

15-MONTH TELEPHONE INTERVIEW

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TELEPHONE INTERVIEW**1. Purpose and description of the Telephone Interview**

All MOST participants will be surveyed by phone approximately 15 months after their baseline examination. The purpose of the phone interview is to:

- reassess knee symptoms
- determine if participant has had knee or hip replacement surgery, and if so, complete Event Notification Form for Knee/Hip Replacement or Death
- determine if the participant is eligible to come into the clinic for the follow up clinic visit and if the clinic visit will be with x-ray (a potential ‘case’) or without x-ray (a potential ‘control’)
- schedule clinic visits for eligible participants
- update participant contact information

The components of the Telephone Interview are listed below:

- Knee symptoms
- Knee injury
- Knee surgery
- Hip pain
- Hip surgery
- Disability
- Clinic visit eligibility (initial)
- MRI eligibility
- Fracture history
- Contact information
- Clinic visit eligibility (final)
- Scheduling a clinic visit for eligible participants

In order to standardize the telephone interview approach, field centers should use the script outlined in Appendix 3. It is important to speak directly to the participant when conducting the Telephone Interview.

Question #23 regarding fracture history and the contact information questions (Questions #24 to #29) should be completed for all participants contacted by phone.

Box A on page 8 of the Telephone Interview First Follow-up Visit Workbook preliminarily determines clinic visit eligibility based on reported knee and hip symptoms and injuries, and Box B (page 15) indicates final clinic visit eligibility after taking into account MRI eligibility. A clinic visit is not scheduled until Box B has been completed.

2. Preparing for the Telephone Interview

Prior to calling the participant, the following materials should be readily available:

- 1) Telephone Interview First Follow-up Visit Workbook with participant ID and acrostic pre-printed.
- 2) Data from Prior Visits Report for First Follow-up Telephone Interview (found on the study website under “Reports”, see Appendix 1 for sample)
- 3) Telephone Interview contact log (Appendix 2)
- 4) Telephone Interview script (Appendix 3)
- 5) Contact information for participant, next of kin and two contacts (from your local records)
- 6) List of MRI-safe surgeries (Appendix 4)
- 7) Scheduling a visit script (Appendix 5)
- 8) Event Notification Form for Knee/Hip Replacement or Death, as needed (Appendix 6)

3. Calling the participant

Participants are mailed the MOST Winter 2005 Newsletter in January of 2005, in which they are notified that they will be contacted by phone for the first follow up. The telephone interview should be scheduled approximately 15 months after the date of the participant’s baseline examination (minimum of 12 months required).

Leaving a message. If the participant is not home, leave your name and phone number, and that you are calling from the MOST study being conducted by the University of Iowa/Alabama. If you are speaking with a person, ask what would be a good time to call back and record this time on the Telephone Interview Contact Log developed by your field center. If you are leaving a message on an answering machine, say what day and time of day you will try to call back. Of course, also leave the phone number of the field center so that the participant has the option of contacting you. Record the day and time of each attempt on the Telephone Interview Contact Log.

Multiple attempts to contact the participant. Attempt to call the participant numerous times (number of attempts to be determined by your field center) and at different times of day and on different days of the week. For example, if the first attempt was during the day, attempt to call the participant after dinner. Record the day and time of each attempt on the Telephone Interview Contact Log. After multiple attempts, leave a message for the participant to call you at their convenience.

Once you reach the participant by telephone, briefly review the purpose of today’s call with them and see if they are willing to complete the telephone interview now. If they are unwilling to complete the telephone interview now, ask them when you can call back, and record the day and time that the participant specifies on your Telephone Interview Contact Log (Appendix 2).

4. Q by Q (Question by Question)

4.1 Q by Q—Knee Symptoms (pages 1-2)

1. Introduce questions: “First, I will be asking you several questions about pain, aching, or stiffness in or around your knees. The first questions will be specifically about your right knee.”

“During the past 12 months, have you had pain, aching, or stiffness in your right knee?”
Skip to Question #3 if they say “No” or “Don’t know.” If they say “Yes”:

- 1a. Ask, “During the past 12 months, have you had pain, aching, or stiffness in your right knee on most days for at least one month?”

Explain what is meant by “most days.” Say, “by ‘most days,’ we mean more than half the days of a month.”

2. Ask, “During the past 30 days, have you had any pain, aching, or stiffness in your right knee?” Skip to Question #3 if they answer “No” or “Don’t know.” If they answer “Yes”:

- 2a. Ask, “During the past 30 days, have you had pain, aching, or stiffness in your right knee on most days?” Again, clarify by saying, “By ‘most days,’ we mean more than half the days of a month.”

Move on to Question #3 if they answer “No” or “Don’t know.” If they answer “Yes”:

Go to Box A (page 8) and mark “Yes” for Question # 1a. Then return to page 2, Question #3 without completing Box A.

