OVERVIEW OF 144-MONTH FOLLOW-UP CLINIC VISIT

TABLE OF CONTENTS

1. Introduction 2
2. Preparation for the 144-month follow up clinic visit....3
2.1 Equipment preparation....4
2.2 Examiner preparation....4
2.3 Participant preparation....4
2.4 Clinic visit preparation 5
3. Order of exams....6
4. Priority of exams....7
5. Procedure checklist and exit interview....7
Appendix 1 Data Collection Forms: REDCap and Teleform....9
Appendix 2 Test Retest Reliability Protocol 10
Appendix 3 Equipment Calibration – Summary....10
Appendix 4 Equipment Repair / Service Log 14
Appendix 5 Pre-Visit Instructions 15
Appendix 6 Consent Tracking....18
Appendix 7 Clinic Visit Procedure Checklist....22
Appendix 8 Data from Prior Visits Report 144-Mo Follow up Clinic Visit (New Cohort)....23
Appendix 9 Data from Prior Visits Report 144-Mo Clinic Visit (Existing Cohort) 24
Appendix 10 Participant Results Reports 26
Appendix 11 144-Month Clinic Visit Components: MOST III vs MOST-SENS....26

1. Introduction

The first clinic visit for the Second MOST Renewal Grant (2015-2020) is a **baseline visit** for a newly recruited cohort (New Cohort) and **144-month follow-up visit** for surviving members of the original cohort (Existing Cohort). New Cohort participants will have completed a Telephone Screen Interview (chapter 2F) and Screening Visit (chapter 2G) which determined that they were eligible for enrollment into the study. Existing Cohort participants will have a Telephone Interview (chapter 2H) at which time they will be asked to participate in additional follow-up at 144-months. Henceforth in this document, both the new baseline and 144-month follow-up visit will be referred to as 144-month follow-up clinic visit.

Existing Cohort participants who are 70 years or older will have the 5-Minute Montreal Cognitive Assessment (MoCA) during the Telephone Interview. Refer to the Telephone Interview chapter 2F for instructions for administering the MoCA and how to proceed with participants assessed as having cognitive impairment. Existing Cohort participants who do not wish to come back for clinics visits and those with bilateral knee replacements will be asked if they wish to continue to be followed by phone using the standard MOST Missed Clinic Visit Telephone Interview (MCVTI).

A self-administered questionnaire is mailed to the participant so it can be filled out at home (SAQ-Home) and brought to the clinic visit. A brief self-administered questionnaire is completed at the clinic (SAQ-Clinic) the day of the clinic visit (self-administered questionnaires are further described in chapter 2I). The 144-month follow-up clinic visit includes a clinic interview (Table 1), and exams (Table 2). Examination protocols are detailed in chapters 3A thru 3S.

During the clinic visit, data will be entered on either Teleform (paper/pen) or REDCap (study website). Appendix 1 shows which forms are collected using Teleform and REDCap. Electronic data collected with specialized equipment and software will be transferred to the Coordinating Center via secure data transfer.

TABLE 1. 144-MONTH CLINIC INTERVIEW (both cohorts)
Knee symptoms past 12 months and past 30 days (most days)
Intermittent / constant knee pain past 7-days (ICOAP)
Knee pain location
Knee buckling (past 3 months)
Knee injury / surgery
Hip pain / surgery
Considering knee or hip joint replacement surgery
Physical therapy: past year for knee problem
Medication history (bisphosphonate ever; knee injections past 6 months; medication to treat or prevent breast or ovarian cancer past year (women only)
Vitamin D (currently using)
Current prescription medication (past 30 days)
Pregnancy / menopause
PASE

