

## REACH II CAREGIVER INCLUSION/EXCLUSION CRITERIA

### Inclusion criteria:

1. Age: 21 years or older
2. Family member of the care recipient
3. Must live with the care recipient or share cooking facilities
4. Must have a telephone that will enable use of CTIS system
5. Must plan to remain in the recruitment area for the duration of the intervention and follow-up.
6. Caregiver role for more than 6 months
7. Must provide on average 4 hours of supervision or direct assistance per day for the care recipient
8. Risk Screening Tool: must have a total score of at least 1 for questions 1 – 3, and a total of at least 2 for questions 4 – 9

### Exclusion criteria:

1. Non-English, non-Spanish speaking
2. Active treatment (chemotherapy, radiation therapy) for cancer
3. Imminent placement of care recipient into a nursing home or with another caregiver (within 6 months)
4. Involvement in another clinical trial for caregivers
5. Participant in REACH I study
6. SPMSQ:  $\geq 4$  errors (see instructions for second level review on the following page)

## REACH II CARE RECIPIENT INCLUSION/EXCLUSION CRITERIA

### Inclusion criteria:

1. NINCDS (MD diagnosis) or cognitive impairment (raw score on MMSE of 23 or less)

### Exclusion criteria:

1. Non-English, non-Spanish speaking
2. History of Parkinson's Disease or a stroke with no reported decline in memory over the past year.
3. Active treatment (chemotherapy, radiation therapy) for cancer
4. More than three acute medical hospitalizations in past year (other than psychiatric or Alzheimer's Disease related admission)
5. Schizophrenia (onset of delusions before age 45) or other severe mental illness
6. Dementia secondary to head trauma (probable)
7. Blindness or deafness if either disability prohibits them from completion of data collection or participation in the interventions
8. MMSE = 0 and Bedbound (confined to a bed or chair for  $\geq 22$  hours per day, for at least 4 of the past 7 days)
9. Planned nursing home admission in 6 months
10. Participant in REACH I study

## **Second Level Review**

If the caregiver has been inconsistent with answers or repeated answers, then the interviewer will administer the SPMSQ. If the caregiver misses 4 or more questions, he/she should be excluded from the study.

## REACH II RECRUITMENT GUIDELINES

### 1. Direct Recruitment of Potential Participants

Each site will develop, in concert with other sites, mechanisms to directly contact potential study participants. This may include, but is not limited to the following strategies:

Brochures - with language and translations appropriate for socio-cultural context of local population.

Newspaper Ads - both daily's and weekly "neighborhood/community" papers; targeted primarily to those who may be disconnected from formal healthcare or social service agencies.

Community Flyers - posted at local community-based resource centers/senior centers/churches/adult daycare centers.

Articles in Newsletters – Alzheimer's Association, local hospital newsletters, "senior focused" newsletters.

Television - local channels and local cable access channels featuring "health spots".

Radio - taped spots or study personnel doing a radio segment.

Targeted Mailings - to Alzheimer's Association, churches, universities, home health agencies, adult daycares and Caregiver's on waiting lists for services; prefaced with a personalized letter.

Community Presentations - study personnel to make presentations at local M.D. offices, home-health agencies, ministerial associations and professional organizations. Get on "talk/training" schedule for local support groups, Alzheimer's Association and other aging-focused agencies. Offer talks/training in both English and Spanish.

Health Fairs - be a presence at any senior-focused health screenings/health fairs. Have a table with brochures, study magnets, "sticky notes", pens/pencils and "goody bags" to put items into.

Community Service - be a presence at any local events (walks, fund-raisers, guest speakers/lectures) related to dementia or dementia patient caregiving, such as the Alzheimer's Association and other aging-focused organizations.

Churches - target a culturally diverse population of churches to speak with; talk with ministers/priests and other on staff support personnel who might have contact with members. Ask permission to place a notice about the study in church bulletin or permission to speak to senior Sunday school classes.

Faxes - utilize weekly "fax-back" forms enabling staff members at local M.D. offices/agencies/adult daycares to send referrals without writing out additional fax's for each referral.

Reminders/Thank you's for Existing Recruitment Sites – Provide ongoing recruitment reminders and restocking of educational materials at each site. Utilize pharmaceutical detailing strategy" via small seasonal treats for office/agency staff and their patients/clients to share accompanied by a thank you note from study personnel.

### 2. Recruitment of Potential Participants Provided by a Community Agency or Organization

Note: This action is permitted by Federal Wide Assurance Policies

Each site will develop an information packet about the study for dissemination to potential participants. These packets will include information on how the potential participant can contact the research team.

Each site will utilize the same Participant Contact form to be provided to the community agency (see form on following page). Specifically, the Participant Contact form will document the consent of the **potential subject** to have their name submitted to the research team.

Local agencies will forward the names of potential participants and the Participant Contact forms to the research team. The research team must then contact the individual, screen them for eligibility, and obtain informed consent. The consent granted by the potential subject is only for having their name submitted and does not grant any other consent. All other consent procedures must be followed. A copy of the signed permission to contact form must be placed in the potential subjects permanent folder. If the potential subject eventually enters the study, this consent sheet will be a part of that permanent record.

