The Gerontologist
Vol. 51, No. S1, S33–S45
doi:10.1093/geront/gnr027

Recruitment and Retention Strategies for Minority or Poor Clinical Research Participants: Lessons From the Healthy Aging in Neighborhoods of Diversity Across the Life Span Study

Ngozi Ejiogu, MD,[1] Jennifer H. Norbeck, MSW,[1] Marc A. Mason, MS,[1,2] Bridget C. Cromwell, BA,[1,2] Alan B. Zonderman, PhD,[1] and Michele K. Evans, MD*,[1]

[1]Health Disparities Research Section, Clinical Research Branch, National Institute on Aging, National Institutes of Health, NIH Biomedical Research Center, Baltimore, Maryland.
[2]MedStar Health Research Institute, Hyattsville, Maryland.

*Address correspondence to Michele K. Evans, MD, Health Disparities Research Section, Clinical Research Branch, National Institute on Aging, National Institutes of Health, NIH Biomedical Research Center, 251 Bayview Blvd, Suite 100 Room 4C-222, Baltimore, MD 21224. E-mail: me42v@nih.gov 410558 8573

Received August 20, 2010; Accepted March 8, 2011
Decision Editors: Anna M. Nápoles, PhD, MPH; Martha Crowther, PhD, MPH

Purpose of the study: Investigating health disparities requires studies designed to recruit and retain racially and socioeconomically diverse cohorts. It is critical to address the barriers that disproportionately affect participation in clinical research by minorities and the socioeconomically disadvantaged. This study sought to identify and rectify these barriers to recruit and retain a biracial (African American and non-Hispanic White) and socioeconomically diverse cohort for a longitudinal study. **Design and Method:** The Healthy Aging in Neighborhoods of Diversity across the Life Span study is a 20-year longitudinal examination of how race and socioeconomic status influence the development of age-related health disparities. One goal was to create a multifactorial recruitment and retention strategy. The recruitment paradigm targeted known barriers and identified those unique to the study's urban environment. The retention paradigm mirrored the recruitment plan but was based on specifically developed approaches. **Results:** This cohort recruitment required attention to developing community partnerships, designing the research study to meet the study hypotheses and to provide benefit to participants, providing a safe community-based site for the research and creating didactics to develop staff cultural proficiency. These efforts facilitated study implementation and enhanced recruitment resulting in accrual of a biracial and socioeconomically diverse cohort of 3,722 participants. **Implications:** Recruiting and retaining minority or poor research participants is challenging but possible. The essential facets include clear communication of the research hypothesis, focus on providing a direct benefit for participants, and selection of a hypothesis that is directly relevant to the community studied

Key Words: Cultural proficiency, Health disparities, Community-based research platform

One of the most vexing issues in clinical research is the difficulty in recruiting and retaining study participants. Recent data suggest that study participation rates among individuals from all walks of life even those from population groups traditionally overrepresented in epidemiologic clinical research has fallen to levels that could endanger

Table 1. Barriers to Recruitment of Nontraditional Research Participants

Individually-based barriers to participation
Fear of being used as a "guinea pig" (Wilets et al., 2003)
Mistrust of government entities (UyBico et al., 2007)
Time required to participate is too much (Keyzer et al., 2005)
Economic constraints and inability to take time off from work (G. M. Corbie-Smith, 2004)
Inability to participate because of existing medical problems (Bolen et al., 2006)
Transportation to and from research location (Blanton et al., 2006)
Community-based barriers to participation
No real-time benefit to participants (G. M. Corbie-Smith, 2004)
Exploitation of a vulnerable population (LaVeist et al., 2000; Wipke-Tevis & Pickett, 2008)
Inadequate knowledge concerning the need for medical research (Wilets et al., 2003)

the successful conduct of some types of research (Galea & Tracy, 2007). This problem is even further accentuated for special populations, particularly those of low socioeconomic or minority status and the aged. The challenges of recruiting minorities for clinical research have been well documented in the literature (Carter-Edwards, Fisher, Vaughn, & Svetkey, 2002; Orden, Dyer, & Liu, 1990; Sullivan-Bolyai et al., 2007). Although the rates of minority enrollment and participation in observational studies are similar to that by nonminorities (Durant et al., 2007; Wendler et al., 2006; Wright et al., 2001), evidence suggests that there are significant barriers to participation for minorities in clinical trials (Ford et al., 2008). Among other factors, individual barriers include mistrustful attitudes based on personal experiences with staff, nurses, and physicians at local institutions; misunderstandings based on poor communications or problems with medical literacy; or unnecessarily time demands for attending clinics, difficulties in arranging appointments, or times required for travel to the facility. Community-based barriers include attitudes that all members of a neighborhood have been treated poorly by an institution or by clinical researchers. Few studies have examined the challenges of recruiting participants from diverse socioeconomic backgrounds regardless of race, despite general agreement about the value of wide representation for addressing disparate health outcomes (Durant et al., 2007; Lai et al., 2006; Sung et al., 2003).

Frequently enumerated barriers for minority or poor research participants as cited in Table 1 include mistrust of researchers and the government, transportation, fear of exploitation, and low levels of familiarity with medical research (Blanton et al., 2006; Bolen et al., 2006; G. Corbie-Smith, Moody-Ayers, & Thrasher, 2004; G. M. Corbie-Smith, 2004; Keyzer et al., 2005; LaVeist, Nickerson, & Bowie, 2000; UyBico, Pavel, & Gross, 2007; Wilets, O'Rourke, & Nassisi, 2003; Wipke-Tevis & Pickett, 2008). The burden of research participation is much heavier on low-income minorities than it is on middle-class Whites (Mattson, Curb, & McArdle, 1985). In addition, the lack of tangible benefits provided by nonintervention studies reduces the motivation to participate (Blumenthal, Sung, Coates, Williams, & Liff, 1995; Dennis & Neese, 2000). Recent research indicates that African Americans are less likely to participate in clinical studies than Whites, possibly because they mistrust researchers based on negative past experiences, fear of exploitation, and concern that they will be harmed (Braunstein, Sherber, Schulman, Ding, & Powe, 2008; Moreno-John et al., 2004).

