

OVERVIEW OF 84-MONTH FOLLOW-UP VISIT

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1. Introduction

The 84-month follow-up visit for all MOST participants includes a telephone interview, a self-administered questionnaire to be filled out at home, a self-administered questionnaire to be filled out in clinic, and a clinic visit that will include an examiner-administered interview (including a medication inventory) and the following exams:

Accelerometry (subset of participants only: check DPVR for eligibility)

- *participants not eligible for or who refuse the accelerometry exam at 84-months will be given the PASE (Physical Activity Scale for the Elderly) questionnaire during the clinic interview.*

Blood pressure

Bone density (DXA) – hip and whole body

Knee MRI

Knee Range of Motion

Knee X-ray

Pain sensitivity (somatosensory assessment)

Performance based measurements (chair stands, 20-meter walk)

Weight

In addition to the exams above, all participants will have anatomic landmarks marked for various tests. Also, during the 84-month visit participants will be asked whether or not they are experiencing pain after the 20-meter walk and chair stands.

Participants who are 70 years or older will have a cognition screen during the 84-month telephone interview. Those who score 3 or less on the Callahan Six-Item Screener will be given a cognition assessment exam during the 84-month clinic visit.

2. Purpose and description of the 84-month telephone interview

During the 84-month follow-up telephone interview, participants will be surveyed by phone approximately 4 weeks prior to their follow-up clinic visit. The purpose of the follow-up phone interview is to:

- reassess knee symptoms
- determine when knee symptoms first began
- determine if the participant is eligible to have an MRI
- schedule 84-month clinic visit (with MRI or without MRI) for all participants
- update participant contact information
- complete cognition screen (participants 70 years of age or older only)

Those participants who report being unable to come in for the 84-month clinic visit will be asked to also complete the Missed Clinic Visit Telephone Interview which includes the following components:

- SF 12 general health question
- Knee injury
- Knee surgery
- Hip replacement surgery
- Modified Charlson Comorbidity Questionnaire
- Injuries, fractures falls
- Knee buckling
- Medication history
- Modified WOMAC Osteoarthritis Index (knee pain)
- Hip pain
- Medication for knee or hip pain
- Helpful aids and devices (adapted from Stanford Health Assessment)
- Household and marital status
- Medical care
- Reliability assessment

3. 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 Workbook with the follow-up visit, participant ID and acrostic pre-printed
- 2) Data from Prior Visits Report for Follow-up Telephone Interview (found on the study website under “Reports,” also see Appendix 1)
- 3) Telephone Interview Contact Log (Appendix 3)
- 4) Telephone Interview Suggested Script (Appendix 4)
- 5) Contact information for participant, next of kin and two contacts (from your local records)
- 6) List of MRI-safe surgeries (Appendix 5) (*if applicable*)
- 7) Scheduling a Visit Script (Appendices 6A-6C)
- 8) Event Notification Form for Knee/Hip Replacement or Death, as needed (Appendix 7)
- 9) Missed Clinic Visit Telephone Interview Workbook (floating forms) (*if applicable*)

4. Calling the participant

Telephone interview followed by clinic visit: The follow-up visit will be scheduled approximately 84 months after the date of the participant’s baseline clinic visit. The follow-up telephone interview should be completed approximately 4 weeks prior to the follow-up clinic 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. 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 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. 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).

5. Telephone cognition assessment

During the 84-month telephone interview only, the Callahan Six-Item Screener will be administered to participants 70 years of age or older. Review the Data from Prior Visits Report for the 84-Month Follow-up Telephone Interview for eligibility. Those participants who score 3 or more will be administered the MMSE-2, a more detailed cognition assessment exam, during the 84-month clinic visit. (See the Cognitive Assessment Operations Manual for more detailed information about administering both the Callahan Six-Item Screener and the MMSE-2 exam.)

6. 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 the participant had a knee replacement less than three months ago, schedule the clinic visit at least three months post-surgery so that knee range of motion can be accurately assessed. 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-6C 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 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, DXA scan and performance examinations.

There will be no urine or blood biospecimen collection during the 84-month visit. The only exception is that women who report pre-menopausal status will provide a nonfasting urine sample for pregnancy screening only. If needed, urine pregnancy screening will be done prior to the DXA, X-ray and MRI exams.