## REACH II PARTICIPANT CONTACT

The person listed below has agreed to be contacted regarding possible entry into REACH II (Resources for Enhancing Alzheimer's Caregiver's Health II).

Patient Name: \_\_\_\_\_

Family member/Caregiver Name: \_\_\_\_\_

Address: \_\_\_\_\_

Street

City

State

Zip Code

Telephone: (H) \_\_\_\_ \_\_\_\_ \_\_\_\_ / \_\_\_\_ \_\_\_\_ \_\_\_\_ / \_\_\_\_ \_\_\_\_ \_\_\_\_

(W) \_\_\_\_ \_\_\_\_ \_\_\_\_ / \_\_\_\_ \_\_\_\_ \_\_\_\_ / \_\_\_\_ \_\_\_\_ \_\_\_\_

When/where/Best time to call: \_\_\_\_\_

Relationship to patient (circle one)    Husband    Wife    Mother    Father  
Son    Daughter    Sister    Brother    Son-in-law  
Daughter-in-law    Friend    Other \_\_\_\_\_

How long have you been caring for the patient?

Referral Source: \_\_\_\_\_ By: \_\_\_\_\_

Person obtaining permission

I agree to have my name forwarded to the REACH II team to be contacted about this research study.

\_\_\_\_\_ Date: \_\_\_\_\_

Caregiver Signature

## REACH II SITE-SPECIFIC RECRUITMENT STRATEGIES

### UA/UAB

Drs. Burgio and Stevens are the current Director and Co-director, respectively, of the UA/UAB REACH I project. Recruitment for this project was centered in the Birmingham metropolitan area through a subcontract to UAB. The same mechanism will be used in the current proposal. One hundred forty (140) caregiver/care recipient dyads were enrolled into the UA/UAB REACH I project. Forty-two percent of the participants were African American/Black. The UA/UAB REACH project concluded recruitment three months before the projected site-specific end date at 100% of the stated goal. We propose to re-institute REACH I recruitment procedures to achieve enrollment of two-thirds of the sample, Whites and African-Americans. We did not include Hispanics/Latinos in REACH I; thus, particular effort will be devoted to recruiting this subgroup in the proposed study, including the employment of a bilingual staff person to serve as our liaison to Hispanic referral sites, and the use of a bilingual answering service to assist with telephone inquiries. Intervention and interviewing activities will be available in both Spanish and English.

In the proposed study, the UAB Alzheimer's Disease Center (ADC), the UAB Center for Aging, and the UAB Geriatric Medicine clinics will serve as university-based recruitment sources. Combined, these sites service dementia patients and their caregivers through approximately 8,500 annual clinic visits and/or telephone inquiries. We will also seek referrals from a number of community-based agencies, including Senior Centers operated by the Alabama Commission on Aging (serving over eight thousand older adults within a 50 mile radius of UAB), and Alzheimer's of Central Alabama (operating a mailing list of over 3700 professional and family caregivers). Each of these referral sites were used in the Alabama REACH I project (see letters of support for additional details). Recruitment is further facilitated by our participation in various community outreach events and media presentations.

Outreach to the Hispanic/Latino Community. Alabama has the third fastest growth rate of Hispanics/Latinos in the nation (U.S. Department of Commerce). In 1999, the Hispanic/Latino population was estimated to be 45,349 individuals with slightly over 5% of this number over the age of 65 (Census data prepared by the Alabama Commission on Aging). Leaders of the Hispanic/Latino community estimate a much higher number of 250,000 individuals statewide. The largest concentration of Hispanics/Latinos is located in the Birmingham area (Jefferson County) with the Birmingham Chamber of Commerce estimating that 65,000 individuals of Hispanic/Latino origin reside in the area.

To facilitate enrollment of Hispanic/Latino caregivers and their family members with dementia, we have modified our well-established and continuing outreach to the African American/Black community to incorporate the successful and culturally sensitive recruitment practices of the Palo Alto and Miami REACH I sites. The program was designed with significant input from Hispanic/Latino leaders of our community and has been endorsed by the Hispanic Coalition of Alabama (see letters of support). The outreach program will concentrate on three points of referral: 1) healthcare centers, 2) faith-based ministries, and 3) employment services.

Healthcare centers. Two healthcare centers serving Hispanics will actively educate the community about the project and provide direct referrals to the project. The Alabama Health Center provides free or low cost general health services to citizens of central Alabama. Approximately 70 individuals of Hispanic/Latino origin are seen per month, of which 5% are over the age of 65. Ms. Lisa Theus, Spanish Interpreter at Health Clinics of Jefferson County, provides language services to approximately 1,000 Hispanic patients per month. While the majority of these patients are under the age of 65, Ms. Theus reports a growing number of young adults present in the clinic with aging parents.

