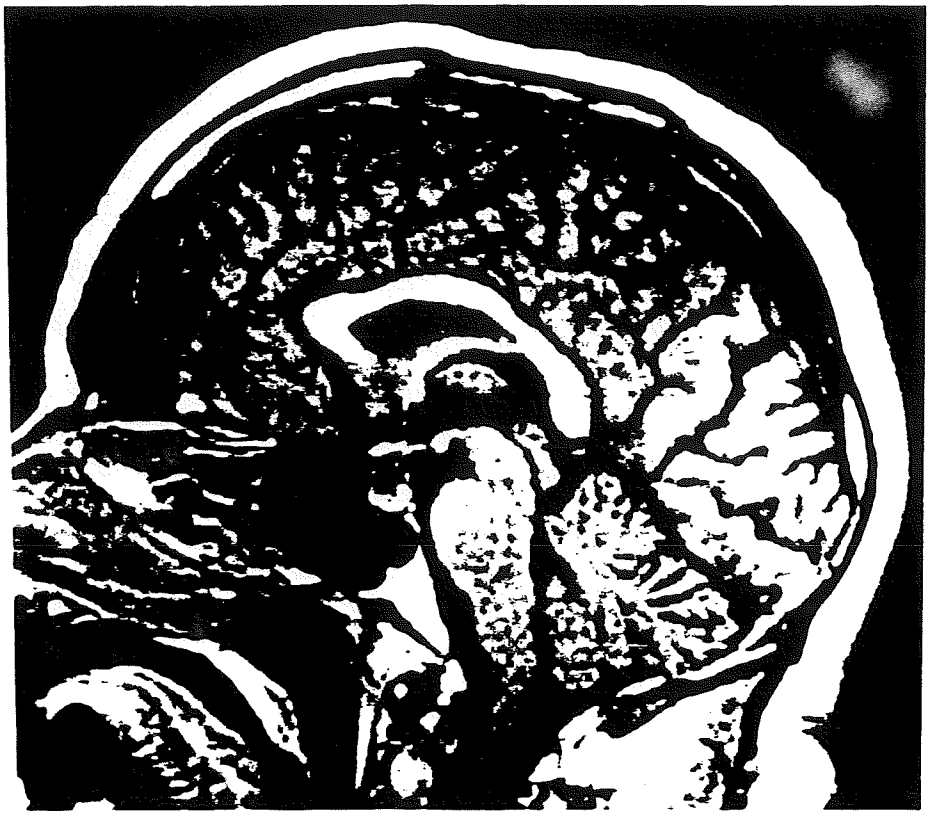
### Anterior Commissure

The Anterior Commissure is a two to three mm vertically ovoid white matter structure located along the anterior wall of the third ventricle at approximately one third of the distance from the bottom of the rostrum of the corpus collosum to the top of the optic chiasm. It has the same signal intensity as the corpus callosum.

### Posterior Commissure

The Posterior Commissure is the small focus of tissue located immediately posterior and superior to the junction of the cerebral aqueduct and the third ventricle.





**Archiving Instructions**

1. Archive on magnetic tape series 1, along with an image demonstrating the graphic alignment of the AC/PC line
2. Archive Series 2 by Echos, if possible.
   a. Archive echo 1 from vertex to base
   b. Archive echo 2 from vertex to base
3. Archive Series 3 from vertex to base
4. If your Field Center chooses to perform additional sequences, please do not include this data on the magnetic tape for intrepretation.

## 6. QUALITY CONTROL - EQUIPMENT AND STUDIES

Image Quality Control - Prior to a CHS participant leaving the FC MRI Unit, the MRI technologist should review all scans. A check to see that the protocol is complete and the scans are technically optimal should be done. If a series needs to be repeated, it should be done at this time, to avoid bringing the participant back.

Equipment - A formal evaluation of the physical performance parameters of each machine will be conducted at regular intervals by the FC using standard manufacturer-recommended evaluation methods. Each FC has at their disposal MR calibration phantoms. The FC should perform a daily scan of the QC phantom. In addition, each MR site is required to make a magnetic tape of these phantom images permitting the evaluation of field homogeneity, noise characteristics, spatial and contrast resolution.

A 1/2 inch magnetic tape containing these phantom scans is to be sent to the MR Reading Center every 6 months according to the following schedule:

November 30, 1991
May 31, 1992
November 30, 1992
May 31, 1993
November 30, 1993

Please label these tapes with the following information: QC Phantom, Field Center Name, and date of QC.

Mail Magnetic Tapes to :
**Linda Wilkins, R.T.**
**Johns Hopkins Hospital**
**Dept. of Neuroradiology**
**Nelson B-100**
**600 N. Wolfe Street**
**Baltimore, Md. 21205**
**(301)955-8216**

## 7. FC PERFORMANCE REPORTS

At the start of the feasibility study the MR RC will site visit each of the 4 Field Centers. The purpose of the site visit will be to meet all CHS personnel and to observe the scanning of a CHS participant.

