

CHAPTER 2

RECRUITMENT ACTIVITIES

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Study Documents Referred to in this Chapter

- Telephone Screening Interview
- SPPB
- Clinic Recruitment Tracking
- Example of Administrative Coordinating Center Recruitment Tracking Report
- Letters to Physicians
- Brochure
- Press Release
- Training Manual
- Phone Consent
- SPPB Consent
- Main Informed Consent
- Site Specific Recruitment Materials

The Cooper Institute

The University of Pittsburgh

Stanford University

Wake Forest University

CHAPTER 2

RECRUITMENT

2.1. Recruitment Strategies

The goal of the study is to enroll 400 total participants across the 4 LIFE field Centers, 100 at each field center. Participants are 70 to 89 years of age and no more than 60% of participants have an EPESE score of 8 or 9 and at least 40% have an EPESE score of 7 or below on the SPPB. The overall goal for minority participation is 25%. The minority target score takes precedence over the score on the SPPB.

2.1.1. General Information

All recruitment related activities are overseen by the Recruitment, Adherence and Retention Committee. The Committee coordinates press and media releases and assists the sites in the preparation of recruitment materials. Each clinical site develops a site-specific recruitment plan to accommodate the variability across centers in catchment area characteristics, media market outlets, and access to older participants. These local recruitment strategies and timelines as well as methods for local monitoring of recruitment yield and training are included in each site specific section beginning with section 2.5. In general, recruitment strategies include the use of radio and television advertisements, direct mail, and presentations at health fairs, senior centers, medical clinics, and churches. Participants in previous studies may also be approached and ineligible participants are asked for friends who might be eligible. All recruitment materials are reviewed by the appropriate field center IRB before being used.

2.1.2. Specific Recruitment Strategies and Tools

A number of specific recruitment strategies and tools are used to recruit volunteers for the study. Because of the unique requirements of study

participants, the primary strategies involve accessing various facilities and community organizations that perform work with seniors with minor disabilities. The Administrative Coordinating Center tracks the various strategies to determine which are most successful at the various sites. (See an example of the Administrative Coordinating Center Report in Appendix A.)

2.1.2.1. Inform the Healthcare Community

A selection of letters to healthcare providers is available to field center recruiters to send to staff, medical clinics, and hospitals informing physicians about the LIFE study. Examples of letters are shown in the Appendix. Brochures describing the study may be included in the letters. Each LIFE field center makes efforts to place brochures in waiting rooms and with physician assistants to give to potential study volunteers.

Each LIFE field center is also urged to make telephone contact with healthcare providers to alert them to these letters and brochures and ask for their assistance in recruiting older adults for this study.

If groups of physicians or healthcare providers are identified as working with a large percentage of potentially eligible older adults, it may be worthwhile for the recruitment coordinator to provide a lunchtime presentation to the office staff about the LIFE study in order to identify office staff that can provide assistance with recruitment.

2.1.2.2. Inform or Prepare Community-at-Large

The LIFE Recruitment Committee prepares a study-wide brochure that can be distributed to the 4 study communities. A draft copy of the brochure is included in the Appendix. Each LIFE field center is urged to identify senior centers, meals-on-wheels programs, visiting nurse associations, veterans administration offices, and civic organizations such as VFWs, LIONS, and ROTARY clubs that may be able to serve as distribution hubs for the study brochures. Grocery

stores, hobby shops, bookstores, and public libraries may also be possible distribution sites within each community.

The Recruitment Committee also prepares press releases for distribution to newspapers, radio stations, and television stations. Each site is urged to contact the public relations department within their institutions to assist in publicizing the study throughout the 9 month recruitment period. An example of a LIFE press release is included in the Appendix B.

2.1.2.3. Inform Potential Participants

Potential participants are informed of the study through presentations at health fairs, church functions, and other community organizations.

Potential participants are also informed of the study throughout the screening steps prior to randomization. This includes:

- A preliminary telephone screen to determine initial eligibility either by telephone or in combination with Informational Orientation sessions.
- The initial assessment of functional abilities where potential participants have the ability to ask additional questions about the study from LIFE clinical staff
- By completing the full informed consent at the first clinic visit, and;
- Asking additional questions about the study at the second clinic visit prior to randomization.

2.1.3. The Recruitment Coordinator Training Manual (RC/TM)

A Recruitment Coordinator Training Manual is developed by the LIFE recruitment committee to provide training to each site's recruitment coordinators on telephone screening procedures. Also, a Frequently Asked Questions Manual (FAQ) will be prepared and updated that will include responses to questions that

potential participants might have about all aspects of the study, which will be included in the Appendix C.

