

TELEPHONE SCREENING

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1. Purpose and description of the telephone screen

The telephone screen is the potential participant's first personal contact with the field center. The purpose of the telephone screen is to:

- Screen potential participants for eligibility
- Schedule a screening visit for eligible screenees
- Obtain names of other household members who are 45 to 69 years and possibly eligible to participate in the study

The essential components of the telephone screen include:

- Providing a brief description of the study
- Confirming demographic information (e.g., name, address, telephone number, age, date of birth)
- Ascertaining study eligibility
- Encouraging participation
- Scheduling Screening Visits for those who are eligible
- Record keeping

In order to standardize the screening approach, field centers should use the script outlined in Appendix 2. It is important to speak directly to the potential participant when conducting the telephone screen. Calls with interested screenees will generally take 10 minutes. However, some of the calls will be considerably shorter -- lasting only about 2 to 5 minutes -- if the contact is not interested in the Multicenter Bone and Joint Health Study (MOST).

The demographic questions (Questions #1 through #6) should be completed for all age-eligible screenees contacted by phone.

2. Preparing for the telephone screen

Prior to calling the screenee, the following materials should be readily available:

- Telephone Screening Interview (in REDCap).
- A Recruitment Contact Log to document previous attempts to contact and screen potential participants. Each field center should develop their own Recruitment Contact Log (Appendix 1).
- Telephone Screen Script (Appendix 2).
- Answers to Possible Questions (Appendix 3).
- Responses to Reasons for Not Participating in MOST (Appendix 4).
- Screenee Characteristics Report

3. Conducting the telephone screen

3.1 Calling the screenee

Determine the best time to call. Review the message that the screenee left saying they were interested to determine the best day and time to call.

Leaving a message. If the screenee is not home, leave your name and phone number, and say you would like to speak with them about their participation in a study being conducted by the University of Iowa/Alabama at Birmingham. If you are speaking with a person, ask what would be a good time to call back and record this time on the Recruitment Contact Log developed by your field center. If you are leaving a voice mail message, say what day and time of day you will try to call back. Of course, also leave the phone number and office hours of the field center so that the screenee has the option of contacting you. Record the day and time of each attempt on the Recruitment Contact Log.

Multiple attempts to contact the screenee. Attempt to call the screenee numerous times (number of attempts to be determined by your field center) and at different times of day and on different days of the week. For example, if the first attempt was during the day, attempt to call the screenee after dinner. Record the day and time of each attempt on the Recruitment Contact Log. After multiple attempts, leave a message for the screenee to call you at their convenience.

Attempting to contact the participant by mail. If none of the phone attempts are successful, you may want to consider sending the screenee a copy of the postcard, with a letter (developed by your field center) indicating that you have been trying to reach them, and asking them to call you at their earliest convenience. Record the date the brochure and letter were sent on the Recruitment Contact Log.

3.2 Introducing yourself to the screenee

Prior to the telephone screen, some screenees will have received an official postcard from the University describing the study and inviting them to participate.

Once you reach the screenee by telephone, describe MOST and see if they are willing to complete the telephone screening interview now (see Appendix 2: Telephone Screen suggested script). If they are unwilling to complete the telephone screen now, ask them when you can call back, and record the day and time that the screenee specifies on the Recruitment Contact Log (Appendix 1).

Briefly review the study with the screenee. A brief description of the study is covered in Appendix C and includes the following basic points:

- **The Multicenter Bone and Joint Health Study** is a university research study that may help us learn how physical activities and other factors affect the health of your bones and joints.
- If you are eligible and agree to participate, you would be seen in our clinic three times and have three telephone interviews over the next two years.
- To determine whether you are eligible for this study, we need to ask you a few questions.

Some screenees may have questions about the study and what is involved. For guidelines on answering common questions, please refer to Appendix 3.

3.3 Determining if the screenee is interested in participating

If the screenee agrees to the screening interview. Go to Section 3.4: Obtaining contact information.

If the screenee initially refuses the screening interview. Ask them why they are not interested in participating. If they state that they are too busy, tell them that the interview will take less than 10 minutes and press for an interview, while still remaining polite and respectful. Ask if there is a better time when you can call them back, perhaps in a few days. If the screenee states that they would like more information about the study for themselves or to review with a family member or doctor, offer to send them more information from the clinic. See Appendices 3 and 4 for possible scenarios and answers to possible questions.

If the screenee is willing to be called back at a later time. Schedule a day and time to call them back. Record the day and time on the Recruitment Contact Log.