TABLE 2. 144-MONTH EXAMINATIONS (both cohorts)
Weight
Blood pressure
Height
Performance measures: chair stands, 20-meter walk, Timed Up & Go (TUG) *(existing cohort only)*, 6-Minute Walk Test (6MWT)
Hand photo
Foot length
Shoe hardness
Gait assessment (OPAL monitors): asymmetry and complexity measurements (during 20-meter walk and 6MWT)
Gait assessment/video (force of heel strike): force plate measure of slope of force at heel strike
Quadriceps muscle power and hip abduction strength
Quantitative sensory testing: conditioned pain modulation (CPM); pressure pain threshold (PPT); temporal summation (TS), peripheral neuropathy (PN)
Hip internal rotation
Falls and buckling diary calendar *(if eligible)*
Knee CT scan *New Cohort: required for study enrollment* *Existing Cohort: eligible if having MRI in one knee and no knee replacement in the other knee (still eligible if other types of metal are in the knee)*
Full-limb x-ray *New Cohort only: required for study enrollment*
Knee X-ray *(PA view bilateral / Lateral view unilateral (done on each eligible knee*))* *New Cohort: knee x-rays done at screen visit* *Existing Cohort: knee eligible if KL<3 (not 'endstage' disease)**
Knee 1.5T MRI extremity scan *Existing Cohort: knees eligible if KL<3, no TKR, knee fits in coil; participant eligible if no MRI contraindications)* *New Cohort: required for study enrollment*
Physical activity over 7 days: accelerometer (AX3 monitor) measurement: take-home & mail back
Fasting blood draw (serum, plasma, buffy coat, whole blood) & urine collection *New Cohort only*

Please see Appendix 11 for information on which exams to administer at the 144-month clinic visit for MOST versus MOST SENS participants.

Test-retest reliability assessment: After certification of examiners and approximately half-way through the 144-month clinic visit, we will evaluate test-retest reliability of key raw data and derived parameters from force plate testing, quantitative sensory testing, sway and gait assessment using Opal 3 accelerometers, and power/strength testing in 60 participants, 30 from each clinic. Retesting will take place approximately 7 days following the initial assessment. It does not have to be the same examiner for the initial and repeat measurements. The test-retest protocol is further described in Appendix 2.

2. Preparation for the 144-month follow up clinic visit

2.1 Equipment preparation

All equipment used for the 144-month follow-up visit should be calibrated and in good working order (see Appendix 3). Also, if there is any problem with any of the equipment or software, an Equipment Repair/Service Log should be completed to maintain a record of the problem and whether the measurement was affected by the problem. The Equipment Repair/Service should also include the action taken to resolve the problem, including the date the problem was encountered and the date it was resolved (Appendix 4).

2.2 Examiner preparation

All examiners must be certified before they begin administering 144-month visit exams. Examiners will be trained by a "master" examiner for the following exams: quantitative sensory testing; force at heel strike, quadriceps power, and hip abduction strength. Examiners will be recertified to administer all exams midway through the examination cycle. See the operations manual specific to each 144-month exam for more information about certification.

2.3 Participant preparation

Each participant who comes to the MOST clinic visit will have been told about the components of the visit during the phone conversation to schedule the clinic visit. There are 3 types of Pre-Visit reminder letters: 1) new cohort participants; 2) existing cohort having knee MRI scan; 3) existing cohort not having knee MRI scan (Appendix 5). Reminder letters should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- date and time of the clinic visit
- that participants take all of their regular medications, as usual
- that new cohort participants come into the clinic fasting at least 12 hours
- that participants should bring loose shorts
- that participants wear the shoes or sneakers that they would usually wear if they knew they were going to be on their feet for a long while, such as waiting in a long line, shopping, or taking a walk, and should not wear dress shoes, high heels, sandals, boots, or clogs
- 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. In addition participants should bring an inhaler or nitroglycerine if this medication is prescribed by their physician.

- that participants should be reminded to bring documentation that it is safe for them to have an MRI if during the follow-up telephone interview they reported having surgery where something was implanted in their body or they 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.

Ideally, reminder phone calls should be made the day before the clinic visit.

2.4 Clinic visit preparation

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

- Consent forms
- Consent Tracking Form (Appendix 6)
- Clinic Visit Procedure Checklist (Teleform) to keep track of which exams were done (Appendix 7)
- A Data from Prior Visits Report (Appendix 8 and 9) should be generated with information that will be needed for the clinic visit
- Your local MOST participant contact information (nonTeleform Form) with the participant's contact information (address, phone number, next of kin, contacts, etc.); this information will be updated in the SAQ-Home workbook.
- A 144-Month SAQ-Clinic workbook (Teleform) preprinted with the acrostic and MOST ID#
- A MOST Participant Results Report (Appendix 10) will travel with the participant during their clinic visit as it will contain information required for later exams and also be given to the participant at the end of their clinic visit
- 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. Quadriceps power and hip strength printed reports will be filed in the participant's chart.
- REDCap forms (Appendix 1) will be accessed through the study website (Data Management, chapter 6 and Website User's Guide, chapter 5, section 4.3 Data entry using REDCap).