2.2. Recruitment Monitoring and Assistance

All methods of recruitment are documented by the each of the LIFE field centers. During the telephone screening interview, potential participants are asked about where they heard about the study on the telephone prescreening form and this data are used to generate regular reports through the 9 month recruitment period on what method(s) provides the greatest yield of eligible participants. These reports are provided to the Recruitment Committee members on a monthly basis and provide data on number of potential participants screened from each of the recruitment sources, eligible participants from the various recruitment sources, and eligible minority participants from the recruitment sources. This information is transmitted between the field center sites so field centers can learn which methods are most successful and which methods are not worth pursuing.

2.2.1. Recruitment Assistance Program (RAP)

If potential participants have difficulties with transportation for screening visits, each site provides financial assistance to reimburse participant transportation. Also, depending on local IRB practices, some sites may offer a small honorarium to recognize the time and effort for participating in each measurement visit. This includes \$10 for the functional assessment. If a potential participant remains eligible they receive an additional \$20 for the remainder of the first screening visit. At each additional in-person screening visit and follow-up visit they receive \$30.

2.2.2. Overview

Data on recruitment methods, eligibility through each of the screening visits, ethnicity, and gender are collected by each of the LIFE field centers and it is monitored on a regular basis by the Recruitment Committee.

2.2.3. Recruitment Goals

Each of the 4 LIFE field centers recruit 100 men and women between the ages of 70 to 89 years, who have an EPESE score below 10, and who are sedentary. No more than 60% of participants have an EPESE score of 8 or 9 and at least 40% have an EPESE score of 7 or below on the SPPB. Approximately 70% of these participants are women and 25% are ethnic minorities. The minority target takes precedence over the score on the SPPB.

2.2.4. Recruitment Monitoring

Monitoring of recruitment is performed by the local LIFE field centers and the Recruitment Committee.

2.2.4.1. Local Monitoring

Each LIFE field center tracks recruitment yields through all screening visits and reasons for ineligibility. They also track methods used for recruitment in order to determine the most successful strategy for their particular site. They also closely monitor gender and ethnic minority recruitment goals to document best methods for recruiting eligible women and men and ethnic minorities. See Section 2.5 for specific minority recruitment strategies.

2.2.4.2. Central Monitoring

The DMAC Center generates regular reports on recruitment yields for each site through all screening visits. These reports are posted on the study website. They also provide regular reports to each site on recruitment of men and women and ethnic minorities. Graphs are also provided to monitor that each clinical site is meeting monthly recruitment goals of 11 to 13 eligible participants each of the 9 recruitment months. The Administrative Coordinating Center also provides data on best recruitment methods for each site.

2.2.5. Processing and Reporting

All sites perform timely data entry so that the DMAQC Center can generate regular monthly recruitment reports that are monitored by each site's recruitment coordinator and the LIFE Recruitment Committee.

2.2.6. Responses to Recruitment Problems

If centers encounter difficulties in recruitment, the Recruitment and Retention Committee (or a designated subgroup) provides assistance responses that are based on the recruitment shortfall and tailored to the needs of the site. The Recruitment Committee organizes a teleconference to discuss the reasons for the shortfall, and to problem solve methods for increasing the number of eligible participants in the following month. If recruitment continues to fall short in the next month, a subcommittee from Recruitment Committee is convened to discuss the recruitment activities over the past month to develop a targeted set of strategies aimed at improving recruitment yields depending on where individuals are being lost during the screening process. For example, recruitment yields could be lower at one site compared to another because clinic conditions may be more intimidating at one site compared to another. If a site is doing all that it can in terms of contacting sources for potential participants, providing a warm and friendly screening environment in which participants feel welcomed, and performing all screening assessments in a timely manner, and recruitment is still falling short, other sites may be asked to assist in recruiting additional numbers.

2.3. Informed Consent

Informed consent is obtained at all stages of screening: verbal consent is obtained before the telephone prescreening, a short consent to conduct the SPPB, and full main consent at the first clinic screening visit. Consent is obtained and the Informed Consent form is signed before any study procedures are performed. Each participant is given a copy of the signed Informed Consent form. Model examples are shown in the protocol.

2.4. Retention Issues during Screening and Enhancing Motivation

In order to enhance retention of participants through the study screening period, it is important that participants be provided with a copy of their study visit schedule that includes a list of procedures that they complete at each visit. Participants should be reminded by telephone or mail of upcoming visits one week ahead of their scheduled visit and one day ahead of their visit. At each assessment visit, contact information should be verified. Some suggestions for enhancing retention are listed below:

- Try to develop a personal relationship with each participant by asking about their family, friends, and upcoming events.
- Be sure to inquire about these things when participants come back for a return visit.
- Develop a tickler file to send out greeting cards for birthdays and other holiday celebrations.
- If a participant is ill, send a get well card. If a participant dies, send a sympathy card to the family.
- Participants should be introduced to all staff even if they are only working with 1 or 2 staff members.
- Be sure that the participant knows how long each visit takes so they can plan their day and know what to expect at each visit.

