

**RECRUITMENT AND SAMPLING**

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## 1. Introduction

We will enroll of two cohorts for longitudinal study: approximately 1,500 returning participants from the original MOST cohort, and recruitment of 1,500 participants into a new cohort approximately equally distributed between the two MOST clinical sites in Birmingham, AL and Iowa City, IA. Potential participants in both cohorts will be administered a screening telephone interview to determine interest in enrollment and eligibility. The new cohort will also attend an in-clinic screening to determine eligibility.

Existing cohort recruitment, mainly through mass mailings, was conducted 2003-5 with 3,026 participants enrolled (1,507 Iowa; 1,519 Alabama). Each center recruited a stratified sample by decile of age and gender according to their proportion of the U.S. population age 50-79 years, and by racial/ethnic minority status according to their representation in the recruitment area communities. Of the 3,026 participants enrolled in the existing cohort, 19 (8 UAB and 11 UI) were of Hispanic ethnicity and 464 (453 UAB; 11 UI) were African American.

The new cohort will consist of subjects without knee OA or with early stage knee OA, when prevention and treatment opportunities are more likely to offer success. The new cohort will consist of 1,200 subjects with no or only mild radiographic knee OA but with knee pain, aching or stiffness in the past 30 days at baseline and 300 participants with no or only mild radiographic knee OA without knee symptoms in the previous 30 days. (See Appendix E for detailed eligibility criteria of both cohorts.)

## 2. Sampling plan

Both clinical centers have dedicated staff for successful recruitment of a diverse community-based participant population. The clinics will again use mass-mailings from existing population-based databases (e.g., driver license and voter registration listings) to recruit a new cohort of 1,500 participants (approximately 750 at each center) stratified by gender and by decile of age according to their proportion of the U.S. population age 45-69 years. The racial/ethnic minorities' status of participants will over-represent their prevalence in the recruitment area communities. For Hispanic participants the goal is 8% (60 participants) at UAB and 10% (80 participants) at UI, and for African Americans th goal of 40% (300 participants) at UAB and 5% (37 participants) at UI.

**Table 1. US CENSUS Bureau report: population by Age and Sex: 2012** (used for calculation).

Age	Both sexes (100%)	Male (48.3%)	Female (51.7%)
	Percent	Percent	Percent
All ages 45 to 69 years	100%	100%	100%
45 to 49 years	22.6%	23.0%	22.3%
50 to 54 years	23.4%	23.7%	23.2%
55 to 59 years	21.4%	21.4%	21.4%
60 to 64 years	18.3%	18.0%	18.7%
65 to 69 years	14.2%	14.0%	14.4%

**Table 2. University of Alabama at Birmingham Recruitment Goals (# of participants)**

Age	All	By Race/Ethnicity			By Gender/Sex		By knee Pain	
		Non-Hispanics		Hispanics	Men	Women	Pain	No Pain
		White or Other	African American					
45 to 49	170	87	69	14	83	87	136	34
50 to 54	176	92	70	14	86	90	141	35
55 to 59	161	84	64	13	77	84	129	32
60 to 64	138	72	55	11	65	73	110	28
65 to 69	105	55	42	8	51	54	84	21
<b>TOTAL</b>	<b>750</b>	390	300	60	362	388	600	150

**Table 3. University of Iowa Recruitment Goals (# of participants)**

Age	All	By Race/Ethnicity			By Gender/Sex		By knee Pain	
		Non-Hispanics		Hispanics	Men	Women	Pain	No Pain
		White or Other	African American					
45 to 49	170	143	9	18	83	87	136	34
50 to 54	176	150	8	18	86	90	141	35
55 to 59	161	136	8	17	77	84	129	32
60 to 64	138	116	7	15	65	73	110	28
65 to 69	105	88	5	12	51	54	84	21
<b>TOTAL</b>	<b>750</b>	633	37	80	362	388	600	150

**3. Initial contacts to potential participants**

**3.1 Targeted mass mailings**

The clinical centers will employ a major direct mail campaign to people in the target age group. Age-eligible people are identified through a variety of sources: HMO membership databases, voter registration tapes, commercial list brokers, etc. These sources usually include name, address, age, sex, and may include ethnicity and race. In addition to these general sources of age-eligible people, the clinics have identified several other enriched sources of participants.