There is no consistent evidence that the aged are less likely to participate in clinical research (Galea & Tracy, 2007). However, there may be special barriers for older individuals, and it is not unreasonable to expect that minority elders may have additional issues that affect study participation. Evidence in the literature suggests that barriers for older individuals are very similar to those noted for younger participants including minorities. These include lengthy appointments, transportation, parking, repeated phlebotomy, and neuropsychological testing (Marcantonio et al., 2008). It is also important to recognize that older participants voice as motivating factors for study participation as the ability to provide societal benefit by participation, availability of home visits, compensation, and provision of transportation (Jefferson et al.). There may be overlap in the barriers that confront minority participants regardless of their age; however, there remains a gap in our knowledge about the specific barriers that uniquely affect minority elders. Longitudinal studies that follow middle-aged minorities through older ages

may highlight specific factors that are relevant disincentives to participation in clinical research by the minority aged.

We developed a longitudinal population-based study of health disparities on a socioeconomically diverse sample of young to middle-aged African Americans and Whites in Baltimore, MD. Specifically, we designed Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) to disentangle the effects of race and socioeconomic status (SES) on risk factors for morbidity and mortality, to examine the incidence and progression of preclinical disease, and to follow-up the development and persistence of health disparities, longitudinal health status, and health risks. In this article, we describe how we identified and met the challenges of recruiting (Wave 1) and retaining (Waves 2 and 3) a biracial and socioeconomically diverse urban cohort.

Methods

Study Design and Conduct

The HANDLS study is a Baltimore-based longitudinal study of a fixed cohort of urban-dwelling adults initially 30–64 years old. HANDLS is conducted by investigators in the Health Disparities Research Section of the Intramural Research Program at the National Institute of Aging (NIA). Initial study recruitment began in 2004 using an area probability sampling design based on the 2000 Census and described in greater detail elsewhere (Evans et al.). The study is approved and monitored for human subject protection by the Institutional Review Board (IRB) at the MedStar Health Research Institute. All participants provide written informed consent for every phase or wave of the study and were compensated $100.00 for participation. The baseline wave of HANDLS was completed in 2009.

We recruited the initial sample in two phases (Wave 1). In the first phase, interviewers selected one to two eligible persons per household by doorstep screening using a computer-generated probability selection method. Once successfully recruited and consented, participants completed household surveys and 24-hr dietary recalls using the United State Department of Agriculture's Automated Multiple Pass Method (AMPM; Raper, Perloff, Ingwersen, Steinfeldt, & Anand, 2004). The 2-hr household survey measures covered the following: subjective well-being, activities of daily living, physical functioning, usual source of care, utilization of care, ethnic identity, discrimination, religiosity and coping, active coping, household composition, demographics, neighborhood characteristics, dental health, and health insurance. Phase 1 concluded with an examination appointment for Phase 2 on mobile medical research vehicles (MRVs) parked in participants' neighborhoods. Schematic floor plans and pictures of the MRVs are available on the HANDLS Web site (http://handls.nih.gov).

In the second phase, blood and urine specimens were collected for comprehensive laboratory testing and a physician and nurse practitioner performed a medical history and physical examination. Intima-media thickness was assessed by carotid Doppler. Electrocardiography was performed, and measures of pulse wave velocity were obtained. Bone mineral density and body composition were measured by dual-energy X-ray absorptiometry. Physical functioning was assessed by grip strength and a lower extremity function test. Nutrition was measured by a second 24-hr dietary recall using the AMPM. A battery of neuropsychological tests assessed cognitive performance, and an audio computer-assisted survey program administered psychosocial inventories. The audio-administered questionnaires included inventories on ethnic identity, income assessment, social support, and psychiatric screening coping strategies. Further information about study measure can be accessed at the HANDLS Web site, http://handls.nih.gov.

Recruitment Plan

Using experience from our three-year pilot study, we developed a multifactorial rubric that identified the primary challenges to recruiting a socioeconomically diverse sample of African Americans and Whites. This recruitment strategy consisted of plans to address barriers that might exist at different levels related to the scientific staff, the community residents, as well as governmental and public safety officials. We employed this approach in a "dress rehearsal" tract to test the effectiveness of our study design. Table 1 outlines the numerous factors in the literature that are barriers to participation for members of minority or low-SES population communities. We categorized these into individual- and community-based barriers. We examined the logistical challenges of doing research in Baltimore City and developed a specific urban framework for our field-based study and identified relevant barriers from reading the pertinent literature, meeting with neighborhood

stakeholders, local health professionals as well as governmental officials, and by creating a community advisory board.

The first step in establishing a physical presence in 12 different communities was to follow the National Health and Nutrition Examination Survey model of mobile examination centers. We designed and procured two vehicles from LifeLineMobile in Cincinnati Ohio (www.lifelinemobile.com) to serve as mobile examination centers. MRV 1 is a 53-foot customized semitrailer with three working areas: an examination room with blood donor station; a cardiovascular fitness and physical performance testing area; and a bone density and vascular studies testing area. MRV 2 is a 40-foot customized self-propelled truck with three interview rooms for cognitive and neuropsychological testing, psychosocial and other questionnaires, and inventories. Initially, we collected biological specimens in MRV 1, but the risk of exposing participants and staff to biohazards led us to design and acquire MRV 3 specifically for specimen collection and consultation.

Retention Strategy

Our retention strategy mirrored the recruitment strategy in that we sought to maintain and further develop communication channels with community residents, local governmental officials as well as to maintain competent staff invested in the research enterprise. The strategy consisted of frequent contact information validity probes, an interim evaluation, and data collection wave, conducting study impact focus groups, maintaining community advisory board contacts, implementing field-based tracking and tracing, developing electronic tracking and tracing protocols, and mail and telephone contact protocols. We used a variety of techniques to update contact information, including a periodic newsletter mailing (*The Healthy Journey*, see http://handls.nih.gov/05Part-04News.htm) and holiday and birthday cards. The high volume of undeliverable mail made it crucial to devise a method to track this transient population using direct methods. The study protocol was initially designed to revisit the cohort after four years, but we introduced an interim study (Wave 2 Interim Follow-up Study) that contacted participants 1.5 years after their initial examination. The interim study was an unusual retention strategy that served multiple purposes by administering the Revised NEO Personality Inventory, testing telephone methods for the AMPM dietary recall, inquiring about interim health status changes, and assessing of study acceptability and the likelihood of continuing participation.

We recontacted members of our Wave 1 Community Advisory Boards as well as other community leaders and stakeholders to update them about our accomplishments and plans for redeploying in the city. We followed these efforts closely with a mail and telephone contact protocol in which we sent letters to participants about when and where we planned to deploy our MRVs in their neighborhoods. These letters invited participants to contact us for an appointment for their follow-up examinations. Two weeks after this mailing, the office-based track and trace staff phoned participants from whom we had not been contacted. When attempted contact by mail and phone were unsuccessful, we deployed our field-based track and trace staff. The field-based track and trace staff began by locating participants by using an intensive search engine, contacting listed next of kin, checking judiciary data bases, canvassing last known address, and visiting neighbors adjacent to last known address.