Clinic Recruitment Tracking Form

(Complete only if participant has permanently dropped out of the recruiting process.)

Participants may miss an SV1 or SV2 visits for a variety of reasons. It is important for the investigators to understand reasons for missed visits to enhance recruitment efforts by the sites and for the overall study. If a participant cannot complete the SV1 visit within the 45 day window from the date of the telephone prescreening or if they cannot complete an SV2 visit within the 28 day window, clinic coordinators should complete a Clinic Recruitment Tracking Form

(see Appendix). This form does not need to be completed if the participant is within these 2 windows. The Clinic Recruitment Tracking form lists 19 potential reasons for missed visits including: no longer interested, illness/health problems, transportation difficulties, cognitive difficulties, transfer to nursing home, time management conflicts, caregiver responsibilities, physician advice, muscle/joint problems, continued forgetting of the appointment, moved out of the area, traveling, personal problems, unable to contact/locate, refusal to give reason, withdrew from study by withdraw of informed consent, dissatisfaction with study, deceased, or other. The recruitment coordinator should mark only the primary reason given by the participant for not returning for an SV1 or SV2. If additional information is given, e.g. personal problems, dissatisfaction with the study this should be briefly written in the comments section. Clinic recruitment tracking data will be reviewed monthly by the Recruitment, Retention and Adherence Committee.

2.5. Site Specific Recruitment Plans

Each field center develops their specific recruitment plans that have been adapted to their particular recruiting environments using previous successful recruitment strategies. Each site locally monitors recruitment activities, develop methods for problem solving recruitment issues, and meet local IRB requirements for approval of brochures and informed consents. Each site also provides training to recruitment staff on the telephone prescreening instrument, telephone etiquette, customer service techniques aimed at enhancing the participant's experience at each field center, and tips for dealing with difficult participants. These site specific plans are detailed alphabetically below and sample recruitment materials are presented in the Appendix D.

2.5.1. The Cooper Institute Recruitment Plan for the LIFE Study

2.5.1.1. Recruitment Strategies and Timeline

The Cooper Institute recruitment team is planning on incorporating several different strategies to recruit participants for LIFE. The recruitment team already has in place several monthly activities where LIFE can be promoted, i.e. Program of the Month, Newsletters, and a new “Promotoras” group. We also plan to inform the senior community through mailings and talks at senior centers and senior social organizations. We are also planning on sending brochures and flyers to local physicians and health centers that serve primarily senior citizens. We also plan to directly recruit from the patient list of the Hampton Medical Clinic, which serves older, minority individuals. The Cooper Institute has good relationships with several large churches in the Dallas-Fort Worth (DFW) area. We call upon the senior ministries, bible study groups, and Sunday school classes to promote the study through their work. Press releases are sent to local newspapers, such as The Dallas Morning News and the Oak Cliff Tribune. We also plan to advertise in those newspapers. In addition to print media, we plan to do several local radio shows, one specifically targeting the senior market. We do a larger scale mailing to lobbying groups in the area, i.e. AARP, NAACP, and LULAC to ask for participants and help in spreading the word. We also have a recruitment core of individuals who have expressed interest in participating in research studies and we can call upon them to participate in the study.

2.5.1.2. Local Monitoring of Recruitment Activities

The Cooper Institute recruitment team meets on a weekly basis to assess the previous week's activities, problem solve, and set goals for the next week.

2.5.1.3. Local Monitoring of Recruitment Yield and Problem Solving Recruitment Issues

Problem solving takes place during the weekly recruitment team meetings. We monitor the weekly randomization of participants. If the yield is dropping, we plan to increase our efforts in physician offices and media advertising. We also call on our Community Advisory Board for guidance and suggestions.

2.5.1.4. IRB Requirements for Oversight of Recruitment Issues

The Cooper Institute IRB must approve all recruitment materials before put into use. The board meets on a quarterly basis and also has an expedited approval process for recruitment materials.

2.5.1.5. Training of Local Staff Regarding Recruitment Activities

The Cooper Institute recruitment team for LIFE is made up of diverse team who bring different strengths to the committee. _J.W._ coordinates the team, with _R.R._ , _T.S._ , and an intern making up the remainder of the team. All staff working with participants will complete the NIH requirements for insuring patient confidentiality. All staff that are administering phone screens go through a phone screen training conducted by _J.W._. This training encompasses using the phone screen instrument, phone etiquette and tips for dealing with difficult individuals.

