

Alzheimer's Disease and Related Dementias Clinical Studies Recruitment Planning Guide



Convened by



National Institute
on Aging

About This Planning Guide

We hope that all clinical research study sites can use and adapt the strategies outlined here, identify barriers to local research participation, develop additional novel recruitment approaches to address them, and share new knowledge from these efforts with other stakeholders so that best practices can be widely disseminated.

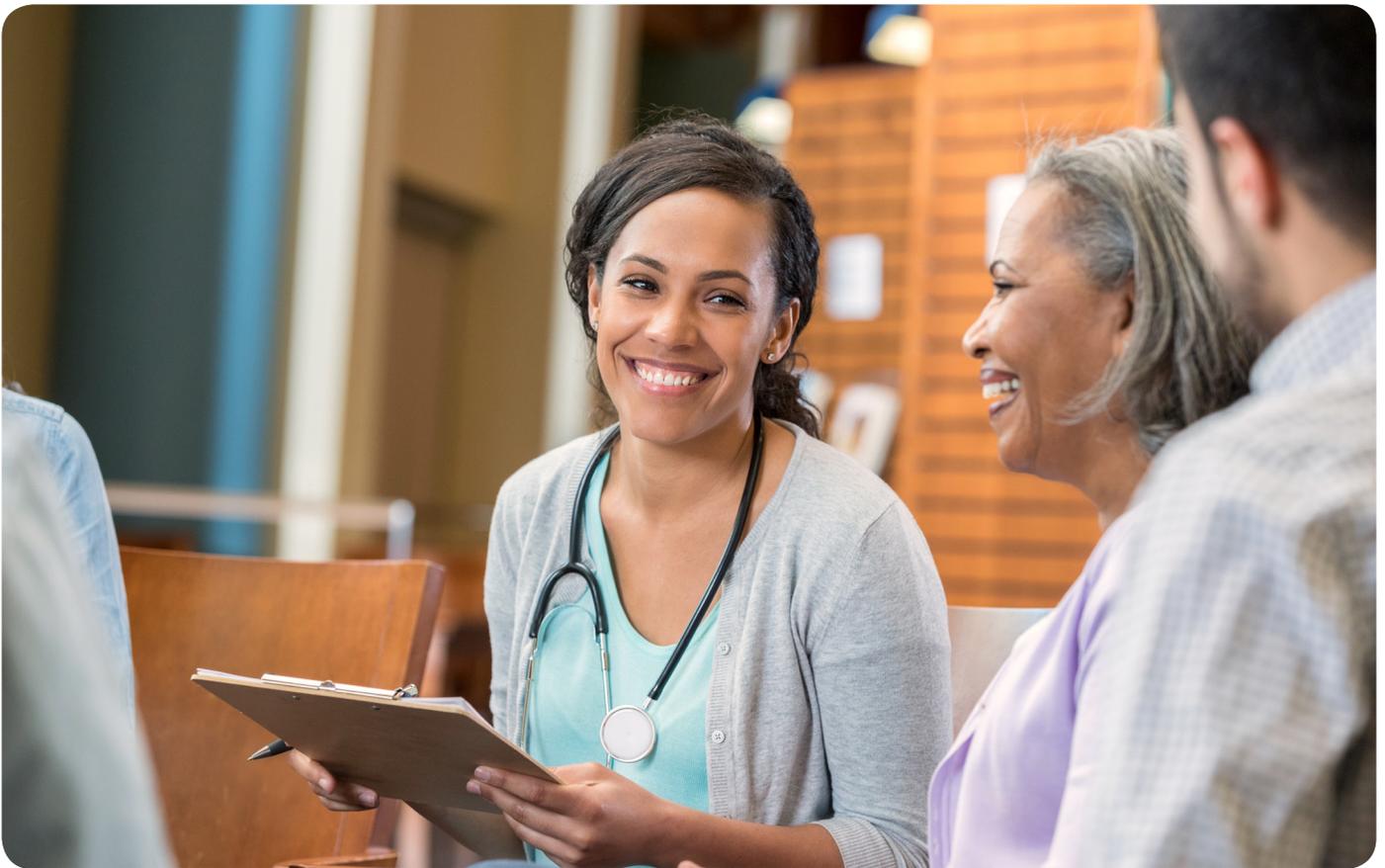
Building a Science of Recruitment

Although every effort has been made to feature robust, scalable, and generalizable strategies for improving community-based local research participation, implementation success will vary. Individual research sites differ widely in their recruitment strengths, challenges, infrastructure, and goals. A dearth of peer-reviewed research on the optimization of recruitment tactics hinders our ability to address this variation, and it is imperative to develop strong, replicable research on recruitment/engagement plans for Alzheimer's research to complement and evaluate the advice featured here. The largest and most lasting successes are likely to be achieved by sites that are able to implement sustainable, mutually supportive strategies in partnership with their local communities. We, therefore, recommend that faculty and staff *continuously* communicate with and meaningfully engage community stakeholders to determine which strategies are most worthwhile by applying process-oriented measures of evaluation that emphasize progress in achieving deeper community collaborations, rather than emphasizing accrual rates alone.