Results

Taking into account the specific challenges of the planned study, which included significant participant burden due to our two-phase approach, we developed a recruitment strategy that identified domains and subdomains of barriers to participation in clinical research. As the study progressed, we identified the levels at which these barriers occurred. The primacy of the barrier domains overlap and changed from neighborhood to neighborhood and thus should not be considered as distinct groups. It is noteworthy that the analyses of the solutions for the barriers were a continuing fluid assessment of the study from participants' perspectives.

Individual Barriers

There were individual barriers and specific individual challenges (subdomains) relevant to recruiting our Baltimore-based cohort (Figure 1). Barriers included mistrust of government and research institutions, transportation issues, economic and time constraints, high disease burden, and personal biases.

Mistrust of Government and Research.—Mistrust of the government and medical research and limited transportation are two of the individual barriers

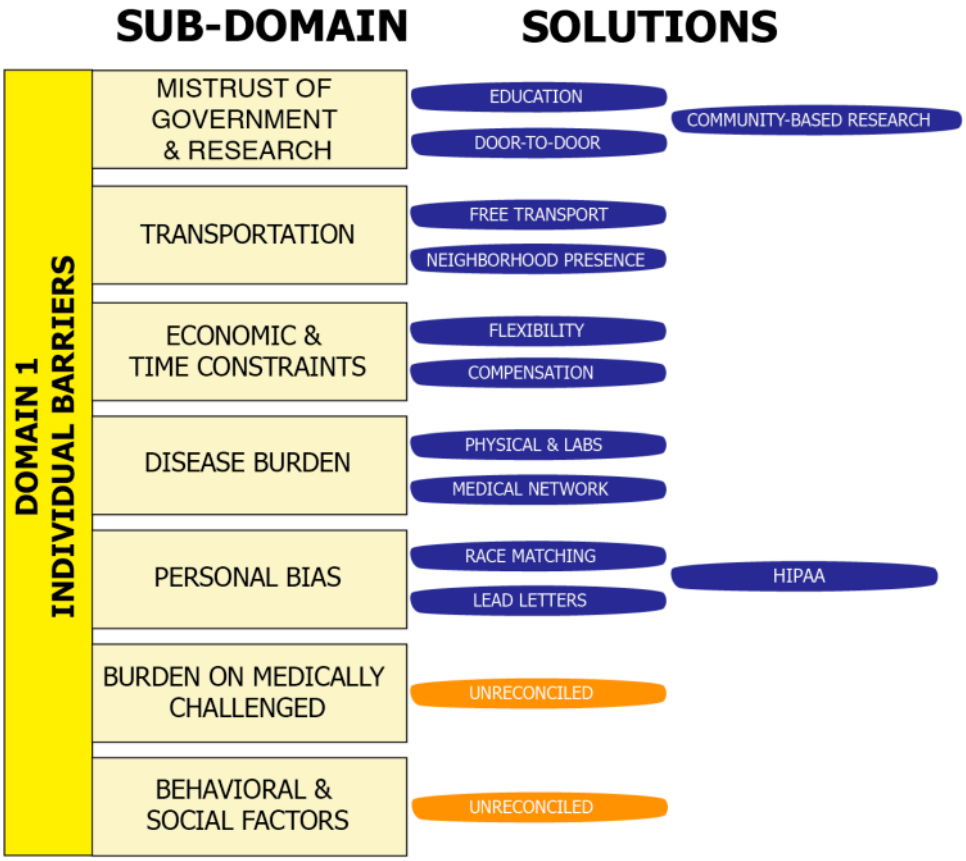

Figure 1. Domain 1—Individual barriers.

that influenced the study design and led us to create and deploy the MRVs in the community as research platforms. Before we moved the MRVs to each neighborhood, the recruitment team educated potential participants on the value of medical research in general and the specific benefits of participation in the HANDLS study. When our field interviewers made their door-to-door recruitment visits, MRVs in the neighborhood were instrumental at putting residents at ease and encouraging further dialogue. Trust was established in part by providing the field interviewers with formal identification badges with the study logo displayed prominently.

Transportation Barriers.—MRVs as a research platform in the neighborhood addressed the barrier of location. Their proximity became an incentive that encouraged potential participants who lacked means of transportation to enroll. We provided transportation to encourage participation in neighborhoods where street crime might have hindered access to the MRVs.

Economic and Time Constraints.—Among all of the barriers to study participation, economic factors and time constraints are the most powerful and difficult to overcome. For some, but not all, monetary remuneration was an important motivator for participation. For many, flexible scheduling was a key to participation regardless of remuneration, given that this study required approximately 8 hr to complete the in-home and MRV-based portions. Including weekends and evenings among the examination times facilitated the participation of individuals who could not take time off from work or childcare responsibilities during regular workdays.

High Disease Burden.—There is a high disease burden among African Americans and individuals in the low-SES cohorts in cities across the United States (Franks, Muennig, Lubetkin, & Jia, 2006). The inability to afford medical care often translates to undiagnosed and poorly managed medical ailments (Halpern et al., 2008; Heron, Stettner, & Haley, 2006; Town, Wholey, Feldman, & Burns, 2007). We provided an opportunity for comprehensive medical examinations and clinical laboratory testing to those who otherwise could not afford such procedures. Furthermore, the study

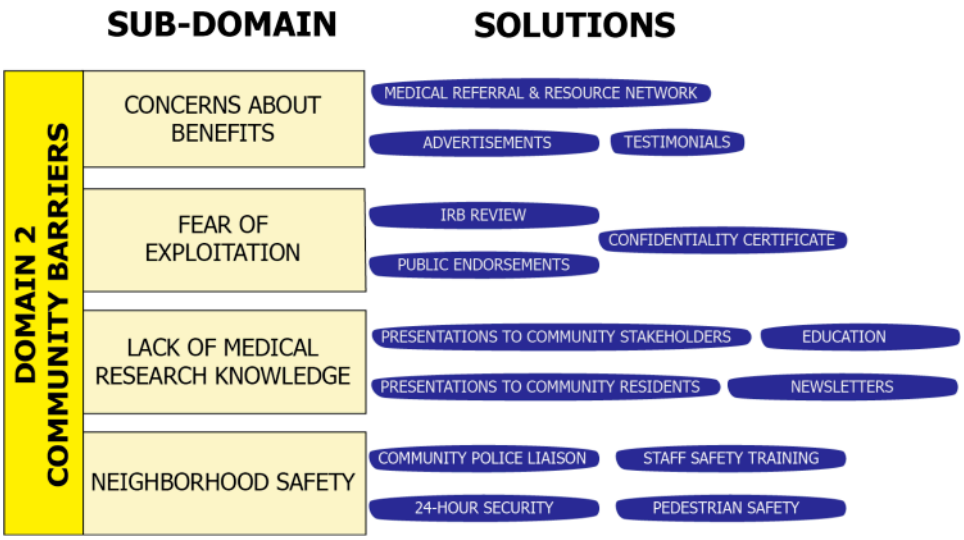

Figure 2. Domain 2—Community barriers.

developed a referral network by forming liaisons with private practitioners, neighborhood clinics, and community health centers where participants with newly diagnosed or poorly managed medical ailments could obtain affordable follow-up care.

