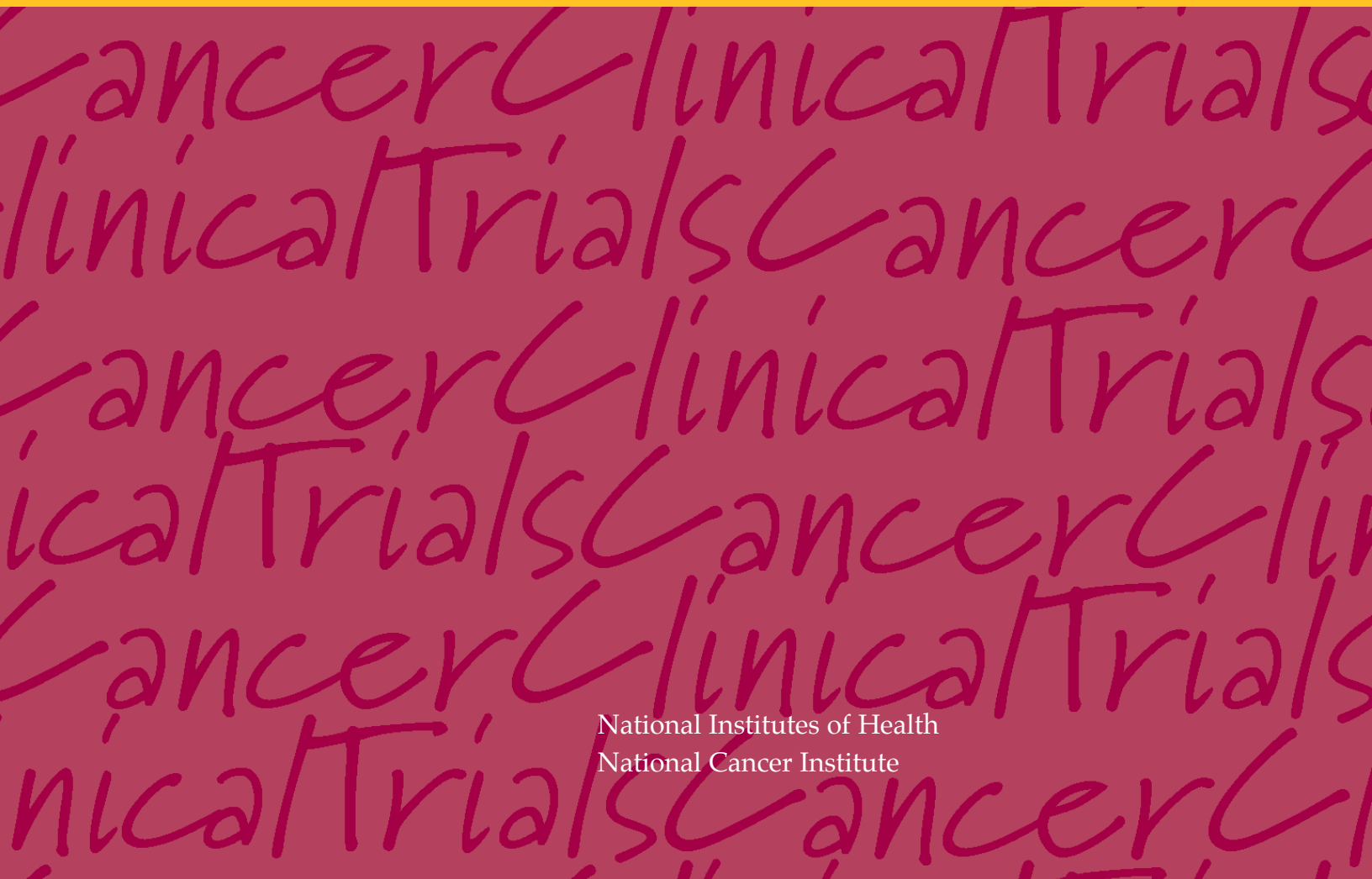


# Cancer Clinical Trials

*A Resource Guide for Outreach,  
Education, and Advocacy*



National Institutes of Health  
National Cancer Institute

# The National Cancer Institute Clinical Trials Education Series

## Cancer Clinical Trials Books

### ***Cancer Clinical Trials: The Basic Workbook***

The self-modulated workbook, with its accompanying activities, will help readers understand why cancer clinical trials are important, how they work, how participants' safety is protected, as well as some of the reasons so few adults participate in these trials. It is designed for individuals who want to develop a basic understanding of clinical trials.

### ***Cancer Clinical Trials: The In-Depth Program***

The textbook expands on the subjects outlined in *The Basic Workbook*. It features additional information on clinical trial design and resources for physician participation and referral of individuals to studies. It is designed for health care professionals and others who seek a more in-depth understanding of clinical trials.

### ***Cancer Clinical Trials: A Resource Guide for Outreach, Education, and Advocacy***

The interactive workbook provides direction and guidance for individuals and organizations interested in developing specific clinical trial outreach and education activities. This guide can also be used along with either/both of the texts listed above.

### ***Trainer's Guide for Cancer Education***

A manual for planning and conducting educational sessions on cancer-related topics, including clinical trials.

## Cancer Clinical Trials Resources

The following resources will help support cancer clinical trial education and outreach efforts.

### **Publications**

Low-literacy **brochures** on cancer clinical trials for potential participants:

- *If You Have Cancer... What You Should Know About Clinical Trials\**
- *If You Have Cancer and Have Medicare... You Should Know About Clinical Trials*

### Clinical trial participant **booklets**:

- *Taking Part in Clinical Trials: What Cancer Patients Need to Know\**
- *Taking Part in Clinical Trials: Cancer Prevention Studies—What Participants Need to Know\**

\*Also available in Spanish

### **Videos**

- A clinical trial awareness video and speaker's guide, "Cancer Trials... Because Lives Depend on It"
- A video and discussion guide on deciding to take part in a clinical trial, "Cancer Clinical Trials: An Introduction for Patients and Their Families"

### **Slide Programs**

Three slide programs are available in PowerPoint on CD-ROM and on the *www.cancer.gov* Web site:

#### *Cancer Clinical Trials: The Basics*

Provides background on why cancer clinical trials are important, how they work, and how participants' safety is protected.

#### *Cancer Clinical Trials: The Way We Make Progress Against Cancer*

A brief community awareness presentation.

#### *Cancer Clinical Trials: In-Depth Information*

Expands on the subjects outlined above, featuring additional information on clinical trial design with resources for physician participation and referral of individuals to studies.

### **Ordering Information**

To order these publications, contact the Cancer Information Service at 1-800-4-CANCER or log onto *www.cancer.gov/publications*. Most materials are available as PDF files on the Web site.

### **The Cancer Information Service**

NCI's Cancer Information Service (CIS), with regional offices throughout the United States, may work with organizations and professionals to plan, implement, and evaluate culturally appropriate clinical trials education programs using the Clinical Trials Education Series. Contact the CIS at 1-800-4-CANCER.

# Table of Contents



# Table of Contents

<b>Introduction</b> .....	<b>1</b>
<b>1. Strategies for Outreach and Education</b> .....	<b>3</b>
Understanding Clinical Trial Barriers .....	3
General Strategies for Educating Diverse Populations .....	7
Specific Strategies for Educating Ethnically Diverse Populations .....	10
Information on Other Underserved Groups .....	39
References .....	42
<b>2. Ways to Educate Yourself</b> .....	<b>47</b>
1. Use NCI Resources .....	48
2. Find Local Clinical Trials in Your Community .....	50
3. Attend Conferences, Meetings, and Workshops .....	53
<b>3. Ways to Educate Others, One-on-One</b> .....	<b>55</b>
1. Get Started—Circle of Connections With Individuals .....	57
2. Talk to Others—Tips .....	58
3. Help Others Understand How to Evaluate Research in the News .....	59
<b>4. Ways to Conduct Community Outreach and Education</b> .....	<b>63</b>
1. Get Started—Circle of Connections With Groups .....	65
2. Expand Your Organization’s “Community” .....	66
3. Prioritize—Develop a Strategy and Philosophy for Outreach and Education .....	69
4. Use NCI Audiovisual Materials to Make Presentations .....	71
5. Distribute Materials .....	71
6. Write Letters for Local Newsletters and Web Sites .....	72
7. Hosting an Information Session/Community Forum— A Step-by-Step Planning Guide .....	77
8. Form an Advocacy Coalition .....	87

<b>5. Ways to Work With the Media</b> .....	<b>95</b>
1. Work With Mass Media—Goals, Timing, and Process .....	96
2. Develop a Media Campaign .....	98
3. Use Media Tools .....	100
<b>6. Ways to Work With Hospitals, Medical Centers, and Universities</b> .....	<b>109</b>
1. Work With Researchers and Health Care Professionals .....	111
2. Serve on an Institutional Review Board (IRB) .....	113
<b>Appendix</b> .....	<b>115</b>
Plan for Action .....	115
Resources .....	120

# Purpose of This Guide and How to Use It

This resource guide is designed to help you find ways to participate and engage your community in clinical trials outreach and education activities. It also will help you figure out how to get involved and how to get started.