**3.2 Community promotion**

Both clinical centers have identified the organizations, agencies, group residences, etc. that have older adults as their clientele. Arrangements can be made to address these groups and solicit participation.

### **3.3 Mass media**

Both centers plan to use the media (newspapers, radio advertisements, television) for informing the community as described above, and for requesting volunteers for the study.

### **4. Tracking contacts**

Each field center will be responsible for devising a system for tracking contacts made to potential participants. Such a system could include the use of a contact log as a worksheet that can be attached to a potential participant's file and notations made each time any type of contact is initiated. The contact log would also provide information about individual interviewer's efforts to contact potential participants. The contact log is not entered into a database; it is a clinic worksheet. (Labels including name and address may be generated and printed and stuck on individual contact logs). An example of such a contact log is included as Appendix B.

### **5. Recruitment reports**

The clinical sites will complete a Recruitment Activity Report (Appendix C) each week and send it (either via the web) to the Coordinating Center.

The coordinating center will generate Recruitment and Eligibility Reports (Appendix D) and post these on the website for the clinical sites and the project office.

Appendix A Recruitment Brochure  
UAB Brochure

Are you concerned about your bone and joint health?



Join a bone and joint health research study today!



This is a research study about how physical activities and other factors affect the health of your bones and joints.

You may qualify if you:

- Are between the ages 45-69
- Do not have rheumatoid arthritis
- Have not had knee replacement surgery

**CALL TODAY!**

Please share with friends and family!

**UAB** THE UNIVERSITY OF ALABAMA AT BIRMINGHAM  
Division of Preventive Medicine  
MT 513, 1720 2nd Ave S  
Birmingham, AL 35294-4410

Call XXX-XXX-XXXX for more information!

U-Iowa Brochure

Are you concerned about your bone and joint health?



Join a bone and joint health research study today!



This is a research study about how physical activities and other factors affect the health of your bones and joints.

You may qualify if you:

- Are between the ages 45-69
- Do not have rheumatoid arthritis
- Have not had knee replacement surgery

**CALL TODAY!**

Please share with friends and family!



COLLEGE OF PUBLIC HEALTH  
Department of Epidemiology  
2405 Iowacrest Drive  
Iowa City, Iowa 52240  
1-800-814-9535  
319-384-5064

Visit us at: [www.PICstudies.com](http://www.PICstudies.com)

Call 800-814-9535 for more information!

Appendix B Sample 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 C MOST Recruitment Activity Report

**MOST Recruitment Activity Report**

*Submit form by Tuesday for recruitment activities for the previous week (Sunday through Saturday).*

**For the period:** \_\_\_\_ / \_\_\_\_ / \_\_\_\_ **through** \_\_\_\_ / \_\_\_\_ / \_\_\_\_

**Clinical site (check one):**

**University of Alabama at Birmingham**       **University of Iowa**

**Staff ID number:** \_\_\_\_\_

**Brochures mailed:** \_\_\_\_\_

**Brochure reply cards received:** \_\_\_\_\_

**Incoming new calls:** \_\_\_\_\_

**Community Outreach:**

1. **Presentations** \_\_\_\_\_  
    • **Attendees at the presentations** \_\_\_\_\_

2. **Print ads** \_\_\_\_\_  
    • **Newspaper** \_\_\_\_\_  
    • **Newsletters** \_\_\_\_\_

3. **Posters** \_\_\_\_\_

4. **Electronic media** \_\_\_\_\_  
    • **Public service announcements radio** \_\_\_\_\_  
    • **Public service announcements TV** \_\_\_\_\_  
    • **Radio ads** \_\_\_\_\_  
    • **Other** \_\_\_\_\_