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. Only prescription medication will be recorded on the Medication Inventory Form at the 84 month follow-up visit. 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 #9a on page 4).

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

6.1 What to do if clinic visit falls outside 6-week telephone interview window

A repeat telephone interview should be done if the participant is being seen more than 6 weeks after the first telephone interview. However, you should NOT fax in the new Telephone Interview data collection form. The new Telephone Interview should be administered at least 2 weeks before the scheduled/rescheduled clinic visit. You should compare the participant's answers to their first interview and post queries to change any answers that are different than what is already in the data system. The one field that will always change will be the date field. Be sure to post a query to change the date. If a different examiner conducts the interview, be sure to post a query to change the Staff ID# as well. All of the queries should be posted at least 2 days before the participant's clinic visit.

7. 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.

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 and time recorded in Box A of the Follow-up Telephone Interview 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, their filled out self-administered questionnaire, and medical documentation showing it is safe for them to have an MRI (if necessary). See Appendix 8 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. 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.

8. Faxing the Follow-up Telephone Interview Workbook

Completed Follow-up Telephone Interview forms should be faxed 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 faxed, but kept in a separate "Pending" file. Once the missing information is obtained, the completed Follow-Up Telephone Interview forms should be faxed as soon as possible.

9. Preparation for the 84-month follow up clinic visit

9.1 Equipment preparation

All equipment being used for the 84-month follow-up visit should be calibrated and in good working order (see Appendix 9). Also, if there is any problem with any of the equipment or software, an Equipment Repair/Service and Software Update Log should be completed to maintain a record of the problem, whether the measurement was affected by the problem, and the action taken to resolve the problem, including the date the problem was encountered and the date it was resolved (Appendix 10).

9.2 Examiner preparation

All examiners must be certified before they begin administering 84-month visit exams. Examiners will be trained by a "master" examiner for the somatosensory assessment (pain sensitivity) exam. Examiners will be recertified to administer all exams at the start of the visit and midway through the examination cycle. See the operations manual specific to each exam for more information about certification.

9.3 Participant preparation

Each participant who comes to the MOST clinic visit will have been told about the contents of the visit during the phone conversation to schedule the clinic visit. Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following (Appendix 8):

- date and time of the clinic visit

- that participants take all of their regular medications, as usual
- that participants should bring loose shorts and wear walking shoes
- if participants use glasses, that they bring both their reading glasses and any glasses that are used for longer distances
- that participants who wear hearing aids should bring or wear them to the clinic
- that participants bring in prescription medications that they have taken in the last 30 days only
- if participants take Vitamin D, they should write down the dosage and bring this information to the clinic
- those participants who, during the follow-up telephone interview, reported having surgery or reported having an injury with a metal object since their last visit, and who said that their doctor said it was safe to have an MRI, should be reminded to bring documentation that it is safe for them to have an MRI

Ideally, reminder phone calls should be made the day before the clinic visit. Please see an example of a reminder letter in Appendix 8.

9.4 84-month follow-up clinic visit preparation

At the time of the clinic visit, the following should be available for each participant:

- Consent forms (check the 84-Month Clinic Visit Data from Prior Visits Report to see if GWAS consents are also needed)
- Consent Procedure Checklist (Appendix 12) (only if not fully completed at 60-month visit)
- A Data from Prior Visits Report / 84-Month Follow up Clinic Visit should be generated with information that will be needed for the clinic visit (see Appendix 2)
- Your local MOST participant contact information with the participant's contact information (address, phone number, next of kin, contacts, etc.)
- An 84-Month SAQ - Clinic Workbook preprinted with the acrostic and MOST ID#
- An 84-Month Follow-up Clinic Visit Workbook preprinted with the acrostic and MOST ID# (this workbook includes the MOST interview) (see Procedure Checklist in Appendix 11)
- A StepWatch and various straps (small, medium, large), StepWatch information sheet, StepWatch Questionnaire, distribution form, and return envelope (see Accelerometry

operations manual chapter.) **Accelerometry is included only for those participants who are eligible: check the Data from Prior Visits Report (DPVR).**

- A Longitudinal MOST Participant Results Summary Report and Longitudinal Report Information Pages to give the participant at the end of their clinic visit (Appendix 13)
- The participant’s chart. Field centers should also keep “progress notes” in the participant’s chart. Progress notes may be used to record examiner comments and questions, and to document protocol problems and their resolution. Each entry should be dated and signed by the examiner recording the note.

