

OVERVIEW OF YEAR 1 (BASELINE) CLINIC VISIT

TABLE OF CONTENTS

Order of Exams	2
Priority of exams	3
MOST Year 1 Pre-Visit Instructions.....	4
MOST Year 1 Participant Results.....	6
MOST Knee X-ray Participant Results Report	10
Equipment Calibration – Summary	15

Eligible participants for the MOST study will be receiving a self-administered questionnaire to fill out at home and bring into the clinic on the day of their clinic visit. They will also be completing a self-administered questionnaire in the clinic.

Participants will be interviewed during their clinic visit and a number of tests will be administered. On the next page is a table with a list of all of the MOST measurements for Year 1 (baseline) and the order in which these should be done.

Also included in this chapter is a guide for prioritizing exams for the rare instance when a participant requests a short visit.

The last three sections of this chapter include a participant results report for the participant to take home with them on the day of their clinic visit, a knee x-ray results report that will be mailed to the participant once the x-rays are read, and a summary of equipment calibration procedures that should be done at each clinical site.

Order of Exams

(measurements are listed in the order in which they appear in the Clinic Visit Workbook):

MEASUREMENT	Order of Exams: Required / Suggested / Anytime
Self-administered Home Questionnaire completed and checked	Anytime
Self-administered Clinic Questionnaire completed and checked	Anytime
Clinic Interview Workbook administered	Required -needs to be completed before the knee, and hip examinations.
Consent and change clothes	Required -consent signed before anything else happens
Blood Pressure	Required -performed before blood draw and isokinetic measurements
Standing Height	Required -done before DXA
Weight	Required -done before DXA and Isokinetic strength
Specimen Collection	Suggested -done early during the visit (fasting blood draw)
Laboratory Processing	Required -done immediately after blood draw
20-meter Walk	Suggested -done just before Isokinetic strength for a warm-up
Chair Stands	Suggested -done just before Isokinetic strength for a warm-up
Isokinetic Strength (Cybex)	Required -done at least 1 hour before or anytime after the MRI, and done after weight
Leg Length	Anytime
Knee Height	Anytime
Laxity	Suggested -done just before proprioception
Proprioception	Suggested -done just after laxity
Knee and Hip Examinations	Required -done after Clinic Interview
Hand Examination	Anytime
Bone Density (DXA)	Required -done after weight and height
Knee X-ray	Anytime
Knee MRI	Required -done after weight; done at least one hour after or anytime before the isokinetic strength measurement.
Confirmatory knee and hip examinations	Required -done after knee and hip examination, if eligible.

Priority of exams

Below is a table that lists those measurements that are high priority in the MOST Year 1 clinic visit. Also listed are measurements that are low and medium priority. In the rare instance that a participant chooses to have a shortened visit, use this list to prioritize which exams to administer; i.e., be sure to complete high priority items. The measurements are in the order in which they appear in the Clinic Visit Workbook.

MEASUREMENT	Priority of Exams High / Medium / Low
Self-administered Home Questionnaire completed and checked	High
Self-administered Clinic Questionnaire completed and checked	Medium
Clinic Interview Workbook administered	High
Consent and change clothes	High
Blood Pressure	High
Standing Height	High
Weight	High
Specimen Collection	Medium
Laboratory Processing	Medium
20-meter Walk	Medium
Chair Stands	Medium
Isokinetic Strength (Cybex)	Medium
Leg Length	Medium
Knee Height	Medium
Laxity	Low
Proprioception	Low
Knee and Hip Examinations	High
Hand Examination	High
Bone Density (DXA)	Medium
Knee X-ray	High
Knee MRI	High
Confirmatory knee and hip examinations	Medium

MOST Year 1 Pre-Visit Instructions

Dear _____:

Your appointment for your MOST Year 1 Clinic Visit has been scheduled for: _____, _____ at _____ a.m. at XXXXXXXXXX, XXXXXXXXX (a map is enclosed). Parking is available XXXXXXXXXXXXXXXXXXXXXXXXXX.