Personal Bias.—Potential participants did not readily open their doors to field recruiters. To overcome this obstacle, we sent "lead letters" ahead of interviewers to introduce the study to neighborhood households. We also matched field interviewers' races with the likely racial composition of the neighborhood as a way to decrease suspicion and increase trust. In spite of this multifaceted approach, there were still certain individual barriers that could not be reconciled.

Medically Challenged.—We determined that the burden of participation outweighed the benefits of their participation for medically challenged individuals. We excluded potential participants at medical risk from this wave of the study. Medical risk was defined as having an acute medical or psychological condition that required urgent medical treatment. These individuals were referred to appropriate sources of health care.

Behavioral and Social Factors.—The ability to recruit young adults in the target neighborhoods was hampered in intractable ways by alcohol and illicit drug use. Intoxication by alcohol or drug abuse led us to exclude individuals who might otherwise have participated. We also excluded participants involved with the criminal justice system (home detention monitoring system in place, residence in halfway houses maintained by the prison system) from Wave 1.

Community-Based Barriers

Perhaps the most important community-based barriers were lack of medical research knowledge and the misconception that there is ongoing exploitation of community members by medical research institutions (Figure 2).

Lack of Medical Knowledge.—Neighborhood Community Advisory Boards (CAB) help garner support from stakeholders and develop relations with the communities (Dancy, Wilbur, Talashek, Bonner, & Barnes-Boyd, 2004; Quinn, 2004). Drawn from the target community, each CAB comprised members or leaders of neighborhood activist or tenant groups, lay church leaders, and local residents. Educating the members of the CAB about health disparities and the need for research in their communities was critical to gaining their trust and support for the study. This was accomplished by presentations outlining the direct benefits of participating in the HANDLS study at community association meetings. The CAB provided critical feedback on the conduct of the study, the acceptability of the study, and neighborhood-specific barriers to participation. In certain neighborhoods, forming a CAB duplicated existing neighborhood associations. Instead, we presented the study to the neighborhood association meeting, which served as the CAB for the neighborhood.

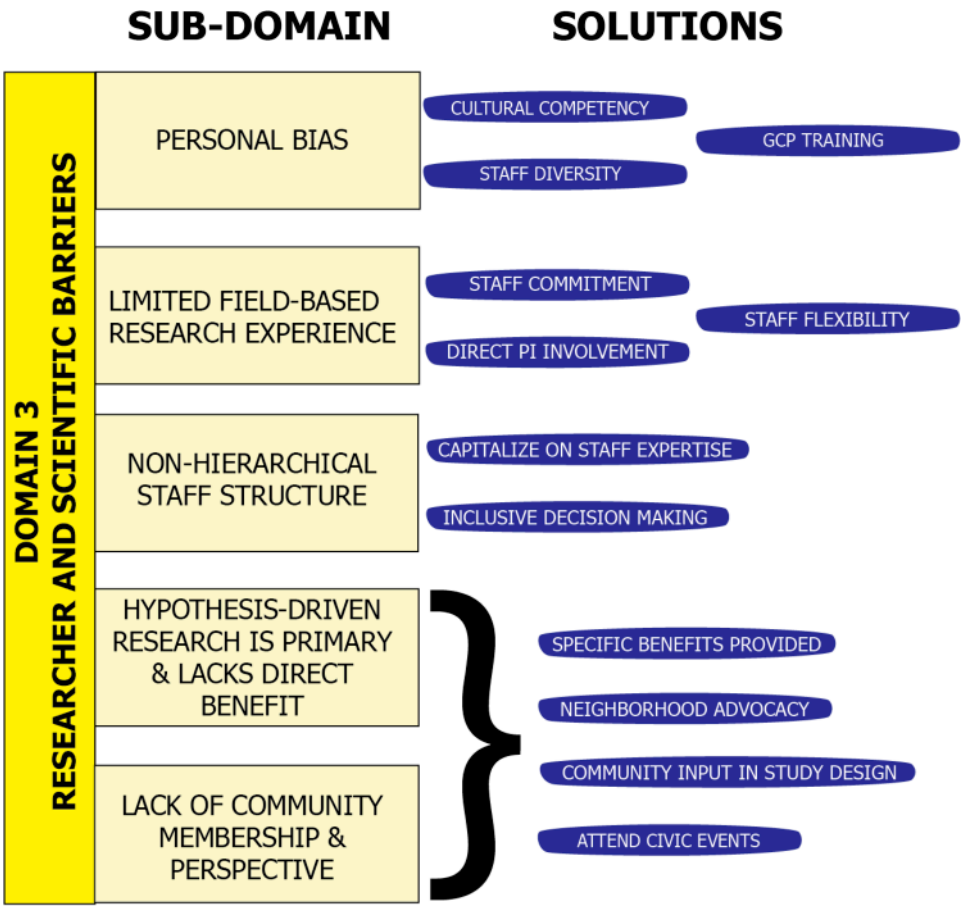

Figure 3. Domain 3—Researcher and scientific barriers.

Government officials, legislators, and their staff were informative sources about the constituent needs and about salient neighborhood characteristics and issues. We presented the study to Baltimore City Council members at City Hall, State Senators in Annapolis, and to Maryland's Senators on Capitol Hill to solicit their support and endorsement of our study. Governmental officials at all levels were eager to learn about our hypotheses on health disparities and supported our study as a benefit for their constituents. On several occasions, they were instrumental in overcoming community-based barriers.

Fear of Exploitation.—We addressed this barrier with our certificate of confidentiality, adherence to the Health Insurance Portability and Accountability Act, to Good Clinical Practice, to Federal human subject policies, and to practices required by our IRB. Most importantly, we explained these policies in terms that our potential participants understood. All written materials were analyzed for readability using the Flesch–Kincaid Readability Scale. A video produced by the HANDLS and NIA IRB Photography and Arts Section was presented to communities and to participants as part of the informed consent process. This video explains the study rationale, presents a tour of the MRVs, and provides a detailed description of the tests and procedures performed as a part of the study (http://www.youtube.com/user/NIAsHANDLS). The HANDLS team also distributed information packets that included documentation of IRB approval, letters of support from legislators, study descriptions, and neighborhood site maps.