10. Order of exams

MEASUREMENT	Order of Exams: Required / Suggested / Anytime
Self-administered Home Questionnaire completed and checked	Anytime
Self-administered Clinic Questionnaire completed and checked	Anytime
Clinic Interview Workbook administered	Anytime
Marking anatomic landmarks	Required -done before somatosensory evaluation and x-ray
MMSE-2 SV (Cognition Exam)	Anytime-only required for some participants: check DPVR
Weight	Required -done before MRI
20-meter Walk	Suggested -done either after or at least one hour before MRI
Chair Stands	Suggested -done either after or at least one hour before MRI
Somatosensory Evaluation (Pain Sensitivity)	Anytime
Knee Range of Motion	Required -done before or after somatosensory evaluation while participant is still on examining table Suggested -done after the chair stands and 20-meter walk
Knee X-ray	Required -done after anatomic landmarks marked
Knee MRI	Required -done after weight Suggested -done either before or at least one hour after the chair stands and 20-meter walk
DXA	Anytime

11. Priority of exams

Ideally, all exams will be performed during the 84-month clinic visit. However, in the rare instance that a participant is not willing to stay in clinic for the full exam, the priority order is listed in the table below. If you suspect that the participant will not stay for the whole visit, administer the high, then medium, then low-priority exams.

MEASUREMENT	Priority High/Medium/Low
MMSE Cognition exam)	High
Blood Pressure	Low
Weight	High
20-meter Walk	High
Chair Stands	High
DXA	Medium
Somatosensory Evaluation	Medium
Knee Range of Motion	High
Knee X-ray	High
Knee MRI	Medium

12. Procedure checklist and exit interview

At the end of the 84-month follow-up clinic visit, an exit interview should be performed to:

- Thank the participant. Be sure the participant knows how much we appreciate their participation.
- Let the participant know that right now we don't have more study visits planned, but we will be contacting them again by phone if that changes. Also, our investigators would like to know if they have a knee replacement surgery in the future and would appreciate it if they would call us if they decide to have this surgery. They can reach us at XXX-XXX-XXXX.
- Answer questions. Some participants may have questions about various examinations.
- Obtain Genome Wide Association Studies (GWAS) consent if participant has an archived DNA sample in storage and GWAS consent was not obtained at 60-month visit. See Data from Prior Visits Report 84-Month Clinic Visit (Appendix 2). If the participant signs this consent, they are giving permission for their DNA to be used for genetics testing.

- Note whether the participant signed the GWAS consent form and the 60-/72-/84-month visit consent form on the Consent Procedure Checklist (Appendix 12) and complete the items on the checklist for those consent forms (UAB #1-2/ UI #1-2). UAB staff will check the Data from Prior Visits Report (DPVR) to determine if 30-month consent data need to be documented (UAB #3).

Also:

- Make sure the 84-Month Follow-up Clinic Visit Workbook Procedure Checklist is completed (Appendix 11); i.e., the header information including the MOST ID #, Acrostic, Date Form Completed, and Staff ID#. Confirm whether each measurement was completed. Review the workbook and complete the Procedure Checklist appropriately. Record on the checklist whether or not a test was completed, was partially completed, whether or not the participant refused a test, or whether the test was not done for some other reason.
- Provide selected longitudinal results including applicable 84-month results (Appendix 13). The Longitudinal Participant Results Summary Report and Longitudinal Report Information Pages should be printed prior to the study visit (see study website Reports link). When available, information from the baseline, 30- and 60-month follow-up visits will be prefilled. The study coordinator will write the 84-month information from the data collection forms. Participants will be given the following longitudinal results:
 - ⇒ Blood Pressure
Tell the participant their blood pressure and advise them about when to repeat the measurement. See the blood pressure operations manual for reporting instructions.
 - ⇒ Height: Weight: Body Mass Index (BMI)
 - ⇒ Knee OA Status
 - ⇒ Knee Pain Score
 - ⇒ Performance Measures:
20-meter Timed Walk; Chair Stands, Timed; Quadriceps and Hamstring Strength
 - ⇒ Accelerometry
 - ⇒ Bone Density (DXA)

13. 84-month quality assurance

Staff performing interviews and examinations are trained and certified in that measurement following the training requirements, certification requirements, and quality assurance checklist. A Certification Form is posted on the study website for each measurement requiring certification before the examiner begins collecting data from participants. Staff must perform that interview or

examination at least once every 30 days to maintain certification. Retraining and recertification is done at least every 12 months.