If the screenee still refuses the screening interview. Thank the screenee for their time. Leave a phone number for them to call in the event that they change their mind and would like more information about MOST.

3.3.1 Obtaining names of other age-eligible people in the household

The postcard sent includes the suggestion that the postcard be shared with other members of the household who are age-eligible for the MOST study. Each screenee who is called or who calls in to the clinic can be asked if there are any other household members who are 45 to 69 years and possibly eligible to participate in the study.

3.4 Obtaining contact information

Tell the screenee that you would like to start by asking them some general questions about themselves. Record all information directly in the recruitment tracking database.

- Name. Ask them for their first name and last name. For difficult names, check that the spelling is correct. Record the full correct name (first, middle initial and last) in the recruitment tracking database.
- Name they go by. Ask the screenee if the first name they gave you is the name they go by? Record their preference.
- Title. Ask the screenee what title they prefer: The choices are: Mr., Mrs., Ms., Miss, Doctor, or Other. Record their preference.
- Address. Ask the screenee for their home address, including city, state, and zip code.
- E-mail address. Ask the screenee if they have and are willing to share their e-mail address. Record.
- Phone number. Record the screenees home phone number and ask them if this is the best number to call during the day. If not, ask for a better daytime phone number and record.
- Best day and time to call. Ask the screenee when is the best day and time to call them. Record their response.

3.5 Obtaining demographic information and age eligibility

1. Ask screenee how they heard about the study. Record all that apply.
2. Age. Ask the screenee how old they are and record their age in the boxes provided. This should be their current age. Individuals less than 45 years old or over 69 years old are not eligible.
3. Date of birth. Ask the screenee when they were born. Record the month, day, and year in the boxes provided. A screenee born on April 8, 1957 should be recorded as "04/08/1957."

4. Gender. Confirm gender, male or female, and record on the form.
5. Ethnicity. Ask the screenee if they consider themselves to be Hispanic or Latino, and record their response.
6. Race. Ask the screenee what their racial background is and mark one response option. If the race they state is not on the list of response options, mark "Other".

3.6 Assessment of eligibility

3.6.1 Knee replacement

7. Knee replacement. Ask the screenee if they have ever had a knee replacement surgery, where all or part of the joint was replaced. If they say "Yes" they are not eligible to be in the study.
8. Considering knee replacement surgery. Ask the screenee if they are considering having knee replacement surgery in the next 12 months. If they are considering knee replacement surgery in either knee, they are not eligible to be in the study.

3.6.2 Walking without assistance

9. Ability to walk by yourself. Ask the screenee if they are able to walk by themselves, without the help of another person and without a walker, cane or other assistive device. Mark "Yes," "No," or "Don't know/refused" by filling in the appropriate bubble. Screenees who respond "No," or "Don't know/refused" are not eligible. Note that if a screenee hesitates when being asked this question, it is important to probe.

3.6.3 Cancer in the past three years

10. Cancer in the past three years. Ask the screenee if, in the past three years, they have been treated for cancer or been told by a doctor that they had cancer or a malignant tumor. Mark "Yes," "No" or "Refused" by marking the appropriate bubble.

If the screenee responds "No," go to Question #11.

If the screenee responds don't know or refuses to answer, they are not eligible.

If the screenee responds "Yes," go to Question #10a.

Ask the screenee what type of cancer(s) they had. Do NOT read the list of cancers. Indicate what type of cancer they had by marking the appropriate bubble(s). You will be asked to mark 3 responses: skin, non-melanoma "Yes" or "No"; skin, melanoma "Yes" or "No"; and other type of cancer "Yes" or "No". All cancers in the past 3 years except for non-melanoma skin cancer make the screenee not eligible.

3.6.4 Other health problems

11. Kidney problems. Ask the screenee if they have problems with their kidneys that required them to have dialysis. Mark "Yes," "No," or "Don't know/refused" by filling in the appropriate bubble. Screenees who respond "Yes," or "Don't know/refused" are not eligible.
12. Other serious health problems. Ask the screenee if they have any other serious health problems that would make it very difficult for them to participate in a research study that will last 2 years. Screenees who respond "Yes," or "Don't know/refused" are not eligible.

