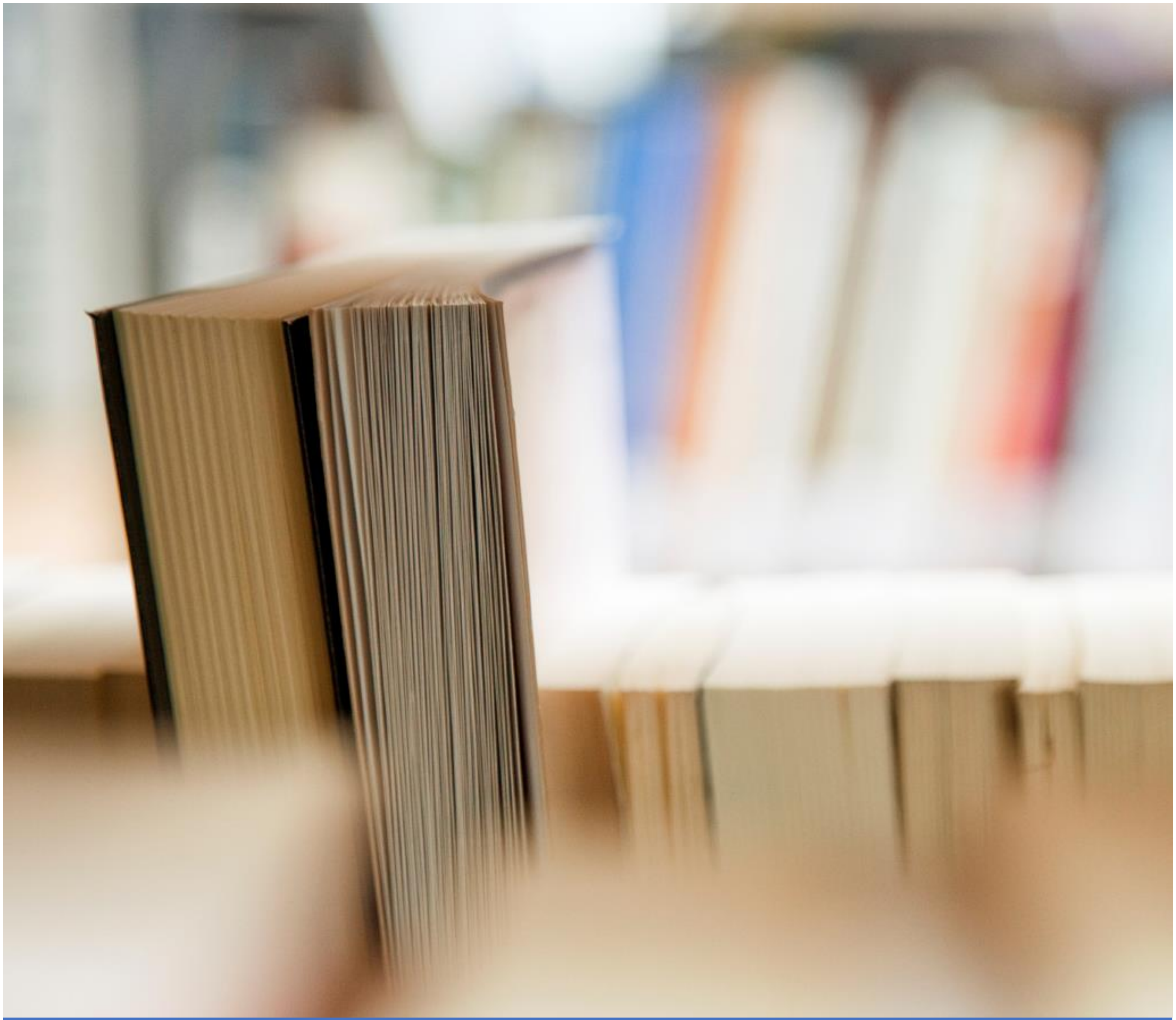

Community Outreach Guide

Tips for research staff and Principal Investigators to “normalize” clinical trials in your community

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WORKING WITH COMMUNITY OUTREACH: REFLECTION CHECKLIST

Share this with your colleagues to see what your research department thinks about these issues.

Question	Very	OK	Not Very
1. How well do we communicate with our community about clinical trials as a quality treatment option?	☐	☐	☐
2. How well are clinical trials messages integrated in outreach and community relations of our larger organization?	☐	☐	☐
3. How well can our medical, clinical or administrative staff appropriately provide positive messages about clinical trials?	☐	☐	☐

If you answered, “OK” or “not very well” to any of these questions, your site may need to implement changes in this area. Take action with the tips from this guide.