Telephone interview quality assurance is detailed in this operations manual (13.1 – 13.3). Refer to the operations manual for quality assurance requirements for the other 84-month measurements.

13.1 Telephone interview 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 84-Month Follow-up (2C)
 - Interviewing Guidelines (2D)
 - Cognitive Assessment (3R)
- Thoroughly review the 84-month Follow-up Telephone Interview Workbook and Missed Clinic Visit Telephone Interview Workbook.
- Practice administering the telephone interview on volunteers (if possible, age-eligible volunteers).

13.2 Telephone interview certification requirements

- Completed training requirements
- Observation and evaluation of three *mock* follow-up telephone interviews (two of which will be done with the Coordinating Center staff, and the other one to be done by the Study Coordinator or their designate). This includes submission of completed Follow-Up Telephone Interview forms.
- Observation and evaluation of three *actual* telephone interviews by the Study Coordinator or their designate.

13.3 Telephone interview quality assurance checklist

The Certification Forms posted on the study website under “Study Documents/Study Forms/non-TELEForm Forms/Certification” guide you through the quality assurance checklist for certification. Submit completed certification forms to the MOST Coordinating Center (MOSTCoordinatingCenter@psg.ucsf.edu). Names of certified staff, staff ID and the date of certification are posted on the study website under “Staff Certification”.

Appendix 1 84-Month Follow-Up Telephone Interview Data from Prior Visits Report

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report**84-Month Follow up Telephone Interview**

Data current as of

Visit Dates

1. Target date for 84-month telephone interview:
2. What was the last contact (TI, MCVTI, or CV)?
3. Date of last contact:

1.0 T Knee MRI History

4. Knee(s) eligible for 84-month MRI:
5. Was participant eligible for MRI at prior visit(s)?
6. Date of the participant's last 1.0 T MRI scan:

Cognitive Screen

7. Is participant 70 years old or older?

Interviewer Note: The below information is needed, if the Missed Clinic Visit Telephone Interview indicated.

Knee Injury / Surgery and Hip Surgery

8. Date knee injuries and surgeries questions last asked:

Knee Replacements

9. Was right knee previously reported as replaced?
10. Was left knee previously reported as replaced?

Hip Replacements

11. Was right hip previously reported as replaced?
12. Was left hip previously reported as replaced?

Health History and Medical Conditions

13. Date comorbidity questions last asked:

Injuries, Fractures, Falls

14. Date injuries, fractures, falls questions last asked:

Appendix 2 84-Month Follow-Up Clinic Visit Data from Prior Visits Report

Participant Name: _____

MOST Participant ID#: _____

Acrostic: _____

MOST Data from Prior Visits Report**84-month Follow-up Clinic Visit**

Data current as of _____

Visit Date

1. Target date for 84-month Clinic Visit:
2. Was the last contact a Clinic Visit or Phone Interview?
3. Date of last MOST contact:
 - 3a. Date knee injuries and knee/hip surgeries questions last asked:
 - 3b. Date comorbidity questions last asked :
 - 3c. Date injuries, fractures, fall questions last asked :

Knee Replacements

4. Was right knee previously reported as replaced?
5. Was left knee previously reported as replaced?

Hip Replacements

6. Was right hip previously reported as replaced?
7. Was left hip previously reported as replaced?

Cognitive Screen

8. Cognitive screen: Is MMSE-2 required?

Bisphosphonate Use

9. Did participant report use of bisphosphonate at the last clinic visit?
10. At the last visit, how many years did the participant report using bisphosphonates?

