

Health ABC

Manual for MR Imaging of the Knee

Version 1.0
September 14, 2001

KNEE MRI

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KNEE MRI**1.0 Introduction**

This manual describes procedures for the follow-up knee MRI exams in Health ABC. We obtained bilateral knee MRIs on participants who reported knee pain and a random sample of controls without knee pain at the Year 2 examination. At the Year 5 examination, all of the participants with knee pain who had an MRI and a random sample of the controls will be asked to obtain a follow-up knee MRI. The participant with baseline knee pain will have a bilateral knee MRI, while the control participants will have only one knee examined, as designated by the Coordinating Center.

The acquisition sequences for the follow-up exam are identical to those used at the baseline examination, as are most of the forms and quality assurance procedures.

IMPORTANT: The goal for the follow-up exams is to duplicate the baseline measurements as closely as possible by carefully following the protocols and procedures described below.

1.1 Background and rationale

Despite the proven value of knee radiography in epidemiological studies of osteoarthritis (OA), radiography is fundamentally limited in a number of ways. Conventional radiographs provide detailed images of cortical and trabecular bone, but cannot directly visualize the articular cartilage or other noncalcified structures in the knee. Osseous findings are common in OA, but tend to arise late in the disease process and may be only secondary consequences of changes in other structures, such as the cartilage, menisci and intra-articular ligaments. Also, radiography is a projectional technique that casts two-dimensional (2D) shadows of the 3D anatomy onto flat sheets of film. This results in morphological distortion, magnification, and superimposition of overlying structures.

MRI offers a number of advantages over radiography for imaging knee OA. MRI has a tomographic viewing perspective, and thus provides cross-sectional images of the anatomy, free of projectional distortion, magnification, or superimposition. This allows osteophytes and other abnormalities to be delineated in regions that might otherwise be obscured with conventional radiography. Moreover, MRI is uniquely able to directly visualize all components of the joint, including the articular cartilage, menisci, intra-articular ligaments, synovium, capsular structures, bone contours, and bone marrow. This allows the knee joint to be evaluated as a whole organ, and

provides a much richer picture of the changes associated with osteoarthritis than is possible with other techniques.

1.2 Purpose of the Manual

The purpose of this manual is to standardize the imaging technique and administrative procedures related to the MRI component of the **Health ABC protocol** for evaluating participants with osteoarthritis of the knee. The manual describes the MRI technique to be used along with the procedures for documenting and shipping the MRI data to UCSF. The manual is designed for the principal investigator, the study coordinator, and MRI technicians involved in this study.

The role of the Osteoporosis and Arthritis Research Group at UCSF will be to verify that all sequences in the protocol were included and that the pulse parameters used were in agreement with the protocol. The images will also be checked for adequate anatomical coverage, signal-to-noise ratio, and the presence of artifacts. If any problems or deficiencies are detected, the Osteoporosis and Arthritis Research Group at UCSF will notify the MRI site and work with them towards a solution. Only rarely would this require repeat examination of a participant.

The Osteoporosis and Arthritis Research Group at UCSF will perform centralized analysis of the MRI data. Assessments will include semiquantitative scoring of articular cartilage, osteophytes, subarticular cysts, bone marrow edema and sclerosis, attrition and remodeling of osseous articular surfaces, the menisci, the cruciate and collateral ligaments, joint effusion, synovitis, intra-articular loose bodies, and synovial cysts and bursae about the knee.

1.3 General study design

Baseline MRI was performed at the Year 2 and 3 Health ABC examination on participants with significant knee symptoms and on controls without symptoms. This is a follow-up study to examine changes in MRI findings over three years.

MRI will be performed using 1.5 Tesla whole body scanners with a circumferential extremity coil. Imaging sequences will include: a fast axial T2-weighted localizer (duration <1 min), a sagittal T2-weighted fast spin echo sequence with fat suppression, and a coronal T2-weighted fast spin echo sequence without fat suppression. The total time required for MRI of both knees, including participant set up, will be approximately 30 minutes.

1.4 Which participants will get MRI? (For Health ABC clinic staff)

All participants who had knee pain and an MRI and a sample of controls who had an MRI during Year 2 or Year 3 of Health ABC will be asked to have another MRI during Year 5. To determine whether or not a participant is eligible for an MRI, refer to the Year 5 Data From Prior Visits Report. Knee pain cases will undergo bilateral imaging while control participants will have MRI of a single knee. The report will also tell you whether both knees, or whether the right or left knee, should be imaged. In some cases, the knee to be imaged will depend on the answers to the Year 5 knee pain questions (Year 5 Clinic Visit Workbook, pages 15-17, questions 2-5). See below:

KNEE MRI ELIGIBILITY

1. Is the participant eligible for a follow-up knee MRI?
(Yes/No)
2. If Yes, which knee should be imaged?
Right/Left/Both Right and Left/*See note below

The knee indicated for control participants is selected based on new knee pain reported since the baseline MRI. If the participant has reported no new knee pain during Year 4, this determination must be made based on any new Year 5 pain. In this case, the words "*See note below" will appear, and the note "Check Year 5 Clinic Visit Workbook, pp. 15-17. If no asterisked answers, image RIGHT knee for even-numbered HABC ID#s, LEFT knee for odd. If some answers are asterisked, image one painful knee." That is, if the participant now has one or more asterisked knee pain questions, the corresponding knee should be imaged. If there are asterisked answers for both knees, only one knee should be imaged. If no answers are asterisked, the knee to be read will be determined by whether the participant's Health ABC ID# is even or odd, as noted above. This rule of thumb may also be used to decide which knee to image if both knees have asterisked answers.