COMMUNITY EDUCATION: BEST PRACTICE TIP SHEET

Principle[1]	**Apply it by…**
Don't promote particular trials in outreach or education programs	☐ Emphasizing the fact that your institution provides quality options for care, including clinical trials *In general, it is not a good idea to undertake any community based recruitment efforts for any specific treatment trial.*
Recognize that the educational needs of the public – differ from those facing a treatment decision	☐ Developing collaborative relationships with community groups and their leadership around educational programming and community outreach, focusing on the quality care you provide through clinical trials. ☐ Offering interactive learning opportunities with local community groups (e.g., civic clubs, churches and disease/condition support groups[2]) ☐ Supporting efforts to educate community about benefits of clinical trials[3,4,5,6,7] ☐ Avoiding disrupting home and work schedules when conducting education or outreach activities, hold meetings after church or other social activities, or in conjunction with community events already taking place. ☐ Using social marketing techniques emphasizing quality care at the site and quality care through clinical trials[8,9] ☐ Providing appropriate and current information regarding open disease/condition clinical trials for the public in a visible, easy- to- use, web-based format ☐ Hosting an "Aware for All" event https://www.ciscrp.org
Create actionable messages and related products for public (non-patients)	"When someone you love is told they have (insert disease/condition), we need to make sure they understand all their options for treatment" ☐ Use easy to understand flyers or brochures with phone numbers that are evergreen ☐ Consider bringing "trinkets" as a way to promote your practice and clinical trials
Don't make assumptions about community attitudes towards clinical research	☐ Finding ways to present clinical trial information that complement the values people in the community hold. These may include access to care, social justice, importance of contributing to research, etc. *For minority communities , the legacy of abuses in research should not be overlooked, but check your assumptions about mistrust about or lack of interest in research before beginning an educational program. Attitudes vary widely.*

Principle[1]	Apply it by…
Use peer to peer education approaches	Training community leaders and/or past trial participants to become Clinical Trial Ambassadors[10,11] *Using peer education (e.g. training community leaders to become community educators about clinical research) may be more successful than solely using research staff or PIs as educators.*
Use education as part of a long-term institutional effort to generate trust and quality care	☐ Demonstrating that your site is "in for the long haul" and is not just interested in recruiting patients for a particular clinical trial. Think about other services your practice can provide. ☐ Being open to learning about community needs to enhance access to care. For example, it may be helpful to incorporate evening and weekend hours into required trial visits ☐ Visibly supporting efforts of community partners to promote disease/condition screening[12] ☐ Promoting ready access to disease/condition screening to help reduce health disparities and as a way to promote quality disease/condition care [13] ☐ Developing systems that build trust and enhance communication at the community level[14] ☐ Developing a Community Engagement Program in clinical research/quality care for all (e.g. *Create a community advisory board to enhance local community support for research, and help you create more accruable trial menus)*[15]
Don't base "success" of educational programs on accrual alone	☐ Measuring increases in inquiry or changes in knowledge, attitudes or behavioral intent
Use appropriate promotional language about research	☐ Emphasizing importance and availability of quality care and treatment options offered through clinical trials *Message: Quality of Care* *"Therapies offered through (clinical trials) should be considered the preferred treatment choice for physicians and patients, if they are available." (NCCN, 2008)* *Message: Access, social justice, generalizability* *Physicians should "strive to make participation in clinical trials a key component of clinical practice and to achieve…high accrual rates of 10% or more. (Institute of Medicine, 2010)*

COMMUNITY BUILDING RELATIONSHIPS AROUND CLINICAL RESEARCH WITH COMMUNITY-BASED ORGANIZATIONS

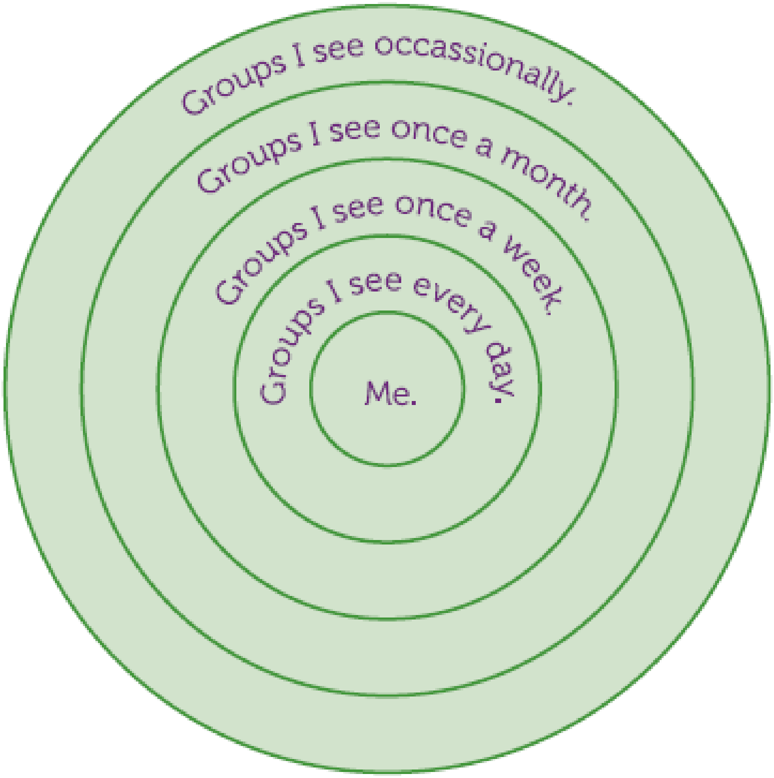
Although research teams may choose to rely only on their own site for recruitment contacts, community organizations and community leaders may also help in recruiting patients. Therefore, it is important that your research team build collaborative relationships with community groups and their leadership. **It is important to consider these activities as on <u>ongoing effort</u> to enhance access to clinical trials, rather than as an approach to enhance recruitment to a particular trial.**