Pregnancy Screen (women only)

11. Did participant previously report being post-menopausal?
 - If "Yes", do NOT ask, "Have you been through menopause or change of life?"
 - If "No" or "Unknown", ask, "Have you been through menopause or change of life?" If the participant says "No", obtain urine sample and administer pregnancy test.

PASE Eligibility

12. Is participant eligible for PASE?
 - If participant refuses accelerometry at 84-months, administer PASE, even if DPVR does not indicate "eligible".

Height

13. Collect height at 84-month (Floating Form)?
14. Baseline height (height in millimeters and height in inches)
15. Was participant standing sideways due to kyphosis?

Weight (weight in kg and lb)

16. Baseline weight
17. 30-month weight:
18. 60-month weight:

X-ray

19. Participant eligible for the following x-rays:

a) PA semiflexed view of right and left knee	
Use the following beam angle(s)	
b) Lateral view of Right knee	
c) Lateral view of Left knee	

1.0 T Knee MRI

- 20. Date of last 1.0T MRI, and which knees were scanned:
- 21. Was participant eligible for an MRI at the time of the 84-month telephone interview?
- 22. Was participant asked to bring medical documentation that shows it is safe to have an MRI scan?
- 23. Knee(s) eligible for 84-month MRI?
- 24. Which knee to scan first? (R/L)
- 25. Interest ranking of knee for repeat: (R/L Highest/High/Low)

Accelerometry (StepWatch) Eligibility

26. Is participant eligible for accelerometry (StepWatch)?
If participant is not eligible for or refuses accelerometry at 84-months, then administer PASE.

Consent Procedure Checklist

- 27. Does participant need to be asked for GWAS consent?
- 28. *UAB only*: Does the participant's 30-month consent information need to be collected?

Medication List From Last Clinic Visit

29. Prescription medication list:

Visit	Medication Name	Formulation Code	Frequency	Duration	Still Using

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	_____
___/___/___	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 Script: Telephone Interview (suggested)

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, update your contact information, [and schedule a clinic visit *(if appropriate)*]. 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 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. Schedule any ancillary study or subcohort examinations if there are any for this follow-up 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. The examiner will need the bottles to record the spelling of your medications.”

“Your clinic visit will last approximately ___ hours and __ minutes. 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 and X-rays taken of both of your knees (if eligible); and we will repeat a few of the measurement and exams that you had at previous visits to the MOST clinic.”

If participant answers “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. Schedule any ancillary study or subcohort examinations if there are any for this follow-up 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. The examiner will need the bottles to record the spelling of your medications.”

“Your clinic visit will last approximately ___ hours and ___ minutes. 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 X-rays taken of both of your knees (if eligible); and we will repeat a few of the measurement and exams that you had at previous visits to the MOST clinic.”

“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 10 or 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? Right now we don’t have more study visits planned but we will be contacting you again by phone if that changes. Our investigators would like to know if you have a knee replacement surgery in the future and would appreciate it if you would call us if you decide to have this surgery. You can reach us at XXX-XXX-XXXX. Thank you again for completing the interview. Goodbye.”

If the participant is not willing to stay on the phone for about 10 or 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 the participant does not wish to schedule a time to complete the additional interview questions, ask them if they would be willing to answer one more question about their general health. If they say, “Yes,” ask them: “In general, would you say your health is: Excellent, Very good, Good, Fair, or Poor.”

If they say “No,” tell them, “Should you change your mind, please give me a call at XXX-XXX-XXXX. My name is _____. Do you have any questions for me? Right now we don’t have more study visits planned but we will be contacting you again by phone if that changes. Our investigators would like to know if you have a knee replacement surgery in the future and would appreciate it if you would call us if you decide to have this surgery. You can reach us at XXX-XXX-XXXX. Thank you for your time and for answering our questions. Goodbye.”

Appendix 7 Event Notification Form for Knee/Hip Replacement or Death



Draft

Reference #:

--	--	--	--



MOST ID #

Acrostic

Date Completed						
	/		/			
Month		Day		Year		

Staff ID #



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.

MOST Floating Form
Version 2.0_2/26/09
MW_(FS)



Draft

Overview of 84-Month Follow-up

Version 1.0p
6/1/13

Appendix 8 MOST 84-Month Follow-up Pre-Visit Instructions

Dear _____:

Your appointment for your MOST Follow-up Clinic Visit has been scheduled for: _____, _____
_____ at _____ a.m. at XXX, XXXX (a map is enclosed). Parking is available
XXXXXXXXXXXXXXXXXX.

