OVERVIEW OF 60-MONTH FOLLOW-UP VISIT

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1. Introduction

The 60-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
Biospecimen collection
Blood pressure
Gait assessment
Isokinetic strength and surface EMG
Knee MRI
Knee X-ray including full limb
Pain sensitivity (somatosensory assessment)
Performance based measurements (chair stands, 20-meter walk, rapid step up and maximal step length)
Peripheral neuropathy
Plantar pressure
Standing height
Vibration perception threshold
Weight

In addition to the exams above, all participants will have anatomic landmarks marked for various tests. Also, during the 60-month visit participants will be asked whether or not they are experiencing pain, once at the beginning of the visit (see Question #1 on the Initial Knee Pain and Urine Collection data collection form on page 72 in the Follow-up Clinic Visit Workbook) and after the 20-meter walk, chair stands, isokinetic strength/sEMG, maximal step length, gait assessment, and plantar pressure exams. It is imperative that the initial pain question and bilateral knee replacement question (Question #2) be asked early in the visit, whether or not a urine sample is being collected.

Participants who are 65 years or older will have a cognitive test.

During a three month period of the 60-month visit cycle, a Test-Retest Reliability Study will be conducted. Thirty participants at each study site will complete Same Day Test-Retest Examinations and thirty participants at each study site will complete 14-Day Test-Retest Questions and Examinations (see Appendix 11).

2. Preparation for the 60-month follow up clinic visit

2.1 Equipment preparation

All equipment being used for the 60-month follow-up visit should be calibrated and in good working order (see Appendix 1). 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, 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 2).

2.2 Examiner preparation

All examiners must be certified before they begin administering 60-month visit exams. Examiners will be trained by a "master" examiner for the following exams: pain sensitivity (somatosensory assessment); surface EMG during isokinetic strength; vibration perception threshold; gait assessment; and plantar pressure. Examiners will be recertified to administer all exams midway through the examination cycle. See the operations manual specific to each 60-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 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 3):

- date and time of the clinic visit
- that participants take all of their regular medications, as usual
- that participants come into the clinic fasting
- 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.
- 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 examples of a reminder letter in Appendix 3.

2.4 60-month follow-up clinic visit preparation

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

- Consent forms
- Consent Procedure Checklist (Appendix 8)
- A Data from Prior Visits Report \ 60-Month Follow up Clinic Visit should be generated with information that will be needed for the clinic visit (see Appendix 5)
- Your local MOST participant contact information with the participant's contact information (address, phone number, next of kin, contacts, etc.)
- A clinic flow sheet to keep track of which exams from which participants are excluded and what time exams were begun (Appendix 6)
- A 60-Month SAQ Questionnaire Clinic preprinted with the acrostic and MOST ID#
- A 60-Month Follow-up Clinic Visit Workbook preprinted with the acrostic and MOST ID# (this workbook includes the MOST interview) (see checklist in Appendix 7)
- A StepWatch and various straps (small, medium, large), StepWatch information sheet, distribution form, and return envelope (see Accelerometry operations manual chapter.)
- A MOST Participant Results Report to give the participant at the end of their clinic visit (Appendix 9)
- 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.

3. Order of exams

MEASUREMENT	Order of Exams: Required / Suggested / Anytime
Consent and change clothes	**Required**-consent signed before anything else happens
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 isokinetic strength/sEMG, GAITrite, Vibration Perception Threshold, Pain Sensitivity, and X-ray
Cognitive Screen	**Anytime**
Blood Pressure	**Required**-performed before blood draw and before Isokinetic Strength / sEMG
Standing Height	**Anytime**
Weight	**Required**-before plantar pressure
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; done just before isokinetic strength as a warm-up
Isokinetic Strength, sEMG	**Required**-performed after knee MRI or at least one hour before MRI
Rapid Step Ups	**Anytime -** with maximal step length
Maximal Step Length	**Anytime** -with rapid step ups
GAITrite	**Suggested**-after 20-meter walk and before isokinetic strength
Plantar Pressure	**Suggested**- after warm-up (Chair Stands, 20-meter Walk, etc.)
Peripheral Neuropathy	**Anytime**-with Vibration Perception Threshold
Vibration Perception Threshold	**Anytime**-with Peripheral Neuropathy
Pain Sensitivity	**Anytime**-with Vibration Perception Threshold
Knee X-ray	**Anytime**
Knee MRI	**Required-**done after weight and either before or at least one hour after the isokinetic strength exam. **Suggested-**done either before or at least one hour after the chair stands and 20-meter walk.
Specimen Collection	**Suggested**-done early during the visit (fasting blood draw)
Laboratory Processing	**Required**-done immediately after blood draw

