

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 clinic visit for eligible screenees
- obtain names of other household members who are 50 to 79 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 clinic visits for those who are eligible
- record keeping

In order to standardize the screening approach, field centers should use the script outlined in Appendix C. It is important to speak directly to the potential participant when conducting the telephone screen. Calls with interested screenees will generally take 10 to 15 minutes. However, some of the calls will be considerably shorter -- lasting only about 2 to 5 minutes -- if the contact is not interested in MOST.

The demographic questions (Questions #1 through #10) should be completed for all age-eligible screenees contacted by phone. Box B on the last page of the Telephone Screening Interview form should be filled out for all screenees, whether or not they are eligible or interested in the study. Those screenees who are not interested should be asked why they are not interested and you should record their reason(s) below the "NOT INTERESTED" box.

2. Preparing for the telephone screen

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

- 1) Blank copy of the Telephone Screening form (Appendix A).
- 2) 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 B).
- 3) Appendix C: Telephone Screen Script.
- 4) Appendix D: Answers to Possible Questions.
- 5) Appendix E: Responses to Reasons for Not Participating in MOST.

3. Conducting the telephone screen

3.1 Calling the screenee

Determine the best time to call. Look on the postcard, or read 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. 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 message on an answering machine, say what day and time of day you will try to call back. Of course, also leave the phone number 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 brochure, 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 brochure from the University describing the study and inviting them to participate; attached to the brochure is a reply card; the reply card gives the screenee the option of providing the best phone number to be reached at, the best time to call, and to request additional information about the study.

Once you reach the screenee by telephone, describe MOST and see if they are willing to complete the telephone screen now (see Appendix C). 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 B).

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

- MOST is a university research study that may help us learn how physical activities, weight, and diet affect knee pain and knee arthritis.
- If you are eligible and agree to participate, you would be seen in our clinic two or three times in the next three 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 D.

3.3 Determining if the screenee is interested in participating

If the screenee agrees to the screening interview. Go to Section 3.4: Obtaining demographic information and age eligibility.

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 C and D 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 letter sent with the brochure includes the suggestion that the brochure 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 50 to 79 years and possibly eligible to participate in the study.

3.4 Obtaining demographic information and age eligibility

Tell the screenee that you would like to start by asking them some general questions about themselves. Record all information directly on the Telephone Screening Interview form.

1. Name. Read the screenee their full name as it is printed on the response postcard that they sent in to the clinic. 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 space provided in Question #1 on the Telephone Screening Interview form. If the screenee does not have a middle initial, leave the space blank. It is critical that you print legibly and stay within the boxes.

Name they go by. Ask the screenee if the first name they gave you is the name they go by? If “No,” write in the name they go by.

Title. Ask the screenee what title they prefer: The choices are: Mr., Mrs., Ms., Miss, Doctor, or Other. If “Other” please specify.

2. Address. Ask the screenee for their home address, including city, state, and zip code. Once again, it is critical that you print legibly and stay within the boxes.
3. E-mail address. Ask the screenee if they have and are willing to share their e-mail address.
4. Phone number. Record the screenee’s 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 in Question #5a on the Telephone Screening Interview form.
5. Best day and time to call. Ask the screenee when is the best day and time to call them. Record their response.
6. 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, 1927 should be recorded as “04/08/1927.”
7. 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 50 years old or over 79 years old are not eligible.

Answer the question: “Is the participant at least 50 and not more than 79 years old?”

If “No” mark the NOT ELIGIBLE box in Box B on page 9 in the Telephone Screening Interview and 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.”

8. Gender. Confirm gender, male or female, and record on the form.
9. Ethnicity. Ask the screenee if they consider themselves to be Hispanic or Latino, and record their response.
10. 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” and write in their response.

3.5 Assessment of eligibility based on weight and knee injury and surgery

Ask the screenee questions about their weight and about knee pain and surgery history.