The MR Reading Center will send a monthly report to each Field Center which will include the following information:
the number of studies sent to the MR Reading Center, number of studies acceptable for interpretation, number of studies rejected for either protocol noncompliance or found to be technically suboptimal. If a Field Center is found to have more than 10% of its studies unacceptable for interpretation, a report documenting reasons for deficiencies will be requested. The FC will be reviewed again in two weeks by the MR RC to insure that corrective measures have been taken.

## 8. ALERTS

### I. Background and Rationale

A. Subjects with certain MR scan abnormalities may require further medical attention. CHS does not assume responsibility for diagnosis and management of its participants. Rather, CHS has assumed an obligation to refer special cases to their local source of medical care. The referral system is based on the urgency of the MR abnormality. An (alert) is defined as an immediate or urgent referral.

### II. Results categories

A. No participant referral indicated
   1. no clinically significant findings

B. No participant referral required.
   1. old infarcts, white matter ischemic changes, atrophy, other chronic abnormalities

C. Urgent referral (alert)
   1. tumor without significant mass effect, subacute infarct, AVM, aneurysm, obstructive hydrocephalus

D. Immediate referral (alert)
   1. acute subdural or epidural hematoma, subarachnoid hemorrhage, acute intraparenchymal hematoma, acute infarct, abscess and suspected tumor with significant mass effect

### III. Reading Center Results Protocol

A. The MR Reading Center physician will record the participant's alert status in the MR results data file at the time of image interpretation.

1. 1 = No referral indicated.
2. 2 = No referral required.
3. 3 = urgent referral required.
4. 4 = immediate referral required.

B. Communication with Coordinating Center

1. The MR Reading Center will send the participants MR results data file to the Coordinating Center by electronic mail.
2. The Coordinating Center will in turn send the MR results data file to the respective Field Center by electronic mail.

C. Communication with Field Center by RC

1. No referral indicated or required
   a) None

2. Urgent referral
   a) The Reading Center physician will type a brief clinical report which will be included with the MR participant's results data file.
   b) The Reading Center will send the participant's MR results datafile (including the alert status and clinical report) to the Field Center Coordinator by electronic mail.
   c) The Reading Center will express mail a film copy of the MR scan to the Field Center Coordinator, if the Field Center does not already have a film copy.

3. Immediate referral
   a) Same as urgent referral, and in addition:
   b) The Reading Center physician will phone the Field Center Coordinator at the time of image interpretation.
   c) If the alert had previously been handled at the Field Center (see below), then no further action is necessary.
   d) If the alert had not been triggered at the Field Center, the Coordinator will contact the CHS participant and the referring physician. Arrangements for further medical evaluation will be made through discussions involving the CHS participant, referring physician, Field Center coordinator and the Reading Center neuroradiologist.

**IV. Field Center Referral Protocol**

A. The referral system at the Johns Hopkins Field Center (Hagerstown) is detailed below. Modifications may be made by individual Field Centers subject to approval by the Reading Center and the Coordinating Center.

B. Communication with Coordinating Center

1. The Field Center Coordinator will review each CHS participant's referral status when the MR results data files are received from the Coordinating Center.

2. Likewise, the Field Center Coordinator will receive and review any MR results data files sent as alerts from the Reading Center.

C. Field Center reporting of results

1. Reporting of results may be made to the CHS participant, referring physician or both in the form of a letter or phone contact. The Field Center Coordinator will make this determination, and if necessary, will consult with the Field Center principal investigator, Field Center neurologist and/or Field Center neuroradiologist.

2. Sample letter to referring physicians - see attached

3. Sample letter to CHS participants - see attached

D. Alerts triggered at the Field Center

1. The MR technologist will immediately alert the local neuroradiologist of any potentially clinically significant abnormality at the time the CHS participant is being imaged.

2. If the local neuroradiologist determines that the MR abnormality constitutes an alert (immediate or urgent referral), then

a) The local neuroradiologist will instruct the technologist tomake a film copy of the MR scan. The Field Center will determine where to store these film copies.

b) The local neuroradiologist will phone the Field Center coordinator, who will contact the referring physician.

c) Arrangements for further medical evaluation will be made through discussions involving the CHS participant, referring physician, Field Center coordinator and the Field Center neuroradiologist.

## 9. DATA TRANSMISSION OF MRI STUDIES

At the completion of the MRI exam, the CHS technician will place a form label identifying that participant on the tape containing his/her data. The CHS technician will write the date the MRI was completed on this label. In addition, a form label for that participant will be placed on the Log Sheet (Attachment 7) for that week, and the date of the MRI scan written in.

Field Center personnel will fill out an MRI Completion Form (Attachment 6) for each participant scheduled for an MRI. The CHS technician will fill in the first question on the form, indicating whether the MRI was completed. The MRI technician will fill out the bottom part of this form for each participant who begins an MRI scan (whether complete or incomplete). Before leaving the MRI area the CHS technician must ascertain that the MRI technician completed the appropriate parts of the form.