Done together

done together

4. Priority of exams

Ideally, all exams will be performed during the 60-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
Cognitive screen	**Medium**
Blood Pressure	**Low**
Standing height	**Low**
Weight	**High**
20-meter Walk	**High**
Chair Stands	**High**
Isokinetic Strength/sEMG	**Medium**
Rapid step ups	**Low**
Maximal step length	**Low**
GAITrite	**Medium**
Plantar pressure	**Medium**
Peripheral neuropathy	**Medium**
Vibration Perception Threshold	**Medium**
Pain Sensitivity	**Medium**
Knee X-ray	**High**
Knee MRI	**Medium**
Specimen Collection	**Low**

5. Procedure checklist and exit interview

At the end of the 60-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.
- Obtain Genome Wide Association Studies (GWAS) consent if participant has an archived DNA sample in storage (See Data from Prior Visits Report 60-Month Clinic Visit (Appendix 5). 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-month visit consent form on the Consent Procedure Checklist (Appendix 8) and complete the items on the checklist for those consent forms (UAB #5-13/ UI #2-8). When time allows, complete the items on the checklist for the participant's baseline consent form (UAB #1-4, UI #1).

Also:

- Make sure the Clinic Flow sheet is completed (Appendix 6); i.e., the header information including the MOST ID #, Acrostic, and the times exams were begun.

- Make sure the 60-Month Follow-up Clinic Visit Workbook Procedure Checklist is completed (Appendix 7); 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 results (Appendix 9). Participants will be given the following 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.

  ⇨ Weight. Weight in pounds should be provided.

  ⇨ Height. Height in feet and inches should be provided.

  ⇨ BMI. A chart is included on the Participant Results Report.

  ⇨ Plantar Pressure Report

  ⇨ National Institute on Aging Arthritis Advice. (OPTIONAL)

- Let participants know that we will be sending them their accelerometry results after they send back the StepWatch.

Appendix 1 Equipment Calibration – Summary

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

Algometer	**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.
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.
Cybex 350	For step by step calibration instructions, see Appendix 1 in operations manual chapter 3M, Isokinetic Strength. Each clinic will have certified weights for calibration. These should be followed once a week when isokinetic strength is being measured (varies by clinic). A reading of 178-182 ft-lbs is acceptable. High or low values may indicate bouncing of weights during calibration while arm is moving. If out of range, repeat calibration once, making sure weights fall smoothly, followed by verification. If the calibration and verifications range is still not correct, call CSMI (781-255-1292). **Daily:** Task: Before testing first participant of the week open Cybex software and click on "Injury Group" tab to add site, year, and week, e.g., for Alabama, group 1 would be MB2009w1; Iowa group 1 would be MI2009w1. Record week number on Cybex Group/Week Number Log
E-Med X	**Calibrated yearly – sent to Novel, Inc. in Munich, Germany**

GAITRite	**Quarterly:** Task 1: Follow instructions in Procedures for Verifying Spatial and Temporal Accuracy of GAITRite (posted on MOST website under Equipment Calibration Forms). Task 2: Calculate the difference between manually-measured distance and GAITRite software computed distance in centimeters at location 1. Calculate the difference between time measured by stopwatch and time computed by GAITRite software in seconds at location 1. If difference between manually measured distance and distance computed by GATIRite software is less than or equal to +/-1.5 centimeters and difference between time measured with a stopwatch and time computed by GAITRite software is less than or equal to +/-1.5 seconds, record results under location 1 and proceed to Task 3. If difference between manually-measured distance and distance computed by GATIRite software is greater than +/-1.5 centimeters and/or difference between time measured with a stopwatch and time computed by GAITRite software is greater than +/-1.5 seconds, repeat the test at location 1 a second time following Tasks 1-2. If differences are too great on a second test, do a third test following Tasks 1-2. If differences are too great on a third test, record the results of the third test under Location 1 and notify clinic QC officer. Task 3: Repeat Tasks 1-2 at location 2. Task 4: Repeat Tasks 1-2 at location 3. *Difference in measurements should be within ± 1.5 centimeters (cm) and ± 1.5 seconds (sec.)*
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.
OrthOne temperature	**Daily OrthoOne Temperature Log** Task: Check am and pm OrthOne room temperature
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.
Temporal Summation Pen	**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 within 0.1 g. Task 5: Remove the filament/stylus from the scale, and ensure the scale returns to zero. Re-zero if necessary. Task 6: Repeat the measurement process (Tasks 2-5) 2 times for a total of 3 measurements 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 8. Task 8: Record the 3 measurements and the highest value of the 3 measurements (achieving repeatability within 1 g of each other). 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.
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 2 Equipment Repair / Service Log