11. Weight. Ask the screenee what their current weight is. If they are not sure, ask them to make their best guess. Record the weight that they tell you. You need to remember the screenee’s age (you can refer back to page 3, Question 7) to review their age, and then check the table in Question #11; e.g., if a woman is age 50 to 59 and weighs more than 154 pounds, fill in the asterisked bubble next to that category. The categories are as follows:

Female, ages 50 to 59: Equal to or greater than 154 lbs.
Female, ages 60 to 69: Equal to or greater than 151 lbs.
Female, ages 70 to 79: Equal to or greater than 148 lbs.
Male, ages 50 to 59: Equal to or greater than 194 lbs.
Male, ages 60 to 69: Equal to or greater than 187 lbs.
Male, ages 70 to 79: Equal to or greater than 182 lbs.
12. Pain, aching, or stiffness in either knee. Ask the screenee whether they have had pain, aching or stiffness in or around either knee? If they say “Yes,” ask them if they have had pain, aching or stiffness in or around their right knee on most days during the past 30 days, and if they have had pain, aching or stiffness in or around their left knee on most days during the past 30 days. The “Yes” bubble is asterisked. When you ask about each knee, be sure to include the script: “By most days we mean more than half the days of the month.”
13. Knee injuries. Ask the screenee whether they have ever injured their knees so badly that it was difficult for them to walk for at least one week. The “Yes” bubble is asterisked.
14. Knee surgery. Ask the screenee whether they have ever had knee surgery. The “Yes” bubble is asterisked.

Complete Box A: Look at the responses to Questions #11 through 14 and see if any of the asterisked responses are marked. If so, mark, “Yes” and continue the interview. If not, go to Box B on page 10 of the Telephone Screening Interview form, tell the screenee that they are not eligible, and thank them for their time.

3.5.1 Further eligibility assessment / exclusions

3.5.1.1 Knee replacement

15. Knee replacement. Ask the screenee if they have ever had a knee replacement surgery. If they say “Yes” ask them which knee. If both knees have been replaced, they are not eligible to be in the study. Go to Box B, and mark NOT ELIGIBLE.

If they have had knee replacement surgery in one knee, ask if they are considering knee replacement surgery in the other knee. If they say, “Yes,” go to Box B, and mark NOT ELIGIBLE. If they say “No,” skip to Question #17.

16. Considering knee replacement surgery. Ask the screenee if they are considering having knee replacement surgery. If they are considering knee replacement surgery of both knees, they are not eligible to be in the study. Go to Box B, and mark NOT ELIGIBLE.

3.5.1.2 Cancer in the past three years

17. 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 #18.

If the screenee refuses to answer, they are ineligible. Go to Box B and choose NOT ELIGIBLE.

If the screenee responds “Yes,” go to question #17a. 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). Mark all bubbles that apply. A screenee may have had more than one type of cancer. Be sure to follow the instructions following the name of each cancer. The instructions indicate whether having that particular type of cancer makes the screenee not eligible. In some cases, the instructions direct you to question #17b. If the screenee is not eligible based on the type of cancer, go to Box B, and mark NOT ELIGIBLE. If the screenee names another kind of cancer that is not on the list of cancers, mark “Other,” write in the name of the cancer, and go to Question #17b.

- 17b. Radiation treatment and/or chemotherapy. Ask the screenee if they received radiation treatment and/or chemotherapy for the cancer. If the screenee indicated that they had more than one cancer, ask if they received radiation treatment and/or chemotherapy for any of the cancers. Mark "Yes," "No," or "Don't know/refused" by marking the

appropriate bubble. Screenees who respond "Yes," or "Don't know/Refused" are not eligible. Go to Box B, and mark NOT ELIGIBLE.

- 17c. Cancer removed by surgery. Ask the screenee if the cancer was removed by surgery. Mark "Yes," "No," or "Don't know/refused" by marking the appropriate bubble. Screenees who respond "No," or "Don't know/refused" are not eligible. Go to Box B, and mark NOT ELIGIBLE.