As an individual or as part of an organization, you can be a critical force in helping people understand the importance of clinical trials. There are many opportunities for clinical trial outreach and education—how you do it is up to you and any organization(s) with which you are involved.

Many avenues exist to support your work, whether you are:

- Interested in clinical trials, working on your own
- Interested in clinical trials, working as part of an organization or group (which may or may not already have clinical trials as part of its mission)
- A health care professional, working as part of an institution, organization, or group

If you are an individual working on your own, this guide can help you think about activities you can do alone, as well as ways you can engage others to work with you.

If you are part of an organization, a group can be designated to read this guide and develop recommendations for action.

Each section is designed to be self-contained and features practical tips and useful tools that can guide you in developing appropriate education and outreach efforts. In general, the activities in each section are organized according to level of effort required.

After you explore a wide range of outreach opportunities, the Plan for Action in the Appendix can help you think through ways to get started and how to plan specific goals for the future.

# Introduction

Clinical Trials / Cancer Clinical Trials



# Introduction

Given your interest in clinical trials, it is likely that you already know quite a bit about how they work, the barriers associated with them, and why they are important.

Whether you are a health care professional who wants to find ways to reach your community, a member of a patient group who wants to educate its members, or someone who wants to engage your group or organization to initiate clinical trial outreach activities, this guide can help you figure out avenues to support your activities. The guide is not designed to be a comprehensive overview; rather, it gives some examples of activities others have engaged in, and provides tools and suggestions for implementation in your community.

By informing your community about clinical trials, you can help people make informed decisions about their cancer treatment or prevention options, including the option of participation in a clinical trial. The more people that participate in clinical trials, the faster we can answer the critical research questions that will lead us to better treatment and prevention options for all cancers.

This workbook is designed to complement the other materials in the National Cancer Institute Clinical Trials Education Series, described at the beginning of this book.

# 1. Strategies for Outreach and Education

# 1

## Strategies for Outreach and Education

### Understanding Clinical Trial Barriers

It is important to understand the reasons why so few adults with cancer participate in clinical trials. A few are listed here.

**Many people with cancer, or those at high risk for developing cancer, are:**

- **Unaware of the option of participating in clinical trials.** Research has consistently shown that most people are not aware that clinical trials could be an option for cancer treatment or prevention.
- **Unwilling to go against their physician's advice or direction.** Research has shown if a person's doctor does not recommend a trial as an option for cancer treatment or prevention, he or she will be very unlikely to participate in one.
- **Fearful, distrusting, or suspicious of research.** For many people, the idea of being "randomized" to one treatment makes them feel they have less control over their care. Many are also fearful of being "experimented upon" and not receiving treatment for their cancer. Many people distrust those in the medical community, based on past negative experiences or the historical abuses of research participants.
- **Unaware of clinical trials.** The reality or the perception that there are no trials in their local community is a barrier for many people.
- **Concerned about potential costs of trials.** Some people who are insured fear that their insurance company won't cover participation in a clinical trial. Those who do not have insurance may worry about costs that are not covered by the trial's sponsor.

- **Facing personal or practical obstacles.** There are many costs, financial and otherwise, to participating in a clinical trial. Time and travel that are required to seek care at a distant trial site may be a concern for many people. The indirect costs of being away from work and family may also be a concern. Finally, some people may not wish to temporarily leave the care of their physician to participate in a trial.

**Many doctors are:**

- **Unaware of clinical trials.** Physicians are not always aware of available clinical trials. Some may not be aware of the local resources or may assume that none would be appropriate for the people they treat.
- **Unwilling to “lose control” of patient’s care.** Most doctors feel that relationships with the people they care for are very important. They want what is best for each person. Some doctors fear that if a person must be referred elsewhere to participate in a trial, they may lose control of the person’s care. They may not understand that every effort is made to maintain the physician relationship, even when a person is in a trial. In addition, many doctors may fear the loss of income if a person is referred elsewhere for his or her cancer care.
- **Under the impression that standard therapy is best.** Many physicians may not adequately understand how clinical trials are conducted or the importance of clinical research. Some physicians believe that the treatment in clinical trials is not as good as the standard treatment they might provide to people. They also may be uncomfortable admitting that there is uncertainty about which treatment is best in a phase 3 clinical trial.

## **Additional Clinical Trial Barriers for Ethnically Diverse Populations**

- **There is long-standing fear, apprehension, and skepticism in minority populations about medical research due to real abuses that have happened in the past (e.g., the legacy of the Tuskegee syphilis study).** Among these populations, there is often widespread fear and distrust of the medical care system as a result of discrimination, indifference, and disrespect. Some may feel that they do not want to give up their rights by participating in a trial, or lose their power by being “experimented upon.” Others may be skeptical about the quality of care that would be provided in a clinical trial. Some may find that trial recruitment strategies are not sensitive to their needs.
- **Doctors may not mention clinical trials as an option for cancer care.** As noted above, many physicians do not refer their patients to clinical trials. However, some physicians may avoid suggesting a clinical trial to their minority patients, out of concern that patients would see him/her as insensitive. Moreover, some physicians may unwittingly discriminate against older patients, or those who are from certain ethnic or cultural backgrounds.
- **Many people may face additional problems accessing clinical trials.** Depending on where they live or their access to transportation, people may have difficulty getting back and forth from a clinical trial site. Those with low income may find it difficult to take time off work or find appropriate childcare. Other barriers, such as a lack of health insurance or lack of general health care, clearly present difficulties in accessing trials.
- **Cultural or ethnic backgrounds may include values and beliefs that are very different from Western medicine.** Many people have cultural beliefs that Western medicine cannot address their health concerns. Different ethnic and cultural views of health and disease (e.g., fatalism, family decisions about treatment, use of traditional healers, prayer, herbal medicines, or use of complementary / alternative health practices) may make clinical trials a less attractive treatment

option. For prevention trials, many may feel that the risk of a potential disease and its consequences may be less important than meeting daily needs.

- **Language and/or literacy barriers may make it difficult for some people to understand and consider participating in clinical trials.** The complexity of forms, including informed consent documents, may also be a barrier to those considering participation in a clinical trial. Translation can also be difficult if the person translating information has not had specialized training.

# General Strategies for Educating Diverse Populations

One of the biggest hurdles for clinical trial education is overcoming suspicion of medical research.

It is important to note that strategies for clinical trial outreach and education will vary, based on the type of trial and its requirements for participation. Although some of the following strategies were designed for cancer prevention trials, many may also be used for other types of clinical trials.

## Strategy 1

Educators should be familiar (and preferably a part of) the communities they are trying to reach. People who are known, trusted, and accountable will be more effective and more believable when discussing clinical trials with community members.

### Suggested Steps

- Use easy to understand language. In some cases this may mean using a community's first language.
- Involve people from the community, especially community leaders. Find ways to develop collaboration and encourage ownership in the outreach program.

### Tip

If you are not a member of the population(s) you seek to work with, you need to develop meaningful partnerships with organizations within those communities.

## Strategy 2

Address important concerns and perceptions, benefits, and risks about clinical trials through one-on-one contact. One-on-one contact is one of the best ways to educate others.

### **Suggested Steps**

- Make sure you do not judge someone's values if they are different from your own. Find ways to present information that complement the values someone holds.
- Address risks and costs in a frank, open, and honest way.
- Stress the importance of enrollment in trials to the family and to future generations.
- Stress the importance of equal access to the highest quality care, including clinical trials. Each person has the right to know and understand every option available with regard to his or her health care.
- Promote the balance of spirituality, faith, medicine, and science.
- See the next section for suggested messages for specific ethnic/ racial groups.

### **Strategy 3**

Discuss potential benefits of participating in a clinical trial, but do not overlook the risks.

#### **Suggested Step**

Discuss the fact that because people are monitored closely under clinical trial protocols, they often receive a higher quality of medical care and followup than do those who are not enrolled in clinical trials.

### **Strategy 4**

Avoid disrupting home and work schedules when conducting education or outreach activities.

#### **Suggested Steps**

- Hold meetings after church or other social activities.
- Suggest incorporating evening and weekend hours into required trial visits.