3. Introduce next few questions: “Now I’ll ask you specifically about your left knee.”

“During the past 12 months, have you had any pain, aching, or stiffness in your left knee?” Skip to Question #5 if they say “No” or “Don’t know.” If they say “Yes”:

- 3a. Ask, “During the past 12 months, have you had pain, aching, or stiffness in your left knee on most days for at least one month?”

Clarify by saying, “By ‘most days,’ we mean more than half the days of a month.”

4. Ask, “During the past 30 days, have you had any pain, aching, or stiffness in your left knee?” Skip to Question #5 if they answer “No” or “Don’t know.” If they answer “Yes”:

- 4a. Ask, “During the past 30 days, have you had pain, aching, or stiffness in your left knee on most days?” Again, clarify by saying, “By ‘most days,’ we mean more than half the days of a month.”

Move on to Question #5 if they answer “No” or “Don’t know.” If they answer “Yes”:

Go to Box A (page 8) and mark “Yes” for Question # IIa. Then return to page 2, Question #5 without completing the rest of Box A.

5. Introduce the next question: “Now I’ll ask you about both knees.”

“During the past 30 days, have you limited your activities because of pain, aching, or stiffness in either knee?”

If they answer “Yes”:

- 5a. Ask, “On how many days did you limit your activities because of pain, aching, or stiffness?” Record the number of days as a two-digit number. For example, if the participant reports “2 days,” enter “02.”

If they answer “No” or “Don’t know”:

- 5b. Ask, “During the past 30 days, have you tried to avoid knee pain or reduce the amount of knee pain by avoiding, changing, or cutting back on any of your normal activities?”

4.2 Q by Q—Knee Injury (page 3)

6. Introduce the next two questions: “The next two questions are about knee injuries.”

“Since your last visit to the MOST clinic, have you injured your right knee badly enough to limit your ability to walk for at least two days?”

7. Ask, “Since your last visit to the MOST clinic, have you injured your left knee badly enough to limit your ability to walk for at least two days?”

4.3 Q by Q—Knee Surgery (pages 4-5)

8. Introduce the next few questions: “The next few questions are about knee surgery.”

Ask, “Since your last visit to the MOST clinic, did you have any surgery in your right knee?”

If they answer “No” or “Don’t Know,” go to Question #10 on page 5. If they answer “Yes,” go on to the next question.

9. Ask, “Since your last visit to the MOST clinic, did you have the following types of surgery in your right knee?” It is important that the participant understands that you are only asking about their right knee at this point.
- “Arthroscopy (where they put a scope) in your right knee?”
 - “Meniscectomy (where they repaired or cut away a torn meniscus or cartilage) in your right knee?”
 - “Ligament repair in your right knee?”
 - Right total knee replacement, where all or part of the joint was replaced?”

If the participant answers “Yes,” complete the Event Notification Form for Knee/Hip Replacement or Death (Appendix 6) and mark “Knee Replacement; Right knee.” Ask the participant the date of the surgery. If they are unsure, ask them to make their best guess. Then go on to Question #9e.

- “Another kind of surgery in your right knee?”
- Please check if any of the answers for Questions #9a-#9e are marked “Yes” and mark the appropriate bubble.

If No: Go on to Question #10 on the next page.

If Yes:

- Ask the participant, “Do you have any metal implants (such as pins, screws, staples, etc.) in your right knee from this surgery?”

If they answer “No” or “Don’t know,” go to Question #10 on the next page.

If they answer “Yes,” this information will be important when you are completing Box A on page 8.

10. Ask, “Since your last study visit did you have any surgery in your left knee?”
If they answer “No” or “Don’t know,” go to Question #12 on page 6. If they answer “Yes,” go on to the next question.

11. Ask, “Since your last study visit did you have the following types of surgery in your left knee?” It is important that the participant understands that you are only asking about their left knee now.
- “Arthroscopy (where they put a scope) in your left knee?”

- b. “Meniscectomy (where they repaired or cut away a torn meniscus or cartilage) in your left knee?”
- c. “Ligament repair in your left knee?”
- d. “Left total knee replacement, where all or part of the joint was replaced?”

If the participant answers “Yes,” complete the Event Notification Form for Knee/Hip Replacement or Death and mark “Knee Replacement; Left knee.” Ask the participant the date of the surgery. If the participant is unsure, ask them to make their best guess. Then go on to Question #11e.

- e. “Another kind of surgery in your left knee?”
- f. i. Please check if any of the answers for Questions #11a-#11e are marked “Yes” and mark the appropriate bubble.

If No: Go on to Question #12 on the next page.

If Yes:

- ii. Ask the participant, “Do you have any metal implants (such as pins, screws, staples, etc.) in your left knee from this surgery?”

If they answer “No” or “Don’t know,” go to Question #12 on the next page.

If they answer “Yes,” this information will be important when you are completing Box A on page 8.

4.4 Q by Q—Hip Pain (page 6)

12. Introduce the next few questions: “The next few questions are about your hip joints. First I’ll ask you about your right hip.”