Equipment Repair / Service 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: ☐☐ ☐☐ ☐☐ Month Day Year
     - b. Please describe how the problem was resolved: _____
   - O No

Version 1.0, 2/24/09

Appendix 3 MOST 60-Month Follow-up Pre-Visit Instructions

MOST 60-Month Follow-up Pre-Visit Instructions – Fasting 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 do not eat or drink anything but water, prescription medications, and vitamins after midnight the night before your visit.
- 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 [*2 to 3 hours if no 1.0 T MRI*] [*3 to 4 hours if 1.0 T MRI*]. 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 60-Month Follow-up Pre-Visit Instructions – Non-fasting 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.
- The visit may take about [*2 to 3 hours if no 1.0 T MRI*] [*3 to 4 hours if 1.0 T MRI*]. 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.

Appendix 4 Data from Prior Visits Report 60-Month Follow up Telephone Interview

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report

60-Month Follow up Telephone Interview

Data current as of

Visit Dates

1. Date of last contact:
2. Was the last contact a Clinic Visit or a Phone Interview?
3. Target date for 60-month Telephone Interview:

1.0 T Knee MRI History

4. Knee(s) eligible for 60-month visit
5. Was participant eligible for MRI at a prior visit?
6. Date of the participant's last 1.0 T MRI scan:

Biospecimen Collection (bilateral knee exclusions are not eligible)

7. Is participant eligible for biospecimen colection?

(If eligible, tell participants that they will be required to fast for 8 hours prior to the visit and provide a second-morning urine void.)

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

Knee Replacements

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

Hip Replacements

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

Cognitive Screen

12. Is the participant age 65 or older now?

Appendix 5 Data from Prior Visits Report 60-Month Follow up Clinic Visit

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report

60-Month Follow up Clinic Visit

Data current as of

Participant's Age

1. Pregnancy Screen:Is the participant a woman between the ages of 55 and 60 (inclusive)?
Ask,have you been through menopause or change of life. If "No", administer pregnancy test.

2. Cognitive screen: Is the participant age 65 or older?

Visit Dates

3. Date of last MOST contact:

4. Was the last contact a Clinic Visit or Phone Interview?

5. Target date for 60-month Clinic Visit:

Knee Replacements

6. Was right knee previously reported as replaced?

7. Was left knee previously reported as replaced?

Hip Replacements

8. Was right hip previously reported as replaced?

9. Was left hip previously reported as replaced?

Bisphosphonate Use

10. Did participant report use of bisphosphonate at the last clinic visit?

11. At the last visit, how many years did the participant report using bisphosphonates?

Participant Name: _____

MOST Participant ID#:

Acrostic:

BL-30-month Medication List

12. BL - 30-month prescription medication list:

Visit	Medication Name	Formulation Code	Frequency	Duration

Participant Name: _____

MOST Participant ID#:
Acrostic:

Baseline Height and Weight
13. Baseline height (height in millimeters and inches):
14. Was participant standing sideways due to kyphosis?
15. Baseline weight (weight in kg and lb):

Isokinetic Strength and sEMG
16. Knee(s) eligible for isokinetic strength exam:
17. Knee(s) eligible for sEMG exam:

Baseline Cybex Chair Settings
18. Baseline Cybex chair settings:

a. Chair Back Angle:
b. Chair Seat Fore/Aft Position:
c. Chair Back Translation:
d. Dynamometer Tilt:
e. Dynamometer Height:
f. Knee/Hip Adaptor:
g. Inner Tube:
h. Outer Tube:

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:
d. Full limb view:

1.0 T Knee MRI
20. Knee(s) eligible for 60-month MRI:
21. Date of last 1.0 T MRI, and which knees were scanned:
22. Was participant eligible for an MRI at the time of the 60-month Follow up Telephone Interview?
23. Was participant asked to bring medical documentation that shows it is safe to have an MRI scan?
24. Was 3-point Dixon of right knee obtained at baseline?
(3-point Dixon is currently not scheduled for repeat at 60-month)
25. Was 3-point Dixon of left knee obtained at baseline?
(3-point Dixon is currently not scheduled for repeat at 60-month)

Biospecimen Collection
26. Is participant eligible for biospecimen collection?

DNA GWAS Consent
27. Does participant have a DNA sample archived?
(If YES, obtain the DNA GWAS consent)

KPAD Study
28. Is the study participant enrolled in the KPAD study?

