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Overcoming Barriers to Enrolling Minorities in Medical Research: What Does the Evidence Say?

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OVERCOMING BARRIERS TO ENROLLING MINORITIES IN MEDICAL RESEARCH: WHAT DOES THE EVIDENCE SAY?

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Abstract Page:

MINORITY RECRUITMENT IN MEDICAL RESEARCH: A MULTI-APPROACH STUDY. Stacy J. UyBico, Cary P. Gross. Department of Internal Medicine, Yale University, School of Medicine, New Haven, CT.

Background: Despite the pervasive underrepresentation of minorities in health research studies, little is known about strategies that aim to increase minority enrollment in research.

Purpose: The purpose of this study was to identify whether elder African American and Latinos were more likely to refuse research participation, identify tangible and specific incentives to improve research participation in this population, and to review the successes and data reporting of recruitment interventions attempted on diverse populations at large, including the non-elderly.

Methods: We conducted a review of Yale OAIC studies to determine minority vs. non-minority research enrollment rates, interviewed key informants about likely barriers and gateways to minority research participation, conducted focus groups and administered a quantitative survey on and to elderly African Americans and Latinos in the New Haven, CT area, and performed a systematic review of published studies attempting to recruit diverse populations.

Results: Results from analyzing OAIC studies determined that elderly minorities were not more likely to refuse research participation. Main themes that emerged from the Key informant interviews and Focus groups were access, the benefits of research and trust in medicine and doctors as well as in researchers and research procedures. Enticements most often identified by survey participants as very important to enrolling in research studies included disclosure of study findings, free health care, 24-hr access to study personnel, explanation of study safety precautions, researchers showing respect, and presence of Spanish speaking research staff for Latinos. The systematic review of attempted recruitment interventions on diverse populations identified that most such studies published do not offer adequate qualitative and quantitative data, are recruiting for preventive studies, are performed more so on African Americans, and that social marketing and community outreach were more commonly attempted when compared to referrals and health system recruitment. Social marketing is successful in leading to the most subjects enrolled with the caveat that it requires a large sample to be screened.

Discussion: Results suggest that minorities can be recruited to medical research, and that innovative methods such as interviewing key informants and conducting focus groups are also particularly helpful in assessing their opinions. Social marketing recruitment interviews appear promising, but better quantitative and qualitative data reporting must be carried out in the future in order to better inform researchers on the ideal ways to recruit diverse populations.

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Introduction:

The NIH Revitalization Act of 1993 [1] authorized that clinical trials be designed to determine whether the variables under investigation affect members of minority groups differently than other subjects in the trial, stating that: *"In the case of any clinical trial in which … members of minority groups will be included as subjects, the Director of the NIH shall ensure that the trial is designed and carried out in a manner sufficient to provide for valid analysis of whether the variables being studied … affect … members of minority groups… differently than other subjects in the trial" [1; 492B(c)]*. Governmental funding agencies, such as the NIH, have instituted new policies stipulating that all sponsored clinical investigations obtain representative numbers of historically underrepresented groups, [2] but despite the federal mandate, those who strive to recruit and retain representative numbers of minority subjects are often frustrated in their attempts to do so [3-5].

Participation of Black and Hispanic minorities in a variety of types of clinical research (trials and surveys) is often lower than necessary to afford representative sampling and to permit valid racial comparisons [4, 6, 7, 8, 9] despite the knowledge that risk factors and disease rates vary by race and ethnicity, and that drug response differs across certain populations [5, 8, 9, 10]. For instance, a recent study [7] on NCI-sponsored cooperative group nonsurgical treatment trials for breast, lung, colorectal or prostate cancers has shown that Hispanics and Blacks were underrepresented. Compared with a 1.8% enrollment fraction in white cancer patients, enrollment fractions of the Hispanic and Black cancer patient pool was only 1.3% each, a statistically significant difference [7]. Another study [6] on participation in AIDS clinical trials showed that 31.8% of whites had participated in a clinical trial while only 17.7% of persons of color had participated, a difference that was also statistically significant. In older adults mental health research, it has been determined that the typical geriatric sample is 86-90% white [5]. Racial differences in health outcomes, disease rates and aggressiveness have long been known to exist. Clinical trials on areas with known health disparities such as diabetes, cardiovascular disease, HIV/AIDS, and cancer have indicated that although federal initiatives have attempted to include a larger population of minorities into research, the inclusion has not translated to reporting of race or results with race analysis, preventing effective therapeutic decisions [11].

Not only have researchers found it difficult to enroll adequate numbers of *minority* participants, but *Black* and *Hispanic older adults* have proven especially difficult to recruit and retain in aging-related research [2-5]. The generalizability of research to Black and Hispanic seniors requires samples that are both large enough for adequate

statistical power and similar enough to the targeted population so that results may be generalized to them [2]. To date, however, little information has been made available to assist researchers in their efforts to achieve sufficiently large and representative samples of aged Black and Hispanic study participants [3, 4]. As a result, investigators have had to proceed uninformed of the most effective strategies for the recruitment and retention of minority seniors. The absence of such information has proven an obstacle to the efficient planning and implementation of aging-related research, in general [4], and to studies of multifactorial geriatric health conditions, in particular.

The difficulties encountered in the recruitment and retention of older minority participants must be surmounted in the interest of public health. Firstly, there are large and increasing numbers of Black and Hispanic older adults [12]. Secondly, the elderly, minorities, and minority elders, in particular, are among the most disabled segments of the US population [5, 13, 14, 15-26]. It appears that age is an additional barrier for minorities when it comes to research enrollment and participation.

BARRIERS TO MINORITY PARTICIPATION:

Several explanations have been offered to explain the low rates of Black and Hispanic participation in research relative to Whites [6, 9, 10, 27, 28-33].

Mistrust is the most common barrier indicated by several studies and serves as a real concern for many Blacks dissuading them from study participation [6, 9]. Given the legacy of past abuses committed against Black participants in medical research, health investigators must counter fears and mistrust engendered by past exploitation if they are to achieve adequate representation of Blacks in clinical research [6, 8, 9, 10, 28, 34]. In particular, the Tuskegee Syphilis Study, in which Black men diagnosed with syphilis were denied antibiotics to cure them of this crippling disease, created “an atmosphere of distrust and suspicion that hampers research efforts in many black American communities” [10: p.124]. The Tuskegee Syphilis Study has created such a political, social, and cultural upheaval that “In the long shadow cast by Tuskegee it has become possible for blacks to believe that AIDS, heroin, and violence together represent a white man’s conspiracy” [35]. Gamble [36] argues that the Tuskegee study is but one example of the racism pervading the history of African Americans with health care institutions and the government, recounting stories of medical students using stolen African American bodies as cadavers and surgeries/medical experimentation performed on slaves without the use of anesthesia before they were put into practice for whites. Additional abuses of minorities by the medical community are well documented, including

court ordered medical procedures during pregnancies of poor women of color, screening African American women for sickle cell anemia without their knowledge or consent, sterilization of African American women without their consent, and Mexican American women becoming pregnant on birth control placebo pills and being denied abortions at their request [37]. African American mental health has historically been used as a justification for slavery, reinforcement of racial inferiority, and scientific reason for segregation [38]. Corbie-Smith, et al [39] demonstrates that African Americans have higher distrust index scores than white respondents by being more likely to indicate that their physicians would not fully explain research participation to them, expose them to unnecessary risks, use them as guinea pigs, and prescribe them medication as a form of experimentation. They were also less likely to believe that they could freely ask their physicians any questions they wanted and more likely to disagree that physicians would not ask them to participate in medical research if physicians knew it could harm them.

Lack of accurate knowledge about research/trials, drugs and the disease is another barrier to minority enrollment in research studies. A study by Harris [40] states that few African Americans have ever participated in a clinical trial, had ever been asked to participate, or knew a friend/family member who had participated. Unson, et al [41] shows that knowledge about the disease (osteoporosis) and treatment (estrogen) correlated with higher participation rates into medical research and differentiated these participants from those who refused participation. Stone, et al [42] demonstrates that persons of color reported less knowledge of clinical trials and were less likely to have been told of clinical trials for which they were eligible, and were half as likely as whites to cite ineligibility as their reason for not participating.

Lack of understanding and trust of informed consent procedures [9] is another substantial barrier to recruitment. African Americans were unaware of any legal protection for research participants and perceived the informed consent documents as a way to protect hospitals and doctors from legal responsibility signifying their belief that signing the paperwork surrenders their rights to autonomy and legal protection [43]. Consent forms have also been classified as educational barriers because they are written at a sophisticated reading level and a cultural barrier if they are not written in a language the patient understands [44].

Other sociocultural barriers to minority participation in research include the real and/or perceived racial and ethnic discrimination [6, 9, 10, 27]. An expressed concern by African Americans is that they would not benefit from the advancements of scientific knowledge because of racial discrimination and poverty [43]. There is also a false view that African American patients cannot follow procedures or understand the research design, and that African

American men are violent and threatening, all contributing to the reluctance of researchers to conduct research on this population [38]. Research bias towards young, single, middle class, White men with above average intelligence has been noted as well as research protocols having inclusion/exclusion criteria such as age and race that are not justified [37]. Many minority populations, particularly Black and Hispanic Americans, report being treated with indifference and disrespect by health care professionals [10, 28-30], which may make them reluctant to volunteer to serve as subjects in medical research. African Americans were more likely to report that their physicians did not: inquire significantly about their pain, tell them how long medications would take to work, explain the gravity of their illness, and discuss examination/test findings with them [36]. Some data has shown that health care providers have prejudicial attitudes towards minority groups (particularly Blacks) which could have consequences in treatment decisions made [45].

Particularly among Hispanic Americans, cultural beliefs about disease etiology and cures (eg. religious views and use of alternative medicines) may influence their potential to participate in medical research [27, 31].

Some Black and Hispanic populations have been shown to delay seeking medical treatment and to underutilize preventive care relative to other populations [28, 30, 32] thereby removing many members of these minority groups from the pool of patients from which medical researchers sample. African Americans are more likely to be assigned to wards after emergency room treatments, assigned to a trainee, go untreated after bladder cancer diagnosis, wait twice as long as Whites for kidney transplants and less likely to get specialist referrals, be accepted into dialysis, and undergo coronary angiographs [37]. Many minorities obtain primary health care in emergency rooms where physicians might not be knowledgeable about research protocols or have enough interest in the patient to refer them for research participation [46]. Such health care disparities only serve as an additional barrier to minority research participation.

Economic barriers, such as lack of access to health care, lack of health insurance, inability to pay for medical services, poor quality health care provided in minority-dense communities, transportation costs, child care costs [27, 28-33] also appear to be crucially important factors affecting minority research participation. There is a strong relation between race and poverty. According to the US census, 30.3% of Hispanics are below the poverty line – a rate not statistically different from that of Blacks but significantly greater than the 8.5% rate among Whites [12]. Poverty among minorities often leads to the neglect of medical needs and lower rates of health service use [27, 18, 47, 48]. As the Surgeon General, David Satcher, MD, recently concluded in a 2001 report on minority mental

health access and care: “minorities tend to be overrepresented among those most vulnerable and in need … including the poor … [and]…disparities in the availability of and access to [mental and physical health] services can be viewed readily through the lenses of racial and cultural diversity, age, and gender …” [18]. Given their greater burden of illness and problems with the availability of and access to health care, elderly Blacks and Hispanics represent groups of Americans most in need of health care and that stand to benefit disproportionately from advances made by medical research.

When researchers attempt to recruit Black and Hispanic seniors, in particular, they have an additional challenge in not only having to confront the above noted difficulties associated with the inclusion of minority participants, [3-5, 8-10, 27, 34] but they must also overcome additional barriers associated with recruiting older adults. In the older population, there exists a higher prevalence of comorbid illness, limited knowledge about medical research, poor vision, hearing, lack of mobility and other functional impairments that may make them ineligible and/or reluctant to participate in clinical trials [13, 14 , 49, 50, 51]. Together, these obstacles make the recruitment of minority seniors especially difficult. In addition to the barriers encountered in the *recruitment* of Black and Hispanic older adults, the *retention* of minority elders in research studies represents yet another research challenge inhibiting the ability to generalize outcomes to minority group participants [4 , 34].

For a variety of reasons that will be explored in this study – mistrust of the medical profession, and sociocultural and economic barriers – researchers have had difficulty achieving adequate and/or representative numbers of minority participants in their studies. There exists a need to obtain first-hand information about the attitudes and beliefs that would influence a targeted minority group member’s decision to participate in research, and what barriers would need to be removed to make such individuals more willing to participate.

INCENTIVES PROPOSED TO INCREASE MINORITY PARTICIPATION:

Although the literature more commonly addresses barriers and impediments to minority research participation (previous section), there have equally been numerous recruitment interventions proposed to increase minority participation. Swanson and Ward classify these recruitment strategies into the following 4 categories: *community methods, health care provider and facilities strategies, individual and family strategies,* and *modifications in research protocols, procedures, and trial management.* *Community methods* include: developing relationships with communities, recruiting community leaders for trial promotion, involving the community for goal

development, recruiting black churches, making public presentations, providing health related information, using community advisors, involving trusted community groups, recruiting in natural settings within the community, demonstrating that the trial will benefit the community, and supporting community celebrations such as Martin Luther King Day. *Health care provider and facilities* strategies include: Providing small grants to minority clinics, recruiting minority physicians and physicians whose patients are predominantly minorities as clinical investigators, establishing networks of community and minority physicians, developing educational materials and programs for community physicians, involving minority health professionals in study design, providing recognition in the community for participating providers, establishing a clinic or study site in the community for the study, and involving primary care providers. *Individual and family strategies* include: Incorporating and understanding cultures, traditions, beliefs, practices, and lifestyle into promotional materials, avoiding the disruption of work and home schedules by having evening and weekend hours in the trial, providing free meals and child care, using support groups to facilitate trial participation, videotapes for recruiting, TV and radio promotion, individual counseling by peers or health care professionals, incentives to participate, transportation, donations rather than fees to cover costs of trial-related services, and having a minority nonparticipant accompany the minority participant. *Modifications in research protocols, procedures, and trial management* suggestions include: translating consent forms, recruitment data management, nonrestrictive eligibility criteria if possible, developing recognizable promotional materials, using an interdisciplinary research team including minorities, using interview and recruiting coordinators known to the community, employing community residents in the study, ensuring adequate staffing to meet special needs of the target population, training for study staff to ensure understanding of concerns and needs of the minority participants, active involvement of investigators in the recruitment phase, assigning nurses as recruiting coordinators, designing studies that offer solutions to problems encountered by specific populations, developing a strategic plan for the recruitment phase, providing educational materials about clinical trials and their benefits, conducting pilot/mock study, and assigning a staff person to assist with form completion [8].

As previously discussed, recruitment of a minority elderly population adds to the challenge due to comorbidities associated with age that are not present with a younger minority population. A very limited number of studies have commented on recruitment strategies/incentives for African American and Hispanic elderly specifically. Arean, et al [52] completed a study showing that the consumer centered approach to recruitment was more successful in recruiting older minorities. Specific interventions included consumer councils, consumer driven

interviews, identified opinion leaders, personalized mailing, face to face recruitment, provider referral, community lectures, community feedback, ethnically matched staff, in home interviews, prescheduled interviews, and patient follow up. It also identified that experienced recruiters were more successful than an ethnically matched recruiter but were less successful than a community member and that provider referrals and face-to-face recruitment were the most important strategies for recruitment in this population. A study by Reed, et al [53] offers feedback regarding the pros and cons to recruiting elderly African Americans via the church, utilizing an advisory board, and offering special services to the community such as health fairs and workshops. Some cons they identified were problems with confidentiality in a church-based research study as well as homogeneity in subject population all recruited from a church setting which in this particular instance, tends to be the healthier, more optimistic, older adults. A study by Dennis, et al [37] on elderly African Americans illustrated that research assistants were unsuccessful in recruiting because they were not trained on how to approach this age group (lacked professional attire, failed to use a method of addressing elders such as Mr./Mrs., and did not allow for social conversation before the start of a research protocol). Gauthier, et al [54] concluded a study on recruiting elderly African Americans by mentioning that an outreach worker and strong ties to community are essential.

CONCLUSIONS AND KNOWLEDGE GAP:

In conclusion, minorities have been historically underrepresented in medical research and it is important to determine whether this is due to higher refusal rates or lack of recruitment attempts. **Because the elderly minority population are an even more challenging group to recruit, it would be most interesting to note whether their refusal rates are higher than elderly white potential subjects.**

Additionally, literature has focused on identifying barriers that prevent minority subjects from participating in medical research. Such articles are always followed by suggestions and proposals/incentives on how these barriers can be overcome to increase minority research participation. **Despite these suggestions on overcoming barriers, there has not been a study to our knowledge that has garnered the opinions of minority members themselves on these commonly suggested recruitment proposals/incentives, particularly those of the elderly minority**. Because minority elders are a more challenging and vulnerable group than younger minorities, they would be a more ideal group to interview regarding such opinions. Their valuable input as to whether they feel these

detailed proposals/incentives would be successful in recruiting them towards research participation are much needed in assisting those trying to recruit more minorities into their research in making a more effective guideline as to how it should be done. With most researchers working within a financial budget and time constraints, it is crucial that the proposals/incentives that would be most well received by potential minority subjects, specifically the elderly, be identified.