There is no one way to begin community outreach. However, strategies include the following:

- Develop collaborative relationships with community groups and their leadership around educational programming and community outreach, focusing on the quality care you provide through clinical trials.
- Find ways to present clinical trial information that complement the values people in the community hold. These may include access to care, social justice, importance of contributing to research, etc.
- Be open to learning about community needs to enhance access to care. For example, it may be helpful to incorporate evening and weekend hours into required trial visits

Getting Started with Community Outreach

In the circles below, write down at least five groups or organizations that may be helpful in conducting outreach to disease/condition patients who may be potential clinical trial participants. The groups do not need to be disease/condition-related, but should have a health focus.



Expand Your Institution's "Community"

It is important to think broadly about other organizations with which your research team can partner. A given geographical area includes many "communities." In the following table, write down the organizations you identified on the previous page.

Then, think about:

- Reaching out to other groups in your community who may be interested in learning about the quality of local disease/condition care for
- Contacting people who can put you in touch with key leaders of these groups

The pages that follow will help you prioritize your outreach efforts. It is important to consider balancing your research team's efforts between groups that are easy to reach with others that will take more effort.

Referral Source Worksheet for General Community Education about Clinical Trials

There are other organizations in your community that can help raise awareness about the quality of care available in your institution as well as the availability of trials in general.

Organization Type	**Examples in My Community**	**What they might be interested in around clinical trials** *(e.g. presentation on quality disease/condition care through clinical trials, survivorship, getting leadership engaged in becoming "Clinical Trial Ambassador" or serving on a Community Advisory Board)*	**Next Steps/Follow Up**
African American-based organizations			
Asian American-based organizations			
Disease/condition-oriented nonprofit organizations with local chapters			
Disease/condition support groups			
Civic organizations			

Organization Type	**Examples in My Community**	**What they might be interested in around clinical trials** *(e.g. presentation on quality disease/condition care through clinical trials, survivorship, getting leadership engaged in becoming "Clinical Trial Ambassador" or serving on a Community Advisory Board)*	**Next Steps/Follow Up**
Churches and other religious institutions			
Chambers of commerce			
Community health Centers/public health clinics			
Employee associations of large companies			
Health clubs			
Health care professional associations *(e.g., doctors, nurses, social workers, health educators)*			
Housing organizations			
Labor union locals			
Latino-based organizations			
Lesbian/gay organizations			

Organization Type	**Examples in My Community**	**What they might be interested in around clinical trials** *(e.g. presentation on quality disease/condition care through clinical trials, survivorship, getting leadership engaged in becoming "Clinical Trial Ambassador" or serving on a Community Advisory Board)*	**Next Steps/Follow Up**
Men's organizations			
Native American organizations			
Professional associations			
Senior citizens' organizations Note: AARP also has state chapters http://www.aarp.org/states/			
Service organizations (e.g., Rotary, Lions, Kiwanis, Jaycees, Junior League)			

Working with Disease/Condition Patient Advocacy/Patient Service Groups

Most of these groups have local chapters. By visiting their websites you can find direct links to local chapters or support groups to help your research team connect with a chapter in your community.

A national organization may have many members across the country who can be informed about your trial. Think about:

- The number of people you seek to recruit for this trial
- If participation in the trial is generally limited to the community in which the lead/participating organization is located
- How an organization's newsletter or web site can help (or is unlikely to help) identify appropriate candidates for your trial

Be "cost-effective" when approaching these groups; you may wish to only communicate with local chapters of these groups who can better assist you with your local recruitment and awareness efforts.

