OVERVIEW OF 168-MONTH FOLLOW-UP CLINIC VISIT

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1. Introduction

The second clinic visit for the Second MOST Renewal Grant (2015-2020) is a **24-month clinic visit** for the newly recruited cohort (New Cohort) and a **168-month follow-up visit** for surviving members of the original cohort (Existing Cohort). New and Existing Cohort participants will have a Telephone Interview (chapter 2H) at which time they will be asked to participate in additional follow-up at 168-months. Henceforth in this document, both the 24-month and 168-month follow-up visit will be referred to as 168-month follow-up clinic visit.

Existing and New Cohort participants who are 70 years or older and who did not complete the 5-Minute Montreal Cognitive Assessment (MoCA) during the 144-month follow-up visit will have MoCA during the Telephone Interview at 168-months. 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 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 168-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) (see Data Management, chapter 6). 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 (see Secure Data Transfer, chapter 7).

Epigenetics Ancillary Study (Yau AS18-01): New cohort participants will be asked to participate in this ancillary study, which includes a non-fasting blood draw and x-rays of both hands. The purpose of this ancillary study is to identify new targets for osteoarthritis (OA) treatment by looking for modifications to DNA that could cause OA. The hand x-rays (as well as the other x-rays already collected at 168-months) will be used to figure out which DNA modifications are related to having OA at more joints. Starting around November 2019, all new cohort participants who are coming in for the 168-month clinic visit will be eligible for this ancillary study. Participants must consent to the DNA testing/buffy coat collection to be enrolled in the ancillary study. In order for buffy coat to be used for epigenetics, the participant would need to answer 'Yes' to 'I give permission to have my blood sample frozen for future DNA/RNA genetic testing and biomarker testing' AND 'Yes' to 'My blood cells and DNA/RNA may be stored/shared for future gene and biomarker research in osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis'. Participants who do not answer 'Yes' to both questions should not be enrolled in the ancillary study.

TABLE 1. 168-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 (since last asked and 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)

TABLE 2. 144-MONTH EXAMINATIONS (both cohorts)
Weight
Blood pressure
Performance measures: chair stands, 20-meter walk, Timed Up & Go (TUG) *(existing cohort only)*, 6-Minute Walk Test (6MWT)
Quantitative sensory testing: conditioned pain modulation (CPM); pressure pain threshold (PPT); temporal summation (TS), peripheral neuropathy (PN)
Knee CT scan *New and Existing Cohort: Not required but, if feasible, acquire CT scan in those participants who were eligible at 144-months but did not get a CT at 144-months (refer to DPVR)*
Knee X-ray *(PA view bilateral / Lateral view unilateral (done on each eligible knee*))* *New and Existing Cohort: knee eligible if KL<3 (not 'endstage' disease)* (refer to DPVR)*
Knee 1.5T MRI extremity scan *New and Existing Cohort: knees eligible if KL<3, no TKR knee fits in coil; participant eligible if no MRI contraindications) (refer to DPVR)*
Hand X-ray (PA view, both hands) *New cohort: Participant eligible if consent to DNA testing/buffy coat as part of Yau AS18-01*
Non-fasting blood draw (plasma, buffy coat and whole blood) *New cohort: Participant eligible if consent to Yau AS18-01*

2. Preparation for the 168-month follow up clinic visit

2.1 Equipment preparation

All equipment used for the 168-month follow-up visit should be calibrated and in good working order (see Appendix 2). 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 3).