## **Key Points for Outreach and Education**

- Clinical trial outreach strategies must incorporate an understanding of a potential participant's decision-making process, his or her culture, family and work life, and economic concerns. Those conducting education and outreach must find ways to present clinical trial information that complement the values people in the community hold.
- Education and outreach strategies should stress the importance of equal access to the highest quality care, including clinical trials. Each person has the right to know and understand every health care option available.
- Clinical trials must be explained in a way that is respectful and easy to understand, addresses someone's fears and concerns, and addresses risks and benefits.
- The research team must ensure that the informed consent process truly reflects a participant's understanding of the risks and benefits of the clinical trial. Involving family, members from the participant's community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

# Specific Strategies for Educating Ethnically Diverse Populations

Research has shown that there are many differences in who gets cancer among people of different races, ethnicities, and socioeconomic backgrounds. Certain racial and ethnic groups, as noted on the pages that follow, are also more likely to die of cancer than other groups. These differences may be due to a variety of reasons, such as late stage of disease at diagnosis, barriers to health care access, history of other diseases, biologic and genetic differences in tumors, health behaviors, and the presence of other risk factors for cancer. In addition, some cancers that have a high rate of developing in one ethnic group are rare and may not be listed among the top ten cancers in the U.S. population as a whole.\* Because rare cancers may not receive as much attention as those in the “top ten,” it is even more important for people of particular ethnic and cultural groups to be aware of research so that they can work to find ways to decrease the burden of these unusual cancers in their populations.

Differences in cancer screening and treatment have also been documented for people of different ages, as well as those from different socioeconomic, educational, and racial/ethnic backgrounds.

\*Based on the National Cancer Institute’s Surveillance, Epidemiology, and End Results (SEER) Program. SEER is the most authoritative source of information on cancer incidence and survival in the United States.

**More information on data sources used in this section:** Cancer incidence data come from the NCI SEER program, covering 14 percent of the U.S. population. Cancer mortality data come from the National Center for Health Statistics (NCHS) and covers the entire U.S. population. Cancer incidence and death rates for some racial and ethnic populations may be limited by problems in ascertaining race and by the misreporting of race and ethnicity on forms used to collect information on cancer incidence, deaths, and the populations at risk. For instance, while reporting race for African-American and White populations is generally considered reliable, biases are more serious for smaller populations, particularly American Indian/Alaskan Natives, as well as for groups living in smaller geographical areas. Additionally, it is important to note that Hispanics can be of any race and are not mutually exclusive from White, African Americans, Asian/Pacific Islanders, and American Indian/Alaskan Natives. These biases can affect trends and comparisons among groups.

## **Ethnically Diverse Populations—Some Definitions**

Diverse populations include minority, ethnic, and racial groups designated by the U.S. Government, including:

- American Indian or Alaska Native
- Asian American
- Black or African American
- Hispanic or Latin American
- Native Hawaiian or other Pacific Islander

Ethnically diverse populations are growing rapidly, and according to the 2000 Census, about 25 percent of the U.S. population reported their race as something other than White.

About 17 percent of the U.S. population over age 5 (more than 44 million people) do not speak English at home. Of these,

- Almost half speak English “less than very well”
- About 60 percent speak Spanish<sup>1</sup>

NCI’s working definition of diverse populations also includes medically-underserved populations, such as rural, low-income, and low-literacy level individuals of any racial or ethnic group. Medically underserved populations are those that lack easy access to, or do not make use of, high-quality cancer prevention, screening and early detection, treatment, or rehabilitation services. In general, these groups experience higher cancer death rates than the U.S. population as a whole.

## **Outreach Strategies**

The strategies listed below are not meant to be a complete overview of barriers and strategies; nor should the information be generalized to all people in these groups. Attitudes within various populations vary greatly, depending on a person’s age, socioeconomic status, community, and other factors. The broad outline here provides some background, context, and strategies for potential education and advocacy efforts.

## Participation of Different Groups in NCI Treatment Clinical Trials<sup>2</sup>

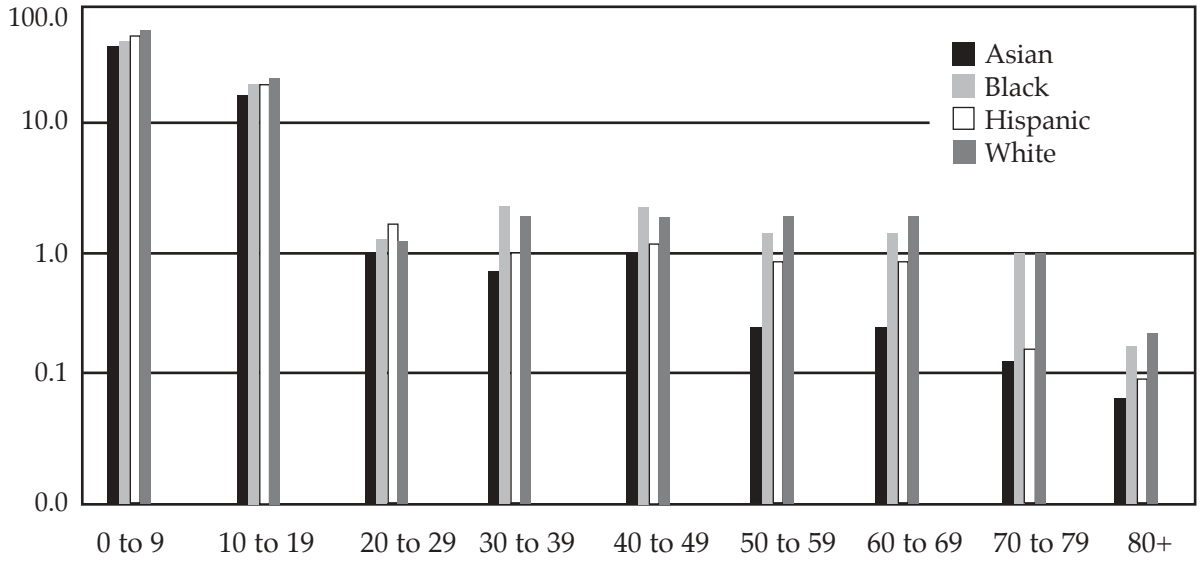
The percentage of White patients enrolled in NCI clinical trials parallels that of the overall U.S. population. However, different patterns are seen for Black, Asian American, and Hispanic cancer patients.

- Black children and young adults have accrual to clinical trials comparable to their White peers, as do Black women.
- Asian American and Hispanic children and young adults have accrual to clinical trials comparable to their White peers.
- The percentage of Black men who have cancer and are 30 to 59 years old who participate in clinical trials is markedly lower than the percentage of White men with cancer in this age group.
- The percentage of Asian Americans and Hispanics aged 30 to 80 that accrue to clinical trials is less than that of Whites.
- In terms of age, those 80 years of age or older are least likely to be enrolled, followed by those aged 30 to 39 years.

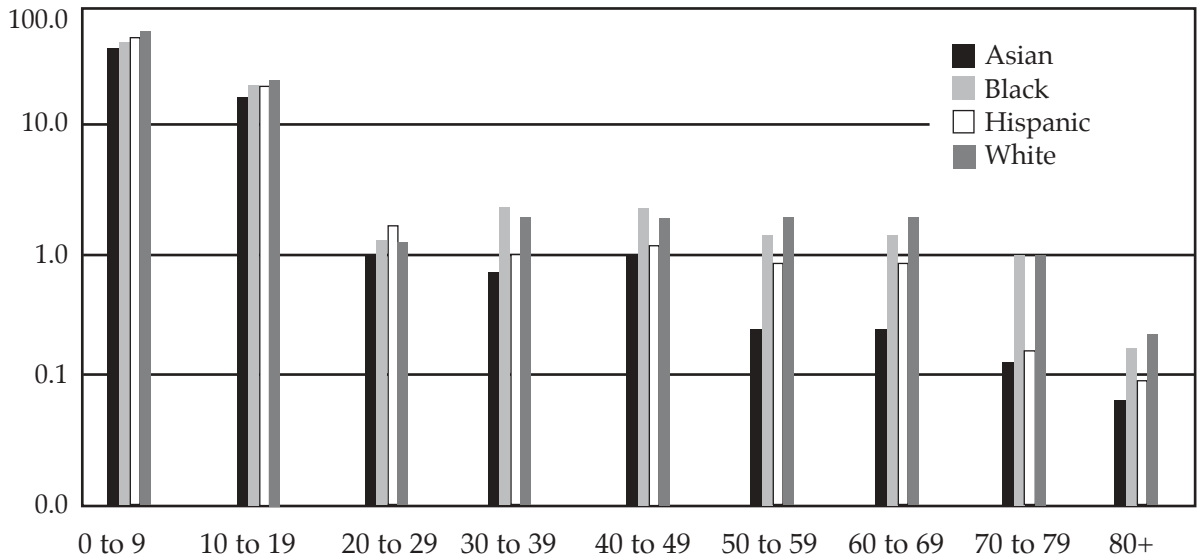
### Patient accrual for NCI-sponsored cancer treatment trials by sex and race/ethnicity<sup>2</sup>

Race/Ethnic Group	Males (%)	Females (%)	Percentage of U.S. Population
White	36	46	72
Black	4	5	12
Hispanic	4	3	12
Asian	1	1	4
American Indian	0.5	0.5	1
Hawaiian/Pacific Islander	0.5	0.5	0.5
Total	44	56	100

**Percentage of estimated United States female population represented in NCI-sponsored cancer treatment clinical trials: log scale (by age and race/ethnic group)<sup>2</sup>**



**Percentage of estimated United States male population represented in NCI-sponsored cancer treatment clinical trials: log scale (by age and race/ethnic group)<sup>2</sup>**



## **African Americans and Clinical Trials**

### *Background*

A person who is Black or African American has origins in any of the Black racial groups of Africa. This definition includes:

- Native-born Black Americans
- Africans
- Haitians
- Residents of non-Spanish-speaking Caribbean Islands of African descent

### *Cancer in African Americans*

*(Unless otherwise noted, all data is age-adjusted incidence or mortality rates between 1992 and 1999.)<sup>3</sup>*

Overall, African Americans had the highest risk of any U.S. racial/ethnic group of not only getting cancer, but also for dying from cancer.