On an assigned day each week, the CHS technician will prepare the tapes for mailing. This will include ascertaining that all tapes are labelled completely, packing them securely, checking the contents of the shipping container against that week's log sheet, copying the log sheet and MRI Completion Forms, stapling the Completion Forms for that week to the original log sheet, and mailing the package to the MRI RC each week. A copy of each log sheet must be kept at the FC.

The Field Center Data Manager will enter the MRI Pre-Scan Interview and Exam Forms and MRI Completion Forms into the computer using Rodepc. These will be sent to the Coordinating Center each week as part of the routine data transmission.

Each tape will include up to 3 MRI scans. If on the assigned shipping day a tape has only 1 or 2 scans on it, it is to be included with that week's shipment. Magnetic tapes should be mailed via UPS 24-48 hr. delivery.

Mail Magnetic Tapes to:

Linda Wilkins, R.T.
Johns Hopkins Hospital
Dept. of Neuroradiology
Nelson B-100
600 N. Wolfe Street
Baltimore, Md. 21205
(301)955-8216

## 10. POST-MRI ACCEPTIBILITY QUESTIONNAIRE

During the feasibility trial, one month after the participant's MRI scan, the FC will call the participant and administer the acceptibility questionnaire. These data will be entered into the computer using Rodepc and transmitted to the CC as part of the weekly data transmission. (Attachment 8)

## 11. CRITERIA FOR FEASIBILITY STUDY

A. Objectives:

1. Estimate prevalence of MR defined stroke and other MR abnormalities

2. Assess validity of MR in defining subclinical stroke in the elderly: compare with clinically defined cerebrovascular disease and cerebrovascular disease risk factors

3. Determine relationship of MR defined gray and white matter changes to clinically defined cerebrovascular disease and cerebrovascular disease risk factors

4. Develop and determine reproducibility and cost of standardized reading protocol

5. Assess acceptability of MR scanning to CHS participants

B. Criteria for evaluating feasibility of full-scale study: A full-scale study of the CHS cohort could be undertaken without reservation if findings from the feasibility study meet the following criteria:

1. Prevalence: MR defined stroke is at least as prevalent as clini-cally defined stroke.

2. Validity: MR defined stroke is significantly more common in subjects with clinically defined stroke and cerebrovascular risk factors than in subjects without cerebrovascular disease or its risk factors.

3. Other MR defined abnormalities: Though not affecting feasibility of full-scale study directly, other MR abnormalities would not be measured in a full-scale study unless they were significantly more common in subjects with clinically defined stroke and cerebrovascular risk factors than in subjects without cerebrovascular disease or its risk factors.

4. Reproducibility and cost: Kappa statistic for agreement on MR defined stroke in duplicate readings is at least 0.5. Key MR findings can be read by a trained neuroradiologist on average in 15 minutes or less.

5. Acceptability: At least 80% of subjects asked to participate in the feasibility study are eligible and willing to participate, and at least 90% of those who do participate state that they would be willing to have another MR scan.

ATTACHMENTS

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7. MRI Log Sheet ..... 30

8. Acceptability of MRI Procedure Form ..... 31

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(The MR Interpretation that will be completed by the Reading Center)

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Form Letter for Reporting Results to Physicians
Form Letter for Reporting Results to Participants

Name
ID#:

*Cardiovascular Health Study*

***MRI EXCLUSION CRITERIA QUESTIONNAIRE***

Is participant eligible on basis of weight? yes [1] no [0] → EXCLUDE—DO NOT CONTACT

## *INTRODUCTORY SCRIPT*

Hello, may I speak to *name of participant?*

I'm calling from the Cardiovascular Health Study conducted by *field center.* We are adding some new features to the study and would like to ask you a few questions about some medical procedures or conditions you may have had. Is this a good time for you?

*Wait for affirmative to continue or if not arrange for a call-back.*

### Record of Calls

| day | date (mmddyy) | time | code* | int |
|---|---|---|---|---|
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ |

*Result Codes (circle the final screening result code):

1 complete
2 partially complete
3 refusal
4 no answer
5 temporarily away
6 language barrier
7 physically/mentally incompetent
8 other, specify: _____

**1** Have you ever had an MRI scan?

yes [1] no [0]

## *EXCLUSION CRITERIA*

**2** Have you ever had surgery in which aneurysm clips were used?

yes [1] no [0]

Where?

Hospital name: _____

City, state: _____

*Check medical records—were metal clips used?*

yes [1] no [0] → EXCLUDE

Name
ID#:

3 Have you ever had metal fragments in your eyes, brain or spinal cord?

yes no
EXCLUDE ← 1 0

4 Do you have a cardiac pacemaker or a heart valve prosthesis?

yes no
EXCLUDE ← 1 0

5 Do you have any internal electrical devices, such as a cochlear implant or spinal cord stimulator?

yes no
EXCLUDE ← 1 0

6 Does participant pass all MRI exclusion criteria?

yes no
Complete "MRI Appointment Information" section ← 1 0

That's all I have to ask you today. Thank you for taking the time to speak with me. We appreciate your participation in CHS.

