OVERVIEW OF SCREENING VISIT

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1. Overview of measurements

MOST participants who have been determined to be potentially eligible for the MOST study based on their telephone screen interview will be seen in the clinic for a Screening Visit to further determine their eligibility. Ideally, these screenees should be seen within 4 weeks (± 2 weeks window) of their telephone screen interview; ideally the maximum time between the telephone screen and Screening Visit is 6 weeks.

The components of the Screening Visit are listed below:

- Consent
- Weight screen
- Willingness to have x-rays, MRI, and CT scans
- MRI knee coil cylinder screen
- MRI eligibility provided during the Telephone Screening
- Menopause history/pregnancy screen
- Knee symptom questions
- Screening knee x-ray

There are 4 REDCap forms that cover the above items:

- Weight
- Imaging-related items, review of MRI eligibility, pregnancy screen
- Interview items (knee symptoms)
- Knee x-ray tracking

Clinics will determine the sequence in which they administer the 4 REDCap forms at the Screening Visit.

1.1 Scripts in protocols and worksheets

Interview component: You are required to use exact script for the interview component of the Screening Visit workbook. Refer to Interviewing Guidelines Operations Manual (Chapter 2E) for instructions on conducting an interview.

Exam components: It is very important that examiners read the entire MOST operations manual. Scripts are included in the operations manual in order to standardize the administration of the many exams given to participants in the study. These scripts clearly identify key points that are important to convey to the participant. Examiners are encouraged to learn the standardized script that appears in the protocols and/or worksheets, but they are free to modify the script in order for the presentation to sound natural, as long as the same information is conveyed to the participants and is presented in the same order as the standardized script. There are exceptions to this rule, however. If a protocol indicates that you should use an exact script do not deviate from the required wording.

2. Working with study participants

Participants in our research studies are NOT patients; they are very valued volunteers who deserve to interact with study staff who are always at their best. The participants are people who are willing, for very little in return, to contribute their time, energy, and honesty about their situations in the hope of making a difference. We need to do everything we can to make their time with us an enjoyable experience.

Research participants are free to refuse to have any test completed and/or to answer any questions that we ask. Because people who volunteer for studies tend to be generous people, refusals rarely happen. When they do occur, it is often because they do not understand what is being asked of them or why it is being requested. Take the time to explain. However, if they still refuse, respect this decision as their absolute right and move to another activity or question.

3. Preparation for the Screening Visit

3.1 Participant preparation

Each participant who comes to the MOST clinic visit will have been told about the contents of the Screening Visit during the phone conversation to schedule the Screening Visit. If there is sufficient time, reminder letters (see Appendix 1) should be mailed approximately 7 to 10 days prior to the visit to emphasize the following:

- Date, time, and place of the Screening Visit.
- Brief description of what to expect during their Screening Visit.
- Wear comfortable clothing; no pantyhose or girdles.
- Bring reading glasses and any other glasses that are used for longer distances.
- Bring or wear hearing aids (if participant wears hearing aids).

Ideally, reminder phone calls should be made the day before the Screening Visit.

3.2 Screening Visit preparation

At the time of the Screening Visit, the following should be available for each participant:

- Consent form.
- A Data from Prior Visits Report should be generated with information that will be needed for the Screening Visit (see Appendix 2).

- A paper print out of the completed Telephone Screen Interview. This can be printed from the Data Inventory section of the MOST Study Website.

- The participant's chart that contain the participant's MOST ID number and Acrostic. 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.

4. Clinic flow and measurements

4.1 Overview of clinic flow

Every effort should be made to keep the visit as short as possible. Also, if the Consent Form is sent out ahead of time, many participants will be ready to sign it right away when they arrive at the field center, instead of taking the time to read it during their Screening Visit.

The 4 REDCap forms listed below cover the above items listed in Section 1 (Overview of measurements):

- Weight
- Imaging-related items, review of MRI eligibility, menopause history/pregnancy screen
- Knee symptoms interview items
- X-ray tracking

Clinics will determine the sequence in which they administer the 4 REDCap forms at the Screening Visit.

4.1.1 Weight

Weight is measured in kilograms using a standard balance beam scale. Population-based studies have consistently shown a link between overweight or obesity and knee osteoarthritis.

If a female participant weighs more than 300 pounds (lbs), she will not be eligible for the study. If a male participant weighs more than 340 pounds (lbs), he will not be eligible for the study.

Although participants will be given a written Participant Results Report at their 144-month follow-up visit that includes weight, please report the participant's weight when you take the measurement.

See Weight Operations Manual (Chapter 3S) for detailed procedures.

4.1.2 Willingness to have x-rays, MRI, and CT scans

The participant will be asked if they are willing to have x-rays, MRI and CT scans. If they answer no, don't know or refused to this question, they will not be eligible for the MOST study.

4.1.3 MRI knee coil cylinder screen

Because joint imaging biomarkers are crucial for MOST, participants must be able to have knee MRI scans to be in the study. It is possible that some participants' knees will be too large or wide to fit into the MRI scanner knee imaging coil. In order to determine whether or not the participant's knee circumference is larger than the circumference of the MRI knee imaging coil, we will use a knee imaging coil cylinder prototype that has the same circumference as the actual knee imaging coil. This coil will be placed on the participant's knees, one at a time and the coil will be completely closed around the knee. If the knee doesn't fit comfortably in the coil, the participant will not be able to have an MRI of that knee. If neither knee fits in the coil, the participant will not be eligible to be part of the MOST study.