#### **African American Men:**

- Of all ethnic and gender groups, African American men have the highest overall rate of having cancer.
- Of all ethnic and gender groups, African American men have the highest overall rate of dying from cancer.
- Of all men, African Americans have the highest incidence and death rates from many cancers, including lung and bronchus, prostate, and colon and rectum cancer. In addition, in 2001, African American men were at least 50 percent more likely to get prostate cancer than were men of any other ethnic group.<sup>4</sup>

Top five cancers: Prostate, lung and bronchus, colon and rectum, oral cavity and pharynx, and stomach

#### **African American Women:**

- Of all women, African Americans have the highest incidence rates for colon and rectal cancer, lung and bronchial cancer, and pancreatic cancer.
- Of all women, African Americans have the highest death rates from many cancers, including breast, colon and rectal, pancreatic, uterine, and cervical cancers.

- While they have the second highest rates of all women of getting breast cancer, they have the highest rate of dying from the disease.

Top five cancers: Breast, colon and rectal, lung and bronchial, uterine, and pancreatic

### *Challenges*

The legacy of the Tuskegee Syphilis Study (in which researchers studied but did not treat African American men with syphilis) has contributed to long-standing mistrust in African American communities concerning clinical research. Widespread skepticism about the medical care system exists as a result of a long history of discrimination, indifference, and disrespect. The oral history contributing to this mistrust is particularly important to recognize and acknowledge.

Some African Americans may believe that if they agree to participate in a trial, they will not be appropriately cared for, nor honestly informed of the risks or the benefits. They may fear that:<sup>5</sup>

- Placebos would be substituted for lifesaving interventions
- Treatments that work would be deliberately withheld
- They would not receive a full course of treatment, especially if funding sources for the clinical trial were no longer available

Other cultural beliefs and attitudes that affect research participation include hopelessness, fatalism, and doubt about the usefulness of cancer prevention and control. Faith, folk remedies, and the role of the family are other important influences for African Americans.<sup>6</sup>

Clinical trials may be a lower priority for African Americans and others who have a low income, less access to transportation and health care, less information about clinical trials, and low levels of literacy. Concerns about family and work responsibilities may also be a significant barrier.<sup>7</sup> African American men have noted concerns about researchers not giving back to the community, being uncomfortable talking about prostate cancer, and past negative experiences with the medical care system.<sup>8</sup>

### *Potential Solutions*

#### Cultural strategies:

- 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 will outsiders.
- Explore partnerships with African American churches, particularly for health issues central to the mission of the church. Faith is a very important part of many African American cultures and the most successful outreach efforts usually involve churches that have two or more paid clergy, and medium or large memberships.
- Ensure that the informed consent process truly reflects the participant's understanding of the risks and benefits of the clinical trial. Involving family, members from the participant's community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

#### Program strategies:

- Talk about trials using one-on-one contact—preferably with another African American person—through churches, schools, civic organizations, and African American sororities and fraternities. Word of mouth can be an effective way to reach others.
- Conduct in person outreach to complement other education efforts using videos, brochures, or advertisements.
- Present real-life situations that exemplify statistics or written messages. Effective dialogue can take place through a church-sponsored forum or an educational session that allows for open discussion and questioning.
- Involve local celebrities, including DJs at African American radio stations, by asking them to share messages about clinical trials.
- Ask newspapers and local media to join in education efforts.
- Provide personal, “real world” discussion of clinical trials and followup in any education program.



### *Key Messages*

Some African Americans may be more interested in clinical trials if they understand that participation means they:

- Contribute to their community and their families
- Join a group of people like themselves nationally, and in their local community

Clinical trial educational messages need to include information on the following topics:

- Severity of the cancer problem nationwide
- Underlying myth that African Americans don't need to be concerned about cancer
- Toll that cancer (especially breast and prostate) is taking on African American women and men—and that we don't know why
- Prevention and treatment options for high-risk African Americans—and the need for more research
- Importance of clinical trials—and what it means for all people if all groups are not represented in a trial
- Laws on participant protection and rights
- What risk means for the individual and others in his or her community

## Asian Americans and Clinical Trials

### *Background*

A person who is Asian has origins in any of the original peoples of the Far East, Southeast Asia, and Indian subcontinent. The term “Asian” refers to persons from the following and other Asian, Southeast Asian, and South Asian backgrounds:

- Chinese
- Vietnamese
- Pakistani
- Filipino
- Cambodian
- Thai
- Japanese
- Hmong
- East Indian
- Korean
- Laotian
- Bangladeshi
- Indonesian
- Sri Lankan
- Nepalese
- Bhutanese
- Sikh
- Burmese

“Asian Americans” and “Pacific Islanders” are two discernibly distinctive groups, comprised of numerous heterogeneous ethnic subpopulations. These broad categories fail to show mortality rates that, in some instances, strongly differ among ethnic groups. Whenever possible, this publication separates out these groups.

U.S. residents who reported they were Asian\* made up 4.2 percent of the total population. Chinese is the leading Asian group (2.7 million) followed by Filipino (2.4 million) and East Indian (1.9 million).<sup>1</sup>

The Asian population includes many groups who differ in language, culture, and length of residence in the United States. Some of the Asian groups, such as the Chinese and Japanese, have been in the United States for several generations and often have literacy, education, and socioeconomic characteristics that are above the national average. On the other hand, groups such as the Hmong, Vietnamese, Laotians, and Cambodians are comparatively

\*Self report, alone or in combination with one or more other races

recent immigrants, and tend to have limited acculturation and poverty rates below the national average. It is important to note that 88 percent of Asian Americans and Pacific Islanders (AAPI) are either foreign-born themselves or have at least one foreign-born parent. Of those who speak Asian and Pacific Island languages at home, more than 22 percent say they speak English “not well” or “not at all.”<sup>1</sup>

### *Cancer in Asians*

*(Unless otherwise noted, all data is age-adjusted incidence or mortality rates between 1992 and 1999.)<sup>3</sup>*

Some Asians are much more devoted to traditional medical practices than to Western medicine. For example, a study of breast and cervical cancer screening in Chinese women found that more than two-thirds had gone to traditional providers for preventive health care, went to temples to pray for their health, and looked to fortune-tellers for guidance.<sup>9</sup> Another study of cervical cancer screening in Cambodian women indicated beliefs that fate cannot be changed by detection, cancer is incurable, and cancer will not develop if traditional practices are used.<sup>10</sup>

Like the Hispanic/Latino population, Asian/Pacific Islanders experience lower incidence and mortality rates overall compared with other minority groups. However, they do experience higher incidence and mortality rates for certain cancers. Based on three-year averages, more than 18 percent of Asian and Pacific Islanders lack health insurance.<sup>1a</sup>

#### **Asian/Asian Pacific Islander men:**

- Of all men, AAPIs have the highest incidence rates of liver and stomach cancer.
- Of all men, AAPIs have the highest death rates from liver cancer.

#### **Asian/ Asian Pacific Islander women:**

- Seventy percent of Asian Americans come from countries with the world’s lowest overall rates of breast cancer, yet after living in the U.S. for as little as 10 years, Asian women have an 80 percent higher risk of getting the disease than recent immigrants.
- In addition, third and fourth generation Asian American women have rates of developing breast cancer that are similar to their neighboring Caucasian women.<sup>11</sup>

- Asian American women in general have the lowest rates of Pap test, mammogram, and breast exam screening of any ethnic group.<sup>6, 11</sup>
- Of all women, Asians have the highest rates of liver and stomach cancer.
- Of all women, Asians have the highest death rates for liver and stomach cancer.

### **Cancer in Specific Asian Groups**

The NCI SEER cancer incidence rates noted in this publication are available for different levels of racial/ethnic detail in each of the time periods (1988-1992 and 1992-1999).