Please be sure to review these instructions for your upcoming clinic visit, since they are very important for the success of your tests:

- Read all enclosed materials.
- Please use the ball-point pen that we have sent to you when you fill out the questionnaire. Please bring the completed questionnaire with you to the clinic.
- The visit may take about [1.5 to 2 hours if no 1.0 T MRI] [2.5 to 3 hours if 1.0 T MRI]. Feel free to bring a morning snack with you.
- Wear comfortable shoes for walking. It would be helpful if you wear a short-sleeved shirt or blouse, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles. Please bring shorts with you (no tight biker shorts).
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances. If you have a hearing aid, bring it with you.
- A plastic bag has been provided for the prescription medications that you have taken in the last 30 days only. Include prescribed eye drops, shots, pain medications, laxatives or bowel medicines, cold medications, cough medications, antacids or stomach medicines, and ointments or salves. Please bring these with you to the clinic.
- If you take Vitamin D, please write down the dosage and bring this information with you to the clinic.
- If you were asked to bring in medical documentation that it is safe for you to have an MRI, please bring this with you to your clinic visit.

Thank you again for your very valuable help in this important research study! We look forward to seeing you.

Please call XXX-XXXX if you have any questions about your visit.

Appendix 9 Equipment Calibration – Summary

Please see the MOST website to download the calibration logs summarized below:

<p>Algometer</p>	<p>Monthly: Task 1: Use calibrated scale. Scale weight is set to 10 pounds and Examiner 1 presses down on scale with rubber pad of algometer, keeping the device vertical and with peak hold on. Examiner 2 watches balance beam and lets Examiner 1 know when balance is achieved. The reading on the algometer should fall with +/- .5 pound for 10 pounds. Task 2: Use calibrated scale. Scale weight is set to 25 pounds and Examiner 1 presses down on scale with rubber pad of algometer, keeping the device vertical and with peak hold on. Examiner 2 watches balance beam and lets Examiner 1 know when balance is achieved. The reading on the algometer should fall with +/- 1 pound.</p>
<p>Blood Pressure</p>	<p><u>Automated Oscillometric Device</u> With Each Use: Task: Check that the connection of the cuff to the tubing is secure and tubing is not kinked. Monthly: Task 1: Inspect cuff and tubing for cracks or tears. Task 2: Check that all blood pressure cuff sizes are available. Twice a year: Inspect the tape used to measure arm circumference for damage or wear twice a year. <u>Conventional Manometer</u> With Each Use Task: Make sure needle is in the zero box. Monthly: Task 1: Check that needle rises smoothly and doesn't bounce when valve is closed. Task 2: Check cuffs, pressure bulb, and manometer for cracks or tears. Task 3: Check pressure control valve for sticks or leaks. Task 4: Check stethoscope tubing and diaphragm for cracks or tears. Task 5: Check blood pressure cuffs for air leaks. Twice a year: Inspect the tape used to measure arm circumference for damage or wear twice a year.</p>
<p>DXA</p>	<p>See "Whole Body and Hip DXA Bone Density" Operations Manual (Chapter 3Q)</p>
<p>OrthOne temperature</p>	<p>Daily OrthoOne Temperature Log Task: Check am and pm OrthOne room temperature</p>
<p>Scale</p>	<p>Monthly Scale Calibration Log Task 1: Check for "float" of beam with both counterweights in zero position. Task 2: Calibrate with 50 kg weight Task 3: Check linearity using volunteer and 5 and 10 kg weights (volunteer alone, volunteer plus 5, 10, 15, and 20 kg weight [or use lb alternatives]) <i>Reading should be within ± .2 kg</i></p>
<p>Temporal Summation Pen</p>	<p>Monthly Temporal Summation Pen Calibration Log Task 1: Before measuring the pen force output, calibrate the gram scale using certified weight(s) according to the manufacturer's specifications. Task 2: Zero the scale initially if necessary. Task 3: Hold the canister vertically over the scale and apply the pen filament/stylus to the scale. Slide the canister down the filament until approximately only 1 cm of filament is visible to ensure the mass is no longer supported by the canister, but the canister is not touching the scale surface. Task 4: Hold this position for approximately 2 seconds to achieve a steady-state gram measure to</p>

