

**FOLLOW-UP TELEPHONE INTERVIEW****TABLE OF CONTENTS**

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## 1. Purpose and description of the telephone interview

Telephone interviews are conducted prior to the 144- and 168(24)-month Follow-up Clinic Visit. The contact at 144-month will also determine Existing Cohort participant interest in enrollment for two additional visits and two interim telephone contacts. All MOST participants will be asked to come in for a follow-up clinic visit at 144- and 168(24)-months, except those participants with bilateral knee replacements or severe cognitive impairment. Participants will be surveyed by phone approximately 4 weeks prior ( $\pm$  2 weeks) to their follow-up clinic visit. The purpose of the follow-up phone interview is to:

- reassess knee symptoms
- administer cognitive assessment (Montreal Cognitive Assessment (MoCA) (5-minute protocol) (Appendix 1)
- assess eligibility for a clinic visit or a Missed Clinic Visit Telephone Interview
- determine if the participant is eligible to have an MRI (*if applicable*)
- schedule clinic visit (with MRI or without MRI) for all participants (*if applicable*)
  - update participant contact information

## 2. Preparing for the telephone interview

In order to standardize the telephone interview approach, field centers should use the script outlined in Appendix 4. It is important to speak directly to the participant when conducting the telephone interview.

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

- 1) Follow-up Telephone Interview with the participant ID and acrostic pre-printed (available in REDCap via the study website)
- 2) Data from Prior Visits Report for Follow-up Telephone Interview (available on the study website under “Reports,” see Appendix 2 for samples)
- 3) Telephone Interview Contact Log (Appendix 3)
- 4) Telephone Interview Suggested Script (Appendix 4)
- 5) List of MRI-safe surgeries (Appendix 5) (*if applicable*)
- 6) Scheduling a visit script (Appendix 6) (*if applicable*)
- 7) Event Notification Form for Knee/Hip Replacement or Death (floating form) (*if applicable*) (available in Teleform via the study website)
- 8) Missed Clinic Visit Telephone Interview Workbook (floating form) (*if applicable*) (available in REDCap via the study website)
- 9) Contact information for participant, next of kin and two contacts (from your local records)
- 10) Stop watch or clock/watch with a second hand for MoCA administration (*if applicable*)

### 3. Calling the participant

Telephone interview at 144-months and 168(24)-months followed by clinic visit (if eligible): The follow-up telephone interview should be completed approximately 4 weeks ( $\pm 2$  weeks) prior to the follow-up clinic visit. The 168-month follow-up telephone interview should be completed approximately 24 months after the 144-month visit.

**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 at Birmingham. 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 voice mail message, 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 to contact the participant 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 to contact the participant 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. The interview should be done with minimal distractions. Do not administer the Telephone Interview if the participant is driving or watching television. 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 3).

### 4. Q by Q (Question by Question)

The interviewer should refer to the Data from Prior Visits Report for the Telephone Interview to determine these two dates (month/year): What is the month and year of last contact? What is the month and year of first MOST clinic visit?

#### 4.1 Q by Q – knee symptoms and general health

Section A of the Telephone Interview. Introduce questions: "First, I am going to be asking you some questions about pain, aching, or stiffness in or around your knees. The first set of questions are about your right knee. Then I will ask you the same questions about your left knee."

1. "During the past 12 months, have you had pain, aching, or stiffness in your right knee?"  
Skip sub-question a. and go to question #3 if they say "No" or "Don't know." If they say "Yes" ask:

- a. “During the past 12 months, have you had pain, aching, or stiffness in your right knee on most days for at least one month? By ‘most days,’ we mean more than half the days of a month.”
2. “During the past 30 days, have you had any pain, aching, or stiffness in your right knee?”  
Skip sub-question a. and go to question #3 if they answer “No” or “Don’t know.” If they answer “Yes” ask:
  - a. “During the past 30 days, have you had pain, aching, or stiffness in your right knee on most days? Again, by ‘most days,’ we mean more than half the days of a month.”