3.6.5 Types of arthritis and other conditions

13. Rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Reiter's syndrome or reactive arthritis, and lupus. Ask the screenee if a doctor ever told them they had rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, or Reiter's syndrome or reactive arthritis, or lupus. Mark "Yes," "No," or "Don't know/refused" by filling in the appropriate response. Screenees who respond "Yes" or "Don't know/Refused" to any of the conditions will be asked about medications, Question #14.
14. Medications. Ask the screenee if they have ever taken any of the following medications:
 - a. Methotrexate
(meth-oh-TREKS-ayt)
 - b. Plaquenil
(PLAK-wen-ill)
also called Hydroxychloroquine
(hy-drox-ee-KLOR-oh-kwin)
 - c. Prednisone/steroids-glucocorticoids
(PRED-nih-sohn)
(GLOO-koh-kor-tih-koyd)
 - d. Sulfasalazine
(sul-fah-SAL-ah-zeen)
 - e. Humira
(hu-MER-a)
also called Adalimumab
(ay-da-LIM-yoo-mab)
 - f. Enbrel (EN-brel)
also called Etanercept
(eh-TAN-er-sept)
 - g. Remicade
(REM-i-kade)
also called Infliximab
(in-FLIX-ih-mab)

- h.** Rituxan
(ri-TUX-an)
also called Rituximab
(ri-TUX-i-mab)

- i.** Actemra
(Ak-TEM-ruh)
also called Tocilizumab
(TOE-si-LIZ-oo-mab)

- j.** Orencia
(aw-REN-see-uh)
also called Abatacept
(a-BAT-a-sept or ah-BAY-tah-sept)

- k.** Cimzia
(SIM-zee-uh)
also called Certolizumab pegol
(SER-toe-LIZ-oo-mab PEG-ol or SERT-oh-LIZ-yoo-mab PEG-ol)

- l.** Simponi
(SIM-puh-nee)
also called Golimumab
(goe-LIM-ue-mab)

- m.** Kineret (KIN-a-ret)
also called anti-IL1RA or Anakinra

- n.** Arava
(uh-RAHV-uh or uh-RAVE-uh)
also called Leflunomide
(leh-FLOON-oh-myd)

- o.** Xeljanz
(zel-jans)
also called Tofacitinib citrate
(TOE-fa-SYE-ti-nib si-trate)

- p.** Benlysta
(ben-LIST-ah)
also called Belimumab
(be-LIM-ue-mab)

- q.** Stelara
(stel ar' a)
also called Ustekinumab
(YOO-sti-KIN-ue-mab)

- r.** Otezla
also called Apremilast

If they answer “Yes” to any of these medications they are not eligible to be in the study.

3.6.6 Fracture history

15. Has a doctor ever told you that you broke or fractured a bone after age 45? This question does not determine eligibility, but is of interest to investigators.

3.6.7 Knee symptoms

Right knee. Introduce questions: “Now I am going to ask you some questions about pain that you may have in your right knee.”

16. “In the past 30 days, have you had any pain, aching, or stiffness in or around your right knee?” If they say “No”, skip to Question #17. If they say “Don’t know/Refused” they are not eligible.

If they say “Yes” ask:

- 16a. “In the past 30 days, have you had constant pain (pain that you have all the time) in or around your right knee?” If they say “No”, skip to Question #17. If they say “Don’t know/Refused” they are not eligible.

If they say “Yes” ask:

- 16b. “Please select the response that best describes, on average, your constant pain in your right knee in the **past 30 days**.”

In the past 30 days, how intense has your constant pain in your right knee been? The 5 response options are...” (*Interviewer Note: Read first 5 response options*)

Not at all
Mildly
Moderately
Severely
Extremely

If they say “Not at all”, “Mildly”, or “Moderately” go to Question #17. If they say “Severely”, “Extremely”, “Don’t know” or “Refused” they are not eligible.

Left knee. Introduce next few questions: “Now I am going to ask you about your left knee.”

17. “In the past 30 days, have you had any pain, aching, or stiffness in or around your left knee?” If they say “No”, skip to Question #18. If they say “Don’t know/Refused” they are not eligible.

If they say “Yes” ask:

- 17a. “In the past 30 days, have you had constant pain (pain that you have all the time) in or around your left knee?” If they say “No”, skip to Question #18. If they say “Don’t know/Refused” they are not eligible.

If they say “Yes” ask:

- 17b. “Please select the response that best describes, on average, your constant pain in your left knee in the past 30 days.”

In the past 30 days, how intense has your constant pain in your left knee been? The 5 response options are...” (*Interviewer Note: Read first 5 response options*)

Not at all
Mildly
Moderately
Severely
Extremely

If they say “Not at all”, “Mildly”, or “Moderately” go to Question #17c. If they say “Severely”, “Extremely”, “Don’t know” or “Refused” they are not eligible.

3.6.8 Screenee characteristics and eligibility to continue

- 17c. Review screenee characteristics: age, gender, ethnicity, race, and knee pain status in the past 30 days for the screenee. Refer to the screenee characteristics report on the MOST study website to determine if the screenee is in a group that is closed to recruitment.