3. Order of exams

MEASUREMENT	ORDER OF EXAMS: Required / Suggested / Anytime
Consent and change clothes	**Required**-consent signed before anything else happens
Urine and Blood Collection (fasting)	**Suggested**-done in the AM as participant is fasting
Laboratory Processing	**Required**-done immediately after blood draw
Blood Pressure	**Required**-performed before blood draw (new cohort), quantitative sensory testing, 20-meter walk, 6MWT, quadriceps power and hip strength
SAQ-Home reviewed for completeness and SAQ-Clinic completed and checked	**Anytime**
Clinic Interview administered	**Anytime**
Standing Height, Foot Length, Shoe Hardness	**Required-**done before quadriceps power and hip strength
Weight	**Required-**done before MRI exam, and quadriceps power and hip strength
20-Meter Walk & 6MWT Force of Heel Strike (FHS)	**Suggested**-done either after or at least one hour before MRI
Chair Stands/ TUG	**Suggested**-done either after or at least one hour before MRI; done just before quadriceps power and hip strength as a warm-up
Quadriceps Power & Hip Abduction Strength	**Required**-performed after knee MRI or at least one hour before MRI
Accelerometry (AX3 monitor)	**Required-**AX3 monitor attached after knee MRI
Hand Photo, Hip internal rotation	**Anytime**
Falls – Buckling Diary Calendar	**Suggested**-during exit interview
Knee X-ray, Full limb	**Anytime**
Knee MRI	**Required-**done after weight, either before or at least one hour after quadriceps power and hip strength and before AX3 monitor attachment **Suggested-**done either before or one hour after the chair stands, TUG, 20-meter walk, 6MWT, and FHS

4. Priority of exams

Ideally, all exams will be performed during the 144-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
Knee CT	High
Knee MRI	High
Knee X-ray	High
Full-Limb X-ray	High
Chair Stands	High
20-meter Walk & 6MWT with Opal	High
Weight	High
Quantitative Sensory Testing	Medium
Force of Heel Strike	Medium
Quad Power & Hip Strength	Medium
Specimen Collection	Medium
Standing Height	Low
Blood Pressure	Low

5. Procedure checklist and exit interview

At the end of the 144-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.
- Answer questions. Some participants may have questions about various examinations.
- If participant eligible (refer to DPVR), explain and give Falls - Buckling Diary Calendar (4 months) and self-addressed and pre-paid envelope to mail calendar diary back to clinic (see chapter 3E).
- Explain and give instructions for AX3 monitor (7 days of wearing, instructions for reattaching, complete questionnaire, self-addressed/stamped envelope to mail to clinic).
- Give Participant Results Reports (Appendix 10) and Information Packet.
- Make sure the Consent Tracking Form (REDCap) (Appendix 6) is completed/submitted.

- Make sure the Clinic Visit Procedure Checklist is completed/submitted (TELEForm, Appendix 7). 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.

Appendix 1 Data Collection Forms: REDCap and Teleform

REDCAP (ELECTRONIC FORMS)

- Telephone Screening Interview
- Screening Visit
- Telephone Interview
- Missed Clinic Visit Telephone Interview
- Clinic Visit
  - Clinic Visit Interview
  - Consent Tracking Form – Existing Cohort
  - Consent Tracking Form – New Cohort
  - Medication Inventory
  - Blood Pressure
  - Standing Height, Foot Length, Shoe Hardness
  - Weight
  - 20-Meter and 6 Minute Walk Test with Opal
  - Timed Up and Go
  - Chair Stands
  - Force of Heel Strike
  - Hand Photo
  - Quadriceps Power and Hip Abduction Strength
  - Quantitative Sensory Testing
  - Hip Internal Rotation
  - Knee X-ray Tracking
  - Full Limb X-ray Tracking
  - Knee CT Tracking
  - Knee MRI Tracking
  - MRI Eligibility
  - Urine Collection
  - Blood Collection
  - Accelerometry (AX3) Distribution
  - Accelerometry (AX3) Clinic Use & Return
  - Falls – Buckling Diary Distribution
  - Falls – Buckling Diary Return
  - PASE (Physical Activity Survey in the Elderly)