3.5.1.3 Other health problems

18. 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. 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. Go to Box B, and mark NOT ELIGIBLE. Note that if a screenee hesitates when being asked this question, it is important to probe. If the screenee will not be able to step up to stand on a stool to have a knee x-ray, they are not eligible to be in the MOST study.
19. Kidney problems. Ask the screenee if they have ever had problems with their kidneys that resulted in the need for hemodialysis or peritoneal 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. Go to Box B, and mark NOT ELIGIBLE.
20. 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 3 years. If they answer "Yes," ask the screenee what their health problem is, and write this in the box below the "Yes" response option. You will need to refer the Telephone Screening Interview form to the Recruitment Coordinator who will later determine whether or not the screenee is eligible for the study. Go on to Question #21 and when you complete Box B, on page 9, you will choose POTENTIALLY ELIGIBLE.

If the screenee answers "Don't know," go on to Question #21 and when you complete Box B, you will choose POTENTIALLY ELIGIBLE.

If the screenee answers "No," mark the "No" response option and go on to Question #21.

If the screenee refuses to answer the question, they are not eligible. Fill in the "Refused" bubble and go to Box B and choose NOT ELIGIBLE.

21. Ankylosing spondylitis, psoriatic arthritis, and Reiters syndrome. Ask the screenee if they have ever had ankylosing spondylitis, psoriatic arthritis, or Reiters syndrome. Mark "Yes," "No," or "Don't know/refused" by filling in the appropriate bubble. Screenees who respond "Yes" are not eligible. Go to Box B, and mark NOT ELIGIBLE.

3.5.1.4 Rheumatoid arthritis

22. Rheumatoid arthritis. Ask the screenee if a doctor ever told them that they have rheumatoid arthritis. Mark "Yes," "No," or "Don't know/refused" by filling in the bubble in the appropriate box. If the screenee says "No," go to Question #29 on page 10. If the screenee says "Yes" or "Don't know/refused," ask Question #23.
23. Rheumatoid arthritis medications. Ask the screenee if they have ever taken any of the following medications:

Methotrexate
(meth-oh-TREKS-ayt)

Plaquenil
(PLAK-wen-ill)
also called Hydroxychloroquine
(hy-drox-ee-KLOR-oh-kwin)

Enbrel (EN-brel)
also called Etanercept
(eh-TAN-er-sept)

Remicade
(REM-i-kade)
also called Infliximab
(in-FLIX-ih-mab)

Arava (uh-RAHV-uh also called uh RAVE uh)
also called Leflunomide
(leh-FLOON-oh-myd)

Gold shots or pills

Prednisone/steroids-gluocorticoids
(PRED-nih-sohn) (GLOO-koh-kor-tih-koyds)

Sulfasalazine
(sul-fah-SAL-ah-zeen)

Kineret (KIN-a-ret)
also called anti-IL1RA

If they answer "Yes" to any of these medications they are not eligible to be in the study. Go to Box B on page 9 and mark NOT ELIGIBLE.

Note: Questions #24 through 28 are completed to determine whether or not the participant has rheumatoid arthritis:

24. Joint stiffness. Ask the screenee if they have ever had morning joint stiffness lasting one hour, and if they say "Yes" if they had this stiffness for more than 6 weeks. If "Yes" place a "1" in the box to the left of the question.
25. Nodules or bumps under skin. Ask the screenee if they ever had nodules or bumps under the skin around the elbow or ankle. If "Yes" place a "1" in the box to the left of the question.
26. Swelling. Ask the screenee if they have had swelling for more than 6 weeks in their wrist, fingers or thumbs, elbows, knees. Be sure to answer for both the left and right sides.

Have the screenee wait a moment while you mark 26a through 26c questions regarding "Yes" answers to 26. Tell the participant: "We are nearly done with the interview. Please hold for a minute. I'll be right with you."

- 26a. Are there three or more "Yes" responses to Questions #24, 25, and 26? If so, place a "1" in the box to the left of the question.
- 26b. Is there at least one "Yes" response for any wrist or finger in Question #26? If so, place a "1" in the box to the left of the question.
- 26c. Is LEFT and RIGHT marked for any one of the joint categories, i.e., wrist, finger(s), elbow, or knee in Question #26? If so, place a "1" in the box to the left of the question.
27. Blood test for rheumatoid arthritis. Ask the screenee if they ever had a blood test for rheumatoid arthritis, and if so, what was the result of the test. If the test was positive, place a "1" in the box to the left of the question.
28. Rheumatoid arthritis score. Add the numbers in the boxes in the left-hand margin of page 9 of the form (to the left of Questions #24 through #27). Record the total score on Question #28. If the number is greater than or equal to 4, mark "Yes." "Yes," indicates that the screenee is ineligible. Go to Box B on page 10 of the Telephone Screen and mark NOT ELIGIBLE.
29. 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" by putting an "X" in the appropriate box. 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.