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

3. “During the past 12 months, have you had any pain, aching, or stiffness in your left knee?”  
Skip sub-question a. and go to question #5 if they say “No” or “Don’t know.” If they say “Yes” ask:
  - a. “During the past 12 months, have you had pain, aching, or stiffness in your left knee on most days for at least one month? By ‘most days,’ we mean more than half the days of a month.”
4. “During the past 30 days, have you had any pain, aching, or stiffness in your left knee?”  
Skip sub-question a. and go to question #5 if they answer “No” or “Don’t know.” If they answer “Yes” ask:
  - a. “During the past 30 days, have you had pain, aching, or stiffness in your left knee on most days? Again, by ‘most days,’ we mean more than half the days of a month.”

Ask them the general health question:

5. “In general, would you say your health is: Excellent, Very good, Good, Fair, or Poor.”

#### **4.2 Q by Q – Montreal Cognitive Assessment (MoCA) (5-minute protocol)**

Section B of the Telephone Interview. Please see Appendix 1 for detailed instructions on administering this cognitive assessment.

#### **4.3 Q by Q – knee replacements**

Section C of the Telephone Interview. The first set of questions will not be asked of the participant.

Refer to the Data from Prior Visits Report (DPVR) to determine if participant has had a knee replacement. Answer the following questions based on information from the DPVR:

“Has participant had either one of their knees replaced (DPVR Question #5 and #7)?

If “Right”, enter date for right knee replacement from DPVR (Question #6) in the MM/DD/YYYY format if available.

If “Left”, enter date for left knee replacement from DPVR (Question #8) in the MM/DD/YYYY format if available.

If “Both”, enter date for right and left knee replacement from DPVR (Question #6, #8) in the MM/DD/YYYY format if available.

If “Right”, “Left”, or “Both” then answer: “Is the participant potentially eligible for MOST-SENS clinic visit? Interviewer Note: Refer to the Data from Prior Visits Report to determine if participant eligible for MOST-SENS (DPVR Question #9).”

If participant has both knees replaced and is NOT eligible for MOST-SENS, complete a Missed Clinic Visit Telephone Interview (MCVTI).

Otherwise, ask: “Since we last asked you on (<insert date from Data from Prior Visits Report>), did you have either one of your knees replaced? **Interviewer Note: Refer to the Data from Prior Visits Report for this interview to be sure right or left knee replacement has not already been reported as replaced.**

If “Yes”, ask: “Which knee was replaced?” and enter date of knee replacement in the MM/DD/YYYY format. Complete an Event Notification Form for each knee replacement reported.

*Note when participant can’t remember dates:* If the participant is unable to estimate a surgery date exactly to the day, but you have a month and year, please enter “01” as the day of the month. If a participant expresses difficulty even remembering what month the surgery took place, please try to get the closest estimate possible, and if the participant only gives a year, enter “01” as the day and “01” (January) as the month. It is very important for the determination of MOST-SENS eligibility to have at least some estimation of the knee replacement surgery date.

The next questions are not asked of the participant. When prompted refer to the DPVR.

“Based on all knee replacement information, is the participant eligible for MOST-SENS clinic visit (**Knee replacement surgery within past 24 months and is NOT a revision**)?” Make determination based on all knee replacement information provided during the interview. If participant has had a knee replacement within the past 24 months and it is NOT a revision, they are eligible for MOST-SENS.

Note: If participant is eligible for MOST-SENS, the clinic visit should be scheduled at least 9 months after the knee replacement surgery.

Is right knee eligible for an MRI according to DPVR (DPVR Question #11)?  
Is left knee eligible for an MRI according to DPVR (DPVR Question #12)?

Based on responses so far, logic programmed into the REDCap form will tell you what type of contact participant is eligible for: Missed Clinic Visit Telephone Interview (MCVTI); Clinic Visit no MRI; or Clinic Visit with MRI.

If participant is eligible for clinic visit (potentially with MRI), say: “MRI scans are an important part of this study. We’d like to ask you some questions to see if you are eligible for an MRI scan.

Would you be willing to have an MRI if it is determined that you are eligible?” **Interviewer Note: Please refer to the Data from Prior Visits Report, Question #10a, to determine if there was a reason not to do an MRI after the first MOST clinic visit. MRI eligibility will be reassessed at this time.**

#### 4.4 Q by Q – MRI eligibility

Section D of the Telephone Interview. Say, “The next few questions are about MRI eligibility.”