There has also not been a complete review of published literature on which recruitment interventions are successful for recruiting minorities into clinical trials. There has been a request for complete reporting of recruitment efforts that includes a description of the racial, ethnic and cultural composition of subjects in trails as more complete reporting of recruitment successes and failures will provide a needed database to outline the most and least effective recruitment strategies across diverse populations [8]. However, the current body of literature has not been formally assessed. Hence, it is unclear which interventions have been evaluated, or whether they have been effective. Furthermore, such body of literature has not been quality assessed and it is important to do so to determine whether the data can support the authors' conclusions regarding the effectiveness of such interventions.

Statement of Purpose (Hypothesis/Aims):

If researchers are to comply with the NIH Revitalization Act of 1993, potentially effective strategies for enhancing the inclusion of minorities and minority seniors into research will first need to be identified, and later tested, so that strategies that prove effective can then be implemented. The specific aims of this project are:

- To identify whether older minorities are more likely to have higher refusal rates for research participation when compared to older non-whites according to Yale's Older Americans Independence Center (OAIC) studies.
- To identify incentives that will counter mistrust issues preventing participation of Black and Hispanic older adults in research, and to obtain specific recommendations as to how these incentives can be effectively implemented by the research team.
- To elucidate opinions of older African Americans and Hispanics on the importance of commonly proposed solutions/incentives to research recruitment found in literature and to subsequently propose guidelines for ideal recruitment of this population.
- To identify which recruitment strategies for diverse populations have been attempted and documented in literature, and which have been deemed successful, followed by an assessment of the qualitative and quantitative data presented in such publications. Guidelines for proper data reporting in minority recruitment studies will also be proposed. This will aim to include minorities of all ages, not limited to the elderly.

Methods:

Overview: To realize such aims, the following 5 phases were carried out:

Phase 1: Explored Yale's Older Americans Independence Center (OAIC) recruitment and retention data, in order to determine whether older minorities would have lower enrollment rates in research studies compared to older non-minorities.

Phase 2: Interviewed key informants to identify important issues in Black and Hispanic older adults' participation in aging-related research, not limited to barriers preventing their research enrollment, but also on identifying incentives to increase participation.

Phase 3: Conducted focus group discussions on ways to promote research participation among Blacks and Hispanic elders. These were community recruited subjects interviewed as a group by using a focus group discussion guide and moderator. Information obtained from Phase 2 was used to inform the focus group discussion guide used for this phase. Focus groups are different from phase 2 because the latter individually interviewed key informants who were deemed by our research team as experts in the field of minority studies.

Phase 4: Administered a quantitative survey to focus group participants to investigate first-hand opinions of minority elders on commonly proposed recruitment strategies found in literature. The survey was created before phase 3 (focus groups) was carried out. Data obtained from phase 2 and background literature review was used to create items included in the survey.

Phase 5: Conducted a systematic review not limited to the elderly on recruitment interventions attempted on diverse populations.

Phase 1: OAIC Research Data

This began with an examination of completed and ongoing OAIC-research studies to identify characteristics associated with participation and non-participation among Black and Hispanic older adults. 10 studies were used and identified as: PEP, Prehab, Driver IDS, Project Recovery, SPECT, Alcohol Use, Visual Attention Training, Traumatic Grief, ICU Cognitive Outcomes, and Pneumonia [55]. Data was analyzed to answer the question as to whether minority elders were more likely than whites to refuse research participation. This phase was performed by Cary Gross, Holly Prigerson, and Joanne McGloin.

PHASE 2: Key Informant (KI) Interviews

The (KI) consisted of five African-American and five Latino individuals drawn from a variety of settings and included church and community organization leaders, mental health and research professionals, academics, hospital administrators and janitorial staff. All persons interviewed were recognized by the authors as knowledgeable about African American and/or Latino older persons' concerns regarding health research participation. The KI interview included fifteen open-ended questions about potential barriers and possible incentives to research participation. Each interview was conducted separately and lasted 60-150 minutes. Content of the completed KI interviews was analyzed to inform the development of the focus group discussion guide and quantitative survey. Specific recruitment strategies were identified and grouped according to specific barriers that they were designed to overcome. This phase was performed by Cary Gross, Holly Prigerson, Joanne McGloin, Ezra Griffith, and Esperanza Diaz.

PHASE 3: Focus Groups Discussions.

Focus group participants included groups of 8-10 older adults (age 65 years and above) who are members of the same racial/ethnic group (primarily Black or Hispanic-identified). Representatives of the groups being targeted for research on multifactorial geriatric health conditions were approached about serving as focus group participants and a recruitment flyer (Appendix A, B) both in English and Spanish was posted throughout the community (Senior Center, Latino clinic). A financial incentive of $25 for participation was offered. Participants signed informed consent forms in English or Spanish (Appendix C, D), and the sessions were recorded for subsequent transcription. Each racial/ethnic group were run separately and the discussion lasted approximately 1½

hours. A total of 4 focus groups (3 African American and 1 Hispanic/Latino) were completed. A trained minority focus group facilitator was responsible for setting the tone for the group interactions, asking broad questions of relevance to the study of recruitment of minority seniors into aging research, and redirecting the potentially challenging group dynamics expected to result. Sites for the focus groups were all located in New Haven, CT. Specifically, focus groups for African Americans were held at Dixwell Senior Center and at La Clinica Hispana for the Hispanic focus group. Because enrolling minority seniors into the focus groups may itself present a challenge, some of the proposed strategies to enhance minority elder participation (e.g. participant payments, running the groups in a location likely to be familiar and convenient for participants, having trusted members of the minority community serve as liaisons to assist in enlisting the participation of minority seniors in the focus group discussions) were employed in an attempt to obtain adequate and representative samples of minority elders for focus group participation. Only the focus group participants and the moderator were present during the focus group discussions. The discussion was audio taped for later transcription and analysis. A Focus Group Discussion Guide was created (Appendix E, F) by the research team in English and was then translated to Spanish for the Hispanic group. The content was a synthesis of the information obtained from the recruitment/retention data and the in-depth interviews with the key informants. The focus group discussion opened with an introduction of a hypothetical scenario of a trial testing high blood pressure medications with an explanation of randomization and the responsibilities of participating (e.g. blood pressure checks, blood draws). Participants were asked to keep this scenario in mind throughout the focus group discussion whenever 'research' was discussed. This was done to ensure that participants were all in a similar mindset when 'research' was discussed throughout the focus groups. The theory behind the use of this hypothetical situation centers on the fact that research studies are so broad and diverse especially with regard to intrusiveness and the authors believed the inclusion of a hypothetical research study would eliminate such varying thoughts on what research study the participants were thinking of throughout the focus groups. Based on a review of the minority research participation literature, themes covered in the Focus group Discussion Guides included: 1. *Open-ended questions* (e.g. Would you participate in this research (the hypothetical scenario offered) and why? Why not?). 2. *Concerns* (e.g. Trust, confidentiality, laws, communication, respect, researchers' financial motive), and 3. *Motivators* (e.g. Financial, staff person in research team to act as assistant, study buddy, community advisory boards, recruiter characteristics). The focus group discussion transcriptions were used to prepare an initial list of themes/codes. A meeting was then conducted with other project investigators to review the initial lists and then

generate a group list of major themes. Both the raw and coded transcripts were entered as data into the NVivo software program. This program assists with the interpretation of qualitative data by searching and exploring the data for emerging patterns and meanings, and by constructing themes and generating test explanations from the data. Once all the sessions were content analyzed by NVivo to the point of saturation (e.g. the point beyond which no new themes emerge), results were extracted. This phase was performed by Cary Gross, Stacy UyBico (created design and first draft of the focus group discussion guide, transcript coding for theme extractions), Holly Prigerson, Joanne McGloin, and Sarah McGraw.

PHASE 4: Quantitative Survey of Focus Group Members

Surveys in English and Spanish (Appendix G, H) for African Americans and Hispanics, respectively were administered following the focus group discussions. The survey was created before the focus group sessions were carried out. Subjects were asked to rate the importance of literature proposed solutions/incentives to increase minority participation in research. Surveys had 16-17 total items to rate as not important, somewhat important, a little important, or very important. Participants were read the survey to remove certain barriers that might be found in this population such as vision impairment or inability to read.

The survey for the Hispanic group had an additional question regarding the importance of a Spanish-speaking research team member but otherwise, was identical to that of the African American group. Responses were then quantified and categorized according to which item received the most votes. This phase was performed by Cary Gross, Stacy UyBico (created first draft of survey items to be included), Holly Prigerson, Joanne McGloin, and Sarah McGraw.

PHASE 5: Systematic Literature Review

This phase was completed by Stacy UyBico, Shani Pavel, and Cary P. Gross.

Data Sources: Data sources included studies that reported on recruitment intervention(s) with respect to a special population and with a parent study that was an intervention. The MEDLINE database was searched up to April 2005, using the exploded Medical Subject Heading terms 1. clinical trials or randomized controlled trials or multicenter studies, and 2. African Americans or Hispanic Americans or African American Continental Ancestry

Group or minority groups or social class or socioeconomic factors or poverty or medically underserved area or urban population, and 3. patient selection or research subjects, and [(enrol$ or recruit$ or particip$ or enlist$ or attrit$ or retent$).mp., and 4. (interven$ or initiativ$ or method$ or strateg$ or increase$ or enhanc$).mp . Further articles were found using hand searching of three journals including Journal of the National Medical Association, Controlled Clinical Trials, and Ethnicity & Disease from January 2002 to April 2005. Additional studies were identified by personal sources and reference sections of relevant studies. This strategy was supplemented by using the Web of Science database to generate a list of articles that cited studies of interest.

Study Selection: Data sources included studies that reported on recruitment intervention(s) with respect to a special population defined as minority, underserved, poor, rural, urban, or inner-city. The parent study (the study for which recruitment was taking place) also had to be an intervention. A study was excluded if it did not meet the aforementioned inclusion criteria such as if the target population was only age specific (i.e. elderly) or gender specific (i.e. women) without meeting the definition for special population as we have defined it. Also, a study was excluded if it was an observational design or survey without an intervention. Three investigators (S.U., S.P, C.P.G.) reviewed 2648 total citations and selected appropriate studies by first searching titles and then abstracts, leading to a total of 96 articles for review. Two investigators (S.U, S.P) reviewed these articles for inclusion or exclusion. Both investigators agreed on 90 of the 96 articles for inclusion (94% agreement) and a third investigator (C.P.G.) reviewed the disagreements for a final group decision. A total of 49 manuscripts were included for analysis but with some presenting data on more than one parent study, a final total of 57 parent studies were included in our review [37, 52, 56-102]. Figure 1 presents the flow diagram for this search methodology.

Data Extraction: Two investigators (S.U, S.P) extracted the following quantitative data from each study: the number approached and/or screened per recruitment intervention, the number eligible for study participation per recruitment intervention, the number enrolled per recruitment intervention, any other statistical data or quantitative data, and data on retention. The following qualitative data were extracted: presence of objectives, demographics of target population, description of recruitment intervention(s), description of locations for recruitment, statement of outcomes, presence of control group and description of its recruitment intervention (control group: present when >1 recruitment intervention attempted and data given separately), determination of which people would receive which recruitment strategy (i.e. randomization, before/after time, multiple geographic locations, etc), balance of the demographics of populations recruited via differing recruitment intervention(s), presence of data including the

number of people approached, screened, eligible and enrolled in the study per recruitment intervention, time and cost per recruitment intervention, use of formal statistical analysis, whether the target population was representative of the larger population, and whether data supported authors' conclusions.

Synthesis of Evidence: Based on the data offered per study, the investigators attempted several calculations that would potentially be meaningful with respect to elucidating the success of each recruitment intervention. Calculations were made according to categories we created for all the recruitment interventions as there were numerous. We chose to categorize the interventions into 4 main categories: social marketing (SM), community outreach (CO), referrals(R), and health system (HS) recruitment. Social marketing includes mass mailing, mass telephone calls, and media (TV, radio, newspaper, magazines, newsletters, brochures, flyers, PSA, specialty publications to a target group). Community outreach includes church recruitment, contact with community leaders and organizations, presentations and meetings usually carried out by research team out in the community, health screenings, house to house/door to door/face to face contact in the community, community events participation with a booth, etc). Referrals include those from friends, family, other participants in the same study, participants from another study, etc. Health system recruitment includes the involvement of the health care provider who is approached by the research staff and possibly asked to refer potential subjects, health center recruitment (research staff or representative physically recruiting in a medical setting such as a clinic or emergency room), and using the patient charts and registry. All other recruitment interventions that could not be categorized in any of the four above were classified as "other" but were not included in the following calculations:

The enrollment percentage (ENP) defined as the # enrolled/# screened per recruitment intervention x 100 was calculated for the purpose of detailing whether a particular recruitment intervention was successful in obtaining enrollments with respect to the number screened by that recruitment intervention. When possible, ENP was calculated for social marketing interventions and "all other interventions" combined (community outreach + referrals + health system). If social marketing was combined with any of the other interventions with one enrollment number given, then it could not be used in this analysis because this precludes the comparison of social marketing vs. "all other interventions". Statistical analysis to calculate p-values were attempted and $p<0.05$ was considered statistically significant. Such studies are included in the results and analyzed. This comparison of social marketing vs. all other interventions was performed because of the hypothesis that casting a broad recruitment net (which is

what social marketing recruitment would do) might lead to less efficiency due to the potential of attracting many ineligible subjects resulting in a lower ENP than all the other recruitment interventions which are more personalized.

In order to describe the source of patients, the investigators also attempted to calculate the ***contribution to study sample*** which was the % of study participants that came from each recruitment intervention, calculated as follows: # enrolled by a recruitment intervention/total # enrolled in study x 100. *Contribution to study sample* was calculated per main recruitment intervention divided into the aforementioned 4 main categories (social marketing, community outreach, referrals, and health system recruitment). On studies that allowed for the above calculations, statistical analyses were performed to calculate p-values in order to determine which of the main recruitment interventions might be successful in attaining enrolled participants and contributing to the largest enrolled sample. Pairwise comparisons of proportions were used. All p-values <0.05 were considered statistically significant and considered in the analysis. For other studies that did not have a p-value calculated, this was due to the fact that a main recruitment intervention category could not be accurately compared against another due to the way the author has combined their recruitment interventions and given one data set for such a combination. Additionally, p-values were not calculated if all the interventions were considered to be under one category (i.e. all were under Referrals). For studies that had data under more than 2 categories, the two largest percentages were used to calculate the p-value.

Manuscript quality was also ascertained. The investigators adapted existing qualitative manuscript forms to derive a qualitative score for each study. The following point criteria and scoring system were used: inclusion of target population demographics (20 points), description of the recruitment intervention(s) (5 points), location of recruitment noted (5 points), time spent per recruitment intervention included (5 points if Yes, 2.5 points if only statement given without the actual time noted), cost per intervention included (5 points if Yes, 2.5 points if only statement given without the actual cost noted), presence of control group and randomization (10 points), OR presence of control group but not randomized (5 points if used time and geography as ways to determine who received what recruitment intervention, 2.5 points if used multiple recruitment interventions at once and are just reporting the results, and variable points from 0-5 points determined by researchers individually if used “other” method), balanced sociodemographic characteristics if there were >1 group receiving differing recruitment interventions (10 points if Yes, 5 points if No but authors mentioned it was not balanced and 0 points if it is unclear or there was a lack of inclusion), recruitment data included: number of people who received the intervention (#

approached or # screened or both) per intervention (6 and 2/3 points), number of people who were eligible per intervention (6 and 2/3 points), number of people who were enrolled per intervention (6 and 2/3 points), and use of statistical analyses to compare recruitment strategies against each other (20 points). An article could score from 0-100 points with a score towards 100 representing an article that more likely contains the above ideal data.

Finally, investigators determined quantitative data from the 57 studies including the population studied, the parent research study type (prevention vs. treatment studies), types of recruitment interventions attempted, and the presence of qualitative data previously mentioned.

Results:

Phase 1: OAIC data

Rates of research participation refusals for non-whites were greater when compared to whites in only 2 of the 10 OAIC studies (PEP and Alcohol Use), leaving the remaining 8 out of 10 studies with greater enrollment refusals from white potential subjects. Table 1 presents the review of OAIC studies and refusal rates by race.

Phase 2: Key Informant (KI) Interviews

Three general themes emerged from the KI interviews including larger themes of access, research benefits, and trust. Table 2 presents these Key Informant Results and the Emergent Themes and Specific Issues of Concern.

ACCESS: First, the theme of access emerged from concern for the challenges of language barriers, levels of literacy, location of research facilities, hearing and vision impairments, transportation difficulties and competing responsibilities. To address the language and literacy challenges, KI's recommended bi-lingual investigators and research staff, culturally sensitive translations, and easily understood study materials. Other strategies to address access for older African American and Latino persons included locating the study in a familiar community site, using adaptive aids to assist persons with vision and hearing difficulties, providing free transportation and parking or making home visits, and offering sitting or care for children or other family members. Flexible scheduling of research appointments and coordination among studies to reduce burden on older participants were also recommended by the KI's.