Terminate interview

## *MRI APPOINTMENT INFORMATION*

*Read description of MRI procedure.*

7 Does participant agree to MRI?

yes no

Appointment made for: ← 1 0

Date: M T W Th F ____/____/____

Time: ____ ____ : ____ ____ AM PM

Reason for refusal:

not interested 1
sick 2
caring for sick person at home 3
claustrophobia 4
other: _____ 5

Interviewer: Date: month day year

ATTACHMENT 2

DESCRIPTION OF MRI PROCEDURE TO PARTICIPANT

(TO BE READ FOLLOWING ADMINISTRATION OF THE MRI EXCLUSION QUESTIONNAIRE VERIFYING THAT THE PARTICIPANT QUALIFIES FOR RECEIVING AN MRI.)

Interviewer: I'd like to speak with you about your chance to participate in a new addition to CHS, magnetic resonance imaging or MRI. The MRI is a painless, non-invasive tool used to measure various medical conditions that are difficult to pick up with other testing methods. It takes detailed pictures of your brain that no other diagnostic tool can take. At present it is the best measure available for detecting small strokes and other changes in the brain. As you might recall, the purpose of CHS is to determine what factors cause heart disease and strokes to occur in older adults. The MRI would give us excellent information concerning the onset of stroke in older Americans. It is an especially sensitive, easily administered test that can be performed in less than half an hour with no special preparation. It is the most detailed and specialized test we have ever offered in CHS. As with all of our information, all results will be shared with you and sent to your physician.

Participant: Before I say yes to this test I need more information.

Interviewer: Certainly. Sometimes changes occur in our bodies without our being aware of them. To detect these changes, we will use this new technique called the MRI. It is the best test available today and provides important information about the brain. It allows us to see changes in the brain which may have occurred in the absence of your having noticed any symptoms.

Interviewer: (Continue only if needed.) MR imaging has no known risks, and it is completely painless. It does not use x-rays, and no dye is injected. The MR imaging machine uses a strong magnet, so if you have a pacemaker, or any electronic implants or metallic objects in your body such as joint pins, metal clips from past surgery, metal fragments or shrapnel, this <u>could</u> interfere with the procedure. No preparation is needed. You don't even have to undress. A technician will ask you to remove any metallic objects such as hearing aids, hairpins, watches, jewelry and clothes with zippers.

Although the examination is painless, it may be noisy. Many people fall asleep during the test, so there's no reason to feel anxious. A technician will help you lie down on a comfortable padded table that slides into a large chamber with

openings at both ends. A speaker and microphone allow you to hear and speak with a technician during the examination. If you have any questions or need help, just ask.

And that's all there is to it. All you need to do is lie still and relax. The machine does all the work. You don't have to hold your breath, and you don't have to stay completely still, but it is best to remain as still as possible since movement can distort the image. While you won't feel anything, you can expect to hear the normal vibration from the built-in radio transmitters and receivers. The test usually lasts about 15 minutes. At the end of the examination you can collect your belongings and resume your normal activities immediately.

The test is important, because you will be contributing valuable information to help doctors learn more about what causes strokes and how to prevent them. Also, it offers you the opportunity to obtain additional information about your health.

We could schedule an appointment for you on _____ or sometime that week if that would be convenient.

*Cardiovascular Health Study*

*MRI EXAM APPOINTMENT*

Name
ID#:

Thank you for agreeing to a Magnetic Resonance Imaging (MRI) examination as part of the Cardiovascular Health Study. Your appointment has been scheduled for:

day: date: time: : am pm

☐ Please come to:

A map and parking instructions are attached.

**Please note that the MRI examination will be performed at a location other than the regular CHS Clinic.**

☐ Transportation will be provided.
The driver will arrive at your home at: : am pm
Please be prepared to leave at that time.

- Please **take any prescription medicine** that you normally take.
- The MRI exam will take approximately one hour. If you have any questions or a problem with your scheduled appointment time, please call the clinic at:
- In addition to the MRI scan, you will be asked a few questions and briefly examined in order to help us interpret the results of the MRI.

**Please bring this sheet with you to the MRI appointment.**

ATTACHMENT 4

CONSENT FOR MAGNETIC RESONANCE IMAGING

Cerebral Magnetic Resonance Imaging for Evaluation of Stroke Risk Factors in the Cardiovascular Health Study (CHS)

Patient Name _____

Patient ID Number _____

Center _____

I have been invited to participate in a research study which is being done to look at the relationship between stroke risk factors and the results of a type of brain scan known as magnetic resonance imaging (MRI). Approximately 300 individuals who are currently participating in the Cardiovascular Health Study (CHS) will be entered into this study.

I understand that, for the MRI study, I will lie on a table and be placed inside of a large device that will take pictures of my head using magnetic fields. The MRI machine does not use ionizing radiation (such as x-rays) and is thought, at this time, to have no significant risk to me. There is no discomfort or physical pain. The study will require that I remain still for about 20 minutes so that the pictures can be made. I understand that I must wear earplugs or earphones since operation of the machine may produce high noise levels which may cause discomfort. With the use of earplugs, the risk to hearing is insignificant. Some people may experience psychological discomfort in the scanner if they are uncomfortable in tight places (claustrophobia).