Racial and Ethnic Minority Groups and Participation in Clinical Trials

As classified by the US Office of Management and Budget (OMB), these groups include:

- American Indian or Alaska Native Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White
- OMB recognized ethnic groups include "Hispanic or Latino"

It is important to note that while these are how various populations are categorized per OMB guidelines, these terms may *not necessarily be how individuals define themselves*. Further, attitudes and beliefs related to medical research varies among group members themselves. Members of the same racial/ethnic group may have different belief systems, attitudes and customs based on factors such as socioeconomic status, geographic locations and individual experiences.

Although rates of adult participation in clinical trials are low overall, rates are even lower among racial and ethnic minority groups.[16,17,18,19,20,21] It is clear from the literature is that members of racial/ethnic minority groups are less likely be approached about clinical trials participation, while the literature also shows that members from these groups are just as willing to take part in health research as whites.[22,23,24,25,26,27,28,29,30]

CLINICAL TRIALS ENGAGEMENT: TIPS FOR WORKING WITH DIVERSE POPULATIONS

The pages that follow discuss some key points to consider when reaching out to diverse populations, including:

- African Americans
- Asians/Asian Pacific Islanders
- Hispanics/Latinos
- Native Americans/Alaskan Natives
- Other groups

Important Note: These points should be not considered a "cook book" for working with these populations.

African Americans and Clinical Trials-Tips for Community Outreach

- Find people who are already active in organizations to help spread the word about clinical trials; people who are known, trusted, and accountable in the community will be better messengers than outsiders
- Explore partnerships with African American-serving organizations as well as churches, particularly for health issues central to the mission of the church
- Conduct in-person outreach to complement other education efforts using videos, brochures, or advertisements
- Explore impact of the disease you are studying in the local community
- Explore the issue of low participation and less likelihood of being asked
- Present real-life situations that exemplify statistics or written messages; effective dialogue can take place through an educational session that allows for open discussion and questioning
- Provide personal, "real world" discussion of clinical trials and follow up in any education program

Asian Americans and Clinical Trials-Tips for Community Outreach

(including people from many countries of origin (including the state of Hawaii) and different degrees of acculturation)

- Invite a health care professional to deliver information about clinical trials–preferably, a doctor or nurse from that community
- Remember to consider feminine modesty and traditional gender role values

Hispanics/Latinos and Clinical Trials-Tips for Community Outreach

- Involve family members in learning about the risks and benefits of clinical trials
- Collaborate with people who are from their communities and who speak Spanish
- Get testimonials from local pastors, Hispanic celebrities, or doctors who have experienced disease/condition themselves
- Take the outreach program out to community and neighborhood centers as well as to other sites that are already familiar to Hispanics. Consider partnering with existing groups
- Use radio, newspapers, and Spanish-language media, especially television and radio talk shows, for outreach

Alaska Natives/Native Americans and Disease/condition Clinical Trials-Tips for Community Outreach

- Work with the community or Tribal Elders, as well as community health representatives and public health nurses, to determine the best ways to conduct outreach and education efforts
- Successful clinical trial outreach requires that the investigator work closely with the tribal IRB in addition to those of the IHS
- Find Native American trial participants who would be willing to discuss his or her experiences in a clinical trial at a community gathering
- Use group activities such as sharing and caring for others
- Incorporate or encourage the use of traditional healing ceremonies as well as spiritual connections, which can be very important for people in these communities
- Use one-on-one or small group education and outreach techniques to respect privacy
- Develop and communicate a mechanism to distribute study intervention to communities and Tribes after trial has concluded

Engaging Other Diverse Groups to Clinical Trials

Group	Key Issues for Research Staff to Consider	Tips for Outreach
Medically underserved and/or those who have limited access to health care: • Populations who live at significant distances from medical facilities • People without transportation to medical facilities • The working poor who do not have medical insurance and are ineligible for Medicare/Medicaid • Immigrants and migrants who cannot access medical care because of language, legal and other barriers	• Verify that any services or income they receive will not be affected by study participation; check with social services • Offer free parking, transportation, and exams when possible • Investigate possibilities for funding from foundations and local community service programs to provide transportation, parking, and other forms of assistance	• Consult with the staff of local free clinics for advice on approaching and communicating with these groups • Keep communications simple and genuine • Partner with local, county and/or city health clinics to provide a recruitment and/or referral site for the medically underserved •
The elderly: • Less likely to seek out clinical trials • More inclined to obtain treatment from "own doctor" • Have lower levels of education • Are particularly fearful of non-payment by third-party payers • May have more difficulty getting to and from distant providers • Face protocol exclusions due to functional status limitations and organ-system abnormalities • Lack physicians' referrals	• Evaluate those in between fitness and frailty, with some co-morbidities but reasonable performance status	• Use in-person contacts as opposed to written materials • Provide updated public transportation information and free transportation, if possible • Remember that low literacy rates are high among this population

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