4.1.4 MRI eligibility provided during the Telephone Screen

Participants will have been asked detailed questions to determine if they are eligible to have an MRI. The MRI technician or their back up should thoroughly review the MRI eligibility information the participant provided during the Telephone Screen and confirm nothing has changed with the participant's MRI eligibility status. The interviewer should refer to the Data from Prior Visits Report to determine if the participant was asked to bring medical records in order to determine if it would be safe for the participant to have an MRI scan. If the participant was asked to bring medical documentation, review the medical documentation to determine if the documentation does or does not confirm that it would be safe for the participant to have an MRI scan. If the medical documentation does not confirm it is safe for the participant to have an MRI scan, then the participant is not eligible for the MOST study.

4.1.5 Menopause history/pregnancy screen

Because joint imaging biomarkers are crucial for MOST, participants must be able to have x-rays, MRI and CT scans to be in the study. If a woman is pregnant, she is excluded from having x-rays, MRIs, or CTs and from the study. Therefore, if a woman is capable of becoming pregnant, as defined by having had a period in the past 12 months, she will be required to have a pregnancy test during the Screening Visit to see if she is pregnant before she has a knee x-ray. All woman will be asked about whether they have ever been pregnant, if they have had an ovary removed and if so, how many ovaries were removed and what age they were when they had their ovaries removed. They will also be asked about whether or not they ever had a hysterectomy. A woman who has had a hysterectomy will not be required to have a pregnancy test. All other women will be asked if they are pregnant or trying to get pregnant. If they answer "Yes," or refuse to answer the question they are not eligible for MOST. Women will also be asked when their last natural menstrual period was. If it was within the past 12 months or the participant does not know and is between 45 and 55 years old, administer a pregnancy test, and answer the question: "Did participant have a positive pregnancy test?" If "Yes" or they refuse the test, the participant is not eligible for MOST. Note that the question "Did participant have a positive

pregnancy test?" should be answered for all women, and includes a "Pregnancy test not required" response option. If a participant mentioned having had a tubal ligation, a pregnancy test is not required.

4.1.6 Knee symptom questions

The interview portion of the Screening Visit will consist of asking the participant about knee symptoms during the past 12 months on their right knee, and then knee symptoms during the past 12 months on their left knee.

4.1.7 Screening knee x-ray

All participants are required to have bilateral fixed flexion knee x-rays in order to determine if they are eligible to be in the study. X-rays will show whether or not a participant has had knee replacements, whether or not they have later stage knee OA, and whether or not they have metal implants or fragments that are likely to cause severe MRI artifacts.

See Knee and Full Limb Radiography Operations Manual (Chapter 3J) for detailed instructions.

4.2 Final eligibility assessment

4.2.1 If determined not eligible during screening visit

During the course of the Screening Visit, a participant may be deemed ineligible for MOST. For example, if the participant's right and left knees do not fit in the MRI knee coil cylinder, you are directed to stop the visit.

Script: "Thank you for coming to the MOST clinic. Although, we will not be asking you to come to another clinic visit, the information you have provided will be very useful for this study. Only a limited number of people are being asked to continue with the study, but we greatly appreciate your time and effort in answering these questions for us."

Feel free to modify this script to reflect the participant's particular clinic experience.

4.3 Procedure checklist and exit interview

At the end of the Screening 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.
- Make sure the Screening Visit forms were completed fully, and that the correct MOST ID number and Acrostic were used.

- Summarize future contact with the study i.e., the baseline clinic visit, including x-ray, MRI, and CT scans. See script below:

  Script: "Thank you for your answers. We will contact you to let you know if you are eligible for the baseline clinic visit. If you are, we will call you to schedule a time for you to come back to the MOST clinic. This will be at no cost to you. During the baseline clinic visit, we will ask some general questions about your health, medical history, and activities. Also at this visit, you will have various examinations, a blood draw, and urine collection. You will also have an x-ray, MRI and CT scan at this visit. There are no internal examinations, drugs, or experimental procedures in this study. Again, if you are eligible we will contact by telephone to schedule your clinic visit and provide further instructions."

Appendix 1 Instructions for Screening Visit for MOST participants

Instructions for Screening Visit for MOST Participants

Dear <Name of MOST Participant>,

Thank you for your interest in the Multicenter Bone and Joint Research Study (MOST). We look forward to meeting you!

You appointment for your visit to the MOST clinic has been scheduled for

_____, _____ / _____ / _____, at _____ : _____ am / pm
Day of Week Month Day Year Time

at <clinic and address> (a map is enclosed). Parking is available in the garage attached to our clinic or van transportation will be provided as prearranged.

Please be sure to review these instructions for your upcoming visit.

- Read all enclosed materials.
- Your visit will include a review of the consent form for the study, a weight measurement, a brief interview, and a knee x-ray.
- Wear comfortable clothing. Please do not wear pantyhose or girdles.
- If you have glasses, bring both your reading glasses and any glasses that you use for longer distances.
- If you have a hearing aid, please bring it with you.

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

Appendix 2 Data from Prior Visits Report

Participant Name: _____

MOST Participant ID#:

Acrostic:

MOST Data from Prior Visits Report
Screening Visit
(New Cohort, 144-Month/Baseline)
Data current as of <today>

Gender:

Current age:

Visit Date
1. Target date for Screening Visit:

1.5 T Knee MRI
2. Was participant asked to bring medical documentation that shows it is safe to have an MRI scan?