Concerns About Benefit to the Population.—We informed CABs and residents about our study's tangible medical benefits. Furthermore, we offered a "referral guide" listing private practice physicians, community health centers, and clinics willing to treat underinsured or uninsured community members. We disseminated information about the study through advertisements in newsletters and fliers posted in churches, stores, and health centers. We also presented testimonials, highlighting the benefits of the study by HANDLS pilot participants.

Neighborhood Safety.—We faced unique security challenges in conducting a field study in free-standing mobile research facilities. This challenge required a continuing dialogue with the Baltimore Police Department (BPD), district commanders, and community affairs police officers. The BPD was receptive and supportive of the goals of the study. They provided important guidance for selecting vehicle deployment sites and included our sites in their routine patrols. The study maintained a liaison with BPD's community affairs division without arousing suspicion from the community. Providing safety for participants and staff also required that we train our staff members on personal and property safety. The MRVs had 24-hr security surveillance by the HANDLS security staff. The use of an automated debit card payment method was adopted for compensation, eliminating the need for on-site cash.

Researcher and Scientific Barriers

We also identified specific barriers that are applicable to researchers and staff (Figure 3).

Personal Bias.—We developed a specific cultural proficiency curriculum to reduce risks that investigators and staff members might unwittingly communicate their personal biases to study participants. This highly individualized and unique cultural proficiency training program exposed research study staff to the cultural context of the research study and potential participants. The course modules were developed by the principal investigators and used outside experts to provide insight into how individual perspectives can facilitate or hinder clinical research. It helped researchers avoid cultural generalizations; introduced researchers to cross-cultural communication techniques; discussed barriers created by ethnocentrism, prejudice, anxiety, assumptions; and discussed the ways stereotyping influences interpersonal relationships with persons from a culture or cultural perspective other than one's own. Different facets of cultural proficiency training are provided yearly. Given the continuous nature of the training, it remained a wellspring from which staff regularly updated their skills for self-examination and raised their self-awareness on the diversity of cultural perspectives and values inherent in the general population from which the study draws participants.

Limited Field-Based Research Experience.—All field staff was required to successfully complete an extensive nine-day training program before beginning door-to-door recruitment efforts in the field. Part of the training required the principal investigators to present the study's objectives and design. The ability of the field staff to obtain cooperation of participants by effectively answering questions and addressing concerns was critical to our recruitment efforts. The field staff was also trained to request a revisit to households who were undecided about enrolling in the study. This allowed us to avoid any impression that we wanted to coerce participation, and it provided eligible participants time to make an informed decision.

Narrow View of Job Responsibility.—Study staff was encouraged to avoid a narrow view of their job or role in the study. Inclusivity of staff is an integral aspect of the study design. The principal investigators led the study but sought the opinion of every staff member when solutions to challenges were being developed. Hierarchical decision making was avoided as much as possible. Suggestions from staff members are solicited on most aspects of the study. Staff learned to exhibit a high level of flexibility to accommodate changes in protocols and scheduling because they were empowered to take initiative in developing plans to address problems as they occurred not retrospectively.

Direct Benefits to Participant.—We designed the HANDLS study to extend specific benefits to participants. Benefits to participants were a deliberate aspect of the study design to address, at least in part, difficulties among urban residents in finding and receiving regularly scheduled preventive and follow-up medical care, even for chronic medical conditions. This study design provides an opportunity for participants to learn about their health through an extended one-on-one contact with our physician and nurses. Even for participants with health insurance, the time spent with the study provided an important opportunity for health education and discussions of medical compliance with prescribed medical regimens.

Lack of Community Membership and Perspectives.—Researchers frequently have difficulty effectively communicating with communities. The HANDLS study team strived to develop an

Table 2. Healthy Aging in Neighborhoods of Diversity Across the Life Span Participant Study Status for South Baltimore, Reservoir Hill, and Forest Park

Study status	Count	Percent
Active participants	590	79.2
Deceased	55	7.4
Dropped, excluded, or withdrawn	41	5.5
Lost to follow-up	56	7.5
Temporarily unavailable	3	0.4
Total	745	100

Table 3. Frequency of Participant Disposition for Those Eligible to Visit the Mobile Medical Research Vehicles (MRVs)[a]

Wave 03 MRV disposition[b]	Count	Percent
Complete visit	419	64.6
MRV show (incomplete visit)	19	2.9
Missed MRV appointment	50	7.7
Eligible and in-process for appointment	161	24.8
Total	649	100

Notes. [a]Eligibility for MRV visit defined by the following three status categories in Table 2: Active participants, lost to follow-up, and temporarily unavailable (n = 649).

[b]Overall MRV show rate calculated directly as: (419 + 19)/649 = 67.5%.

open communication channel by developing a bidirectional relationship with the community. Using the vehicles as health screening sites at high visibility city-wide events such as the Hispanic Festival, the NAACP African American Heritage Festival, and Gospel Fest provided an important opportunity for Baltimore residents to visit the vehicles and meet the staff outside of the researcher–study participant setting. Perhaps most importantly, it demonstrated active participatory community citizenship on the part of the HANDLS research entity. The team used this avenue to gather information about potential barriers to participation. Monetary compensation preference over gift tokens was one of the suggestions garnered from these interactions and was integrated into the study design.

Recruitment and Participant Accrual

Our recruitment strategy facilitated participation and made the study accessible to minority or poor research participants. Using this unique and multifaceted approach, we recruited 3,722 participants over four years. Over four years, we recruited 3,722 participants, 2,200 of whom were African Americans (59%) and 1,522 Whites (41%). The HANDLS response rates were 67% for completed household interviews and 75% for completed baseline MRVs examinations (Evans et al.).

Retention

The approach to retention and the Wave 2 interim visit that had a high recontact rate were labor intensive but useful as strategies for retention. Wave 3 examinations started in July 2009. Evaluation of the success of the retention strategy is incomplete, but data from the first three neighborhoods to be revisited are promising. Thus far, our return rate is 67.5% after the first nine months in the field for the first physical reexamination (Wave 3).