I am not pregnant and 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.

There will be no additional costs to me as a result of my participation in this study.

I understand that the use of this device will not replace any other diagnostic procedure which might be of benefit to my health. I am aware that I may refuse to participate in this study and may withdraw from it at any time. Neither failure to join nor withdrawal from the study will affect the availability of my medical care at this institution.

The CHS 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 I do not have a personal physician, the CHS study will help me to find one.

I also understand that the Institutional Review Board of this institution requires that I be given the following information: If an injury or illness occurs as a direct result of my participation in this study, (institution name) will pay for medical treatment reasonably necessary to treat that injury or illness. No other compensation is available. Additional information may be obtained from the _____ at (____) ____-____. Information concerning the General Liability Insurance of the (institution name) may be obtained from _____ at (_____) _____-_____.

Further information about the study or my participation in it is available from the investigator(s), Dr. _____ at (_____) _____-_____. Any questions regarding my rights as a research subject should be addressed to the Chairman of the Institutional Review Board of (institution name) at (_____) _____-_____.

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 (NHLBI), which has funded this study. The investigators have the right to use information obtained, on an anonymous basis, for further research or scientific presentations. I understand that in any publication or public disclosure of the information resulting from this study, my identity will be kept confidential.

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

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

_____ _____
Patient's Signature Date

_____
Print Patient's Name

_____ _____
Person Informing Patient Date

_____ _____
Witness Date

Cardiovascular Health Study

MRI PRE-SCAN INTERVIEW AND EXAMINATION

Name

ID#:

## INTERVIEW

**1** Have you ever had an injury that resulted in loss of consciousness? (knocked out)

How many times? ___ ___

yes 1 | no 0 | don't know 9

**2** Have you ever been in a coma?

What was the cause? _____ _____

yes 1 | no 0 | don't know 9

**3** Have you ever been told you had cerebral palsy?

yes 1 | no 0 | don't know 9

**4** Have you ever had cancer?

What type? _____ _____

yes 1 | no 0 | don't know 9

**5** Have you ever been told you had a brain tumor?

yes 1 | no 0 | don't know 9

**6** Have you ever had an operation on your brain?

What for? _____ _____

yes 1 | no 0 | don't know 9

**7** Have you ever had a seizure or convulsion?

yes 1 | no 0 | don't know 9

Only as a child?

yes 1 | no 0 | don't know 9

Within the last 5 years?

yes 1 | no 0 | don't know 9

**8** Do you have loss of memory other than for people's names?

yes 1 | no 0 | don't know 9

**9** Have you ever had migraine headaches?

yes 1 | no 0 | don't know 9

Is this a doctor's diagnosis?

yes 1 | no 0 | don't know 9

**10** Have you ever been told by a doctor that you had any other neurological disease, for example M.S. or Parkinson's disease?

What disease? _____ _____

yes 1 | no 0 | don't know 9

**11** What hand would you normally use to throw a ball to hit a target?

left 1

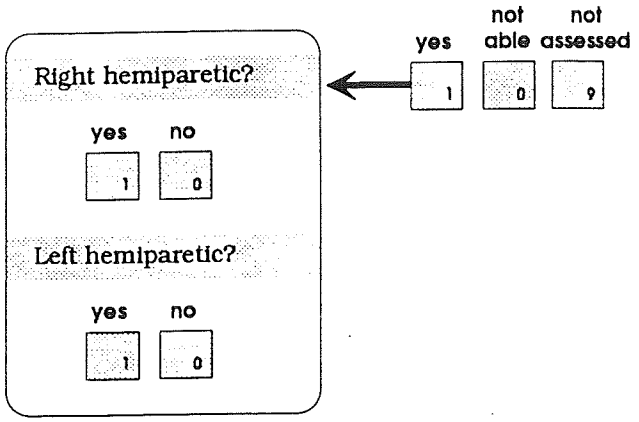
ambidextrous 2

right 3

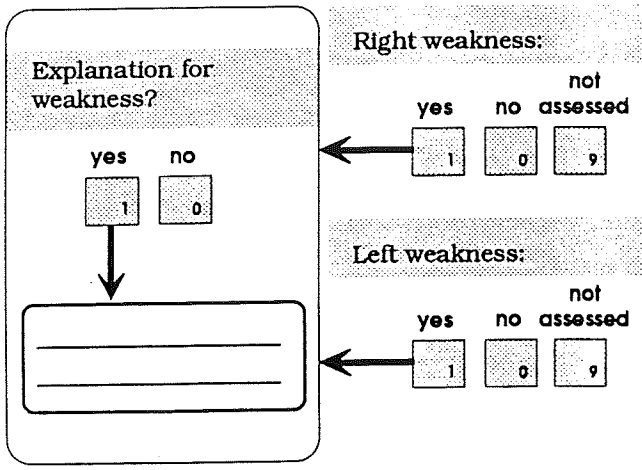
## EXAMINATION

Name
ID#:

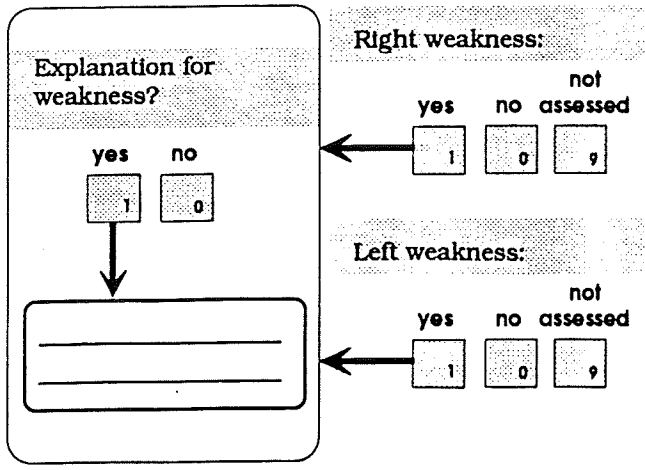
**12** Is the participant able to walk 15 feet?



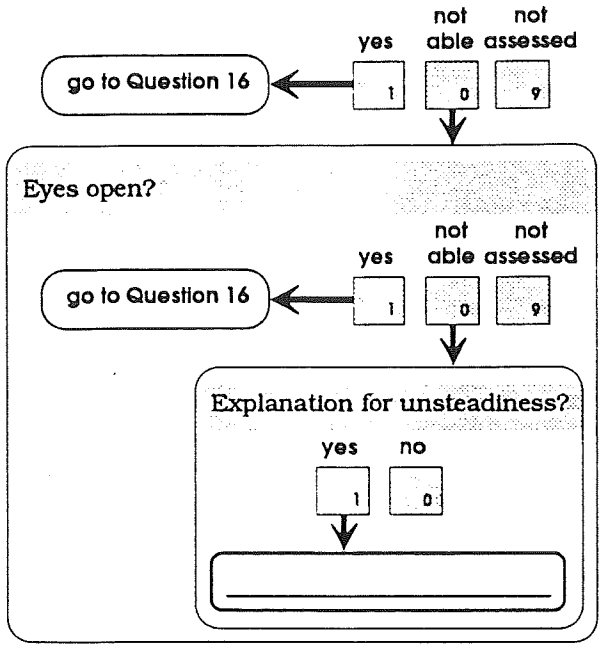

**13** Walking on toes:



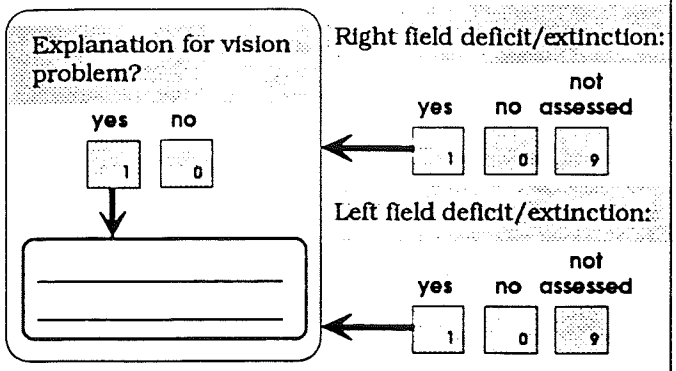

**14** Walking on heels:



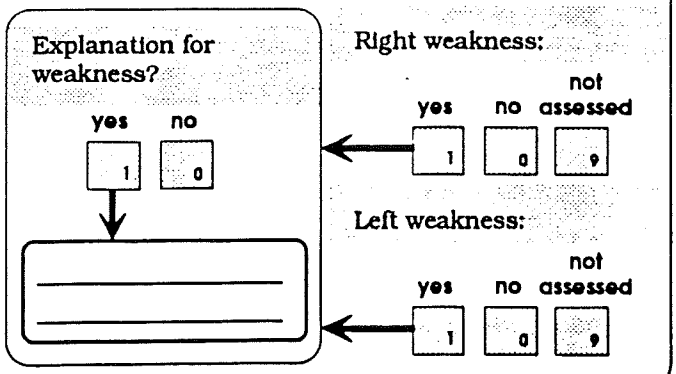

**15** Station (15 seconds): eyes closed?




**16** Visual field deficit/extinction:




**17** Pronator drift:




Interviewer:

Date: month day year

Name
ID#:

*Cardiovascular Health Study*

*MRI COMPLETION FORM*

## *TO BE COMPLETED BY CHS TECHNICIAN:*

**1** Was MRI completed?

yes [1] → Date: ___ ___/___ ___/___ ___

attempted, incomplete [2] → Date: ___ ___/___ ___/___ ___

Reason:

claustrophobia [1]

other, specify: _____ [2]

Tape sent to RC? Yes ☐ No ☐

not attempted [0] →

no show [1]

rescheduled for ___ ___/___ ___/___ ___ [2]

refused to sign informed consent [3]

refused, other: _____ [4]

other: _____ [5]

Technician: Date: month day year

## *TO BE COMPLETED BY MRI TECHNICIAN:*

**2** Please fill in the blanks with the order of Scanning Pulse Sequence. (If all series were completed in order, enter 1 2 3.)