TELEFORM (PAPER FORMS)

- Self-Administered Questionnaire – Home
- Self-Administered Questionnaire – Clinic
- Clinic Visit Procedure Checklist
- Lab Processing
- Biospecimen Storage Box
- Missed Follow-up Contact
- Change in Enrollment Status
- Event Notification Form for Knee/Hip Replacement or Death
- Knee Replacement Report
- Hip Replacement Report
- Knee or Hip Replacement Adjudication Report
- Report of Death
- Confirmation of Death

Appendix 2 Test Retest Reliability Protocol

Purpose

Test-Retest (+7days) reliability is used to examine how reliable an examination measurement is: a measurement is performed twice, i.e., the same examination is given to a group of participants at two different times. If the exam measurement is reliable then each participant should have a similar score for exams done at the two different times. When the examinations are done close enough together in time that the underlying physical characteristic has not changed, then the differences between test and retest are largely due to measurement error. When the exams are separated by a long enough interval that the underlying physical characteristic may have changed, then the differences between test and retest can reflect both measurement error and inherent biological variability in the underlying characteristic. An exam may be reliable over the very short term (low measurement error) but less reliable over a longer interval due to biological variability so that a measurement made on a given day may not be a stable indicator of the underlying characteristic over a longer period of time.

After certification of examiners and approximately half-way through the 144-month clinic visit, we will evaluate test-retest reliability of key raw data and derived parameters from force plate testing, quantitative sensory testing, sway and gait assessment using Opal 3 accelerometers, and power/strength testing in 60 participants, 30 from each clinic. Retesting will take place approximately 7 days following the initial assessment. It does not have to be the same examiner for the initial and repeat measurements. With a sample size of 60, an ICC of 0.80 would be estimated with an approximate 95% CI width of +/- 0.09 (see additional estimation in the Table 1 below).

Table 1.
Estimation of 95% confidence interval for the ICC values based on sample size (N=60 and N=40)

	Sample size N=60	Sample size N=40
ICC target	95% CI width of +/-	95% CI width of +/-
0.90	0.05	0.06
0.80	0.09	0.11
0.70	0.13	0.16
0.60	0.16	0.20 tot

Test-Retest (+7days) Examinations will be done for selected exams in order to determine the stability of the measurements and/or in which exams significant practice or learning effects are likely to be present. An interval of 1 week (and no more than 14 days) will be sufficient time to minimize practice and learning effects and to capture variability related to highly labile characteristics of osteoarthritis such as joint pain, but insufficient time for major changes in underlying physical characteristics.

Examinations to be completed at Retest Visit (total for all exams: 60 minutes)

- Blood Pressure (7 minutes): required for Quadriceps Power and Hip Abductor Strength
- Quadriceps Power and Hip Abductor Strength (20 minutes)

- Opal monitor during Sway Posture and 20-Meter Walk (6 minutes)
- Force of Heel Strike (12 minutes)
- Quantitative Sensory Tests: Temporal Summation using Punctate Probe Set and Conditioned Pain Modulation / Pressure Pain Threshold (15 minutes)

Participants

- 60 participants total (30 U-Iowa and 30 UAB participants) per exam will be enrolled in the Test-Retest Reliability Study. It is not necessary for every participant to complete every exam, but a total of 30 participants at each clinic must have Test-Retest for each exam in the reliability protocol.
- Participants can be from the New Cohort or Existing Cohort.
- Test-Retest Study selection will be a convenience sample with targeted recruitment for 50% women / men and 50% age 45-64 / 65-79 years old at time of study enrollment.

Timeline

- Clinic will start after IRB approval is obtained.
- Test-Retest Reliability Study to be completed by August 2017 (ideally within 3 months of starting)
- Retest exams to be completed 7 days (up to 14 days is allowable) after the 144-month clinic visit.

Retest Time Estimate (total time approximately 60 minutes)

- Retest Visit (+7 days) = 60 minutes per participant

IRB Approval

The Test-Retest Study protocol and informed consent will be approved by the local IRB prior to starting.