2.5.2. University of Pittsburgh

2.5.2.1. Recruitment Strategies and Timeline

The LIFE study recruitment strategy follows the protocol that has been successfully utilized by the Department of Epidemiology for numerous epidemiologic and clinical studies. The Health Studies recruitment office specializes in recruiting at-risk volunteers from the local population. Study participants are recruited from the community using age-appropriate mailing lists. With technical assistance from the Epidemiology Data Center, the recruitment office manages several large computerized population-based lists. Data sources include governmental and purchased public domain lists from various commercial vendors. The study mailing consists of a specially designed brochure with a 1-800 phone number and tear-off return card, a letter of invitation from the Principal Investigator and when available, print media coverage about the study. A clear description of inclusion and exclusion criteria described in the

mailing information has been critical to efficient phone screening and recruitment efforts in our prior studies.

Enhancing the mass mailings we:

- send letters to PCPs and local churches from the PI
- obtain in cooperation with the University of Pittsburgh Health Sciences News Bureau public service announcements and PI interviews in print and electronic media
- conduct presentations at local churches, senior centers and congregate dwelling units

Interested individuals can mail the return card on the brochure or call our 24 hour answering service. Skilled recruitment staff follow up as soon as possible to discuss the study, to screen for eligibility and schedule the first screening visit. We are projecting 15 screening visits per week.

Following this interview, those eligible receive an appointment letter with date and time of the appointment, travel instructions with map and parking directions if needed. Potential participants receive reminder calls the day before the appointment. Also, reminder cards are mailed if the appointment is scheduled more than two weeks after the interview.

Minority recruitment:

- targeted mailings to African-American populations
- appearances on African-American radio shows
- interactive discussions with African-American church congregations, community centers, clinics and housing authority buildings
- recognition of the importance of the time commitment
- provide van transportation for clinic appointments

The timeline of these activities are shown in Table 1 below.

2.5.2.2. Local Monitoring of Recruitment Activities

- number of telephone calls and response cards from recruitment method tabulated daily
- rate of response to recruitment efforts calculated weekly
- telephone screeners collect names and numbers of interested participants and call them as soon as possible
- every call made by telephone screener is documented and reasons for ineligibility are tallied weekly as well as cumulatively

2.5.2.3. Problem Solving Recruitment Issues

- weekly meetings with Principal Investigator, Project Coordinator, Recruitment Director and staff
- weekly recruitment staff meetings

2.5.2.4. IRB Requirements for Oversight of Recruitment Issues

IRB requirements are expedited as needed

2.5.2.5. Training of Local Staff Regarding Recruitment Activities

| March 2004 | April 2004 | May 2004 | June 2004 | July 2004 | August 2004 | September 2004 | October 2004 | November 2004 |
|---|---|------------------------------------|---------------------------------------|------------------------------------|-----------------------------|-----------------------------|-----------------------------|------------------------------------|
| PI letter to PCP and churches | 1000 bulk rate mailings to 15217 | 600 bulk rate mailings | Bulk rate mailings | Bulk rate mailings | Bulk rate mailings | Bulk rate mailings | Bulk rate mailings | <i>Bulk rate mailings</i> |
| Press release sent to media | Community presentations | Community presentations | Community presentations | Community presentations | Community presentations | Community presentations | Community presentations | <i>Community presentations</i> |
| 2000 bulk rate mailings to 15217 ages 80-89 | 1000 bulk rate mailings to 15217 ages 70-79 | PI interview on WQED radio station | PI interview on Gospel radio stations | Pittsburgh Post-Gazette article | Bulk rate mailings to 15221 | Bulk rate mailings to 15218 | Bulk rate mailings to 15206 | <i>Bulk rate mailings to 15208</i> |
| | | <i>15232 ages 70-89</i> | | <i>Bulk rate mailings to 15213</i> | | | | |

Table 1. University of Pittsburgh: Timeline for Recruitment Activities

2.5.3. Stanford University

2.5.3.1. Recruitment Strategies and Timeline

We apply a variety of recruitment strategies that have been found very effective in recruiting similar participants in previous programs. It is very important to mention that different target audiences are going to be at different stages in the adoption of the recruitment process, and these stages require a variety of media and advertising strategies. These media and advertising strategies include: churches, advertisement on local radio and local newspapers (San Jose Mercury News), posters, flyers, direct mailing, advertisement at local community organizations serving older adults (e.g. local chapters of AARP, Self-Help for the Elderly, Mission Neighborhood Centers, etc.), contacting past participants for referrals, and current prospects.