2.2 Examiner preparation

All examiners must be certified before they begin administering 168-month visit exams. Examiners will be recertified to administer all exams midway through the examination cycle. See the operations manual specific to each 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 2 types of Pre-Visit reminder letters: 1) new/existing cohort participants with MRI scan; 2) new/existing cohort participant without MRI scan (Appendix 4). 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 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 if necessary
- Consent Tracking Form (Appendix 5): complete for new cohort participant for Yau AS18-01; also complete if not completed during 144-month follow-up clinic visit OR participant changes/updates consent responses
- Clinic Visit Procedure Checklist (Teleform) to keep track of which exams were done (Appendix 6) (Note: exams that are NOT part of the 168-month follow-up clinic visit have been prefilled "Not done/ Not applicable")
- A Data from Prior Visits Report (Appendix 7) should be generated with information that will be needed for the clinic visit
- Your local MOST participant contact information (non-Teleform Form) with the participant's contact information (address, phone number, next of kin, contacts, etc.). Please confirm contact information with participant and update as necessary.
- A 168-Month SAQ-Clinic workbook (Teleform) preprinted with the acrostic and MOST ID#
- A MOST Participant Results Report (Appendix 8) 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. Clinical 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.
- 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 *(if necessary)* and change clothes	**Required**-consent signed before anything else happens
Non-fasting blood draw *(new cohort if consent to Yau AS18-01)*	**Required-**collect after blood pressure
Laboratory Processing	**Required-**done immediately after blood draw
Blood Pressure	**Required**-performed before quantitative sensory testing, 20-meter walk, 6MWT
SAQ-Home reviewed for completeness and SAQ-Clinic completed and checked	**Anytime**
Clinic Interview administered	**Anytime**
Weight	**Required-**done before MRI exam
20-Meter Walk & 6MWT	**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
Knee and Hand *(new cohort if consent to Yau AS18-01)* X-ray	**Anytime**
Knee MRI	**Required-**done after weight **Suggested-**done either before or one hour after the chair stands, TUG, 20-meter walk, and 6MWT

4. Priority of exams

Ideally, all exams will be performed during the 168-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 MRI	High
Knee X-ray	High
Chair Stands	High
20-meter Walk & 6MWT without Opal	High
Weight	High
Quantitative Sensory Testing	Medium
Blood Pressure	Low

5. Procedure checklist and exit interview

At the end of the 168-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.
- Give Participant Results Reports (Appendix 8) and Information Packet.
- Make sure the Clinic Visit Procedure Checklist is completed/submitted (TELEForm, Appendix 6). 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. (Note: exams that are NOT part of the 168-month follow-up clinic visit have been prefilled “Not done/ Not applicable”).

Appendix 1 Data Collection Forms: REDCap and Teleform

REDCAP (ELECTRONIC FORMS)

- Telephone Interview
- Missed Clinic Visit Telephone Interview
- Clinic Visit
  - Clinic Visit Interview
  - Consent Tracking – Existing Cohort *(if not completed at 144-months or response(s) change)*
  - Consent Tracking – New Cohort *(for Yau AS18-01 and/or if response(s) change)*
  - Medication Inventory
  - Blood Pressure
  - Weight
  - 20-Meter and 6 Minute Walk Test without Opal
  - Timed Up and Go *(Existing Cohort only)*
  - Chair Stands
  - Quantitative Sensory Testing
  - Knee X-ray Tracking
  - Full Limb/Hand X-ray Tracking *(hand x-ray new cohort for Yau AS18-01)*
  - Knee CT Tracking *(if applicable)*
  - Knee MRI Tracking
  - MRI Eligibility
  - Blood Collection *(new cohort for Yau AS18-01)*

TELEFORM (PAPER FORMS)

- Self-Administered Questionnaire – Home
- Self-Administered Questionnaire – Clinic
- Clinic Visit Procedure Checklist
- Lab Processing *(new cohort for Yau AS18-01)*
- 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 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.
MRI	**Daily MRI Temperature Log** Task: Check am and pm MRI room temperature **Daily Quality Assurance (DQA) scans**
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]) *<u>Reading should be within ± .2 kg</u>*

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 3 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 ↓

a. Date problem was resolved:

☐☐ ☐☐ ☐☐

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

O No

9. Was a software update required?
(Note: software updates should not be installed without Coordinating Center approval.)

O Yes ↓

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

b. Software version number (if appropriate): _____

c. Comments: _____

O No

Version 2.0, 07/15/10

Appendix 4 Pre-Visit Instructions

MOST 24-/168-Month Follow-up Pre-Visit Instructions
Existing/New Cohort Participants (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 XXXXXXXXXXXXX.

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.
- 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 24-/168-Month Follow-up Pre-Visit Instructions
Existing/New 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 *2 hours.* Feel free to bring a morning snack with you.
- 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.

Appendix 5 Consent Tracking

Confidential

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:

_____

10-01-2019 15:02 projectredcap.org REDCap

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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

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/NIH database:

   ◯ Yes
   ◯ No

6a. My information in the GWAS/NIH 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/NIH 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/NIH 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

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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.