Appendix 6 MOST 60-Month Follow-up Clinic Flow

Clinic Flow

Visit	MOST ID #	Acrostic	Date of Clinic Visit
● 60-month ○ 84-month	M		Month / Day / 20 Year

☐ Urine collected ☐ Meds brought ☐ SAQ Home completed ☐ SAQ Clinic completed
☐ Pregnancy test required

Excluded	Measurement	Start Time	Stop Time	Comments
	Consent/SAQ Home reviewed	: ○ am ○ pm		
☐	Blood Pressure (before blood draw or 30 min after)			
☐	Blood draw (ASAP)			
	Anatomic landmarking			
	Initial knee pain assessment	: ○ am ○ pm		
	Clinic interview completed			
☐	Cognitive Screen (65 or older)			
	Standing Height / Weight			
	20-meter Walk	: ○ am ○ pm		
	Chair Stands	: ○ am ○ pm		
☐	Isokinetic Strength / sEMG	: ○ am ○ pm		
☐	Rapid Step Ups	: ○ am ○ pm		
☐	Maximal Step Length	: ○ am ○ pm		
☐	Gaitrite	: ○ am ○ pm		
☐	Plantar Pressure	: ○ am ○ pm		
☐	Peripheral Neuropathy			
☐LMTP ☐LTT ☐LRS ☐RMTP ☐RTT ☐RRS	Vibration Perception Threshold	: ○ am ○ pm		
☐RRU ☐RP ☐RTT ☐LRU ☐LP ☐LTT	Pain Sensitivity			
☐ R knee ☐ L knee	Knee X-ray	: ○ am ○ pm	: ○ am ○ pm	
☐ R knee ☐ L knee	OrthOne 1.0 T Knee MRI	: ○ am ○ pm	: ○ am ○ pm	
☐	Accelerometry			
	Laboratory processing			
	Exit interview		: ○ am ○ pm	

Date forms scanned: _____ / _____ / _____ Notes: _____

Abbreviations :R=right; L=left; MTP=metatarsophalangeal joint; P=patella; RS=radial styloid; RU=radial ulnar joint; TT=tibial tuberosity

MOST Follow-up
Clinic Visit Flow Sheet

Appendix 7 MOST 60-Month Follow-up Procedure Checklist

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FOLLOW-UP CLINIC VISIT WORKBOOK
PROCEDURE CHECKLIST

Visit	MOST ID #	Acrostic	Date Form Completed	Staff ID#
○ 60-month ○ 84-month			Month / Day / 20 Year	

Measurement	Page #	Completed	Partially completed	Participant refused	Not done/ Not applicable
1. Was Self-administered Home Questionnaire completed/checked?		○	○	○	○
2. Was Self-administered Clinic Questionnaire completed/checked?		○	○	○	○
3. Was Clinic Interview administered?		○	○	○	○
4. Medication Inventory	29	○	○	○	○
5. Cognitive Screen	30	○	○	○	○
6. Blood Pressure	32	○	○	○	○
7. Standing Height	33	○	○	○	○
8. Weight	33	○	○	○	○
9. 20-meter Walk	34	○	○	○	○
10. Chair Stands	36	○	○	○	○
11. Isokinetic Strength / sEMG	39	○	○	○	○
12. Rapid Step Ups	45	○	○	○	○
13. Maximal Step Length	47	○	○	○	○
14. Gaitrite	49	○	○	○	○
15. Plantar Pressure	52	○	○	○	○
16. VPT & Pain Sensitivity Exclusions	55	○	○	○	○
17. Peripheral Neuropathy	57	○	○	○	○
18. Vibration Perception Threshold	58	○	○	○	○
19. Pain Sensitivity	60	○	○	○	○
20. Knee X-ray	66	○	○	○	○
21. OrthOne 1.0 T Knee MRI	67	○	○	○	○
22. Initial Pain & Urine collection	72	○	○	○	○
23. Phlebotomy	73	○	○	○	○
24. Laboratory processing	74	○	○	○	○
25. Accelerometry	75	○	○	○	○

◆Page 1◆

MOST Follow-up Clinic Visit Workbook

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Appendix 8 MOST Consent Procedure Checklist

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CONSENT PROCEDURE CHECKLIST

University of Alabama at Birmingham

MOST ID #	Acrostic	Date Form Completed	Staff ID#
M B		Month / Day / 2 0 Year	B

MOST

● Yes ○ No **I. MOST BASELINE VISIT: Did participant sign a consent form at the baseline visit?**
If yes, complete questions 1 - 4. If no, skip to section II.

Storage of Specimens

○ Yes ○ No **1.** 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 **2.** 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, oteoporosis, 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 **3.** 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.