Be sure to fill out page 19 in the Year 5 Clinic Visit Workbook (See Appendix 1). Answer Question #11: "Is the participant eligible for a follow-up knee MRI?" If the participant is eligible for a knee MRI, be sure to fill out all of page 1, and Questions 7 through 11 on page 2 of the Knee MRI Tracking Form (Appendix 2). You should also check the Data from Prior Visits Report to see which knee(s) should be imaged and mark "Scan right knee" and/or "Scan left knee" on Question #13 on page 3 of the Knee

MRI Tracking Form. The partially completed Knee MRI Tracking Form should then be sent to the MRI center for completion of questions 12-16.

If the participant refuses the MRI, mark the “No” response option to Question #12 on the Knee MRI Tracking Form and mark “Participant refused” to answer the question “Why wasn’t an MRI obtained?” **Important: Fill out a Knee MRI Tracking Form for all participants who are eligible for knee MRIs whether or not they agree to have the MRI(s)!**

1.5 MRI evaluation

MR images will be analyzed with a semi-quantitative whole-organ scoring method.

1.6 Training and certification of MRI technologists

Each MRI facility participating in Health ABC should designate a study coordinator who is responsible for assigning technicians to the study and assuring that the procedures described in this manual are followed.

Only designated and certified technicians should perform the examinations for Health ABC. Each technician and coordinator involved in the study will have a unique Health ABC Staff ID number. It is preferred that no more than 2 or 3 technicians be assigned to Health ABC at each MRI facility.

A representative of the UCSF OARG will visit each site to review the study procedures with the study coordinator and MRI technicians. Technicians will be certified based on the review at OARG of the first five Health ABC participants scanned.

2.0 MRI Protocol

2.1 MRI contraindications (For Health ABC clinic staff)

The following are standard contraindications for MRI. These should be assessed at the Field Center using the Health ABC form at the time of enrollment into the MRI follow-up study and participants should be excluded from the study as appropriate. Each facility may have additional assessments to identify exclusions.

Contraindication (assessment)

- Body weight in excess of about 250 lb (measured weight at clinic visit). Participants with a large body circumference may not fit in the MRI bore. This weight is only an approximate cutoff. Many participants who are over this weight, especially those who are tall, may undergo MRI depending on body shape, since it is the size of the bore rather than weight, per se, that is the limiting factor. If a participant is over 250 lbs, take a quick measurement of waist and hip circumference over clothing (tape should bring clothing into contact with skin). The circumference of the bore is 176 cm (actual bore circumferences may differ by center). Anyone with a waist or hip circumference above 160 cm is unlikely to fit in the bore.
- * Cardiac pacemaker (“Do you have a heart pacemaker?”)
- * Aneurysm clips of any age (“Have you ever had surgery to repair an aneurysm?”)
- * Metallic fragments in the eyes (“Have you ever had an injury in which metal or metal fragments may have entered your eye?”)
- * Vascular clips less than 2 months old (“Have you had any surgery in the past 2 months?”). MRI for these participants can be scheduled at a later date that is past the 2-month exclusion window).
- * Cardiac valve prosthesis (“Have you ever had surgery to insert a valve into your heart?”)
- * Cochlear implants (“Have you had a hearing device surgically implanted in your ear?”). This does not include a standard hearing aid which can be removed.
- Knee replacement (“Have you had a knee replacement in either knee?”). MRI on the knee opposite the replaced one will be distorted.
- Claustrophobia (“Do you have claustrophobia?”). For those who answer yes, determine if they are willing to attempt the test. True claustrophobia is relatively uncommon (2-3%). Participants with claustrophobia will know who they are, and these people will probably not be willing to attempt the test. Others may say they are uncomfortable in small spaces, but may tolerate MRI without difficulty. It is useful to make an attempt in persons who seem uncertain or who have mild concern. MRI information booklets or a picture of someone in the bore for a knee exam may be helpful in orienting the participant.

* Denotes a safety-related contraindication. In general, “Don’t know” and “Refused” for these questions should be considered a contraindication.

2.2 Participant setup

Positioning

Positioning of the knee in the magnet must be reproducible from visit to visit in order to allow accurate comparison of serially acquired images. The participant should be imaged supine with the leg in neutral position and the patella pointing straight up rather than in slight external rotation as is commonly the routine in clinical imaging protocols. External rotation is more difficult to reproduce on serial exams and complicates image interpretation in this study. Additionally, the knee must be well immobilized in the circumferential extremity coil with foam padding.

Participant comfort and prevention of motion artifacts

The comfortable installation of the participant at the beginning of the examination is critical to limiting motion artifacts. Care should be exercised in positioning the cushions and pads around the knee in the extremity coil to make the examination as comfortable as possible. Ear plugs or music through headphones should be included along with pillows, blankets, and verbal reassurance.

2.3 Imaging parameters

MRI header:

In addition to the standard information usually entered on the setup screen when starting a new participant (name, sex, age, etc), three pieces of information unique to Health ABC **must** be entered. The participant's Health ABC ID# (which can be obtained from the Knee MRI Tracking Form), the Health ABC Staff ID# of the MRI technician, and the leg imaged (right or left). A diagram of the setup screen for the Park Avenue MRI center with this information in the correct location is shown below.