Answer the question: “Based on the questions answered so far, is this screenee eligible to continue the Interview?” If enough participants have been enrolled in the study with the participant’s characteristics, mark “No” to this question. If “No”, stop the interview. Inform the screenee that there are (or may be) enough participants enrolled in the study with these characteristics at this time. If it is determined later that the screenee may still be eligible for the study, you can call them back to complete the screening interview.

“There are or may be enough participants enrolled in the study with your characteristics at this time. If we determine later that you may still be eligible for the study, we will call you back to see if you are still interested and complete the interview. Thank you.”

3.6.9 Imaging willingness and pregnancy

18. Willingness to have imaging. Ask screenee: “This study includes x-rays, MRI and CT scans. Are you willing to have x-rays, MRI and CT scans?”
If “No” or “Don’t know/Refused”, screenee is not eligible.

19. Women only. Ask women only: “This study includes x-rays, MRI and CT scans, so if you are pregnant or trying to get pregnant, you are not eligible for this study. Are you pregnant or trying to get pregnant?”
If “Yes” or “Don’t know/Refused”, screenee is not eligible.

3.6.10 MRI eligibility

20. Weight. Ask screenee weight: “About how much do you weigh? If you are not sure, please make your best guess.”

If “Don’t know/Refused”, screenee is not eligible.

If “Weight known:” Complete Question #20a.

Interviewer Note: enter weight: _____ pounds

If weight is greater than 300 pounds (for WOMEN) or greater than 340 pounds (for MEN), screenee is not eligible. These are the weight limits for the fitting in the MRI.

If the screenee cannot have an MRI scan they are not eligible for the study.

MRI eligibility. The next set of questions are asked to ensure that the participant does not have implants or embedded metal objects in their body that might create a health hazard or interfere with imaging during an MRI scan

21. Introduce next questions: “The next few questions are about MRI eligibility.”
“Have you ever had an implant or device surgically implanted in your body?”

If “No”, go to Question #22.

If “Refused”, screenee is not eligible

- 21a. If “Yes” or “Don’t know” say: “The next few questions will be about specific implants. Please tell me whether any of the following was implanted in your body during surgery:”

Ask the participant to answer “Yes” or “No” to each of the following (and mark the appropriate response):

- i. “Electronic implant or device, such as a cochlear implant”
- ii. “Magnetically-activated dental implant or dentures, magnetic eye implant, or other magnetic device”
- iii. “Heart pacemaker”
- iv. “Implanted heart defibrillator”
- v. “Internal electrodes or wires, such as pacemaker wires or bone growth/bone fusion stimulator wires”
- vi. “Neurostimulation system, such as spinal cord stimulator or gastric electrical stimulation system”
- vii. “Surgically implanted insulin or drug pump”

- viii. “Tissue expander with magnetic port, such as inflatable breast implant with magnetic port”
- ix. “Brain aneurysm surgery, brain aneurysm clip(s) or coil(s)”

If “Yes,” or “Don’t know/Refused” to any of the above implants, the screenee is not eligible.

If “No,” to all of the above implants, go on to Question #21b.

The next set of screening questions help determine whether a participant may be eligible for an MRI, even if they have an implant or injury by metal object, if they have appropriate medical documentation stating their implanted device/object is MRI-safe.

- 21b. “Please tell me whether any of the following was implanted in your body during surgery:” Ask the participant to answer “Yes” or “No” to each of the following (and mark the appropriate response):
- i. “Stent, filter, coil, or clips”
 - ii. “Shunt (spinal or intraventricular)”
 - iii. “Vascular access port or catheter, such as a central venous catheter or PICC line”
 - iv. “Surgically implanted hearing device (not a regular hearing aid) or prosthesis in your ear”
 - v. “Eyelid spring, wire or weights”
 - vi. “Penile implant or prosthesis” (*men only*)
 - vii. “Heart valve”

The next two questions help to determine whether the screenee should be excluded from having an MRI scan and therefore not eligible for study due to injury by metal object.

22. “Have you ever had an injury in which metal fragments entered your eye and you had to seek medical attention?”
23. “Have you ever had an injury in which metal fragments such as shrapnel, BB, or bullet entered your body?”
- 24a. If “Yes” or “Don’t know/Refused” to any of the items in Question #21b, #22, or #23, determine if participant is willing to ask their doctor for medical documentation to help determine whether it is safe for them to have an MRI scan. Ask:

“Do you have or would you be willing to ask your doctor for your medical documentation for this implant/metal fragment so that we could determine whether it would be safe for you to have an MRI scan?”