BENEFITS: The second emergent theme was the benefits of research both to the individual participant and to the community. Benefits to the older individual included the potential for better health as a result of the research or from screening or other health services that might be provided to study participants. Non-health related benefits to individual participants included direct compensation such as payments to study subjects. Benefits to the community were the relevance of the research to the needs of the community and whether the results would help the people in the community. KI's recommended involving community members on an advisory panel early in the process of defining the study question, refinement of the study design and the conduct of the study.

TRUST: The final theme to emerge from the KI interviews was the theme of trust, both in medicine and doctors and also in researchers and research procedures. Trust in physicians and Western medicine arose around the issues of adverse medication side effects, skepticism about the efficacy of medicine in general, concern about

medical errors, and concern about prejudicial treatment and racism. Strategies recommended by the KI's to address these included educating potential study participants about study safeguards to health and building trust and respect in relationships between the medical community and minority study participants. KI's raised important concerns specific to research: that researchers may lie or conduct experiments for their own benefit, that findings are often presented in such a way as to perpetuate racial or ethnic stereotypes and that participants' confidentiality will not be protected. To address these challenges, KI's suggested the following strategies to manifest respect for the concerns of older African- American and Latino study participants: that the justification for the study be clearly emphasized, making fully transparent why the problem and the study results are important to the particular racial/ethnic minority group, if not the general population; the use of a study buddy or culture broker; reporting back to participants and the community; passing on the knowledge gained from the study; and emphasizing the safeguards to privacy.

Phase 3: Focus Groups (FG)

Table 3 presents the Emerging Themes and Specific Comments from the Focus Groups. The same themes of Access, Benefits and Trust were evident.

ACCESS*:* FG members expressed concern about communication. FG participants reported difficulty in understanding research or medical jargon. "They use words you don't understand." Members of the Latino focus group were unanimous in rating the strategy of having study staff members who speak Spanish as very important. "I think all doctors should be bilingual." Not only language and terminology, but also being listened to and having things explained in a thorough, unhurried manner about all aspects of the research that were important to FG members. "They really don't listen to me." "Take time and talk to me." Having someone else, especially a trusted and supportive family member, in the room to advocate for them when the older person might not be in a position to do so was generally regarded as a favorable option. "What you might miss, your family might pick up." "I would feel much more secure with family." The respectful attitude of the research staff, including good manners, personal attention, honesty, and expressions of being caring was important to FG participants. Staff matching by ethnicity alone was not considered sufficient for attracting older African American and Latino persons to research studies. While not all respondents felt it was necessary that the staff person be someone they already knew and trusted, FG discussants noted that the recruiter should be someone who was knowledgeable and respectful with a "pleasant

voice" and manner, using "Mr." or "Mrs." until invited to use a more familiar name, punctual for all appointments; and demonstrating a thorough knowledge of the study and all procedures.

BENEFITS -The group members affirmed the importance of the research topic as a motivator. "First of all, you have to know why they are doing this". FG participants indicate the importance of being educated about the research and the disease under study. The potential benefits of research to the individual were attractive to African American and Latino FG members. "I would be willing to try. . . you might get better results." Appropriate monetary compensation was preferred by older persons as a means of acknowledging their contribution of time and effort to the research. Likewise, sharing personal test results with participants was viewed positively. Potential benefits of research to other people were discussed in the FG's. "Many people have high blood pressure." "I'm not only thinking of myself - I'm thinking of generations to come, or somebody that I may be helping." "I may be dead and gone but with that research it might help somebody else." Across all four groups, almost all participants wanted to be informed as to how the results of the research study would benefit other people with high blood pressure.

TRUST - Most of the FG participants had personal experiences with their primary care physicians that influenced their opinions about medical research participation, both positively and negatively.

The recommendation of a trusted personal physician to participate in research was identified as a key factor in decision making for those who had such a doctor-patient relationship. "I would mostly leave it up to the doctor." "If a doctor says to me, 'you know there's a new medicine…let's try this.' He wouldn't direct the wrong stuff." The absence of a solid and consistent relationship with their physicians was noted by some FG discussants who stated: "Every time you turn around, you see another doctor", implying that the lack of doctor patient relationship might not allow physicians to recommend research participation in such a scenario. Yet another perspective came from FG members who held strong beliefs, such as never giving blood or never taking medicine that limited their interest in medical care altogether including any health related research participation.

Another important finding was the difficulty experienced by the focus group participants to differentiate between a "researcher" and a "physician". When repeatedly asked about their feelings regarding the research team, participants would consistently dwell on the treatment they have received as patients with physicians.

Reasons to mistrust researchers were offered. FG participants, particularly those in the African American focus groups, did not believe in researchers' ability to maintain confidentiality. Group members voiced the opinion that once a person provides information, it cannot be secured, even by the best-intentioned researcher. Most people

endorsed skeptical views with statements made such as: “In today’s age, confidentiality is out the window” and “With the social security number, they know more about you than you know about yourself”. The existence of racial bias was endorsed by the group members in terms of both the exclusion of minorities from beneficial research, prior abuses of African-American people in particular, and prejudicial presentation of results. “Every time they do a study it’s always just whites.” “The Blacks were the guinea pigs.” “There are so many times that research is done and the percentage of the negative seems to always be on the Blacks.” FG members suggested that research participation for older minority persons could be made attractive with assurance that all racial groups are equally represented in all arms of a study. Strong statements, such as “They gave all those men syphilis and didn’t tell them-that really turned me off” indicate that trust remains a crucial component affecting minority research participation. FG’s were seriously concerned about safety issues: the risk of adverse events; the possibility of losing the benefits of a current medication by replacing it with an investigational drug; and the rush to market of new medical products. Providing a call line to contact the study with any question or problem was a well-received incentive. “Someone you could call 24 hours no matter what the problem-that person would be an asset to the program.” Also, providing a “study buddy” or enlisting a family member to help interpret study instructions may help place potential respondents at ease.

FG results depict unexpected ambivalence about the influence of community leaders on participation in research. “Who determines who is a community leader?” “People want to decide for themselves.”

The financial interest of the investigator was found to be less important than other issues for prospective study participants. “If the person participating is going to get money, I think the researchers should also.” “I think it’s ok if he’s going to do it the right way.”

Phase 4: Quantitative Survey (QS)

Table 4 presents results on the Quantitative Survey items.

Items indicated as very important >90% of the time were: study staff member speaks Spanish (Hispanic group only), and told the study results would benefit people with high blood pressure. Items indicated as very important 80-89% of the time were: free health care, researchers making available a 24 hour study hotline for emergency contact, researchers explain how they monitor problems and that they will stop the study if any should arise with the subject, researchers show respect, researchers explain what they have done to ensure study safety,

researchers will share study results with subject, subject is told how the results will benefit the African American or Latino people, and researchers explain the laws to protect subjects and punishment they receive if they do not abide. Items indicated as very important in 70-79% of the time were: researchers tell subjects they will not be used as guinea pigs, research staff explains the study to a family member, and the subject is told the study is confidential. Items indicated as very important 60-69% of the time were: member of research team is trusted by subjects, and researchers tell subjects the study results will be shared with the African American or Latino community. One item was indicated as very important 50-59% of the time and this was community leaders approving and supporting the study. The last item indicated as very important 40-49% of the time was that subjects are told whether the researcher might gain money from the research (financial conflict of interest).

Phase 5: Systematic Review

49 articles with data on 57 total studies were reviewed. See Figure 1 for data regarding assembly of study sample.

Description of the studies included in this analysis are presented in Table 5, separated by population targeted for recruitment, parent research study type, and types of recruitment interventions.

Population Targeted for Recruitment: The populations included in the 57 studies reveal that most included analysis or study of African Americans (83%) while slightly less than half included Hispanics/Latinos (46%). 58% of studies also included a population other than the aforementioned such as Whites or other minority groups (i.e. Asian, Native American, etc). Older or Elderly populations when defined by authors consisted of 23% of the studies, rural population in 4% of studies and low SES or underserved populations in 18% of studies.

Parent Research Study Type: Quantification of the parent research study type with larger comparisons of prevention vs. treatment studies was performed. Results identified that 76% of the studies are prevention studies and only 24% were treatment studies. Further breakdown of the type of preventive and treatment study under categories of drug, behavior/lifestyle, screening test, surgery and other are also presented. Behavior/lifestyle was the most popular under prevention studies (41%) and drugs under treatment studies (10%). The fact that majority of the studies included were on prevention studies will have important implications on other results obtained, especially with regards to the likeliest most successful recruitment intervention identified by this review (see discussion section).

Types of Recruitment Interventions: The types of recruitment interventions attempted in the 57 studies were quantified. Social marketing was used in 81% of studies, Community outreach in 81% of studies, Referrals in 28% of studies, and Health system in 53% of studies. Social marketing strategies in order of popularity were as follows: Media (68%)>Mass mailing (42%)>Mass telephone calls (14%). When further analyzing media interventions, the popularity of the subcategories was as follows: newspapers/magazines (51%) > flyers (46%) > radio (44%) > TV (39%) > other (23%)> newsletter and brochure (19% each) > PSA (7%) > specialty publications to target groups (5%). The "other" category under media includes bulletins, posters, videotapes, internet or was not otherwise specified. Further breakdown of community outreach is as follows: church (39%) > contact with community leaders and organizations (35%)> presentations/meetings in the community (33%)> community events/table/booths (25%) > health screenings (19%) >house to house/door to door/face to face contact (16%)> other (5%). Further breakdown of referrals suggests the following in order of popularity: Referrals from friends/family (18%) > other participants in the study (12%)> other (12%) > another study (5%). Further breakdown of Health system recruitment is as follows: health care provider was approached by research staff or asked to refer (37%)>recruitment at a health center (28%)>recruitment via patient chart review or registry (19%). 16% of the studies used an "Other" recruitment intervention not categorized in any of the above, including an ethnically matched recruiter or language interpreter (16%), direct compensation (18%), convenience (14%), having a study buddy (2%), and a questionnaire sent home to children's parents in the Hooks study [72] (2%). Direct compensation was divided into financial gain such as money and coupons (14%) and other gifts such as mugs, T-shirts, pins, etc (5%).

Study Quality:

Quality of Study Reporting results are presented in Table 6. The 57 studies were data abstracted for qualitative data reporting in 7 categories including description of recruitment study and interventions, assessing efficacy of intervention, controlling for bias, data reporting, external validity/generalizability, internal validity, and retention of participants after enrollment.

Description of Recruitment Study and Interventions: All (100%) of the studies reported their hypothesis or objective, the target population demographics, described their recruitment interventions and the locations for which recruitment would take place. However, only 16% of the studies reported the time spent per recruitment intervention

and an additional 19% of studies made a statement indicating which of their method(s) were more time-efficient although without any actual data offered to support their statement. The remaining majority of studies did not mention time (65%). With respect to cost, only 12% of studies reported actual cost per recruitment intervention with an additional 11% of studies making a statement regarding which recruitment intervention(s) were cost-effective although without actual data to support such statement. The remaining majority of studies did not mention cost (77%).

Assessing Efficacy of Intervention: Results show that 72% had a control group, defined as a recruitment intervention for which all others are compared. If the authors did not explicitly state which recruitment intervention was their control group, the data reviewers would identify the control as the recruitment intervention carried out that was attempted first in a chronological fashion or the cheapest or the easiest or the quickest to carry out. Studies that did not have more than one distinct recruitment intervention for which all other interventions were compared against were classified as having no control. All of the 41 studies determined to have a control group adequately described the recruitment intervention for the control group (100%).

Controlling for Bias: Of the 41 studies with a control recruitment intervention, only 2 studies used randomization as means to determine which group would receive which recruitment intervention (5%). Of these remaining 39 studies, 39% attempted multiple recruitment interventions at once, 34 % attempted recruitment intervention(s) only to subsequently follow after time with other interventions, and 15% decided based on geography (location determining the recruitment interventions that could differ, such as clinic based recruitment or multiple recruitment centers geographically separated). In 12% of studies, authors stated that groups receiving differing recruitment interventions were similar with regard to sociodemographic and clinical characteristics, but in 68%, it was unclear whether this was the case or not. In 20% of the studies, authors stated that the groups were not similar.

Data Reporting: Only 49%, 30%, and 56% of studies reported the number approached/screened, eligible, and enrolled per recruitment intervention, respectively. Furthermore, only 21% of studies used formal statistical analysis to compare recruitment interventions.

External Validity/Generalizability: With respect to populations that received recruitment interventions, only 18% were actually representative of the entire population from which they were recruited, 11% were not

representative as declared by authors, and the remaining 72% of studies had unclear data as to whether this was the case.

Internal Validity: Only 19% of studies had a control group and a statistically significant difference in enrollment observed amongst the recruitment interventions attempted. In an additional 39% of studies, this was maybe the case as these studies had a control group without a statistically significant difference in enrollment although by observing the quantitative data, there appears to a difference in enrollment amongst the recruitment interventions attempted. In the remaining 42%, this was not the case as these studies either lacked a control group or had insufficient data.

Retention of Participants After Enrollment: Only 39% of the studies discussed retention, with 16% further discussing retention with respect to the recruitment intervention (i.e. “Those recruited via community outreach were more likely to be retained in the study than those recruited via media”).

Quality Score:

Table 7 presents the study quality score per study for all 57 studies. All studies had a mean quality score of 51 out of 100 points, a median of 47, range of 30-85, and Q1 of 39, Q3 of 61.

Enrollment Percentage (ENP):

There were 11 studies that satisfied our methodology criteria for ENP calculation and are included in Table 8. P-values presented in this table were calculated to identify a difference in % enrolled between social marketing and “all other interventions”. Of the 8 statistically significant studies, 5 showed that “all other interventions” was more effective and 3 showed that social marketing was more effective. Overall, there was not compelling evidence that all other interventions was superior to social marketing, although they suggest that this might be the case if more studies were included.

***Contribution to Study Sample*:**

Table 9 presents the *Contribution to study sample* table for the 27 studies that allowed for this calculation. Studies with P-values <0.05 were considered statistically significant and their results will be presented here.

Table 9a presents the additive data for all the included statistically significant studies.

ALL STUDIES: For all such studies when considered together, health system recruitment was the most successful intervention in 6 studies of the 12.5 studies that attempted it (a study was counted only 0.5 instead of 1 if it had HS combined with another category like CO. This additive method was used for all of the results here). 6/12.5 equals 48% which means that 48% of the time that it was attempted, HS recruitment was the most successful in getting the most enrolled subjects. Social marketing follows and was the most successful intervention in 8 studies of the 17 studies that attempted it. This means a 47% (8/17) chance that it was the most successful recruitment intervention when it was attempted. Referrals were the most successful in 3 of the 6.5 studies that attempted it, meaning a 46% chance of being the most successful recruitment intervention when it was attempted. Lastly, community outreach was the most successful in 2 of the 15 studies that attempted it, meaning a 13% chance of being the most successful recruitment intervention when it was attempted.

BLACKS: Using similar additions as above, when just analyzing studies with Blacks as the target population, 10 studies were statistically significant. Health system recruitment was the most successful recruitment intervention in 4 of the 6 studies that attempted it (67%), social marketing in 3 of the 8 studies (38%) and community outreach and referrals were successful only 25% of the time each (2/8 studies for CO and 1/ 4 for R).

HISPANICS: For studies with Hispanics as the target population, there were 4 statistically significant studies. Referrals were the most successful in 2 out of 2 studies that attempted it (100%), followed by social marketing in 2 of the 4 studies (50%) and both community outreach and health system recruitment were successful 0% of the time each (0/3 studies for CO and 0/3 for HS).

Health system recruitment appears to be very popular with Blacks and referrals with Hispanics. Social marketing did moderately well for both populations and community outreach fared the worst.

OTHER: For studies with an “Other” population as the target population (non Black or Hispanic), there were 5 studies that were statistically significant. Social marketing was the most successful in 3 of the 5 studies that attempted it (60%), followed by health system recruitment in 2 of the 3.5 studies (57%) and both community outreach and referrals in 0% of the time (0/4 for CO and 0/0.5 for R).

Again, social marketing appears to perform well with community outreach being unimpressive throughout populations, including this “Other” population.

Discussion:

This multi-approach investigation has offered several interesting results on minority recruitment in medical research.

Phase 1: OAIC Research Data on Elderly Minorities

Determining from the OAIC studies that minorities are not more likely to refuse research participation when compared to non-minorities has significant implications. This suggests that the focus should be on outreach efforts as there already exists an agreeable population rather than on changing deep-seated attitudes and beliefs such as distrust which is a common “barrier” commonly blamed as the reason for their under representation in research studies. Several studies have proposed that minorities do not have equal enrollment rates in health research when compared to non-minority groups. It has been reported [7] that although enrollment in cancer trials is low for all patient groups, minorities were less likely to enroll in cooperative group clinical trials when compared with whites. This appears to be selective to cancer type, however, with blacks having significantly lower enrollment fractions in breast, lung, and colorectal cancer trials but comparable representation in prostate cancer trails when compared to whites suggesting that equal participation can be achieved when factoring research design, marketing and recruitment strategies used for prostate cancer trials. [7] To further support that minorities might not have higher refusal rates to research participation, there has also been suggestion that published studies on minority recruitment lack proper results reporting leading to an inability to evaluate their recruitment altogether [103]. Additionally, a recent study reviewing the consent rates by race or ethnicity in 20 health research studies has suggested that there are very small differences in minority willingness to participate in health research when compared to non-Hispanic whites. The continued under representation of minorities, therefore, suggests that researchers should focus efforts on methods that offer participation rather than changing attitudes as this population can be successfully recruited.[104] This is hopeful information for researchers attempting to recruit minorities into studies as they are a group that can be recruited with proper methodology after all.