The South Baltimore, Reservoir Hill, and Forest Park neighborhoods had 745 participants. As shown in Table 2, 79.2% of those participants are still active five years after study enrollment. However, 7.5% have been lost to follow-up. Almost as many, 7.4% are reported deceased by neighbors and relatives or confirmed by the National Death Index. As expected, some participants that have been contacted have declined continued participation or unable to participate (most times because of serious illness or confinement in a skilled nursing facility). This is classified as withdrawn, excluded, or dropped. There are participants who cannot be revisited at this time because they are presently involved with the criminal justice system.

Table 3 shows detailed disposition of the 649 active participants. One hundred and sixty-one participants are still eligible and in the process of being contacted. About 67.5% have been reexamined at the MRVs. A visit is categorized as incomplete if the participant could not complete all the measures. About 7.7% of the participants missed their MRV appointments and will be rescheduled. The data presented in Tables 2 and 3 are a very limited snapshot of the entire cohort. More complete data will be available when we finish the Wave 3 examinations in 2012.

Health disparity is not just the difference in disease prevalence between two groups of people, but the severity and rate of progression of the disease. With a mean age of 47.7 years (range from 30 to 64), our study cohort is not a sample of a geriatric population. However, in the three neighborhoods revisited thus far, we observed significant decline in the health status of some participants. This unanticipated decline in the health status created a logistical challenge to daily study operations. We have

developed an evaluation tool to assess participants' abilities to give informed consent and navigate the logistical challenges associated with examinations on the MRV. The tool is administered on the phone by the nurse practitioner or physician. The primary goal is to determine participants' abilities to compensate for a specific physical limitation so the staff can accommodate the participant.

Unfortunately, the telephone assessment does not in every case accurately identify individuals with severe impairment because participants overestimated their ability to perform tasks. Consequently, the staff has unwittingly agreed to examine several severely handicapped participants on the MRV, a situation that puts the staff at the risk of injury. The limitations of the phone assessment tool have led to the development of an inventory that will be used by the trace and tracking personnel to assess the abilities of the participant during a home visit before scheduling an appointment.

Discussion

Our success recruiting 3,722 participants suggests that a multifactorial methodology facilitates recruitment in multiracial studies that seek to enroll both low- and high-SES cohorts. There are peculiar environmental challenges in conducting research from a base in an urban community. Nevertheless, the value gained from this type of study far outweighs the challenges presented by the environment. Recruiting a socioeconomically and racially diverse cohort into a noninterventional research study requires paying particular attention to the recruitment design. We identified known recruitment barriers as well as other challenges unique to our study population. We developed a multilevel and multifactorial recruitment methodology that focused on overcoming the barriers, some of which we anticipated and others we did not anticipate. We overcame these barriers by engaging in continuous reexamination of the issues presented by each neighborhood and finding solutions to them. This fluid methodological approach makes the HANDLS study design unique because the solutions to recruitment barriers varied from neighborhood to neighborhood.

Unlike in some community-based research where the participants come to the research center, we developed a community-based platform within the neighborhoods, the MRVs, to conduct our research. Another important aspect of involving communities in research recruitment efforts is to consider that each community and culture has its own unique barriers and that a recruitment strategy employed in one community may not be as successful in another (Betancourt, 2006; Christopher, Watts, McCormick, & Young, 2008; Sung et al., 2003). The HANDLS team participated in social events within the community to interact with the city residents and increase awareness of the study. We did not use these events for participant recruitment. Other noninterventional studies such as the Coronary Artery Risk Development in Young Adults and the Jackson Heart Study recruited participants from phone listings or incorporated already existing study participants. These studies had low response rates in low-SES African Americans and Whites (Friedman et al., 1988; Wyatt et al., 2003). Among urban adults, researchers using phone listings risk excluding potential participants. Many potential participants' only phone access is "pay as you go mobile" or non-working/unlisted phone number. Studies recruiting from churches accrued nonrepresentative cohorts. Compared with the demographics of the county, low-SES African American males were underrepresented even when the participating churches were predominantly African American (Carter-Edwards et al., 2002). Instead of using churches or other institutions as recruitment platforms, HANDLS invited the leaders of the various churches in the sample neighborhoods to become members of our CABs and integrated their suggestions into the study design.

The CABs were especially concerned about the individual benefits of participation. Consequently, we designed our study to give immediate tangible benefit to participants by providing comprehensive laboratory workups and physical examinations. The prospect that the examination would occur every three years was a considerable benefit since it may serve as the only preventive medical exam for some of the participants until their next HANDLS visit. We were particularly guided by data reported by G. Corbie-Smith, Thomas, Williams, and Moody-Ayers (1999) that African Americans would be more interested in participating in medical research if there was honest communication between the research investigators and participants.

We were very clear about the anticipated participant burden, the risks associated with participation, and especially took time to explain that we were unable to provide ongoing medical care but would facilitate as best as we could health care access for chronic or newly diagnosed conditions.

Although we have been able to facilitate entry into the health care system for participants in need of continuing care, issues of health care access over the long term may be an unresolved issue for the working poor unable to qualify for government sponsored compensated care. This may be a factor in our future success and for research in general among minority populations.

Cross-cultural research must be culturally sensitive (Friedemann, Pagan-Coss, & Mayorga, 2008). In designing HANDLS, we recognized that the researchers and staff might direct their personal bias unwittingly toward the participants. The cultural proficiency training enabled HANDLS staff to recognize and reconcile how their personal biases could influence their interactions with persons from a culture other than their own.

The successful implementation of HANDLS is attributable in part to the hands-on approach and open door policy of the principal investigators. They emphasized the importance of soliciting contributions from all personnel involved with the study. This motivated the staff to invest in the goals of our study resulting in staff flexibility and staff retention. The high level of satisfaction in the participant exit survey demonstrates the commitment of the staff members. Without an integrated and invested research staff, the successful implementation of the most tactically designed longitudinal study will be futile.

With staff and participant safety as a major concern, the HANDLS team researched each neighborhood, reviewed the crime statistics, and followed local news events for every neighborhood in which we deployed the MRVs. In addition, we considered the seasonal variations in the types and volume of crime as we planned the months to visit each neighborhood. Thus, neighborhoods with high crime rates in summer were visited in the winter months and vice versa. However, the seasonal deployments became a barrier in some neighborhoods where the residents were away during the summer and the recruitment from these neighborhoods was lower than anticipated.