Right to be informed of genetic condition

○ Yes ○ No **4.** You wish to know your results if a gene is found that is linked to a medically treatable genetic disease.

○ Yes ○ No **II. MOST 60-MONTH VISIT: Did participant sign a consent form at the 60-month visit?**
If yes, complete questions 5 - 7. If no, skip to section III.

Videotape of legs

○ Yes ○ No **5.** You agree to have your legs videotaped (which may include your face) during your walking speed measurement.

Storage of Specimens and Study Information

○ Yes ○ No **6.** You agree to allow the study to use all information and samples collected on you (including results of questionnaires, clinic examinations and blood tests).

○ Yes ○ No **7.** You agree to allow your blood samples to be stored by MOST investigators 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 **III. MOST GENETICS SUBSTUDY (GWAS): Did participant sign a GWAS consent form?**
If yes, complete questions 8 - 13. If no, stop here.

Storage of Specimens

○ Yes ○ No **8.** 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 **9.** Research projects studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA.

○ Yes ○ No **10.** Research projects studying other diseases (for example, cancer or heart disease).

Sharing of Samples

○ Yes ○ No **11.** Researchers studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA.

○ Yes ○ No **12.** Researchers studying other diseases (for example, cancer or heart disease).

Sharing of Information

○ Yes ○ No **13.** Include my information in the GWAS database.

→ If yes, information can be released to:

○ Yes ○ No **13a.** Researchers studying medical conditions including OA, osteoporosis, other musculoskeletal related conditions, and risk factors for OA and how people respond to treatment.

○ Yes ○ No **13b.** Researchers studying any disease.

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CONSENT PROCEDURE CHECKLIST

University of Iowa

MOST ID #	Acrostic	Date Form Completed	Staff ID#
M I		Month / Day / 2 0 Year	I

MOST

● Yes ○ No **I. MOST BASELINE VISIT: Did participant sign a consent form at the baseline visit?**
If yes, complete question 1. If no, skip to section II.

Specimen Storage

○ Yes ○ No **1.** I give my permission to have my blood sample frozen for future testing.

○ Yes ○ No **II. MOST 60-MONTH VISIT: Did participant sign a consent form at the 60-month visit?**
If yes, complete questions 2 - 3. If no, skip to section III.

Specimen Storage and Sharing

○ Yes ○ No **2.** My blood and urine may be stored/shared for future research in osteoarthritis.

Data Storage and Sharing

○ Yes ○ No **3.** My data may be stored/shared for future research in osteoarthritis.

○ Yes ○ No **III. MOST GENETICS SUBSTUDY (GWAS): Did participant sign a GWAS consent form?**
If yes, complete questions 4 - 8. If no, stop here.

Specimen Storage and Sharing

○ Yes ○ No **4.** My blood cells and DNA may be stored/shared for future gene research in osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis.

○ Yes ○ No **5.** My blood cells and DNA may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc.).

Data Storage and Sharing

○ Yes ○ No **6.** My information may be included in a national GWAS database.

○ Yes ○ No **7.** My information in the GWAS database may be shared with researchers studying medical conditions including osteoarthritis, osteoporosis, other musculoskeletal related conditions, and risk factors for osteoarthritis and how people respond to treatment.

○ Yes ○ No **8.** My information in the GWAS database may be shared with researchers studying any disease.

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Appendix 9 MOST 60-Month Follow-up Participant Results

60-Month Follow-up Results Report

We would like to thank you for your participation in the MOST study. These tests were done for research purposes only and were not intended to diagnose any health problems. We will not be providing the results of many of the tests that were done, such as for the knee MRI, gait assessment, muscle strength, and walking speed tests, since we do not know yet what results are considered "normal" for these tests.
For the results that we do provide, we encourage you to share them with your doctor.
If you have any questions, please call the MOST clinic at:
( ) _____.

Participant Name: _____

Blood pressure: ____ ____ ____ / ____ ____ ____ **mm Hg**

Normal:	Less than 120 / 80 mm Hg
Prehypertention:	120-139 / 80-89 mm Hg
Hypertension:	140 / 90 mm Hg or higher

Based on your blood pressure taken today, the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure recommends that you:

- ☐ Have your blood pressure rechecked within 1 year
- ☐ Have your blood pressure rechecked within 2 months
- ☐ See your doctor about your blood pressure within 1 month
- ☐ See your doctor about your blood pressure in 1 week
- ☐ See your doctor about your blood pressure immediately

If you have any specific questions about your blood pressure, please talk with your doctor.

Version 1.0, 2/24/09

Height: ____ feet ____ inches

Weight: ____ ____ ____ pounds

Body Mass Index: Body mass index (BMI) is a measure of body fat based on height and weight that applies to both adult men and women. The left column lists height. The numbers at the top are weight. Where the two come together is BMI.