Faith-based Ministries. We will collaborate with four Christian denominations to obtain referrals from the churches' Hispanic outreach programs. Brenda Bullock, Director of Hispanic Ministries of the Roman Catholic Dioceses of North Alabama, oversees the largest outreach program of all religious denominations. Ms. Bullock estimates that over 400 Hispanics/Latinos attend Sunday Masses at each of the two Birmingham parishes (approximately 25% are over the age of 65). Rev. Ernesto Obregon, Diocesan Missioner to Hispanic Ministries, provides spiritual and supportive services to Hispanics/Latinos throughout the Alabama Dioceses of the Episcopal Church. He indicates that a growing number are over the age of 65 or care for an aging relative over the age of 65. Steve Murphy, Missionary with the National Plan for Hispanic Ministry of the United Methodist Church (UMC), works within existing UMCs in North Alabama to provide a wide range of services for Hispanics/Latinos. Through Mr. Murphy, we will inform and educate all Pastors of UMCs in the North Alabama Annual Conference about the proposed project. Mr. Murphy will coordinate referral of potential participants from these sources.

Employment Services. Spanish Communications, Inc. publishes the sole Spanish language publication in Central Alabama. The publication serves multiple purposes, but is primarily an employment guide for Hispanics/Latinos. At present, the publication reaches approximately 70,000 Hispanic/Latinos. Of those, 10-15% are 65 and older. Spanish Communications, Inc. will assist with recruitment in two ways: 1) educational ads about the project will run frequently in the publication, and 2) Carlos Urdeneta, President of Spanish Communications, will distribute brochures in the community as well as personally refer Hispanics/Latinos caring for family members with memory problems.

### **Memphis**

University of Tennessee Preventive Medicine has participated in 19 large scale, multi-site clinical trials with older persons. Our research team has worked together on multiple studies, including REACH. For our 5 recent studies (n=128 to 375), percentages of men ranged from 11% (for a VA caregiver study) to 78%, and percentages of Blacks from 25-61%. The PI, Dr. Burns, has more than a decade of experience as a practicing geriatrician, during which time he has been engaged in clinical trials involving drug and behavioral interventions. For the Memphis REACH site, Dr. Burns was PI, Dr. Nichols co-PI, and Drs. Martindale-Adams and Graney were co-investigators.

Our successful recruitment approach emphasizes social marketing, applying marketing techniques to design, recruitment, retention and intervention strategies, and cultural competence, the ability to Respond respectfully and effectively to individuals from varying cultures (Nichols, et al., 2000, 2001). We currently work with 20 primary care physicians, the Aging Commission of the MidSouth and the 50 members of the Alzheimer's Network who refer individuals to REACH, and our ability to recruit Black and White caregivers is proven. Although we have not recruited in the Latino/Hispanic community, we will expand our community outreach approach to this population, utilizing the expertise of the Palo Alto and Miami sites.

As we have done in other studies, we will utilize our contacts in local health, social service, religious, Alzheimer's and aging networks for recruitment. All data on the Latino community are from local publications, primarily from the University of Memphis. From 1990 to 2000, the Hispanic population in the Memphis MSA grew from 8,116 to 53,628. Latino organizations suggest that this number is much higher. The local utility company has 90,000 households with Spanish surnames and Latino-Memphis Conexión estimates a population of 150,000 Latinos (We follow local usage and terminology used by government and other researchers (e.g., Hispanic for census data, and Latino in other cases). Several local economic impact studies have documented that recent immigrants have chosen Memphis due to the availability of employment. Many businesses, service agencies and religious organizations have expanded their services and workforces by hiring Spanish-speaking or bilingual workers. In addition, there are currently three weekly Spanish-language newspapers published in Memphis and two Spanish-language radio stations as well as 26 businesses (as of Fall, 2000) catering to Latinos, including restaurants, bars, supermarkets, video-rental stores, churches, bakeries, and discos. Several economic indicators suggest that a large portion of the Latino population is not seasonal (e.g., number

and timing of health care visits, rising home ownership. Our community outreach will focus in three areas: health care, churches, and other community/non-profit organizations.

Several local health care organizations have actively recruited Latino patients. The largest providers are the Regional Medical Center (MED), the local public hospital, and the Health Department. The MED has a coordinator of Spanish Programs and 3 translators. In December 2000, 30% of MED patients were Latino. The MED is served by the Memphis/Shelby County Health Department. In an evaluation of the Health Department's Hablemos Español translation program, 2191 patients were seen from 6/99-3/00. Data are not available for individuals over 65, although 1.14% were over 45 years of age. Three local clinics/physician's offices have high percentages of Latino patients. The Christ Community Medical Clinics have three offices in areas with high concentrations of Latino residents. Both Medicos Para La Familia and Dr. Gumersindo Leal's four person private practice see only Spanish-speaking patients. Choices Counseling is the only County-certified Latino mental health provider in the local area.