Specifically, our main strategies are to give brief presentations or informational meetings at different ethnic local community senior centers, perform free functional testing at community centers and health fairs, broadcast public service announcements on local radio and cable TV stations (including those geared to specific ethnic groups) to achieve broad local reach of target audience, generate articles and feature stories in local newspapers, publish press releases on wire service agencies, magazines and selective newsletters geared to older adults. In addition to these strategies we do direct mailings to past participants, post ads on Stanford e-mail distribution lists, develop posters and flyers (in English and Spanish) that are placed at major community organizations, free health clinics (Rotacare) senior mobile home parks, community classes, grocery stores (e.g., Whole Foods, Trader Joe's, Draegers), nutritional centers, libraries, specialty stores (e.g., Jamba Juice, GNC) attend round tables in Santa Clara and San Mateo County to network with other organizations, utilize "word of mouth" through contact with present and past volunteers/participants, and eventually sponsor an event or health fair in collaboration with one of the community organizations we have worked with in the past.

To attract and enhance the recruitment of the different ethnic groups we contact different ethnic community organizations (e.g., Avenidas Senior Center, El Concilio of San Mateo County, Mission Neighborhood Centers, Casa MACSA in San Jose, OnLok Senior Center, East Palo Alto Senior Center, etc), as well as ESL adult classes centers, Immigration community services, Citizenship Fairs, Community Health Centers, senior mobile home parks, and media agencies geared specifically to ethnic groups in this geographical area (e.g, radio stations that target the Latino community - KSOL 98.9 and 99.1 FM). Eventually, the main goal is to develop a systematic referral system with most community agencies. Our timeline with recruitment goals and for recruitment activities are presented in Table 1 and Table 2, respectively.

Table 1. Recruitment Timeline and Goals

| LIFE Project recruitment Timeline Chart | | | | | | | | | | | | |
|---|-----|-----|-----|-----|-----|------|-----|-----|-----|-----|-----|-----|
| Cumulative Numbers | | | | | | | | | | | | |
| RECRUITMENT | | | | | | | | | | | | |
| Year 1 (2004) | | | | | | | | | | | | |
| Timeline | Jan | Feb | Mar | Apr | May | June | Jul | Aug | Sep | Oct | Nov | Dec |
| Project Year (2004) | | | | | | | | | | | | |
| Recruitment | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| Year 01 (2004) | | | | | | | | | | | | |
| | Jan | Feb | Mar | Apr | May | June | Jul | Aug | Sep | Oct | Nov | Dec |
| PARTICIPANTS | Q1 | | | Q2 | | | Q3 | | | | | |
| TARGET TOTAL BY QUARTER | | | | 33 | | | 66 | | | 100 | | |
| ACTUAL TOTAL BY QUARTER | | | | | | | | | | | | |
| Percent of Target | | | | | | | | | | | | |
| Target total/month part.(n=100) | 0 | 0 | 0 | 11 | 22 | 33 | 44 | 55 | 66 | 77 | 88 | 100 |
| TARGET FEMALE BY MONTH (65%) | 0 | 0 | 0 | 8 | 15 | 23 | 31 | 39 | 46 | 54 | 62 | 70 |
| ACTUAL FEMALE BY MONTH | | | | | | | | | | | | |
| Percent of Target | | | | | | | | | | | | |
| TARGET MALE BY MONTH (35%) | 0 | 0 | 0 | 4 | 8 | 12 | 15 | 19 | 23 | 27 | 31 | 35 |
| ACTUAL MALE BY MONTH | | | | | | | | | | | | |
| Percent of Target | | | | | | | | | | | | |
| TARGET MINORITY BY MONTH (25%) | 0 | 0 | 0 | 3 | 6 | 8 | 11 | 14 | 17 | 19 | 22 | 25 |
| ACTUAL MINORITY BY MONTH | | | | | | | | | | | | |
| Percent of Target | | | | | | | | | | | | |

Table 2. Timeline of Recruitment Activities

| Lifestyle Interventions and Independence For Elders (LIFE) | Year 01(2003) | | | Year 02 (2004) | | | | | | | | | | | |
|--|---------------|-----|-----|----------------|-----|-----|-----|-----|------|-----|-----|-----|-----|-----|-----|
| | Oct | Nov | Dec | Jan | Feb | Mar | Apr | May | June | Jul | Aug | Sep | Oct | Nov | Dec |
| RECRUITMENT ACTIVITIES | | | | | | | | | | | | | | | |
| PARTICIPANTS (n=100) | | | | | | | | | | | | | | | |
| Develop marketing plan | ● | | | ● | | | | | | | | | | | |
| Develop screening form | ● | | | ● | | | | | | | | | | | |
| Develop recruitment materials | | ● | | ● | | | | | | | | | | | |
| brochures(English/Spanish) | | | | ● | ● | | | | | | | | | | |
| PSA | | | | ● | ● | | | | | | | | | | |
| Press Release | | | | ● | ● | | | | | | | | | | |
| letters | | | | ● | ● | | | | | | | | | | |
| flyers | | | | ● | ● | | | | | | | | | | |
| press/mkt. packets | | | | ● | ● | | | | | | | | | | |
| Translate mkt.materials into Spanish | | | | ● | | | | ● | | | | | | | |
| Start contacting local newspapers and radio | | | | | | | | ● | | | | | | | |
| Start community media promotion | | | | | | | | | ● | | | | | | |
| Develop participant's mailing list | | | | | | | | ● | | | | | | | |
| Start Direct mailing to potential participants | | | | | | | | ● | | | | | | | |
| past participants | | | | | | | | ● | | | | | | | |
| past prospects | | | | | | | | ● | | | | | | | |
| current prospects | | | | | | | | ● | | | | | | | |
| Colleagues/MDs | | | | | | | | ● | | | | | | | |
| Publications | | | | ● | | | | ● | | | | | | | |
| referral sources | | | | | | | | ● | | | | | | | |
| Develop Informational meetings/tours | | | | | | | | ● | | ● | | | | | |
| Start contacting community agencies | | | | ● | | | | | | | | | | | ● |
| Start setting up referral system | | | | | | | | ● | | | | | | | ● |