Finally, the strategies described below will likely continue to evolve as they are implemented and adapted to meet specific needs of different communities. We strongly encourage all clinical research sites to deploy these and other similar strategies, continue to identify barriers to local research participation, develop additional novel recruitment interventions to address them, and share new knowledge from these efforts with the National Institute on Aging (NIA) so that best practices can be disseminated widely.

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Introduction

Recruitment and retention of diverse—in the broadest sense of the word—participants in Alzheimer’s and related dementias clinical trials and studies is a known challenge. To improve the representativeness of participants in this critical research, we must focus on inclusivity and diversity in age, race/ethnicity, language, sex, education, socioeconomic status, comorbidities, co-occurring treatments, geographic region, and cognitive status. To do this, we must engage with communities, address barriers at the local level, and support people with dementia and their families in their efforts to participate. Although more research is needed to identify best practices, the most promising efforts for improving recruitment and retention of diverse participants focus on building community relationships and addressing specific local-level barriers (Grill & Galvin, 2014).

Community-based efforts will focus on developing equitable and sustainable community partnerships and promoting health and science literacy of all community members. Researchers and study sites, community-based organizations, and people with dementia and their families all have important roles to play in engaging local communities (see Figure 1).

Figure 1. Effective Recruitment = Intentional & Equitable Community Engagement

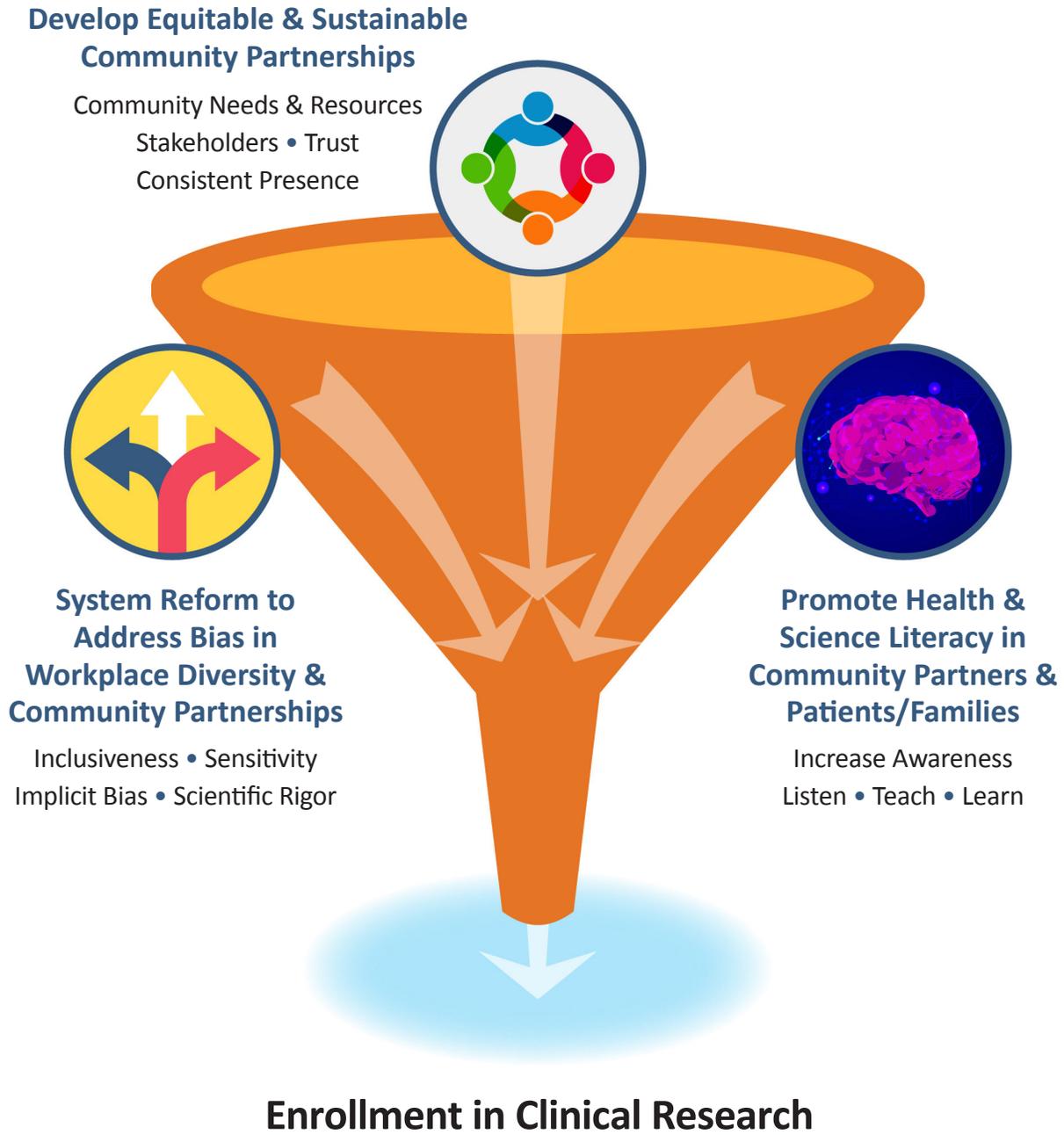


Figure 1 provides a visual schematic of three key interrelated and mutually reinforcing strategies that are essential to the support of a dynamic and effective community engagement model. This model has the potential to iteratively support recruitment and retention of participants from many backgrounds and with different experiences and challenges into Alzheimer’s and related dementias research. The tenets of this model and specific tactics to implement the key strategies are described below.

