CARDIOVASCULAR HEALTH STUDY

FIELD CENTER

MAGNETIC RESONANCE IMAGING

MANUAL OF OPERATIONS

Revised November 5, 1997

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1. BACKGROUND, RATIONALE AND GOALS

The purpose of the CHS MRI 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 feasibility study consisted of 300 participants and was conducted from November 1991 through February 28, 1992. The main trial began in June 1992, and was completed in August 1994. Protocol defined MRI's were performed on 3,658 participants at the 4 CHS Field Centers. The MRI Reading Center performed interpretations of these images in a standardized and reproducible manner.

During the conduct of CHS, it became clear that stroke detected by clinical examination was too infrequent to permit assessment of some stroke risk factors within the contract period. The NHLBI proposed to improve detection rates for stroke risk factor correlation and has added cerebral magnetic resonance imaging (MRI) to the CHS follow-up examination which will begin in June 1997.

1. Objectives

The first major task will be to implement and supervise an MR Comparability Study on approximately 300 MR studies from the baseline MRI examination. Based on the results of this study, a CHS MR committee, including representatives from the RC, will then determine the necessity to perform additional reader training to achieve the same standard of reading as the baseline study. A pilot study consisting of 80 MRI studies, 20 at each Field Center will also be performed to assess data quality and protocol adherence. MRI exams (as detailed within this protocol), will then be performed on approximately 3,600 CHS participants.

The repeat MRI data will be used to further the original objectives of CHS. The new objectives for the continuation period are to: 1)Identify risk association with clinical disease by accumulation of events; 2) Determine whether presence of progression of subclinical disease (abnormalities detected not-invasively without signs or symptoms) are better predictors of clinical disease than traditional risk factors; 3) Identify determinants of change in subclinical disease; 4) Identify characteristics of subgroups at low risk for developing CVD.

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 repeat MRI data will provide the basis for testing a number of hypotheses about the

relationships between cardiovascular risk factors, subclinical evidence of CerebroVD as reflected by MRI and the prevalence and incidence of clinical CerebroVD, including stroke, TIA and vascular dementia. In particular, these repeat MRI data will be used to further the original objectives. 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. Identify risk associations with clinical disease by accumulation of events.

   a. Compare risk estimates in subgroups of participants, such as women vs. men, African-American vs. Caucasian, those older vs. younger than 75 years, or those with vs. without prevalent clinical or subclinical disease.

   b. Compare risk estimates in subtypes of disease, such as fatal vs. non-fatal myocardial infarction, symptomatic vs. silent myocardial ischemia, or fatal vs. non-fatal stroke.

   c. Compare estimates of longer term (5-10 year) vs. short term (1-3 year) CVD risk.

2. Determine whether presence or progression of subclinical disease (abnormalities detected non-invasively without signs or symptoms) are better predictors of clinical disease than risk factors.

3. Identify determinants of change in subclinical disease.

4. Identify characteristics of subgroups at low risk for developing CVD (in whom preventive measures may be unnecessary).

2. MRI EQUIPMENT

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

1. Hagerstown	GE Signa	1.5T
2. Bowman Gray	GE Signa Advantage	1.5T
3. Sacramento	GE Signa Advantage	1.5T
4. Pittsburgh	GE Signa Advantage	1.5T

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 MRI study will be sent from the CC to FC. The FC will then begin to contact cases to invite them to participate in the MRI follow-up study.

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 pilot study 80 cases must be scanned and sent to the MRI RC. This requires accrual of 20 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 2-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 MRI Exclusion Criteria Questionnaire (Attachment 1) will be asked.

C. INSTRUCTIONS FOR COMPLETING THE MRI PRE-SCAN INTERVIEW AND EXAMINATION (Attachment 5)

The purpose of this procedure is to examine the participant prior to his/her receiving a magnetic resonance image (MRI) from a neurologic perspective. It is critical that the MRI Pre-Scan Interview and Examination be done within a very short interval prior to the MRI scan. The maximum amount of time that may pass between the pre-scan exam and the MRI itself is 30 days. Once the participant has qualified for the MRI and an MRI has been scheduled, this form may be completed in the clinic **IF THE MRI IS SCHEDULED WITHIN 30 DAYS.** If the scan is scheduled beyond a 30 day period, or if the original appointment is canceled or rescheduled, a new pre-scan exam will need to be done prior to the MRI.

No special equipment is needed for this procedure other than a chair for the participant to sit in during the interview and enough space to observe a 15-foot walk.

1. MRI PRE-SCAN INTERVIEW AND EXAMINATION DEFINITIONS

- **Coma** A coma is defined as a state of unconsciousness from which a person cannot be aroused, even by powerful stimulation.

- **Cerebral Palsy** A persistent qualitative motor disorder appearing before the

age of three years due to non progressive damage to the brain.

- **Hemiparetic** In this procedure hemiparetic refers to weakness of the arms or legs during observation of gait. It is a spastic gait that reveals an increase in muscular tone. The limb, usually on one side, is moved forward with difficulty and often swings out and in a semicircle as the participant walks.

- **Seizure** A sudden attack or recurrence of disease, usually associated with epileptic symptoms marked by a momentary break in thought an activities (see convulsion below).

- **Convulsion** A violent involuntary contraction or series of contractions of the voluntary muscles.

- **Migraine** An often familial symptom complex of periodic attacks of vascular headache, usually temporal and unilateral at onset, commonly associated with irritability, nausea, vomiting, constipation or diarrhea, and often photophobia (abnormal visual intolerance of light).