The next three questions are for the interviewer. Tell the screenee: "We are nearly done with the interview. Please hold for a minute. I'll be right with you."

30. "Don't know" answer to Question #17. If the screenee didn't know whether they had cancer or what kind of cancer they had, mark "Yes" to Question #30. The screenee is POTENTIALLY ELIGIBLE (mark in Box B).
31. "Yes" or "Don't know" answer to Question #20. If the screenee didn't know or answered "Yes" to Question #20, the Recruitment Coordinator will later decide if they are eligible to be in the study; mark Question #31 "Yes" and mark POTENTIALLY ELIGIBLE IN Box B.
32. Confirmation of eligibility. If there are any other reasons that you think the Recruitment Coordinator should confirm eligibility, mark Question #32 "Yes" and mark POTENTIALLY ELIGIBLE IN Box B.

3.52 Final eligibility determination

Questions #11 through #32 in the Telephone Screening Interview assess eligibility for MOST. Each of the eligibility questions in the telephone screen has "NOT ELIGIBLE" written next to a response which would make the screenee ineligible for participation in MOST. If the screenee's response to any of the questions has "NOT ELIGIBLE" written next to the box, then they are ineligible for the study.

It is critical to review every question carefully to determine whether the screenee is ineligible on any of the eligibility questions.

If the screenee is ineligible, mark "NOT ELIGIBLE" by putting an "X" in Box B and skip to section 4.3 in this chapter.

4. Scheduling clinic visits for eligible screenees

If the screenee's responses to all eligibility questions make them eligible for participation in MOST, mark "Yes" by putting an "X" in the ELIGIBLE box in Box B. Schedule a clinic visit.

4.1 Screenee is eligible and agrees to schedule a clinic visit

Screenee agrees to schedule clinic visit. If the screenee agrees to schedule an appointment for a clinic visit, clearly record the appointment date and time in the space provided in Box B of the Telephone Screening Interview Form.

Clinic visits should be scheduled within 5 weeks of the telephone screen (*ideally, within 3 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 clinic visit does not take place within a 90-day period, the Telephone Screening Interview has to be repeated. An e-mail that includes the Screening 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, delete the original telephone

screening interview from the data system, use the same Screening ID# and acoustic for the repeat screen, then enter the new Telephone Screening Interview into the data system.

Tell the screenee that they will be receiving a consent form and questionnaire in the mail. They will be asked to not eat for 8 hours before their clinic visit and will be asked to bring in the completed questionnaire.

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 clinic visit. The visit will last approximately 5 hours and will consist of questions about their health, medical history, and activities; and there will be physical performance tests, x-rays, and other tests. Tell them that they will be receiving a questionnaire and consent form in the mail. Thank the screenee for their time and effort, and their participation in this important study.

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

If the screenee refuses to schedule a clinic visit at this time, mark "NOT INTERESTED" by putting an "X" in the "NOT INTERESTED" Box in Box B of the Telephone Screening Interview form, 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 clinic 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 clinic 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 clinic visit

a) 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 MOST.

b) If the screenee is ineligible after the telephone screen:

Mark NOT ELIGIBLE in Box B of the Telephone Screening Interview form:

- 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 clinic visit reminder

Once the screening interview is complete, but before you hang up the telephone with the screenee, review the form to make sure that all questions have been filled out carefully and completely.

Bookkeeping 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 clinic visit, the date and time recorded in Box B on the Telephone Screening Interview form should also 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 clinic 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. Scanning the Telephone Screening Interview form

As mentioned above, completed Telephone Screening Interview forms should be scanned as soon as possible, but ideally no longer than 1 to 2 days after completion.