Outline of the prompt screen when starting a new MR exam (Park Avenue)

ID: HA+ 4 digits with no space

Name:

Sex:

Age:

Status:

Req. number:

Weight (lb):

Referred by:

Diagnostician:

Operator: *Health ABC Staff ID# of technician performing exam should be entered in this field*

Patient history:

Protocol:

Study description: *side examined for example Right knee*

Figure A

Proper participant setup should ensure correct positioning of the knee and sufficient participant comfort to limit motion artifacts and minimize the likelihood of participant dropouts.

All parameters for the Health ABC protocol should be pre-programmed into the MRI computer in order to limit the potential of human error. The total examination time including 10-minutes participant setup is approximately 30 minutes for both knees. **Bandwidth should be 16 kHz for all sequences.**

1. Axial T2-weighted fast spin echo (FSE) localizer including entire patella:
 - 2500 / 60 (or 64) (TR msec / TE msec),
 - 20 cm field of view (FOV),
 - 4 mm / 1 mm (slice thickness / interslice gap),
 - 256 x 128 matrix,
 - frequency encoding anterior-posterior, phase Right-Left,
 - 16 echo train length (ETL),
 - 1 excitation (NEX),
 - [Imaging time = 25 sec].

2. Sagittal T2-weighted fast spin echo (FSE) including entire synovial cavity; localize the slices from sagittal to medial.
 - 4217 / 60,
 - 14 cm FOV,
 - 4 mm / 0.5 mm (about 20 slices),
 - 256 x 224 (or 256) matrix,
 - frequency encoding anterior-posterior,
 - 8 ETL,
 - 2 NEX,
 - No phase wrap (NP),
 - frequency-selective fat suppression,
 - [Imaging time = 4:00 or 4:30 min, depending on the size of the matrix].

3. Coronal T2-weighted FSE:
 - 3500 / 60,
 - 14 cm FOV,
 - 4 mm / 0.5 mm,
 - 256 x 256,
 - frequency encoding medial-lateral,
 - 8 ETL,
 - 2 NEX,
 - No Phase wrap (NP),
 - [Imaging time = 3:51 min]..
 - Coverage should include the entire femorotibial joint but not the patella as shown in Fig. 1.]

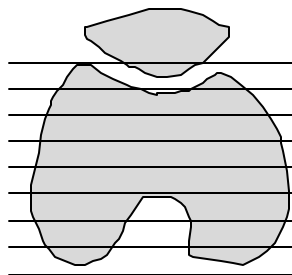


Figure 1. Coronal slice selection. Selected using axial localizer from Sequence 1 to cover entire femorotibial joint, but not the patella.

2.4 Examples of images

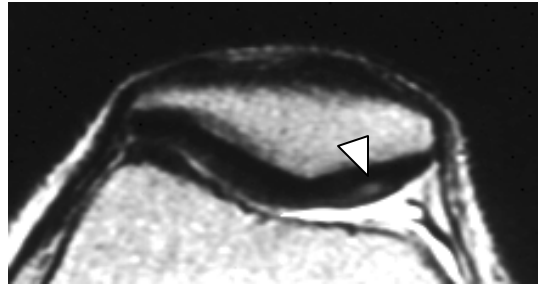


Figure 2: Axial T2-weighted fast SE image. These images will serve as localizers for other sequences but also for assessing cartilage, osteophytes and patellar subluxation. In this patient, the patella shows a focus of increased signal intensity (arrowhead) indicative of chondromalacia in the cartilage over the medial facet.



Figure 3: Sagittal T2-weighted Fast Spin-echo image with Fat Saturation. In contrast to synovial fluid, which shows high signal intensity with this technique, normal cartilage appears low in signal intensity. A focal

cartilage defect is seen within the femoral condyle adjacent to the posterior horn of the medial meniscus.

2.5 Common mistakes or artifacts

Fat saturation failure or omission:

Frequency-selective fat saturation pulse must be used in the sagittal T2-weighted fast spin echo sequence. It eliminates chemical-shift artifacts along cartilage margins and is essential for detecting bone marrow edema. Fat saturation failure can occur over areas of irregularly shaped anatomy, such as the patella. Usually, this artifact does not extend to the patellar cartilage, but can interfere with assessment of patellar marrow edema. Accidental omission of the frequency-selective fat saturation pulse is a significant oversight.

Motion artifacts:

Participant motion artifacts can be minimized by positioning the participant comfortably using cushions and pads around the knee, and emphasizing the importance of lying still to the participant.

2.6 Filming protocol

Format

The three sequences should be filmed. Images should be printed with a 3 x 4 format (12 images per film) with the anatomy depicted from lateral to medial (sagittal) (fig. 4), posterior to anterior (coronal), and superior to inferior (axial). Images should be ordered from the left to the right and from the top to the bottom of the film. Sequences should be filmed on a separate sheet (i.e., two different sequences should not appear on the same sheet). The first image on the top left should be the localizer showing the slice selection. Sections at the periphery of the coverage that do not include any relevant anatomy need not to be filmed.