- **Ambidextrous** Able to perform acts requiring manual skill with either hand.

- **Stations** Stations is described as the ability to stand erect with both feet on the floor with eyes closed for a specific period of time.

- **Visual Field** Visual field is the amount of peripheral vision that an individual has. In this exam, the participant's visual field is compared to that of the examiner's.

- **Pronator Drift** This refers to a drifting of outstretched arms, held palms up, involving a flexion toward the chest with a downward shift; only asymmetric responses are considered a deficit in this exam.

2. INTERVIEW QUESTIONS

The first section of the form asks participants about specific conditions or diseases that they currently have or may have had in the past. The presence of these conditions may be a precursor or result of specific types of lesions or of neurologic finding in the exam.

Codes for Questions 1 through 10
Record '1 -Yes' if the participant responds in the positive, '0 -No' if response is negative, and '9 - Unknown' if the participant doesn't know or cannot remember.

Record all dates in mm/dd/yy format. If the exact date is not know, collect the most information that the participant can remember, e.g. month and year only, or year only and enter '99' in the date field for the unknowns.

Question 1. Have you ever had an injury that resulted in loss of consciousness?

- You may note that this is also known as being "knocked out" or "passed out" as a result of the injury.
- There is no minimum as to the amount of time during which the loss of consciousness occurred.

If the participant responds yes

- Ask and record the number of times that this has occurred. Each different occurrence is considered one time.
- Record dates beginning with the most recent.

Question 2. Have you ever been in a coma?

- You may explain that being is a coma is a term for being unconscious for a period of time (see definition above).

If the participant responds yes

- Ask and record the cause or the reason for the coma (e.g. car accident, head injury, etc).
- Record date of the occurrence. If it has occurred more than once, just record the most recent event. If the exact date is known, record the date of the coma or the first day if it lasted more than one day.

Question 3. Have you ever been told you have cerebral palsy?

- While those who have been diagnosed with cerebral palsy should be aware of the condition, you may explain that it is a type of motor or muscular disorder (e.g. paralysis) that is caused by non-progressive brain damage that appears during early childhood.

Question 4. Have you ever had cancer?

- All types of malignant neoplasms should be noted, including lymphomas and hematopoietic neoplasms. Do not include benign tumors.

If the participant responds yes

- Record the type of cancer or the site of the primary tumor. If more than two have occurred, record those that the participants believe are most significant.
- Record date of the occurrence. If more than one diagnosis occurred, record the most recent.

Question 5. Have you ever been told you had a brain tumor?

- Any type of tumor of the brain should be noted, benign or malignant. A tumor that has been removed is also included here.

  If the participant responds yes
  - Record the date of the diagnosis. If more than one tumor occurred, record the most recent.

Question 6. Have you ever had an operation on your brain?

- Any surgery of the brain should be recorded, including surgery for removal of tumors noted above.

  If the participant responds yes
  - Record the type and reason for the operation. If more than one operation occurred, note number of operations in text field.
  - If yes, record date of the operation. If more than one operation occurred, record the most recent.

Question 7. Have you ever had a seizure or convulsion?

- Record occurrence of any seizure or convulsion that has ever taken place throughout the participant's life, including childhood. See above for definitions.

  If the participant responds yes
  - Determine if the event was childhood only (skip to Question 8) or more recent.
  - If the seizure/convulsion occurred within the last five years, record dates of the three most recent occurrences, most recent first.

Question 8. Do you have a loss of memory other than people's names?

- This should be answered according to the participant's interpretations. Do not provide your own interpretation.

Question 9. Have you ever had migraine headaches?

- Migraine headaches may be defined according to the participant's interpretations; a physician's diagnosis is not necessary for the first part of the question. If the participant asks for an explanation, you may read the definition provided above.

  If the participant responds yes
  - Ask if this was a physician's diagnosis and record accordingly.

Question 10. Have you ever been told by a doctor that you have one of the following?

- Parkinson's Disease
- Alzheimer's Disease
- Other dementia
- Other neurologic conditions, problems or disease

If the participant responds yes

- Record the date of first diagnosis.

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

- This wording is used to determine handedness. Please record 1 - left hand, 2 - ambidextrous, 3 - right hand.

- Ambidextrous should be chosen if the participant is just as likely to throw a ball with his/her right hand as with his/her left hand; there is no preference.

Measured Walk (Gait Testing)

- This question requires asking the participant to walk in flat shoes or in stocking feet if shoes with high heels are worn to observe the gait. This is not a timed walk and any pace is acceptable. This question is looking for evidence of hemiparesis (weakening of arm and leg on the same side of the body).

- When this is on one side, which is usually the case with a hemiparetic gait, the affected limb is moved forward with difficulty occasioned by the lack of freedom of movement in all of the joints (stiffness). In addition, the toe of the affected side tends to be forced downward. This leads to an abduction and circumduction of the limb in order to move it forward. This is often observed as the foot swinging out and in a semi-circle as it comes forward. Affected individuals often change their shoes so that the toe is worn on the outer side.

- For hemiparesis of the leg, look for circumduction (i.e. leg motion out to the side in a circular swing). In the arm, look for decreased arm swing. For both, look for asymmetry, i.e. is there circumduction in one leg compared to the other; is there a decreased arm swing compared to the other. Complete the form as follows:

Question 12. Is the participant able to walk 15 feet?