An example of appropriate medical documentation is a card or a letter from the participant’s physician stating that the implanted device is safe for an MRI. Please consult with your MRI technologist or on-site investigator if you have any questions about acceptable medical documentation.

If “No” screenee is not eligible for safety reasons,.

If “Yes” make a note to yourself to remember to ask the screenee to bring in medical documentation with them to Screening Visit, if they are determined eligible for a Screening Visit.

- 24b. Interviewer Note: is there any other reason why this participant would not be eligible for an MRI and mark appropriate response.

Do not ask the participant the question, but if there is any other reason the screenee would not be eligible for an MRI scan, please mark the “Yes” response.

The MRI scanner used in this study is a peripheral MRI scanner meaning that the person sits in a lounge chair and only the knee (not the entire body) is put inside the MRI machine. The machine will make noise, so if the person previously had an MRI and couldn’t tolerate the sounds (even with ear plus) that may be one reason why the screenee might not be a good candidate for MRI.

25. Surgery. “Are you planning to have surgery in the next 2 months?”

If “No” or “Don’t know/Refused” go to Question #26.

If “Yes” go to Question # 25a and #25b.

- 25a/25ai. “Do you know the date your surgery is scheduled?”

If “Yes”, “What is the date of your scheduled surgery?”

Record the date in MM/DD/YYYY format.

“To determine if you are eligible for an MRI, I’d like to know the type of surgery you are having. What type of surgery will you have?”

- 25b. Refer to the list of surgeries/procedures that do not require a 2-month wait.

Interview Note: Is the surgery on the list?

Do not ask the participant the question, but if the surgery is on the list, please mark the “Yes” response and go to Question #26.

If “No”, schedule clinic visit 2 months after surgery date if screenee is eligible.

Re-contact the participant 2 months after the date of the participant’s surgery to reassess eligibility (you will likely need to re-administer the entire telephone screening interview). It may be helpful to make a note of this on the Recruitment Contact Log.

26. Moving in the next three years. Ask the screenee if they plan to move out of the (Birmingham/Iowa City) area in the next three years. Mark "Yes," "No," or "Don't know/Refused". If the screenee is a snowbird or leaves town for several months during the year, they will still be eligible if they can leave an address and phone number where they can be reached while they are away, and are still willing to come into the field center for clinic visits, or be available for completing future questionnaires.

3.6.11 Final eligibility determination

Questions #2-#3, #7-#14, and #16-#26 in the Telephone Screening Interview assess eligibility for MOST. If the screenee's response to any of the questions makes the screenee not eligible, the interview will stop.

4. Scheduling a screening visit for eligible screenees

If the screenee's responses to all eligibility questions make them eligible for the Screening Visit, schedule the Screening Visit.

4.1 Screenee is eligible and agrees to schedule a Screening Visit

Screenee agrees to schedule a Screening Visit. If the screenee agrees to schedule an appointment for a Screening Visit, record the appointment date and time in your scheduling calendar.

Screening visits should be scheduled within 4 weeks of the telephone screen (*ideally, within 2 weeks of the telephone screen*). If you need to call back to schedule an appointment, ask the screenee what day and time within the next several weeks would be good for calling back to schedule an appointment. If the screening visit does not take place within a 90-day period, the Telephone Screening Interview has to be repeated. An e-mail that includes the ID# and acrostic and explanation about why the interview must be repeated should be sent to the Coordinating Center. After the Coordinating Center responds to this e-mail and has deleted the original Telephone Screening Interview from the data system, a new Telephone Screening Interview can be conducted. Use the same ID# and acrostic for the repeat screen.

Tell the screenee that they will be receiving a consent form (this will be a site-specific decision).

Tell the screenee that they will receive a confirmation notice in the mail in the next few days (time permitting) or a phone call reminding them of the day and time of the visit. Be sure to give the screenee your name and the phone number of the clinic to call if they need to reschedule the visit for any reason.

Tell the screenee what to expect at the screening visit. The visit will last approximately 30 minutes and will consist of a short interview, a weight measurement, an exam to see if their knees will fit in the knee coil for the MRI scan and knee x-rays. Thank the screenee for their time and their participation in this important study.

4.2 Screenee is eligible but does NOT agree to schedule a screening visit

If the screenee is eligible but refuses to schedule a screening visit at this time, mark "NOT INTERESTED" on the Telephone Screening Interview, and ask the participant why they are not interested. Mark all of the reasons that apply.