Phases 2, 3, 4: Key Informant Interviews, Focus Group study of Minority Elders, Quantitative Survey of Minority Elders

Specific strategic recommendations on study design and recruitment to promote inclusion of African American and Latino older persons based on the findings of this study, specifically the key informant interviews, focus groups, and quantitative survey, are presented in Table 10.

To summarize, researchers should attend to "selling" the public and personal health importance and relevance of their study to the targeted ethnic minority older adult sample. The desire to help others has been reported as an important motivator for older African Americans [105] and Latinos [106] and our FG participants have reiterated this. It is important, therefore, to inform potential subjects how the study may benefit society in general, as well as other people with a specific medical condition and, if applicable, their specific racial/ethnic community. Opportunities to provide free health care via study participation should be considered and explained to the potential study participant with a clear description of the usual care vs. the experimental treatment.

Additionally, investigators need to enhance study access by responding to potential participants' requirements for transportation, assistance with care giving, flexible scheduling and cultural accommodations, such as translation. Study aims and methods should be made as transparent as possible and attempts should be made to include family members in recruitment and enrollment in the study. Offering older African-American and Latino study subjects the choice of involving family members may be an important enticement to their participation. This might involve educating family members regarding the study and its importance and allowing family members to participate and ask questions and act as advocates for their relative. This enhanced strategy for recruitment of older minorities has not been as well documented in the literature and should be further explored.

Community advisors may be helpful for informing study design and recruitment but even with their endorsement and support, each older person must be recruited as an autonomous individual; each with personal concerns and questions about the importance, the safety, and the confidentiality of the study as the general dislike of using community advisors were evident from the FG participants' comments. Whether refraining from using community advisors during recruitment translates well in the field remains to be further explored as involvement of community "experts" or "advisory boards" is usually one of the most commonly proposed recruitment strategies in

literature as a successful way to recruit minority populations [5, 53, 107, 108, 109]. However, [80] found that having consultants resulted in more culturally sensitive recruitment materials, but did not increase recruitment.

To foster trust and demonstrate respect, investigators and staff must demonstrate fairness in study design such as research treatment allocation, conduct themselves with generation sub-cultural awareness, and make greater efforts to ensure safeguards to privacy and health. With regard to the issue of respect, older minorities felt very particular about the way they should be recruited (addressed as "Mr." or "Mrs.", knowledgeable recruiter with a pleasant voice and manner) thus indicating that character, professionalism, and experience with recruiting elderly minorities might be superior to simple ethnic matching of recruiters to subjects.[37, 52]

With respect to the issue of confidentiality, statements from the FG discussions imply that privacy is unimportant but this might be because the participants generally did not rely on privacy protection in the modern world and deemed it almost inevitable that there would be a leak of their personal information. Evidently, greater efforts are needed to ensure confidentiality with this population due to the likelihood of having this deep-seated fatalistic belief. It is important that researchers explain extensively the confidentiality measures with the understanding that this population might think skeptically about the reality of confidentiality being maintained-possibly via an easy to understand step-by-step discussion as to how researchers will make every effort to maintain confidentiality and the legal repercussions they face should it not be observed. It is arguable that confidentiality is an important issue to this population but because they do not believe it is possible in today's world, they discounted it as unimportant.

It was remarkable to observe the general confusion of FG participants with differentiating between researchers and clinical physicians. Negative experiences, therefore, about their health care as managed by their physicians likely negatively impacts their views on research participation as they might assume researchers are all physicians/clinicians. These findings underscore the challenge of ensuring that patients understand the difference between research and patient care. Prior work has demonstrated that the therapeutic misconception – the belief that participating in a research study will yield a tangible benefit – is pervasive among study participants. Thus, while it is important to ensure that study subjects recognize that research is distinct from routine medical care, it is also important for researchers to recognize that African American and Latino older persons' views about enrolling in health research studies can be affected by their perceptions of how health care providers have treated them in the past.

It was interesting to note that financial conflicts of interest by the researcher were not an issue for the participants in our focus groups. The consensus seemed to be that clinicians/researchers gaining financially was a "normal" part of the research process. Just as many individuals may have had difficulty discerning between research and clinical care, the relevance of financial conflicts may not be recognized as potentially detrimental to scientific validity or patient safety. Or, as with confidentiality, African American and Latino older persons may feel this issue is beyond their control.

Opinions of African American and Latino older adults regarding commonly proposed research recruitment enhancements have not been widely published. Reactions from minority seniors themselves regarding potential incentives for recruitment into healthcare research provide fresh, direct, first-hand information to inform the development of relevant recruitment guidelines. Given ubiquitous financial and time constraints experienced by researchers, it is imperative that recruitment strategies they employ are responsive to the needs and desires of the specific targeted study group.

Phase 5: Systematic Literature Review on Special Populations

This systematic review of the literature confirms that numerous recruitment interventions for this population have been attempted. Strategies included 4 main categories of recruitment interventions according to our classification-social marketing, community outreach, referrals and health system recruitment. Social marketing and community outreach were the most commonly attempted but referrals and health system were also impressively used. Media had the most impressive numbers under social marketing with the use of newspapers, TV, radio and flyers as broad range traditional recruitment methods not surprisingly very high. Mass mailing was also used very commonly but telephoning which is more time and effort consuming of the social marketing methods was less represented in our studies. The fact that community outreach methods are attempted as often as social marketing is impressive because this is a very time and energy consuming process compared to social marketing. It also takes a different level of commitment from the researcher to seek out the community in a personal way, but these results show that it is indeed occurring. Church recruitment and interaction with community organizations and leaders are very popularly attempted of the community outreach methods, which is to be expected as these are again some of the more specific and commonly proposed recruitment interventions for the minority population. Health system recruitment is an important way to recruit such a population because it is also done in a personal manner and allows

for effective eligibility screening such as when done via patient registries, charts and physician referrals. It is interesting to note that it continues to be popularly used with recruiting minorities even though some literature state that such a population is distrustful of medical personnel. Referrals are also popularly attempted and would be a promising intervention for this population as referrals are coming from trusted people such as friends and family or other study participants that could answer their concerns about research participation.

With respect to parent research study type, more publications are needed from studies exploring treatment as most of the studies that made this review are prevention studies, which might actually be more difficult studies to recruit minorities as health prevention is not always a priority in this population [58]. Treatment studies could possibly lead to very different results as to which recruitment interventions were most successful in enrolling subjects and contributing to the study sample enrolled.

Also, most minority recruitment studies are on African Americans with less focusing on Hispanic Americans, Asian Americans, Native Americans, and other minority populations, likely correlating with population statistics. With respect to recruitment of minority elders, researchers must not only confront the difficulties associated with the inclusion of minority participants but they must also overcome challenges often encountered when recruiting older adults into disease-oriented clinical trials, such as a higher prevalence of comorbid illness, limited knowledge about medical research, poor vision, hearing, lack of mobility and other functional impairments that may make them ineligible and/or reluctant to participate in clinical trials. [13, 14, 49, 51]. A significant fraction of our studies were recruitment for elderly minorities indicating that they are a studied population.

As a vast number of publications on minority enrollment in medical research discuss both recruitment and retention, it was interesting to note that only a few of these studies went as far as to include retention data and more ideally, retention data with respect to the recruitment intervention. This might be important because it is possible that subjects recruited via certain recruitment interventions (most likely the personal ones such as community outreach and referrals) might have better retention in the study as opposed to someone recruited via impersonal methods (mail, media, etc). This remains difficult to elucidate with only a minority of these studies reporting on retention.

To identify which recruitment interventions were most successful in getting enrollments based on the number screened is important because interventions that are able to get a large enrolled sample without needing a large screening sample are very efficient. This is a factor researchers should know about prior to recruitment if at all

possible. Our data showed that “all other interventions” (community outreach, referrals, and health system) were more successful than social marketing with enrolling participants that were being screened and was therefore, more efficient. This suggests an intuitive point that social marketing requires a larger sample to be screened in order to get a substantial enrolled sample. This is expected as social marketing is composed of mass mailing, telephoning and media which are usually random and impersonal in order to reach a wide, broad, and massive audience to inform them of the research enrollment opportunity. This, therefore, leads to a large number screened that might be ineligible for the study and subsequently, a lower enrollment rate. The other recruitment interventions, however, are composed of community outreach, referrals, and health system which are more personalized and likely more effective in obtaining a sample that is more eligible for enrollment.

To elucidate which recruitment interventions were truly successful and as importantly, unsuccessful, the calculations for *contribution to study sample* were helpful as they allowed us the ability to understand which recruitment intervention lead to the most subjects enrolled in the end. Looking at all the studies on Table 9 and 9a, it appears that health system recruitment, social marketing, and referrals were quite successful as 48%, 47%, 46%, (respectively) of the time they were attempted, they resulted in being the most successful recruitment intervention of that study. The main outlier is community outreach which was the most successful in a mere 13% of the time it was attempted. This is a surprising result considering that community outreach is a very popularly proposed intervention to recruit such a diverse and special population. Although it is usually more time and cost inefficient, researchers are told that such a personal way of recruitment would be more successful than broad based, impersonal and more traditional recruitment such as social marketing (telephone, mass mailing, media) when dealing with this challenging to recruit population. Our results suggest otherwise.

When just focusing on the 10 studies with Blacks as the target population, health system recruitment appears to be the positive outlier with being the most successful recruitment intervention in 67% of the time it was attempted. Since health system recruitment includes involving a health care provider referring patients to be potential research subjects or recruitment from a health center, it is interesting to note that this intervention succeeded with Blacks as published literature states that Blacks can be distrustful of the medical system and health care providers such as physicians. Some of our focus group participants even stated that their doctors could not be trusted. Perhaps it is the personal nature they are recruited in a professional health-centered environment by a physician that leads to its success in enrolling this group. Black focus group participants did mention that they would

like their recruiter not necessarily to be the same race or ethnicity, but to be professional, well dressed and respectful and one would think a health-worker attempting to recruit would exhibit such characteristics. Social marketing was the next most promising intervention, being the most successful intervention in recruiting the Black population 38% of the time. This is also surprising as these traditional and impersonal ways of recruitment are expected to work on non-minority groups that are less likely to be distrustful of research. This data shows that Blacks can be recruited successfully with broad, wide ranging and impersonal methods such as media, telephoning and mass mailing. Interestingly, community outreach and referrals, which are arguably very personal ways to recruit and likely to be successful in such a population, were the most successful in an unimpressive 25% of the time, each. This is again contrary to the published literature suggesting that community outreach strategies would be very successful in recruiting Blacks.

Overall, when it comes to the recruitment intervention that is likely to lead to the most enrolled subjects in the end, social marketing appears to be the most successful throughout. Important to note is the limitation that most of our included studies had parent studies that were on prevention rather than treatment and most diseases studied were common such as hypertension, cancer prevention, coronary artery disease, etc. Social marketing could intuitively be successful for such studies as they are commonly found in a random population vs. a rare or acute disease that might require health center recruitment such as chart/patient registry recruitment. Results also suggest that health system recruitment might be successful for Blacks and referrals for Hispanics, but these are more hypothesis generating results due to lack of studies and the need to further explore differences across target populations in the future is evident. Community outreach can certainly be used as another recruitment intervention to support the other interventions should the research staff have the financial support and time to attempt it, but would likely be less successful in leading to a substantial enrolling pool as a sole recruitment intervention. It has its value in supporting the other recruitment interventions as community outreach does command in some way that the research team interface with the community and by doing so, can lead to the alleviation of distrust issues that can be a barrier. This investment in meeting and interacting with community members can only be a positive experience for both parties if done in a proper and respectful manner and should not be discarded as an option. This review has simply suggested that other ways of recruiting such as the traditional methods of mass mailing, telephoning and media can also be very successful in this minority and special population.

Although social marketing appears to be successful in leading to the most enrolled subjects, it did have the caveat of needing to screen a larger population to obtain a substantial enrolling pool. Therefore, researchers need to weigh their resources of time, financial budget, effort, and expertise in order to choose which of the recruitment interventions are truly ideal for the population they are attempting to recruit.

As this review has suggested lack of standard data reporting with minority recruitment, we have attempted to create guidelines indicating an ideal manner for doing so. Table 11 presents such guidelines, separated by quantitative and qualitative data that we argue should be presented in any publication on minority recruitment.

Quantitative data to include in the reporting are the # screened, # eligible and # enrolled per recruitment intervention. This would allow for calculations determining which recruitment intervention lead to the most subjects screened (greatest reach), most eligible participants (relevant reach), and enrolled, which could be determined by how personal the recruitment intervention was if minorities truly respond better to the more personal interventions such as community outreach that is more likely to involve face-to-face contact, referrals from trusted people, and health system recruitment for those that trust this setting. When at all possible in multi-racial studies, the above data should be reported not just per recruitment intervention but also per race and/or ethnicity. For instance, it would be ideal to note that for the recruitment intervention of using the TV, researchers recruited 12 African Americans, 10 Hispanics, and 2 Whites. This allows for the comparison between minorities and non-minorities as well as amongst different minority groups. Also, future publications should report the same quantitative data in as specific of a way as possible so instead of grouping all media recruitment interventions together, for instance, they should give quantitative data for each specific media intervention (flyers vs. bulletins vs. TV, etc). Although some of our studies allowed for this detailed breakdown, there were too many combinations of recruitment interventions with one data set given, forcing us to eventually divide into the four larger categories of social marketing, community outreach, referrals, and health system recruitment and even in doing this, there were still studies that combined amongst these larger groups and gave one data set for their entire combination, making comparisons difficult. Additionally, time and financial expenses are an issue with minority recruitment as researchers in the past have determined them a "challenging" population to recruit in this regard. It is important to report the amount of time and cost per recruitment intervention as this could affect decision making for researchers who are constrained by such factors when choosing which recruitment interventions to utilize in their recruitment attempts. For all studies that aim to

report data comparing recruitment interventions, statistical analysis complete with p-values should be reported to determine whether one intervention was truly better in a statistically significant manner.

As far as reporting qualitative data, all 57 studies had a low mean Quality Score of only 51 out of 100 points indicating the need for more comprehensive data reporting. The importance of whether author's conclusions were supported by the study data is paramount for critical reasons. With only 21% of the studies using formal statistical analysis to compare recruitment interventions against each other, it was unsurprising that the minority of studies therefore had the data to support the authors' conclusions. The implications of this are important in that the validity of authors' conclusions and study outcomes can be questionable, which leads to difficulty in interpreting the data that is presented by such studies. Table 11 further recommends guidelines on the basics of qualitative data reporting that should be included such as reporting the recruitment objectives, the demographics of the target population and the sample population, a full detailed description of recruitment interventions, locations where recruitment took place, and the main outcomes. Additionally, studies should attempt to have a control recruitment group (more than one main recruitment intervention) to allow for comparison. In a large subset of our studies (16/57), there was not a control group which indicates that researchers lumped together all their recruitment interventions and did not compare amongst such interventions or they only had one main recruitment intervention. Also, randomization as a way to determine which population would receive which recruitment intervention is the most ideal method to exclude bias and minimize altered results. Lastly, authors need to report that different populations they are recruiting via different recruitment interventions are balanced with regard to sociodemographic or clinical characteristics and that they are representative of the larger population from which they were recruited.

At a time when minority recruitment for research continues to be an important issue that many still find continuously challenging, it is vital not only to have proper data reporting in publications of minority recruitment but to also consider innovative ways to increase minority participation. For instance, the National Cancer Institute has a Minority-Based Community Clinical Oncology Program (MBCCOP) that has attempted to enhance minority participation in cancer clinical trials by outreach and management capacity in healthcare institutions that serve large numbers of minority cancer patients. Thus far, they have demonstrated their ability to do so with more than 5,500 minority cancer patients over the past decade enrolling in NCI-sponsored clinical trials through the MBCCOP network. [110]This suggests that minorities can be recruited when the effort is made and perhaps, with ideal data

reporting and new methods such as the MBCCOP, the goals of the NIH with respect to minority recruitment can be realized more effectively.