5. **Other activities** \_\_\_\_\_

**Comments:**  
\_\_\_\_\_

**Number of screening visits scheduled:** \_\_\_\_\_

**SUBMIT**

**RESET**



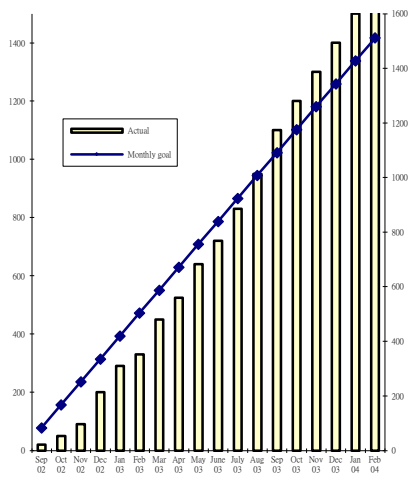
Appendix D MOST Recruitment and Eligibility Reports

Table 1 (Both Clinics) Eligibility and recruitment by Age category

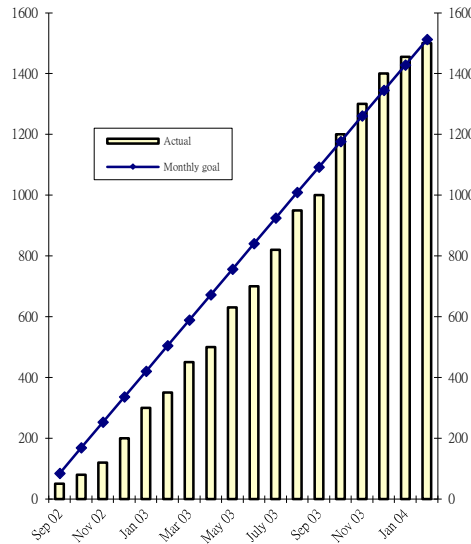
Status	Age/Clinic											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	UAB	UIOWA	UAB	UIOWA	UAB	UIOWA	UAB	UIOWA	UAB	UIOWA	UAB	UIOWA
Screened	70	70	60	60	60	60	60	60	60	60	310	310
Eligible	20	20	20	20	20	20	20	20	20	20	100	100
Enrolled	10	10	10	10	10	10	10	10	10	10	50	50
% of screened	14%	14%	17%	17%	17%	17%	17%	17%	17%	17%	16%	16%
Goal	170	170	176	176	161	161	138	138	105	105	750	750
% of goal completed	6%	6%	6%	6%	6%	6%	7%	7%	10%	10%	7%	7%

Chart 1. Monthly recruitment effort report

Univ of Iowa Cumulative Monthly Recruitment Goal vs Actual



UAB Cumulative Monthly Recruitment Goal vs Actual



**Table 2A (UAB clinic) Eligibility and recruitment by Age and Sex**

Status	Age/Sex (M=Men; W=Women)											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	M	W	M	W	M	W	M	W	M	W	M	W
Screened	30	40	30	30	30	30	30	30	30	30	150	160
Eligible	10	10	10	10	10	10	10	10	10	10	50	50
Enrolled	5	5	5	5	5	5	5	5	5	5	25	25
% of screened	17%	13%	17%	17%	17%	17%	17%	17%	17%	17%	17%	16%
Goal	83	87	86	90	77	84	65	73	51	54	362	388
% of goal completed	6%	6%	6%	6%	6%	6%	8%	7%	10%	9%	7%	6%

**Table 2B (UAB clinic) Eligibility and recruitment by Age and Race/Ethnicity (minority groups only)**

Status	Age/Race (AA=African American) or Ethnicity (Hisp=Hispanics)											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp
Screened	15	20	15	15	15	15	15	15	15	15	75	80
Eligible	5	8	5	8	5	8	5	8	5	8	25	40
Enrolled	3	2	3	2	3	2	3	2	3	2	15	10
% of screened	20%	10%	20%	13%	20%	13%	20%	13%	20%	13%	20%	13%
Goal	69	14	70	14	64	13	55	11	42	8	300	60
% of goal completed	4%	14%	4%	14%	5%	15%	5%	18%	7%	25%	5%	17%