We recommend that incomplete forms, such as those with information pending, not be scanned, but kept in a separate “Pending” file (indexed by name). Once the missing information is obtained, the completed Telephone Screening Interview form should be scanned as soon as possible.

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
 - Interviewing Guidelines
 - Telephone Screening
- Read MOST materials sent out to screenees
 - Brochure
 - 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.

- Observation and evaluation of two *mock* phone screens using the Telephone Screening Interview (at least one mock interview should be observed by the QC Coordinator or their designate).
- Observation and evaluation of one *actual* phone screen by the QC Coordinator or their designate.

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 MOST study
- Correctly obtains demographic information
- Correctly assesses whether participant is in the right age range to be in the study
- Potential eligibility correctly assessed regarding age and weight (Question #11)
- Correct response option chosen for Box A (based on asterisked potentially eligible responses)
- Follows skip patterns in questionnaire
- Reads script and questions exactly as written on the Telephone Screening Interview (same order, same wording)
- Accurately records participant's responses on telephone screen interview form
- Explains pause(s) necessary for interviewer to complete form
- Accurately determines eligibility
- 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 scannable forms
- At the end of interview, reviews telephone screen for completeness

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
- Focuses participant's attention on questions while always being polite
- Treats participants with respect
- Maintains a professional and friendly manner; leaves participant with overall feeling of well-being

Appendix A Telephone Screening Interview


 2804

Telephone Screening Interview


MOST

Screening ID #	Acrostic	Date Interview Completed	Staff ID#
<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> / <input type="text"/> <input type="text"/> <input type="text"/> <small>Month Day Year</small>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Thank you for your interest in the **MOST** study.

MOST is short for Multi-center Osteoarthritis Study. This is a university research study that will help us learn how physical activities, weight, and diet affect knee pain and knee arthritis. Information gathered in this study may help us to better understand how to prevent and treat arthritis. You don't need to have arthritis or joint pain to participate. This study is open to men and women between the ages of 50 and 79. This study will not involve taking any medications or changing your eating or exercise habits. **MOST** will last 3 years and will require two or three clinic visits in [Iowa City] [Birmingham].

How did you hear about the **MOST** study? *(Interviewer Note: Mark all that apply.)*

<input type="radio"/> Brochure <input type="radio"/> Doctor <input type="radio"/> Flyer <input type="radio"/> Friend/family <input type="radio"/> Mail <input type="radio"/> Newspaper	<input type="radio"/> Radio advertisement <input type="radio"/> Television <input type="radio"/> Other <i>(Please specify: _____)</i> <input type="radio"/> Don't know/Don't remember <input type="radio"/> Refused
---	---



Telephone Screening Interview

Screening ID #	Acrostic														
<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> </table>									<table border="1"> <tr> <td> </td><td> </td><td> </td><td> </td><td> </td><td> </td> </tr> </table>						
<i>Office Use Only</i>															



7. How old are you? years

Is the participant at least 50 and not more than 79 years old?

Yes

No

NOT ELIGIBLE.
Complete Box B.

8. Confirm gender, male or female Male Female

9. Do you consider yourself to be Hispanic or Latino?
 Yes No Don't know/Refused

10. What is your racial background? *(Interviewer Note: Mark one response option.)*

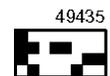
White or Caucasian More than one race *(Please specify: _____)*

Black or African American *(_____)*

Asian Other *(Please specify: _____)*

American Indian or Alaskan Native Don't know/Refused

Hawaiian or Other Pacific Islander




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MOST

15. Have you ever had knee replacement surgery, where all or part of the joint was replaced?

- Yes No Don't know/Refused

15a. Which knee was replaced?

Right knee only Left knee only Both knees

NOT ELIGIBLE.
 Complete Box B.

15b. Are you considering having knee replacement surgery in your other knee in the next 12 months?

Yes No Don't know

NOT ELIGIBLE.
 Complete Box B.

Go to Question #17.

16. Are you considering having knee replacement surgery in the next 12 months?

- Yes No Don't know/Refused

16a. Which knee are you considering for knee replacement surgery?