- Record '1 - Yes' if the participant is able to walk 15 feet; record '0 - Not able' if unable to walk 15 feet, and record '9 - Not Assessed' if you are not able to perform the task for a reason other than physical disability (in which case the answer would be '0')

If the participant is able to walk 15 feet

- Record any observations of hemiparesis on the right side or left side. Use the following rules when making the decision:

    - If you are sure based on the leg, code '1-Yes';
    - If you are unsure based on the leg, look at the arm.
    - If the arm on the same side is swinging less than the opposite arm, code '1- Yes';
    - If you are unsure based on the leg, and the arm swing provides no additional evidence, code '0 - No'.

Walking on Heels and Toes

- These two exercises are used to assess balance and strength in the foot.

    - Ask the participant to remove his/her shoes before doing this exercise. If the participant is wearing a leg brace, have him/her remove the brace and attempt to assess weakness

    - If possible, and a second technician is available, spot the participant. One technician may spot the participant while the other steps back to observe the exercise. It is permissible to allow the participant to hold the technician's hand if needed.

Question 13. Walking on Toes

- Ask the participant to take six steps walking away from you, three steps with each foot. Stand behind the participant and watch the heels. Look for asymmetry. If the heel of the right foot is falling down,code '1 - Yes' for right weakness. If the heel of the left foot is falling down, code '1 - Yes' for left weakness. The heel does not have to touch the ground to be coded yes. If he/she can take three or more steps on the balls of each foot without falling, the result is normal. '9 - Not Assessed' means that the participant is unable to walk or refuses.

  If weakness is observed, ask the participant if he/she knows the reason for the weakness. Possible causes include diabetes, peripheral neuropathy, arthritis or hip replacement. If there is a known cause for the weakness, record it in the space provided.

Question 14. Walking on Heels

- Ask participant to take six steps toward you, three steps with each foot. As he/she walks to you, observe the toes and the front of the foot. Look for symmetry. If the toes of the right foot are

falling down, code '1 - Yes' for right weakness. If four or more steps are taken with each foot on the heels without touching the ball of the foot to the floor, the result is normal. '9 - Not Assessed' means the participant is unable to walk or refuse.

- If weakness is observed, ask the participant if he/she knows the reason for the weakness. Possible causes include diabetes, peripheral neuropathy, arthritis or hip replacement. If there is a known cause for the weakness, record it in the space provided.

Question 15. Station

- Station involves the ability to stand in an erect position with both feet together with eyes closed for fifteen seconds. The test should be done WITH EYES CLOSED FIRST. Eyes open is only done if the participant is unable to hold his/her station with eyes closed.

Shoes should remain off (from last procedure)

- Ask the participant to stand with feet side by side, touching each other, arms at side. If the participant cannot stand with feet touching because of large legs or ankles, ask him/her to put their feet as close together as possible.

- Ask the participant to close his/her eyes for fifteen seconds. Code '0 - Not Able' only if the persons foot moves. Swaying or arm swinging are acceptable as long as the foot does not move and the eyes do not open.

- If the person is able to stand for fifteen seconds with eyes closed, skip to Question 16; there is no need to do the procedure with eyes open. If he/she is unable to do the procedure with eyes closed, attempt to do it with eyes open.

- If the participant is unable to do the procedure with eyes open, ask him/her if there is a reason for this unsteadiness. Record response in the space provided.

Question 16. Visual Field Deficit/Extinction

This exercise evaluates the peripheral vision of the participant.

- Shoes may be placed back on feet as this procedure is done in a seated position.

- Ask the participant to sit in chair. Technician should sit in a chair

facing the participant with knees almost touching and upper bodies remaining about three feet apart.

- Ask the participant to look at the technician's nose. Technician should hold his/her arms out so that hands are 3-4 inches above the participants's eye level and a shoulder width apart (use participants shoulders as a guideline, about 16-18 inches). Technician's hands should be positioned half way between him/her and participant (about 18 inches in front of participant).

- Say to the participant "Point to the finger that is moving". Wiggle the index fingers on the right hand, wait for a response; wiggle the fingers on the left hand, wait for a response, and wiggle the fingers on both hands, wait for a response. Then move both hands down so that they are 3-4 inches below the participant's eye level , still shoulder width apart. Say to the participant "Point to the finger that is moving". Repeat the finger wiggles, each hand separately then together.

Coding

If the participant points to the correct hands on all trials, code '0 - No' deficit or extinction on either the right or left side.

If the participant is not able to see one side, either when fingers were wiggled separately or at the same time, code '1 - Yes' for the side on which they had the vision problem. Code according to the participant's right or left side (not yours).

'9 - Not assessed' refers to any reason for not assessing visual field deficit/extinction including refusals.

If either left or right side is coded '1 - Yes', indicating a problem, ask the participant if he/she has any known visual problems. Record any explanations in the space provided.

Question 17. Pronator Drift

This exercised evaluates the participant's ability to hold arms outstretched in a steady position with eyes closed.

- The participant is seated in a chair facing the technician.

- Ask the participant to hold his/her arms outstretched, palms up, just below shoulder level, elbows slightly bent. You may tell the participant to pretend thathe/she is catching water in his/her palms. It is important that the palm is flat; do not allow the thumb to be elevated above the

horizontal plane of the palm. You may position the participant's hands for them if there is difficultly with the initial position.

Observe any drift in the arms. Specifically, check for:

- one hand drifting downward;
- one hand pronating (thumb moves upward or inward).
- This may also be described as a flexion movement of the arm toward the chest with turning in of the hand associated to a downward drift. Arm going up or thumb going out is normal. Only asymmetric responses are recorded as abnormal.

Code the observed weakness according to the affected arm '1 Yes' if drift is observed, '0 - No' if none is observed, and '9 - Not assessed' if the procedure was refused or not assessed for any reason.