**Table 2C (UAB clinic) Eligibility and recruitment by Age and Knee pain**

Status	Age/Clinic											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain
Screened	30	40	30	30	30	30	30	30	30	30	150	160
Eligible	10	10	10	10	10	10	10	10	10	10	50	50
Enrolled	5	5	5	5	5	5	5	5	5	5	25	25
% of screened	17%	13%	17%	17%	17%	17%	17%	17%	17%	17%	17%	16%
Goal	136	34	141	35	129	32	110	28	84	21	600	150
% of goal completed	4%	15%	4%	14%	4%	16%	5%	18%	6%	24%	4%	17%

**Table 3A (U-Iowa clinic) Eligibility and recruitment by Age and Sex**

Status	Age/Sex (M=Men; W=Women)											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	M	W	M	W	M	W	M	W	M	W	M	W
Screened	30	40	30	30	30	30	30	30	30	30	150	160
Eligible	10	10	10	10	10	10	10	10	10	10	50	50
Enrolled	5	5	5	5	5	5	5	5	5	5	25	25
% of screened	17%	13%	17%	17%	17%	17%	17%	17%	17%	17%	17%	16%
Goal	83	87	86	90	77	84	65	73	51	54	362	388
% of goal completed	6%	6%	6%	6%	6%	6%	8%	7%	10%	9%	7%	6%

**Table 3B (U-Iowa clinic) Eligibility and recruitment by Age and Race/Ethnicity (minority groups only).**

Status	Age/Race (AA=African American) or Ethnicity (Hisp=Hispanics)											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp	AA	Hisp
Screened	7	10	7	7	7	7	7	7	7	7	35	38
Eligible	4	2	4	2	4	2	4	2	4	2	20	10
Enrolled	3	1	3	1	3	1	3	1	3	1	15	5
% of screened	43%	10%	43%	14%	43%	14%	43%	14%	43%	14%	43%	13%
Goal	9	18	8	18	8	17	7	15	5	12	37	80
% of goal completed	33%	6%	38%	6%	38%	6%	43%	7%	60%	8%	41%	6%

**Table 3C (U-Iowa clinic) Eligibility and recruitment by Age and Knee pain**

Status	Age/Knee pain											
	Age 45 to 49		Age 50 to 54		Age 55 to 59		Age 60 to 64		Age 65 to 69		All ages	
	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain	Pain	No pain
Screened	30	40	30	30	30	30	30	30	30	30	150	160
Eligible	10	10	10	10	10	10	10	10	10	10	50	50
Enrolled	5	5	5	5	5	5	5	5	5	5	25	25
% of screened	17%	13%	17%	17%	17%	17%	17%	17%	17%	17%	17%	16%
Goal	136	34	141	35	129	32	110	28	84	21	600	150
% of goal completed	4%	15%	4%	14%	4%	16%	5%	18%	6%	24%	4%	17%

## Appendix E Existing and New Cohort Eligibility Criteria (Taken from the MOST Study Protocol, Section)

### 3.2. Population

#### 3.2.a. Existing cohort

Surviving participants in the original cohort who have not withdrawn consent will be eligible and contacted by mail and telephone, and invited to participate. Of the 3,026 participants enrolled from 2003-5, we anticipate that approximately 1,500 surviving participants will be enrolled in the new study. The estimate is based on approximately 80% participation rate among the 1,890 subjects who attended the 84-month follow-up clinic visit and are eligible for the new study.

The existing cohort will be age 62-91 years, average age approximately 71 years, at the start of this study. This cohort will consist of participants who already have symptomatic knee OA, in many cases advanced disease, or who had risk factors at the start of MOST but have not developed symptomatic knee OA.

#### 3.2.a.i. Inclusion and Exclusion Criteria

##### Inclusion criteria

- Surviving member of MOST cohort (enrolled 2003-2005)
- Willing to participate in the clinic examinations and/or telephone interviews

##### Exclusion criteria

- Not competent to give informed consent

#### 3.2.a.ii. Recruitment

Existing cohort recruitment, mainly through mass mailings, was conducted 2003-5 with 3,026 participants enrolled (1,507 Iowa; 1,519 Alabama). Each center recruited a stratified sample by decile of age and gender according to their proportion of the U.S. population age 50-79 years, and by racial/ethnic minority status according to their representation in the recruitment area communities. Of the 3,026 participants enrolled in the existing cohort, 19 (8 UAB and 11 UI) were of Hispanic ethnicity and 464 (453 UAB; 11 UI) were African American.