Plan Ahead: Questions to Consider

Before even initially contacting individuals, organizations, and agencies, preplanning your specific outreach approach and setting up related policies and procedures will help ensure thoughtful recruitment and retention of participants. Laying out plans for communication interactions and creating timelines before the recruitment begins may save time and effort and build better working relationships. These activities give the research team, as well as potential participants, a map for how recruitment, retention, and reporting of results will proceed.

These are questions to consider in planning for recruitment.

Consider the needs of the study participants.

- Who are potential participants (e.g., women, racial/ethnic diverse communities, children and families, older adults, rural communities, people with mental or physical disabilities, etc.)? What specific requirements/needs might they have to participate in the study?
- What benefits and motivators are there to encourage participation? How will this study benefit the participants or others?
- What barriers and obstacles will potential participants need to overcome (e.g., invasive procedures, time of visits, transportation, language differences, unfamiliarity or mistrust, competing trials, etc.)? How can you help them?
- Are there logistical adjustments you can make to the protocol or clinic operations to make it as easy as possible to participate (e.g., adjusting eligibility criteria, weekend hours, use of in-home technology or mobile monitoring, etc.)?
- Will you provide appropriate incentives, such as transportation, gifts cards, payment for time to participate, or child care?

Engage the community.

Long-term relationships with communities require an ongoing commitment before, during, and after the trial. Factors to consider include:

- What current relationships and level of trust do you have within the community? Are these relationships ongoing, or do they need to be established or recharged?
- How does this study meet the priorities of the community? Is there a way to align the goals of the study with the needs of the community?
- How will you ask for and incorporate community input into the study?
- Do the demographics of the speakers reflect the demographics of the community? This is important to convey “we” rather than “you and them” in the messaging.
- Will you need to plan for native speakers to interpret the language of the community? This shows respect and interest in the culture and the needs of the community.
- Have you considered how you may be able to contribute continuously to the community (such as participation in a health fair, sharing plans and presenting research results directly with the community, serving on community advisory boards, etc.)?

Plan messaging and informational materials.

- Who may be in the best position to deliver messages that connect with and build trust within the community? Is it the principal investigator, a study clinician, a recruitment specialist, or another study staff member?

- What are the best channels to deliver messages to your study population? Do they include social media, traditional print/radio/TV media, targeted mailing, or in-person events? Should you involve advocacy organizations or other intermediaries?
- In designing educational materials for potential participants, what images, language, literacy level, etc. are appropriate, interesting, engaging, and effective? Seek input from community collaborators.
- How will you handle privacy? Always consider the privacy implications of any outreach effort.

Think about these logistical and administrative factors.

- How will you respond to the questions and needs of potential participants? Are you prepared for phone/email inquiries? Initial screenings? Have staff members fielding these inquiries received cultural sensitivity training?
- Will the community targeted for recruitment have ready access to computers, mobile devices, and telephones? If not, alternative approaches must be considered.
- It is important that study candidates receive timely responses from the clinic. How will this need affect staff scheduling? What is a timely response? How will you communicate the response time (e.g., 2 days, by email, 48 hours)? Establish a standard and let participants know what to expect.
- Potential participants with cognitive difficulties, e.g., traumatic brain injury, stroke, mild cognitive impairment (MCI), mild dementia, may require additional considerations to remember appointments, complete forms, and communicate with study staff.
- Do you have a plan for dealing with surges in inquiries? Is there a system in place that permits prioritization of targeted individuals into the screening pipeline? If so, ensure that this procedure is consistently utilized so that community members from a targeted group have a similar experience.
- How will you communicate the limitations for study participation to a volunteer?
- How will you handle volunteers who do not qualify for the trial? Is there a local or national registry that can accept a referral? Would they be eligible for another research study? For relationship-building in the community it is important to NOT shut a door when potential candidates inquire as to how they might participate in research. It is often with much hesitation and new courage that a candidate decides to make this first call. Helping the candidate find an appropriate alternative for participation, if deemed ineligible for a given study, helps to create a positive and reinforcing research experience.

Resources

ADORE Resources

In addition to this planning guide, NIA has developed a web-based Recruitment Repository, called [Alzheimer's and Dementia Outreach, Recruitment, and Engagement \(ADORE\) Resources](#), to collect and disseminate best practices, tools, and materials supporting recruitment efforts. Repository materials include examples of:

- Community/needs assessments
- Consent materials
- Formative, process, and outcome evaluation reports
- Messaging and outreach (including social media)
- Models, best practices, and case studies for community outreach and engagement
- Presentation materials
- Research articles and white papers
- Sample budgets
- Sample recruitment and retention plans
- Study promotion materials (flyers, brochures, etc.)
- Technology tools and workforce/staffing models
- Training guides and technical assistance tools
- Use of incentives and/or screening models
- Validated assessment tools, instruments, and decision aids
- Videos

NCATS Resources

The National Center for Advancing Translational Sciences (NCATS) at NIH Trial Innovation Network offers many self-service tools and resources to help investigators throughout the entire life cycle of their projects, from study design to participant recruitment and engagement. Features of the network include a single institutional review board system, master contracting agreements, quality-by-design approaches, and a focus on evidence-based strategies for recruitment and patient engagement. The goal is not only to execute trials better, faster, and more cost-efficiently, but also to be a national laboratory to study, understand, and innovate the process of conducting clinical trials.