- If pronator drift is observed, ask the participant if he/she has any problems with their shoulders. Arthritis, previous surgery, or a rotator cuff injury are all reasons for the weakness. Record the responses in the space given.
- If the participant points to the correct hands, on all trials, code '0 - No' deficit or extinction on either the right or left side.
- If the participant is not able to see one side, either when fingers were wiggled separately or at the same time, code '1 -Yes' for the side on which they had the vision problem. Code according to the participant's right or left side (not yours).

  '0 - Not assessed' refers to any reason for not assessing visual field deficit/extinction including refusals.

After completion of these procedures, the CHS technician will escort the participant to the MRI imaging area for the scan.

D. 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 metallic objects, including jewelry, dentures, hearing aids, hairpins, etc. and secure all items in the participant's locker. The technologist should explain to the participant that the exam should take approximately 30 minutes. 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

For purposes of archiving and retrieval, it is imperative that the CHS Identification number be placed in the ID Field, and that the name field be filled with the letters CHS and the ID number. Please follow the example below:

ID: CHS1234567 NAME: CHS1234567

Errors in this step may result in irretrievable loss of MRI data from the study.

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 RC 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.
4. Series 4 - Axial SPGR T1-weighted images

Please perform the imaging sequences in the order specified above. 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 image data 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 or optical storage media.

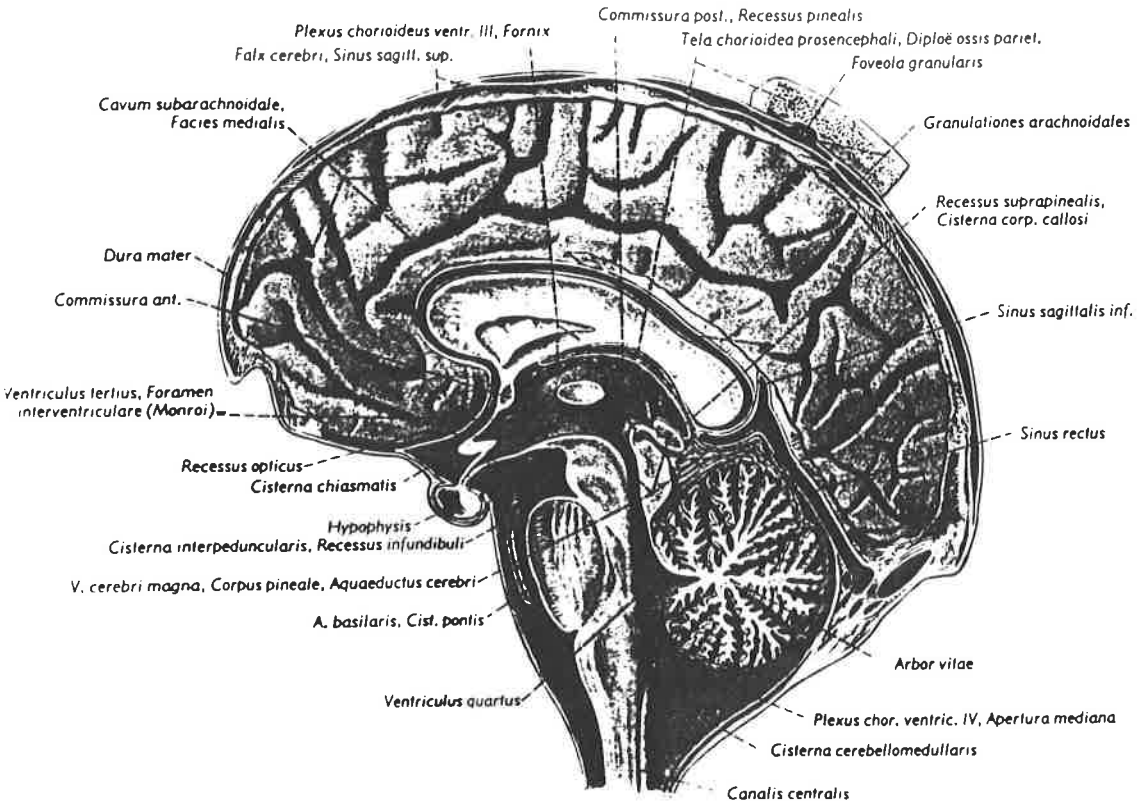
B. CHS MRI IMAGING PROTOCOL

Series 1 - Sagittal T1-weighted localizing scan used to identify AC/PC line, TR 500 (400-600), TE 20 (<35), 5mm, 0 gap, 256 x 128 matrix 1 nex, FOV 24 cm, images centered to midline. (approximate scan time 1:12)

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 Interleaved, 256 x 192 matrix, 1/2 nex, (1 nex on less than 1T scanners), variable band width (SD=16 kHz/T2=4 kHz), FOV 24 cm, 3/4 rectangular FOV, images obtained from vertex to skull base. (approximate scan time 9:12)

Series 3 - Angled (Parallel to AC/PC line) axial T1-weighted scans TR 500 (400-600), TE 20 (<35), 5 mm Interleaved, 256 x 192 matrix, 1 nex (2 nex on less than 1T scanners), 3/4 rectangular FOV 24 cm, cover vertex to skull base. The slice positions on series 2 and 3 should match. (approximate scan time 2:40)

Series 4 - Axial SPGR T1-weighted scans, SAT inferior, graphic Rx, TE 5, TR 35, 45 degree flip angle, FOV 24 cm, rectangular FOV, 1.5mm slice thickness, 256 x 192 matrix, 1 nex, frequency direction A/P, center frequency H2O, images obtained from vertex to skull base. If coverage is a problem please include the entire vertex with exclusion of portions of the brainstem as necessary. (approximate scan time 10:49



C. ARCHIVING INSTRUCTIONS

1. Archive on appropriate storage media series 1.
2. Archive Series 2 from vertex to base.
3. Archive Series 3 from vertex to base.
4. Archive Series 4 from vertex to base.
5. If your Field Center chooses to perform additional sequences, please do not include this data on the magnetic tape for interpretation.