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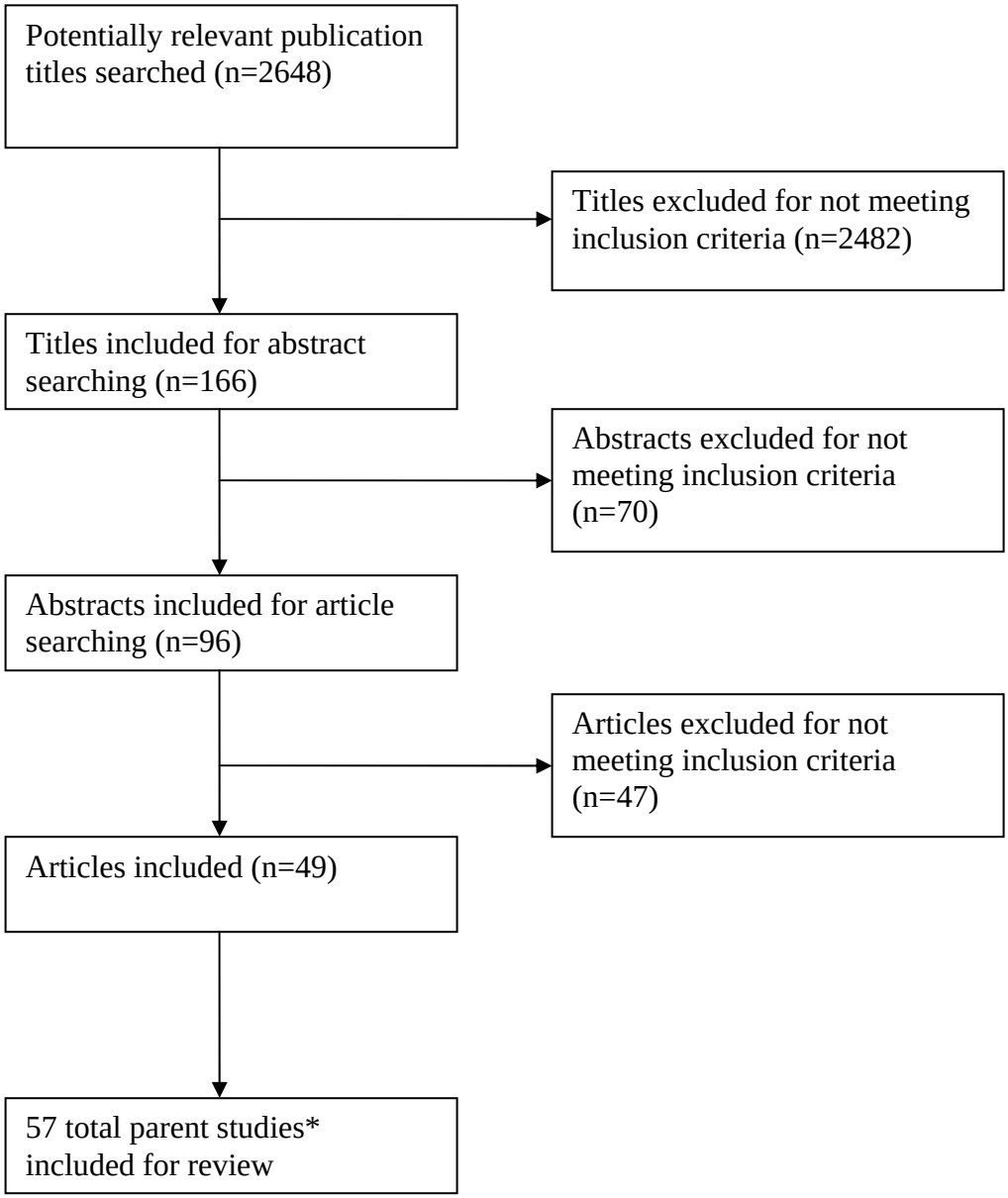
Figures and Tables:

Fig 1: Flow Diagram of Search Methodology for Systematic Review of Recruitment Interventions Attempted on Diverse Populations



*A few articles discussed and reported data on >1 parent study so although only 49 articles were included, there were a total of 57 studies analyzed for the purposes of this review

Table 1: Refusal Rates According to Race Among Studies Sponsored by the OAIC

Study	Objective	White			Non-White		
		Total Eligible	% who refused	95% CI	Total Eligible	% who refused	95% CI
PEP	Identify events precipitating functional decline	761	10.4%	(8.3%, 12.8%)	82	12.2%	(6.0%, 21.3%)
Prehab	Ameliorate functional decline	251	31.9%	(26.1%, 38.0%)	37	14.3%	(1.8%, 42.8%)
Driver IDS	Reduce driving impairment	245	32.2%	(26.4%, 38.5%)	14	14.3%	(1.8%, 42.8%)
Project Recovery	Reduce risk of delerium among hospital pts.	1337	40.2%	(37.5%, 42.8%)	195	39.0%	(32.1%, 46.2%)
SPECT	Describe SPECT results in pts with delerium	65	66.2%	(53.4%, 77.4%)	11	63.6%	(30.8%, 89.1%)
Alcohol Use	Describe alcohol consumption among cognitively impaired	832	16.9%	(14.5%, 19.7%)	95	21.1%	(13.4%, 30.6%)
Visual Attention Training	Improve visual attention among drivers	38	28.9%	(15.4%, 45.9%)	4	25.0%	(0.6%, 80.5%)
Traumatic Grief	Develop diagnostic criteria for traumatic grief	439	33.5%	(29.1%, 38.1%)	31	22.6%	(9.6%, 41.1%)
ICU Cognitive Outcomes	Identify factors associated w/ adverse outcomes in ICU pts	334	8.4%	(5.6%, 11.9%)	99	4.0%	(1.1%, 10.0%)
Pneumonia	Identify Predictors of Pneumonia in nursing home pts	553	3.6%	(2.2%, 5.5%)	119	1.7%	(0.2%, 5.9%)

Table 2: Issues Identified in Minority Recruitment Emerging from Key Informant Interviews

Themes	Specific Issues
Access	➢ Language (Spanish speaking research staff, translated documents) ➢ Literacy (Documents understandable to education level of subjects, methods to overcome illiteracy considered) ➢ Location (accessible location) ➢ Hearing/vision impairment (take this into account and attempt to overcome it with innovative methods of explaining research) ➢ Transportation (make available) ➢ Competing responsibilities (convenience for subjects as they are busy)
Benefits of Research: <u>Benefits to Participant</u> <u>Benefits to Community</u>	 ➢ Direct benefit to personal health (emphasize this) ➢ Compensation (financial or other token of appreciation) ➢ Are study aims relevant to community needs/concerns? (Question researchers need to ask) ➢ Will the results help people in community? (Researchers share results with community)
Trust: <u>Trust in Medicine/Doctors</u> <u>Trust in Researchers & Research Procedures</u>	 ➢ Medication side effects (Explain to subjects) ➢ Skepticism about efficacy of medicine (Address concerns) ➢ Medical errors (Address this as a concern subjects might have) ➢ Concerns about prejudice/racism (Address this as a concern subjects might have) ➢ Researchers will lie (Address as a concern) ➢ Researchers will perform experiments for their own benefit (Address as a concern) ➢ Data will be used to perpetuate racial/ethnic stereotypes (Address how this will not happen) ➢ Lack of confidentiality (Address as a concern)

Table 3: Emerging Themes and Statements Made from Focus Group Members Regarding Minority Research Participation

Emerging Themes	Specific Comments
Communication issues:	"I do not speak English." "I think all doctors should be bi-lingual." "They really don't listen to me." "Take time and talk to me." "I think it would have something to do with the (researcher) really going through and talking to you about it, make you understand it." "They use words you don't understand."
Family involvement	"It would be helpful if you could have a family member in the (research) discussion. . . make it plain for them to know" "What you might miss, your family might pick up." "I would feel much more secure with family."
What would help • Operations	"Take personal care with the person during the study" Someone you could call 24 hours no matter what the problem - that person would be an asset to the program" "Don't call me by my first name. . .You don't know me and I'm not here on a social visit. . . It's like a child coming into first grade." "Have a quality assurance person there asking the participants if they were treated well." "If you have whites, blacks, Latinos together in a group"
What would help • Attitude	"Make us feel safe." "Really care about what is going on." "Be honest." "A pleasing voice is appealing to the elderly. . . It wins confidence." "Manners and integrity are very important." "Good bedside manner." "Researcher should be comfortable with all levels of people"
Importance of Research Topic	"First of all, you need to know why they are doing this." "I think a new blood pressure medication would be welcomed in the community because it's a common problem."
Benefits of research	"I would be willing to give it a try. . . The newer one (med.) might be more beneficial – you might get better results." "I'm not only thinking of myself – I'm thinking of generations to come, or somebody that I may be helping." "I may be dead and gone but with that research it might help somebody else."
Influence of community leaders on research participation	"Who determines who is a community leader?" "People want to decide for themselves."
Influence of personal physician on research participation	"I would mostly leave it up to the doctor." "If a doctor says to me, you know there's a new medicine. . . let's try this. . . He wouldn't direct the wrong stuff."
Prior Personal Experiences Medical Care	"I always have a different doctor." "Every time you turn around you see another doctor."

Table 3: Emerging Themes and Statements Made from Focus Group Members Regarding Minority Research Participation (Continued)

Beliefs:	"I don't believe in giving blood." "I never did believe in taking medication."
Confidentiality	"In today's age confidentiality is out the window." "With the social security number, they know more about you than you know about yourself." "If a person had something really serious in their family or even themselves,, they have second thoughts about doing it (research). Because you don't want everybody to know."
Experience with Racism	"The Blacks were the guinea pigs." "Every time they do a study it's always just whites" "There are so many times that research is done and the percentage of the negative seems to always be on the black." "Caucasians don't give a damn about you."
Trust/mistrust	"Recent problems, like pharmaceuticals companies falsifying records" "They gave all those men syphilis and didn't tell them; that really turned me off." "You know they could say one thing but do another." "Is it just going to affect blacks or is it for whites also?" "It's hard to know if they really want your well-being."
Safety issues	"I wouldn't be interested. . . because blood pressure medications can throw you off in other areas. . . it could damage other organs in your body." "Fear of switching from a medication that's working." "Years ago a product had to be experimented with, used on animals for ten years before it was taken to humans.. . Now it's rushed to humans."
The researcher might gain money from the research.	"If the person participating is going to get money, I think the researchers should also." "I think it's ok if he's going to do it the right way."

Table 4: Quantitative Survey Results Administered to Older African American and Latino Subjects Regarding Importance of Strategies to Increase Minority Research Participation

Specific Strategies and (Actual % Results)	% Rated Very Important (N=44)
A member of the study staff speaks Spanish (Asked of Latino group only). (100%) You are told how the results of the study will benefit people with high blood pressure. (91%)	>90%
Anyone who joins the study gets free health care (eg, screenings, physicals, referrals, treatment). (88%) Researchers give you a 24-hour study phone number and tell you that you can contact them anytime you have a question or problem. (86%) Researchers explain how they watch for any health or other problems resulting from the study and will stop the study if you experience problems. (86%) Researchers show you respect. (86%) Researchers tell you all they have done to make sure the study is safe. (81%) Researchers will share results of your study tests with you. (81%) You are told how the results of the study results will benefit African American/Latino people. (81%) Researchers tell you about laws to protect study participants and any punishment they receive if they do not follow the laws. (80%)	80-89%
Researchers tell you that you will not be used as a guinea pig. (79%) A member of the research staff explains the study to your family. (77%) You are told that the information collected about you on the study is confidential. No one outside of the study staff will know your personal health information (confidentiality). (73%)	70-79%
Someone you trust works on the research team. (68%) Researchers tell you the general results of the research will be shared with the African American/Latino community. (65%)	60-69%
Community leaders approve and support the study. (50%)	50-59%
You are told whether or not the researcher might gain money from the research. (42%)	40-49%

Table 5: Description of Studies Included in Systematic Review of Recruitment Interventions Attempted on Diverse Populations

Population Targeted for Recruitment:	No. of studies/%
African Americans	47 (83%)
Latino/Hispanics	26 (46%)
"Other" racial/ethnic group	33 (58%)
Older/Elderly	13 (23%)
Rural	2 (4%)
Low SES/Underserved	10 (18%)
Parent Research Study Type:*	
PREVENTION:	
Drug	7 (12%)
Behavior/Lifestyle	24 (41%)
Screening Test	4 (7%)
Other	10 (17%)
TOTAL PREVENTION STUDIES:	***45 (76%)***
TREATMENT:	
Drug	6 (10 %)
Behavior/Lifestyle	4 (7%)
Surgery	0 (0%)
Other	4 (7%)
TOTAL TREATMENT STUDIES:	***14 (24%)***
Types of Recruitment Interventions:	
Approach	**# Studies**
Social Marketing	**46 (81%)**
Mass mailing	24 (42%)
Mass telephone calls	8 (14%)
Media:	39 (68%)
TV Advertisements	22 (39%)
Radio Advertisements	25 (44%)
Newspaper Advertisements and/or Magazines	29 (51%)
Newsletter	11 (19%)
Brochure	11(19%)
Flyer	26 (46%)
PSA (not specified method)	4 (7%)
Specialty publications to target group	3 (5%)

Table 5: Description of Studies Included in Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Continued Media Recruitment Interventions	
Other(specify): (bulletin, posters, videotape, internet ad, not otherwise specified)	13 (23%)
Community Outreach	**46 (81%)**
Church	22 (39%)
Contact with community leaders and organizations	20 (35%)
Presentations and/or meetings (usually by investigators to and with community)	19 (33%)
Health Screenings	11(19%)
House to house/door to door canvassing or face-to-face in community setting	9(16%)
Community events/table/booth	14 (25%)
Other (specify): saw class, hospital employees, not otherwise Specified	3 (5%)
Referrals	**16 (28%)**
Referred by friends/family	10 (18%)
Referred by other participants in the study	7(12%)
Referred by another study	3(5%)
Other (specify): staff, employers, coworkers	7 (12%)
Health system	**30 (53%)**
Health care provider approached or asked to refer	21 (37%)
Health care center recruitment (staff recruiting in clinic)	16 (28%)
Registry/patient chart review	11(19%)
Other	**9 (16%)**
Ethnically matched staff/recruiter or language interpreter	9 (16%)
Direct Compensation	10 (18%)
Financial Gain (money, coupons)	8 (14%)
Other Gifts (mugs, T-shirts, pins, etc)	3(5%)
Convenience (parking, transportation, child care, rapid and convenient clinic visits, etc)	8 (14%)
Study Buddy	1(2%)
Questionnaire**	1(2%)

*2 OF THE 57 STUDIES SATISFIED MORE THAN ONE CATEGORY SO THE TOTAL IS 59.

** Hooks article, could not be categorized into other interventions

Table 6: Quality of Data Reporting from Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations

Number of Studies that include the following information:	**# of studies/ %**	**Points given for Quality Score**
I. Description of Recruitment Study and Interventions		
Main hypothesis and objectives of recruitment described	57 (100%)	
Demographics of target population described	57 (100%)	20
Recruitment intervention(s) described in sufficient detail to allow replication	57 (100%)	5
Time spent to complete recruitment intervention(s) noted. Yes No Time mentioned, but actual data not given	 9 (16%) 37 (65%) 11 (19%)	 5 0 2.5
Cost to complete recruitment intervention(s) noted. Yes No Time mentioned, but actual data not given	 7 (12%) 44 (77%) 6 (11%)	 5 0 2.5
Recruitment settings (e.g. church, senior center) described	57 (100%)	5
Main outcomes of the study were described	53 (93%)	
II. Assessing Efficacy of Intervention		
Presence of a control group	41 (72%)	
Recruitment intervention for control group were described (denominator is 41)	41 (100%)	

Table 6: Quality of Data Reporting from Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Number of Studies that include the following information:	# of studies/ %	Points given for Quality Score
III. Controlling for Bias		
Method for determining which recruitment intervention a population would receive: (denominator is 41)		
Randomization	2 (5%)	10
Time (added more recruitment interventions as time went on)	14 (34%)	5
Geography (different locations for recruitment)	6 (15%)	5
Multiple recruitment interventions attempted simultaneously on different groups	16 (39%)	2.5
Other	1 (2%)	2.5
Geography AND multiple interventions	2 (5%)	5
For populations that received differing recruitment interventions, were they balanced with regard to sociodemographic/clinical characteristics? (denominator is 41)		
Yes	5 (12%)	10
No	8 (20%)	0
Unclear	28 (68%)	5
IV. Data reporting		
Reported the # approached or screened per recruitment intervention	28 (49%)	6 and 2/3
Reported the # eligible for study participation per recruitment intervention	17 (30%)	6 and 2/3
Reported the # enrolled in the study per recruitment intervention	32 (56%)	6 and 2/3
Reported the use of formal statistical analysis (p values, confidence intervals, etc) to assess the success of recruitment interventions	12 (21%)	20

Table 6: Quality of Data Reporting from Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Number of Studies that include the following information:	# of studies/ %	Points given for Quality Score
V. External Validity/Generalizability		
For populations receiving recruitment intervention(s), were they representative of the entire population from which they were recruited? Yes No Unclear	 10 (18%) 6 (11%) 41 (72%)	
VI. Internal Validity		
Are author's conclusions supported by the study data? Yes No Maybe	 11 (19%) 24 (42%) 22 (39%)	
VII. Retention of Participants after Enrollment		
Retention data described or discussed by authors	22 (39%)	
Retention data offered that is specific to recruitment intervention(s)(e.g. Those recruited by community screenings had better retention than those recruited by media)	9 (16%)	

Table 7: Study Quality Score Based on 100 Point Scale Maximum in Decreasing Order for Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations

Study Name	Quality Score
Harris, K	85
Brewster, WR	85
Linnan, LA	85
Ford, ME	83
Lee, RE	81
Unson, CG	80
Coleman, EA	78
Baigis, J	75
Arean PA (PASS)	75
Kiernan, M	73
Arean PA (PEPUP)	73
Lewis, CE	71
Larkey, LK	66
Pinto, BM	63
Oakley, A	61
Hooks, PC	58
Rowland, RM	58
Ives, DG	56
Smith, SR	55
Whelton, PK	55
Fouad, MN	53
Fitzgibbon, ML (FRITAA)	51
Blumenthal, DS	51
Dennis, BP (The Neighborhood Outreach Program)	50
Dennis, BP (Dietary Adherence in an Urban Black Population)	50
Burroughs, AR	49
Fitzgibbon, ML (Hip Hop to Health)	48
Wisdom, K	48
Moinpour, CM	47
Stoy, DB	47
Hill, MN	46
Nacif de Brey, V	44
Whitehorse, LE	44
Brill, PA	43
Schoenfeld, ER	42
Bailey, JM	40
Warren-Findlow, J	40
Royal, C	39
Kennedy, BM	39

Table 7: Study Quality Score Based on 100 Point Scale Maximum in Decreasing Order for Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Study Name	Quality Score
Gallagher-Thompson, D	39
Escobar-Chaves, SL	39
Powell, IJ	39
Yancey, AK	39
Vollmer, WM	38
Nichols, L	38
Derose, KP	37
Sorkness, CA	37
Sorkness (Colchicine)	37
Sorkness (SOCS)	37
Sorkness (SLIC)	37
Pletsch, PK	35
Yancey, A	33
Zhu, K	33
Paskett, ED (PPT)	30
Paskett (PCPT)	30
Paskett (FoCaS)	30
Gorelick, PB	30

Table 8: Enrollment Percentage (ENP)-The % of screened patients who eventually enrolled in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations

Study Name	Study Description and Study Population for OTHERS section	Target Population (Majority)	Social Marketing: % Enrolled	All Other: % Enrolled	p-value +
Fitzgibbon, ML.*.	Dietary Intervention	Black	7.4%	8.4%	p=0.22
Whelton, PK.*.	Drug therapy on Hypertension and Kidney Disease RCT	Black	8.9%	**28.3%**	**p<0.001**
Hill, MN*.**.	Community health worker to reduce high blood pressure RCT	Black	**32.5%**	14.2%	**p=0.001**
Coleman, EA	Elderly wellness intervention study-prevention RCT	Black	38.7%	**73.2%**	**p<0.001**
Hooks, PC.	Community and family diet and exercise intervention	Black	13.0%	**30.4%**	**p=0.001**
Brewster, WR	Cancer prevention study RCT	Hispanic	**51.4%**	26.3%	**p<0.001**
Lee, RE	Home based walking intervention RCT	Hispanic	26.5%	**55.6%**	**p<0.001**
Lewis, CE.	Dietary Prevention RCT	Majority non-Hispanic white/other. Also African American and Hispanic. Separate data for minorities.	**11.7%**	9.7%	**p=0.004**

Table 8: Enrollment Percentage (ENP)-The % of screened patients who eventually enrolled in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Study Name	Study Description and Study Population for OTHERS section	Target Population (Majority)	Social Marketing: % Enrolled	All Other: % Enrolled	p-value +
Arean PA	Randomized trial on psychosocial interventions for depression	Majority White. Also, Black, Latino, Other. Separate data for minorities.	26.7%	33.3%	p=0.312
Arean PA.	Randomized trial on social service model of care	Majority White. Also Black, Latino, Other. Separate data for minorities.	25.5%	**44.7%**	**p=0.001**
Unson, CG^^^.	Osteoporosis drug trial compared to placebo	Majority White. Also African American and Hispanic. Separate data for minorities.	22.4%	21.9%	p=0.878

ENP calculated as: # enrolled/# screened per recruitment intervention

+P-value for difference in % Enrolled b/w social marketing and other interventions
^^^=Hispanic market segment 1 not counted as it was not clear what the recruitment intervention breakdown was of this population recruited.
*=Total population was of that ethnic or racial group (e.g. If listed as “Blacks”, whole enrolled sample was black).
**=# approached was denominator used (not # screened)

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations

Contribution to study sample: % of study participants from each recruitment intervention								
Study Name	**Study Description**	**Majority Population Recruited (If white, state others)**	**Social Marketing (SM):**	**Community Outreach (CO):**	**Referrals(R):**	**Health system (HS):**	**Study Quality Score**	**p-value** [+]
Lewis, CE. $.	Dietary Prevention RCT	Majority non-Hispanic white/other. Also African American and Hispanic. Separate data for minorities.	**88.2%**	2.3%	8.3 %		71	**p<0.001**
Pinto, BM. $.	Physical activity program for cancer RCT	Majority Caucasian. Also Asian/Pacific Islander, African American, Native American, Unspecified.	38.4%			**57.0%**	63	**p=0.015**
Arean PA	Randomized trial on psychosocial interventions for depression	Majority White. Also, Black, Latino, Other. Low income. Separate data for minorities.	28.2%			**71.8%**	73	**p<0.001**
Arean PA. $.	Randomized trial on social service model of care	Majority White. Also Black, Latino, Other. Separate data given for minorities.	**68.6%**	13.2%		18.2%	75	**p<0.001**
Linnan, LA ^	Randomized cancer prevention intervention study	Mostly White. Also Spanish.				Active - 53.3%. Passive - 46.7%	85	

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Contribution to study sample: % of study participants from each recruitment intervention								
Study Name	**Study Description**	**Majority Population Recruited (If white, state others)**	**Social Marketing (SM):**	**Community Outreach (CO):**	**Referrals(R):**	**Health system (HS):**	**Study Quality Score**	**p-value** [+]
Unson, CG^^^. $.	Osteoporosis drug trial compared to placebo	Majority White. Also African American and Hispanic. Separate data given for minorities.	**49.4%**	37.5%			80	**p=0.028**
Ives, DG* (all white).	Health Promotion Project RCT.	All White, rural.	100%^				56	
Rowland, RM. $.	Randomized trial of physical activity	Mostly White. Also, Black. Oversampled low income group.	Total: 94.2**%^** (Mailing: 6.9% Telephone: 87.3%)	4.0% ^			58	
Harris.*.	Smoking cessation RCT	Blacks	**89.0%**			11.0%	85	**p<0.001**
Fitzgibbon, ML.*.	Dietary Intervention	Blacks	27.9%	**72.1%.**			51	**p<0.001**
Ford, ME.*.	Cancer screening efficacy	Blacks	69.1%^ (composed of 20.7%, 23.1% and 25.3%)	30.9%^			83	

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Contribution to study sample: % of study participants from each recruitment intervention								
Study Name	**Study Description**	**Majority Population Recruited (If white, state others)**	**Social Marketing (SM):**	**Community Outreach (CO):**	**Referrals(R):**	**Health system (HS):**	**Study Quality Score**	**p-value +**
Baigis, J.	Aerobic conditioning program RCT	Blacks	41.5%^			**58.5%^**	75	**p=0.006**
Blumenthal, DS.*.	Cancer screening education RCT	Blacks	**83.9%**			16.1%	51	**p<0.001**
Whelton, PK.*. $.	Drug therapy on Hypertension and Kidney Disease RCT	Blacks	21.3%.	0.0%.	3.2%.	**67.0%.**	55	**p<0.001**
Hill, MN*. $.	Community health worker to reduce high blood pressure RCT	Blacks	6.4%	1.5%	42.2%	49.5%	46	p=0.14
Coleman, EA	Elderly wellness intervention study-prevention RCT	Blacks	**68.3%**	5.8%	25.8%		78	**p<0.001**
Hooks, PC. $.^	Community and family diet and exercise intervention	Blacks	11.7%	27.0%	36.9%		58	p=0.114

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Contribution to study sample: % of study participants from each recruitment intervention								
Study Name	**Study Description**	**Majority Population Recruited (If white, state others)**	**Social Marketing (SM):**	**Community Outreach (CO):**	**Referrals(R):**	**Health system (HS):**	**Study Quality Score**	**p-value +**
Wisdom, K. *.$.	Diabetes self management RCT	Blacks	19.3%	13.8%		**60.6%**	48	**p<0.001**
Royal, C. *.	Cancer genetic linkage study	Blacks	16.3%	2.3%		**81.4%**	39	**p<0.001**
Kennedy, BM. $.	Dietary effects on blood pressure RCT	Blacks	**79.4%**	1.5%	19.2 %		39	**p<0.001**
Yancey, A. $. *.	Randomized eating and exercising intervention trial for cancer prevention	Blacks	25.5%^		**74.5%**		33	**p<0.001**
Larkey, LK. *.	Longitudinal study targeting cardiovascular disease, osteoporosis and cancer	Hispanics			By Embajadoras: 86.7% . By untrained Anglo women: 13.3%. By untrained Hispanic women: 0% .		66	
Brewster, WR.	Cancer prevention study RCT	Hispanics	**56.9%**			43.1%	85	**p<0.001**

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

Contribution to study sample: % of study participants from each recruitment intervention								
Study Name	**Study Description**	**Majority Population Recruited (If white, state others)**	**Social Marketing (SM):**	**Community Outreach (CO):**	**Referrals(R):**	**Health system (HS):**	**Study Quality Score**	**p-value +**
Nacif de Brey, V. *.	Randomized evaluation of Arthritis course	Hispanics	24.9%	27.4%	**39.2%**	8.6%	44	**p=0.006**
Lee, RE	Home based walking intervention RCT	Hispanics	**64.3%**	35.7%			81	**p<0.001**
Escobar - Chaves, SL. $.	Physical activity validation study	Hispanics, Blacks in equal number	50.0%^	12.2%^	37.8%	See CO column ^	39	
Whitehorse, LE. $. *.	Physical Activity Program	Hispanics	2.3%	9.5%	**58.5%**	28.4%	44	**p<0.001**

^ (Linnan): Active Recruitment means employees were contacted by researchers when they actively opted to be contacted vs. Passive Recruitment which means employees were contacted from list given to researchers by employers

^(Rowland): *SM column:* mailing and telephone only. *CO column:* combination of CO=church, contact with community organizations/leaders, door to door canvass and SM=newspaper, brochure, flyer and R=referrals from neighbors. S.M appears to be successful but other methods were added subsequently to primary telephoning to increase participation.

Table 9: Contribution to Study Sample in Studies Included in the Systematic Review of Recruitment Interventions Attempted on Diverse Populations (Continued)

^(Ives): Contribution to study sample: *SM column*: Mailing: 55.9%. Mailing and telephone: additional 23.6%. Mailing and Telephone and Scheduling: additional 10.6%. Mailing and aggressive telephoning and scheduling: additional 9.9%.
^ (Ford): *SM column*: Different arms of social marketing composed of mailing, telephone, info gathering in various combinations for the three arms here. *CO column:* Also had social marketing composed of enhanced mailing and African American phone interviewers but also with the addition of church recruitment here.
^(Baigis): *SM and CO column*: Combination of Newspaper, Flyer, specialty publications, church, presentations, community events AND HS=health care provider data involved here. *HS column*: Recruitment at a health center only.
^(Hooks): OTHER category not listed: Questionnaire sent home (did not fit other categories): Contribution to study sample: 21.6%.
^ (Escobar-Chaves): *SM column:* TV, radio, newsletter, flyer. *CO column:* Has SM=newspaper and CO=church, contact with community leaders/organizations, presentations, community events, and HS=health care center recruitment. *R column:* referrals from friends, family and coworkers.
^^chose recruitment intervention %'s to present rather than quant data per minority center
^^^=Hispanic market segment 1 was not counted as it was not clear what the recruitment intervention breakdown was of this population recruited.
+= p-values were only calculated for those studies that allowed for comparison across the larger four categories of SM, CO, R and HS. Combinations amongst the four categories were allowed only again if they still allowed for a clean comparison with another category (i.e. SM and CO combined vs HS but not SM and HS combined vs another HS method).
$=does not add up to 100% (authors omitted data or there was an other or unknown recruitment category) or data was only from subset of total enrolled
*=Total population was of that ethnic or racial group (e.g. If listed as “Blacks”, whole enrolled sample was black).

Table 9a: Which recruitment intervention contributed most to the study sample? (Summation of Table 9)

By using Table 9, this table is to sum the # of times the RI was the most successful one in the study with respect to the # of times it was attempted

	ALL		OTHER POPULA-TION		BLACKS		HISPANICS	
Social Marketing	**8/17**	**47%**	3/5	60%	3/8	38%	2/4	50%
Community Outreach	**2/15**	**13%**	0/4	0%	2/8	25%	0/3	0%
Referrals	**3/6.5**	**46%**	0/0.5	0%	1/4	25%	2/2	100%
Health System	**6/12.5**	**48%**	2/3.5	57%	4/6	67%	0/3	0%
RESULTS summary:		**HS>SM> R>CO**		SM>HS> CO AND R (tie)		HS>SM> CO AND R (tie)		R>SM> CO AND HS (tie)

Numerator: # of times that intervention was the most successful in contributing to the study sample
Denominator: # of times it was attempted
0.5 points was given instead of 1.0 if the intervention was a combination (ie SM and CO).
Only studies with statistically significant p-values were included here

Table 10: Recommended Elements for Study Design and Recruitment to Promote Inclusion of African American and Latino Older Persons
(From Key Informant Interviews, Focus Groups and Quantitative Survey)

	Potential Interventions
Access/ Language	Involvement of Spanish speaking investigators and study staff. Culturally appropriate translation of all study materials. Develop study materials that are free of jargon and easy to understand. Adapt vision and hearing aids into study protocol
Access/ Family involvement	Give potential study subjects the choice of involving family members. Educate family members regarding the study and its importance. Allow family members to participate and ask questions and to act as advocates for their older relative.
Access/ Logistics	Free transportation and parking or home visits Offer sitting/care options Flexible scheduling Coordination among studies to avoid burden Members of the research team must be trustworthy, professional and pleasant, but not necessarily ethnically matched.
Benefits/ Knowledge about research	Inform potential subjects how the study might benefit them personally and/or society in general and, if applicable, their specific ethnic communities. Payments to subjects Offer free health care services as part of study participation (eg. screenings, physicals, referrals) Explain Study Justification Emphasize why problem and study results are important
Benefits/ Community involvement	Conduct study in community (if possible) Involve community members with research, eg, choice of study question, relevance of the study, refinement of study design, conduct of study but make sure to recruit subjects as unique individuals Reporting back to participants and community when study results become available what was learned from the study
Trust/ Confusion of physician vs. researcher	Carefully explain to potential study subjects the distinction between usual care and study assessments or treatments. Enlist a liaison: Study buddy or cultural broker

Table 10: Recommended Elements for Study Design and Recruitment to Promote Inclusion of African American and Latino Older Persons (Continued)

Trust/ Safety Concerns	Inform potential participants that the study will be stopped if any adverse effects occur. Inform potential participants of study safeguards. Inform potential participants about laws for their protection as research subjects Provide a 24 hour phone number for any questions or concerns Prepare study staff to address the issue of prior abuses
Trust/ Confidentiality	Emphasize safeguards to privacy Address the specific means by which confidentiality will be protected, with the understanding that older African Americans in particular might be skeptical about privacy protection

Table 11: Guidelines for Data Reporting in Minority Recruitment Studies

Quantitative Data:	**Qualitative Data:**
Report # screened per recruitment intervention	Report objectives of recruitment study
Report # eligible for study per recruitment intervention	Report demographics of target population and sample population. If there are differences, comment on why.
Report # enrolled in study per recruitment intervention	Describe recruitment interventions in detail
Report time spent per recruitment intervention	Describe locations where recruitment took place
Report cost of each recruitment intervention	Clearly state main outcomes of recruitment
Report retention with respect to recruitment intervention	Have a control group (>1recruitment intervention to allow for comparison)
Use formal statistical analysis to compare recruitment interventions	Use randomization when possible to determine which population will receive which recruitment intervention. If randomization is not used, state how this was done
Report # screened, # eligible, and # enrolled in study per recruitment intervention by race to allow for comparison between minorities and non-minorities as well as amongst different minority groups	If there is >1 group receiving different recruitment interventions, state that they are balanced with regard to sociodemographic or clinical characteristics
Attempt to give quantitative data for each specific recruitment intervention within a category (i.e. TV, radio, and flyers are all social marketing but it would be best to give data for each of the methods when possible vs. just one data set for all social marketing methods). This will allow for future comparisons within a larger category such as social marketing (TV vs. radio vs. newspaper, etc)	State that subjects receiving recruitment interventions were representative of entire population from which they were recruited

Appendix:

A. Flyer for African American Group Recruitment (English)
B. Flyer for Hispanic Group Recruitment (Spanish)
C. Informed Consent (English)
D. Informed Consent (Spanish)
E. Draft of focus group discussion guide (English) for African American group
F. Draft of focus group discussion guide (Spanish) for Latino group
G. Draft of African American Quantitative Survey (English)
H. Draft of Hispanic Quantitative Survey (Spanish)

A.Flyer for African American Group Recruitment (English)

Yale University

****

Seeks men and women age 65+ for a study of opinions about medical research.

You qualify, if you:

- Can attend one focus group session
- Can speak and read in English
- Are willing to share your opinions in a group

Study involves:

- 1 focus group meeting for 90 minutes at _____on ____day at (time)
- Completing a confidential opinion survey

You will receive:

- Refreshments
- $25 payment to you.