Trial Innovation Network:

<https://trialinnovationnetwork.org>

Recruitment & Retention Toolbox:

<https://trialinnovationnetwork.org/recruitment-retention-toolkit/?key-element=1681>

Recruitment Innovation Center:

<https://trialinnovationnetwork.org/recruitment-innovation-center/?key-element=1600>

NIH Resources

The [NIH Clinical Research Trials and You](#) website is a resource for people who want to learn more about clinical trials. [Clearly Communicating Research Results across the Clinical Trials Continuum](#) is a resource for researchers and trial sites on how to communicate with participants clearly and directly as they join the study and throughout the process.



1: Develop Equitable and Sustainable Community Partnerships Founded on Trust

Respect for potential and enrolled participants is a fundamental principle. Researchers know about this and other requirements and responsibilities of clinical research with human subjects. But it is critical that scientists also learn how to reach out to and communicate in their communities before, during, and after a trial. Educating the public about health and clinical research may help raise general awareness about the important role research plays in safeguarding health and quality of life. These efforts, however, are only the beginning.

The key to encouraging public support for and participation in clinical research is trust in the institution and the research team by the community. Researchers must take the time and make the effort to build and then maintain this trust. Communicating directly with participants as they consider joining a study, as they complete the screening process, as they enroll in a study—and then as they complete and finish a study—is critical to earning and maintaining trust.



Timeline: Trust requires time to develop. Expect to invest a minimum of 2 years building strong community partnerships prior to study recruitment.

Task 1. Develop new and foster existing community partnerships to increase awareness of community needs, perceptions, and engagement interest.

Step 1: Assess Community Needs

- Gather existing data on the local and targeted community.
 - Collect available Centers for Medicare & Medicaid Services ([CMS](#)) data on Alzheimer’s disease prevalence by county level to guide targeting and recruitment goals.
 - Collect [census data](#) on race, ethnicity, education, religion, and geographic distribution to inform local targeting and recruitment goals.
 - Complement CMS and census data with qualitative reports to best account for individuals with low health-seeking behavior (e.g., older men, those living alone or with low access to health care and other basic resources, undocumented individuals).
 - Identify publicly available community health assessments from hospitals, universities, etc. Example from Kansas City, KS: https://www.kcoi.com/wp-content/uploads/2017/03/CHNA_2016.pdf.
 - If a recent community assessment is not available, use existing tools (such as [this one](#)) and collaborate with community partners to complete.

Step 2: Identify and Develop Community Partnerships

- Identify and meet with available support services for referrals and recruitment partners (social services, clinical services, behavioral health, assisted living facilities, faith groups, Eldercare Locator, Area Agency on Aging, City Office on Aging, AARP, those living with dementia, etc.), with a view toward leveraging existing networks to reach vulnerable populations.

- Attend community events as guests (not speakers) to learn more about the community and its leaders/stakeholders.
- Host presentations to introduce your organization to the local community and the proposed tactics and tools for outreach.
- Identify a minimum of one or two key stakeholder collaborators to identify geographical areas of focus and to assist in engagement of targeted communities.
- Develop an effective communication strategy to support ongoing, bidirectional flow of information with the local community.
- Work with community partners to prioritize needs and develop a responsive outreach program, prominently featuring the voices of those living with dementia.

Success Indicators

- Two to three key community partnerships initiated within 6 to 8 months
- Successful identification and interface with community gatekeepers—individuals of high influence within communities of interest
- Number of new community partners per year
- Number of new inquiries from the community per quarter for educational presentations
- Number of invitations to meet with community partners

Lessons Learned

- 💡 Respect of and adherence to the results of the community assessment data result in higher participation and retention in studies.
- 💡 Working with the community to establish partnerships, obtain information about its members, and collaboratively develop plans for outreach and engagement prior to implementation improves long-term success of recruitment and retention, and thus sustainability, of research programs.

- 💡 Recognizing the community as the expert is an effective way to ensure that the community has a voice at the table when planning outreach and community engagement activities to support research.
- 💡 An enduring and meaningful community presence can build the reputation of research, the investigator, and the supporting institution.
- 💡 Community engagement tactics to support recruitment take months to years but can result in a sustainable and successful outreach program. Consider and value success indicators intermediary to study accrual.

Step 3: Develop and Disseminate Culturally Sensitive, Customizable Messaging Tools and Other Outreach Resources

- Develop a culturally sensitive document with key information about the impact of Alzheimer’s disease or other forms of dementia for each of the targeted communities, as well as information about the research project for lay and professional audiences. Seek feedback from community partners about the appropriateness and effectiveness of these materials.
- Using information from the community needs assessment and input from community partners, identify best-fit modalities for information delivery (messengers) and appropriate/effective communications channels for each of the targeted communities (e.g., for Hispanics, for men, for adults with MCI), to include face-to-face activities, radio, newsletters, and faith-based events.
- Leverage a broad spectrum of interactive communication technologies (e.g., Internet, cell phones), particularly for populations who live in rural areas or alone.
- Ensure that materials are linguistically accessible by leveraging centralized translation services that may be modified/approved by local community champions.
- Develop a list of local media outlets (e.g., minority-owned or -focused media outlets and

publications, local television stations, rural newspapers or radio shows, support groups, church gatherings, health fairs, and events).