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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 6 Clinic Visit Procedure Checklist

43657

CLINIC VISIT
PROCEDURE CHECKLIST

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

MOST

● First exam ○ Repeat exam 1 ○ Repeat exam 2 ○ Repeat exam 3

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

MOST
Clinic Visit Procedure Checklist
Version 8/19/19
Q01

43657

Appendix 7 Data from Prior Visits Report 168-Month Follow up Clinic Visit (New and Existing Cohort)

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report

168-/24-month Follow-up Clinic Visit

Data current as of <today>

Gender
Estimated age
Cohort

Visit Date
1. Target date for 168-/24-month Clinic Visit:
2. Type of last contact:
3. Date of last MOST contact: (month and year)

Pregnancy Screen (New cohort)
3a. Did participant require a pregnancy test at baseline Screening Visit?
If yes, reassess need for pregnancy test. If last natural menstrual period was within the past 12 months, administer pregnancy test. If both ovaries removed or hysterectomy, pregnancy test not required

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?

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?

X-ray
13. 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	

Knee MRI
14. Date(s) of last MRI, and knee(s) scanned:
15. Participant eligible for MRI at the time of the 168-/24-month Telephone Interview?
16. Participant asked to bring medical documentation that shows it is safe to have an MRI scan?
16a. Type of implant or metal injury requiring medical documentation:

17. Knee(s) eligible for 168-/24-month MRI?
    17a. Right knee
    Exam numbers:
    FOV:
    Coil:
    Old or new protocol:
    17b. Left knee
    Exam numbers:
    FOV:
    Coil:
    Old or new protocol:
18. Priority knee to scan (start with this knee if still eligible after completing MRI Eligibility Form)

19. Alternate knee to scan if priority knee not eligible:

CT Scan

20. Participant eligible for knee CT scan (always bilateral)?
20a. Participant eligible for Standing CT (Ulowa only)?

Consent Procedure Checklist

21. DNA in storage?

Medication List From Last Clinic Visit

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

Visit	Medication Name	Formulation Code	Frequency	Duration

Appendix 8 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	24-month
Screen Visit Date	12/04/2017	
Clinic Visit Date	12/18/2017	xx/xx/xxxx
Blood Pressure	108/ 39 mm Hg	**mm Hg**
Height	5 ft 00 in	Not done
Height in centimeters[1]	152.4 cm	Not done
Weight	157 pounds	**pounds**
Weight in kilograms[1]	71 kilograms	**kg**
Body Mass Index	30	
Knee OA Status	Right: No OA Left: No OA	Right: Left:
Knee Pain Score[2]	Right: 0 Left: 0	Right: Left:
Toe Sensitivity	Right: Reduced sense Left: Normal	Right: Left:
Performance Measures		
20-Meter Timed Walk	29.1 seconds	**seconds**
6-Minute Walk Test	.36 miles	**miles**
Chair Stands, Timed	20.3 seconds	**seconds**

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

Participants Results Report for New Cohort, 5/21/18

Participant Results Report - Existing Cohort

Participant ID#: MX00000
Acrostic: TEST
Participant: _____

We would like to thank you for your continued 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	Baseline	30-Month	60-Month	84-Month	144-Month	168-Month
Visit Date	08/19/2003	03/16/2006	06/22/2009	07/29/2011	07/29/2016	xx/xx/xxxx
Blood Pressure	147/ 53 mm Hg	134/ 74 mm Hg	121/ 61 mm Hg	108/ 39 mm Hg	108/ 39 mm Hg	mm Hg
Height[1]	5 ft 01 in	Not done	5 ft 00 in	Not done	5 ft 00 in	Not done
Height in centimeters[2]				Not done	152.4 cm	Not done
Weight	176 pounds	174 pounds	183 pounds	157 pounds	157 pounds	pounds
Weight in kilograms[2]					71 kilograms	kg
Body Mass Index	33	33	35	30	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	Right: KR Left: KR
Knee Pain Score[3]	Right: 10 Left: 35	Right: 5 Left: 75	Right: 30 Left: 30	Right: 0 Left: 1	Right: 0 Left: 1	Right: Left:
Toe Sensitivity			Right: Reduced sense Left: Normal		Right: Reduced sense Left: Normal	Right: Left:
Performance Measures						
20-Meter Timed Walk	22.3 seconds	24.1 seconds	23.4 seconds	29.1 seconds	29.1 seconds	seconds
6-Minute Walk Test					.36 miles	miles
Chair Stands, Timed	21.6 seconds	Not done	19.2 seconds	20.3 seconds	20.3 seconds	seconds
Timed Up and Go (TUG)					7.12 seconds	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).

Participants Results Report for Existing Cohort 5/21/18