Since your first MOST clinic visit in *<insert date from Data from Prior Visits Report>*, have you had any surgery or anything implanted in your body? **Interviewer Note: Please refer to the Data from Prior Visits Report, Question #10a, to determine if participant has reported an implant in the past and probe if inconsistent.**

If “No:” Go to questions about metal fragments which are the next series of questions after surgery/implant questions.

If “Don’t know” or refused, skip surgery subquestions and ask about specific implants.

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/YYYY 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 on the data collection form or Appendix 5) and answer the question “Is the surgery on the list?”.

If the surgery is not on the list, remember to schedule the clinic visit (if participant is determined eligible for an MRI) at least 2 months after the date of the surgery. If the clinic visit cannot be scheduled within 2 months of the Telephone Interview, the Telephone Interview should be re-administered at least 2 weeks before clinic visit.

If you can’t schedule the clinic visit within 6 weeks of the Telephone Interview, you will need to 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.

If the surgery was for a knee or hip replacement, remember to fill out the Event Notification Form for Knee/Hip Replacement or Death.

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 dental implant or dentures, magnetic eye implant, or other magnetic device”
- 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)”

If any of the items in the question above (i-ix) are marked “Yes” or “Don’t know/Refused”, the participant is not eligible for an MRI. Answer the reliability question and then mark “Clinic visit no MRI.”

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 during surgery.” 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”

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 first MOST clinic visit in *<insert date from Data from Prior Visits Report>*, have you had an injury in which metal fragments entered your eye and you had to seek medical attention?”

“Since your first MOST clinic visit in *<insert date from Data from Prior Visits Report>*, have you had an injury in which metal fragments such as shrapnel, BB, or bullet entered your body?”

If none of the items in the questions above (i-vii and fragments entered eye or body) are marked “Yes” or “Don’t know/Refused”, determine if there is any other reason why this participant would not be eligible for an MRI, and mark appropriate bubble.

If any of the items in the question above (i-vii and fragments entered eye or body) are marked “Yes” or “Don’t know/Refused” determine if participant is willing to ask their doctor for medical records to help determine whether it is safe for them to have an MRI scan. Ask:

“Do you have or would you be willing to ask your doctor for medical documentation 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.

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

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, participant has had bilateral knee replacements), please mark the “Yes” bubble and make a note of reason in participant’s chart if possible.

Based on the answers to the MRI eligibility questions, it will be determined whether the participant is eligible for an MRI and this will be displayed automatically in the Telephone Interview in REDCap.

If participant is eligible for the MRI, ask, “Are you planning to have surgery in the next month?”

If “Yes:” ask:

“What is the date of your scheduled surgery?” Record the date in MM/DD/YYYY format. Then say “To determine when you are eligible for an MRI, I’d like to know the type of surgery you are having” and ask, “What type of surgery will you have?” 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 on the data collection form or in Appendix 5) and answer the question “Is the surgery on the list?”

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

*Reminder note when participant can’t remember dates:* If the participant is unable to estimate a surgery date exactly to the day, but you have a month and year, please enter “01”



as the day of the month. If a participant expresses difficulty even remembering what month the surgery took place, please try to get the closest estimate possible, and if the participant only gives a year, enter “01” as the day and “01” (January) as the month.

#### 4.5 Q by Q – reliability

Interviewer only: Answer the following question: “On the whole, how reliable do you think the participant’s responses to this questionnaire are?”

#### 4.6 Q by Q – clinic visit eligibility, interest, and interviewer assessment

The next question is about type of clinic visit (Question #18) the participant is eligible to have when they come in for a clinic visit. Depending on the answers to the MRI eligibility questions, Clinic Visit with MRI, Clinic Visit no MRI or MCVTI only will be marked. The eligibility status of the participant will be displayed in the REDCap Telephone Interview as one of the following:

Eligible for MRI  
Eligible for clinic visit with MRI

OR

Not eligible for MRI  
Eligible for clinic visit no MRI

OR

Participant eligible for MCVTI

Thank the participant for their time and for answering your questions and schedule the appropriate type of clinic visit.

If the participant does not agree to come in for a clinic visit (Question #19), mark the “NOT INTERESTED” bubble and ask the participant why they are not interested at this time. Record the reason.