- Develop and maintain a calendar of community events for outreach activities. Share this information using well-used communication channels.
- Identify community champions (spokespeople) with a connection to Alzheimer’s or other forms of dementia to share their stories as part of outreach programming (at events, in newsletters, on radio shows, etc.).
- Develop a strategy to evaluate the effectiveness of community outreach, e.g., tracking engagement for social media, websites, and hotlines.
- Provide community partners with messaging toolkits, e.g., social media language, images, and blog posts.
- Expand community partnerships beyond traditional networks (e.g., heart, cancer, kidney, diabetes associations and foundations) to increase cross-pollination for education, outreach, and recruitment via coalition approaches.

Success Indicators

- Development of appropriate and community-vetted educational and recruitment materials and messaging for the target community
- Number of website clicks, mailing list signups, hotline calls, invitations to community events, invitations to speak, and media requests
- Number of requests for information about Alzheimer’s disease or other forms of dementia and/or about research
- Attendance at events from community targeted for outreach
- Number of requests to serve as volunteers, spokespeople, or board members
- Number of new community partners who represent or provide services for the targeted population

- ✔ Number of stories and featured content pieces circulated by community partners

Lessons Learned

- 💡 The audience must be able to relate to the information and images provided in educational and recruitment materials. If the images in the outreach documents do not resemble the demographics of the recipients' population or community, the materials may be perceived as irrelevant or of little value.
- 💡 Inclusive outreach materials do not assume particular lifestyle or demographic details, such as convenience of transportation, ease of study site contact/access, family size/structure, or familiarity with research.
- 💡 The most effective outreach emphasizes personal relevance of the message.
- 💡 Bus signage, print media, and TV spots may not be the most effective means of reaching underserved or isolated populations.
- 💡 When developing outreach materials, the style of communication should be conversational and include everyday language, referencing specific traditions and/or cultures to optimize the perception and experience of inclusiveness.
- 💡 Engaging community spokespeople is an important strategy to build bridges between the partners and academic research.
- 💡 Providing training for community partners and compensation for invested time and expertise communicates respect and appreciation.

Step 4: Develop Realistic Recruitment Targets with Input from Community Partners

- Work with local partners to develop realistic goals for recruitment and to achieve buy-in and thus support to accomplish these goals.

Success Indicators

- ✔ Consistency in pace of enrollment into studies
- ✔ Diversity (of race, ethnicity, geographical region, education, gender, sexual orientation, religion) of study population
- ✔ Consistency in number of referrals from current participants
- ✔ Number of new participants
- ✔ Retention of participants from vulnerable/underserved populations
- ✔ Number of projects that achieved diversity recruitment goals
- ✔ Number of new collaborative partnerships and/or projects
- ✔ Number/success of satellite recruitment sites

Lessons Learned

- 💡 Recruitment goals must be realistic and attainable but also meet the standards of scientific rigor (i.e., power) or the results cannot be stated with certainty, which does not serve the community well.
- 💡 Recruitment goals should be supported by an operationalized plan that involves community engagement, education, and outreach that will ultimately support recruitment into a research study. Recruitment without local engagement and outreach will not be sustainable.
- 💡 Regular review of goals and assessment of success is critical to ensure perpetual progress.

Task 2. Develop and maintain trust between community stakeholders and research teams to build strong, sustainable community partnerships and shared ownership of the research mission.

Step 1: Develop a Community Advisory Board (CAB)

- Consult with community partners to develop a potential list of CAB members.
- Recruit members who reflect the diversity of the local community and catchment area.
- Identify board members who serve as community leaders.
- Consider including a research participant and/or caregiver on the board to provide a personal perspective.

Step 2: Work with CAB Members to Develop the Board's Mission to Ensure Ongoing Community Presence and Responsiveness to Community Needs

- Host a meet-and-greet to initiate a CAB.
- Identify a community co-chair to serve as liaison.
- Develop a CAB mission statement that describes the reciprocity of the members with the academic institution, the general purpose of the advisory group, and clear metrics of accountability for the institution and CAB membership.
- Develop a scope of work and expectations for CAB members that include term limits if needed.
- Develop and implement a voting and leadership structure and operation guidelines that will meet the goals of the CAB.
- Develop and implement training opportunities to support CAB members in key roles that impact and influence the work.
- Have clear definitions of “advisory” to share with the CAB and the institution.
- Mutually agree upon a minimum number of community engagement activities that will be hosted, with CAB members as collaborators and attendees.

- Provide facilitation skills training for all CAB members; develop subcommittees as needed.
- Develop an action-oriented agenda for meetings.
- Host multiple team-building opportunities at CAB meetings.