2.5.3.2. Local Monitoring of Recruitment Activities

The Recruitment Coordinator prepares recruitment reports for presentation at weekly meetings with the Principal Investigator, Project Director, and other LIFE staff. These reports include a visual display of current recruitment numbers contrasted with targeted recruitment goals. Data are presented by ethnicity, gender, and EPESE score. These reports also present recruitment yields by recruitment strategy. For example, we are able to track which recruitment strategy (e.g., newspaper ad, radio ad, community presentation, etc.) results in the greatest yield of African-Americans, Latinos, men, women, and individuals with lower EPESE scores. These data prove invaluable as the LIFE team addresses recruitment issues that may arise.

2.5.3.3. Problem Solving Recruitment Issues

2.5.3.4. IRB Requirements for Oversight of Recruitment Issues

All recruitment materials developed for the LIFE study are submitted to the Stanford IRB for approval.

2.5.3.5. Training of Local Staff Regarding Recruitment Activities

The Project Director and/or other staff attending centralized training sessions are responsible for training local staff on protocol issues related to recruitment for the LIFE study. Stanford has a dedicated Recruitment Coordinator who is responsible for developing recruitment strategies and developing rapport with local community agencies/groups in order to disseminate information about the LIFE study and reach diverse populations.

2.5.4. Wake Forest University

2.5.4.1. Recruitment Strategies and Timeline

At Wake we identify 4 kinds of recruitment strategies: lead-based, population-based, location-based, and relationship development. Lead-based recruitment

means that approaching people who have already identified themselves as being interested in participating in research conducted at our facility. We already have a waiting list of people potentially interested in the study to call, and also maintain a data base (VITAL) that includes the names of community residents that have been screened for or participated in other studies who have agreed to be approached. Population-based less targeted appeals to mass-audience and includes: mass-mailings, posters, billboards, TV and radio advertising. Location-based recruitment is recruitment done at particular places where a large number of eligible participants are likely to be found such as senior centers, physician offices and health fairs and the like. Finally, relationship building refers to activities that are meant to raise awareness of the study among people who might be potential gatekeepers for potential participants. This would include contacts with physicians or presentations to administrators of facilities catering the needs of the elderly.

We use all four approaches in recruiting for the LIFE study. We divide the recruitment period into 4 intervals. The table below provides a general idea of the order in which we roll out different strategies. We begin the recruitment using strategies that have been successful for us in the past. Of course, this plan is adapted based on the success of varying strategies at the other field centers. Also, we estimate it takes about a month to judge the success of a given strategies and another week to implement an alternative strategy. Therefore, our local recruitment team discusses recruitment progress weekly to measure our success and adapt accordingly.

All fliers, ads, brochures are IRB approved prior to use.

Description of Planned Recruitment Strategies:

- Have numerous IRB approved ads. These ads can be used for flyers as well as newspaper and TV. We monitor response and develop new ads as necessary.

- Place 1 3 x 5 W-S Journal Place Ad 1 on a Monday, Tues, and Wed to start recruitment.
- Front page article in the VITAL newsletter in spring (Month 1-3). Reaches over 1500 people over 50 who are interested in research. Can put an ad in the Fall publication as well.
- Place an ad in Infinity newsletter to run for next 5 years in a rotation. (The WFBMC has approximately 31,000 inpatients a year, 260,000 outpatients a year, and 11,000 employees.)
- Place flyers around Medical Center, WFU, Wendy's, Mt. Zion, local libraries, Best Health, etc.
- Talks at Best Health, Calvary Baptist Church (Senior Group), Mt. Zion Senior Group (African American Church).
- Events: Any event at the GRC represents the LIFE study. (Dixie Classic Fair Senior Day, Brookridge Health Fair, etc)