D. 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. Localize on the Anterior Commissure at approximately at approximately one third of the distance from the bottom of the rostrum of 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.

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 QC at least monthly. 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.

An optical disk, or other digital storage media agreed upon by the MRI RC containing these phantom scans is to be sent to the MR Reading Center every 6 months according to the following schedule:

Prior to Pilot Study
November 30, 1997
May 31, 1998
November 30, 1998
May 31, 1999

Please label these tapes/disks 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 21287
(410) 955-8216

7. FC PERFORMANCE REPORTS

At the start of the pilot study the MR RC will site visit each of the 4 Field Centers. The purpose of the site visit will be to meet CHS personnel and to observe the scanning of a CHS participant and insure adequate comprehension and performance of designated protocols.

The Coordinating Center will send a monthly report to each Field Center and to the MR Reading 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
2. 2 = No participant 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 data file (including the alert status and clinical report) 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 neuro-radiologist and/or Field Center neurologist.

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 <u>immediately</u> 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 to make 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 Log Sheet (Attachment 7), and include the date of the MRI scan in the appropriate place.

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/disk for mailing. This will include ascertaining that all tapes/disks 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.

A. PROCEDURE FOR OPTICAL DISKS / DAT TAPES

Field Centers using optical disks or DAT tapes will allocate the number of disks/tapes needed to hold 900 MRI studies. These optical disks will become the property of the CHS MR RC and should contain the CHS MRI protocol studies on them. At the end of the study or when an optical disk becomes full, whichever occurs first, the optical disk will be sent to the CHS MR RC for permanent storage.

At the beginning of the study the CHS FC and the MR RC will establish a rotation exchange process for these optical disks. The optical disk should be labelled with a permanent label indicating which disk it is. For example:

CHS MRI Study
Disk/Tape #1

The CHS FC will place studies from approximately one weeks studies on disk #1. The MRI disk/tape log (Attachment 7) should be completed with all pertinent information. This log should be copied prior to mailing by the study coordinator. The log will be added to each time more participant studies are added to the disk.

At the completion of the 10 studies for the week, this disk and the original log which accompanies it should be sent to the MR RC :

Mail Disks/Tapes to:

Linda Wilkins, R.T.
Johns Hopkins Hospital
Dept. of Neuroraidology
Nelson B-100
600 N. Wolfe Street
Baltimore, MD 21287
(410) 955-8216

When disk/tape #1 has been sent to the RC the FC should then start the next batch of participant studies on disk/tape #2 and start a new log for disk/tape #2. This log should then be sent following the same procedure as was used for disk/tape #1.

Upon receipt of the disks the MR RC data manager will archive these studies, check off the studies received by shipment date and will mail back to the FC the disk/tape so that more CHS MRI studies can be added. Studies are never to be deleted from these optical disks/tapes. The MR RC will be retaining a separated log for each disk/tape in the rotation. The rotation exchange of disks/tapes may require 3-4 disks being utilized at any one time to eliminate any inefficiency or delay due to mailing or scheduling constraints.

This system will result in 2 separate logs, one at the MR RC and one at the CHS FC. Each disk/tape will have a separate log associated with it.

10. CRITERIA FOR PILOT STUDY

A. Objectives:

1. Reassess validity of MR in defining subclinical stroke in the elderly: compare with clinically defined cerebrovascular disease and cerebrovascular disease risk factors and previous MR examinations

2. Document reproducibility and maintain cost of standardized reading protocol

3. Assess new measures to improve acceptability of MR scanning to CHS participants

4. Evaluate new scanning methods to reduce participant refusal for scanning and determine comparability with baseline studies

5. Assess feasibility of full-scale study: A full-scale follow-up study of the CHS cohort could be undertaken without reservation if findings from the feasibility study meet the following criteria:

> a. Any modification to the initial CHS MRI protocol must be statistically comparable to the initial protocol by direct comparison. Key MRI findings can be read by trained neuroradiologist or imaging technologist on average in 15 minutes or less.
>
> b. 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

page

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2. Script for Description of MRI Procedure to Participant..... 29
3. MRI Exam Appointment Form..... 31
4. Informed Consent Form for Magnetic Resonance Imaging..... 32
5. MRI Pre-Scan Interview and Examination..... 34
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   Form Letter for Reporting Results to Physicians
   Form Letter for Reporting Results to Participants

Cardiovascular Health Study

YEAR 10 MRI EXCLUSION CRITERIA QUESTIONNAIRE

Name
ID#:

Public reporting burden for this collection of information is estimated to average 20 minutes, including the time for reviewing instructions, gathering needed information and completing and reviewing the questionnaire. If you have any comments regarding this burden, please send them to: Attention: PRA Reports, Clearance Officer, PHS 721-B Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, and to the Paperwork Reduction Project (0925-0334). Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

1 Is participant eligible on basis of weight?

YES ☐ 1 NO ☐ 0 → EXCLUDE

2 Did you have an MRI with CHS several years ago?

YES ☐ 1 NO ☐ 0 DON'T KNOW ☐ 9

3 Did you have an MRI outside of CHS?

YES ☐ 1 NO ☐ 0 DON'T KNOW ☐ 9

↓

When? (If more than one, give date of most recent.)