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 24-page questionnaire. Please bring the completed questionnaire with you to the clinic.
- Please do not eat or drink anything but water after midnight the night before your visit. If your visit is scheduled for 1:00 pm or later, please do not eat or drink anything but water, prescription medications, and vitamins after 8:00 am the morning of your clinic 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). If you have an afternoon appointment, we will send a urine collection cup and instructions to you in the mail.
- The visit may take about 5 hours. Feel free to bring a morning snack with you.
- Wear comfortable shoes for walking. It would be helpful if you wear a short-sleeved shirt or blouse, since this will make taking your blood pressure easier. Do not wear pantyhose or girdles. You will be asked to change clothes for some tests. If you have a pair of shorts (no tight biker shorts), please bring them with you, so we can easily examine your knee.
- Do not wear jewelry to the clinic since this may make it more difficult to do your bone scan (wedding rings are OK).
- 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 AND non-prescription medications that you have taken in the last 30 days only. Include eye drops, shots, supplements, vitamins, 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 Year 1 Participant Results

Participant Name: _____
(Please print)

Date of Year 1 Clinic Visit: ____ / ____ / ____
Month Day Year

Height: ____ feet ____ inches

Weight: ____ ____ pounds

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.

		Weight (lbs)																				
		120	130	140	150	160	170	180	190	200	210	220	230	240	250	260	270	280	290	300	310	320
Height (ft,in)	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	

BMI Categories:

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

Note that the score is valid for both men and women, but it does have some limits.

It 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.

Bone Mineral Density

Thank you for participating in the MOST study. Attached are the results from your bone density test from your Year 1 clinic visit. The World Health Organization (WHO) has developed guidelines to help doctors interpret these results and identify individuals who may be at greater risk for breaking a bone (fracture). The purpose of this letter is to help you and your doctor understand your bone density measurement.

What is a bone density measurement?

A bone density test measures how much calcium is contained in certain bones, such as the hip. In general, lower bone density and lower calcium means that the bone is weaker.

What do bone density measurements mean?

We all lose bone as we get older, but some people lose bone faster than others. Certain factors can reduce bone density, such as smoking, low calcium intake, lack of exercise, high alcohol intake, use of some medications, and some medical conditions.

Individuals with low bone density have weaker bones, and weaker bones are more likely to fracture during an accident (even a minor accident such as a fall). However, not all women and men with low bone density will have fractures and, occasionally, even those with high bone density will suffer a fracture.

What are my bone density results?

Your hip bone density value was compared to that of young women and men and is at the level checked below:

_____ Normal
_____ Low
_____ Osteoporosis

If your bone density is checked as "low" or "osteoporosis," we suggest that you discuss these results with your personal doctor. We would be happy to forward these results to your doctor.

If you have questions regarding these results, please contact _____
_____ at _____ .

Blood Pressure: _____ / _____ mm Hg

Normal:	Less than 120	and	less than 80 mm Hg
Prehypertension:	120-139	or	80-89 mm Hg
Hypertension:	140 and above	or	90 and above mm Hg

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

- Recheck blood pressure within 1 year Comments: _____
- Recheck blood pressure within 2 months _____
- See your doctor in 1 month _____
- See your doctor in 1 week _____
- See your doctor immediately _____

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

Hand exam

Examining the hands can help us know whether or not you have osteoarthritis. Your results are listed below:

- _____ You have no bony enlargements in any joints of your hands
 - _____ You have _____ bony enlargement(s) in the joints of your right hand
 - _____ You have _____ bony enlargement(s) in the joints of your left hand
-

Laxity

In this test, we measure varus-valgus laxity, or side-to-side motion at the knee. Laxity comes from some looseness of the support structures (like the ligaments) at the sides of the knees. Laxity may play a role in the development and progression of knee osteoarthritis by causing abnormal stresses on the knee joint. This test is being done for research purposes and we do not yet know what results are normal.