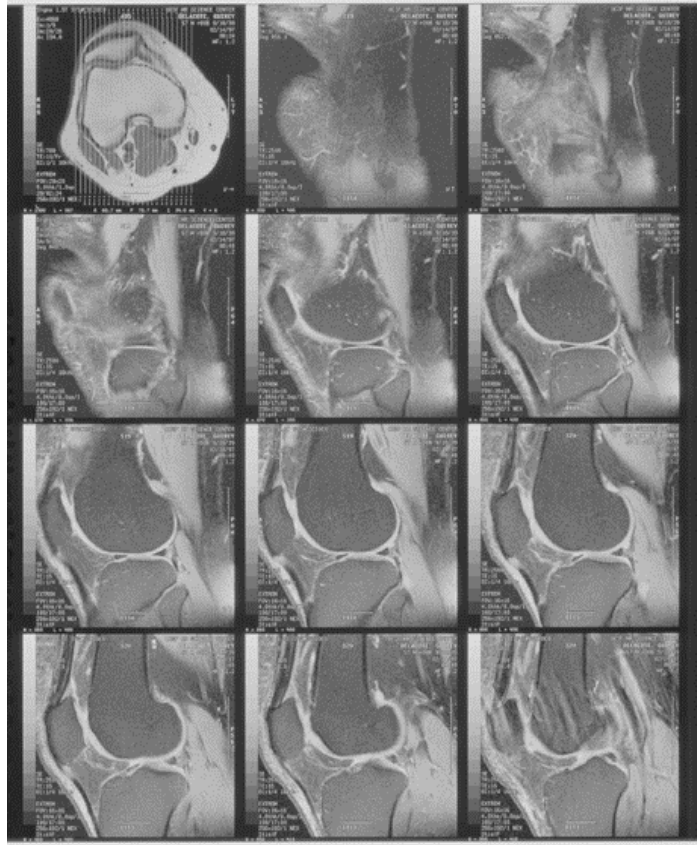


Figure 4: Proper film formatting of sagittal images. Images are printed 12 frames per film (3 x 4 format), with the localizer showing slice locations positioned in the upper left corner.

Magnification

Magnification should be the same from one examination to another for the same participant and should be documented on the MRI Logsheet (Appendix 3).

Windowing and leveling

Image window and level settings should be selected as in routine clinical practice to maximize discrimination of anatomy and pathology.

3.0 Data handling on site

All completed MRIs should be sent to the MRI reading center every two weeks. It is anticipated that all exams taken over the two-week period will fit on a single CD or optical disk. A complete MRI packet consists of the optical disk or CD labeled with each participant whose MRIs are included on the disk, plus individual participant packets with:

- Completed MRI logsheet
- Hard copies of the MRI films (3 sequences, one per film) in a separate jacket for each participant
- A completed Knee MRI Tracking Form.

3.1 Completing the MRI Logsheet

MRI Logsheets are provided to the clinical sites. Specific MRI information regarding the participant visit should be recorded onto this MRI Logsheet for each knee exam performed. Prior to shipping the data, a photocopy of each participant Logsheet must be made. A copy of the MRI Logsheet should be kept in the participant's clinic visit folder at the Health ABC clinic. The original should be included in the package and sent to the OARG at UCSF. A separate Logsheet must be used for each participant and for each visit.

An example of the MRI Logsheet (Appendix 3) is enclosed in this manual.

All of the following fields MUST be completed in the Logsheet by the MRI site prior to forwarding the data to the HABC clinical center:

Page 1. To be completed at MRI Center

- HABC Enrollment ID and Acrostic.
- Date of MRI exam using the date format (mm/dd/yy).
- Clinical site (check one).

Completeness of participant's MRI packet.

- Record examination number assigned by the MRI software for the right and left knees.
- Film magnification: none or 1.2.
- Internal Quality Assurance (QA) performed at time of exam
 - Sequences checked (check OK or not OK).
 - Important: Record sequential number of the optical disk / CD used to record the exam. This number is the only link between a participant ID and the specific optical disk / CD containing their data.
 - optical disk / CD optical disk contents checked (check OK or not OK).
 - MRI exam and QA check performed by (HABC Staff ID).
- Comments: Note reasons for any "not OK" in QA check. Specify changes to the protocol, such as change in the frequency encoding axis.

Page 2. Field Center QA

- The date that the participants scan data and films are shipped to OARG (UCSF). Use format mm/dd/yy (To be filled out by the HABC clinic).
- HABC Staff ID # of MRI coordinator checking packet completeness.

3.2 Labeling the images

The following information should appear on:

1. the MRI header (so that it will appear on the printed film copy and optical disk/CD) (see Figure A, Section 2.3)
2. the film copy jacket.
 - Clinic location and name (e.g., Memphis – Park Avenue)
 - "HABC" and participant enrollment ID (e.g., HA1000) for the MRI header, this information must be written in the "ID" field)
 - Participant name or acrostic
 - Date of MRI exam (mm/dd/yy)

- The side imaged (right or left) should be indicated on:
 - the film copy by annotating the localizer scan, and
 - the MRI header by entering “Right” or “Left” into the “Description” field.
- NOTE: Each knee has a different examination number.
- The MRI technician's Health ABC Staff ID# should be entered in the operator field on the setup screen

Use one film jacket per participant.

Each participant's images should be stored on optical disk / CD. **Follow the manufacturer's directions that come with the optical disk / CD before applying the label(s).** (Also, see 3.4 below)

Label the optical disk / CD with the following information:

- Use the color-coded, prenumbered stick-on label provided by OARG (each site will have its own color). If this label is not available, use the optical disk / CD manufacturer's label and assign a unique, sequential number to the label.
- **Participant enrollment ID and exam date (mm/dd/yy) for each of the examinations** should be included on the optical disk / CD.