_____ _____ _____

Options: 1 = Series 1: P1 Sagittal
2 = Series 2: Spin density/T2 Oblique Axial
3 = T1 Oblique Axial
4 = Other, explain: _____

**3** Was oblique axial scan parallel to the AC/PC line?

yes [1] no [0]

**4** Were any emergent alert conditions noted?

yes [1] no [0]

Specify the condition: _____

Who was notified? _____

Date: ___ ___/___ ___/___ ___

Technician: Date: month day year

[redacted] MRI Weekly Log Sheet

DATES: mo day year
to: mo day year

Field Center:

Form completed by:

Page of

Field center please complete

Place participant label below

Date MRI completed

MRI reading center use only

Tape number

Name
ID#:

*Cardiovascular Health Study*

## *ACCEPTABILITY OF MRI PROCEDURE*

### *INTRODUCTORY SCRIPT*

Hello, may I speak to *name of participant.*

This is *name of interviewer* from the Cardiovascular Health Study. About a month ago you had an MRI scan done as a part of CHS. We were wondering if we might ask a few questions about your experience. Is this a good time?

### Record of Calls

| day | date (mmddyy) | time | code* | int |
|---|---|---|---|---|
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |
| S M T W R F S | __ __ __ __ __ __ | __ __ : __ __ am pm | | __ __ __ |

*Result Codes (circle the final screening result code):

1 complete
2 partially complete
3 refusal
4 no answer
5 temporarily away
6 language barrier
7 physically/mentally incompetent
8 other, specify: _____

**1** Did you feel any pain or discomfort during the test?

yes 1 no 0

**2** What kind of discomfort?

If yes—on a scale of 1-5 with 1 being minor and 5 being severe, how bad was this discomfort?

| | yes | no | unk | mild | | | | severe |
|---|---|---|---|---|---|---|---|---|
| pain in neck/back | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |
| stiffness in neck/back | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |
| "closed in" feeling (claustrophobia) | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |
| anxiety or fear | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |
| discomfort from noise | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |
| other, specify: _____ | 1 | 0 | 9 | 1 | 2 | 3 | 4 | 5 |

**3** Do you have any suggestions as to how we could make this procedure more comfortable?

| | yes | no | don't know |
|---|---|---|---|
| shorten the duration | 1 | 0 | 9 |
| use a softer table | 1 | 0 | 9 |
| reduce the noise level | 1 | 0 | 9 |
| other, specify: _____ | 1 | 0 | 9 |

Name
ID#:

4 Would you be willing to have this procedure again in the future?

yes (1) no (0)

5 May I ask why not? (record response in full)

_____

_____

_____

6 Is there anything we could do to make the procedure more acceptable to you in the future?

yes (1) no (0)

7 May I ask what that might be? (record response in full)

_____

_____

_____

***EXIT SCRIPT***

Thank you again for your time.

Interviewer: Date: month day year

# CHS MR Scan Coding Form

Revised 10/11/91

## I. Patient Data

A. CHS ID number :
B. Acrostic :
C. Date this form initiated :
D. Date of MR scan :
E. Source of MR scan :
F. Date MR sent to R.C. :
G. Field center comments :
   1. Alert
   2. Other

## II. MR Scan Data

A. System Manager
   1. Date MR received from F.C. :
   2. Date of optical archive :
   3. Quality control
      a) Scan protocol correct?
      b) Full data set received?
   4. Comments:

## III. Radiologist Interpretation

A. Reader ID : 1, 2, 3, 4, etc. (or initials)

B. Date of interpretation: (today's date entered automatically)

C. Technical adequacy : good, adequate, inadequate (skip reading)

D. Global brain atrophy
   1. subjective
      a) ventricles : linear scale from 1 - 10
      b) sulci : linear scale from 1 - 10
   2. objective
      a) central sulcus width : (mm)
      b) bicaudate width : (mm)
      c) inner table width : (mm)
   3. symmetry : vent = sulci, vent > sulci, vent < sulci

E. Focal brain atrophy : yes, no (skip section)
   1. grade : mild, moderate, severe
   2. lateralization : right, left
   3. location : use G.6. menu (below)

F. White matter changes
   1. grade : linear scale from 1 - 10
   2. predominant location : periventricular = subcortical, pv > sc, pv < sc
   3. symmetry : right = left, right > left, right < left
   4. perivascular spaces : normal, increased, markedly increased
   5. brain stem lesions : none, few (1-2), several (3-5), many (>5)