BMI less than 25 is normal; 25.0 to 29.9 is overweight; 30 or greater is obese.

BMI may **overestimate** body fat in athletes and others who have a muscular build. It may **underestimate** body fat in older persons and others who have lost muscle mass.

Height (ft,in)	Weight (lbs)																				
	120	130	140	150	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320
4'10"	25	27	29	31	34	36	38	40	42	44	46	48	50	52	54	57	59	61	63	65	67
4'11"	24	26	28	30	32	34	36	38	40	43	45	47	49	51	53	55	57	59	61	63	65
5'0"	23	25	27	29	31	33	35	37	39	41	43	45	47	49	51	53	55	57	59	61	63
5'1"	23	25	27	28	30	32	34	36	38	40	42	44	45	47	49	51	53	55	57	59	61
5'2"	22	24	26	27	29	31	33	35	37	38	40	42	44	46	48	49	51	53	55	57	59
5'3"	21	23	25	27	28	30	32	34	36	37	39	41	43	44	46	48	50	51	53	55	57
5'4"	21	22	24	26	28	29	31	33	34	36	38	40	41	43	45	46	48	50	52	53	55
5'5"	20	22	23	25	27	28	30	32	33	35	37	38	40	42	43	45	47	48	50	52	53
5'6"	19	21	23	24	26	27	29	31	32	34	36	37	39	40	42	44	45	47	49	50	52
5'7"	19	20	22	24	25	27	28	30	31	33	35	36	38	39	41	42	44	46	47	49	50
5'8"	18	20	21	23	24	26	27	29	30	32	34	35	37	38	40	41	43	44	46	47	49
5'9"	18	19	21	22	24	25	27	28	30	31	33	34	36	37	38	40	41	43	44	46	47
5'10"	17	19	20	22	23	24	26	27	29	30	32	33	35	36	37	39	40	42	43	45	46
5'11"	17	18	20	21	22	24	25	27	28	29	31	32	34	35	36	38	39	41	42	43	45
6'0"	16	18	19	20	22	23	24	26	27	29	30	31	33	34	35	37	38	39	41	42	43
6'1"	16	17	19	20	21	22	24	25	26	28	29	30	32	33	34	36	37	38	40	41	42
6'2"	15	17	18	19	21	22	23	24	26	27	28	30	31	32	33	35	36	37	39	40	41

Peripheral Neuropathy (sensitivity in your big toe area)

☐ Normal
☐ Reduced sensitivity: Please share these results with your physician.
☐ Sensation is absent: Please share these results with your physician.

Version 1.0, 2/24/09

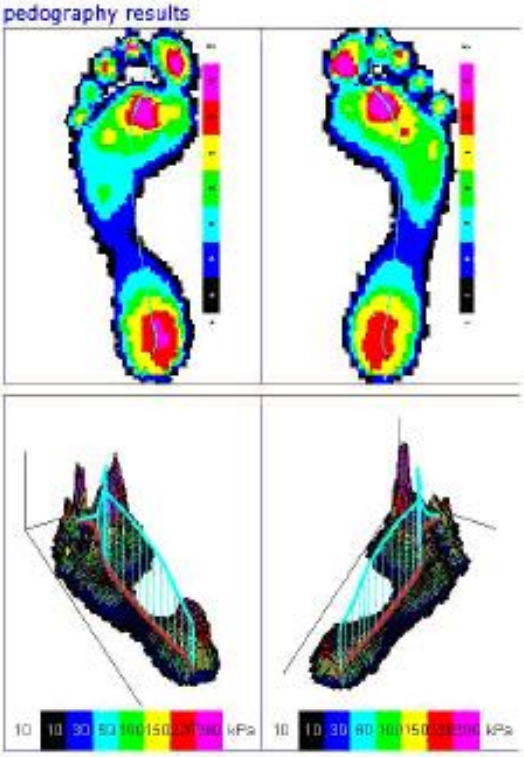
art and science
quality in pressure distribution measurement
novel

MOST

Patient ID:

Patient ID: mb01234

pedography results



Anamnesis

Diagnosis

Conclusion/ Therapy/ Comments

The colorful footprints that you see in this report depict the pressure under your feet when you walk. The areas that appear in red or violet are areas of higher pressure, while the areas that appear in black or blue are areas of lower pressure. Areas that appear in yellow or green are areas of your foot that experience moderate pressure when you walk.