	<p>within 0.1 g.</p> <p>Task 5: Remove the filament/stylus from the scale, and ensure the scale returns to zero. Re-zero if necessary.</p> <p>Task 6: Repeat the measurement process (Tasks 2-5) 2 times for a total of 3 measurements</p> <p>Task 7: All measurements should be within 1 g of 60 g and 1 g of each other; if not, repeat Tasks 2-5 up to 3 times until 3 consecutive measurements are within the specified criteria. If 3 consecutive measurements are not within the specified criteria, go to Task 9.</p> <p>Task 8: Record the 3 measurements and the highest value of the 3 measurements (achieving repeatability within 1 g of each other).</p> <p>Task 9: If values are not within 1 g of 60 g and 1 g of each other, 1) check the filament for any visible damage that may alter the force readings, 2) remove the mass and weigh separately to ensure the mass has not been altered and 3) notify the clinic QC Officer who will notify Lars Arendt-Nielsen at the Center for Sensory-Motor Interaction. Do NOT continue to use this pen device for further testing until it can be correctly calibrated or replaced.</p>
<p>von Frey filaments</p>	<p>Twice a year Each von Frey filament will be replaced every 6 months.</p>
<p>X-ray beam angle</p>	<p>Monthly X-ray Beam Angle Log (for each angle: 5, 10, and 15)</p> <p>Task 1: Angle tube so that it is at [5][10][15] degrees caudal according to the dial.</p> <p>Task 2: Place inclinometer on top of x-ray tube.</p> <p>Task 3: On the inclinometer, read off the actual degrees of this beam angle.</p> <p>Task 4: If above reading is not [5][10][15] degrees caudal, adjust the beam angle so that the inclinometer reads [5][10][15] degrees and mark this on the x-ray tube.</p>

Appendix 10 Equipment Repair / Service and Software Update Log



Equipment Repair/Service and Software Update Log

Alabama Iowa

1. Equipment with problem: _____

2. Date problem(s) encountered:
Month Day Year

3. Describe problem: _____

4. Were you able to obtain partial or complete data using the equipment during this problem?
 Yes No

<p>a. Did the problem affect the measurement? <input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know</p> <p>b. Please describe: _____ _____</p>	<p>How long was the equipment out of service? <input type="text"/> <input type="text"/> days</p>
--	--

5. How many participants missed having a complete measurement?: participants

6. Will the participants be asked to return to clinic for this measurement?:
 Yes No

7. Describe the action taken to solve the problem: _____

8. Was the problem resolved?
 Yes No

<p>a. Date problem was resolved: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</p> <p>b. Please describe how the problem was resolved: _____ _____</p>

9. Was a software update required?
(Note: software updates should not be installed without Coordinating Center approval.)
 Yes No

<p>a. Date software update installed: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> Month Day Year</p> <p>b. Software version number (if appropriate): _____</p> <p>c. Comments: _____</p>
--

Version 2.0, 07/15/10

Appendix 11 MOST 84-Month Follow-up Procedure Checklist



FOLLOW-UP CLINIC VISIT WORKBOOK
PROCEDURE CHECKLIST



Visit	MOST ID #	Acrostic	Date Form Completed	Staff ID#
<input type="radio"/> 60-month <input type="radio"/> 84-month	<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	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Measurement	Page #	Completed	Partially completed	Participant refused	Not done/ Not applicable
1. Was Self-administered Home Questionnaire completed/checked?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
2. Was Self-administered Clinic Questionnaire completed/checked?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
3. Was Clinic Interview administered?		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
4. Was PASE administered? (Floating Forms: See DPVR)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
5. Was MMSE-2 administered? (Floating Forms: See DPVR)		<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
6. Medication Inventory	29	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
7. Blood Pressure	32	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
8. Weight	32	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
9. 20-meter Walk	34	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
10. Chair Stands	36	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
11. Pain Sensitivity	55	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
12. DXA Bone Density	65a	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
13. Knee X-ray	66	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
14. OrthOne 1.0 T Knee MRI	67	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
15. Accelerometry	75	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

◆Page 1◆



MOST Follow-up
Clinic Visit Workbook
Version 3.0 3/7/11
HR




Appendix 12 MOST Consent Procedure Checklist



CONSENT PROCEDURE CHECKLIST

University of Alabama at Birmingham

84-Month Clinic Visit

MOST ID #	Acrostic	Date Form 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"/> <small>Month Day Year</small>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>



1. (Examiner Note: Refer to DPVR) Does participant need to be asked for GWAS consent?