There are currently between 33-35 churches in Memphis that provide Spanish-language services, ranging from translation of existing services to the entire range of church activities in Spanish and designed for Latinos. The Latino-focused Church of Christ activities were begun prior to 1997 by Chris Stewart, Hispanic Church Planter with Memphis Urban Ministries. This organization, which coordinates CofC activities, commissioned a study from the Regional Economic Development Center to help them plan for the growth and needs of the Latino population (Lawrence, et al., 1997). Episcopalian activities have been focused at St. Elisabeth's parish, with high percentages of Latino parishioners and residents. There are currently five Catholic churches offering services to Latinos, with Sacred Heart and St. Michael's the most prominent.

Latino-Memphis Conexión (LMC), formed in 1995, is a collaborative that works to coordinate interested agencies, institutions, businesses, organizations and individuals in order to build relationships between Spanish speakers and the larger Memphis community. Areas of focus for the 7 LMC staff include health care (assisting with information, access, translation, transportation) English classes, the annual Latino-Memphis Fiesta, the largest fiesta in the Mid-South, and information and referral for the Latino and larger community (social services, health care, legal services and professional services). We will also work with local attorneys and the County Victims Assistance Center bi-lingual advocate.

Because caregivers will be seen at home, many potential recruitment and retention barriers such as transportation and respite care, are minimized. Incentives also are offered to CGs, including \$25.00 for each data collection visit; birthday and holiday cards; and \$10 grocery certificates as an additional retention incentive for caregivers who are possible dropouts.

## **Miami**

We have been successful in recruiting diverse populations of older adults in the tri-county area of Miami-Dade, Broward, and the West Palm Beaches for a vast number of projects. For REACH I we were able to successfully recruit 225 caregivers/care recipient dyads, (111 White-non-Hispanic and 113 Hispanics of Cuban descent). In addition, we had high rates of participant retention (94% at the 6 month assessment point, 87% at 12 month assessment point, and 82% at the 18 month assessment point). The primary reasons for participant dropout included: caregiver's or care recipient's illness or death, a change of caregiver, and relocation.

For REACH II we intend to use the recruitment strategies that were successful in REACH I, and expand them to recruit both Hispanics of non-Cuban descent, and African Americans/Blacks. This latter group has been successfully recruited for several projects such as the Center for Research and Education on Aging and Technology Enhancement, and Tele-Care (a project that assists caregivers of cancer patients). REACH I recruitment efforts were supported by a variety of agencies and community organizations including the Alzheimer's Association and two local Memory Disorder Clinics affiliated



with the University of Miami under the direction of Dr. Eisdorfer. Support from these agencies will continue for this project. The recruitment plan employs five sources of referrals/outreach:

Alzheimer's Association. We have a long relationship with the local Alzheimer's Association. The Association has contact with about 6000 caregivers of varying race/ethnicity per year. The Alzheimer's Association has agreed to assist us with recruitment by advertising the project in their newsletter and informing potentially eligible caregivers.

Alzheimer's Disease Clinics/Centers. Both the *Wien Center for Alzheimer's Disease and Memory Disorders* and the *Memory Disorders Center* will actively educate their clients about the project and provide us with direct referrals. The *Wien Center for Alzheimer's Disease and Memory Disorders* has a community-based memory disorders screening program that evaluates approximately 300 community dwelling elderly per year. The *University of Miami Memory Disorders Center* sees about 132 new patients a year. Both clinics treat patients from diverse backgrounds including: African Americans/Blacks, White non-Hispanics, and Hispanics.

Religious Organizations: We have a strong relationship with the Archdiocese of Miami which represents all ethnic and cultural groups in Miami. The Archdiocese was instrumental to our recruitment efforts in REACH. Radio Peace and Catholic Hospice have also provided with assistance. In addition other religious organizations have allowed us to speak at their senior ministries and distributed our materials.

Outreach to the African-American/Black Community. Miami has an active African American/Black population. To facilitate enrollment of this population, we will modify our well-established and continuing outreach to this to incorporate successful and culturally sensitive practices used in other sites (e.g. Birmingham). Various local organizations that directly serve the African American/Black community, such as the Senior Companion Program and the Alzheimer's Association, will assist us with recruitment (see letters of support). Efforts will also be made with the local African American/Black religious and civic organizations.

Easter Seals. This day care center serves approximately 300 individuals per year (19% White non-Hispanic, 23% African American, and 58% Hispanic). Easter Seals also offers a dementia specific in-home respite program, and serves as a community forum for various caregiving trainings.

Senior Companion. This program provides respite to caregivers in the community. It is composed of diverse seniors including: Hispanic (55%), African American (31%), Creole (11%), and White non-Hispanic (3%). They have served as ambassadors for REACH. They are a part of the Elder Services Division in the county, have links with other local agencies that serve the elderly.

Use of the Local Media. The University of Miami has strong relationships with the local media including newspapers and publications and Radio/TV shows. Throughout the years publications such as the Miami Herald, which also publishes "El Nuevo Herald" have featured our programs as human-interest stories. The Spanish and English radios (e.g. Channel 6, Telemiami Radio) have also been helpful

In sum, we have established recruitment mechanisms that are already in place and successful in recruiting large numbers of race/ethnically diverse Alzheimer's Disease patients and their caregivers. We do not anticipate any difficulty recruiting the required number of subjects for the current investigation.