Let the participant know that you want them to wait for you to completely finish reading the next question before they answer.

“During the past 30 days, have you had any pain, aching, or stiffness in or around your right hip? This includes pain in the groin and front and sides of the upper thigh. Do not include pain that was only in your lower back or buttocks.”

If they answer “No” or “Don’t know,” go on to Question #13.

If they answer “Yes”:

12a. Ask, “During the past 30 days, have you had pain, aching, or stiffness in your right hip on most days?”

Say, “By ‘most days,’ we mean more than half the days of a month.”

13. Introduce the next question, “Now I’ll ask you about your left hip.”

Let the participant know that you want them to wait for you to completely finish reading the next question before they answer.

Ask, “During the past 30 days, have you had any pain, aching, or stiffness in or around your left hip? This includes pain in the groin and front and sides of the upper thigh. Do not include pain that was only in your lower back or buttocks.”

If they answer “No” or “Don’t know,” go on to Question #14 on page 7.

If they answer “Yes”:

13a. Ask, “During the past 30 days, have you had pain, aching, or stiffness in your left hip on most days?”

Say, “By ‘most days,’ we mean more than half the days of a month.”

4.5 Q by Q—Hip Surgery/Disability (page 7)

14. Ask, “Since your last visit to the MOST clinic, did you have a right total hip replacement, where all or part of the joint was replaced?”

If they answer “Yes,” please complete the Event Notification Form for Knee/Hip Replacement or Death and mark “Hip Replacement; Right hip.” Ask the participant for the date of the surgery. If they are unsure, ask them to make their best guess. Then go on to Question #15.

15. Ask, “Since your last visit to the MOST clinic, did you have a left total hip replacement, where all or part of the joint was replaced?”

If they answer “Yes,” please complete the Event Notification Form for Knee/Hip Replacement or Death and mark “Hip Replacement; Left hip.” Ask the participant for the date of the surgery. If they are unsure, ask them to make their best guess. Then go on to Question #16.

16. Ask, “Are you able to walk by yourself without the help of another person and without a walker?”

4.6 Q by Q—Clinic Visit Eligibility Box A (page 8)

Box A assesses whether or not participant is potentially eligible to come for a clinic visit based on self-reported knee pain, whether or not the participant was randomly selected as a potential control, and whether or not the participant had a knee replacement.

At this point, please inform the participant that you will put them on hold for a few minutes while you complete Box A. Tell them, “Thank you for your answers so far. Please hold a moment while I review your answers. I will be right with you.”

Box A should be filled out left to right and top to bottom. Begin with the right knee in Question #I, answering parts a-e as directed. After finishing with the right knee, move on to Question #II for the left knee. Finally, complete summary Question #III.

I. Right Knee

- a. You should have already filled out the “Yes” bubble while completing Question #2a on page 1. If it is blank, check to make sure that Question #2a on page 1 is also blank. If so, mark “No” for Question #Ia.

If the “Yes” bubble is marked: Go to part b.

If the “No” bubble is marked: Go to part c.

- b. Refer to the Data from Prior Visits Report for First Follow-up Telephone Interview and mark whether or not participant had right knee pain at baseline.

If “Yes”: Go to Question #II.

If “No”: Go to part d.

- c. Refer to the Data from Prior Visits Report for First Follow-up Telephone Interview and mark whether or not participant’s right knee was randomly selected as a potential control knee.

If “Yes”: Go to part e.

If “No”: Go to Question #II.

- d. Refer to Question #9d on page 4 and to the Data from Prior Visits Report for First Follow-up Telephone Interview. If at least one of these indicates the participant had a right knee replacement, mark “Yes” and go on to Question #II. This participant’s right knee is not eligible.

If participant has not had their right knee replaced, mark “No.” This participant’s right knee is eligible as a potential ‘Case’. Go to Question #II.

- e. Refer to Question #9d and 9fii on page 4 and to the Data from Prior Visits Report for First Follow-up Telephone Interview. If at least one of these indicates the participant

had a right knee replacement, or has a metal implant in their knee, mark “Yes” and go on to Question #II. This participant’s right knee is not eligible.

If participant has not had their right knee replaced and does not have a metal implant in their right knee, mark “No.” This participant’s right knee is eligible as a potential “Control.” Go to Question #II.

II. Left Knee

- a. You should have already filled out the “Yes” bubble while completing Question #4a on page 2. If it is blank, check to make sure that Question #4a on page 2 is also blank. If so, mark “No” for Question #IIIa.

If the “Yes” bubble is marked: Go to part b.

If the “No” bubble is marked: Go to part c.

- b. Refer to the Data from Prior Visits Report for First Follow-up Telephone Interview and mark whether or not participant had left knee pain at baseline.

If “Yes”: Go to Question #III.

If “No”: Go to part d.

- c. Refer to the Data from Prior Visits Report for First Follow-up Telephone Interview and mark whether or not participant’s left knee was randomly selected as a potential control knee.