Longitudinal studies are necessary to advance research on health disparities. The reexamination rate of 67.5% in three neighborhoods attests to the successful retention modality we have deployed. This was achieved when we incorporated our unique interim wave, extensive field-based tracking, and the experiences of other researchers into our retention design. The inclusion of medical benefits into the study design motivated individuals who had no access to health care to return and obtain these services. We frequently conducted participant contact information probes, which is an important retention practice in longitudinal studies (Yancey, Ortega, & Kumanyika, 2006). Including monetary compensation for participation may have helped to retain the low-SES cohort who otherwise would be lost to follow-up. Our attrition rate of 15% thus far is comparable to other studies (Gilliss et al., 2001; Kuhns, Vazquez, & Ramirez-Valles, 2008). Thus, to retain participants in this transient and vulnerable population special efforts are essential. While our experience does not provide an exact recipe for successful recruitment and retention, it is clear that direct community involvement by staff and principal investigators and a diverse well trained and culturally competent staff are critical elements.

Viewed as a whole, these individual initiatives are a crucial part of the study. Taken together, these efforts comprise a novel, comprehensive recruitment paradigm that was created to implement this study.

Limitations

The age range for our study cohort is relatively large and cannot address the age-specific challenges of recruiting a geriatric population. However, the underlying principles are the same. Our longitudinal study will provide the opportunity for us to assess through middle age to old age the factors that facilitate continued study participation over a 20-year period. This will provide a window into minority aging and the factors that enhance participation rates or become barriers or disincentives. We cannot elucidate which specific element of our multidimensional strategy was most successful because we did not collect data from successfully enrolled participants or from those who declined. It must also be stated that we have crafted and used these strategies in an urban environment so they may or may not be applicable to a rural or suburban environment. Another limitation is that we included only two races in HANDLS because we based our sampling expectations on the 2000 census. Had we started later, we might have included Latinos because their numbers are increasing in Baltimore. Finally, although our sample is demographically representative of Baltimore City, we may have a healthy bias because potential participants with underlying medical diseases may have declined participation.

Conclusions

The multifactorial methodology facilitates recruitment within biracial studies that seek to enroll both low- and high-SES cohorts. There are peculiar environmental challenges encountered by conducting a research study from a base in an urban community, but the value gained from conducting this type of study far outweighs the challenges presented by the environment. Cultural proficiency training enhances researchers and staff skills in interacting with diverse groups of participants and possibly enhancing recruitment. The successful implementation of a multitier research study design requires an invested and motivated research team. The Wave 3 protocol, in keeping with the longitudinal study design, maintains many of the same study domains as the baseline Wave 1 but includes new areas of critical health disparities including: renal function, care giving, financial literacy, health literacy, and neurodegenerative disease. We will also continue to refine our retention paradigm for use by us and others interested in age-associated health disparities and minority aging in general.

Funding

The National Institute on Aging, Intramural Research Program at the National Institutes of Health funded this work. We also recognize the consistent funding support of Dr. John Ruffin of the National Center on Minority Health and Health Disparities, National Institutes of Health.

Acknowledgments

We thank LifeLine Technologies of Cincinnati who fabricated the medical research vehicles and who have provided conscientious and skilled support since their deployment. We thank all members of the HANDLS staff past and present for their dedication to the goals and objectives of the study and their excellent execution of the protocol.

References

Betancourt, J. R. (2006). Cultural competence and medical education: Many names, many perspectives, one goal. *Academic Medicine*, *81*, 499–501.

Blanton, S., Morris, D. M., Prettyman, M. G., McCulloch, K., Redmond, S., Light, K. E., et al. (2006). Lessons learned in participant recruitment and retention: The EXCITE trial. *Physical Therapy*, *86*, 1520–1533.

Blumenthal, D. S., Sung, J., Coates, R., Williams, J., & Liff, J. (1995). Recruitment and retention of subjects for a longitudinal cancer prevention study in an inner-city black community. *Health Service Research*, *30*, 197–205.

Bolen, S., Tilburt, J., Baffi, C., Gary, T. L., Powe, N., Howerton, M., et al. (2006). Defining "success" in recruitment of underrepresented populations to cancer clinical trials: Moving toward a more consistent approach. *Cancer*, *106*, 1197–1204.

Braunstein, J. B., Sherber, N. S., Schulman, S. P., Ding, E. L., & Powe, N. R. (2008). Race, medical researcher distrust, perceived harm, and willingness to participate in cardiovascular prevention trials. *Medicine (Baltimore)*, *87*, 1–9.

Carter-Edwards, L., Fisher, J. T., Vaughn, B. J., & Svetkey, L. P. (2002). Church rosters: Is this a viable mechanism for effectively recruiting African Americans for a community-based survey? *Ethnicity & Health*, *7*, 41–55.

Christopher, S., Watts, V., McCormick, A. K., & Young, S. (2008). Building and maintaining trust in a community-based participatory research partnership. *American Journal of Public Health*, *98*, 1398–1406.

Corbie-Smith, G., Moody-Ayers, S., & Thrasher, A. D. (2004). Closing the circle between minority inclusion in research and health disparities. *Archives of Internal Medicine*, *164*, 1362–1364.

Corbie-Smith, G., Thomas, S. B., Williams, M. V., & Moody-Ayers, S. (1999). Attitudes and beliefs of African Americans toward participation in medical research. *Journal of General Internal Medicine*, *14*, 537–546.

Corbie-Smith, G. M. (2004). Minority recruitment and participation in health research. *North Carolina Medical Journal*, *65*, 385–387.

Dancy, B. L., Wilbur, J., Talashek, M., Bonner, G., & Barnes-Boyd, C. (2004). Community-based research: Barriers to recruitment of African Americans. *Nursing Outlook*, *52*, 234–240.

Dennis, B. P., & Neese, J. B. (2000). Recruitment and retention of African American elders into community-based research: Lessons learned. *Archives of Psychiatric Nursing*, *14*, 3–11.

Durant, R. W., Davis, R. B., St George, D. M., Williams, I. C., Blumenthal, C., & Corbie-Smith, G. M. (2007). Participation in research studies: Factors associated with failing to meet minority recruitment goals. *Annals of Epidemiology*, *17*, 634–642.

Evans, M. K., Lepkowski, J. M., Powe, N. R., LaVeist, T., Kuczmarski, M. F., & Zonderman, A. B. (2010). Healthy aging in neighborhoods of diversity across the life span (HANDLS): Overcoming barriers to implementing a longitudinal, epidemiologic, urban study of health, race, and socioeconomic status. *Ethnicity & Disease*, *20*, 267–275.

Ford, J. G., Howerton, M. W., Lai, G. Y., Gary, T. L., Bolen, S., Gibbons, M. C., et al. (2008). Barriers to recruiting underrepresented populations to cancer clinical trials: A systematic review. *Cancer*, *112*, 228–242.