### **Palo Alto**

At the Palo Alto site we will continue to utilize a number of successful recruitment strategies that allowed us to enroll a sample of 110 Latina caregivers in the REACH I project. We will also add additional strategies and community partners, since REACH II will include African American/Black caregivers at all sites, and previously, at Palo Alto, we recruited only Hispanic/Latina and Caucasian

caregivers. A brief description of each program or community partner follows, with their expected contribution to the recruitment process for Palo Alto.

Center for Aging in Diverse Communities at the Univ. of CA in San Francisco (UCSF) is funded by NIA, NINR, and the office of Research in Minority Health. It is a resource center committed to increasing research on the concerns of aging Latinos and African Americans. It conducts community outreach activities, developing centralized lists of community-based organizations serving minority elders throughout the San Francisco Bay Area and ensures the participation of these communities in setting research agendas that will meet their needs. CADC helped REACH 1 by linking the project with community representatives and potential research subject pools, and this will continue in REACH II.

Alzheimer's Association on the Greater San Francisco Bay Area is a very active organization with a specific focus on minority outreach and programming to the African American community. A new office has been established in the Oakland area which is staffed by African Americans and which is in a region with the high-density population of African Americans. In REACH I, we worked closely with their full time multicultural outreach manager to publicize the program – for example, in their quarterly newsletter, which is distributed to over 30,000 professionals and families. We also collaborate with them regularly to organize and present workshops on dementia and family caregiving in several languages; this is a powerful recruitment tool. Dr. Gallagher-Thompson is co-chair of the Multicultural Advisory Committee and spends many volunteer hours promoting multicultural outreach for the Association.

Mexican American Community Services Agency, Inc. (MACSA) is an agency that serves primarily frail Latino elders in Santa Clara county (which has the largest Latino population in this area) by offering dementia day care programming and services in the Spanish language. MACSA was a strong recruitment site for REACH I since we worked hand-in-hand with their staff to provide additional services (through the research protocol) to their participants.

Catholic Charities: Eastside Neighborhood Center in San Jose is a multipurpose senior center that provides a wide variety of services to very low income African and Latino seniors and their families, including some with undetected dementia disorders. In the past we have conducted workshops there and participated in health fairs and other events where it is appropriate to market our services.

Monterrey County Dept. of Social Services Office of Aging and Community Services, located in Salinas, CA (which is in the heart of a major agricultural region, provides an extensive in-home health screening and maintenance program for Latino seniors and their families many whom have undetected dementia. By training the in-home support service workers to recognize dementia, and by providing services that augment what the county can provide, we have established a successful partnership with this very large and growing Office. This will continue in REACH II.

Besides relying on these agencies, we will also mount an outreach effort to churches and other ministries serving African American and/or Latino elders from San Francisco to Salinas. We will also continue use of several successful methods of recruiting Caucasian/White caregivers, including: print and other media announcements and advertisements, posting of flyers at senior centers and agencies serving the frail elderly, and continued education of physicians, nurses, and other professionals, to encourage direct referrals. Finally, in order to successfully retain subjects in the study through to the final assessment point (6 months after enrollment), a variety of strategies will continue to be used, including: payment of the caregiver \$25 for each assessment interview; use of bilingual/bicultural staff for interviews and interventions; in-home interviews scheduled at times convenient for the caregiver; thank-you notes and special occasion cards, to indicate our appreciation for their time and effort; and family, provision of written information at regular intervals, and referrals to other ongoing programs upon completion of this project, if indicated.

## **Philadelphia**

The Philadelphia site has a collaborative relationship with the Philadelphia Corporation for Aging (PCA), who will serve as the primary recruiter for this project. PCA, one of the largest of the 700 Area Agencies on Aging, has provided essential support and service programs to over 65,000 individuals each year in Philadelphia county. Additionally PCA provides support to a vast network of senior centers and neighborhood satellites that serve low income White, African American and Latino populations. PCA has been the primary recruiter for several federally funded research studies at the Philadelphia site, including the first REACH initiative. We thus have a well-established and effective infrastructure in place for recruiting family caregivers through PCA. In REACH I, of the 255 caregivers recruited by Philadelphia, 85% were obtained through PCA. Of this group, 50% were African American and 75% were female, the target groups for our study site.

PCA provides in-home care to 9,294 people and care management through community care options to an additional 1,108. We will support a part-time staff member at PCA who will serve as the recruiter. The recruiter will first review cases of individuals who are either on a wait-list or have received PCA in-home care services, using a form developed for REACH I that operationalizes two eligibility criteria: presence of a family caregiving who lives with the client and presence of memory loss. Memory loss is defined as a score of 2-10 on the Short Portable Mental Status Questionnaire (Higher scores indicate greater cognitive impairment).