Each optical disk can have only two labels. The labels must not be put on the sides over regions where the metal cover of optical disk can slide. The MRI center should read the instructions and look at the figure showing disk labeling carefully so as to label the disk properly (see section 3.4 below). These labels must neither interfere with the operation of disk nor jam the computer drive.

If CDs are to be used, it is recommended that the HABC IDs and dates of exams be written directly on the disk using a proper pen.

3.3 On-site quality assurance (QA)

The MRI tech and the MRI coordinator for Health ABC at the site have the responsibility of ensuring that the quality of the shipment (image data, MRI Tracking Form, and Logsheet) are checked BEFORE the package is sent to the clinical center for shipment to the OARG.

Each participant exam should be checked for:

1) Completeness:

- a) All three sequences for each knee
- b) Complete and accurate MRI Logsheet
- c) Completed MRI Tracking Form (**which must be returned to the Field Center along with the rest of the packet for the participant**)

2) Reproducible technique:

The data has been acquired using the correct MRI parameters in strict accordance to the OARG MRI protocol. In some cases, the exact recommended MRI parameters cannot be achieved for one reason or another, e.g., the TR or field of view may have to be increased slightly for an unusually large knee to achieve full anatomical coverage. It is important that any such deviations from protocol be documented and explained on the MRI Logsheet and implemented in all subsequent MRI visits. [Note: the only deviations allowed are: increase of TR and increase of FOV to allow adequate anatomical coverage and use of 1.2 magnification.]

3) Image quality: Images should be checked at the time of the exam (before the participant leaves) by the MRI tech for proper anatomic coverage, adequate signal-to-noise ratio, and the absence of artifacts:

- a) Motion artifacts: Images that are degraded by participant motion artifacts should be repeated once following correction of any cause of participant discomfort or anxiety. Often verbal reassurance is sufficient to allay mild participant anxiety. However, severe claustrophobia may require that the participant be withdrawn from the study.
- b) Metallic artifacts in acquired scans: these images should be sent to OARG in the usual way, with the problem noted on the log. OARG will determine whether the images can be analyzed.
- c) Aliasing: The use of No Phase Wrap should avoid aliasing. Rarely, phase and frequency encoding directions must be swapped. This should be avoided, particularly on the coronal images, as the current frequency-encoding direction has been selected to minimize chemical-shift artifacts along femorotibial cartilage margins. It is important that any such deviations from the original protocol be documented and explained on the MRI Logsheet, and that the changes be replicated in all subsequent MRI visits.

3.4 Labeling optical disks

Optical disks have to be labeled very carefully. **It is very important that the labels do not obstruct the region of the disk where the metal cover of the disk slides.** See Figure 5.

To orient yourself, hold the optical disk so that the metal cover is at the top and the writing is right side up. If side A is facing you, the metal cover will slide to the right. Therefore, the label must be placed on the left side of the disk. On Maxell optical disks, this area is labeled “A.” On Hewlett Packard disks, this is the area where it is not labeled “A.”

If the B side is facing you, the metal cover slides to the left. Therefore, the label can only be placed on the right side. On Maxell disks, this area is labeled “B.” On Hewlett Packard disks, this is the area where it is not labeled “B.”