Continued participation in MOST (Question #19b) will also be assessed at this time. Do not ask the participant the question, but if there is any reason the participant will not/should not continue to participate in MOST (e.g., cognitive difficulties, dissatisfied with study, etc. ), please mark the “No” bubble. Please note that a “No” response will remove the participant from the Visit Scheduling Report for future contacts.

If “not interested” ask the participant “Would you be willing to stay on the phone for about 15 more minutes to answer a few more questions about your knees, hips, medications, and health history?” (Question #20). If they say “Yes,” complete the Missed Clinic Visit Telephone Interview Workbook and then ask if they have any further questions and thank them for their

time. If they answer “No,” ask if you can call them back to complete the Missed Clinic Visit Telephone Interview and schedule that interview time.

Ask if they have any further questions and thank them for their time. If the participant will not have a follow-up clinic visit at this time, inform them about when they can expect to be contacted next.

At the end of the interview, the examiner should answer the following questions in the Telephone Interview (#21a-d) based on their judgment:

During the administration of this interview:

“Did the participant complain about not being able to hear the questions?”

If yes: “Did the participant complain throughout the interview or only during the cognitive test, i.e., the MoCA?”

“Did the participant speak with or listen to another person in the room?”

“Were there distractions in the room, such as a ringing telephone, noisy TV, etc.?”

“Were there connectivity issues, such as bad signal, lost connection, etc.?”

## 5. Scheduling a clinic visit

The clinic visit should be scheduled between 2 to 6 weeks (ideally, 4 weeks) after 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. See Appendix 6A-C for suggested script for scheduling a clinic visit.

Tell the participant that they will receive a confirmation notice in the mail in the next few days and/or a phone call reminding them of the day and time of the visit. They will also receive a self-administered questionnaire in the mail that they should fill out and bring with them to the clinic visit. Be sure to give the participant your name and the 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:

The length of the clinic visit with or without a knee MRI is detailed in the study protocol. The clinic visit consists of a brief questionnaire, clinic interview (where questions about knee symptoms and medication use will be administered), knee MRIs on both knees (if MRI-eligible), knee X-rays, knee CT scan (if eligible for MRI and no knee replacements; refer to the Telephone Interview Data from Prior Visits Report and updated information from the Telephone Interview to determine), and performance examinations detailed in the Follow-Up Clinic Visit Overview Operations Manual chapter 2A.

For all participants scheduled for a clinic visit: tell the participant to bring in all their prescription medications that they have taken in the past 30 days as well as to bring in all prescription medications taken by injection with a needle, intravenously through a tube connected to the arm, or with a skin patch that they took during the past 12 months. Only prescription medication will be recorded on the Medication Inventory Form. In addition, they should bring in medical

documentation that shows it is safe for them to obtain an MRI if necessary as determined by MRI eligibility questions in the Telephone Interview.

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

### **5.1 What to do if clinic visit falls outside 6-week telephone interview window**

A repeat telephone interview should be done if the participant is scheduled for clinic visit more than 6 weeks after the first telephone interview. A new Telephone Interview data collection form should be completed in REDCap and the “Repeat exam 1” should be marked. The new Telephone Interview should be administered at least 2 weeks before the scheduled clinic visit.

## **6. Record keeping and mailing clinic visit reminder**

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

Bookkeeping 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 can be recorded in the Telephone Interview and 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, their completed self-administered questionnaire (mailed prior to clinic visit), and medical documentation showing it is safe for them to have an MRI (if necessary). See Overview of the 144-month Follow-up Clinic Visit Operations Manual chapter 2A for a sample 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 3 for an example) developed by your field center and record the appropriate information about the call. If obtained during the Missed Clinic Visit Telephone Interview, 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. Submitting the Follow-up Telephone Interview Workbook

Completed Follow-up Telephone Interview forms should be “submitted” immediately upon completion in REDCap.

## 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 Follow-up Visit (2A, 2C)
  - Interviewing Guidelines (2E)
  - Telephone Interview (2H)
- Thoroughly review the Follow-up Telephone Interview in REDCap or paper form
- Practice administering the telephone interview on volunteers (if possible, age-eligible volunteers).