If “Yes”: Go to part e.

If “No”: Go to Question #III.

- d. Refer to Question #11d on page 5 and to the Data from Prior Visits Report for First Follow-up Telephone Interview. If at least one of these indicates the participant had a left knee replacement, mark “Yes” and go on to Question #III. This participant’s left knee is not eligible.

If participant has not had their left knee replaced, mark “No.” This participant’s left knee is eligible as a potential ‘Case’. Go to Question #III.

- e. Refer to Question #11d and #11fii on page 5 and to the Data from Prior Visits Report for First Follow-up Telephone Interview. If at least one of these indicates the participant had a left knee replacement, or has a metal implant in their knee, mark “Yes” and go on to Question #III. This participant’s left knee is not eligible.

If participant has not had their left knee replaced, mark “No.” This participant’s left knee is eligible as a potential “Control.” Go to Question #III.

- III. a. Refer to the right column of Questions #I and #II.

If either Question #Id or Question #IId is marked “No,” then participant is eligible as a potential case (mark “Yes” for Question #IIIa). Go to Box B on page 15 and mark the “ELIGIBLE FOR ‘CASE’ CLINIC VISIT” bubble. Then return to page 9 and continue with Question #17. Do not schedule the participant’s clinic visit appointment yet at this point.

If neither Question #Id nor Question #IId is marked “No,” the participant is not eligible as a potential case for either knee. Mark “No” for Question #IIIa and go to Question #IIIb.

- b. If either Question #Ie or Question #IIe is marked “No,” then the participant is eligible as a potential control (mark “Yes” for Question #IIIb). Go to Box B on page 15 and mark the “ELIGIBLE FOR ‘CONTROL’ VISIT” bubble. Then return to page 9 and continue with Question #17. Do not schedule the participant’s clinic visit appointment yet at this point.

If participant has not been determined to be eligible as either a potential Case or potential Control at this point, they are not eligible for a clinic visit. Mark “No” for Question #IIIb and mark the “NOT ELIGIBLE FOR CLINIC VISIT” bubble in Box B on page 15. Then go to page 12, Question #23.

4.7 Q by Q—MRI Eligibility (pages 9-11)

Unless you have been directed to go to Question #23, go to Question #17.

17. Refer to the Data from Prior Visits Report for First Follow-up Telephone Interview and mark whether or not the participant was eligible for an MRI scan at baseline.

If “No”: Go to page 11, Question #21 and mark “No” for Question #21. You will skip the rest of the MRI Eligibility questions of the interview.

If “Yes”: Say, “The next few questions are about MRI eligibility.”

- 17a. Ask, “Since your last MRI scan at the MOST clinic, have you had any surgery or anything implanted in your body?”

If “No”: Go to Question #18a on page 10.

If “Don’t know” or refused: Go to Question #17c.

- 17b. If “Yes”: Ask, “What type of surgery or implant was it?” Record this information in the space provided. Then ask, “When was the surgery?” Please probe if the participant is unsure. Record the date of the surgery in MM/DD/YY format. If the time interval between the date of the surgery and today’s date is

within 2 months, check to see if the type of surgery is on the MRI-safe surgery list found in Appendix 4.

If the surgery is not on the list, remember to schedule the clinic visit (if participant is determined eligible) at least 2 months after the date of the surgery.

- 17c. If a participant cannot have an MRI scan and they are not determined eligible as a potential case, they will not be eligible to come in for a first follow-up clinic visit. The next set of questions are asked to ensure that the participant does not have implants or embedded metal objects in their body that might create a health hazard or interfere with imaging during an MRI scan. Say, “The next few questions will be about specific implants. Please tell me whether any of the following was implanted in your body during surgery:” Ask the participant to answer “Yes” or “No” to each of the following (and mark the appropriate bubble):
- i. “Electronic implant or device, such as a cochlear implant”
 - ii. “Magnetically-activated implant or device, such as magnetically-activated dental implant or dentures, or magnetic eye implant”
 - iii. “Heart pacemaker”
 - iv. “Implanted heart defibrillator”
 - v. “Internal electrodes or wires, such as pacemaker wires or bone growth/bone fusion stimulator wires”
 - vi. “Neurostimulation system, such as spinal cord stimulator or gastric electrical stimulation system”
 - vii. “Surgically implanted insulin or drug pump”
 - viii. “Tissue expander with magnetic port, such as inflatable breast implant with magnetic port”
 - ix. “Brain aneurysm surgery, brain aneurysm clip(s) or coil(s)”
- 17d. Check to see whether any of the items in Question #17c (i-ix) are marked “Yes” or “Don’t know/Refused.” Mark the appropriate bubble. If “No,” go on to the Question #17e. If “Yes,” this participant is not eligible for an MRI. Go to Question #21 on page 11 and mark “No.”
- 17e. The next set of screening questions help determine whether a participant can be eligible for an MRI, even if they have an implant or injury by metal object, if they have appropriate medical documentation stating their implanted device/object is MRI-safe. Say, “Please tell me whether any of the following was implanted in your body:” Ask the participant to answer “Yes” or “No” to each of the following (and mark the appropriate bubble):
- i. “Stent, filter, coil, or clips”
 - ii. “Shunt (spinal or intraventricular)”
 - iii. “Vascular access port or catheter, such as a central venous catheter or PICC line”