Leg length and knee height

Differences in leg length between your right and your left leg may cause problems in the way that you walk, and may be related to your chances of getting osteoarthritis. Knee height gives us a good idea of your real height because knee height does not change over time the way total height does. Both of these measurements are being done for research purposes.

Proprioception

Proprioception means position sense or knowing where your limbs (legs) are in space without looking at them. In this test, we are measuring the angle at which your knee is bent and your ability to reproduce that angle. Impaired or altered position sense (proprioception) may play a role in the development and progression of knee osteoarthritis by causing abnormal stresses on the knee joint. This test is being done for research purposes and we do not yet know what results are normal.

Laboratory (blood and urine) tests

We will be using some specimens from these tests to see how much Vitamin C, Vitamin D, Vitamin E, and parathyroid hormone you have in your body. Other specimens will be saved for future analysis that may be useful for research purposes.

Muscle strength, balance, and walking speed tests

We do not know yet what results are considered "normal" for these tests. You are helping us understand how to prevent disability as we get older.

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. However, we encourage you to share these results with your doctor. If you have any questions, please call the MOST clinic at: () _____ .

MOST Knee X-ray Participant Results Report

Participant Name: _____

(Please print)

Date of knee x-ray: ____ / ____ / ____
 Month Day Year

Thank you for participating in the MOST Study!

Arthritis of the knee is very common in people your age and often causes pain and disability. **Osteoarthritis**, also called degenerative arthritis, is the most common type of arthritis in older people. As part of MOST, we are using x-rays and Magnetic Resonance Imaging (MRI) to study the causes of knee pain and **osteoarthritis** (OA) of the knee. In people with knee pain, doctors usually get an x-ray to see if it is **OA**. X-rays do not show all of the problems in the knee that can cause pain and often x-rays show changes of osteoarthritis that do not need to be treated. Whether you need treatment depends on whether you are having knee pain or other knee symptoms.

The x-rays from this study were read by a trained non-MD reader. These include a PA and lateral films, both weight bearing. ‘Possible osteoarthritis’ is present when there is a tiny or possible osteophyte, an outgrowth of bone near the joint. ‘Osteoarthritis’ is present when there was a larger, definite osteophyte with or without narrowing of the joint space.

Results from your knee x-rays:

<p>The standing x-ray of your RIGHT knee showed:</p> <p><input type="checkbox"/> No osteoarthritis <input type="checkbox"/> Possible osteoarthritis <input type="checkbox"/> Osteoarthritis</p>	<p>The standing x-ray of your LEFT knee showed:</p> <p><input type="checkbox"/> No osteoarthritis <input type="checkbox"/> Possible osteoarthritis <input type="checkbox"/> Osteoarthritis</p>
--	---

The use of knee MRI in OA is primarily a tool for research. Because the knee MRIs in MOST are being used for research, they are being looked at very carefully and in great detail. While we are grateful that you got an MRI to help with the study, unfortunately, it will not be possible to share these results with you. **It is very important to remember that these are research findings and your usual doctor visit would not include an MRI of the knee for arthritis pain.**

Thank you!

From National Institute on Aging - Arthritis Advice

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 COX-2 inhibitors and NSAIDs (nonsteroidal anti-inflammatory drugs such as ibuprofen and naproxen). These drugs reduce swelling without use of stronger drugs like cortisone or other steroids. COX-2 inhibitors are a newer type of drug. They work like NSAIDs but may cause fewer side effects.

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.

The National Institute on Aging (NIA) has a 48-minute video showing you how to start and stick with a safe exercise program. The Institute also has an 80-page companion booklet. Call 1-800-222-2225 (TTY: 1-800-222-4225) for more information. Before beginning any exercise program, talk with your doctor or health care worker.

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.

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.