Eligible cases are compiled, and twice a month a mailing goes out to 50-100 family caregivers whose relatives meet these study criteria. They receive a letter on official PCA letterhead and a postage-paid return postcard to be completed and returned to TJU. The letter explains study intent and invites the caregiver to respond by either calling the phone number provided or mailing back the postcard. Caregivers who do not respond within a month will be sent a second letter emphasizing the importance of the study and its benefits to participants. PCA will provide a weekly update of recruitment activities including the number of charts reviewed, first letters mailed, and second letters mailed. PCA will also send letters to 500-600 service providers in Philadelphia, inviting them to inform their clients who may be eligible and interested in participating.

Recruitment of Hispanic/Latino caregivers is a new aspect for the Philadelphia site. According to the U.S. Census Bureau, 5.6 percent (89,193) of Philadelphia's population was Hispanic/Latino (of any race) in 1990. The 1999 estimate is 7.5 percent. PCA serves a substantial numbers of Hispanic/Latinos, the majority of whom are Puerto Rican or from Central America. We plan to recruit our Hispanic/Latino sample largely through PCA, using the same procedure as described above. The recruiter will identify Hispanic/Latino caregivers and mail letters of invitation translated into Spanish. In addition, PCA has a Latino Advisory Group which will guide our recruitment efforts to obtain the Hispanic/Latino sample. We will meet with them to initiate the recruitment process, review recruitment materials and their translation, and assure cultural relevance. We will meet thereafter on an as-needed basis.

Three advantages of recruiting through PCA are: (1) the PCA population includes many low-income racially and ethnically diverse elders; (2) caregivers are willing to participate because of the study's affiliation with PCA; and (3) as a service agency, PCA can assist in disseminating the results of REACH to the clinical community and its own service providers.

In addition to PCA recruitment strategies, a secondary recruitment strategy will be to place display ads in neighborhood newspapers. This strategy has worked best when ads are placed in a series, for 4-6 consecutive weeks. Ads will also be placed in the major Hispanic/Latino newspaper in Philadelphia, La Actualidad.

## **INFORMED CONSENT**

Written informed consent from the caregiver is an integral part of this study. All caregivers must give written consent before becoming study participants and assent/proxy consent must be obtained for the care recipient. The consent forms are reviewed and signed at the time of the initial home visit prior to the baseline assessment and prior to administering the MMSE to the care recipient. Participants will be encouraged to ask for clarification about the forms and discuss concerns about the study at this time.

The Coordinating Center and Intervention sites worked together to develop an informed consent shell. Each of the Intervention sites then modified the shell based on the guidelines of their University's Institutional Review Board. Although these forms and procedures may vary slightly, the description of what is offered to the participant is identical across sites. Following is an example of a caregiver and a care recipient consent form.

## **Multisite Intervention Trial for Diverse Caregivers**

**Investigators: Drs. Alan B. Stevens and Louis D. Burgio**

**Sponsor: National Institutes of Health (NIH)**

### *Caregiver Consent Form*

#### **WHAT IS INFORMED CONSENT?**

You are being asked to take part in a research study. Before you can make an informed decision about whether to participate, you should understand the possible risks and benefits associated with this study. This process is known as *informed consent* and means that you will:

- Receive detailed information about this research study;
- Be asked to read, sign and date this informed consent form, once you choose to participate. If you have questions, please be sure to ask for an explanation before you sign this form;
- Be given a copy of this signed and dated form to keep for your own records.

#### **INTRODUCTION AND STUDY PURPOSE:**

You agree to participate in a research study entitled, “Multisite Intervention Trial for Diverse Caregivers,” which is being conducted by The University of Alabama at Birmingham (UAB) and The University of Alabama (UA). The purpose of this study is to evaluate the benefits of an in-home program for a family member who is caring for an individual with memory problems.

#### **PROCEDURES/TREATMENTS**

If you agree to participate in this study, the following procedures will be performed over a 6-month period:

- (1) First, a personal interview lasting up to two hours will occur in your home at a time that is convenient for you. You will be asked questions about your health and the health of your family member, how you are feeling, and some of the difficulties you may be having with taking care of your family member.
- (2) You will be assigned by chance, like by the flip of a coin, to one of two groups.
- (3) If assigned to Group A, within the next six months, you will receive up to 15 contacts including up to 12 home visits and 5 telephone sessions with a member of the research team. These visits will provide basic information about resources in the community, caregiving and memory loss and will teach new ways of managing behavior problems, stress and coping, or other areas of caregiving difficulty. The phone visits will use a screen-phone that works like a normal telephone but will also allow you to access the research team. You will be taught how to use the

system and asked about its usefulness. The system will be removed from your home at the end of your participation in the project. There will be no cost to you for the visits or for the phone.

- (4) If assigned to Group B, during the next six months, you will be mailed educational materials about Alzheimer's disease and caregiving, and 2 phone calls to check on you. At the end of six months, you will be invited to a workshop. At this workshop, you will be offered other resources and programs, such as information about community resources, caregiving and memory loss. You will be provided training on new ways of managing behavior problems, stress and coping, or other areas of caregiving difficulty.
- (5) You will be interviewed in your home six months following the initial interview. This interview will be similar to the initial interview.
- (6) As part of the study, we will be looking at the costs of health care that you receive, including both Medicare costs and the costs of health care you may have paid on your own. To do this, we will request your plan number. Giving us this number will not affect your care in any way now or in the future.