Appendix 3 Equipment Calibration – Summary

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

Algometer	**Monthly Calibration Log** 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.
Blood Pressure	**<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.
Force plate	No calibration required unless equipment used > 24 months.
Lab temperature	The temperature of the room where the lab specimens are processed, the temperature of the refrigerator and the freezer should be checked daily, and recorded on the daily temperature log.
Load cell	No calibration required for the hip strength load cell.
MRI	**Daily MRI Temperature Log** Task: Check am and pm MRI room temperature **Daily Quality Assurance (DQA) scans**
NORM	**Monthly Calibration Log** The calibration log is automatically stored and uploaded to the SFCC. Contact CSMi if calibration is not in the acceptable range.

Scale	**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]) *Reading should be within ± .2 kg*
Stadiometer	**Daily Stadiometer Calibration Log** Task: Calibrate stadiometer with 600 mm rod. Reading must be 600 mm.
von Frey filaments	**Twice a year** Each von Frey filament will be replaced every 6 months.
X-ray beam angle	**Monthly X-ray Beam Angle Log (for each angle: 5, 10, and 15)** Task 1: Angle tube so that it is at [5][10][15] degrees caudal according to the dial. Task 2: Place inclinometer on top of x-ray tube. Task 3: On the inclinometer, read off the actual degrees of this beam angle. 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.

Appendix 4 Equipment Repair / Service Log

Equipment Repair/Service and Software Update Log

O **Alabama** O **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?

O Yes ↓

a. Did the problem affect the measurement?
O Yes O No O Don't know

b. Please describe: _____
_____
_____

O No ↓

How long was the equipment out of service?

☐☐ days

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

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

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

8. Was the problem resolved?
O Yes O No

↓

a. Date problem was resolved: ☐☐ ☐☐ ☐☐

b. Please describe how the problem was resolved: _____
_____
_____

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

↓

a. Date software update installed: ☐☐ ☐☐ ☐☐
Month Day Year

b. Software version number (if appropriate): _____

c. Comments: _____

Version 2.0, 07/15/10

Appendix 5 Pre-Visit Instructions

MOST 144-Month Follow-up Pre-Visit Instructions – New Cohort Participants

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 XXXXXXXXXXXXXX.

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.
- Please fast for 12 hours prior to your clinic visit (no eating or drinking, except for water, prescription medications and vitamins).
- Take all your regular medications and vitamins, as usual.
- Drink plenty of water before you come into the clinic.
- We will collect a urine sample from you. Collection will be the second void of the day (whenever possible).
- The visit may take about *4 hours*. Feel free to bring a morning snack with you. Additional time will be needed to go to Radiology for your knee CT scan.
- Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a long while, such as when shopping, waiting in a long line, or taking a walk. Do not wear dress shoes, high heels, sandals, boots, or clogs.
- 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 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.

MOST 144-Month Follow-up Pre-Visit Instructions – Existing Cohort (with MRI)

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 XXXXXXXXXXXXXX.

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 *4 hours*. Feel free to bring a morning snack with you. Additional time will be needed to go to Radiology for the knee CT scan.
- 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.
- Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a long while, such as when shopping, waiting in a long line, or taking a walk. Do not wear dress shoes, high heels, sandals, boots, or clogs.
- 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.

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.

MOST 144-Month Follow-up Pre-Visit Instructions – Existing Cohort Participants (without MRI)

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 XXXXXXXXXXXXXX.

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.
- Take all your regular medications and vitamins, as usual.
- The visit may take about *3 hours.* Feel free to bring a morning snack with you. Additional time will be needed to go to Radiology for your knee CT scan.
- Bring with you the walking shoes or sneakers that you would typically wear if you knew that you were going to be on your feet for a long while, such as when shopping, waiting in a long line, or taking a walk. Do not wear dress shoes, high heels, sandals, boots, or clogs.
- 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 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 6 Consent Tracking

Consent Tracking – New Cohort

Confidential

Page 1 of 2

MOSTv4 Consent Tracking - New Cohort

Please complete the survey below.

Thank you!

Time stamp start

_____

Visit

◯ Baseline/144-month
◯ 24-month/168-month

ID:

_____
(AANNNNN)

Acrostic:

_____
(AAAA)

Date exam completed:

_____

Staff ID#:

_____
(ANN)

Clinic:

◯ UAB
◯ Ulowa

1. Participant consented to participate in the MOST Study:

◯ Yes
◯ No

Participant is not eligible to participate in study.