- iv. “Surgically implanted hearing device (not a regular hearing aid) or prosthesis in your ear”
- v. “Eyelid spring, wire or weights”
- vi. “Penile implant or prosthesis” (*men only*)
- vii. “Heart valve surgery”

- 18a. The next two questions help to determine whether a participant should be excluded from having an MRI scan due to injury by metal object. Ask, “Since your last visit to the MOST clinic, have you had an injury in which metal fragments entered your eye and you had to seek medical attention?”
- 18b. Ask, “Since your last visit to the MOST clinic, have you had an injury in which metal fragments such as shrapnel, BB, or bullet entered your body?”
19. Review the answers you marked for Questions #17e (i-vii) and #18a-18b to see whether or not any of these answers are marked “Yes” or “Don’t know/Refused.” Mark appropriate bubble.

If No: go to Question #20

If Yes: go to Question #19a.

- 19a. Ask, “Do you have or would you be willing to ask your doctor for your medical records so that we could determine whether it would be safe for you to have an MRI scan?”

An example of appropriate medical documentation is a card or a letter from the participant’s physician stating that the implanted device is safe for an MRI. Please consult with your MRI technologist or on-site investigator if you have any questions about acceptable medical documentation.

If “No”: For safety reasons, participant is not eligible for an MRI scan. Skip to Question #21 on page 11 and mark “No” for Question #21 (do not answer Question #20).

If “Yes”: Make a note to yourself to remember to ask the participant to bring in medical documentation with them to clinic, if they are determined eligible for a clinic visit.

20. Do not ask the participant the question, but if there is any other reason the participant would not be eligible for an MRI scan (e.g., Participant tells you that they refuse to have another MRI), please write down the reason and mark the “Yes” bubble. Then go to Question #21 and mark “No”.

21. If the participant is ineligible for an MRI scan, the “No” bubble should already be marked (you were directed to mark “No” from Questions #17, 19, and 20). If the “No” bubble has not been marked: mark “Yes” and go to Question #22.

If the “No” bubble is marked: Go to Question #21a.

- 21a. Refer to Question #IIIa in Box A on page 8 to see if the participant is eligible as a potential ‘Case’. Mark appropriate bubble.

If “Yes”: Check to make sure that the “ELIGIBLE FOR ‘CASE’ CLINIC VISIT” bubble is marked in Box B on page 15. Then go to page 12, Question #23 (skip Question #22).

If “No”: Change the status of the participant to “NOT ELIGIBLE FOR CLINIC VISIT” in Box B on page 15. After marking the bubble, go to page 12, Question #23 (skip Question #22).

22. Ask, “Are you planning to have surgery in the next month?”

If “No” or “Don’t know/Refused”: go to Question #23.

If “Yes”: Go to Question #22a.

22a. Ask, “What is the date of your scheduled surgery?” Record the date in MM/DD/YY format. Then ask, “What type of surgery will you have?” and record the type of surgery in the space provided. Refer again to the list of surgeries that do not require a 2-month wait (found in Appendix 4). If the surgery is on that list, then change the answer of Question #22 to “No.” If surgery is not on that list, do not scan this participant’s telephone interview forms. Re-contact the participant 2 months after the date of the participant’s surgery to reassess eligibility (you will need to re-administer the entire telephone interview). It may be helpful to make a note of this on the Telephone Interview Contact Log.

4.8 Q by Q—Fracture History (page 12)

23. Fracture information will be obtained for all participants, regardless of whether or not they are eligible for a first follow-up clinic visit. Ask, “Since your last visit to the MOST clinic, did a doctor tell you that you broke or fractured a bone?”

If “No” or “Don’t know/Refused”: go to Question #24 on page 13.

If “Yes”: Ask Questions #23a-23b.

- 23a. Ask, “Were you told that you broke or fractured or hip?” Mark appropriate bubble.

- 23b. Ask, “Were you told that you had a fracture of the spine or fracture of the vertebrae?” Mark appropriate bubble.

4.9 Q by Q—Contact Information (pages 13-14)

Contact information will be updated for all participants, regardless of whether or not they are eligible for a first follow-up clinic visit. Refer to the contact information you have from baseline for this participant (in your local records) for the next few questions.

24. Say, “We would like to update all of your contact information this year. The address that we currently have listed for you is...”

Read the participant’s address from the baseline contact information records.

Ask, “Is the address that we currently have correct?” Mark appropriate bubble. If address is incorrect, please record the correct street address, city, state, and zip code in your local records.