Franks, P., Muennig, P., Lubetkin, E., & Jia, H. (2006). The burden of disease associated with being African-American in the United States and the contribution of socio-economic status. *Social Science & Medicine*, *62*, 2469–2478.

Friedemann, M. L., Pagan-Coss, H., & Mayorga, C. (2008). The workings of a multicultural research team. *Journal of Transcultural Nursing*, *19*, 266–273.

Friedman, G. D., Cutter, G. R., Donahue, R. P., Hughes, G. H., Hulley, S. B., Jacobs, D. R., Jr, et al. (1988). CARDIA: Study design, recruitment, and some characteristics of the examined subjects. *Journal of Clinical Epidemiology*, *41*, 1105–1116.

Galea, S., & Tracy, M. (2007). Participation rates in epidemiologic studies. *Annals of Epidemiology*, *17*, 643–653.

Gilliss, C. L., Lee, K. A., Gutierrez, Y., Taylor, D., Beyene, Y., Neuhaus, J., et al. (2001). Recruitment and retention of healthy minority women into community-based longitudinal research. *Journal of Womens Health and Gender Based Medicine*, *10*, 77–85.

Halpern, M. T., Ward, E. M., Pavluck, A. L., Schrag, N. M., Bian, J., & Chen, A. Y. (2008). Association of insurance status and ethnicity with cancer stage at diagnosis for 12 cancer sites: A retrospective analysis. *Lancet Oncology*, *9*, 222–231.

Heron, S. L., Stettner, E., & Haley, L. L., Jr. (2006). Racial and ethnic disparities in the emergency department: A public health perspective. *Emergency Medicine Clinics of North America*, *24*, 905–923.

Jefferson, A. L., Lambe, S., Chaisson, C., Palmisano, J., Horvath, K., & Karlawish, J. (2011). Clinical research participation among aging adults enrolled in an Alzheimer's Disease Center research registry. *Journal of Alzheimers Disease*, *23*, 443–452.

Keyzer, J. F., Melnikow, J., Kuppermann, M., Birch, S., Kuenneth, C., Nuovo, J., et al. (2005). Recruitment strategies for minority participation: Challenges and cost lessons from the POWER interview. *Ethnicity & Disease*, *15*, 395–406.

Kuhns, L. M., Vazquez, R., & Ramirez-Valles, J. (2008). Researching special populations: Retention of Latino gay and bisexual men and transgender persons in longitudinal health research. *Health Education Research*, *23*, 814–825.

Lai, G. Y., Gary, T. L., Tilburt, J., Bolen, S., Baffi, C., Wilson, R. F., et al. (2006). Effectiveness of strategies to recruit underrepresented populations into cancer clinical trials. *Clinical Trials*, *3*, 133–141.

LaVeist, T. A., Nickerson, K. J., & Bowie, J. V. (2000). Attitudes about racism, medical mistrust, and satisfaction with care among African American and white cardiac patients. *Medical Care Research and Review*, *57*(Suppl. 1), 146–161.

Marcantonio, E. R., Aneja, J., Jones, R. N., Alsop, D. C., Fong, T. G., Crosby, G. J., et al. (2008). Maximizing clinical research participation in vulnerable older persons: Identification of barriers and motivators. *Journal of the American Geriatrics Society*, *56*, 1522–1527.

Mattson, M. E., Curb, J. D., & McArdle, R. (1985). Participation in a clinical trial: The patients' point of view. *Controlled Clinical Trials*, *6*, 156–167.

Moreno-John, G., Gachie, A., Fleming, C. M., Napoles-Springer, A., Mutran, E., Manson, S. M., et al. (2004). Ethnic minority older adults participating in clinical research: Developing trust. *Journal of Aging and Health*, *16*(5 Suppl.), 93S–123S.

Orden, S. R., Dyer, A. R., & Liu, K. (1990). Recruiting young adults in an urban setting: The Chicago CARDIA experience. *American Journal of Preventive Medicine*, *6*, 176–182.

Quinn, S. C. (2004). Ethics in public health research: Protecting human subjects: The role of community advisory boards. *American Journal of Public Health*, *94*, 918–922.

Raper, N., Perloff, B., Ingwersen, L., Steinfeldt, L., & Anand, J. (2004). An overview of USDA's dietary intake system. *Journal of Food Composition and Analysis*, *17*, 545–555.

Sullivan-Bolyai, S., Bova, C., Deatrick, J. A., Knafl, K., Grey, M., Leung, K., et al. (2007). Barriers and strategies for recruiting study participants in clinical settings. *Western Journal of Nursing Research*, *29*, 486–500.

Sung, N. S., Crowley, W. F., Jr., Genel, M., Salber, P., Sandy, L., Sherwood, L. M., et al. (2003). Central challenges facing the national clinical research enterprise. *Journal of American Medical Association*, *289*, 1278–1287.

Town, R. J., Wholey, D. R., Feldman, R. D., & Burns, L. R. (2007). Hospital consolidation and racial/income disparities in health insurance coverage. *Health Affairs (Millwood)*, *26*, 1170–1180.

UyBico, S. J., Pavel, S., & Gross, C. P. (2007). Recruiting vulnerable populations into research: A systematic review of recruitment interventions. *Journal of General Internal Medicine*, *22*, 852–863.

Wendler, D., Kington, R., Madans, J., Van Wye, G., Christ-Schmidt, H., Pratt, L. A., et al. (2006). Are racial and ethnic minorities less willing to participate in health research? *PLoS Medicine*, *3*, e19.

Wilets, I., O'Rourke, M., & Nassisi, D. (2003). How patients and visitors to an urban emergency department view clinical research. *Academic Emergency Medicine*, *10*, 1081–1085.

Wipke-Tevis, D. D., & Pickett, M. A. (2008). Impact of the Health Insurance Portability and Accountability Act on participant recruitment and retention. *Western Journal of Nursing Research*, *30*, 39–53.

Wright, J. T., Jr., Cushman, W. C., Davis, B. R., Barzilay, J., Colon, P., Egan, D., et al. (2001). The Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial (ALLHAT): Clinical center recruitment experience. *Controlled Clinical Trials*, *22*, 659–673.

Wyatt, S. B., Diekelmann, N., Henderson, F., Andrew, M. E., Billingsley, G., Felder, S. H., et al. (2003). A community-driven model of research participation: The Jackson Heart Study Participant Recruitment and Retention Study. *Ethnicity & Disease*, *13*, 438–455.

Yancey, A. K., Ortega, A. N., & Kumanyika, S. K. (2006). Effective recruitment and retention of minority research participants. *Annual Review of Public Health*, *27*, 1–28.