G. Infarcts : yes, no (skip section)
   1. number (label according to order of vascular territory, see G.6 below))

2. side : right, left
3. size (mm) : RL, AP. Z
4. predominant MR signal
   a) T1 : increased, normal, decreased
   b) PD : increased, normal, decreased
   c) T2 : increased, normal, decreased
5. hemorrhagic? : acute, subacute, chronic, none
6. vascular territory and location
   a) cerebrum
      (1) ACA
         (a) frontal
         (b) parietal
         (c) caudate head
      (2) MCA
         (a) frontal
         (b) parietal
         (c) temporal
      (3) PCA
         (a) parietal (posteromedial)
         (b) temporal (posteroinferior)
         (c) occipital
   b) cerebellum
      (1) SCA
      (2) AICA
      (3) PICA
   c) deep gray/white matter
      (1) Lenticulostriate MCA
         (a) caudate (not head)
         (b) lentiform nuclei (putamen, globus pallidus)
         (c) internal capsule, anterior limb
         (d) internal capsule, posterior limb
      (2) Perforators PCA & basilar
         (a) thalamus
         (b) midbrain
         (c) pons
         (d) medulla
   d) Watershed
      (1) ACA-MCA
         (a) frontal-parietal
         (b) frontal-temporal
      (2) MCA-PCA
         (a) temporal-parietal
         (b) temporal-occipital
         (c) parietal-occipital

H. Parenchymal hematoma : yes, no (skip section)
   1. number (separate menu for each)
   2. side : right, left
   3. size (mm) : RL, AP, Z

4. age : acute, subacute, chronic
5. location and vascular territory
   a) use G.6 menu (above)

I. Other diagnosis : yes, no (skip section)
   1. intracranial
      a) congenital: e.g., arachnoid cyst
      b) inflammatory, infectious
      c) neoplasm
      d) hydrocephalus
      e) hemorrhage: e.g., SDH, EPH, SAH
      f) vascular: e.g., AVM, aneurysm
   2. extracranial
   3. other

J. Alert Status
   1. None
      a) no clinically significant findings
   2. Routine
      a) old infarcts, white matter ischemic changes, atrophy, other chronic abnormalities
   3. Urgent
      a) tumor without significant mass effect, subacute infarct, AVM, aneurysm, obstructive hydrocephalus
      b) CLINICAL REPORT:

   4. Immediate (PHONE CALL TO FIELD CENTER REQUIRED)
      a) acute subdural or epidural hematome, subarachnoid hemorrhage, acute intraparenchymal hematoma, acute infarct, abscess and suspected tumor with significant mass effect
      b) CLINICAL REPORT:

**Field Center Form Letter for reporting results to referring physician**

**Date:** ----

**To:** ----

**From:** ----

**Re: Results of Cardiovascular Health Study (CHS) brain MRI**

**Dear Dr. --------,**

**Your patient, ---------, has participated in a study of magnetic resonance imaging (MRI) of the brain and atherosclerotic risk factors as part of the Cardiovascular Health Study (CHS). CHS is an epidemiologic study of risk factors for coronary heart disease and stroke in people over 65 years of age. The study does not provide diagnosis, medical advice or treatment to participants. The scanning protocol is an abbreviated research MRI an is not equivalent to a standard clinical study. The results of the brain MRI are reported below (circled).**

**(A) No significant abnormality for age. There may be atrophy or small vessel white matter ischemic changes, both of which are common in asymptomatic elderly patients.**

**(B) Other chronic findings (aside from atrophy or small vessel disease) which are not unusual in elderly patients, such as old infarction, old hemorrhage or old trauma.**

**(C) There is --------- fill in the blank from the Reading Center Alert Report). You or your staff should have already received a phone call regarding this abnormality. If you have not been contacted, you may call us at the number listed below.**

**Please let us know if you have any questions regarding the above. If you desire further information, please contact the Cardiovascular Health Study Coordinator, Ms. Joel Hill, at 222-222-2222.**

**Field Center Form Letter for reporting results to CHS participants**

Date: ----

To: ----

From: ----

Re: Results of Cardiovascular Health Study (CHS) brain MRI

Dear (CHS participant),

Thank you for participating in the study of magnetic resonance imaging (MRI) of the brain as part of the Cardiovascular Health Study (CHS). We hope the experience was a pleasant one, and we are grateful for the time and effort volunteered by you and the other CHS participants.

Please remember that this MRI examination is only designed for research purposes, and therefore is limited in scope and is <u>not</u> the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of your MRI of the brain are reported below:

(use three separate letters, or circle)

(1) Normal for age.

(2) There may be minor chronic findings which are often seen in elderly patients. These should not be a cause for concern on your part.

(2) There is a possible finding which may require further medical evaluation. You may have already received a call from your doctor, or from the Cardiovascular Health Study Coordinator, regarding this matter.

Please let us know if you have any questions regarding the above. If you desire further information, please contact the Cardiovascular Health Study Coordinator, Ms. Joel Hill, at 222-222-2222.

Thank you again for your participation in the Cardiovascular Health Study.

Sincerely,