Right knee only Left knee only Both knees

NOT ELIGIBLE.
 Complete Box B.

17. In the past three years, have you been treated for cancer or been told by a doctor that you had cancer or a malignant tumor?

- Yes No Don't know Refused

Go to Question #17a.

Go to Question #18.

Refer to Recruitment Coordinator.
 Go to Question #18.

NOT ELIGIBLE.
 Complete Box B.

♦ Page 5 ♦

MOST T4_Telephone Int
Version 1.3 3/1/2003

39018

Telephone Screening

Version 1.0p
May 2009



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Telephone Screening Interview

17a. Please tell me what type of cancer you had.
(Interviewer Note: Don't read list; Mark all that apply.)

- Acute Leukemia → NOT ELIGIBLE. Complete Box B.
- Brain → NOT ELIGIBLE. Complete Box B.
- Breast → Go to Question #17b
- Cervical → Go to Question #17b
- Chronic Leukemia → NOT ELIGIBLE. Complete Box B.
- Colon → Go to Question #17b
- Esophagus → NOT ELIGIBLE. Complete Box B.
- Liver → NOT ELIGIBLE. Complete Box B.
- Lung → NOT ELIGIBLE. Complete Box B.
- Lymphoma → NOT ELIGIBLE. Complete Box B.
- Melanoma → NOT ELIGIBLE. Complete Box B.
- Multiple Myeloma → NOT ELIGIBLE. Complete Box B.
- Pancreas → NOT ELIGIBLE. Complete Box B.
- Prostate → Go to Question #17b
- Rectal → Go to Question #17b
- Skin
- Melanoma → NOT ELIGIBLE. Complete Box B.
- Nonmelanoma → Go to Question #18
- Stomach → NOT ELIGIBLE. Complete Box B.
- Uterine → Go to Question #17b
- Other *(Please specify: _____)* → Go to Question #17b.

17b. Did you receive radiation treatment and/or chemotherapy for cancer?
(Interviewer Note: Tamoxifen for breast cancer is not chemotherapy)

- Yes → NOT ELIGIBLE. Complete Box B.
- No
- Don't know/Refused → NOT ELIGIBLE. Complete Box B.

17c. Was cancer removed by surgery?

- Yes or "Watchful Waiting" for prostate cancer
- No → NOT ELIGIBLE. Complete Box B.
(Exception: "Watchful Waiting" for prostate cancer.)
- Don't know/Refused → NOT ELIGIBLE. Complete Box B.



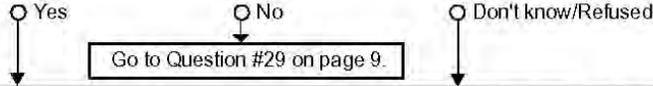


Screening ID #	Acrostic
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Telephone Screening Interview

22. Has a doctor ever told you that you have Rheumatoid Arthritis?



23. Have you ever taken any of the following doctor-prescribed medications for Rheumatoid Arthritis?

<p>a. Methotrexate (meth-oh-TREKS-ayt)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>b. Plaquenil (PLAK-wen-ill) also called Hydroxychloroquine (hy-drox-ee-KLOR-oh-kwin)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>c. Enbrel (EN-brel) also called Etanercept (eh-TAN-er-sept)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>d. Remicade (REM-i-kade) also called Infliximab (in-FLIX-ih-mab)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>e. Arava (uh-RAHV-uh or uh-RAVE-uh) also called Lefunomide (teh-FLOON-oh-myd)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>f. Gold shots or pills</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>g. Prednisone/steroids-glucocorticoids (PRED-nih-sohn) (GLOO-koh-kor-tih-koyd)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>h. Sulfasalazine (sul-fah-SAL-ah-zeen)</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>
<p>i. Kineret (KIN-a-ret) also called anti-IL1RA</p>	<p><input checked="" type="radio"/> Yes →</p> <p><input type="radio"/> No</p> <p><input type="radio"/> Don't know</p>	<p>NOT ELIGIBLE. Complete Box B.</p>





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Telephone Screening Interview

24. In the morning, have you ever had joint stiffness in any joints lasting at least one hour?
 Yes No Don't know/Refused