25. Say, “The telephone number(s) that we currently have for you is (are)...”

Read the participant’s phone number(s) from the baseline contact information records.

Ask, “Are the telephone numbers(s) that we currently have correct?” Mark appropriate bubble. If the phone number is incorrect, please record the correct area code and phone number for your local records.

26. Ask, “Do you expect to move or have a different address in the next 6 months?”

Mark appropriate bubble. If participant is planning to move within the next 6 months, record the new street address, city, state, and zip code for your local records.

27. You will next update the contact information for the participant’s next of kin and two contacts. Refer to the baseline contact information records to see whether or not participant has identified their next of kin. If participant has not yet identified their next of kin, mark “No” and go to Question #28. Otherwise, mark “Yes” and go to Question #27a.

- 27a. Review the participant’s next of kin contact information. Say, “You previously told us the name and address of your next of kin. Please tell me if the information that I have is still correct.” Read the next of kin’s name and address and ask, “Is the name and address of your next of kin correct?”

If participant answers “Yes” or refuses to answer, go to Question #29.

If participant answers “No” or “Don’t know,” go to Question #28.

28. Say, “Please tell me the name, address, and telephone number of your next of kin. How is this person related to you?” Record the name, street address, city, state, zip code, telephone number, and how the person is related to the participant for your local records.
29. Refer to the baseline contact information records to see whether or not participant has identified their two contacts. If participant has not yet identified two contacts, mark “No” and go to Question #30. Otherwise, mark “Yes” and go to Question #29a.
- 29a. Review the participant’s information for their two contacts. Say, “You previously told us the name and address of your two contacts. Please tell me if the information that I have is still correct.” Read the first contact’s name and address and ask, “Is the name and address of your (relationship to participant) correct?” Repeat with the second contact.
- If participant answers “Yes” to both or refuses to answer, go to Box B on the next page.
- If participant answers “No” or “Don’t know” for either of the two contacts, go to Question #30.
30. Say, “Please tell me the name, address, and telephone number of your (first/second) contact. How is this person related to you?” Record the name, street address, city, state, zip code, telephone number, and how the person is related to the participant for your local records. Repeat for second contact if necessary.

4.10 Q by Q—Clinic Visit Eligibility Box B (page 15)

Box B determines final eligibility for the participant to come in to for a clinic visit. One of the bubbles in Box B indicating participant’s eligibility status (ELIGIBLE FOR CASE CLINIC VISIT, ELIGIBLE FOR CONTROL VISIT, or NOT ELIGIBLE FOR CLINIC VISIT) should be marked already. Thank the participant for their time and for answering your questions.

If participant is eligible, schedule a clinic visit.

If participant is not eligible, inform them they will be contacted again in approximately 12 months to schedule a clinic visit. Ask if they have any questions for you.

If the participant is eligible but does not agree to come in for a clinic visit, mark the “NOT INTERESTED” bubble in Box B and ask the participant why they are not interested at this time. Record reason(s), and inform the participant that they will be contacted again in approximately 12 months.

5. Scheduling a clinic visit for eligible participants

The clinic visit should be scheduled between 2 to 8 weeks (ideally, within 4 to 5 weeks) of the date of the Telephone Interview. If you need to call back to schedule an appointment, ask the participant what day and time within the next several weeks would be good for calling back to schedule an appointment.

Tell the participant that they will receive a confirmation notice in the mail in the next few days (time permitting) or a phone call reminding them of the day and time of the visit. Be sure to give the participant your name and phone number of the clinic to call if they need to reschedule the visit for any reason.

Tell the participant what to expect at the visit:

For those eligible for a potential Case clinic visit, the visit will last approximately 2 to 3 hours. The case clinic visit consists of a self-administered questionnaire, clinic interview (where questions about knee symptoms and medication use will be administered), weight measurement, knee MRIs on both knees (if MRI-eligible), knee X-rays, and a knee and hip exam.

For those eligible for a potential Control clinic visit, the visit will last approximately 1 to 2 hours. The control clinic visit consists of a self-administered questionnaire, clinic interview (where questions about knee symptoms and medication use will be administered), weight measurement, and knee MRI.

Tell the participant to bring in all their prescription and non-prescription medications, supplements, and vitamins that they have taken in the past 30 days. In addition, they should bring in medical documentation that shows it is safe for them to obtain an MRI (if they answered “Yes” to Question #19a on page 10).

Finally, thank the participant for their time, effort, and participation in this important study.

6. Record keeping and mailing clinic visit reminder

Once the telephone interview is complete, but before you hang up the telephone with the participant, review the form to make sure that all questions have been filled out carefully and completely.

Book-keeping procedures to re-contact participants who have recently had surgery or have a surgery scheduled or who just wish to be called back at a future time should be formalized at each field center. The use of various “Pending” files to keep track of deferred interviews should be considered.

If an appointment is made for a clinic visit, the date and time recorded in Box B of the Telephone Interview First Follow-up Visit Workbook should also be entered in a clinic scheduling book or electronic scheduling system.