Although the SEER program routinely collects detailed racial/ethnic information on the cancer patients in its coverage areas, the lack of comparable detail in the racial/ethnic county-level population estimates from the U.S. Census Bureau means that incidence rates for certain racial/ethnic groups can be calculated only for time periods centered on the decennial census. For example, county-level census information for Asian and Pacific Islanders by subgroups (Chinese, Filipinos, Hawaiians, etc.) is still only available from the 1990 Census.

From 1988 to 1992, Chinese, Japanese, Korean, and Vietnamese\* groups all had higher rates of getting liver and intrahepatic bile duct (IHB) and stomach cancers than Whites, and Chinese and Japanese had higher mortality than Whites from these two cancers, as well.<sup>12</sup> In this same time period, Korean and Vietnamese women had higher incidence rates of cervical cancer than White women.<sup>12</sup>

\*Liver and IHB not calculated for Vietnamese women

From 1988 through 1992, the top five cancers for many Asian groups are as follows:<sup>12</sup>

**Women**

	Breast	Cervical	Colon/Rectal	Lung/Bronchus	Ovarian	Stomach	Thyroid	Uterus
Chinese	X		X	X	X			X
Filipino	X		X	X			X	X
Japanese	X		X	X		X		X
Korean	X	X	X	X		X		
Vietnamese	X	X	X	X		X		

**Men**

	Colon/Rectal	Lung/Bronchus	Non-Hodgkin's Lymphoma	Liver/Intrahepatic Bile Duct	Prostate	Stomach	Urinary/Bladder
Chinese	X	X		X	X	X	
Filipino	X	X	X	X	X		
Japanese	X	X			X	X	X
Korean	X	X		X	X	X	
Vietnamese	X	X		X	X	X	

### *Challenges*

Values in many Asian cultures may be different than the Euro-American system, with decisions reached by consensus, group welfare being of primary value, and individual life not as sacred.<sup>23a</sup> In some Asian cultures, the family is responsible for treatment decisions and the patient is not told of his or her diagnosis.

Many in the Asian immigrant communities need a lot of support as they learn about clinical trials, and they need to feel safe asking questions. “Saving face” in public is important. In many cases, Asian immigrants may feel it is disrespectful to ask questions of doctors or health professionals.

Recent immigrants also may be dealing with a combination of educational, social, and health problems, along with emotional difficulties related to separation and isolation. Many are in low-wage jobs and need to get permission to take time off work to take care of health care needs.

The language barrier also is difficult to overcome. Many Asians do not speak English, and this may not be readily apparent. There are so many Asian languages that deciding on the language(s) in which information should be printed is difficult. This barrier is particularly important in issues surrounding informed consent. The informed consent process is intimidating for all people and is especially so for those with limited English skills.

### *Potential Solutions*

#### Cultural strategies:

- Assess how long the groups you are trying to reach have been in this country, as well as the countries of origin represented. It is important to fit the educational outreach to the culture and to use people from the communities to reach community members.
- Involve family members in learning about the risks and benefits of clinical trials, but resist using them as translators of medical information. In particular, avoid having children—who may be more proficient in English than their parents—serve as translators. It is preferable to enlist someone who is trained for this work.
- Ensure that the informed consent process truly reflects the participant’s understanding of the risks and benefits of the clinical trial. Involving family members from the participant’s community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

#### Language strategies:

- Find respectful ways to make sure that information is being understood. Someone who does not understand English may say “yes” or nod, even if they do not understand what is being said. To ensure that the person you are talking with understands what you have said, staff may ask, “Many people have a hard time understanding information like this. I want to make sure that I explain it clearly. Could you please tell me, in your own words, what I have just said.”
- When translating materials, at least two bilingual, bicultural translators should be used. In addition, materials should be pilot-tested with the target audience.

Program strategies:

- Use health fairs, which have been successful when organized by community members, and involve the leadership of existing Asian groups in clinical trial outreach.
- If possible, translate clinical trial information to be used in ethnic newspapers. Many immigrant groups get their health information from press that is printed in their own languages.
- Invite a professional to deliver information about clinical trials. Preferably, a doctor or nurse from that community should be invited who can encourage others to ask questions. Often, laypeople do not have much credibility as an information source.
- Keep workshops or programs short (30 to 40 minutes) because many new immigrants may have more than one job, in addition to other responsibilities.
- While recent immigrants may not have been concerned with breast cancer in their countries of origin, it is important to educate these women about their increased risk for this disease.

*Key Messages*

- A family's receptivity to cancer treatments and trials will depend on the experience that relatives have had with the medical system. For example, if a relative did not survive cancer, it may be taboo to talk about him or her.
- Remember to consider feminine modesty and traditional gender role values.



## Native Hawaiians and Other Pacific Islanders and Clinical Trials<sup>13</sup>

Native Hawaiians and Pacific Islanders are often aggregated nationally into the “Other” category or currently the “Asian American/Pacific Islander” or AAPI category. It is important to note that these are two discernibly distinctive groups, comprised of numerous heterogeneous ethnic subpopulations.

These groupings have obscured disparate mortality rates that are prevalent in one group and not the other. Whenever possible, this publication separates out these groups.

### *Background*

Native Hawaiians and other Pacific Islanders of Polynesian, Micronesian, and Melanesian ancestry\* make up 0.3 percent of the total U.S. population.<sup>1</sup> This group comprises more than 25 diverse groups with variations in historical backgrounds, languages, and cultural traditions.

Among Pacific Islanders in the United States, Native Hawaiians are the largest group, comprising 58 percent (211,014). Three-fourths of Pacific Islanders live in the states of California and Hawaii and they are a relatively young population, with a median age of 25 years and an average family size of 4.1.

The term “other Pacific Islanders,” refers to the peoples of Polynesia, Micronesia, and Melanesia, and includes:

- Chamorros
- Samoans
- Fijians
- Tongans
- Tahitians
- Marshallese
- Chuukese
- Kosraen
- Yapese
- Pohnpeian
- Palauan
- Other Pacific Islanders

\*Alone or in combination with one or more races.

Within this group are six U.S.-associated Pacific Island jurisdictions—the Federated States of Micronesia, the Republic of Palau, the Republic of the Marshall Islands, Guam, American Samoa, and the Commonwealth of the Northern Marianas—that have various political relationships with the United States.

The population of the U.S.-associated Pacific Island jurisdictions is approximately 427,000. The health status varies within and among the jurisdictions, but is generally worse than for Americans. The jurisdictions must contend with health conditions found in both developing countries (e.g., malnutrition, dengue fever, cholera, and tuberculosis) and developed countries (e.g., diabetes, heart disease, and cancer).

### *Cancer in Native Hawaiians*

#### Hawaiian Men:

(For the years 1988-1992)<sup>12</sup>

- Have the second highest cancer mortality, behind only African Americans
- Of all men and of all ethnic groups,
  - Have the highest cancer mortality for non-Hodgkin's lymphoma
  - Have the second highest rates for cancers of the lung and bronchus and pancreas

Top five cancers: Lung and bronchus, prostate, colon and rectum, stomach, and non-Hodgkin's lymphoma

#### Hawaiian Women:

(For the years 1988-1992)<sup>12</sup>

- Are tied with African Americans for the second highest cancer mortality (second only to Alaska Natives).
- Of all women and all ethnic groups:
  - Have the highest death rate for cancers of the stomach and uterus
  - Have the second highest incidence rates for cancers of the lung and bronchus

Top five cancers: Breast, lung and bronchus, colon and rectum, uterine, and stomach

### *Cancer in Pacific Islanders*

Cancer surveillance and databases are rudimentary or non-existent in most of these jurisdictions, making cancer rates unknown.

What is known is that cancer is among the top three causes of death. The most commonly reported cancers for males were cancers of the lung and prostate, and for females, cancers of the breast, cervix, and lung.

### *Challenges*

- A history of oppression, higher prevalence of behavioral risk factors, ineffective cancer prevention and control efforts, and poor access to state-of-the-art services for cancer prevention, early detection, and treatment (including low representation in clinical trials) contribute to increased cancer risk and mortality among Native Hawaiians and other Pacific Islanders.
- Many Native Hawaiians and Pacific Islanders are socio-economically disadvantaged and underserved in terms of access to health and social services.
- In the United States, many Pacific Islanders do not speak English at home.
- There is a general distrust of research among island communities. This distrust can also have negative consequences for those participating in a trial, such as poor compliance or avoidance.
- Geographic barriers are a problem for many Pacific Islanders; clinical trials are unavailable for most Western Pacific and Samoan communities and rural Hawaiian communities.
- The conduct of many clinical trials lacks cultural sensitivity and does not address language needs; it also does not interpret cultural behaviors and preferences.

