

4. RECRUITMENT PROCEDURES

Recruitment is tracked through the CC and efforts are coordinated through the CC based on feedback from the Steering Committee, Study Managers/Coordinator Committees and the DSMB. Otherwise, each site continuously advertises the study until their goal is met. Sites distribute IRB approved recruiting material and record the effectiveness of each method. Reports regarding phone traffic and recruitment progress continuing into screening visits and enrollment status are provided to the CC. However, evaluation of the success of various recruiting methods will be shared informally between the sites due to anticipated site-specific differences. Each site is making an effort to recruit an ethnically diverse group based on the demographics of their region.

4.1 Recruitment Procedures at the Pennington Biomedical Research Center

4.1.1 Pennington Biomedical Research Center employs a Recruiting and Media Services Manager that develops all advertisements and letters, oversees all recruiting activities and ensures successful recruiting for studies conducted at the Pennington Center. This manager, the CALERIE recruiter and the CALERIE Study Manager work closely together to make the recruiting plan and decisions needed throughout the study enrollment. All ads, flyers or any other advertising materials are sent to the NIA for approval and then forwarded to the PBRC IRB for final review and approval before being put to use. All ads, etc are added to the MOP once approvals have been obtained. Please refer to Appendix 4-A for recruiting materials from PBRC.

Flyers are placed in the PBRC recruiting areas as well as distributed at libraries, churches, and places of business. Staff members participating in church health fairs or health awareness days at local businesses promote the study by distributing flyers and providing verbal explanation and details regarding the study, presenting the study, and talking to potential participants. PBRC usually participates in 1 to 2 health fairs per month. "Word-of-mouth" is used as an effective recruitment tool. This method will be used to help recruitment and enrollment.

Direct contact by mailings is a major recruitment strategy. Information on age and BMI for over 60,000 people interested research studies is available in the PBRC database. The study coordinator and study manager sends a query request to the Computer Services Department of PBRC. The query request specifies the following search criteria: 25 to 45 years of age, BMI of 23 to 27.99 and non-smokers. The database identifies all people who meet the specified criteria and generates a report that is provided to the recruiting department. This report contains the name and address of all participants in the PBRC database that meet the basic inclusion criteria provided. The report is then used as a mailing list for the recruiting department. The recruiter prints out mailing address labels and sends out the prior approved letter (see Section 4 – Appendix A), which briefly explains the study. The letters are mailed in batches of 100 every 4 days. The next approach is to contact Mail Comm. Inc. Mail Comm. is a local Direct Marketing Specialist that can provide mailing lists for select zip codes in the Baton Rouge area. These mailing lists can be adapted to include specific ages and/or gender. Mail Comm. print post cards with a summary of study information and mails them to potential

participants on this list. The Mail Comm. post cards are sent out in batches of 1000 every 4 days to achieve a manageable load of incoming calls. Additionally, information about the CALERIE study will be printed on LSU employee check stubs. This is a form of free advertisement that will reach campus faculty and employees.

Ads are placed in the large local newspaper, The Advocate. The ads are placed starting Thursday and run until Sunday. This will be done once a month or more frequently as needed to meet enrollment deadlines. Ads will also be placed in smaller regional papers serving rural areas in the greater Baton Rouge region. These papers include The Ascension Citizen (serving Ascension Parish), The Livingston Parish News (serving Livingston Parish) and the Riverside Reader (serving West Baton Rouge Parish). These papers are printed once a week; therefore ads would run in the weekly issue and will appear as needed to meet enrollment timelines.

Ads are placed in the Interfax Daily, which is sent to business offices daily. This is a one-page paper sent to businesses in the Baton Rouge area. Ads are placed on a weekly basis and appear in all 5 issues of the week. The recruiting and media services manager places ads as needed to meet enrollment timelines.

Additionally, radio ads are used as one of the main media resources. Clear Channel Broadcasting is contacted for the recording of ads. A local radio celebrity serves as the voice of the ads. The ad is written by the Recruiting and Media Services Manager and the CALERIE Study Manager. Clear Channel broadcasting owns 4 major stations in the Baton Rouge area. These include 96.1 KRVE (Adult Contemporary), 101.5 WYNK (Country), 102.5 WFMF (Top-40) and 1150 AM WJBO (News/Talk). By using Clear Channel Broadcasting, we reach the majority of our study population that are radio listeners. Once ads are recorded, they run on all Clear Channel stations at peak travel times (6:30 am to 9:00 am and 3:00 pm to 6:00 pm). During each time interval, the ads are usually run at least twice. We choose the number of times to run the ad and the duration of the ad (days, weeks, months, etc) based on the enrollment needs and deadlines.