### 8.2 Certification requirements

- Completed training requirements
- Administer two *mock* follow-up telephone interviews while being observed by the QC Coordinator or their designate.
- Administer one *mock* follow-up telephone interview with a Coordinating Center staff member. This includes submission of completed Follow-Up Telephone Interview form (saved as PDF file prior to submitting in REDCap).
- 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 Follow-Up Telephone Interview Workbook (*if paper version*)
- Reads script and questions exactly as written in the Follow-up Telephone Interview Workbook (same order, same wording)
- Accurately records participant’s responses on form
- Explains pause(s) necessary for interviewer to complete form

- Accurately determines missed clinic visit or clinic visit (with or without MRI) eligibility (if applicable)
- If necessary, accurately completes Event Notification Form for Knee/Hip Replacement or Death
- Reads correct script for clinic visit with or without MRI (if applicable)
- Schedules appointment or time to call back for appointment (if applicable)
- If participant is not interested, correct script read and participant thanked for their time (if applicable)
- Follows the guidelines for recording data on REDCap forms
- At the end of interview, reviews form for completeness and successfully submits form

**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 Montreal Cognitive Assessment (MoCA) (5-minute protocol)****1. Introduction**

The Montreal Cognitive Assessment (MoCA) (5-Minute Protocol) will be administered to existing cohort participants age 70 years and older during the MOST 144- and 168-month Telephone Interview. It was designed as a rapid screening assessment for mild cognitive dysfunction.

**2. Background and rationale**

Cognitive function may decline as a result of certain risk factors and diseases. This in turn could adversely impact the physical functioning and quality of life of older adults. After a certain level of decline, dementia can develop. Dementia is a major illness and cause of disability among the elderly.

The purpose of assessing cognitive function at follow-up in MOST is to define those with cognitive stability or decline at follow-up so responses to questionnaires can be adjusted for data analysis as appropriate.

**3. Safety issues and exclusions**

Participants age 70 years and older at the time of the Telephone Interview are eligible for the cognitive assessment portion of the interview. There are no other exclusions for this interview. A cognitive assessment can appear to be intrusive and, therefore, examiners must pay close attention to the participant and avoid an emotional reaction that may disrupt the performance level.

**4. Detailed measurement procedures**

Examiners should thoroughly familiarize themselves with the data collection forms, testing procedures and the scoring criteria before administering the cognitive assessment.

To familiarize with the administration of the questions, it may be helpful to observe an experienced interviewer asking these questions by watching the following YouTube video:

<https://www.youtube.com/watch?v=ryf8SG0NQLQ>

The video shows the entire MoCA assessment, but in MOST we will administer the 5-minute version with 4 subtests described in Section 4.1.

## 4.1 Administration of MoCA

The Montreal Cognitive Assessment (MoCA) (5-Minute Protocol) was designed as a rapid screening instrument for mild cognitive dysfunction. It consists of 4 subtests examining 5 cognitive domains including attention, verbal learning and memory, executive functions/language, and orientation.

Examiners should thoroughly familiarize themselves with the testing procedures and the scoring criteria before administering the cognitive screen.

Before administering the MoCA, participants should be advised to turn off the radio or television and to go to a quiet area for the interview. Do not administer the Telephone Interview if the participant is driving or watching television.

During the administration of the cognitive screen, give at least 3 seconds for a response, but do not converse or offer extra help. When a participant gives an incorrect answer the examiner records accordingly and proceeds to the next item. If the participant asks how they are doing, say, “We appreciate your effort.”

The total possible score is 30 points. If a participant has a score of 17 or less, the Telephone Interview should be stopped and the joint replacement questions in the Missed Clinic Visit Telephone Interview (MCVTI) should be administered. Proceed immediately to the MCVTI, and respond “Yes” to the question “Will you administer the short version of the MCVTI?” This will take you to the joint replacement questions.

Note: If a participant fails the MoCA but the interviewer feels that the participant’s responses to the questionnaire are fairly reliable or very reliable (e.g., issues with the MoCA may be due to hearing difficulties and are not due to cognitive difficulties), the clinic may schedule the participant for a Clinic Visit (as long as the projected type of contact on the DPVR, Question #14 says “Clinic Visit (*with or without images*)”).

### Q by Q

#### 4.1.1 Age and assistance with interview

Administration of Questions 6 & 7. Confirm the participant’s age with the participant. For an estimate of age, see the Telephone Interview Data from Prior Visits Report to see if the participant is 70 years or older. If age is different from estimated age, probe participant if appropriate (i.e., interviewer determines if probing would risk upsetting the participant or compromise retention).