### *Potential Solutions*

#### Cultural strategies:

- Tailor the educational outreach to the culture and use “cultural brokers” (members of the community) to reach other community members.
- Include the family unit, which for many Native Hawaiians and Pacific Islanders includes extended family members and friends, when educating about the risks and benefits of clinical trials. The role of the woman is central to the family in many Pacific Island cultures.
- Ensure that the informed consent process truly represents the participant’s understanding of the risks and benefits of the clinical trial. Involving family, members from the participant’s community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

#### Program strategies:

- Use personal contacts through a family member or a friend to do education and outreach.
- Explain the benefits of research to the community at large.
- Address issues of medical care that are not covered by clinical trials, as these are an important concern for participants who may not have insurance or are underinsured.

## **Native Americans and Clinical Trials** <sup>14,15</sup>

### *Background*

A person who is considered Native American has origins in any of the original peoples of North or South America (including Central America) and maintains tribal affiliation or community attachment.

The term “Native American” refers to:

- American Indians
- Alaska Natives:
  - Aleuts
  - Eskimos [Athap(b)asc(k)ans]

Native Americans are made up of culturally distinct and diverse communities. The United States contains 511 federally recognized tribes, with Native American people living in every State. The largest tribes are Cherokee and Navajo. More than 9 percent of the U.S. population reported American Indian or Alaska Native status in the 2000 Census.<sup>1</sup>

### *Indian Health Service*

There are more than 300 hospitals and health clinics, located on or near Indian reservations, run by the Indian Health Service (IHS). In recent years, many tribes have assumed management of some of these health care facilities.

The Indian clinics and hospitals are unable to provide the high-tech medical care needed to diagnose and treat cancer. For this reason, the IHS Contract Health Services program pays for Indian health care provided by non-IHS providers. However, this program is chronically short of funds. Depending on the region/tribe, its local priorities, and funding remaining in the service contract, certain treatments may not be available. At present the Contract Health Services does not reimburse for many treatments that are deemed “experimental,” which keeps many Indian people out of clinical trials.

Although 54 percent of Native Americans live in urban areas, less than 2 percent of the IHS budget is spent in urban clinics.<sup>6</sup> These clinics are severely underfunded and must rely on other sources of support, including Medicaid revenue. Many urban Indians choose to return to their home reservations for care.

Based on 3-year averages, American Indians and Alaska Natives were the least likely of the major racial groups to have health insurance.<sup>1A</sup>

### **Cancer in Native Americans**

*(Unless otherwise noted, all data is age-adjusted incidence or mortality rates between 1992 and 1999.)<sup>3</sup>*

While American Indian/Alaska Natives experience some of the lowest cancer rates among all ethnic groups, they do experience higher incidence and mortality for certain cancers. Cancer is the second leading cause of death among Native Americans and is the leading cause of death among Alaskan Native women.<sup>16,17</sup>

#### **American Indian/Alaska Native Men:**

- Of all men and all ethnic groups, have the highest mortality rate for kidney and renal cancer

Top five cancers: Prostate, lung and bronchial, colon and rectal, kidney and renal pelvis, and stomach

#### **American Indian/Alaska Native Women:**

- Of all women and all ethnic groups,
  - Have the highest incidence rate of gallbladder cancer
  - Have the highest mortality rate for kidney and renal cancer

Top five cancers: Breast, colon and rectal, lung and bronchial, uterine, and ovarian

### *Alaska Natives*

(For the years 1988-1992)<sup>12</sup>

Alaska Native men had the highest rates of getting colon and rectal cancer among all ethnic groups.

In this same time period, Alaska Native women had the highest rates for getting and dying from colon, rectal, and lung cancer among ethnic groups, and their rates of getting cervical cancer were twice as high as those for White women.

The top cancers:

- Men: Lung and bronchus, colon and rectum, prostate, and stomach
- Women: Breast, colon and rectum, lung and bronchus, and cervical

### *American Indians (living in New Mexico)*

American Indian men had the highest rates of all ethnic groups of getting kidney cancer. In this same time period, American Indian women had higher rates of cervical, and ovarian cancers than the U.S. White female population.

The top cancers in American Indians:

- Men: Prostate, colon and rectal, kidney and renal pelvis, and lung and bronchus
- Women: Breast, ovarian, colon and rectal, gallbladder, and uterine

### *Challenges*

- A history of disrespect, racism, and poverty has contributed to a distrust of science and research by Native American populations. To protect the interests of Native American people, many tribes have their own Institutional Review Board (IRB), in addition to those required by the Indian Health Service (IHS) or tribal facility. Successful clinical trial outreach requires that the investigator work closely with the tribal IRB in addition to those of the IHS.

- Native Americans are a culturally distinct and diverse community. Their beliefs about cancer and experiences with diabetes, alcoholism, poverty, and traditional roles can significantly affect the success of clinical trial education programs.
- On average, Native Americans are younger, have a lower rate of high school completion, and have higher rates of poverty and unemployment than Whites.<sup>6</sup>
- Many Native people do not have access to quality health care.
- Many tribes do not have a word for cancer in their languages, and historically the disease was thought of as something that affected only the “White man.” Some Native Americans may hold a fatalistic attitude toward cancer, and fear that if they talk about cancer or even think about it, they might catch it.
- It is unlikely that Native Americans would participate in a cancer trial without endorsement from other Native Americans, yet there are few cancer survivors to serve as role models.
- Informed consent forms and procedures may serve as a barrier to recruitment because the language used in such forms may not be well understood.
- Because of other pressing health issues, such as diabetes, obesity, and substance abuse, in addition to extreme poverty, cancer screening and treatment may not be as important to some Native people.
- There may be a tribal taboo on the loss of body parts that needs to be discussed in relation to clinical trials.
- Transportation is an important barrier for Native Americans who live in rural areas.
- Differences in communication styles are important to consider. Many Native Americans are reserved, reluctant to ask questions, or don’t discuss their health problems. Body language also is important, with respect for personal space and friendly gestures such as smiling and eye contact being key.
- Traditional roles are such that women are usually caretakers who often place their needs last. In addition, Native American women value modesty and privacy, and many Native American couples find a male health care provider for women unacceptable.



### *Potential Solutions*

#### Cultural strategies:

- Use group activities such as sharing and caring for others because they are universal concepts among Native people, and should be a part of any clinical trial education program.
- Incorporate the use of traditional healing ceremonies as well as spiritual connections, which can be very important for people in these communities.
- Family plays a central role in American Indian life. The needs of the family may take precedence over the needs of the individual. When appropriate, the patient's family should be involved in the decision-making process.
- Ensure that the informed consent process truly represents the participant's understanding of the risks and benefits of the clinical trial. Involving family, members from the participant's community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

#### Language strategies:

- Use easy-to-understand language and a gentle approach to education and outreach. Try to include materials that portray Native Americans.
- Make sure that patient consent forms are understood. Reading out loud or encouraging consultation with others may be important.

Program strategies:

- Emphasize that participation in a trial can help improve cancer care for the next generation.
- Use stories and visual tools that focus on the family.
- Use one-on-one or small group education and outreach techniques to respect privacy.
- Work with community or tribal elders, such as community health representatives and public health nurses, to find out the best ways to conduct outreach and education efforts.
- Find out if transportation is needed to get to the site.
- Use public service announcements on Native American radio.

*Key Messages*

- Messages should be culturally relevant and include issues related to family and community.
- Tribal beliefs are very diverse and programs should be designed on a site-specific basis with the help of tribal advisors.

## Hispanics and Clinical Trials

### *Background*

The terms “Hispanic” and “Latino” refer to people born in North, Central, and South America, and in the Caribbean whose language is Spanish. Someone who is Hispanic or Latino is a person of Mexican, Puerto Rican, Cuban, Central or South American, or other Spanish culture or origin, regardless of race.