Success Indicators

- CAB members' introductions of research staff to community members
- Diversity of CAB membership, with respect to reflecting diversity of local/targeted populations and those living with dementia
- CAB member referrals for research participation
- Number of attendees at meetings and events
- Number of annual meetings held versus cancellations
- CAB member attendance at meetings and community events
- CAB member retention/growth

Lessons Learned

- 💡 Identify key stakeholders prior to implementing a recruitment plan if possible.
- 💡 Use a co-facilitation style: one research clinic member, one community member.
- 💡 Develop a community-led consensus model for conducting business.
- 💡 Provide the meeting at community-friendly times. Be respectful of members' time.
- 💡 Start and conclude CAB meetings on time.
- 💡 Allow the CAB to develop agenda/research items.
- 💡 Meet only with a purpose, never for the sake of simply holding a meeting.
- 💡 Encourage face-to-face contact as much as possible.
- 💡 Provide food and refreshments and respect preferences.
- 💡 Consider compensation or an incentive package for CAB membership.



2: Promote Health and Science Literacy for Healthcare Providers, Community Partners, Patients, and Families

Increasing awareness and engagement can empower people from diverse communities to participate in clinical research, including individuals with Alzheimer’s and related dementias, their family members and caregivers, healthy adults, health professionals, businesses, and the general public. To improve public understanding of the role and importance of clinical trials, education and outreach should capitalize on existing resources to provide basic information about brain health, symptoms and risk factors of Alzheimer’s or related dementias, diagnosis and treatment options, and opportunities for participation in clinical research.



Timeline: Expect to invest at least 1 year working in the community to deliver a multifaceted health education program prior to study recruitment.

Task 1. Develop health literacy about cognitive health, Alzheimer's disease, and other forms of dementia, and engage with community partners to plan and disseminate curricula.

- Leverage existing (or develop openly accessible) sources of culturally, educationally, and linguistically appropriate health materials.
 - These materials will focus on basic health, research, and medical information, beyond Alzheimer's-specific research studies (e.g., the Centers for Disease Control and Prevention's [Healthy Aging/Healthy Brain](#) initiatives).
 - Advertise research participation within broader health- and wellness-oriented education (i.e., a public health model rather than a medical model), as misinformation about fundamental aspects of medicine and research is a substantial barrier to care.
- Access and contribute to national repositories of resource materials (e.g., [NIA's ADORE](#), [Being Patient](#), [Alzheimer's Association](#)) that can provide education and training on dementia-related and clinical-trial topics to local participants and influencers (e.g., healthcare providers, health educators, research navigators, community-based service organizations, faith-based organizations, family members).
- Provide educational events for professional healthcare providers and integrate education into existing continuing medical education (CME)-based training, particularly for primary care physicians in community health centers.
- Utilize community events to increase health literacy (e.g., lunch-and-learn series, lay presentations, memory screening events, town hall meetings, and health fairs).
 - Build events for families rather than restricting to older adults.
- Offer tours of the research space after introducing concepts of research to the community.
- Address community concerns and barriers to participation. Directly address "elephants in the room" regarding past atrocities in research.
- Feature local voices of those living with dementia and current or past research participants.
- Utilize multimedia and geotargeted approaches when and where possible to deliver dementia-related and clinical-trial training to individuals and their families.
- Ensure education-based technology is user- and mobile-friendly.
- Identify, train, and certify champions to discuss clinical trials and research within communities.
- Create a bureau of speakers who are aware of specific cultural needs and challenges of the local community to provide community education and training for clinicians and other healthcare providers.
- Ensure that messaging is culturally and linguistically appropriate for targeted audiences, as use of specific phrasing may be interpreted radically differently across demographic groups.
- Share short vignettes on dementia, caregiving, and research (in hosted online webinars, during hosted home-based support groups, and via social media). Featured faces and voices should be inclusive and local where possible, with time allocated for interaction such as Q&A.
- Build time and resources for community engagement, marketing, outreach, and education into recruitment plans and budgets during the grant-writing phase, and ensure that earmarked funds are reserved for these activities as the award period progresses.

Success Indicators

- ☑ Development of new or modification of existing relevant health education resources for the target population with regard to age, race/ethnicity, language, education, sex, and cognitive status
- ☑ Number of educational events for community members and professionals
- ☑ Attendance at these educational events
- ☑ Number of referrals to research emanating directly or indirectly (e.g., referral by a community partner in attendance) from these events
- ☑ Number of new community partners evolving from educational events
- ☑ Results of event evaluations by attendees
- ☑ Event attendee change in attitude about clinical research and willingness to participate in research
- ☑ Results of CAB member feedback about educational events

Lessons Learned

- 💡 Participation in educational events is often encouraged by friends and family who provide social support and through recommendations from physicians and other community contacts (Rivers et al., 2013).
- 💡 Patients viewing video-based educational materials on clinical trials had a significantly greater increase in knowledge and decrease in attitudinal barriers compared to patients viewing text-based materials (Meropol et al., 2016; Jacobsen et al., 2012).
- 💡 Ensure that materials are accessible and appropriate for family/fictive (nonbiological) kin structure beyond the potential research participant, as they may be influential in a participant enrolling in or continuing with a study.
- 💡 Be sure to regularly report back to targeted communities with updates about recent study enrollment progress and results.
- 💡 It is far more difficult to introduce these tactics after running into recruitment difficulties than to plan for them in advance.

Task 2. Foster conversation opportunities between potential participants and their trusted advisors, including healthcare providers and other community partners, support services, church ministries, and family.