1a. Enter date:

_____

2. I give my permission to have my blood sample frozen for future DNA/RNA genetic testing:

◯ Yes
◯ No

3. My blood cells and DNA/RNA may be stored/shared for future genetic research in osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis:

◯ Yes
◯ No

04/04/2016 11:45am www.projectredcap.org REDCap

Confidential

4. My blood cells and DNA/RNA may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.):

   ◯ Yes
   ◯ No

5. Notification about genetic finding that has a known treatment to prevent or lessen an important disease:

   ◯ Yes, please notify me
   ◯ No, do not notify me
   ◯ Not applicable

6. My information may be included in a national GWAS database:

   ◯ Yes
   ◯ No

6a. My information in the GWAS database may be shared with researchers studying musculoskeletal related conditions, and health conditions that affect musculoskeletal diseases:

   ◯ Yes
   ◯ No

6a. My information may be shared with researchers studying osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis:

   ◯ Yes
   ◯ No

6b. My information in the GWAS database may be shared with researchers studying for other health problems (such as cancer, heart disease, or other non-musculoskeletal related conditions):

   ◯ Yes
   ◯ No

6b. My information in the GWAS database may be shared with researchers for studying other health problems (such as cancer, heart disease, etc.):

   ◯ Yes
   ◯ No

7. Vital Status Searches with Social Security Number, Medicare number and date of birth (UAB) or Social Security Number Usage (U-Iowa):

   ◯ Yes, agree/allow
   ◯ Do NOT agree/allow

8. Geocoding:

   ◯ Yes, allow collection and use of address
   ◯ Do NOT allow collection and use of address

9. Audio/Video Recording:

   ◯ Yes
   ◯ No
   ◯ Not applicable

10. Allow investigators to take a photo of my hands.

    ◯ Yes
    ◯ No

    Time stamp stop

    _____

Consent Tracking – Existing Cohort

Confidential

MOSTv4 Consent Tracking - Existing Cohort

Please complete the survey below.

Thank you!

Time stamp start

_____

Visit

◯ Baseline/144-month
◯ 24-month/168-month

ID:

_____
(AANNNNN)

Acrostic:

_____
(AAAA)

Date exam completed:

_____

Staff ID#:

_____
(ANN)

Clinic:

◯ UAB
◯ Ulowa

1. Participant consented to continue in the MOST Study:

◯ Yes
◯ No

Confirm participant does not consent to continue in the study. If they don't consent, complete Change in Enrollment data collection form.

1a. Enter date:

_____

1b. Type of consent:

◯ MCVTI
◯ Clinic visit

1bi. Consent method:

◯ Consent without discussion between a research team member and the subject.
◯ Consent after a discussion between a research team member and the subject.

Confidential

2. Notification about genetic testing finding that has a known treatment to prevent or lessen an important disease:

   ◯ Yes, please notify me
   ◯ No, do not notify me
   ◯ Not applicable (did not previously consent to DNA storage and/or useage)

3. Vital Status Searches with Social Security Number, Medicare number and data of birth (UAB) or Social Security Number Useage (U-Iowa):

   ◯ Yes, agree/allow
   ◯ Do NOT agree/allow

4. Geocoding:

   ◯ Yes, allow collection and use of address
   ◯ Do NOT allow collection and use of address
   ◯ Not applicable

5. Audio/Video Recording:

   ◯ Yes
   ◯ No
   ◯ Not applicable (consent form doesn't have opt-in/opt-out consent)

6. Allow investigators to take a photo of my hands:

   ◯ Yes
   ◯ No

   Time stamp stop

   _____

Appendix 7 Clinic Visit Procedure Checklist

Draft

CLINIC VISIT PROCEDURE CHECKLIST

Cohort	Visit	MOST ID #	Acrostic	Date Form Completed	Staff ID#
O E O N	O BL/144m O 24m/168m			Month / Day / Year	