The next question is: Is the participant 70 years old or older and are you going to administer the MoCA? The 4 response options are: “Yes, eligible and started to administer”; “No, not eligible”; “Not done/Refused”; and “Not done/Clinic discretions”.

If the participant is 70 years old or older and you are administering the MoCA, mark “Yes, eligible and started to administer”.

Do not administer the test unless the participant is 70 years or older. If the participant is not 70 years old or older, mark “No, not eligible”.

If the participant is eligible to do MoCA (age 70 and older) but refuses, mark “Not done/Refused”

If you are re-administering the Telephone Interview (e.g., clinic visit is not within 6 weeks of Telephone Interview) and the MoCA was already completed during the first Telephone Interview, there is no need to administer it again. Mark the “Not done/Clinic discretion”. As always, we rely on the clinic’s judgement. If participant is eligible (age 70 and older) and for some other reason you won’t do the MoCA (e.g., retention issue, etc.), mark “Not done/Clinic discretion”.

Please note that the protocol is to administer the MoCA on participants age 70 years and older. Given this, if you are re-administering the TI and the participant is now over age 70, please do the MoCA.

If the participant is 70 years or older and you are administering the MoCA, ask “Are you doing this interview with assistance?”

#### **4.1.2 Attention: immediate recall of 5 words**

Administration of Question 7a: The examiner reads a list of 5 words at a rate of one per second, giving the following instructions:

“I would like to ask you some questions that ask you to use your memory.”

“This is a memory test. I am going to read a list of words that you will have to remember now and later on. Listen carefully. When I am through, tell me as many words as you can remember. It doesn’t matter in what order you say them. Please repeat these words for me: FACE-VELVET-CHURCH-DAISY-RED.”

Record “Correct” for each word the participant recalls on this first trial; otherwise mark “Error/Refused”. When the participant indicates that (s)he has finished (has recalled all words), or can recall no more words, read the list a second time with the following instructions: “I am going to read the same list for a second time. Try to remember and tell me as many words as you can, including words you said the first time.” Record “Correct” for each word the participant recalls on this first trial; otherwise mark “Error/Refused”.

At the end of the second trial, inform the participant that (s)he will be asked to recall these words again by saying, “I will ask you to recall those words again at the end of the test.”



Note: If the participant mishears one or more of the recall words (e.g., “face” as “faith”) and then correctly recalls the word they think they heard, score the word as correct.

Scoring: 1 point is given for each word correctly recalled in first trial; maximum 5 points.

#### **4.1.3 Executive functions/language: 1-minute verbal fluency**

Administration of Question 7b: The examiner gives the following instruction: “Tell me as many words as you can think of that begin with a certain letter of the alphabet that I will tell you in a moment. You can say any kind of word you want, except for proper nouns (like Bob or Boston), numbers, or words that begin with the same sound but have a different suffix, for example, love, lover, loving. I will tell you when to stop. Are you ready? [Pause] Now, tell me as many words as you can as fast as you can that begin with the letter F as in Frank [time for 60 sec]. Stop.”

Record an “F” for each correct response in the text field provided in REDCap. After the 60 seconds is up, count the number of “F” and record number correctly given in 60 seconds in the field provided.

Note: 1) If the participant mishears “F” as “S” during the instructions of the verbal fluency section, correct the participant as quickly as possible and restart the timer (60 seconds). Words that start with “S” should not be counted because the number of acceptable words is different compared to words that start with “F.” 2) If a participant gives “frank” as an answer it can be counted as correct since this word can be used as both a noun and an adjective.

Scoring: 0.5 points for each correct word/output; maximum 9 points.

#### **4.1.4 Orientation: 6-item date and geographic orientation**

Administration of Questions 7c-7e: The examiner gives the following instructions: “Tell me the date today”. If the participant does not give a complete answer, then prompt accordingly by saying: “Tell me the [year, month, exact date, and day of the week].” Then say: “Now, tell me the name of the place where you are...Which city is it in.” Please note that exact date refers to the day of the month.

The participant must tell the exact date and the exact place (name of office, home, etc.). No points are allocated if participant makes an error of one day for the day and date. Record “Correct” for each correct response; otherwise mark “Error/Refused”.