__ __ / __ __ / __ __
M M D D Y Y

Where?

Hospital name: _____

City, State: _____

Why?

_____

_____

EXCLUSION CRITERIA

4 Have you ever had a surgery in which aneurysm clips were used?

YES ☐ 1 NO ☐ 0

↓

Where?

Hospital name: _____

City, State: _____

Check medical records—were metal clips used?

EXCLUDE ← YES ☐ 1 NO ☐ 0

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

EXCLUDE ← YES ☐ 1 NO ☐ 0

6 Do you have a pacemaker?

EXCLUDE ← YES ☐ 1 NO ☐ 0

7 Do you have an artificial heart valve?

YES ☐ 1 NO ☐ 0

When was it put in?

1970 OR BEFORE ☐ 1 AFTER 1970 ☐ 0

What type is it? (If "unknown," prompt for ball-in-cage)

STARR EDWARDS OR BALL-IN-CAGE ☐ 1 → EXCLUDE

UNKNOWN ☐ 9

DEFINITE ANSWER: NOT BALL-IN-CAGE ☐ 0

Where was it put in?

Hospital name: _____

City, State: _____

Check medical records—was ball-in-cage used?

EXCLUDE ← YES ☐ 1 NO ☐ 0

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

EXCLUDE ← YES ☐ 1 NO ☐ 0

9 Does the participant pass all MRI exclusion criteria?

Complete "MRI Appointment Information" section ← YES ☐ 1 NO ☐ 0

END OF INTERVIEW

Name
ID#:

MRI APPOINTMENT INFORMATION

Read description of MRI procedure.

10 Does participant agree to MRI?

YES ☐ 1

Appointment made for:

Date: M T W Th F Sa Su

__ __/__ __/__ __

Time:

__ __:__ __ AM PM

YES, BUT AT ANOTHER TIME ☐ 2

Contact for appointment after:

__ __/__ __/__ __

NO ☐ 0

Reason for refusal:

NOT INTERESTED ☐ 1

SICK ☐ 2

CARING FOR PERSON AT HOME ☐ 3

CLAUSTROPHOBIA ☐ 4

HAD PREVIOUS MRI ☐ 5

OTHER: _____ ☐ 6

May we contact your doctor to obtain a copy of the film from this exam?

YES ☐ 1 NO ☐ 0

Interviewer: _____ Date: ☐☐ ☐☐ ☐☐ (month day year)

ATTACHMENT 2

DESCRIPTION OF MRI PROCEDURES TO PARTICIPANT

(THIS SCRIPT IS OPTIONAL AND CAN BE USED IF DEEMED NECESSARY)
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 the follow-up 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 within less than an hour with no special preparation. It is most detailed and specialized test we have ever offered in CHS. In the initial CHS MRI study approximately 3,800 participants successfully completed MRI. The results on the initial study resulted in important and unique information about the aging brain. 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 compare your previous MRI with this new MRI. It is the best test available today and provides important information bout the brain. It allows us to see changes in the brain which may have occurred in your brain since the previous MRI and 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 could interfere with the procedure. No preparation is needed. You don't even have to undress. A technologist 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 technologist 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 technologist 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 th built-in radio transmitters and receivers. The test usually lasts about 30 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.

MRI Appointment Reminder ATTACHMENT 3

Thank you for agreeing to have the Cardiovascular Health Study (CHS) MRI scan. Your appointment has been scheduled for:

day: _____ **date:** _____ **time:** _____ am / pm

☐ Please come to:

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

Very Important

Please **review the consent form and fact sheet** that were mailed to you recently. They contain important instructions for your visit.

If you have any questions, please call Cheryl Stanglin at 734-3219 .We look forward to seeing you again.

7-9-92. Form 108

MRI Appointment Reminder

Thank you for agreeing to have the Cardiovascular Health Study (CHS) MRI scan. Your appointment has been scheduled for:

day: _____ **date:** _____ **time:** _____ am / pm

☐ Please come to:

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

Very Important

Please **review the consent form and fact sheet** that were mailed to you recently. They contain important instructions for your visit.

If you have any questions, please call Cheryl Stanglin at 734-3219 .We look forward to seeing you again.

7-9-92. Form 108

ATTACHMENT 4
CONSENT FOR MAGNETIC RESONANCE IMAGING

Cerebral Magnetic Resonance Imaging forEvaluation of Stroke Risk Factors in the Cardiovascular Health Study

Participant Name_____

Participant ID Number_____

Center_____

I have been invited to participant 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 3,600 individuals who are currently 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 less than an hour 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 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 physicians 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 presentation. 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.