Proposed Recruitment Plan for LIFE
from
Wake Forest Field Center

| | Months 1-2 | Months 3-4 | Months 5-6 | Months 7-9 |
|---|-----------------------|-----------------------|-----------------------|-----------------------|
| Clinic Visits Needed (Assuming 4 EPESE's to get 1 elig.) | 48 per month | 48 per month | 48 per month | 48 per month |
| Calls to our wait list (A) | X | | | |
| W-S Journal (B) | X | X | X | X |
| Vital Newsletter Spring & Fall (A) | X | | | X |
| Infinity newsletter (B) | X | X | X | X |
| Flyers (B) | X | X | X | X |
| Events (C,B) | X | X | X | X |
| Website (B) | X | X | X | X |
| Word of Mouth (A) | X | X | X | X |
| Targeted Mass Mailings (B) | | X | X | X |
| TV (B) | | X | X | X |
| Talks (At least monthly) (C,D) | X | X | X | X |
| Pepper referral process (A) | X | X | X | X |
| Doctor's office recruiting (C) | | | If Needed | If Needed |
| Screenings at Senior Apartment Complexes (C) | | X | X | X |

A-Lead based

B-Population based

C-Location based

D-Relationship development

2.5.4.2. Local Monitoring of Recruitment Activities

The LIFE study data system is useful in tracking the recruitment process for those participants who consent to phone screen. However, it is necessary for the clinics themselves to develop a tracking system to monitor the effectiveness of various recruitment strategies in generating contacts for the study. The reason this is important, is that it helps to monitor whether the proper message is getting out. For example, if a TV ad generates 100 calls, but only 1 of the callers is interested in the doing the phone screen once hearing more about the study, it would be evident that the message delivered was not appropriate and should be changed.

All recruiters at the Wake Forest Site are to maintain a contact log to record the disposition of all contacts related to LIFE recruitment.

- The elements collected are:
- Date of Contact
- Recruitment tool the contact is responding to
- Whether the contact went on to the phone screen
- For those not going on to the phone screen, the recruiters attempt to ascertain the contacts, gender, race, and reason for not wanting to continue in the screening process.

These logs are tabulated weekly to provide information on the kinds participants that each recruitment tool is bringing in.

Once the phone consent is obtained, and the phone screen has been administered, DMAQ Center helps us track the following items both weekly and cumulatively throughout the recruitment period.

- Number of phone screens
- Number of phone screen eligibles

- Number of EPESE assessments done
- Number of EPESE eligibles
- Number of SV1 visits done
- Number of SV1 eligibles
- Number of Behavioral Run-ins offered
- Number of Behavioral Run-Ins completed
- Number randomized

Using these counts we follow reports tracking the yields through the recruitment process both overall and broken down by ethnicity, zip, age, recruitment source, and EPESE score.

The recruitment goals require that there be approximately 40% of participants with EPESE scores of 7 or below and 25% minority participation. We use the information gathered in the first two months of the study to gauge approaches that are more successful in recruiting participants matching the study profile.

2.5.4.3. Problem Solving Recruitment Issues

2.5.4.4. IRB Requirements for Oversight of Recruitment Issues

2.5.4.5. Training of Local Staff Regarding Recruitment Activities

All recruiters are trained LIFE coordinators. In addition to the regular LIFE training, staff involved in recruiting are required to do practice phone screens and screening visits.

Appendix A

Example of Administrative Coordinating Center

Recruitment Tracking Report

Appendix B

Press Release

CONTACT: PR Department Rep here
telephone number here
e-mail address here

New Study Looks for Ways to Delay Disability in Older Adults

Name of Institution here one of four research centers for study

City of Release here – As the life expectancy of Americans increases, learning how to prevent or delay age-related physical disability has become a major health priority. _____ (name of local institution here) is one of four centers in the country that will study whether physical activity and other lifestyle changes can help older adults retain their independence.

The Lifestyle Intervention and Independence for Elders (LIFE) study is funded by the National Institute on Aging (NIA). The study will include 400 adults who are 70 to 89 years old. It will especially target those who are having difficulty doing daily activities such as walking, getting out of chairs or climbing stairs.

The LIFE study is also being conducted in Dallas, TX, Palo Alto, CA, Pittsburgh, PA, and Winston Salem, NC (leave off local site).

“Other studies have looked at pieces of the disability puzzle, such as seeing whether increasing muscle strength affects the ability to walk further, said _____ (name of local PI, Institution). “But we want to answer the larger question: Does a program of activity or change in lifestyle patterns prevent physical disability? Our goal is to find strategies that will help people remain independent longer so they can live in their own homes and participate in the day-to-day activities.”