Scoring: 1 point for each item correctly answered; maximum 6 points.

#### **4.1.5 Memory: delayed recall and recognition of 5 words learned in first item**

Administration of Question 7f: Ideally 5 minutes has passed (it is not necessary to time) since the beginning of the MoCA administration (Question 7a). The examiner gives the following instruction: “I read some words to you earlier, which I asked you to remember. Tell me as many of those words as you can remember.”

Mark “Correct without any cue” for each of the words correctly recalled spontaneously without any cues.

Following the delayed free recall trial, prompt the participant with the semantic category cue provided below for any word not recalled. Mark “Correct with cue” if the participant remembered the word with the help of a category or multiple-choice cue. Prompt all non-recalled words in this manner.

If the participant does not recall the word after the category cue, give him/her a multiple choice trial, using the following example instruction, “Which of the following words do you think it was, NOSE, FACE, or HAND?”

Use the following category and/or multiple-choice cues for each word, when appropriate:

FACE:	<u>category cue</u> : part of the body	<u>multiple choice</u> : nose, face, hand
VELVET:	<u>category cue</u> : type of fabric	<u>multiple choice</u> : denim, cotton, velvet
CHURCH:	<u>category cue</u> : type of building	<u>multiple choice</u> : church, school, hospital
DAISY:	<u>category cue</u> : type of flower	<u>multiple choice</u> : rose, daisy, tulip
RED:	<u>category cue</u> : a color	<u>multiple choice</u> : red, blue, green

Scoring: 2 points for each of the words spontaneously recalled; 1 point for each of the words by cued recall or recognition but not spontaneously recalled; maximum 10 points.

## 4.2 Scoring

**TOTAL SCORE**: The REDCap form will sum all subscores listed; maximum 30 points.

When the interviewer has completed administration of the MoCA, the interviewer will be asked: “Will you continue the Telephone Interview?” (Question #8)

Please mark response to this question considering the following:

- If score  $\leq 17$ , interviewer to determine if cognitive difficulties would prevent participant from continuing in the study (if continuing, interviewer determines responses are “Very reliable” or “Fairly reliable”).
- If MoCA not administered or score  $> 17$ , mark “Yes” to Question #8 to continue the interview.
- If “No” to Question #8, participant will not be having a clinic visit.

Note: If a participant fails the MoCA but the interviewer feels that the participant’s responses to the questionnaire are fairly reliable or very reliable, the interviewer may continue the Telephone Interview. Mark “Yes” to the question, “Will you continue the Telephone Interview?”

If the Telephone Interview will NOT be continued and score of 17 or less, say: “There is an indication of memory changes that you may want to discuss with your personal physician. Before we end the interview, I have a few additional questions.”

Stop the Telephone Interview (“No” to Question #8). Mark reliability assessment in Question #17 (section 4.5), “MCVTI only” in Question #18, and “Not interested” in Question #19 (Is participant interested?). The participant should be asked the joint replacement questions in the Missed Clinic Visit Telephone Interview. Proceed immediately to the MCVTI, and respond “Yes” to the question “Will you administer the short version of the MCVTI?” This will take you to the joint replacement questions.

At the end of the interview say: “May we contact you again in the future?”

Score of 18 or more: Continue Telephone Interview

**Appendix 2 SAMPLE - Follow-up Telephone Interview Data from Prior Visits Report**

Participant Name: \_\_\_\_\_

MOST Participant ID#:

Acrostic:

**MOST Data from Prior Visits Report****144-Month Telephone Interview**

Data current as of &lt;&gt;

Gender  
Estimated age**Visit Dates**

1. Target window for Telephone Interview:
2. Date last contact (KR screen contact or prior)
3. Date of last contact with information (CV or MCVTI)
4. Type of last contact with information

**Right Knee Replacement**

5. Was right knee previously reported as replaced?
6. What was the surgery date of the right knee replacement?

**Left Knee Replacement**

7. Was left knee previously reported as replaced?
8. What was the surgery date of the left knee replacement?

**9. Is participant eligible for MOST-SENS?****Eligibility for images during clinic visit (x-ray, MRI and CT scan)**

10. Date of first MOST clinic visit
  - 10a. Was there a reason not to do MRI in the past?
11. Is Right knee eligible for imaging?
12. Is left knee eligible for imaging?
13. Is participant eligible for CT scan (based on KL grade; non-KR participant)
14. **Projected type of 144m contact** (CV with MRI, CV without MRI or MCVTI)

**Hip Replacements**

15. Was right hip previously reported as replaced?
16. Was left hip previously reported as replaced?

Appendix 3 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	_____

CLINIC VISIT DATE \_\_\_/\_\_\_/\_\_\_  
TIME \_\_\_:\_\_\_ AM/PM

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

**Appendix 4 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 schedule a clinic visit (*if appropriate*)]. Do you have time to talk right now?