← 24a. Did you have this morning stiffness for more than 6 weeks?
 Record 1 Yes No Don't know

← 25. Have you ever had nodules or bumps under the skin around the elbow or ankle?
 Record 1 Yes No Don't know/Refused

26. Have you ever had swelling in any of the following joints lasting more than 6 weeks?

	<u>LEFT</u>	<u>RIGHT</u>
i.) Wrist?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused
ii.) Any finger or thumb? (not joint closest to fingernail)	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused
iii.) Elbow?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused
iv.) Knee?	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused	<input type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Don't know/Refused

Interviewer Script: "We are nearly done with the interview. Please hold for a minute. I'll be right with you."

← 26a. Interviewer: Are there 3 or more "Yes" responses to Questions #24a, #25, and #26?
 Record 1 Yes No

← 26b. Interviewer: Is there at least one "Yes" response for any wrist or finger in Question #26?
 Record 1 Yes No

← 26c. Interviewer: Is LEFT and RIGHT marked "Yes" for any one of the above joint categories, i.e.,
 Record 1 wrist, finger(s), elbow, or knee in Question #26? Yes No

27. Have you ever had a blood test for Rheumatoid Arthritis?
 Yes No Don't know/Refused

← What was the result?
 Record 1 Positive Negative Don't know

TOTAL SCORE FOR QUESTIONS #24a THROUGH #27: (Add total from boxes above)

28. Is the TOTAL SCORE greater than or equal to 4? Yes No
 Total Score

NOT ELIGIBLE.
Complete Box B.





Telephone Screening Interview

Screening ID #	Acrostic

Office Use Only



29. Are you planning to move out of the area in the next three years?

Yes No Don't know/Refused

NOT ELIGIBLE.
Complete Box B.

STAFF USE ONLY

(Interviewer Note: Complete these questions to determine eligibility.)

"We are nearly done with the interview. Please hold for a minute. I'll be right with you."

30. Did screenee answer "Don't know" to Question #17?

Yes No

Mark POTENTIALLY ELIGIBLE
in Box B.

31. Did screenee answer "Yes" or "Don't know" to Question #20?

Yes No

Mark POTENTIALLY ELIGIBLE
in Box B.

32. Are there any other reasons why you think the Recruitment Coordinator should confirm eligibility?

Yes No

Mark POTENTIALLY ELIGIBLE
in Box B.

Box B

POTENTIALLY ELIGIBLE

"Thank you for your time and for answering questions. You may be eligible for the MOST study. I need to confirm your eligibility. Someone from our office will be calling you back soon to let you know if you are eligible, and if so, to set up a study visit. Goodbye."
(Interviewer Note: Refer to Recruitment Coordinator.)

ELIGIBLE

"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 this study."
(Interviewer Note: Read text from card about study visits.)

Appointment scheduled **Date:** _____ **Time:** _____

Call back for appointment **Date:** _____ **Time:** _____

NOT ELIGIBLE

"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."

NOT INTERESTED

"Can you tell me the reason you are not interested in participating?"
(Interviewer Note: Don't read list; Mark all that apply.)

- No time/too busy
- Too much trouble
- Illness (self)
- Illness (family member)
- Afraid of potential medical finding during clinic visit
- Don't like doctors/health care professionals
- Concerned about radiation exposure
- Concerned about pain/discomfort during clinic visit
- Refused
- Other *(Please specify: _____)*

"Thank you for your time and for answering our questions. Goodbye."



Appendix B 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	_____
___/___/___	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 C Telephone Screen suggested script

Hello, my name is _____, calling from the _[UI][UAB]___ for the MOST study.

May I please speak with _____?

(If the person is available)

I'm calling from the University of Alabama/Iowa for the MOST study.

Recently, we received a [message][postcard] stating that you are interested in the MOST 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 MOST study.

MOST is short for Multi-center Osteoarthritis Study. This is a university research study that will help us learn how physical activities, weight, and diet affect knee pain and knee arthritis. Information gathered in this study may help us to better understand how to prevent and treat arthritis. You don't need to have arthritis or joint pain to participate. This study is open to men and women between the ages of 50 and 79. This study will not involve taking any medications or changing your eating or exercise habits. MOST will last 3 years and will require two or three clinic visits in [Iowa City][Birmingham].