For more information or to reserve a place,
call _____ at (203)._____

B.Flyer for Hispanic Group Recrutiment (Spanish)

Yale University

****

.Busca mujeres y hombres mayores de 65 años para un estudio sobre su opinión sobre investigación medica.

Usted puede participar si:

- Puede asistir a una sesión de un grupo de enfoque
- Puede leer y hablar ingles
- Esta dispuesto a compartir su opinión con un grupo

El estudio consiste:

- Un grupo de enfoque que durara 90 minutos en _____el día ____a las _____ (hora)
- Completar una encueste confidencial de opinión

Usted recibirá:

- Refrigerios
- .$25 dólares como pago por su participación

Para más información o para reservar un lugar
Llame _____ al teléfono (203)._____

C.Informed Consent (English)

INFORMATION SHEET FOR TAKING PART IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE (ATTACHMENT3)

Title: Promoting Research Participation among Black and Hispanic Seniors
(HIC # 12665)
Principal Investigator: Holly Prigerson, PhD
Funding Source: NIA Pepper Center 1-P30-AG021342-01

Invitation to Take Part.
We invite you to take part in a Focus Group. A focus group is a meeting of 8 to 10 people to talk about one topic.

What the Project is about.
This focus group is for our study called, "Promoting Research Participation among Black and Hispanic Seniors." The reason for the Focus Group is to hear the thoughts and opinions of typical Black and Hispanic older persons. We want to learn about what might discourage or encourage taking part in research studies.

Why You are Invited
You have been invited because your are over 65 and Black or Hispanic. You are the type of person we want to hear from.

What will happen, if you agree to take part in the research study
If you agree, we will ask you to come to one focus group meeting. The people in the focus group will talk about what might discourage or encourage _____(ethnic group) older persons from joining research studies.
The focus group will be held at _____am pm_____day, _____(date) at _____(location). The meeting will last for about 90 minutes. There will be an introduction. Next, the group leader will ask people to share their thoughts and opinions. Then the leader will read a list of questions with answer choices. People will be asked to circle their answer. There are no right or wrong answers. It is what people think. The meeting will be tape- recorded. Refreshments will be served.

Risks and Inconveniences
During the focus group, there is a chance of people becoming upset when they talk about painful personal experiences. If this happens, you do not have to stay. You may leave. If necessary, the focus group will be stopped.
There is a possibility of a break in confidentiality. Care will be taken to reduce this possibility. The tapes and typed copies will not have information that could identify any individual. The tapes and typed copies will be stored in a locked file cabinet. Your name will never be used in any report written about this study.

Benefits
This study will not help you directly. But we hope the information from this study will help Black and Hispanic older persons take part in future studies, if they want to.

Economic Considerations
At the end of the meeting, you will be paid $25 dollars for your time.

Confidentiality

The focus group is not anonymous. You may know someone in the group. Or, someone may know you. We will tell everyone: "What is said in the group should stay in the group." Before we start, we will ask if people want to use first names only, or the first initial of last names (like, Mr. X), or simply "Sir"/"Madam." No one's full name or full last name will be recorded on purpose. If this happens accidentally, it will be erased from the tape.

There is some possibility of a break in confidentiality. Care will be taken to reduce this possibility. Some of the things we do to reduce the chances of a break in confidentiality are:

1. The staff are trained in to protect privacy.
2. The tape has a unique identifier without the date and place of the meeting
3. The tape is quickly stored in a locked file cabinet in Dr. Prigerson's office.
4. The tape is heard only by the doctors and research staff.

Voluntary Participation

You are free to choose not to take part in the focus group., If you decide to take part, you are free to withdraw from the study at any time. If you choose not to take part or if you withdraw, it will not hurt your relationship with the doctors or with Yale New Haven Hospital."

Questions

We have used some unfamiliar terms in this form. Please feel free to ask about anything you do not understand. Think about this research study and the consent form carefully. Take as much time as you need to make your decision.

_____ _____

Signature of Primary Investigator Phone

Or

_____ _____

Signature of Person Obtaining Consent Phone

If you have any questions or if you have a any problem with the study, you may call the study leader, Dr. Holly Prigerson, (203) 974-7721. If you have any questions about your rights as a research subject, you may call the Yale School of Medicine Human Investigation Committee at (203) 785-4688.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED IN THE HIC OFFICE

THIS FORM IS VALID ONLY UNTIL: _____

HIC PROTOCOL #: _____

INITIALED: _____

D. Informed Consent (Spanish)

PAGINA DE INFORMACION PARA PARTICIPAR EN UN PROYECTO DE INVESTIGACION
ESCUELA DE MEDICINA DE LA UNIVERSIDAD DE YALE

Titulo: Promoción para que participen en investigaciones Negros e Hispanos de edad mayor HIC # 12665)
Investigador Principal: Holly Prigerson, PhD
Fuente de Financiamiento: NIA Pepper Center 1-P30-AG021342-01

Invitacion a participar.
.Le invitamos a participar en un Grupo de Enfoque. Los grupos de enfoque son reuniones de 8 a 10 personas en los que se habla sobre un tema.

Sobre que es el proyecto.
Este grupo de enfoque es para el estudio llamado "Promoción para que participen en Investigaciones Negros e Hispanos de edad mayor". La razón de este grupo de enfoque es que queremos conocer cual es la opinión de Negros e Hispanos típicos de edad mayor. Queremos aprender que los alienta o desalienta para participar en estudios de investigación

Por que se le invito a usted
A usted se le invito por que es mayor de 65 años y es Negro o Hispano. Usted es el tipo de persona cuya opinión queremos conocer.

Que sucede si usted esta de acuerdo en participar en este estudio de investigación
.
Si esta de acuerdo en participar se le invitara a uno de las reuniones del grupo de enfoque. Las personas en el grupo de enfoque hablaran sobre que alienta o desalienta _____ (grupo étnico) de edad mayor para ser parte de proyectos de investigación.
El reunión del grupo de enfoque será a las _____AM/PM el día _____ (fecha) en _____ (lugar). La reunion se llevara aproximadamente 90 minutos. Habra una introducción. Después el líder del grupo invitara a los participantes a compartir sus ideas y opiniones. Despues el líder leerá una seria de preguntas que tienen varias respuestas. Se les pedirá a las personas que pongan un círculo en su respuesta a cada pregunta. No hay respuesta correcta o incorrecta. Es lo que la gente piensa. La reunión será grabada. Se servirán refrigerios (refrescos y cosas ligeras)
Riesgos y conveniencias
.
Durante el grupo de enfoque, es posible que algunas personas se molesten cuando hablen sobre experiencias personales dolorosas. Si esto sucede usted no debe de quedarse en la reunión. Si usted quiere puede irse. Si es necesario se parara el grupo de enfoque. Puede haber una perdida de confidencialidad. Se tomaran medidas para disminuir esta posibilidad. Las cintas grabadas y el material que se mecanografiara no tendrá información que pueda identificar a ningún participante. Las cintas y las copias escritas se guardaran bajo llave. Su nombre nunca se usara en los reportes que se hagan sobre este estudio.
Beneficios
Este estudio no lo beneficiara a usted directamente. Pero esperamos que la información de este estudio ayude si así lo desean a que Negros e Hispanos de edad avanzada participen en estudios futuros

Consideraciones económicas
Al finalizar la reunión a usted se le pagaran por su tiempo $25.00 dólares
Confidencialidad

. El grupo de enfoque no es anónimo. Puede ser que usted conozca a alguien del grupo. O alguien del grupo puede conocerle a usted. Les diremos a todos: “Lo que se dice en el grupo se queda en el grupo”. Antes de que comencemos preguntaremos si las personas quieren usar solamente su nombre o la primera inicial de su apellido (como Sr. X), o simplemente Señor/Señora No se grabara apropósito el apellido o el nombre completo de ninguno de los participantes. Si accidentalmente esto sucede se borrara de la cinta

Hay posibilidad que se de una perdida de confidencialidad. Algunas de las cosas que hacemos para disminuir la probabilidad de que se de una perdida de confidencialidad son:

1. El personal esta entrenado para proteger la privacia (intimidad).
2. La cinta tiene un identificador único, que no usa ni el lugar ni la fecha de la reunión.
3. La cinta se guarda rápidamente bajo llave en in archivero en la oficina del Dr. Prigerson
4.. La cinta solo es escuchada por los doctores y el personal de investigación.

Participación Voluntaria

Usted esta en libertad de elegir no participar en el grupo de enfoque. Si usted decide participar puede cambiar de opinión en cualquier momento y dejar de participar. Si usted decide no participar o deja de participar su relación con los doctores o con el Hospital New Haven Yale no será afectada.

Preguntas

.Probablemente hemos usado algunas palabras con lo que usted no esta acostumbrado. Por favor siéntese en libertad de preguntar lo que no entiende. Por favor piense con cuidado sobre este estudio y la forma de consentimiento. Tome el tiempo que le sea necesario para tomar su decisión.

_____ _____

Firma del Investigador Principal Teléfono

o

_____ _____

Firma de la persona que obtuvo el consentimiento Teléfono

Si tienen preguntas o dudas o si tiene algún problema relacionado al estudio, usted puede llamar al líder del estudio Dr. Holly Prigerson, (203-974-7721). Si usted tiene preguntas sobre sus derechos como sujeto de investigación usted puede llamar al Comité de Investigación de Medicina Humana de Yale University (203 785-4688)

ESTA FORMA NO ES VALIDA A MENOS QUE LA SIGUIENTE CASILLA HAYA SIDO LLENADA EN LA OFICINA DE HIC

THIS FORM IS VALID ONLY UNTIL ESTA FORMA ES VALIDA SOLO HASTA : _____

PROTOCOLO HIC #:
_____

INITIALES: _____

E. Draft of Focus Group Discussion Guide (English) for African American group

Promoting Research Participation among
Black & Latino Older Adults

- INTRODUCTION

  - As participants enter, offer snacks.

- PURPOSE OF FOCUS GROUP

Thank you for coming today. . The reason for this focus group is to understand how older [African American/Latino] people feel about joining medical research studies. We will also talk about ways that researchers can make elderly people feel more comfortable about joining a research study. After the discussion, we will read a brief list of questions we'd like you to answer. . We will not ask you to take part in any other research after today.

As you know, we reached you through [name of site]. This study is for the Yale University Program on Aging. My name is [_____]. I will help with today's discussion. I am not with Yale University. I am an independent consultant just for this focus group.

The information from this focus group will be used to design medical research studies sensitive to the needs of older [Af.Amer/Latinos]. Research is used to find treatments for health problems. Research also makes sure the treatments work and are safe. But, these treatments can only help individuals from different races and ethnic groups if individuals from all races and ethnic groups take part in the research studies. Medical researchers cannot find better treatments for the health problems of [Af.Amer/Latino] elders unless Af. Amer and Latino elders take part in research studies.

[READ CONSENT STATEMENT]

Before we begin, I want to go over a few ground rules. I want to make sure everyone is comfortable and has a chance to give their opinions.

1. First, we hope that you will feel comfortable talking about your personal experiences. But, we know people may feel uncomfortable or uneasy sharing some experiences. For example, some of you may know one another. We fully respect your decision not to answer a particular question if you feel it would make you uncomfortable.

2. It is important that today's discussion remain confidential. I ask that our conversation not leave this room. Please use only your first name. Please refer to others by first name only. That will allow us as much privacy as possible.

3. Today's discussion will be tape-recorded. We record all conversations for an accurate report of what was said. You will not be identified on the tape other than by your first name. The tape will be typed up but your first name will not be part of the written form. The tapes will not be used for any other reason and will be destroyed at end of the project. The researchers plan to publish a report, so that other researchers can know about how elderly people feel about research studies.

It is important that only one person speaks at a time. Please speak up so we can hear all your comments. If more than one person speaks at a time, it is very difficult to get a clear recording. We want to hear what everyone says.

4. Please do not talk with your neighbor. It can interfere with the taping.

5. Feel free to share your feelings and opinions, even if you disagree with what someone else has said. . We would like to hear everyone's views.

6. This is a group discussion. I will try to make sure everyone has a chance to speak. I will try to make sure no one dominates the discussion. Please don't be offended if I gently cut you off.

7. Are there any questions before we begin? We have a lot to discuss. Let's get started.

First, I would like each of you to introduce yourself. Tell us your name. Then, very briefly tell us whether or not you have ever thought about taking part in a research study before today.

START TAPE RECORDING. ASK AGAIN IF EVERYONE IS COMFORTABLE WITH TAPING THE SESSION.

- QUESTIONS

People may have concerns about taking part in medical research studies. I want to ask you about some of these concerns and how to ease them.

To help our discussion, I want you to think about the questions in terms of a possible medical research study. This is not a real study. We will only use the study as an example. Let's say this is a study to test a new medicine for high blood pressure. There will be older white, Latino and African American people in the study. To find out if this new medicine is better than the old blood pressure medicine, the researchers will divide the people into two groups. They will be divided randomly, like flipping a coin. One group will be given the new medicine. The other group will get the old medicine. No one will know if they are taking the new or the old medicine. Everyone, regardless of their ethnicity or race, will have an equal chance of getting the new or the old medicine.

Everyone will be asked to come to the hospital for a blood pressure check once a month, for 6 months. They will also have two blood tests during the study. They will be asked questions about themselves and how they take their medicine.

GENERAL OPEN-ENDED:

1. Would you be willing to take part in the study to test the new blood pressure medicine? Why or why not?

CONCERNS

2. Think about older [AA/Latinos]. What are some of the concerns older [AA/Latinos] might have about joining a study like the blood pressure study? [PROBE: Worries about traveling to the hospital, fears about not understanding the study rules, pain of blood drawing, complications as a result of treatment, other questions.]

    a. FOR THE TOP 2-3 MENTIONED, ASK: What can researchers do to help ease the concern about [NAME CONCERN]?

3. Some people decide not to join medical research studies because they do not trust researchers, doctors, or the medical system. Do you think lack of trust might keep older [AA/Latinos] of all ages from taking part in a medical research study? Why? What do you mean by trust?

    a. What can researchers do to help gain trust from elderly people?

4. Some people worry that if they join a research study, their personal health information would not be kept private. They worry that their private information would be given to others without their permission. If you were asked to take part in the blood pressure medicine study, would you worry that your health information might not be kept private? Would this influence your decision to take part in the blood pressure medicine study? Why or Why not?

    a. How could researchers assure you that the information you share in the blood pressure study would be treated confidentially, not released without your permission?

    b. There are laws that penalize researchers who release confidential information without permission. Would knowing about this law make you feel more comfortable about joining the blood pressure study? What else could researchers do to help people feel more comfortable about their privacy?

5. Sometimes there are communication problems. There are language differences. A researcher might talk too fast. A person might have difficulty reading. Some words might be difficult to understand. Print on forms might be too small. The study might require using unfamiliar technology, like computers.
    a. Do you think communication problems might be a concern for older [Latino/AA] people thinking about joining the blood pressure study? Why or why not?

    b. What communication problems do you think might arise for older [Latino/AA] people in a research study?

6. Do you think older [Latino/AA] individuals feel researchers might not show respect? Why or why not?

7. What are some things that might make an older [Latino/AA] person feel more respected by the researchers?

8. Sometimes researchers gain financially from research. For example, a researcher in the blood pressure study may own part of a company interested in the new medicine. If the results show that the new medicine is better than the old medicine, the researcher might earn more money.

    a. What do you think about this?

    b. If you knew the researcher might gain financially from the results of the study, would this affect your willingness to take part in the blood pressure study? Why?

MOTIVATORS:

9. People who decide to take part in medical research have different reasons for joining. What are some of the reasons why an older [AA/Latino] might decide to take part in a study like the blood pressure study?

10. Sometimes researchers encourage people to take part in a medical research study by offering cash payments, gift certificates, church donations, or grocery store coupons. What do you think about these offers?

    a. Which would most likely encourage older [AA/Latino] to take part in the blood pressure study?

b. Which would be least likely to influence an older [AA/Latino] to join the study?

c. What is the minimum amount of money someone might want for taking part in the blood pressure study?

d. Is there an amount that would be too much? Is there an amount would make someone feel suspicious or not want to participate? What is it? Why?

11. Some people feel more comfortable joining a research study, if they have someone to help them. Some studies hire a person whose job is to help the study participants. This person might make appointments, arrange rides for study tests, help read and explain materials, or answer questions about the study.
    Would older [AA/Lat] be more willing to participate in the blood pressure study if they knew there was a staff person to help them? Why or why not?

12. Some studies offer participants a "study buddy". A "study buddy" may be another study participant o r someone who just completed the study. This "buddy" would go to the study appointments with you.
    Would older [AA/Latinos] be more likely to take part in the blood pressure study if they had a "study buddy"? Why/Why not?

13. Would the health problem being studied make a difference in your decision to take part in a medical research study? For example, would you be more likely to take part in a study of high blood pressure than a study of mental health problems?

14. Some people suggest that researchers recruit a board of African Americans/Hispanics to advise the study. The board might encourage people to take part in the study.
    If researchers were to form a community advisory board, what kinds of people should be part of this group? (PROBES: Who are community leaders? Who are the people in your community you trust the most? What can they do to interest people in the study (write letters, call you, etc)?)