Yes →

 No →

2. Did participant sign a GWAS consent form?

Yes →

 No, not asked for any reason →

 No, refused/declined →

Storage of Specimens

Yes No **2a.** You give permission for your specimens and DNA to be stored by MOST investigators future studies. Your name or other information that could identify you or your family will not be released.

Use of samples and DNA in medical research projects

Yes No **2b.** Research projects studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA.

Yes No **2c.** Research projects studying other diseases (for example, cancer or heart disease).

Sharing of Samples

Yes No **2d.** Researchers studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA.

Yes No **2e.** Researchers studying other diseases (for example, cancer or heart disease).

Sharing of Information

Yes No **2f.** Include my information in the GWAS database.

→ If yes, information can be released to:

Yes No **2fi.** Researchers studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA and how people respond to treatment.

Yes No **2fii.** Researchers studying any disease.

3. (Examiner Note: Refer to DPVR) Does the participant's 30-month consent data need to be collected?

Yes →

 No →

3a. What is the approval date in the IRB stamp on the participant's 30-month consent form (top right corner)?

3/3/06 →

 10/3/06 →

Storage of Specimens

Yes No **3ai.** You agree to allow the study to use the information and samples collected on you (including results of questionnaires, clinic examinations and blood tests).

Yes No **3aii.** You agree to allow your blood samples and DNA to be stored by the MOST Research study for future studies. These will include medical research projects on related medical conditions, including osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis. Your name or other information that could identify you or your family will not be released.

Yes No **3aiii.** You agree to allow the study to analyze DNA extracted from blood samples for genetic information by qualified scientists studying osteoarthritis, osteoporosis, and other risk factors for osteoarthritis, understanding that the information will be kept confidential at all times.

MOST Consent Procedure Checklist - UAB
Version 3.0 3/7/11
PF



Appendix 13 MOST Longitudinal Participant Results Summary Report

Participant ID# Example with mock results
Acrostic:

MOST Participant Results Summary

Participant: _____

We would like to thank you for your continued participation in the Multicenter Osteoarthritis Study (MOST). We thought that you would enjoy seeing the results of a number of tests that you had during your clinic visits. These tests were done for research purposes only and were not intended to diagnose any health problems. If you have any questions, please call the MOST clinic.

Measurement	Baseline	30-Month	60-Month	84-Month
Visit Date				
Blood Pressure	120/68 mm Hg	128/74 mm Hg	122/76 mm Hg	_____ mm Hg
Height*	5 ft 06 in	Not done	5 ft 06 in	Not done
Weight	151 pounds	156 pounds	160 pounds	_____ pounds
Body Mass Index	24	25	26	Not available
Knee OA Status	Right: Possible Left: Possible	Right: Yes Left: Possible	Right: Yes Left: Possible	Not available
Knee Pain Score**	Right: 0 Left: 0	Right: 22 Left: 9	Right: 7 Left: 5	Right: _____ Left: _____
Performance Measures				
20-Meter Timed Walk	19.0 seconds	15.1 seconds	17.6 seconds	_____ seconds
Chair Stands, Timed	17.0 seconds	8.6 seconds	8.2 seconds	_____ seconds
Quadricep and Hamstring Muscle Strength in Newtons (N)***	Right: Quadriceps: 5 N Hamstrings: 5 N Left: Quadriceps: 3 N Hamstrings: 16 N	Not done	Right: Quadriceps: 64 N Hamstrings: 93 N Left: Quadriceps: 46 N Hamstrings: 75 N	Not done

*Changes in height may be due to measurement or data entry error.

**Scale is from 0 (no pain) to 100 (severe pain)

***1 Newton (N)= 1/4 pounds force.