You should not be at all alarmed if you see a few areas of red or violet where high pressure is being exerted on your foot. It is entirely normal for some areas of the foot to experience higher pressures and other areas of the foot to experience lower pressures. In most people, the foot is very well-adapted to absorb the pressures to which it is exposed. On the other hand, if you are diabetic, your foot may have lost some of its ability to respond ideally to the high pressure that may be exerted on it.

If you are diabetic, and you notice some areas of your footprint that appear brightly colored in red or violet, you should bring this printed report with you to your next doctor's visit. Your doctor may be able use the information to make recommendations about how best to care for your feet and minimize your risk of pressure-related foot problems.

Generated on: 12/5/2008	Generated by:	Date of visit: 12/2/2008	Patient ID: mb01234	

- 1 -

Appendix 10 From National Institute on Aging - Arthritis Advice

Arthritis Advice
From the National Institute on Aging

Arthritis is one of the most common diseases in this country. It affects millions of adults and half of all people age 65 and older.

Arthritis causes pain and loss of movement. It can affect joints in any part of the body. It often is a chronic disease, which means that it can affect you over a long period of time. The more serious forms can cause swelling, warmth, redness, and pain.

There are more than 100 different kinds of arthritis and many different symptoms and treatments. Scientists do not know what causes most forms of arthritis. They understand some better than others.

Osteoarthritis (**OA**) mostly affects cartilage—the tissue that cushions the ends of bones within the joint. OA often affects the hands and the large weight-bearing joints of the body, such as knees and hips.

OA occurs when cartilage begins to fray, wear, and decay. In some cases, all of the cartilage may wear away between the bones of the joint, leaving bones that rub against each other. Symptoms can range from stiffness and mild pain that comes and goes, to severe joint pain. OA can cause:

- Joint pain
- Less joint motion
- And sometimes, disability

Scientists think there may be several causes for OA in different joints. OA in the hands or hips may run in families. OA in the knees is linked with being overweight. Injuries or overuse may cause OA in joints such as knees, hips, or hands.

Treatment. Rest, exercise, a healthy, well-balanced diet, and learning the right way to use your joints are key parts of any arthritis treatment program. Treatment is different for each kind of arthritis.

Right now there are no treatments that cure OA, except surgery to replace joints. But improving the way you use your joints through rest and exercise and keeping your weight down will help you control the pain.

There are some drugs that help people manage OA pain. They are called NSAIDs (nonsteroidal anti-inflammatory drugs such as ibuprofen and naproxen). These drugs reduce swelling without use of stronger drugs like cortisone or other steroids.

3/2/05

Warning Signs

The warning signs of arthritis are:

- Swelling in one or more joints
- Stiffness around the joints that lasts for at least 1 hour in the early morning
- Constant or recurring pain or tenderness in a joint
- Difficulty using or moving a joint normally
- Warmth and redness in a joint

If any one of these symptoms lasts longer than 2 weeks, see your regular doctor or a doctor who specializes in arthritis (a rheumatologist). The doctor will ask questions about the history of your symptoms and do a physical exam. The doctor may take x-rays or do lab tests before developing a treatment plan.

What Else Can You Do?

Along with taking the right medicines, exercise is key to managing arthritis symptoms. Daily exercise, such as walking or swimming, helps keep joints moving, reduces pain, and strengthens muscles around the joints. Rest also is important for joints affected by arthritis.

Three types of exercise are best for people with arthritis:

- **Range-of-motion** exercises (for example, dancing) help keep normal joint movement and relieve stiffness. This type of exercise also helps you stay flexible.
- **Strengthening** exercises (for example, weight training) help keep or increase muscle strength. Strong muscles can help support and protect joints affected by arthritis.
- **Aerobic or endurance** exercises (for example, bicycle riding) improve cardiovascular fitness, help control weight, and improve overall function. Some studies show that aerobic exercise also may reduce swelling in some joints.

Along with exercise, some people find other ways to help ease the pain around joints. These include applying heat or cold, soaking in a warm bath, swimming in a heated pool, and controlling or losing weight. Weight control is key for people who have arthritis because extra weight puts extra pressure on many joints. Weight loss can lower stress on joints and help prevent more damage.

Your doctor may suggest surgery when damage to the joints becomes disabling or when other treatments fail to reduce pain. Surgeons can repair or replace damaged joints with artificial ones. In the most common operations, doctors replace hips and knees.

3/2/05

Unproven Remedies

Many people with arthritis try remedies that have not been tested. Some of these remedies, such as snake venom, are harmful. Others, such as copper bracelets, are harmless but also useless. The safety of many unproven remedies is unknown.