If the screenee does not wish to schedule a Screening Visit, but expresses interest in being called back at a later date, record an agreed-upon date and the time in the spaces provided on the Recruitment Contact Log. Be aware, however, that if the screenee does not have a screening visit within a 90-day period that they will have to be re-screened.

4.3 Screenees who refuse the telephone screening interview, or are ineligible to participate in MOST, or refuse to schedule a screening visit

- If the screenee refuses the telephone screening interview

Thank the screenee for their time. Leave a phone number for them to call in the event that they change their mind and would like more information about the Bone and Joint Health Study.

- If the screenee is ineligible after the telephone screen

Tell the screenee: "You are not eligible to be part of the study, but the information you provided will be very useful. Thank you for your time and for answering our questions. Goodbye."

5. Record keeping and mailing screening visit reminder

Once the screening interview is complete, but before you hang up the telephone with the screenee, review book-keeping procedures to re-contact screenees who are unsure about participating in the study, or screenees who wish to be called back at a future time should be formalized at each field center. The use of various "Pending" files to keep track of deferred interviews should be considered.

If an appointment is made for a Screening Visit, the date and time should be entered in a clinic scheduling book or electronic scheduling system.

Fill out a reminder card (if time permits) with the date and time of the screening visit and mail it to the screenee.

Fill out the Recruitment Contact Log developed by your field center and record the appropriate information about the call.

6. Submit the Telephone Screening Interview form

Once the Telephone Screening Interview is complete and has been reviewed, the form should be submitted immediately.

7. Quality Assurance

7.1 Training Requirements

The interviewer requires no special qualifications to perform this assessment. Previous interviewing experience will be helpful. Training should include:

- Read and study the following operations manual chapters:
 - Recruitment and Sampling (2D)
 - Interviewing Guidelines (2E)
 - Telephone Screening (2F)
- Read MOST materials sent out to screenees
 - Postcard
 - Any field-specific materials
- Thoroughly review the Telephone Screening Interview
- Review and discuss with field center manager or recruitment coordinator MOST eligibility criteria and eligibility questions
- Review responses in operations manual for participants who refuse the telephone screen
- Review responses to reasons for not wanting to participate in MOST
- Review answers to possible questions.
- Practice administering the Telephone Screening Interview on volunteers (if possible, age-eligible volunteers).

7.2 Certification requirements

Completed training requirements.

- Administer two *mock* Telephone Screening Interviews while being observed by the QC Coordinator or their designate.
- Administer one *mock* Telephone Screening Interviews with a Coordinating Center staff member.

7.3 Quality assurance checklist

Administration of the Telephone Screening Interview

- Asks participant if they are willing to complete the telephone screen now
- Describes the Multicenter Bone and Joint Health Study
- Correctly obtains demographic information
- Probes participant if prompted because age and date of birth inconsistent
- Reads script and questions exactly as written on the Telephone Screening Interview (same order, same wording)
- Accurately records participant's responses on telephone screening interview form
- Explains pause(s) necessary for interviewer to complete form
- If participant eligible reads correct script for eligible participants
- If participant eligible schedules appointment or time to call back for appointment
- If participant not eligible, correct script read and participant thanked for their time
- Follows the guidelines for recording data on electronic data entry (REDCap) forms

Interviewing Techniques

- Reads slowly, speaks clearly and uses appropriate inflection when speaking
- Reduces the chance of bias by maintaining a neutral attitude toward participant's answers
- Able to elicit accurate and complete information using non-directive probes
- Keeps interview on track by presenting questions at a regular pace
- Focus' participant's attention on questions while always being polite
- Treats participant's with respect
- Maintains a professional and friendly manner; leaves participant with overall feeling of well-being

Appendix 1 Recruitment contact log

ID#:

NAME: _____ SEX: _____

ADDRESS: _____ AGE: _____

PHONE: _____ Best time to call: S M T W T F S ____:____AM
PM

DATES OF CONTACTS	DAY OF WEEK	TIME	TYPE OF CONTACT*	RESULTS/COMMENTS
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____
____/____/____	S M T W T F S	____:____AM PM	M T P	_____

PLEASE REFER TO RECRUITMENT RESULT CODES ON THE RECRUITMENT STATUS LOG SHEET

FIRST APPOINTMENT DATE ____/____/____

TIME ____:____AM
PM

RESCHEDULED APPOINTMENT DATE ____/____/____

(if needed) TIME ____:____AM
PM

*CODES: M = Mail
T = Telephone
P = Personal

Appendix 2 Telephone Screen suggested script

Hello, my name is _____, calling from the [UI][UAB]___ for the Multicenter Bone and Joint Health Study.