15. The person who asks you to join a research study is sometimes called a "recruiter." This is different from your doctor. It is usually someone who works on the study staff. Their job is to find people interested in joining a study and talk to them about taking part. Are there personal characteristics of a recruiter that would make you more likely to join the study? (PROBES: Same age? Same ethnicity)?

F. Draft of Focus Group Discussion Guide (Spanish) for Hispanic Group

PROMOCIÓN PARA QUE PARTICIPEN EN INVESTIGACIONES NEGROS E HISPANOS DE EDAD MAYOR

- INTRODUCCION

  - Cuando entren los participantes ofrézcales los aperitivos (snack).

- PROPOSITO DEL GRUPO DE ENFOQUE

Gracias por venir el día de hoy. La razón para que se reúna este grupo de enfoque es para entender como se sienten las personas (africoamericanas/latinas) de edad avanzada acerca de la participación en estudios de investigación médica. También hablaremos sobre lo que los investigadores pueden hacer para que la gente de edad avanzada se sienta mas cómoda sobre la participación en estudios de investigación. Después de la discusión, leeremos una pequeña lista de preguntas que nos gustaría que usted conteste. No le pediremos a usted que participe en otra investigación después del día de hoy.

Como usted sabe, llegamos a usted a través de (nombre del sitio). Este estudio es para el Programa de Envejecimiento de la Universidad de Yale. Mi nombre es [_____]. Yo ayudare en la discusión de este día. Yo no soy parte de la Universidad de Yale. Soy un consultor independiente solo para este grupo de enfoque.

.. La información de este grupo de enfoque será usada para diseñar estudios de investigación medica que sean sensibles a las necesidades de las personas de edad [Afrooamericanas/Latinas]. Las investigaciones se usan para encontrar tratamientos a problemas de salud. Los investigadores también se aseguran de los tratamientos funcionan y son seguros. Pero, estos tratamientos solo ayudan a individuos de diferentes grupos étnicos y razas si individuos de diferentes razas y grupos étnicos participan en los estudios. Los Investigadores pueden encontrar mejores tratamientos para problemas de salud de [afroamericanos/latinos] de edad avanzada solo si .Afroamericanos/ Latinos de edad avanzada participan en los estudios de investigación.

[Lea declaración de aceptación]

Antes de empezar, quiero repasar las reglas de participación. Quiero estar seguro(a) que cada persona se siente cómoda y tiene la oportunidad de dar su opinión.

8. . Primero, confiamos en que usted se sienta cómodo hablando sobre sus experiencias personales. Pero sabemos que algunas personas pueden sentirse incomodas o tensas compartiendo algunas de sus experiencias. Por ejemplo, algunos de ustedes pueden conocerse. Nosotros respetamos su decisión de no contestar una pregunta particular si piensa que le causara incomodidad

9. Es importante que las discusiones de este día sean confidenciales. Les pido por favor que nuestras conversaciones no salgan de este cuarto. Por favor use solo su nombre de pila. Refiérase a otros participantes por su nombre solamente (sin mencionar el apellido). Esto nos dará una mayor privacia (confidencialidad).

10. .La discusión que tengamos este día se grabara. Grabamos todas las conversaciones para tener un record preciso de lo que se dijo. Usted solo será identificado en las grabaciones por su nombre (sin mencionarse el apellido).Se hará una copia escrita de la grabación; en la forma escrita ni siquiera se mencionara su nombre. Las grabaciones no se usaran para ninguna otra casa y serán destruidas al terminar el proyecto

Es importante que solo una persona hable a la vez. Por favor hable en voz alta para poder escuchar sus comentarios. Si mas de una persona hable a la vez es difícil hacer una buena grabación. Queremos escuchar lo que cada uno diga.

11. .Por favor no hable con su vecino. Puede interferir con la grabacion.

12. .Sientase en libertad de compartir sus sentimientos y opiniones, aun cuando no estén de acuerdo con las de otra(s) persona(s). Queremos escuchar la opinión de cada uno de los participantes.

13. Este es un grupo de discusión. Tendré certeza que cada persona tiene la oportunidad de hablar y que ninguna persona domina las discusiones. Por favor no se ofenda si le interrumpo gentilmente

14. . ¿Hay algunas preguntas antes de que comencemos? Tenemos mucho que discutir. Empecemos.

Primero, quisiera que cada uno se presente. Díganos su nombre de pila. Después en forma breve díganos si con anterioridad alguna vez pensó en participar en un estudio de investigación

INICIE LA GRABACION. PREGUNTE OTRA VEZ SI TODOS ESTAN COMODOS CON QUE SE GRABE LA SESION.

- <u>PREGUNTAS</u>

La gente puede estar preocupada por participar en estudios de investigación médicos. Quiero preguntarles sobre algunas de estas preocupaciones y como resolverlas

. Para facilitar nuestra discusión les planteare preguntas en términos de un posible estudio de investigación médica. Lo que les planteo no es un estudio real. Lo usaremos solo como un ejemplo. Digamos que este es un estudio sobre una medicina para presión arterial alta. Participara gente de edad, blanca, latina y africanoamericano...Para saber si la nueva medicina es mejor que una medicina que ya se usan para presión arterial los investigadores dividirán a los participantes en dos grupos. Los grupos se formaran al azar, como cuando se hecha un volado con una moneda, Un grupo recibirá la nueva medicina. El otro grupo recibirá la medicina vieja. Todos, independientemente de su raza o etnicidad, tendrán la misma posibilidad de recibir la medicina nueva o la medicina vieja

. Se les pedirá a todos que vayan al hospital para que se les tome la presión arterial una vez al mes, por seis meses. También se les harán dos análisis de sangre durante la duración del estudio. Se les harán preguntas sobre ellos mismos y sobre como toman las medicinas.

GENERAL ABIERTA:

16. ¿Estaría dispuesto a participar en un estudio para probar la nueva medicina para la presión arterial?

17. Piense en gente de edad ´[afroamericanos/latinos]. ¿Cuales serian las preocupaciones que gente de edad [AA/Latina] tendría para participar en un estudio como el de la medicina para la presión arterial? [SONDEE: Preocupaciones para viajar al hospital, miedo por no entender las reglas del estudio, dolor al tomar la sangre, complicaciones que resulten del tratamiento. Otras preguntas –[[SI SE MENCIONA CONFIANZA , VAYA A #5 Y VENTILE ESTO; DESPUES VUELVA A ESTA SECCION]

    a. PARA LOS 2 O TRES QUE MAS SE MENCIONEN, PREGUNTE:¿Que pueden hacer los investigadores para aliviar o disminuir esta preocupación [mencione la preocupación]?

18. . Las personas que deciden participar en investigación médica tienen diversas razones para hacerlo. ¿Cuales son algunas de las razones por las que personas de edad [Afroamericanos-Latinos] podrían decidirse a participar en un estudio como el de la presión arterial?

ASUNTOS ESPECIFICOS:

19. . En ocasiones los investigadores reciben retribuciones financieras por investigaciones. Por ejemplo, un investigador en el estudio de presión arterial puede ser dueño de parte de la compañía interesada en la nueva medicina. Si los resultados demuestran que la nueva medicina es mejor que la vieja medicina, el investigador puede ganar dinero.

    c. ¿Que piensa sobre esto?

    d. Si usted hubiera sabido que el investigador podría ganar financieramente de los resultados del estudio ¿afectaría esto su decisión de participar en el estudio de presión arterial? ¿Por qué?

20. Algunas personas deciden no participar en estudios de investigación medica por que no le tienen confianza a los investigadores, doctores o al sistema medico. ¿Cree usted que falta de confianza podría ser una razón por la que [AA/Latinos] de mayor edad no participarían en un estudio de investigación medica? [PODRIAMOS COMBINAR 5 Y 6 Y SOLO PREGUNTAR SOBRE LA/AA DE MAYOR EDAD] ¿Por qué?

    Que pueden hacer los investigadores para ganarse la confianza de la gente de edad avanzada?

21. Algunas personas se preocupan porque piensan que si se unen a un proyecto de investigación no se mantendrá en secreto su información personal de salud. Se preocupan de que información sobre ellos se le dará a otras personas sin su consentimiento. ¿Si a usted se le pidiera que participe en el estudio de presión arterial, se preocuparía usted de que su información de salud no se mantenga en forma privada? ¿ Influiría esto sobre su decisión de participar en el estudio de la medicina para la presión arterial? ¿Por qué o por que no?

    c. ¿Como podrían los investigadores asegurarle a usted que la información que compartió en el estudio sobre la presión arterial será tratada confidencialmente, y no se le dará a nadie sin su permiso?

    d. Hay leyes que castigan a los investigadores que sin permiso hacen pública información confidencial. ¿Conocer sobre esta ley le haría sentir mas cómodo acerca de su participación en el estudio de la presión arterial? ¿ Que mas pueden hacer los investigadores para que la gente se sienta mas cómoda en relación a su privacia (intimidad)

22. . En ocasiones hay problemas de comunicación. Hay diferencias de idiomas. Un investigador puede hablar muy rápido. Alguien puede tener dificultades leyendo. Algunas palabras son difíciles de entender. La letra impresa puede ser muy chica. El estudio puede requerir que se use tecnología con la uno no esta familiarizado, como computadoras
    a. Cree usted que problemas de comunicación puede ser una asunto que preocupa a las personas[Latinas/AA] de edad mayor al pensar sobre su participación en el estudio de presión?¿Por que o porque no?

    b. ¿Que problemas de comunicación cree usted que saldrían a la vista durante la participación que personas de edad [latinos/AA] en estudios de investigación?

23. ¿Cree usted que gente [Latinos/AA] de edad avanzada sienten que los investigadores no los respetan?¿Porque o porque no?

24. ¿Que cosas cree usted que se pueden hacer para que una persona[latino/AA] de edad avanzada se sienta mas respetada por los investigadores?

25. MOTIVADORES: En ocasiones los investigadores alientan a personas a que participen en un estudio de investigación médica ofreciendo pagos en efectivo, certificados de regalo, donaciones a Iglesias o cupones para supermercados. ¿Qué piensa usted de esto?

    a. ¿Que cosa seria la mas probable para animar a ¨[latinos/AA] de edad avanzada a participar en el estudio de presión arterial?

    b. ¿Que cosa seria la menos probable para animar a [latinos/AA]?a participar en el estudio

    c. ¿Cual es la menor cantidad de dinero que una persona quisiera para participar en el estudio de presión arterial?

    d. ¿ Hay una cantidad que seria demasiada?¿hay alguna cantidad que causaría que alguien tuviera sospechas o no quisiera participar? ¿Qué cantidad es esta?

26. . Algunas personas se sienten mas cómodas participando en un estudio de investigación si hay alguien que les ayuda. Algunos estudios contratan a personas cuyo trabajo es ayudar a los participantes en el estudio. Esta persona puede hacer citas, hacer arreglos de transportación para ir a las pruebas del estudio, ayudar en la lectura y explicar el material, o contestar preguntas del estudio
    ¿Cree usted que [latinos/AA] viejos estarían más dispuestos a participar en el estudio de presión arterial si supieran que hay una persona del personal dedicada a ayudarlos? ¿Por qué o porque no?

27. Algunos estudio ofrecen a los participantes un “compañeros para el estudio”. Un compañero para el estudio puede ser otro participante en el estudio o alguien que acaba de completar el estudio. Este compañero iría con usted. a las citas del estudio
    Cree usted que [latinos/AA] de edad avanzada tendrían mayor posibilidad de participar en el estudio de presión arterial se tuvieran un “compañero para el estudio” ¿Por qué o porque no?

28. ¿Según usted el problema de salud que se estudia, seria un factor en su decisión de participar en el estudio de investigación medica? Por ejemplo, ¿seria más probablemente que se participe en un estudio sobre presión arterial que en un estudio sobre salud mental?

29. Algunas personas han sugerido que los investigadores contraten a un consejo de [latinos/AA] como consultores en el estudio. El consejo podría animar a personas a participar en el estudio.
    Si los investigadores estarían dispuestos a formar un Consejo Consultivo Comunitario, ¿que tipo de personas deberían de estar en este grupo? (SONDEE: ¿Quiénes son líderes comunitarios? ¿Quienes son las personas en su comunidad q a las que le tiene mayor confianza? ¿Qué pueden hacer para interesar a la gente en el estudio (escribir cartas, llamar por teléfono, etc.)?

30. La persona que le pide o lo invita a participar en un estudio de investigación a veces se le llama reclutador. Eso es diferente de su doctor. Es una persona que trabaja con el personal del estudio. Su trabajo es encontrar gente interesada en participar en el estudio y hablarles sobre su participación. Que características personales debe de tener el reclutador para que probablemente lo convenza a usted para que participe en el estudio. (SONDEE: ¿la misma edad? ¿la misma raza-grupo étnica?)

G. Draft of African American Quantitative Survey (English)

SURVEY – Dixwell Newhallville

Imagine that you have high blood pressure, and you have been asked to join a research study. One half of the people in the study would get a new blood pressure medicine, and one half would get the usual medicine. The researchers think that the new medicine might work better, but they are not sure. You are not sure if you want to participate. Please rate the importance of the following incentives – these are things that the researchers could do that would make it more likely that you would join the study *(Circle one answer for each question):*

1. Someone you trust works on the research team.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
2. Community leaders (such as a pastors) approve and support the study.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
3. Researchers tell you about laws to protect study participants and any punishment they receive if they do not follow the laws.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
4. Researchers explain how they watch for any health or other problems resulting from the study. They tell you that they will stop the study if you experience problems.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
5. You are told that the information collected about you on the study is confidential. No one outside of the study staff will know your personal health information.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
6. You are told how the results of the study will benefit people with high blood pressure.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
7. Anyone who joins the study gets free health care such as:	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4

- Screening tests.
- A complete physical exam
- Referrals for health care

- On-going treatment
- Free or cheaper medication

8. You are told how the results of the study results will benefit African American/Black people.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
9. You are told whether or not the researcher might gain money from the research.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
10. Researchers will share results of your study tests with you, for example results of any blood tests or blood pressure readings.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
11. A member of the research staff explains the study to your family.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
12. Researchers give you a 24-hour study phone number and tell you that you can contact them anytime you have a question or problem.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
13. Researchers tell you that the general results of the research will be shared with the African American/Black community.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
14. Researchers tell you that you will not be used as a guinea pig.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
15. Researchers tell you all that they have to done to make sure the study is safe.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4
16. Researchers show you respect.	Not Important	Somewhat Important	A Little Important	Very Important
	1	2	3	4

H. Draft of Hispanic Quantitative Survey (Spanish)

ENCUESTA

Imagínese que usted tiene alta presión arterial, y que se le ha pedido que participe en un estudio de investigación. La mitad de los participantes en el estudio recibirán una nueva medicina para alta presión arterial, y la otra mitad recibirá una medicina que ya se usa para presión arterial alta. Los investigadores piensan que la nueva medicina puede ser mejor, pero no están seguros. Usted no esta seguro si quiere participar. Por favor valore la importancia de los siguientes incentivos- cosas que los investigadores podrian hacer para convencerlo que si participe en el estudio- *(Pongale un circulo alrededor de la respuesta adecuada para cada pregunta):*

1.Alguien a quien usted le tiene confianza trabaja en el grupo de investigación	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
2.. Lideres comunitarios (como un sacerdote) aprueba y apoya el estudio.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
3. Los investigadores le informan sobre las leyes que protegen a los participantes en el estudio y sobre los castigos que investigadores reciben si no siguen las leyes.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
4. Los investigadores le explican como vigilan, si como consecuencia del estudio se dan , problemas de salud y de otra índole.. (Le dicen que ellos lo sacaran a usted del estudio si a usted se le presentan problemas) [1]	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
5.. A usted le dicen que la información obtenida sobre usted en el estudio es confidencial. Nadie fuera del personal del estudio, conocerá su información personal de salud	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
6.. A usted le dicen como los resultados del estudio beneficiaran a personas que tienen alta presión arterial	No es importante 1	Somewhat Important 2	Un poco importante 3	Muy importante 4
7.:Cualquier persona que participa en el estudio recibe atención medica gratuita como: ▪ Pruebas de detección de enfermedades ▪ Examen fisico completo ▪ Referencia a especialistas para atención medica	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4

- Continuación de tratamientos medico ya iniciado
- Medicamentos baratos o gratuitos.

8.. Le dicen a usted como los resultados de este estudio beneficiaran a los Latinos.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
9.. Le dicen a usted si los investigadores ganaran dinero de la investigación	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
10. El personal del estudio habla español con usted.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
11.. Los investigadores compartirán los resultados de las pruebas que le hagan a usted como exámenes de sangre, o las lecturas de la presión arterial	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
12 Un miembro del personal de investigación le explica el estudio a su familia	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4

13. Los investigadores le dan un numero de teléfono que puede usar las 24 horas y le dicen que los puede llamar en cualquier momento cuando tenga preguntas o problemas	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
14. Los investigadores le dicen que los resultados globales del estudio se compartirán con la comunidad hispana.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
15.. Los investigadores le dicen que usted no será usado como un conejillo de las indias.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
16. Los investigadores le dicen todo lo que han hecho para asegurarse que el estudio es seguro (inofensivo)	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4
17. Los investigadores le muestran respeto.	No es importante 1	Algo importante 2	Un poco importante 3	Muy importante 4