Some people try taking dietary supplements, such as Glucosamine and Chondroitin, to ease arthritis pain. Scientists are studying these and other alternative treatments to find out if they work and are safe. More information is needed before any recommendations can be made.

Here are some signs that a remedy may be unproven:

- The remedy claims that a treatment, like a lotion or cream works, for all types of arthritis and other diseases;
- Scientific support comes from only one research study; or
- The label has no directions for use or warnings about side effects.

National Institute on Aging
U. S. Department of Health and Human Services
National Institutes of Health
January 2002

3/2/05

Appendix 11 MOST 60-Month Test-Retest Reliability Protocol

60-Month Test-Retest Examinations

Purpose

Test-Retest 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 (e.g., several months). Limitations of short-term (e.g., same day) test-retest reliability include test order, practice, and learning effects in which the process of testing or the results of the initial test influence the results of the retest. Retesting after a longer interval (e.g., several weeks) will minimize these effects.

Same Day Test-Retest Examinations –(estimated participant time: 34 minutes*) will be done for MOST 60 month visit exams in which short-term test-retest reliability in a setting such as MOST has not been previously evaluated and for which practice and learning effects are likely to be small. There should be a minimum of 60 minutes between the Test-Retest Examinations whenever possible. The participant does not have to complete the entire clinic visit before Test-Retest of any given examination.

- sEMG during Isokinetic Strength (13.6 minutes) The sEMG adhesive pads must be removed and reapplied prior to the Retest Exam.
- GAITrite (8.3 minutes)
- Plantar Pressure (12 minutes)

**time estimates are based on the U-Iowa MOST 60-Month Visit Clinic Flow data collection forms*

14 Day (± 7 days) Test-Retest Questions and Examinations – (estimated participant time: 60 minutes*) will be done for selected questions and exams in order to determine the stability of the measurements and/or in which questions and exams significant practice or learning effects are likely to be present (e.g., pain sensitivity). An interval of 2 weeks will be sufficient time to minimize practice and learning effects and to capture variability related to highly labile characteristics of OA such as joint pain, but insufficient time for major changes in underlying physical characteristics. The same examiner that completed the Test Examination should give the Retest Examination whenever possible, particularly for the Balance, Peripheral Neuropathy, Vibration Perception Threshold, and Pain Sensitivity/Sensation Examinations.

** time estimates are based on the U-Iowa MOST 60-Month Visit Clinic Flow data collection forms*

Pain Questions –(6 minutes)

For the 14 day Test-Retest we will also repeat selected joint pain questions just prior to and during the Retest Exams to document differences in joint pain between the two time points that may affect variability in the measurements.

- Initial joint/knee pain (interviewer administered prior to any retest exams are done with the participant comfortably seated) *CVW, Page 72, Question #1*
- Frequent knee symptom questions, past 30 days (interviewer administered) *CVW, Page 2, Questions #2/2a and Page 6, Questions #13/13a*

- WOMAC Knee Pain, past 30 days (self-administered) *SAQ Clinic, Page 1, Questions #1a-f and Page 3, Questions #5a-f*
- Homunculus (self-administered) *SAQ Home, Pages 10-11, Questions #21 and Page 12, Questions #22*

Examinations –(53.6 minutes)

- Balance (Rapid Step Ups & Maximal Step Length) (5 minutes)
- GAITrite (8.3 minutes)
- Plantar Pressure (12 minutes)
- Peripheral Neuropathy (2 minutes)
- Vibration Perception Threshold (7.6 minutes)
- Pain Sensitivity/Sensation: 2 gram and 26 gram touch: temporal summation, pinprick, and pressure pain threshold (18.7 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 must have Test-Retest for each exam in the protocol. Test-Retest Study selection will be a convenience sample with targeted recruitment for 50% women / men and 50% age 50-64 / 65-79 years old at time of study enrollment.

It would be best if all or the majority of the test-retest protocol was done with MOST participants.

Reimbursement

Participants that complete the Same Day Test-Retest Examinations will receive a $25 gift card and participants that complete the 14 Day Test-Retest Questions and Examinations retest questions and examinations will receive a $50 gift card to reimburse for travel and time.

Timeline

- Start after IRB approval is obtained (December 2009).
- Test-Retest Reliability Study to be completed in 3 months time.
- 14 Day (± 7 days) Test-Retest exams and pain questions to be completed 14 days (± 7 days) after the 60-month clinic visit.

Retest Time Estimate (total time approximately 1.5 hours)

- Same Day Test-Retest = 34 minutes per participant
- 14 Day (± 7 days) Test-Retest = 60 minutes per participant

IRB Approval

The Test-Retest Study protocol and informed consent will be submitted to the local IRB for review/approval prior to starting.