Finally, TV ads are run. The Pennington Center's Communications Department uses local TV media to place study related interviews on local TV station's morning shows and health segments. The local TV stations with morning shows and health segments are WAFB TV 9 and WBRZ TV 2. The morning show appearances can occur as often as weekly and frequency is decided based on study enrollment needs. The local health segments are a daily occurrence on the 5 o'clock and 6 o'clock evening news. Reports on the study during these health segments can be run monthly and frequency is decided based on study enrollment needs. These venues provide an excellent opportunity to describe the study, and the exposure is free.

4.2 Recruitment Procedures at Tufts University

4.2.1 Preparation by CALERIE Team – Study Coordinator and Study Manager

- Establish a schedule for regular meetings with the TUFTS recruiter and recruiting team (CALERIE staff) to review recruitment progress, and calendar of advertising events that are being conducted each month and budget and strategies

- Ensure that all advertising material carries the same consistent contact information so all calls inquiring about the study are routed to one place through a single number. Include the central CALERIE website address for the study on all printed materials and flyers so applicants can get some preliminary information about the study
- Ensure that the site PI reviews all advertisement material.
- Ensure that all advertising materials have been reviewed by the NIA. Any study wide recruitment material must also be approved by the Steering Committee.
- Ensure that all advertising material is IRB approved well in advance so as to allow for a smooth flow in the recruitment process
- File all approved advertising material in the MOP appendix
- Ensure that sufficient copies of all recruitment material is available at all times and is ordered as stores appear to be depleted
- Obtain all appropriate permission letters (e.g. from IRB, institution heads, people in charge) for use of databases, common space, and facilities used when recruiting.

4.2.2 Recruitment Media and Materials

- Tufts Human Nutrition Research Center on Aging (HNRCA)– database of previous volunteers
- Tufts Intranet and Campus television screens
- Flyers
- Mailing lists
- Television
- Radio
- Recruitment letters targeted to Male members of household
- Local Newspapers
- Community newspapers
- Articles by PI in newsletters and local papers
- “Craigslist” and other reputable internet sites
- Word of mouth, health fairs

4.2.3 Recruitment

Tufts HNRCA – database of previous volunteers

- Study coordinator meets with the recruiter to review the HNRCA database and identify all men and women who meet the age and BMI range for CALERIE.
- Refine this list to exclude participants from the CALERIE pilot study as well as anyone with known exclusion criteria like smoking, major diseases and medical conditions.
- Print the name, phone number, and basic contact information from this refined list and generate mailing labels.

- Affix the mailing labels to postcards that have the study contact information so interested candidates can call in to be phone screened.

Tufts Intranet and Campus Television Screens

- Recruiter and study coordinator prepare material and email it to the Tufts community.
- Using the Tufts intranet (via email), the recruiter periodically posts announcements describing the study, which will be sent to all Tufts affiliated institutions' employees and students, including those at Tufts-New England Medical Center and all of the professional schools.

Flyers

- Recruiter and study coordinator prepares attractive flyers with tear away contact slips.
- Post the flyers at all Tufts sites, at grocery stores, community gymnasiums, health clubs, corporations, churches and other such high traffic gathering areas to improve study visibility in Boston and the surrounding area.
- Distribute flyers to outreach and extension program sites where HNRCA speakers often visit to connect with the public. These sites provide an excellent and free opportunity to describe the study.
- Maintain a log of where the flyers were posted and the people in charge of distribution so they can be monitored and replenished periodically.

Mailing lists

- Purchase direct mailing lists from Fidelity Communications.
- Select the mailing lists based on specific zip codes and demographic specifications (age, sex and some ethnic groups) in the Boston and greater Boston areas that are matched for probability of finding people with the characteristics required for the CALERIE study population
- Use the address labels from these purchased mailing lists and send postcards with contact information for the study.
- Regulate the number of cards mailed at each time so there is a steady flow of responses.