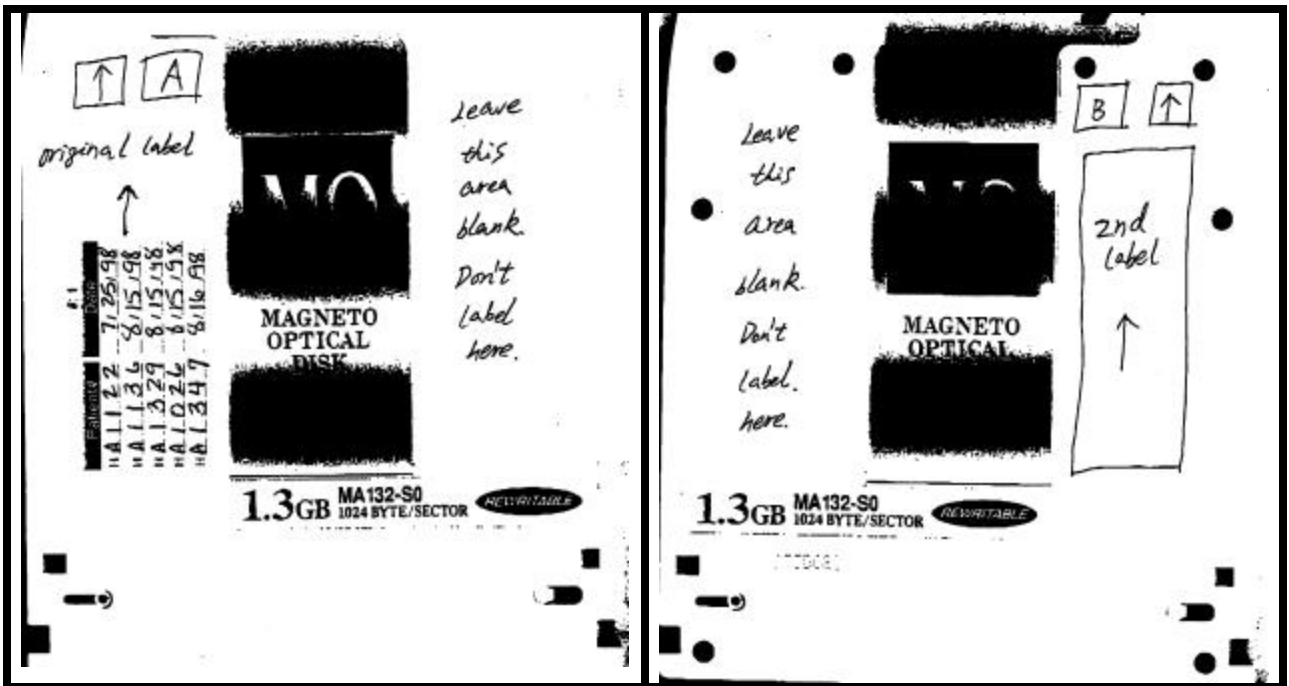


Figure 5: Proper labeling of a Maxell optical disk

It is very easy to test whether you are putting the label in the right place. If you can move the metal cover without it passing over the label, you’ve got it right. Obviously, you should be careful not to touch the disk itself. Another suggestion might be to use only one brand of optical disk so you can always label in the same way and you will be less likely to make this mistake.

Please make sure that everyone at your institution who labels optical disks fully understands these instructions. The Field Center QC Coordinators (Sandra Van Eck at Memphis and Piera Kost at Pittsburgh) are responsible for double-checking that these labeling rules have been followed before sending the shipment on to the Reading Center. Any questions regarding labeling rules or shipments should be directed to Jing Li at (415) 502-2477.

3.5 Shipment to OARG at UCSF

A complete shipment consists of the following items:

1. Log sheets (one per participant) showing the information of participants whose scans are included in the shipment. The log sheet for each participant must show: 1) HABC enrollment ID #, 2) Acrostic #, 3) Date of MRI, 4) Field center, 5) Date of shipment, 6) MRI coordinator ID #, 7) Exam numbers, 8) Film magnification factor, 9) Optical disk / CD #, 10) MRI technician ID #.
2. Hard copy of the films (all 3 sequences for each knee scanned) with each participant in separate, labeled jackets;
3. Optical disks / CDs with the archived images for each participant labeled with the SEQUENTIAL NUMBER of the OPTICAL DISK or CD, and the HABC ENROLLMENT ID #, EXAM # and EXAM DATE of each participant on the disk.

These shipments should be sent at least every 2 weeks to the Reading Center.

It is the responsibility of the MRI Coordinator at each facility to ensure the completeness of each shipment before giving it to the Field Center to send to the Reading Center. This includes checking that all disks and tapes are labeled correctly and that for every participant log sheet there is a corresponding entry on an optical disk or CD label, and vice versa. All hard copies of scans (3 per knee) should be in a separate labeled jacket for each participant on the log sheet.

In addition, the QC person at each Field Center (Piera and Sandra) is responsible for checking the contents of each package before shipping. Again, this includes checking that all disks and tapes are labeled and that each participant on the log sheet appears on one of the labels. If a shipment does not conform to the guidelines above, it should be returned to the MRI center for correction.

If these procedures are followed, there should be no reason that the Reading Center would receive incomplete shipments. If, however, anything is missing from a shipment, the Reading Center will contact the MRI center directly and cc the Coordinating Center.

Requests for repeat scans, in the event that the initial scan was not usable or is missing, will be sent directly to the QC Coordinator at the Field Center. While it is desirable to get usable scans on all eligible participants, we realize that practical considerations may make it undesirable to ask some participants to come back for a repeat MRI. Therefore, it will be left up to the clinical and professional judgment of the QC Coordinator to decide whether to re-contact the participant. If a participant will not be re-contacted or is contacted and refuses to undergo a repeat MRI, you must notify the Reading Center, so that this can be noted in the database comments field and a repeat request will not be sent.

Send the shipment to:

HABC c/o Jing Li
OARG Quality Assurance Center
University of California, San Francisco
350 Parnassus Avenue, Suite 150
San Francisco, CA 94117-1349

For each shipment, complete the Health ABC Knee MRI Shipment Notification form, and fax a copy to the OARG at UCSF (Appendix 4).

Complete the form by filling in:

- MRI site identification
- Date of shipment and expected delivery date
- Courier and airway bill # (remember to keep your copy of the Airway bill).
- Range of exam dates included in shipment (mm/dd/yy to mm/dd/yy)

4.0 Data handling at UCSF

All image data will be sent on hard copies and optical disks / CDs to UCSF for centralized analysis.

4.1 Quality reading of images

The images will be checked using the Knee MRI Logsheet (Appendix 3) to ensure that all sequences in the protocol were included and that the pulse parameters used were in

agreement with the protocol. The images will also be checked for adequate anatomical coverage, signal-to-noise ratio, and the presence of artifacts.

Confirmation that the image data was received will be faxed to the clinical site within 3 working days of receipt of the images to allow a repeat examination to be performed within 1 week of the original examination, if necessary.

If problems with image quality or protocol adherence are encountered, UCSF will interact directly with the study center to correct the problem.