As a reminder, the questions that we will ask you are common for persons participating in research studies of aging. They include medical information, activities performed and memory changes. These typically are a normal process of getting older. (Go to the telephone interview in REDCap.)

*(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 5 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 6A Script – scheduling a visit – includes MRI**

“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 and schedule a clinic visit.*

“That’s great. We will see you at [time] on [date].

“You will be receiving a letter describing how to prepare for your clinic visit in the mail. You will also be receiving a questionnaire in the mail that we would like you to fill out and bring in with you to your clinic visit. We would like you to bring in all your prescription medications that you have taken in the past 30 days as well as to bring in all prescription medications taken by injection with a needle, intravenously through a tube connected to the arm, or with a skin patch that they took during the past 12 months. The examiner will need the bottles to record the spelling and dosage information.

“Your clinic visit will last approximately 4 hours (*see Overview of the 144-month Follow-up Clinic Visit Operations Manual chapter*). At this clinic visit, you will fill out a brief questionnaire; an interviewer will ask you questions about your knees and medication use; you will have knee MRIs, X-rays taken on both of your knees (if eligible), and a knee CT scan (if no knee replacements); we will repeat a few of the measurement and exams that you had at your first visit to the MOST clinic and you may have a few measurements that you have not yet had” (see Overview of the 144-month Follow-up Clinic Visit Operations Manual chapter).

*If participant requires medical documentation (a “Yes” to question about willingness to ask their doctor for MRI safety documentation):* “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? 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. Thank you for your time today. Goodbye.”



**Appendix 6B Script – scheduling a visit – NO MRI**

“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 and schedule a clinic visit.*

“That’s great. We will see you at [time] on [date].”

“You will be receiving a letter describing how to prepare for your clinic visit in the mail. You will also be receiving a questionnaire in the mail that we would like you to fill out and bring in with you to your clinic visit. We would like you to bring in all your prescription medications that you have taken in the past 30 days as well as to bring in all prescription medications taken by injection with a needle, intravenously through a tube connected to the arm, or with a skin patch that they took during the past 12 months. The examiner will need the bottles to record the spelling and dosage information.

“Your clinic visit will last approximately 3 hours (see Overview of the 144-month Follow-up Clinic Visit Operations Manual chapter). At this clinic visit, you will fill out a brief questionnaire; an interviewer will ask you questions about your knees and medication use; you will have X-rays taken on both of your knees (if eligible); we will repeat a few of the measurement and exams that you had at your first visit to the MOST clinic and you may have a few measurements that you have not yet had” (see Overview of the 144-month Follow-up Clinic Visit Operations Manual chapter).

“Do you have any questions for me about any of this? 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. Thank you for your time today. Goodbye.”

**Appendix 6C Script – participant not interested in coming in for 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?” Determine if the participant wants time to think about coming into the clinic for the follow-up visit. If you determine that they will not be coming to the clinic, then proceed with the Missed Clinic Visit Telephone Interview script.

Ask the participant “Would you be willing to stay on the phone for about 15 more minutes to answer a few more questions about your knees, hips, medications and health history?”

If the participant agrees to the additional telephone interview questions:

- Complete the Missed Clinic Visit Telephone Interview Workbook
- End the interview  
“Thank you for your time and for answering our questions. Do you have any questions for me? Thank you again for completing the interview. We will be contacting you again by phone in about \_\_\_\_\_ months for the MOST study. Goodbye.”

If the participant is not willing to stay on the phone for about 15 more minutes:

- Ask the participant “Can we schedule a time so I can call you back to answer the questions?” Schedule the time with the participant to complete the phone interview.
- If they say “No,” tell them, “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. Do you have any questions for me? Thank you again. Goodbye.”