## **COST OF PARTICIPATION IN THE RESEARCH**

There will be no cost to you for participating in this research.

## **RISKS**

There are minimal risks associated with participation in this study. One risk is that you may experience discomfort or fatigue in having project staff call or visit your home. Also, responding to some questions may be upsetting to you. However, these risks are minimal, and a trained interviewer will be able to help you should this occur. You can stop at any point if you feel too tired to continue with the interviews or the home visits. Although we will attempt to keep all information confidential, there is also a minimal risk that personal information about you could be released by accident or by mistake.

## **ALTERNATIVE TREATMENTS**

Your alternative is not to participate in this study. Educational materials and support on the topic of dementia caregiving are available from community organizations. We know of no other treatment or service similar to this research project.

## **CONFIDENTIALITY**

Care will be taken to preserve the confidentiality of all information you provide. The confidentiality of any central computer record will be carefully guarded, and no information by which you can be identified will be released or published. Your records, with regard to participation in this study, may be subject to review by UAB and UA Institutional Review Boards (IRB). Also, the health care professionals involved in this research have the legal responsibility to report suspected cases of abuse, neglect, or exploitation to the appropriate legal authorities.

The information collected in each interview will contain only an identification code and will be kept in a locked file drawer in the Division of Gerontology and Geriatric Medicine located at 933 19<sup>th</sup> St. South,

Birmingham, AL. Interview information will be stored separately from any documentation containing names or other identifying information.

Parts of the home interview and/or sessions with a member of the research team may be audio-taped strictly for research purposes. These tapes will also be kept confidential, with identification codes only, and will be kept in a locked file drawer at the Division of Gerontology and Geriatric Medicine.

In addition, the following agency may request, and will be given access to records of participants in the study: National Institute on Aging/National Institute of Nursing Research. Information provided will only have an identification code and will not contain your name.

### **COMPENSATION IN THE CASE OF INJURY**

The UAB and the National Institutes of Health have made no provision for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge.

### **BENEFITS TO YOU AND OTHERS**

You may not benefit directly from your participation in this study. However, there may be a benefit to society, in general, from the knowledge gained in connection with your participation in this study. Any information obtained from this research study, which may be important to your health, will be shared with you.

### **NEW FINDINGS**

Significant new findings developed during the course of the research that may relate to your willingness to continue participation will be provided to you by a member of the research team.

### **PAYMENT**

You will receive payment for your participation in this study of up to \$50 for two in-home interviews (\$25 for first interview, \$25 for second interview).

### **ADDITIONAL INFORMATION/QUESTIONS**

If you have any questions or concerns about this research, you are free to ask questions about these procedures and to ask for additional information from the persons identified on this consent form as the Principal Investigators, their designated representative, or any other members of the research team involved. You may contact either Principal Investigator, Dr. Alan Stevens of UAB at (205) 934-7916, or Dr. Louis Burgio of UA at (205) 348-7518. Should you have any questions regarding your rights as a research participant, you may contact Ms. Sheila Moore, Director of the UAB Office of the Institutional Review Board for Human Use (IRB), at 205-934-3789, or 1-800-822-8816, press option #1 and ask the operator for extension 4-3789 between the hours of 8:00 a.m.

and 5:00 p.m., Central Time, Monday through Friday. You may also contact Dr. James Lepper, Chair of the UA IRB at 205-348-1355.

### **DISCLOSURE OF FINANCIAL INTEREST**

The sponsor of this research study, the National Institute of Nursing Research, is paying UA and UAB to conduct this study.

**SUBJECT WITHDRAWAL**

Your participation in this research is voluntary. You have been told what your participation will involve, including the possible risks and benefits. Your participation in this research project may be terminated if the procedure is determined to be inappropriate for you.

You may refuse to participate in this investigation or withdraw your consent and discontinue participation in this study at any time without penalty and without affecting your future care or your ability to receive medical treatment at UAB.

**LEGAL RIGHTS**

You are not waiving any of your legal rights by signing this consent form.

**SIGNATURES**

You affirm that you have read the preceding or it has been read to you and discussed with you. A copy of this consent form will be given to you. Your signature below means that you have freely agreed to participate in this project.

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date



## **Multisite Intervention Trial for Diverse Caregivers**

**Investigators: Drs. Alan B. Stevens and Louis D. Burgio**

**Sponsor: National Institutes of Health (NIH)**

### *Care Recipient Consent Form*

#### **WHAT IS INFORMED CONSENT?**

You are being asked to take part in a research study. Before you can make an informed decision about whether to participate, you should understand the possible risks and benefits associated with this study. This process is known as *informed consent* and means that you will:

- Receive detailed information about this research study;
- Be asked to read, sign and date this informed consent form, once you choose to participate. If you have questions, please be sure to ask for an explanation before you sign this form;
- Be given a copy of this signed and dated form to keep for your own records.