To determine whether you are eligible for the study, I need to ask you a few questions. Optional: Are there other people in your household who are between the ages of 50 and 79 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 brochure to the household member.*

(Go to Question #1 of Telephone Screening Interview Form.)

IF REFUSES TELEPHONE SCREEN: *Refer to Response C (see page 29)*

IF NOT ELIGIBLE AFTER TELEPHONE SCREEN: *Refer to Response B (see page 29)*

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 study."

This is a 3-year study funded by the National Institute on Aging. It is being done in two clinics in the United States – one here in Iowa City and the other is in Birmingham, Alabama. 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 why people develop knee osteoarthritis and whether physical activities, weight and other factors affect knee pain and the progression of the disease. If you decide to participate in this study, you will be asked to attend two or three clinic visits in [Birmingham][Iowa City] over the next 3 years.

There will be a number of tests and measurements and questionnaires to complete at your first visit. You will have basic measurements such as height and weight, blood pressure and pulse. You will have a fasting blood draw, knee x-rays, an MRI and bone density measurements. You will also have a hand exam and possibly a knee and hip exam. 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 measurements. These are all described in the study consent form that we will send to you with your appointment reminder letter. This visit will last about 5 hours.

After you have been enrolled in the study for 18 months, you will have a telephone visit to find out about whether you are having any new knee or hip symptoms. You will also receive a questionnaire sent to you to complete and return to us by mail.

Everyone will be asked to attend the final study visit after participating in the study for 3 years. We will repeat some of the tests and measurements you had at the first visit.

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 first study visit. 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 consent form and a questionnaire in the mail. You will also be receiving a letter describing how to prepare for your clinic visit. You will need to fast for the blood test at this appointment. Please do not eat anything or drink anything other than water for 8 hours prior to your appointment. You may drink lots of water, and take any medications, but not vitamins. Don't drink any other beverage or eat any food after midnight the night before your appointment.

We would also like for you to bring all of your medications with you to this appointment. Please bring a bag with the bottles for all prescription and non-prescription medications (including vitamins and supplements). The examiner will need the bottles to record the spelling and dosage information.

Do you have any questions for me about any of this? Well, I have you scheduled for _____. You will receive a reminder letter about a week or two before that date. Please call me if you think of any questions after we hang up. My name is _____ and our phone

number is 319-384-5055 or toll-free, 1-800-348-4692. 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 CLINIC 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 Box B in 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. Thanks 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 D Answers to possible questions

Question: How is the MOST Study special?

Response: As we age, the cartilage that cushions our joints sometimes becomes worn out and our knees, hands, or hips bother us. The goals of the MOST Study are to find clues as to how physical activities, strength, and weight might relate to disability. In the last few years, the methods to measure cartilage, bone, and strength have improved tremendously. This is one reason why the study is special.

Another reason is our emphasis on knee problems. MOST takes a comprehensive look at possible causes of osteoarthritis of the knee. This is one of the unique aspects of MOST.

Question: I don't know. Three years is a long time to do anything. I might not be around at the end.

Response: Three years is a long time. We realize that all kinds of things could happen. However, we still want you and will be grateful for as much participation as you are willing to give.

Question: How often will I have to come to the clinic?

Response: You will be asked to come into the clinic two or three times in 3 years. In addition, we will call you a year and a half after your first clinic visit.

Question: Will I be paid to participate?

Response: No, you will not be paid to participate. However, a number of tests that could be useful to your doctor will be done for free.

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.

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 and bone density tests. These results will be available right away.

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.

Question: Can I still be in the study if I don't want x-rays? I don't like to take extra x-rays.

Response: X-rays are our way to measure the condition of your knee joints. We need this information to look at changes over the next three years. This is the only test that MOST participants must have to be in the study.

Question: Does the bone density measure involve radiation?

Response: Yes, but the amount of radiation is very small, less than one chest x-ray.

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 E 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 Institutional Review Board and the National Institutes of Health.