MOST

O First exam O Repeat exam 1 O Repeat exam 2 O Repeat exam 3

Measurement	Completed	Partially completed	Participant refused	Not done/ Not applicable
1. Consent Procedure Checklist	O	O	O	O
2. Was SAQ - Home completed/checked?	O	O	O	O
3. Was SAQ - Clinic completed/checked?	O	O	O	O
4. Was Clinic Interview administered?	O	O	O	O
5. Medication Inventory	O	O	O	O
6. Blood Pressure	O	O	O	O
7. Standing Height, Foot Length, & Shoe Hardness	O	O	O	O
8. Weight *(existing cohort)*	O	O	O	O
9. 20-meter Walk / 6-Minute Walk Test	O	O	O	O
10. Opal O Equip failure	O	O	O	O
11. Timed Up & Go (TUG) *(existing cohort)*	O	O	O	O
12. Chair Stands	O	O	O	O
13. Force of Heel Strike O Equip failure	O	O	O	O
14. Hand Photo O Equip failure	O	O	O	O
15. QuadPower/Hip Strength O Equip failure	O	O	O	O
16. Quantitative Sensory Testing (QST)	O	O	O	O
17. Hip Internal Rotation	O	O	O	O
18. Knee X-ray *(existing cohort)* O Equip failure	O	O	O	O
19. Knee Full Limb X-ray *(new cohort)* O Equip failure	O	O	O	O
20. Knee CT O Equip failure	O	O	O	O
21. Knee MRI 1.5 T O Equip failure	O	O	O	O
22. Urine Collection *(new cohort)*	O	O	O	O
23. Blood Collection *(new cohort)*	O	O	O	O
24. Laboratory Processing *(new cohort)*	O	O	O	O
25. Accelerometry (AX3) O Equip failure	O	O	O	O
26. PASE	O	O	O	O
27. Falls-Buckling Diary Calendar Packet	O	O	O	O

MOST
Clinic Visit Procedure Checklist
Version 1.0 12/7/15
Q01

Draft

Appendix 8 Data from Prior Visits Report 144-Mo Follow up Clinic Visit (New Cohort)

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report (New Cohort)

Baseline/144-month Clinic Visit

Data current as of <today>

Gender
Current age

Visit Date
1. Target date for 144-month Clinic Visit:
2. Date of Screening Visit with x-ray: (month and year)

Pregnancy Screen
2a. Did participant require a pregnancy test at the Screening Visit?

X-ray
3. Does participant need to repeat an x-ray?
   3a. Comments about X-ray repeats:

1.5 T Knee MRI
4. Was participant asked to bring medical documentation that shows it is safe to have an MRI scan?
   4a. Does the medical documentation confirm that it would be safe for the participant to have to have an MRI scan?
5. Knee(s) eligible for 144-month MRI?

Falls and Buckling Calendar
6. Participant eligible for falls and buckling calendar:

Appendix 9 Data from Prior Visits Report 144-Mo Clinic Visit (Existing Cohort)

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report (Existing cohort)

144-month Follow-up Clinic Visit

Data current as of <today>

Gender
Estimated age

Visit Date
1. Target date for 144-month Clinic Visit:
2. Type of last contact:
3. Date of last MOST contact: (month and year)

Right Knee Replacement
4. Right knee replaced?
5. Surgery date of right knee replacement?

Left Knee Replacement
6. Left knee replaced?
7. Surgery date of left knee replacement?

MOST-SENS (ancillary study)
8. Participant eligible for MOST-SENS visit? (9 to 24 months after KR)
   8a. Which knee is the index knee for CPM/PPT (R/L/Both)?

Hip Replacements
9. Right hip previously reported as replaced?
10. Left hip previously reported as replaced?

Bisphosphonate Use
11. Participant reported use of bisphosphonate at the last clinic visit?
12. Years participant reported using bisphosphonates at the last clinic visit?

Height
13. Was participant standing sideways due to kyphosis?

X-ray
14. Participant eligible for the following x-rays:

a) PA semi-flexed view of right and left knee	
Use the following beam angle(s)	
b) Lateral view of right knee	
c) Lateral view of left knee	

1.5T Knee MRI
15. Date of last 1.0T MRI, and knee(s) scanned:
16. Participant eligible for MRI at the time of the 144-month Telephone Interview?
17. Participant asked to bring medical documentation that shows it is safe to have an MRI scan?
    17a. Type of implant or metal injury requiring medical documentation:

18. Knee(s) eligible for 144-month MRI?
19. Priority knee to scan (if still eligible after completing MRI Eligibility Form)
20. Alternate knee to scan if priority knee not eligible:

CT Scan

21. Participant eligible for knee CT scan (always bilateral)?

Consent Procedure Checklist

22. DNA in storage?

Medication List From Last Clinic Visit

23. Participant reported taking an RA medication?
24. Prescription medication list from last visit:

Visit	Medication Name	Formulation Code	Frequency	Duration

Appendix 10 Participant Results Reports

Participant Results Report - New Cohort

Participant ID#: MX00000
Acrostic: TEST

Participant: _____

We would like to thank you for your participation in the Multicenter Bone and Joint Health 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	Screen Visit / Baseline
Screen Visit Date	3/23/2017
Baseline Date	
Blood Pressure	mm Hg
Height	ft in
Height in centimeters[1]	cm
Weight	247.4 pounds
Weight in kilograms[1]	112.2 kg
Body Mass Index	
Knee OA Status	Right: No OA Left: No OA
Knee Pain Score[2]	Right: Left:
Toe sensitivity	Right: Left:
Performance Measures	
20-Meter Timed Walk	seconds
6-minute Walk Test	miles
Chair Stands, Timed	seconds

[1]Height and weight required in metric units for Knee Power/Hip strength exam.
[2]Scale is from 0 (no pain) to 100 (severe pain).

Participant Results Report - Existing Cohort

Participant ID#:
Acrostic:

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	144-Month
Visit Date	08/19/2003	03/16/2006	06/22/2009	07/29/2011	
Blood Pressure	147/ 53 mm Hg	134/ 74 mm Hg	121/ 61 mm Hg	108/ 39 mm Hg	mm Hg
Height[1]	5 ft 01 in	Not done	5 ft 00 in	Not done	ft in
Height in centimeters[2]					cm
Weight	176 pounds	174 pounds	183 pounds	157 pounds	pounds
Weight in kilograms[2]					kg
Body Mass Index	33	33	35	30	
Knee OA Status	Right: KR Left: Severe OA	Right: KR Left: Severe OA	Right: KR Left: KR	Right: KR Left: KR	Right: KR Left: KR
Knee Pain Score[3]	Right: 10 Left: 35	Right: 5 Left: 75	Right: 30 Left: 30	Right: 0 Left: 1	
Toe sensitivity	Not done	Not done	Right: Reduced sensation Left: Normal	Not done	
Performance Measures					
20-Meter Timed Walk	22.3 seconds	24.1 seconds	23.4 seconds	29.1 seconds	seconds
6-minute Walk Test	Not done	Not done	Not done	Not done	miles
Chair Stands, Timed	21.6 seconds	Not done	19.2 seconds	20.3 seconds	seconds
Timed Up and Go Test	Not done	Not done	Not done	Not done	seconds

[1]Changes in height may be due to measurement or data entry error.
[2]Height and weight required in metric units for Knee Power/Hip strength exam.
[3]Scale is from 0 (no pain) to 100 (severe pain).

Appendix 11 144-Month Clinic Visit Components: MOST III vs MOST-SENS

Measurement & Instrument	MOST III participant only (not eligible for MOST-SENS)	MOST III and MOST-SENS (unilateral knee replacement)	MOST-SENS only (bilateral knee replacement)
Telephone Interview	X	X	X
Consent Tracking- Existing cohort	X	X	
Clinic Visit Interview	X	X	X
20-Meter (with Opal)	X	X	X[4]
6-Minute Walk (with Opal)	X	X	
Accelerometry (AX3)	X	X	X
Blood Pressure	X	X	X
Chair Stands	X	X	X
Cybex		X	X
Falls and Buckling Diary Return	X	X	
Force of Heel Strike	X	X	
Hand Photo	X	X	
Hip Internal Rotation	X	X	
Medication Inventory	X	X	X
PASE	X[1]	X	X
Quad Power and Hip Strength	X	X[2]	X[2]
Quantitative Sensory Testing	X	X[3]	X[3]
Standing Height, Foot Length and Shoe Hardness	X	X	
Timed Up and Go	X	X	
Weight	X	X	X
Knee CT	X	X	
Knee X-ray	X	X	
Knee MRI	X	X	
MRI Eligibility Confirmation	X	X	

[1] administer to all participants even if participant does do the AX3

[2] optional

[3] protocol includes PPT on index knee

[4] no Opal