#### **INTRODUCTION AND STUDY PURPOSE:**

You agree to participate in a research study entitled, “Multisite Intervention for Diverse Caregivers,” which is being conducted by The University of Alabama at Birmingham (UAB) and The University of Alabama (UA). The purpose of this study is to evaluate the benefits of an in-home program for a family member who is caring for an individual with memory problems.

#### **PROCEDURES/TREATMENTS**

If you agree to participate in this study, there will be an assessment of your abilities whereby you will be asked to name some objects, do some calculations, write a sentence, and follow some simple commands. In addition to being administered this test, research staff will also observe you for a brief period of time, and information about you will be obtained from your relative. It should take less than 20 minutes for you to complete everything.

You will have a follow-up interview in your home six months following the initial interview. This follow-up interview will be similar to the initial interview. The total duration of the study will be six months.

#### **COST FOR PARTICIPATION IN THE RESEARCH**

There will be no cost to you for participating in this research.

#### **RISKS**

There are minimal risks associated with participation in this study. One risk is that you may experience discomfort or fatigue in having project staff call or visit your home. Also, responding to some questions

may be upsetting to you. However, these risks are minimal, and a trained interviewer will be able to help you should this occur. You can stop at any point if you feel too tired to continue with the interviews or the home visits. Although we will attempt to keep all information confidential, there is also a minimal risk that personal information about you could be released by accident or by mistake.

## **ALTERNATIVE TREATMENTS**

Your alternative is not to participate in this study. We know of no other treatment or service similar to this research project.

## **CONFIDENTIALITY**

Care will be taken to preserve the confidentiality of all information you provide. The confidentiality of any central computer record will be carefully guarded, and no information by which you can be identified will be released or published. Your records, with regard to participation in this study, may be subject to review by the UAB and UA Institutional Review Boards (IRB). Also, the health care professionals involved in this research have the legal responsibility to report suspected cases of abuse, neglect, or exploitation to the appropriate legal authorities.

The information collected in each interview will contain only an identification code and will be kept in a locked file drawer in the Division of Gerontology and Geriatric Medicine located at 933 19<sup>th</sup> St. South, Birmingham, AL. Interview information will be stored separately from any documentation containing names or other identifying information.

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In addition, the following agency may request, and will be given access to records of participants in the study: National Institute on Aging/National Institute of Nursing Research. Information provided will only have an identification code and will not contain your name.

## **COMPENSATION IN THE CASE OF INJURY**

The UAB and the National Institutes of Health have made no provision for monetary compensation in the event of injury resulting from the research, and in the event of such injury, treatment is provided, but is not free of charge.

## **BENEFITS TO YOU AND OTHERS**

You may not benefit directly from participation in this study. However, there may be a benefit to society, in general, from the knowledge gained in connection with your participation in this study. Any information obtained from this research study, and which may be important to your health, will be shared with you.

## **NEW FINDINGS**

Significant new findings developed during the course of the research that may relate to your willingness to continue participation will be provided to you by a member of the research team.

**PAYMENT**

You will not receive payment for participating in this study.

**ADDITIONAL INFORMATION/QUESTIONS**

If you have any questions or concerns about this research, you are free to ask questions about these procedures and to ask for additional information from the persons identified on this consent form as the Principal Investigators, their designated representative, or any other members of the research team involved. You may contact either Principal Investigator, Dr. Alan Stevens of UAB at (205) 934-7916, or Dr. Louis Burgio of UA at (205) 348-7518. Should you have any questions regarding your rights as a research participant, you may contact Ms. Sheila Moore, Director of the UAB Office of the Institutional Review Board for Human Use (IRB), at 205-934-3789, or 1-800-822-8816, press option #1 and ask the operator for extension 4-3789 between the hours of 8:00 a.m. and 5:00 p.m., Central Time, Monday through Friday. You may also contact Dr. James Lepper, Chair of the UA IRB at 205-348-1355.

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**SIGNATURES**

You affirm that you have read the preceding or it has been read to you and discussed with you. A copy of this consent form will be given to you. Your signature below means that you have freely agreed to participate in this project.

\_\_\_\_\_  
Participant

\_\_\_\_\_  
Date

\_\_\_\_\_  
Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Principal Investigator

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness

\_\_\_\_\_  
Date

\_\_\_\_\_  
Person Obtaining Consent

\_\_\_\_\_  
Date

## REACH II RETENTION STRATEGIES

Each site will develop, in concert with other sites, mechanisms to maintain interest and motivate caregivers to remain in the study. These may include, but are not limited to the following strategies:

- Participant payment at the baseline and follow-up interviews
- Telephone lines serviced by bilingual/bicultural staff
- Coverage of transportation, parking, and respite costs for caregivers as needed
- Postcard reminders
- Consistent follow-up by phone and mail for missed sessions
- Mail contact between scheduled assessments including thank you notes for caregiver participation in the interviews, holiday and birthday greetings, and get well and bereavement cards. Special effort should be made to consider the religious and cultural backgrounds of participants. For example, do not send birthday or holiday cards to people who are Jehovah's Witnesses.
- Study updates

Remember to carefully track reasons for discontinuation in the study.