In the mainland United States today the largest groups within the Hispanic community are:

- Mexican (58.5 percent)
- Puerto Rican (9.6 percent)
- Central American (4.8 percent)  
(Salvadorian, Guatemalan, Honduran, Nicaraguan, Panamanian, and other people from countries in Central America)
- South American (3.8 percent)  
(Colombian, Ecuadorian, Peruvian, Argentinean, Venezuelan, Chilean, and other people from countries in South America)
- Cuban (3.5 percent)<sup>1</sup>

The Hispanic population is the fastest growing ethnic group in the United States. In the 2000 Census, Hispanics eclipsed African Americans to become the second largest ethnic group, with 12.5 percent of the population reporting Hispanic or Latino status. Hispanics as a group comprise many different races and ethnicities. Within these subpopulations, other differences exist according to culture, beliefs, lifestyles, and experiences, but Hispanics agree that certain commonalities go beyond specific nationalities. In general, the U.S. Hispanic population is younger, with more people per household, and has lower rates of employment, less education, and lower economic status than do Whites.<sup>6</sup>

There are 28 million U.S. residents aged 5 and older who speak Spanish at home—about 10 percent of the U.S. population. These percentages vary greatly throughout the United States; for example, states like California, Texas, and New Mexico, have approximately 30 percent of residents who speak languages other than English.<sup>1</sup>

Among all those who speak Spanish at home, almost half speak English “less than very well.” It is important to note that in 2000, 68 percent of the U.S. Hispanic population is foreign-born or had at least one parent who was foreign-born.<sup>1</sup>

### *Cancer in Hispanics\**

*(Unless otherwise noted, all data is age-adjusted incidence or mortality rates between 1992 and 1999.)<sup>3</sup>*

Although Hispanics had the largest reduction in cancer mortality rates of any U.S. ethnic group (-1.6 percent), they also had the greatest number of uninsured people. Based on three-year averages, more than 33 percent of all Hispanics lack health insurance coverage.<sup>1a</sup> A recent study showed that uninsured Hispanic women are more than two times more likely to be diagnosed with breast cancer at a later stage than other women, and uninsured Hispanic men are almost four times more likely to be diagnosed with a later stage of prostate cancer than non-Hispanics.<sup>19</sup>

While Hispanics/Latinos have lower incidence and death rates overall compared with those of African Americans and Whites, they do experience higher rates for certain cancers.

#### Latino/Hispanic men:

- Have the third highest incidence and death rates for prostate cancer

Top five cancers: Prostate, lung and bronchus, colon and rectal, non-Hodgkin's lymphoma, and stomach

#### Latina/Hispanic women:

- Have the highest incidence rates for cervical cancer and the second highest death rate from the disease.

Top five cancers: Breast, colon and rectal, lung and bronchus, cervical, and uterine

\*“Hispanic” is not mutually exclusive from Whites, African Americans, Asian/Pacific Islanders, and Native Americans.

### *Challenges*<sup>20</sup>

- Many Hispanics have strong religious and cultural beliefs. Some may believe strongly in “fatalismo” (fatalism) and “resignación” (resignation)—that diseases or illness cannot be controlled because they are inherited.
- Many may use folk remedies [such as “uña de gato” (cat’s nail)] to treat cancer, or wait until they are in serious pain to see a doctor.
- In one study, barriers that were identified by Latinas considering a cervical cancer trial included transportation, fear of getting a placebo, care of children and family, and care from a male provider.<sup>7</sup>
- Although Spanish is one language, regional dialects need to be considered when translating materials.
- The language barrier is particularly important in issues surrounding informed consent. The informed consent process is intimidating for all people and is especially so for those with limited English skills.
- Some Hispanics think that cancer treatment will only prolong life but that no effective cure exists for the disease. Even if people are treated, it is felt that the type of treatment depends on the person’s ability to pay.
- Hispanics may not obtain health care until they are very sick and cannot perform normal functions. This adds to the number and severity of health problems that need to be evaluated. However, women are more likely than men to seek medical care.
- Many in the Hispanic community feel that doctors do not communicate well with them and they do not feel well informed about trials. Many feel that doctors may have financial interests in a trial, and there is a lack of trust around participating in scientific research.
- A sense of fatalism and resignation is usually strongest in women and older men. This may make people feel that treatment is useless.
- Machismo is a barrier because men feel they are the family protectors and should not show weakness.

- Hispanics' biggest barriers to accessing health care are money, time, and language. Other common problems include lack of insurance, problems with transportation or childcare, and getting off work to see a doctor.
- Although face-to-face interaction is important, Hispanics would not welcome unknown health educators or volunteers into their homes. Men lack trust in a Federal Government source, while most women tend to trust it.

### *Potential Solutions*

#### Cultural strategies:

- Collaborate with people who are from the communities and speak Spanish. Community members can identify with people who have a direct tie to their situation. Personal interaction is very important. Testimonials from local pastors, Hispanic celebrities, or doctors who have experienced cancer themselves are beneficial.
- When translating materials, at least two bilingual, bi-cultural translators should be used to translate materials. In addition, materials should be pilot-tested with the target audience.
- Involve family members in learning about the risks and benefits of clinical trials. Sometimes children have learned to speak English more quickly than their parents, so they can be helpful in translating forms and brochures. It is important to note, however, that using children as translators has both pros and cons. It is preferable to use someone who is trained for this work.
- Ensure that the informed consent process truly reflects the participant's understanding of the risks and benefits of the clinical trial. Involving family, members from the participant's community, and culturally competent staff are some ways to help verify that the participant has received the information in a way that he or she can understand and made the decision to participate voluntarily.

#### Language strategies:

- Find respectful ways to make sure that information is understood. When people do not understand English, they may say "yes" or nod, even if they do not understand what is being said. To ensure that the person you are talking with understands what you have said, staff may ask, "Many people

have a hard time understanding information like this. I want to make sure that I explain it clearly. Could you please tell me, in your own words, what I have just said.”

- When translating materials, at least two bilingual, bicultural translators should be used. In addition, materials should be pilot-tested with the target audience.

Program strategies:

- 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 that are already working with the community.
- Use family-oriented, positive messages as much as possible to offer hope.
- Use radio and newspapers for outreach. Spanish-language media—especially television and radio talk shows—are popular sources of health-related information for many in these communities. Printed materials with many pictures/illustrations and minimal text are preferred.

## **Information on Other Underserved Groups**

### **Older Adults**

When considering older people and clinical trials, it is important to note that approximately 60 percent of all cancers occur in people aged 65 and older, and the number of people over age 65 is expected to double by the year 2033. The elderly are an important group to include in clinical trials.

Because of mobility problems, transportation (including escort assistance) is one of the most important challenges specific to older people. Literacy issues (see below) are also a challenge that must be addressed when educating older adults.

Fostering positive doctor-patient interaction is another difficulty because often the older population is reluctant to question or challenge doctors and may be afraid to offend by changing doctors. This is compounded when doctors do not refer older adults to trials because of the assumption that they are too old or sick for a trial.

Older persons are more likely to be living on fixed incomes, so the financial aspects of clinical trial participation may be heightened. The family, or other social support, is another important consideration because it is often involved in the older person's treatment and decision-making process.

It is important to inform older adults that Medicare reimburses for all routine care costs for its beneficiaries participating in clinical trials.

### **People with Low Literacy Skills<sup>19</sup>**

"Many Americans face the serious problem of not being able to read or understand information. According to the 1992 National Adult Literacy Survey (NALS), some 40 to 44 million of the 191 million adults in the United States are functionally illiterate. Another 50 million are only marginally literate. Functional literacy represents more than just the ability to read. It involves reading comprehension as well as the ability to compute, communicate, write, and solve problems. These skills are especially important for patients in acquiring general information and applying it to their specific circumstances."

"When applied to the health system, low functional literacy translates into low health literacy. Health literacy is defined as the ability to obtain, interpret, and understand basic health information and services, as well as competence and motivation to use such information and services in ways that enhance one's health. Most health-related educational materials use simplified printed materials to convey information, assuming that people can read. Most adults do read, but many have difficulty understanding what they read and applying generalized information to their own specific situation."

"One common assumption is that certain populations have low levels of functional literacy. For example, traditionally "underserved" populations such as those with low incomes are labeled as having low levels of functional literacy simply because they are, on average, less educated. However, low functional literacy is not defined by race, class, or even educational attainment."



### **Ways to Help People With Low Health Literacy Skills**

“**One-on-one assistance** is the most effective technique for educating this group. In addition to helping people gain a better understanding of the clinical trial and their health needs, one-on-one assistance fosters trust between patients and the counselors or health care professionals who help them. Comprehension should be ascertained, but not by asking, “Do you understand?” Often the “teach back” method works well.”

“**Group assistance** offers an arena in which people can obtain information from educators and through the questions asked by others in the group. This technique often supplements one-on-one counseling.”

“**Visual tools** are designed to simplify concepts such as instructions for care that are too complicated to understand in written form or through verbal communication. Visual tools are particularly useful to those who cannot read at all. Videotapes may be useful tools, but followup discussion is necessary in order to ascertain comprehension.”

### **Lesbian, Gay, and Bisexual Individuals**

The lesbian, gay, and bisexual (LGB) community is diverse in terms of cultural background, ethnic or racial identity, age, education, income, rejection or acceptance of societal stereotypes, and prejudice. As with other minority groups, discrimination and bias can play a role in inadequate medical assessment, treatment, and prevention of LGB health problems. In addition, lesbians may be at a greater risk of cancer because of issues associated with health care access, delayed or lack of childbearing, screening, and insurance.