- Build a contact database of community organizations, physicians, and individuals to facilitate regular correspondence.
- Develop regularly scheduled email or an e-newsletter campaign to provide educational and event information on cognitive health, dementia, and clinical trial topics.
- Create regular (e.g., quarterly) information sessions on research opportunities that are community-based and accessible to diverse audiences, including those living with dementia.
- Build on targeted advertising and popular social media platforms to engage families and communities about Alzheimer's and other forms of dementia.
- Work with healthcare systems and providers to create customized research referral links and alerts through electronic health record (EHR) systems.
- Provide feedback to primary care providers regarding their patients who are enrolled in studies, and offer them updates on scientific advances.
- Develop strategies to include providers in the planning of research studies so that they are partners, not just potential sources of referrals.
- Create formal and informal opportunities for community advocates and champions to liaise with the public (e.g., community events, health campaigns).
- Partner with faith communities to promote research participation within their assemblies.
- Build awareness through the use of social media and community activities, particularly leveraging young voices and energies to draw attention to research opportunities.

Success Indicators

- ☑ Growth trajectories of database contacts
- ☑ Number of responses to email/e-newsletter campaigns
- ☑ Number of new subscriptions to newsletters and social media accounts
- ☑ Growth trajectories in social media followers
- ☑ Growth in social media-based discussions about dementia (e.g., track through use of geotagged or geofenced hashtags)
- ☑ Prevalence of calls to action in advertising
- ☑ Growth trajectories in referrals through EHR

Lessons Learned

- 💡 Implicit bias in healthcare professional interactions: Provider interactions with underserved individuals are shorter than interactions with whites, and clinical trials are less frequently discussed. When trials are discussed, less time is devoted to the topic (Eggly et al., 2015).

- 💡 Willingness to consent: Despite attitudes and beliefs that could affect racial/ethnic minority groups' willingness to participate in research, studies show that, overall, these individuals are as likely as whites to consent if they are offered the opportunity (Langford et al., 2014; Simon et al., 2004; Wendler et al., 2006; Svensson et al., 2012).
- 💡 Barriers to participation: The bridge between community research literacy and community research participation comes through the reduction of barriers to research participation. If the study site reduces barriers related to transportation, time investment, and family and financial burdens, well-informed communities will readily participate.



3: Implement System Reforms and Infrastructure to Address Bias in Workforce Diversity and Cultivation of Community Bridges to Increase Capacity for Inclusive Outreach

To advance Alzheimer’s and related dementias clinical research, we must build the capacity and improve the infrastructure of research study sites, registries, and referral networks to recruit and retain more qualified study participants.

To improve the representation of participants in research, it is essential to focus on increasing inclusivity and diversity in age, race/ethnicity, language, sex, education, socioeconomic status, comorbidities, co-occurring medical conditions, geographic region, and cognitive status. To recruit and retain a diverse and skilled workforce, research teams need to develop a staffing strategy that is appropriate to the project’s outreach and recruitment goals for its target populations. They should develop guidelines to recruit and retain a diverse and inclusive professional workforce at all levels of the team, and ensure that the leadership and site personnel are representative of the target population. The research team should assess and attempt to quantify implicit bias at research sites, provide training for staff to increase cultural competency and awareness of implicit bias, and implement evidence-based interventions to reduce implicit bias at the individual or group level.



Timeline: Expect to invest at least 6 months assessing and addressing inherent bias in research clinic operations and relationships that have the potential to impact the team’s ability to successfully recruit and retain participants from diverse backgrounds. Efforts to ensure retention begin with infrastructure reform prior to enrollment, and continue for the duration of the research study.

Task 1. Increase workforce diversity and engagement of community bridges to address bias.

Step 1: Develop a Strategy to Evaluate and Reduce Implicit Bias in the Workforce

- Assess and quantify implicit bias at the academic and community research sites: operationalize the metrics and the approach to meet this goal.
- Assess diversity of study staff, researchers, and principal investigators.
- Identify and provide resources to facilitate this assessment.
- Develop a dissemination plan for results to individuals and groups who were assessed.
- Identify existing resources for cultural competency training at the home institution, or leverage other public or private resources (e.g., [UCLA resources](#)).
- Provide training modules on recognizing implicit bias.
- Identify evidence-based interventions to reduce implicit bias at the individual or group level.
- Develop a plan for intervention delivery (e.g., who, what, how) that includes engagement of, and accountability to, community partners.
- Identify ways to expose study staff to life with dementia in the target community (e.g., [Washington University's Dementia Understanding Opportunity Program](#)).
- Identify ways to include those living with dementia and their family members on the study staff, advisory boards, and local engagement teams.
- Identify ways to incentivize training and motivate individuals to participate in reducing implicit bias.