Television and Radio

- Prepare effective messages for TV and radio with help from the public relations department
- Strategically stagger radio and TV advertisements using a monthly schedule planner to cover weekdays and weekend days, as well as different times during the day, in order to reach the most broad and diverse audience possible.
- Run TV ads on the local channel WCBV – Channel 5.
- Run radio ads on Mix 98.5 because their listening audience falls into the exact demographics we are recruiting for this study. Request the days we would like it to run (the times are at the discretion of the stations).
- Plan the placement of advertisements for times and programs geared towards what is projected to be the study demographic and target them. For example for radio, target peak-commuting times, and for TV choose popular viewing times throughout the day. Prime radio times for the station we selected are throughout

the day and evening, and this is a station where the listeners tend to stay at this location and not scan the dial.

- Monitor the frequency of ad placement and adapted to suit study enrollment and progress.

Local and Community Newspapers

- Place well-formatted advertisements strategically using a planned schedule in the local newspapers such as the Boston Globe and the Metro. Cover weekdays and weekend days.
- Place ads in the local community newspapers such as the Bay State Banner, the Patriot Ledger, Boston Phoenix and City Shopper.
- Submit health related articles written by the CALERIE PI and study staff to periodically run in the local community newspaper sections where the study is advertised.

Other Methods

- Encourage sharing of study information by word of mouth.
- Explore the use of "Craigslist", the website for the Patriot Ledger and other reputable internet sites for free/low cost posting of our study.
- Attend health fairs, distribute flyers, and talk to people to specifically help in recruitment for the study.
- Use recruitment letters targeted at males since the majority of responses to advertisements in the past have been from females.
- Recruit minorities by advertising in local publications such as the Boston Banner, Dorchester Reporter, and Mission Hill Gazette, which are some of the area newspapers whose reading audience has a high percentage of minorities.
- Use the HNRCA's Community Boards minority representatives who are connected to specific minority groups.

Conduct recruiting efforts to ensure that participants reflect the demographic composition of the Boston area. Explore any cost effective, smart and new techniques that appear promising so as to maximize recruitment and realize our goals/target.

4.3 Recruitment Procedures at Washington University

Recruitment for Phase 2 of CALERIE at Washington University employs several methods to attract individuals in the appropriate age range with diverse racial and ethnic backgrounds. Submit all recruitment material to the NIA and the Washington University Human Studies Committee review board for approval prior to use. In addition, submit for review and approval all study-wide recruitment material to the CALERIE phase II Steering Committee.

4.3.1 Recruitment materials

- E-mail messages / PSA
- Recruitment letters
- Flyers
- Television and radio interviews

- Volunteers for Health Services

4.3.2 Recruitment

Emails/PSA

The first recruitment approach involves mass e-mail messages distributed to employees of Barnes-Jewish Hospital and Washington University School of Medicine. This method targets participants who work in close proximity to our facility.

- Contact Nancy Webb at the IMCSS (1-314-632-3080, nwebb@im.wustl.edu).
- Forward the recruitment email to her.
- The recruitment message is forwarded on to the Barnes Hospital network, the Washington University email server and the Barnes Jewish Hospital Physicians email list. (All Medical School and Hospital divisions are included on these lists.
- One email list should be targeted at a time. Determine the level of response prior to sending a mass email to multiple email lists.
- Reply emails are directed to the study coordinator (mschram@im.wustl.edu)
- Information on how to reply to interested participants can be found in Chapter 5.3.

Mass mailings

CALERIE phase II utilizes mass mailings (through the postal service). Mailing labels have been purchased from InfoUSA, Inc. and have been chosen based upon study-specific demographics.

- Study Manager or Study Recruiter provides a copy of the study recruitment letter to Vicki Reckamp in the Applied Physiology lab (she is in charge of printing and sending recruitment letters, 314-362-3506).
- Send Batches of 100 letters out on a weekly basis.
- Mail Personalized letters describing the study and inviting study participation to individuals residing in zip codes in the St. Louis area. Minority participants are targeted by sending letters to areas known to be heavily populated by minority groups.
- Replies are directed to the study recruiter
- Study manager reviews response and determines if there is any need to change the number of letters being sent on a weekly basis.

Flyers

Place CALERIE II recruitment flyers throughout Washington University and Barnes Hospital. These flyers are placed in strategic locations to target a wide variety of interest.

- Contact Volunteers for Health (VFH 314- 362-1000) to determine the best locations to hang study flyers.
- Place flyers in high traffic areas in the Hospital and on both the Medical and Hilltop campus.