May I please speak with _____?

(If the person is available)

I'm calling from the University of Alabama at Birmingham/Iowa.

Recently, we received a message stating that you are interested in the Multicenter Bone and Joint Health Study. Do you have a few minutes to talk now?

Yes

No



When may I call back?

(Record date and time on the Recruitment Contact Log developed by your field center)

Thank you for your interest in the Multicenter Bone and Joint Health Study. This study is also referred to as the MOST study. This is a university research study that will help us learn how physical activities and other factors affect the health of your bones and joints. Information gathered in this study may help us to better understand bone and joint health. This study is open to men and women between the ages of 45 and 69. This study will not involve taking any medications or changing your eating or exercise habits. This study will last 2 years and will require coming to a short visit to confirm your eligibility, two clinic visits in [Iowa City][Birmingham], and two telephone interviews.

To determine whether you are eligible for the study, I need to ask you a few questions. It should take about 10 minutes.

Optional: Are there other people in your household who are between the ages of 45 and 69 years and who might be interested in being in the MOST study? *If the screenee says "Yes," ask them for the person's name and phone number. If the screenee feels uncomfortable about sharing this information, ask them to give the postcard to the household member.*

(Start the Telephone Screening Interview.)

IF REFUSES TELEPHONE SCREEN: *Refer to Response C (see page 21)*

IF NOT ELIGIBLE AFTER TELEPHONE SCREEN: *Refer to Response B (see page 21)*

IF ELIGIBLE AFTER TELEPHONE SCREEN: Thank you for your time and for answering our questions. The information will be very useful in the study. It does look like you are eligible to participate in the screening visit.

This is a 2-year study funded by the National Institute on Aging. It is being done in two clinics in the United States – one here in [Birmingham][Iowa City] and the other is in [Birmingham][Iowa City]. This study involves tests and measurements only. Study participants will not receive any medications or treatment during this study. This study is gathering information about how physical activities and other factors affect the health of your bones and joints. If you decide to participate in this study, you will be asked to attend a short visit to confirm your eligibility, two clinic visits in [Birmingham][Iowa City], and two telephone interviews over the next 2 years.

The first visit will be a screening visit which includes a short interview, a weight measurement, an exam to see if your knees will fit in the knee coil for the MRI scan, and knee x-rays to confirm your eligibility. If eligible, there will be a number of tests and measurements and questionnaires to complete at your next clinic visit. You will have basic measurements such as height and blood pressure. You will have a fasting blood draw, knee and full-limb x-rays, an MRI, and a CT scan. You will also be asked to wear a physical activity monitor for 7 days. We will gather information about your medical history and record the medications that you are taking. We will also do a variety of other tests and walking measurements. These are all described in the study consent form that will be reviewed with you during the Screening Visit and if eligible, the clinic visit. The Screening Visit will last about 30 minutes and the clinic visit lasts about 4 hours.

After you have been enrolled in the study for 8 months and 16 months, you will have a short telephone interview to find out about any new changes in your bone and joint health.

Everyone eligible will be asked to attend the final study visit after participating in the study for 2 years. We will repeat some of the tests and measurements you had at the main clinic visit. This visit will last about 2 ½ hours.

Do you have any questions? Does the study sound like something you would be interested in doing?

SCHEDULE APPOINTMENT: The next step is for us to schedule your screening visit. This visit will last about 30 minutes and include knee x-rays. Do you have a calendar handy? Are there any days of the week you would prefer to have your appointment?

(Check available dates and times.)

The first appointment we have available is _____. Would that work for you?

(If date and/or time doesn't work, find an alternate date/time.)

That's great. We will see you at _____ (time) on _____ (date). *(Remind screenee of your name.)*

You will be receiving a letter describing how to prepare for your visit.

Do you have any questions for me about any of this?

Well, I have you scheduled for _____. You will receive a reminder letter/postcard about a week before that date. Please call me if you think of any questions after we hang up. My name

is _____ and our phone number is <UAB: 205-975-7522/UI: 319-467-1155 or toll-free, UI: 1-800-814-9535>. You will not be given any medications or treatment during this study. Thank you for your time today.

IF ELIGIBLE, BUT REFUSES OR HESITATES**TO MAKE AN APPOINTMENT FOR SCREENING VISIT:** *Refer to Response A***RESPONSE A:
ELIGIBLE, BUT REFUSES OR HESITATES
TO MAKE AN APPOINTMENT FOR CLINIC VISIT**

“Is there a specific reason you could share with us about why you don't want to schedule an appointment at this time?”