For more information on arthritis contact:

National Institute of Arthritis and Musculoskeletal and Skin Diseases NIAMS Information Clearinghouse

1 AMS Circle
Bethesda, Maryland 20892-3675
301-495-4484
877-22-NIAMS (226-4267)
TTY: 301-565-2966
Fax: 301-718-6366
E-mail: niamsinfo@mail.nih.gov

<http://www.niams.nih.gov>

American College of Rheumatology/Association of Rheumatology Health Professionals

1800 Century Place
Suite 250
Atlanta, GA 30345-4300
404-633-3777
Fax: 404-633-1870
E-mail: acr@rheumatology.org

<http://www.rheumatology.org>

Arthritis Foundation

P.O. Box 7669
Atlanta, GA 30357-0669
1-800-283-7800, or check the telephone directory for your local chapter
Fax: 404-872-0457
E-mail: help@arthritis.org

<http://www.arthritis.org>

For more information about health and aging, call or write:

**National Institute on Aging
Information Center**

P.O. Box 8057

Gaithersburg, MD 20898-8057

1-800-222-2225

1-800-222-4225 (TTY)

E-mail: niainfo@jbs1.com

<http://www.nia.nih.gov>

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

Equipment Calibration – Summary

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

Blood Pressure	<p>Daily Automated Oscillometric Device Task 1: Check that device is turned off after each participant. Task 2: Check that air is squeezed from cuff</p> <p>Daily Sphygmomanometer Equipment Check log Task 1: Check Sphygmomanometer for correct zero. Task 2: Check that the meniscus is a smooth, well-defined curve.</p> <p>Monthly Automated Oscillometric Device Task 1: Check for cracks or tears in cuff or tubing. Task 2: Check that all cuff sizes are available.</p> <p>Monthly Sphygmomanometer Equipment Check Log Task 1: Check mercury column. Task 2: Check for cracks or tears in glass tube, cuffs, pressure bulb, and manometer and stethoscope tubing and diaphragm. Task 3: Check that cap at top of calibrated glass tube is securely in place. Task 4: Check for spilled mercury in case. Task 5: Check pressure control valve.</p>
Cybox 350	<p>For step by step calibration instructions, see Appendix 1 in Isokinetic Strength operations manual chapter. Each clinic will have certified weights for calibration. These should be followed once a week if daily calibrations at the beginning of the study showed that the calibration is accurate. 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).</p>
Dolorimeter	<p>Daily Dolorimeter Calibration Log Task: Examiner should recalibrate pressure daily before performing joint Exam. By pushing thumb against rubber pad until 1.4 kg of pressure is applied; and pushing fore/index fingers against rubber pad until 1.4 kg of pressure is applied.</p>
DXA	<p>Phantom</p> <p>Local Hologic Tissue Bar – 1 time/week</p> <p>Local Hologic Spine Phantom 3 to 5 times/week and always on day participants are scanned</p> <p>Local Hip Phantom – 3 times/week</p> <p>Local Whole Body Phantom – 3 times/week</p> <p>Whole Body Air Scan 1 time/week</p> <p>Hologic “Gold Standard” Hip, Spine, and Block phantoms - “Traveling Phantoms” that are mailed to the clinical center and scanned one time, usually near the beginning of the study.</p>
Electrogoniometer	<p>Daily Electrogoniometer Calibration Log Task: Calibrate electrogoniometer with hand-held goniometer. <i>Reading must be within 88 to 92 degrees</i> If not, see QC officer.</p>
Lab temperature	<p>Daily Laboratory Temperature Log Task: Check freezer, refrigerator, and processing room temperatures</p>
OrthOne temperature	<p>Daily OrthoOne Temperature Log Task: Check am and pm OrthOne room temperature</p>
Scale	<p>Monthly Scale Calibration Log Task 1: Check for "float" of beam with both counterweights in zero position. Task 2: Calibrate with 50 kg weight Task 3: Check linearity using volunteer and 5 and 10 kg weights (volunteer alone, volunteer plus 5, 10, 15, and 20 kg weight [or use lb alternatives]) <i>Reading should be within $\pm .2$ kg</i></p>

Stadiometer	Daily Stadiometer Calibration Log Task: Calibrate stadiometer with 600 mm rod. <i>Reading must be 600 mm</i>
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.