Success Indicators

- ☑ Implementation of a strategy to assess and address implicit bias in the workplace that is feasible and has buy-in from the research team and the community partners

- ☑ Number of research staff members who have participated in cultural competency and/or bias training
- ☑ Recruitment and retention of broadly diverse study staff at all levels
- ☑ Long-term reduction in assessed implicit bias metrics
- ☑ Reported ease of involvement and access by individuals from diverse backgrounds, including those living with dementia

Step 2: Develop Guidelines to Recruit and Retain a Diverse and Inclusive Professional Workforce at All Levels of the Research Team

- Identify the project's outreach target populations and develop a staffing and outreach strategy that is appropriately sensitive to this goal.
- Develop employment descriptions that capture relevant experiences with the target communities and specialized skills (e.g., language facility, familiarity with the community, experience in health disparities or health equity).
- Identify opportunities to leverage staffing resources from other academic departments or community partners that align with the target community.
- Develop flexibilities or incentives in job requirements that enable a broader range of individuals to be involved as study staff.
 - May include discounts/access to child or adult care
 - Access or availability of transit/telecommuting
 - Availability of health benefits
 - Some flexibility with part-time or full-time status to accommodate family/kin/faith/travel obligations

Success Indicators

- Diversity in the demographics of the staff that mirrors the target population
- Retention history of racial/ethnic minority staff members

Lessons Learned

-  Work with Human Resources when hiring to ensure the institution's hiring practices are followed (i.e., specific rules and practices that serve to protect against discrimination at all levels).
-  Leverage community partnership knowledge, experience, and connections to identify sources of candidates for new employment opportunities.
-  It is imperative that community engagement and conversations be facilitated by a culturally competent member of the study team (or his/her appointed agent), but that the full burden of managing/developing these relationships be handled by a broader team from the local study site. While it is important that the community see familiar faces on the study team, cultural competence is the responsibility of all study staff, not only those who understand targeted communities.
-  At the same time, it is also important to identify study staff who have the skills to develop relationships with targeted/local community populations and to provide regular protection of her/his time for this work, incentivize metrics of success beyond study accrual, and ensure that recruitment and outreach activities are not marginalized and deprioritized.

Task 2. Expand trial design to encourage participation of larger and more diverse communities and avoid “closing a door” to interested individuals.

- Relax exclusion and inclusion criteria, including documentation requirements, when possible to permit increased diversity in participant characteristics and thus less restricted access to research.

- Increase flexibility in protocols by allowing selected components of the clinical studies to be conducted in convenient and familiar locations for participants (Gabow, 2003).
- Add local clinicians to study staff to promote familiarity with research protocols and stronger community partnerships (e.g., see [Dr. Gregory Talavera's profile](#)).
- For individuals who fail to meet entry criteria for a particular study, offer other research opportunities so there are no “closed doors” to those who express an interest in participating.
- Implement a plan to support institutional and community-wide coordination among research groups and clinical/social services, including ensuring that study sites are fully accessible to local communities.
- Develop reasonable, culturally appropriate, and value-driven incentives for research participation (i.e., consider direct payment with cash or gift cards instead of reimbursement for participant costs).
- Create clear institutional or site-level guidelines and training focused on differentiating between recruitment and coercion, and include CAB members and other community partners in the development of this program.

Success Indicators

- Accrual to clinical trials from diverse/targeted populations (e.g., Hispanics, men, individuals with MCI)
- Number of individuals from the targeted population inquiring about research participation
- Number of new referrals to research from individuals of the targeted population
- Retention of individuals in research from the targeted population
- Number of individuals referred from other research laboratories within the academic institutions or local area (attests to successful bidirectional partnerships in participant referrals)

Lessons Learned

- Consider ethical issues that increase risk for coercion, including incentives and recruitment of individuals with low literacy, for whom English is a second language, or who have a cognitive impairment.
- The need to obtain Social Security numbers and other forms of identification may deter immigrant communities from study participation.
- Giving back to the participant (e.g., individual feedback regarding laboratory results and/or cognitive assessments, compensation): Consider the person and his or her community in context. What's important to one person may not be important to another (e.g., compensation may be more important for some individuals given their different financial needs).

Task 3. Provide participants with individualized and genuine attention and demonstrate commitment to ongoing outreach.

- Enlist a research navigator, ideally from the local targeted community, to assist with recruitment and to assist participants as they move through all phases of screening, enrollment, and study participation.
- Develop or leverage existing data management systems to track participant correspondence and to support ongoing relationships with current, past, and potential research participants.
- Identify goals for the participant retention program (e.g., monthly contact to show continued appreciation) and strategies to accomplish program goals (e.g., luncheons, personal notes, newsletters providing regular research progress updates).
- Host annual events summarizing research and thanking current research participants and their families/kin structure.

- Consider offering individualized research feedback at the end of the study (or at regular intervals), such as z-scored global cognitive measures, so that participants may understand how they have performed.
 - Caution must be taken so that these data do not unduly influence future research performance and are not taken to indicate clinical diagnosis.

Success Indicators

- Retention record
- Number of new referrals/recruits into research studies, sourced from current participants
- Change in attitude about research participation (data can be obtained using tools such as a research satisfaction survey)
- Willingness to engage in future research studies
- Positive reviews of the research study (based on responses to a research satisfaction survey)
- Diversity of database participants
- Diversity of research navigators

Lessons Learned

- Creation of a sense of common purpose and understanding with patients/participants may assist in reducing bias and increasing cooperation and trust (Gaertner, 2009; Gaertner & Dovidio, 2010).
- Genuine interaction with participants that conveys appreciation and respect results in higher rates of retention, enrollment, and referrals to research.
- Improvements in participant satisfaction are likely to improve participant retention, as well as significantly drive referrals to potential participants, particularly within racial/ethnic minority, rural, and other underserved communities.

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