Fill out a confirmation notice/clinic visit reminder letter with the date and time of the clinic visit and mail it to the participant. The note should include a reminder for the participant to bring in their medications and supplements and a medical documentation showing it is safe for them to have an MRI (if necessary). See Overview of First Follow-up Operations Manual for a sample of a reminder letter. If there is not enough time to mail a letter, a phone call reminder should be made.

Fill out the Telephone Interview Contact Log (See Appendix 2 for an example) developed by your field center and record the appropriate information about the call. The participant's updated contact information (including the contact information for their next of kin and two additional contacts) should also be entered in your local records.

7. Scanning the Telephone Interview First Follow-up Visit Workbook

Completed telephone interview forms should be scanned as soon as possible, but ideally no later than 1 to 2 days after completion.

We recommend that incomplete forms, such as those with information pending, not be scanned, but kept in a separate "Pending" file (indexed by name). Once the missing information is obtained, the completed telephone interview form should be scanned as soon as possible.

8. Quality assurance

8.1 Training requirements

The interviewer requires no special qualifications to perform this assessment. Previous interviewing experience will be helpful. Training should include:

- Read and study the following operations manual chapters:
 - Overview of Study (1)
 - Overview of First Follow up (2A)
 - Interviewing Guidelines (2B)
 - Telephone Interview (2C)
- Read MOST materials sent out to screenees
 - Winter 2005 Newsletter
- Thoroughly review the Telephone Interview First Follow-up Visit Workbook
- Practice administering the telephone interview on volunteers (if possible, age-eligible volunteers).

8.2 Certification requirements

- Completed training requirements

- Observation and evaluation of five *mock* telephone interviews (three of which will be done with the Coordinating Center staff, and the other two to be done by the Study Coordinator or their designate).
- Observation and evaluation of three *actual* telephone interviews by the Study Coordinator or their designate.

8.3 Quality Assurance Checklist

Administration of Telephone Interview

- Asks participant if they are willing to complete the telephone interview now
- Describes purpose of today's call
- Follows skip patterns in questionnaire
- Reads script and questions exactly as written in the Telephone Interview First Follow-up Visit Workbook (same order, same wording)
- Accurately records participant's responses on form
- Explains pause(s) necessary for interviewer to complete form
- Accurately determines initial clinic visit eligibility in Box A
- Accurately determines final clinic visit eligibility in Box B
- If necessary, accurately completes Event Notification Form for Knee/Hip Replacement or Death
- If participant is eligible, reads correct script for potential case or control clinic visit
- If participant is eligible, schedules appointment or time to call back for appointment
- If participant is not eligible, correct script read and participant thanked for their time
- Follows the guidelines for recording data on scannable forms
- At the end of interview, reviews forms for completeness

Interviewing Techniques

- Reads slowly, speaks clearly, and uses appropriate inflection when speaking
- Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
- Able to elicit accurate and complete information using non-directive probes
- Keeps interview on track by presenting questions at a regular pace
- Focuses participant's attention on questions while always being polite
- Treats participants with respect
- Maintains a professional and friendly manner; leaves participant with overall feeling of well-being

Appendix 1—Data from Prior Visits Report First Follow-up Telephone Interview

Participant Name: _____

MOST Participant ID# : TB00001

Acrostic: AAAA

**MOST
Data from Prior Visits Report
First Follow up Telephone Interview****Visit dates**

1. Date of baseline enrollment visit: **5/19/2003**
2. Target date range for Telephone Interview: **02/21/2005 – 02/26/2005**

Knee pain

3. Did participant have right knee pain at baseline? **No**
4. Did participant have left knee pain at baseline? **No**

Control status

5. Was participant's right knee selected as a control knee? **Yes**
6. Was participant's left knee selected as a control knee? **No**

Knee replacements

7. Was right knee replaced? **No**
8. Was left knee replaced? **No**

MRI history

9. Was participant eligible for an MRI at baseline? **Yes**

Appendix 2—Telephone Interview contact log

ID#: _____

NAME: _____ SEX: _____

ADDRESS: _____ AGE: _____

PHONE: _____ Best time to call: S M T W T F S ___:___ AM/PM

DATES OF CONTACTS	DAY OF WEEK	TIME	RESULTS/COMMENTS
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____
___/___/___	S M T W T F S	___:___ AM / PM	_____

CLINIC VISIT DATE ___/___/___
TIME ___:___ AM / PM

RESCHEDULED CLINIC VISIT DATE ___/___/___
(if needed) TIME ___:___ AM / PM

Appendix 3—Telephone Interview suggested script

Hello, my name is _____, and I am calling from _____ [UI][UAB] for the MOST study.

May I please speak with _____?

(If the person is available)

I am calling to follow up with you about your participation in the MOST study. I would like to ask you some questions about your knees and hips and update your contact information. Do you have time to talk right now? (Go to Question #1 of the Telephone Interview.)