Some of their reluctance may be due to temporary circumstances and the screenee may actually have "potential." Other screenees, however, should not be talked into an appointment, since they will probably cancel.

If the screenee is still unwilling to schedule an appointment, complete the Telephone Screening Interview form as NOT INTERESTED, and record the reason that they do not want to be part of the study.

**RESPONSE B:
NOT ELIGIBLE AFTER TELEPHONE SCREEN**

"You are not eligible to be part of the study, but the information you provided will be very useful. Thank you for your time and for answering our questions. Goodbye."

**RESPONSE C:
REFUSED TELEPHONE SCREEN**

“Is there a specific reason you could share with us about why you don't want to proceed with an interview at this time?”

Some of their reluctance may be due to temporary circumstances and the screenee may actually have "potential." Ask if there is a better time to call them back. If so, record the time on the Recruitment Contact Log.

“I would like to thank you for taking the time to talk with me. If you have any questions or change your mind and would like more information about MOST, please feel free to call me anytime at () _____ - _____ .”

Appendix 3 Answers to possible questions

- 1. Question:** How is the Multicenter Bone and Joint Health Study (MOST) special?

Response: The goals of the Multicenter Bone and Joint Health Study are to use innovative new technologies to investigate how physical activity, the way our limbs and joints move as we walk, bone density around our joints, calcium crystals in our joints, and other factors affect bones and joints in persons ages 45-69. By studying these factors in relatively young and healthy people there is a good chance we can identify factors that will contribute to maintaining good bone and joint health as we age.
- 2. Question:** I don't know. Two years is a long time to do anything. I might not be around at the end.

Response: Two years is a long time. We realize that all kinds of things could happen. However, we still want you to join and will be grateful for as much participation as you are able to give.
- 3. Question:** How often will I have to come to the clinic?

Response: You will be asked to come into the clinic for a short visit to confirm eligibility and then for a clinic visit two times in 2 years. In addition, we will call you 8 months and 16 months after your first clinic visit.
- 4. Question:** Will I be paid to participate?

Response: You will be reimbursed for your time and travel.
- 5. Question:** Do I have to pay for the medical tests or will my insurance be billed?

Response: No, all of the tests are free! No one will be billed. You will receive copies of some test results that you can share with your own doctor.
- 6. Question:** What type of results will I receive? Also, when will I get these results?

Response: You will receive the results from the blood pressure, height, and weight. These results will be available right away.
- 7. Question:** If I am in the study, do I have to stop taking any medication I am currently on? I take a water pill for my blood pressure.

Response: No, this study will not interfere with your usual medical care. We will ask you periodically what prescription and over-the-counter medicines you are taking.
- 8. Question:** Can I still be in the study if I don't want x-rays, MRIs or a CT scan? I don't like to take extra x-rays.

Response: X-rays, MRIs and CT scans are our way to measure the condition of your knee joints. We need this information to look at changes over the next two years. These are the only test that MOST participants must have to be in the study.

9. **Question:** I live in (Arizona, Los Angeles, Europe, etc.) for the winter months. Can I still be in your study?

Response: Yes, but it is important that we know where to reach you during those months and when you will return to the Birmingham/Iowa City area. Once you return to the area, we will schedule your clinic visit.

Appendix 4 Responses to reasons for not participating in MOST

- 1. Reason:** Need time to think it over.

Response: If you need more time to think about your involvement with the study, that's fine. May I call you back sometime within the next week or so?

Yes: When is a convenient time for me to call?
(Record on Recruitment Contact Log.)

No: I'd like to thank you for taking the time to talk with me.
If you have any questions, please feel free to call me at ____.
- 2. Reason:** Personal health.

Response: I'm sorry to hear you're not feeling well. I'll call you in a few weeks to see if you're feeling better. You may want to schedule an appointment then.
- 3. Reason:** Family member's health problem.

Response: It's very difficult when someone in the family is ill. Can I call you in a few weeks/months to see if your situation has changed and if you want to consider scheduling an appointment?
- 4. Reason:** Want to talk it over with family member (husband/daughter, etc.) or need more information.

Response: I could send ____ (family member) some information on the study and call you back once you have had a chance to discuss it with them. If you like, we could also talk with _____.
- 5. Reason:** Not interested/refused.

Response: Thank you for taking the time to answer these questions for me.
If you should change your mind about participating, please call me.
- 6. Reason:** Fear of radiation.

Response: All of our tests are safe. The amount of radiation is very small.
In addition, our research has been approved as being safe by the University of Iowa/Alabama at Birmingham Institutional Review Board and the National Institutes of Health.