In this study, surviving participants in the existing cohort will be contacted by telephone to determine interest in enrollment for two additional visits and two interim telephone contacts. Those who do not wish to come in for clinic visits and those with bilateral total knee replacements will be asked if they wish to continue to be followed by phone for key outcomes using the standard MOST "Missed Clinic Visit Follow-up Interview." (See Appendix A). Refer to the Telephone Interview procedures manual for instructions about how to proceed with participants with cognitive impairment as determined by the 5-minute Montreal Cognitive Assessment (MoCA) [9].

#### 3.2.b. New cohort

The new cohort will consist of subjects without knee OA or with early stage knee OA, when prevention and treatment opportunities are more likely to offer success. The new cohort will consist of 1,200 subjects with knee pain, aching or stiffness at baseline and 300 participants without any knee symptoms in the previous 30 days.

Participants with knee pain (1,200 participants, 600 per clinic)

- Pain aching or stiffness in one or both knees in the past 30 days, with neither knee having constant pain that is of severe or greater intensity

Participants with no knee pain (300 participants, 150 per clinic)

- Both knees without any knee pain, aching, or stiffness in the previous 30 days

Radiographic knee OA in participants with, and without, knee pain

- Both knees with KL grades of radiographic OA of 0, 1, or 2 in the tibiofemoral (TF) and patellofemoral (PF) compartments

### 3.2.b.i. Inclusion and Exclusion Criteria

We will recruit a community-based sample of 1,500 men and women aged 45-69 years of age with the knee pain and radiographic knee OA characteristics described above. As with the existing cohort, enrollment targets will be stratified by gender and by decile of age according to their proportion of the U.S. population age 45-69 years. Participants will be without any serious health conditions or plans to relocate that would likely limit their follow-up to less than 2-3 years.

#### Inclusion Criteria: Determined During Telephone Screen Interview

- 1,200 participants who answer “Yes” for one or both knees to the question: “In the past 30 days, have you had any pain, aching, or stiffness in or around your right/left knee?”
- 300 participants who answer “No” for both knees to the question: “In the past 30 days, have you had any pain, aching, or stiffness in or around your right/left knee?”

#### Exclusion Criteria: Determined During Telephone Screen Interview

- Either knee with pain in the past 30 days that is reported as “constant” and described as “severely intense” or “extremely intense”, as determined by questions from the Intermittent and Constant Osteoarthritis Pain (ICOAP) Questionnaire
- Rheumatoid or inflammatory arthritis (based on self-report and use of medications specific to these conditions)
- Serious health condition e.g., end-stage renal disease, etc. that would likely limit follow-up to less than 2-3 years
- Plan to relocate out of geographic region in next 3 years
- Not able to walk without the aid of a person or assistive device
- Knee joint replacement surgery in either knee
- Unwilling or ineligible at baseline to have all four baseline imaging exams (knee x-rays, full-limb x-rays, extremity MRI and CT scan of the knees) and the two 24-month follow-up exams (knee x-rays and extremity MRI scan)
- Not competent to give informed consent

#### Exclusion Criteria: Determined by Knee X-ray Obtained at the Screening Clinic Visit

- Advanced structural tibiofemoral or patellofemoral knee OA disease (KL grade 3 or 4) in either knee.

### 3.2.b.ii. Recruitment

For the new cohort, we will use community-based recruitment as was done for the original cohort.

Both clinical centers have dedicated staff for successful recruitment of a diverse community-based participant population. The clinics will again use mass-mailings from existing population-based databases (e.g., driver license and voter registration listings) to recruit a new cohort of 1,500 participants (approximately 750 at each center) stratified by gender and by decile of age according to their proportion of the U.S. population age 45-69 years, and by racial/ethnic minorities' status according to their representation in the recruitment area communities. In this study we plan to enroll 1,500 participants and over-recruit Hispanic participants with a goal of 8% (60 participants) at UAB and 10% (80 participants) at UI, and over-recruit African Americans with a goal of 40% (300 participants) at UAB and 5% (37 participants) at UI.