5.0 Questions regarding the techniques outlined in this manual should be directed to:

Ali Guerhazi, MD

Phone: (415) 476-4524 Fax: (415) 502-2486

E-mail: ali.guerhazi@oarg.ucsf.edu

Souhil Zaim, MD

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Questions regarding data management should be directed to:

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Department of Radiology, Quality Assurance Center
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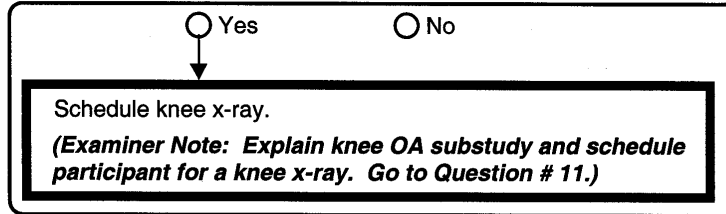
APPENDIX 1 Knee MRI Eligibility



KNEE X-RAY ELIGIBILITY ASSESSMENT

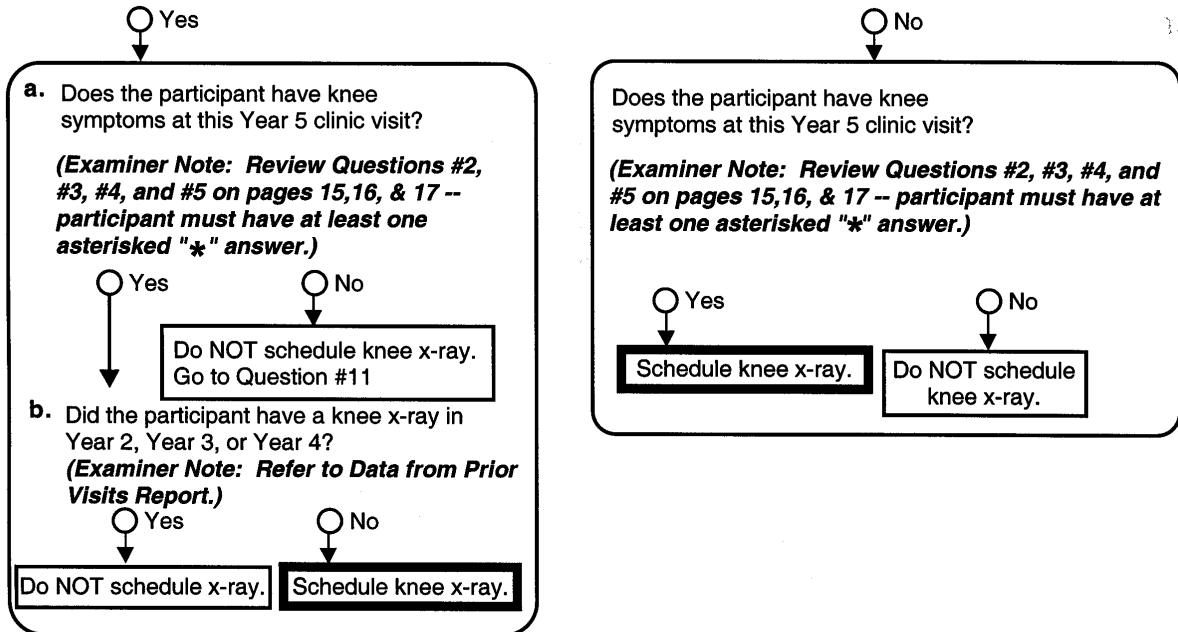
9 Is the participant eligible for a follow-up knee x-ray?

(Examiner Note: Refer to Data from Prior Visits Report.)



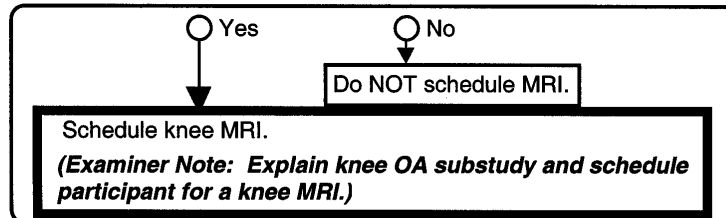
10 Did the participant have knee symptoms that met eligibility criteria for a knee x-ray in Year 2, Year 3, or Year 4?

(Examiner Note: Refer to Data from Prior Visits Report.)



11 Is the participant eligible for a follow-up knee MRI?

(Examiner Note: Refer to Data from Prior Visits Report.)



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APPENDIX 2 Knee MRI Tracking Form



HABC Enrollment ID #	Acrostic	Date Form Completed	Staff ID #
H <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> / <input type="text"/> / <input type="text"/> Month Day Year	<input type="text"/> <input type="text"/> <input type="text"/>

KNEE MRI TRACKING FORM

Annual clinic visit: Year 5 Other (*Please specify*) _____
 Year 6 _____
 Year 7 _____

1 Name of Health ABC participant: _____
 First Name Middle Initial Last Name

2 Does participant weigh > 250 lbs (>113.5 kg)?
 (*Examiner Note: Do not re-weigh participant. Check weight measurement in the Clinic Visit Workbook.*)

Yes No

Measure waist and hip circumference.
 Is maximum circumference ≥ 160 cm?
 Yes No

Do not test. Go to Question #11.

3 Do you have a heart pacemaker?
 Yes No Don't know Refused

Do not test. Go to Question #11. Do not test. Go to Question #11. Do not test. Go to Question #11.

4 Have you ever had a surgery to repair an aneurysm?
 Yes No Don't know Refused

Do not test. Go to Question #11. Do not test. Go to Question #11. Do not test. Go to Question #11.

5 Have you ever had an injury in which metal or metal fragments may have entered your eye?
 Yes No Don't know Refused

Do not test. Go to Question #11. Do not test. Go to Question #11. Do not test. Go to Question #11.

6 Have you ever had any surgery to insert a valve into your heart?
 Yes No Don't know Refused

Do not test. Go to Question #11. Do not test. Go to Question #11. Do not test. Go to Question #11.