_____ _____

Participant's Signature Date

_____

Print Participant's Name

_____ _____

Person Informing Participant Date

_____ _____

Witness Date

OMB #-0925-0334 Exp: 3/98

ATTACHMENT 5

Cardiovascular Health Study

YEAR 10 MRI PRE-SCAN INTERVIEW AND EXAMINATION

Name
ID#:

Public reporting burden for this collection of information is estimated to average 20 minutes, including the time for reviewing instructions, gathering needed information and completing and reviewing the questionnaire. If you have any comments regarding this burden, please send them to: Attention: PRA Reports Clearance Officer, PHS 721-B Hubert H. Humphrey Building, 200 Independence Avenue SW. Washington, DC 202201, and to the Paperwork Reduction Project (0925-0334). Office of information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

INTERVIEW

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

YES ☐ 1 → How many times? ☐

NO ☐ 0

DON'T KNOW ☐ 9

Dates (most recent first):

__ __/__ __/__ __
M M D D Y Y

2 Have you ever been in a coma?

YES ☐ 1 → What was the cause? _____

NO ☐ 0

DON'T KNOW ☐ 9

Most recent date:

__ __/__ __/__ __
M M D D Y Y

3 Have you ever been told you had cerebral palsy?

YES ☐ 1 → Date of diagnosis:

NO ☐ 0

DON'T KNOW ☐ 9

__ __/__ __/__ __
M M D D Y Y

4 Have you ever had cancer?

YES ☐ 1 → What type? _____

NO ☐ 0

DON'T KNOW ☐ 9

Date of diagnosis:

__ __/__ __/__ __
M M D D Y Y

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

YES ☐ 1 → Date of diagnosis:

NO ☐ 0

DON'T KNOW ☐ 9

__ __/__ __/__ __
M M D D Y Y

6 Have you ever had an operation on your brain?

YES ☐ 1 → What for? _____

NO ☐ 0

DON'T KNOW ☐ 9

Date:

__ __/__ __/__ __
M M D D Y Y

7 Have you ever had a seizure or convulsion?

YES ☐ 1 → Only as a child?

NO ☐ 0

DON'T KNOW ☐ 9

YES	NO	DON'T KNOW
☐ 1	☐ 0	☐ 9

Within the last 5 years?

YES	NO	DON'T KNOW
☐ 1	☐ 0	☐ 9

Dates: (most recent first)

__ __/__ __/__ __
M M D D Y Y

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 → Is this a doctor's diagnosis? YES ☐ 1 NO ☐ 0 DON'T KNOW ☐ 9

NO ☐ 0

DON'T KNOW ☐ 9

10 Have you ever been told by a doctor that you had any of the following?

Parkinson's disease:

YES ☐ 1 → Date of diagnosis: ___ ___/___ ___/___ ___ (M M D D Y Y)

NO ☐ 0

DON'T KNOW ☐ 9

Alzheimer's disease:

YES ☐ 1 → Date of diagnosis: ___ ___/___ ___/___ ___ (M M D D Y Y)

NO ☐ 0

DON'T KNOW ☐ 9

Other dementia:

YES ☐ 1 → Date of diagnosis: ___ ___/___ ___/___ ___ (M M D D Y Y)

NO ☐ 0

DON'T KNOW ☐ 9

Other neurologic:

YES ☐ 1 → Date of diagnosis: ___ ___/___ ___/___ ___ (M M D D Y Y)

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

Name
ID#:

EXAMINATION

12 Is the participant able to walk 15 feet?

YES ☐ 1 → Right hemiparetic? YES ☐ 1 NO ☐ 0 Left hemiparetic? YES ☐ 1 NO ☐ 0

NOT ABLE ☐ 0

NOT ASSESSED ☐ 9

13 Walking on toes:

Right weakness:

YES ☐ 1 → Explanation for weakness? YES ☐ 1 NO ☐ 0

NO ☐ 0

NOT ASSESSED ☐ 9

Left weakness:

YES ☐ 1 → _____

NO ☐ 0

NOT ASSESSED ☐ 9

14 Walking on heels:

Right weakness:

YES ☐ 1 → Explanation for weakness? YES ☐ 1 NO ☐ 0

NO ☐ 0

NOT ASSESSED ☐ 9

Left weakness:

YES ☐ 1 → _____

NO ☐ 0

NOT ASSESSED ☐ 9

Name
ID#:

15 Station (15 seconds): eyes closed?

YES 1 → go to question 16

NOT ABLE 0

NOT ASSESSED 9

Eyes open?

YES 1 → go to question 16

NOT ABLE 0 →

NOT ASSESSED 9

Explanation for unsteadiness?

YES 1 NO 0

16 Visual field deficit/extinction:

Right field deficit/ extinction:

YES 1 →

NO 0

NOT ASSESSED 9

Explanation for vision problem?

YES 1 NO 0

Left field deficit/ extinction:

YES 1 →

NO 0

NOT ASSESSED 9

17 Pronator drift:

Right weakness:

YES 1 →

NO 0

NOT ASSESSED 9

Explanation for weakness?

YES 1 NO 0

Left weakness:

YES 1 →

NO 0

NOT ASSESSED 9

Interviewer:

Date: month day year

OMB #-0925-0334 Exp: 3/98

ATTACHMENT 6

Cardiovascular Health Study

YEAR 10
MRI COMPLETION FORM

Name
ID#:

Public reporting burden for this collection of information is estimated to average 20 minutes, including the time for reviewing instructions, gathering needed information and completing and reviewing the questionnaire. If you have any comments regarding this burden, please send them to: Attention: PRA Reports, Clearance Officer, PHS 721-B Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201, and to the Paperwork Reduction Project (0925-0334). Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503.