(If the person is unavailable)

Can you tell me when would be a good time to call back?

I will try calling back on [Date] at [Time].

You can also have _____ call me at (XXX) XXX-XXXX. My name is _____ . Thank you.

Appendix 4—MRI-safe surgeries

MRI Safety: Surgeries on this list do not require a 2-month wait period:

- adhesion destruction or manipulation (nonsurgical)
- biopsy without surgical incision
- cyst removal with needle
- dental bridgework
- dental fillings
- destruction of kidney, bladder, or urethral stones by forced ultrasound energy
- dilation and curettage (D&C) not for terminating pregnancy and not following delivery
- injections:
 - injection of anesthetic into peripheral nerve
 - injection of anesthetic into spine
 - injection of non-anesthetic into spine
 - joint or ligament injection
- insertion of catheter for intravenous fluids into vein (not indwelling catheter)
- non-metallic foreign body removal (such as glass)
- periodontal surgery
- radial keratotomy
- rubber-banding of hemorrhoids
- skin biopsy / skin cancer removal
- spinal tap without implant
- suturing of a superficial cut
- wart removal

Appendix 5—Scheduling a visit script

For participant eligible for a potential CASE CLINIC VISIT:

Your visit will last approximately 2 to 3 hours. At this clinic visit, you will fill out a brief questionnaire, an interviewer will ask you questions about knee symptoms and medication use, you will have your weight measured, have knee MRIs and X-rays taken on both of your knees, and you will have a knee and hip exam.

For participant eligible for a potential CONTROL CLINIC VISIT:

Your visit will last approximately 1 to 2 hours. At this clinic visit, you will fill out a brief questionnaire, an interviewer will ask you questions about knee symptoms and medication use, you will have your weight measured, and have a knee MRI.

For both potential CASES AND CONTROLS:

The next step is for us to schedule your clinic visit. Do you have a calendar handy? Are there any days of the week you would prefer to have your appointment?

(Check available dates and times.)

That's great. We will see you at [time] on [date]. *(Remind participant of your name.)*

You will be receiving a letter describing how to prepare for your clinic visit in the mail. We would like you to bring in all your prescription and non-prescription medications, vitamins, and supplements that you have taken in the past 30 days. The examiner will need the bottles to record the spelling and dosage information.

If participant answers "Yes" to Question #19b on page 10: In addition, we would like you to bring in/ask your physician for a copy of your medical records showing that it is safe for you to have an MRI scan.

Do you have any questions for me about any of this? Well, I have you scheduled for _____. You will receive a reminder letter soon in the mail. Please call me if you think of any questions after we hang up. My name is _____ and our phone number is XXX-XXX-XXXX or toll-free, 1-800-XXX-XXXX. You will not be given any medications or treatment during this study. Thank you for your time today. Goodbye.

For participant not eligible for clinic visit:

Thank you for your time and for answering our questions. That's all the information that I need from you at this time. We will be contacting you in about 12 months to schedule a MOST clinic visit. Do you have any questions for me? Thank you again for your time. Goodbye.

For participant that is eligible for, but not interested in coming for a clinic visit:

Your participation in this important study is appreciated. Can you tell me why you aren't interested in coming to the MOST clinic at this time?

Should you change your mind, please give me a call at XXX-XXX-XXXX. My name is _____.

Thank you for your time and for answering our questions. We will be contacting you again in about 12 months. Do you have any questions for me? Thank you again. Goodbye.

Appendix 6—Event Notification Form for Knee/Hip Replacement or Death

 15123		Reference #:	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="radio"/> First Follow-up Visit <input type="radio"/> Second Follow-up Visit
MOST ID #	Acrostic	Date Completed		Staff ID #
<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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
		Month	Day	Year

Event Notification Form for Knee/Hip Replacement or Death

Instructions: Please complete one Event Notification Form for EACH event (knee/hip replacement or death) that is reported. Assign and log a unique reference number for each event reported (see upper left hand corner).

1. How was the event reported? *(Mark only one.)*

Follow up telephone interview
 Clinic-initiated phone contact (other than the follow up telephone interview, such as a scheduling call)
 Participant called clinic
 Spouse or other contact called clinic
 Clinic visit
 Other *(Please specify: _____)*

If information was not obtained from participant, please complete:

Name of person: _____

Relationship to participant: _____

2. Type of event: *(Mark only one. If multiple joint replacements, complete one Event Notification Form for each joint replacement.)*

Knee replacement →

2a. Which knee was replaced? Right knee Left knee

2b. Date replaced: / /
(Estimate if unsure)
 Month Day Year
Please obtain medical records and complete Knee Replacement Report.

Hip replacement →

2c. Which hip was replaced? Right hip Left hip

2d. Date replaced: / /
(Estimate if unsure)
 Month Day Year
Please obtain medical records and complete Hip Replacement Report.

Death →

2e. Date of reported death: / /
(Estimate if unsure)
 Month Day Year
Please obtain death certificate and complete Report of Death.