Page Link #





KNEE MRI TRACKING FORM

7 Have you had a hearing device surgically implanted in your ear (not a regular hearing aid)?

Yes

No

Don't know

Refused

Do not test. Go to Question #11.

Do not test. Go to Question #11.

Do not test. Go to Question #11.

8 Have you had a total knee replacement in either knee?

Yes

No

Don't know

Refused

Do not test. Go to Question #11.

9 Have you had any surgery in the past two months?

Yes

No

Don't know

Refused

Test should be scheduled after 2 months have passed since surgery.

Do not test.

Do not test.

10 Do you have claustrophobia?

(Examiner Note: Only definite claustrophobia is a firm contraindication. True claustrophobia is relatively uncommon [2-3%]. Participants with claustrophobia will know who they are. Some may say they are uncomfortable in small spaces, but may tolerate MRI without difficulty. It is useful to make an attempt in persons who seem uncertain or who have mild concern.)

Yes

No

Don't know

Refused

Determine if participant is willing to try the test.

11 Is the participant eligible for an MRI?

Yes

No

12 Was an MRI obtained?

Yes

No

Why wasn't an MRI obtained?

Participant ineligible

Participant did not show up for MRI appointment

Participant refused

Other (Please specify:

Grid for specifying other reasons

Grid for specifying other reasons

STOP.

Page Link #





KNEE MRI TRACKING FORM

Examiner Note:
Refer to Data from Prior Visits Report to determine which knee should be scanned and mark appropriate box(es).
MRI Technician:
Please scan only specified knee(s).

13 Was MRI obtained for each of the following sites?

Scan Right knee

a. Axial T2-weighted FSE

Yes No → Reason: _____

b. Sagittal fat suppressed T2-weighted FSE

Yes No → Reason: _____

c. Coronal T2-weighted FSE

Yes No → Reason: _____

Scan Left knee

a. Axial T2-weighted FSE

Yes No → Reason: _____

b. Sagittal fat suppressed T2-weighted FSE

Yes No → Reason: _____

c. Coronal T2-weighted FSE

Yes No → Reason: _____

14 At which facility was the MRI taken?

Memphis Park Avenue

Memphis: Other

Pittsburgh UPMC

Other (*Please specify:*

--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--	--

)

15 What was the Health ABC staff ID# for the MRI technician?

--	--	--

16 What date was the MRI completed?

		/				/			
Month			Day				Year		

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**APPENDIX 3
(page 2 of 2)**



FOLLOW-UP KNEE MRI LOG (cont.)

TO BE COMPLETED BY QC COORDINATOR AT FIELD CENTER

Please confirm the following:

- Optical disk is labeled with this participant's Health ABC Enrollment ID# and date of exam
- Log sheet is complete:
 - Health ABC Enrollment ID #
 - Date MRI taken
 - Acrostic
 - Optical Disk/CD #
 - Exam #
- Film
 - Jacket is labeled with Health ABC Enrollment ID #
 - Jacket is labeled with date MRI taken
 - Film not required
- Health ABC MRI Tracking Form is completed and returned

Date shipped to Reading Center

/ /
 Month Day Year

QC Coordinator ID#:

TO BE COMPLETED AT READING CENTER

Date received:

/ /
 Month Day Year

Received and checked by: _____

TO BE COMPLETED AT READING CENTER

		UCSF QA	
		Left	Right
Exam Number:	_____		
Film magnification factor:	_____		
Note: If "not OK" specify reasons below in comments section (include number, e.g., 1, 2, 3, or 4)			
① Axial FSE T2 localizer	<input type="checkbox"/> OK <input type="checkbox"/> not OK	<input type="checkbox"/> OK <input type="checkbox"/> not OK	
② Sagittal FSE T2 w/fat suppression	<input type="checkbox"/> OK <input type="checkbox"/> not OK	<input type="checkbox"/> OK <input type="checkbox"/> not OK	
③ Coronal FSE T2	<input type="checkbox"/> OK <input type="checkbox"/> not OK	<input type="checkbox"/> OK <input type="checkbox"/> not OK	
④ Optical disk/CD# <input type="text"/>	<input type="checkbox"/> OK <input type="checkbox"/> not OK	<input type="checkbox"/> OK <input type="checkbox"/> not OK	
⑤ Quality Assurance			
Initials: _____			
<input type="text"/> / <input type="text"/> / <input type="text"/> Month Day Year			
Comments:	Accuracy of sequence:	Accuracy of sequence:	
(Please note: include reasons for "not OK" checks here and specify changes in the protocol: for example, change in the frequency encoding axis. Include the number: eg., 1, 2, 3, or 4)	Artifacts:	Artifacts:	
	Other:	Other:	

APPENDIX 4 HEALTH ABC KNEE MRI SHIPMENT NOTIFICATION

TO: Jing Li, OARG-UCSF

FAX: (415) 502-2486

FROM: _____

- SITE ID: Memphis Park Avenue
 Memphis: Other
 Pittsburgh UPMC
 Other

FAX: _____

RE: MRI Shipment of Health ABC Participant Data

Message

The following data is being sent to you today _____
(today's date)

For delivery on _____
(date)

VIA: Mail Delivery service: _____ Airbill # _____
(airbill number)

Exam Date Range of Participants Included:

// to //
Month Day Year Month Day Year

Please call _____ at _____ if you have any questions.
(name) (telephone number)

Response from OARG:

Shipment received on: //
Month Day Year

Not received as of: //
Month Day Year

Comments: _____