Study participants will be randomly assigned to one of two health programs. One group will attend classes and demonstrations promoting successful aging and will include topics like nutrition, communicating with health-care professionals and foot care. The other group will participate in moderate-intensity physical activity that includes aerobic,

strength and flexibility training. Participants will receive free health screenings during the one-year study.

“During the course of their lives about half of all persons age 65 years or older will become so severely disabled as to need a nursing home admission,” said _M.P_ , M.D., from Wake Forest University Baptist Medical Center in Winston Salem, N.C., who will lead the study. “What we learn in LIFE has the promise of benefiting a very large segment of the older population.”

The local investigators are _S.B._, M.S., P.E.D., at the Cooper Institute, Dallas, TX; _A.K._, Ph.D., at Stanford University, Palo Alto, CA; _A.N._, M.D., M.P.H., at the University of Pittsburgh, Pittsburgh, PA; and _S.K._, Ph.D., at Wake Forest University Baptist Medical Center.

The centers are currently recruiting participants for the study that begins in April. For more information, or to learn if you qualify, call _____(local recruitment telephone number).

Appendix C

Training Manual

Appendix D

Site Specific Recruitment Materials

The Cooper Institute

February 18, 2004

To Whom It May Concern:

The Cooper Institute, a non-profit research facility, is currently recruiting for a new study called Lifestyle Interventions and Independence for Elders (LIFE). LIFE is testing two different programs to help older adults make changes in their lives to help them to enhance the quality of their lives and remain independent members of their community for a longer period of time. In past recruitment efforts, we have received a number of referrals from area churches and church related organizations throughout the DFW community.

We are currently recruiting adults who are:

- 70 to 85 years old;
- We are especially interested in including persons who are having difficulty doing their daily activities such as walking, getting out of chairs, and climbing stairs;
- Not involved in a regular, structured program of physical activity or another research study involving lifestyle programs;
- Live within a reasonable commuting distance of The Cooper Institute.

There is no cost to participate in this study. Eligible participants are placed in either one of two programs. One program provides strategies for Successful Aging and includes classed and demonstrations on many topics such as nutrition, communicating with health care professionals, and foot care. The other program provides help on how to be more physically active, including fitness, strength, flexibility, and balance training. Both groups have regular contact with our trained staff for up to 2 years. For their time and effort, participants receive health and medical screening examinations at no cost. Participants receive monetary compensation for their time upon completion of the screening and follow-up clinic visits.

Individuals who live or work within a 15-mile radius of the Cooper Institute are encouraged to call. If you believe this could benefit individuals in your congregation, we would appreciate it if you could post the brochures, include the information in a newsletter or bulletin, or announce it at gatherings. An initial telephone interview is the first step to determine eligibility.

Interested participants should call ____.

If you have any questions, please feel free to call me at _____. Thank you for your help.

Sincerely,

__J.W.__, Recruitment Team Leader

«First» «Last»

«Address»
«City», «State» «Zip»

Dear «Title» «Last»:

We are currently recruiting for a new study called Lifestyle Interventions and Independence for Elders (LIFE). LIFE is testing two different programs to help older adults make changes in their lives to help them to enhance the quality of their lives and remain independent members of their community for a longer period of time. You previously indicated an interest in participating in research studies at The Cooper Institute.

We are currently recruiting adults who are:

- 70 to 85 years old;
- We are especially interested in including persons who are having difficulty doing their daily activities such as walking, getting out of chairs, and climbing stairs;
- Not involved in a regular, structured program of physical activity or another research study involving lifestyle programs;
- Live within a reasonable commuting distance of The Cooper Institute.

There is no cost to participate in this study. Eligible participants are placed in either one of two programs. One program provides strategies for Successful Aging and includes classed and demonstrations on many topics such as nutrition, communicating with health care professionals, and foot care. The other program provides help on how to be more physically active, including fitness, strength, flexibility, and balance training. Both groups have regular contact with our trained staff for up to 2 years. For their time and effort, participants receive health and medical screening examinations at no cost. Participants receive monetary compensation for their time upon completion of the screening and follow-up clinic visits.

An initial telephone interview is the first step to determine eligibility. Interested participants should call ____.

Sincerely,
J.W.
Recruitment Team Leader

The University of Pittsburgh
PDF FLYER here sent separately

**Stanford University
Flyer sent separately**

Wake Forest University

SAMPLE ADVERTISEMENT

DO YOU HAVE DIFFICULTY

- Getting in or out of a car?
- Walking up the stairs?
- Carrying Groceries?
- Getting into and out of a chair?

If so then the LIFE study may be for you!

Wake Forest University is conducting a research study which provides either a walking based program or a series of programs on Successful Aging where you learn about important health topics.

You may qualify if you:

- Are 70-89
- Have mild to moderate levels of difficulty performing any of the tasks listed above

If you are interested, please call the Geriatric Research Center at ____or ____.