- Contact local businesses, colleges and grocery stores to inquire about letting us place flyers at their stores.
- Place Flyers at any local businesses, churches, colleges, and grocery stores that agree to help with recruitment.
- Permission to post flyers at these locations is needed before flyers can be placed.
- Flyers may be changed as needed. Consult VFH to verify that any new locations are approved. The IRB and NIA must also approve any format or content changes to the study flyer prior to use.

TV interviews

Television and radio are utilized to recruit for CALERIE phase II. The local TV and radio stations in St. Louis have health reporters who cover local health related stories. Schedule the health reporters from Ch 2(ABC), Ch 4 (CBS) and Ch 5 (NBC) to interview the investigator and research participants during local broadcasts. Focus on times that most people are home. No mid day broadcasts. All interviews must air between 5-7 am and 6–10 pm. Interviews may run more than once. The interviews must include descriptions of the study, perspectives from current or previous participants, eligibility criteria, and contact information so that those who may be interested in participating can call or e-mail the study team for additional information.

- Contact Nicole Vines in the PR department (314-636-0105).
- Forward study information to her including inclusion/exclusion criteria, contact information and PI's schedule. Ask that the interview be done in the lab.
- Arrange for Phase I study participants to be interviewed. Contact previous participants who have agreed to help recruit for Phase II.
- Nicole Vines contacts the local media and sets up interviews with the PI.
- Perform no more than 1 interview at a time. Multiple interviews or TV spots will result in a response that we will be unable to accommodate.
- Large call volume usually corresponds with these interviews. Other methods of recruitment may need to be slowed during these times. Study manager evaluates recruitment progress and decides if other recruitment efforts need to be increased or decreased. Calls need to be returned within 24 hours by the phone screener. If a specific recruitment effort increases call volume past this point, the study manager stops other methods of recruitment until call volume slows.

Volunteers for Health

The “Volunteer for Health” program is operated by the Washington University Center for Clinical Studies as a recruitment mechanism for clinical trials conducted throughout the medical center.

- Contact VFH (314- 362-1000, located on the 2nd floor of Barnes Hospital in the main lobby).
- They have several levels of service ranging from free publicity to a monthly fee for more involved recruitment.

- **Registration (Free)**– posting IRB approved flyers in the following venues: VFH website, VFH office, 6 VFH display cases, and VFH binders – used at health fairs.
 - **Phone service** (\$35/month) – use of high capacity phone number with dedicated voice mailbox that holds 45 minutes of messages. Messages from callers are transcribed and faxed to study recruiter
 - **Patient education newsletter system** (\$.40/ mailing).
 - **VFH study related poster** (\$85 – poster, \$110 – banner).
 - **Public relations and advertising assistance** (\$30/hour) – VFH will assist in arranging funded advertisement for the study. In addition, VFH can provide up-to-date information about local media, and offer assistance with print, radio or TV advertising. Fee dependent of the level of assistance.
- Utilize the free VFH database. VFH forwards all possible participants that match initial criteria to the study coordinator
 - Utilize their website posting and flyer/poster cases.
 - Study Manager – Follow recruitment progress and determine if additional VFH services are needed.
 - If it is deemed necessary, the study PI must ok the use of funds to further VFH involvement.

Appendix 4-A PBRC Advertising Materials

Example of Appendix Item – All three sites will include site-specific recruitment material in the Chapter 4 appendix following approval of these items by the NIA and site-specific IRB. It was decided by the screening/recruitment committee to leave the items out of the current MOP version until they have been reviewed for approval. The following is an example of a recruitment flyer from PBRC. Similar items from each site will be included in the final MOP.

Pennington Biomedical Research Center is looking for healthy, normal weight to slightly overweight volunteers to participate in a 2-year research study testing the effects of calorie restriction on healthy aging. Participants will receive free dietary counseling and medical evaluations.

Some participants will be required to eat breakfast and dinner meals at the Pennington Center with lunches and weekend meals packed to go for a 5-week period followed by the remaining time in the study consisting of following a prescribed diet at home.

Participants will be asked to follow a reduced calorie diet or follow a standard diet.

There will be a two-day inpatient stay required on 5 separate occasions. Volunteers will go through various testing procedures that may include fat and muscle biopsies.

To qualify, volunteers must be:

- Normal weight to slightly overweight (Body Mass Index of 23 to 28)
- Non-smoker
- Non-diabetic
- On no medication (birth control, ok)
- Ages 25 to 45

Participants will receive a stipend for completing the study.