TO BE COMPLETED BY CHS TECHNICIAN

1 Was MRI completed?

yes → 1
Date: __ __/__ __/__ __ (M M D D Y Y)

attempted, incomplete → 2
Date: __ __/__ __/__ __ (M M D D Y Y)

Reason:
- claustrophobia 1
- other, specify: _____ 2

Was tape sent to MRI Reading Center? yes 1 no 0

not attempted → 0
- no show 1
- rescheduled for: __/__/__ (M M D D Y Y) 2
- refused to sign informed consent 3
- refused, other: _____ 4
- ill 5
- ineligible 6
- physically unable 7
- other. _____ 8

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: TI Sagittal
2—Series 2: Spin density/T2 Oblique Axial
3—Series 3: TI Oblique Axial
4—3D Axial SPGR
5—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: __/__/__ (M M D D Y Y)

Technician: Date: month day year

TO BE COMPLETED BY MRI READING CENTER

Tape number:

Date received: month day year
Date archived: month day year
Date of dBase entry: month day year

ATTACHMENT 7

CHS OPTICAL DISK/TAPE LOG

LOG FOR DISK/TAPE #_____ **Date Received_____**

For RC Use Only

PARTICIPANT ID# & ACROSTIC	DATE OF MR STUDY	DATE OF SHIPMENT	Exam #	Restored	√ IARS

CHS STUDY COORDINATOR TO COPY THIS LOG AND RETAIN AT FC AND SEND ORIGINAL TO MR RC.

CHS Reading Summary

CHS ID #

Entry #

Entry date

checkdigit checkbit

Acrostic

Tape number

Date of MR scan

Date rec from FC

Date sent to CC

Optical archive date

Warehouse date

Series 1 ?

Series 2 ?

Series 3 ?

Full data ?

AC/PC?

Protocol?

Technical adequacy

QC status ?

---

ventricles ○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9

sulci ○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9

white matter ○0 ○1 ○2 ○3 ○4 ○5 ○6 ○7 ○8 ○9

bifrontal distance

inner table distance

central sulcus width

WM location

WM symmetry

bs lesions

pv spaces

other dx?

alert status

large infarcts (≥ 3 mm)?

small infarcts (< 3 mm)?

focal brain atrophy?

parenchymal hematoma?

alert text

Reader ID

Type of reading

Date of int

date modified?

case finished?

	infarct #1	infarct #2	infarct #3	infarct #4	infarct #5
number					
side					
RL dim					
AP dim					
# slices					
T1 signal					
PD signal					
T2 signal					
hemorr?					
loc 1					
loc 2					
loc 3					
loc 4					
series #					
image #					

ACA: frontal

ACA: parietal

MCA: frontal

MCA: parietal

MCA: temporal

PCA: parietal

PCA: temporal

PCA: occipital

supCerebellarA

AICA

PICA

deep cerebellar WM

caudate

lentiform nuclei

int cap ant limb

int cap post limb

thalamus

midbrain

pons

medulla

Wshed ACA:MCA

Wshed MCA:PCA

deep cerebral WM

BG number

BG side

Dark on T1?

series #

image #

WM number

WM side

series #

image #

BS number

BS side

series #

image #

	hematoma #1	hematoma #2	hematoma #3
number			
side			
RL dim: cm			
AP dim: cm			
# slices			
T1 signal			
PD signal			
T2 signal			
age			
location 1			
location 2			
location 3			
location 3			

August 9, 1994

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 and is not equivalent to a standard clinical study. The results of the brain MRI performed on February 5, 1994 are repor below.

Finding	Present?
Old infarct > 5 mm	no
Old hematoma	no

Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4001060

August 9, 1994

Dear Mrs. :

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. It is not the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of the MRI you had on February 5, 1994 showed:

Your MRI is normal for your age.

Please let us know if you have any questions regarding the above. Thank you again for your participation in the Cardiovascular Health Study.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4001060

August 9, 1994

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 and is not equivalent to a standard clinical study. The results of the brain MRI performed on July 17, 1993 are reported below.

Finding	Present?
Old infarct > 5 mm	no
Old hematoma	no

There is a 2.2 x 2.3 cm mass adjacent to the right sigmoid sinus, dark on all pulse sequences; probably a meningioma or thrombosed aneurysm.

You or your staff should have already received a phone call or letter regarding this abnormality. If you have not been contacted, please call us.

Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4502043

August 9, 1994

Dear Mrs. :

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. It is not the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of the MRI you had on February 14, 1994 showed:

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

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4070321

August 9, 1994

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 and is not equivalent to a standard clinical study. The results of the brain MRI performed on February 14, 1994 are repo below.

Finding	Present?	Number	Side	Location
Old infarct > 5 mm	yes	1	RIGHT	PONS
Old hematoma	no			

There are multiple hemosiderin deposits under 1cm in both hemispheres consistent with multiple cavernous hemangiomata.

You or your staff should have already received a phone call or letter regarding this abnormality. If you have not been contacted, please call us.

Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4070321

August 9, 1994

Dear Mrs. :

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. It is not the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of the MRI you had on February 5, 1994 showed:

Your MRI is normal for your age.

Please let us know if you have any questions regarding the above. Thank you again for your participation in the Cardiovascular Health Study.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4001060

August 9, 1994

Dear Dr. :

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Finding	Present?	Number	Side	Location
Old infarct > 5 mm	yes			
		1	LEFT	INT CAP ANT LIMB
		2	RIGHT	LENTIFORM NUCLEI
Old hematoma	no			

Please do not hesitate to call if you have any questions regarding the above.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4020731

August 9, 1994

Dear Mrs. :

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. It is not the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of the MRI you had on July 17, 1993 showed:

> Minor chronic findings which are often seen in people of your age. These should not be a cause for concern on your part.

Please let us know if you have any questions regarding the above. Thank you again for your participation in the Cardiovascular Health Study.

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4020731

August 9, 1994

Dear Mrs. :

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. It is not the same as the standard MRI examination which your doctor might order. Keeping this limitation in mind, the results of the MRI you had on February 14, 1994 showed:

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

Sincerely,

John Robbins, MD, MHS
Principal Investigator

ID: 4070321