Little information is available about specific clinical trial barriers for the LGB population. Significant barriers that must be addressed include:

- Previous negative health care experiences
- Fear of sexual orientation disclosure
- Perceived or actual exclusion from health promotion campaigns
- Misinformation about risks and screening
- Exclusion of significant others

# References

1. U.S. Census Bureau. U.S. Department of Commerce, Census 2000. Available at <http://www.census.gov>
- 1a. U.S. Census Bureau. U.S. Department of Commerce Health Insurance Coverage: 2001 Issued September 2002. Available at <http://www.census.gov>
2. Sateren, W. B., Trimble, E. L., Abrams, J., Brawley, O., Breen, N., Ford, L., McCabe, M., Kaplan, R., Smith, M., Ungerleider, R., Christian, M. C. (2002). How sociodemographics, presence of oncology specialists, and hospital cancer programs affect accrual to cancer treatment trials. *Journal of Clinical Oncology* Apr 15;20(8):2109-17.
3. Edwards, B. K., Howe, H. L., Ries, L. A. G., Thun, M. J., Rosenberg, H. M., Yancik, R., Wingo, P. A., Jemal, A., Feigal, E. G. (2002). Annual report to the nation on the status of cancer, 1973-1999, featuring implications of age and aging on the U.S. cancer burden. *Cancer* May 15;94(10):2766-2792. Supplemental data on SEER Cancer Incidence 1992-1999 and SEER Cancer Prevalence 1992-1999 Available at <http://seer.cancer.gov/reportcard/supplemental.html>
4. American Cancer Society. (2002). *Cancer facts and figures 2002*. Atlanta, GA: Author.
5. Roberson, N. L. (1994). Clinical trial participation: Viewpoints from racial/ethnic groups. *CANCER Supplement*, 74(9), 2687-2691.
6. Guilano, A. R., Mokuau, N., Hughes, C., Tortolero-Luna, G., Risendal, B., Ho, R. C. S., Prewitt, T. E., & McCaskill-Stevens, W. J. (2000). Participation of minorities in cancer research: The influences of structural, cultural, and linguistic factors. *Annals of Epidemiology*, 10(8), S22-S34.
7. Brown, D.R., Fouad, M. N., Basen-Enguist, K., & Tortolero-Luna, G. (2000). Recruitment and retention of minority women in cancer screening, prevention, and treatment trials. *Annals of Epidemiology*, 10(8), S13-S21.
8. Royal, C. D., Baffoe-Bonnie, A., Kittles, R., Powell, I., Bennett, J., Hoke, G., Pettaway, C., Weinrich, S., Vijayakumar, S., Ahaghotu, C., Mason, T., Johnson, E., Obeikwe, M., Simpson, C., Mejia, R., Boykin, W., Roberson, P., Frost, J., Faison-Smith, L., Meegan, C., Foster, N., Furbert-Harris, P., Carpten, J., Bailey-Wilson, J., Trent, J., Berg, K., Dunston, G., & Collins, F. (2000). Recruitment experiences in the first phase of the African American hereditary prostate cancer (AAHPC) study. *Annals of Epidemiology*, 10(8), S68-S77.
9. Lee, M. (1999). Breast and cervical cancer early detection in Chinese American women. *Asian-American Pacific Islander Journal of Health*, 6, 358-367.
10. Taylor, V., Jackson, J., Schwartz, S., Yasui, Y., Tu, S., & Thompson, B. (1999). Cervical cancer control in a Cambodian American population. *Asian-American Pacific Islander Journal of Health*, 6, 368-377.

11. Shinagawa, S. M., Kagawa-Singer, M., Chen, M. S., Tsark, J. U., Palafox, N. A., & Mackura, G. (1999). Cancer registries and data for Asian Americans and Native Hawaiians and Pacific Islanders: What registrars need to know. *Journal of Registry Management*, 26(4), 128-141.
12. Miller, B. A., Kolonel, L. N., Bernstein, L., Young, Jr., J. L., Swanson, G. M., West, D., Key, C. R., Liff, J. M., Glover, C. S., Alexander, G. A., et al. (Eds). (1996). *Racial/ethnic patterns of cancer in the United States 1988-1992* (NIH Publication No. 96-4104). Bethesda, MD: National Cancer Institute.
13. Papa Ola Lokahi. (May 1, 2001). Personal communication. Honolulu, HI and Tsark, J. U. (1998). Cancer in Native Hawaiians. *Pacific Health Dialog*, 5, 315-327.
14. Hodge, F. S., Weinmann, S., & Roubideaux, Y. (2000). Recruitment of American Indians and Alaska Natives into clinical trials. *Annals of Epidemiology*, 10(8), S41-S48.
15. Burhansstipanov, L. (Director, Native American Cancer Research Corporation). (April 2001). Interview. Pine, CO.
16. U.S. Department of Health and Human Services. (1997). *Regional differences in Indian health*. Rockville, MD: Indian Health Service.
17. Lanier, A. P., Holck, P., Kelly, J., Smith, B., & McEvoy, T. (1999). *Alaska Native cancer survival report*. Anchorage, AK: Alaska Native Health Board.
18. U.S. Census Bureau. US Department of Commerce, Health Insurance Coverage, by Selected Characteristics: Issued October 1999. Available at <http://www.census.gov>
19. American College of Physicians—American Society of Internal Medicine. (2000). *No health insurance? It's enough to make you sick. Latino community at great risk*. Philadelphia: Author. Available: American College of Physicians-American Society of Internal Medicine, 190 N. Independence Mall West, Philadelphia, PA, 19106.
20. National Cancer Institute. (1996). *Communicating with Hispanic cancer patients: A focus group study*. Washington, DC: Author.
21. Center for Medicare Education. (2000). *Considering health literacy*. (Issue brief, volume 1, no. 6). [Online], Available: <http://www.MedicareEd.org>

***Other sources utilized for this section include:***

- Alexander, G. A., Chu, K. C., & Ho, R. C. S. (2000). Representation of Asian Americans in clinical cancer trials. *Annals of Epidemiology*, 10(8), S61-S67.
- Atkinson, J., & Hartmuller, V. (1994). Strategies for minority recruitment. In *PCPT minority recruitment manual*. Bethesda, MD: National Cancer Institute.
- Brant, J. (1996). Breast cancer challenges in American Indian women. In K. H. Dow (Ed.), *Contemporary issues in breast cancer* (pp. 243-252). Sudbury, MA: Jones and Bartlett.

- Brant, J., Fallsdown, D., & Iverson, M. (1999). The evolution of a breast health program for Plains Indian women. *Oncology Nursing Forum*, 26(4), 731-739.
- Bunn, P., & Krebs, L. (1997). *Colorado blueprint: Women and minorities in cancer care trials*. Denver, CO: University of Colorado Comprehensive Cancer Center.
- Center for Lesbian, Gay, Bisexual, and Transgender Health. (2000). *Lesbian, gay, bisexual, and transgender health: Findings and concerns*. New York: Columbia University's Joseph L. Mailman School of Public Health.
- Chen, A. M. (1996). Demographic characteristics of Asian and Pacific Islander Americans: Health implications. *Asian-American and Pacific Islander Journal of Health*, 4, 40-49.
- Chu, K. C. (1998). Cancer data for Asian Americans and Pacific Islanders. *Asian-American and Pacific Islander Journal of Health*, 6(2), 130-139.
- Haynes, M. A., & Smedley, B. D. Committee on Cancer Research Among Minorities and the Medically Underserved. (1999). *The unequal burden of cancer: An assessment of NIH research and programs for ethnic minorities and the medically underserved*. Health Sciences Policy Program, Health Sciences Section, Institute of Medicine. Washington, D.C.: National Academy Press.
- Hughes, C. K, Tsark, J. T., Kenui, C. K., & Alexander, G. A. (2000). Cancer research studies in Native Hawaiians and Pacific Islanders. *Annals of Epidemiology*, 10(8), S49-S60.
- Kagawa-Singer, M., Millon-Underwood, S., Burhansstipanov, L., & Munet-Vilaro, F. (1994). Nursing research and underserved populations. In *Proceedings of the Third National Conference on Cancer Nursing Research*. Atlanta, GA: American Cancer Society.
- Lin-Fu, J. S. (1994). Ethnocultural barriers to health care: A major problem for Asian and Pacific Islander Americans. *Asian-American and Pacific Islander Journal of Health*, 2, 290-298.
- McCabe, M. S., Varricchio, C. G., & Padberg, R. M. (1994). Efforts to recruit the economically disadvantaged to national clinical trials. *Seminars in Oncology Nursing*, 10(2), 123-129.
- Millon-Underwood, S. (1994). Barriers to minority participation in clinical trials. In *PCPT minority recruitment manual*. Bethesda, MD: National Cancer Institute.
- Millon-Underwood, S., Sanders, E., & Davis, M. (1993). Determinants of participation in state-of-the-art cancer prevention, early detection/screening, and treatment trials among African-Americans. *Cancer Nursing*, 16(1), 24-33.
- National Cancer Institute. (1997). *Talking to patients and the public about cancer clinical trials: Findings from NCI's "Science Awareness Research."* Bethesda, MD: Author.

National Clearinghouse for Alcohol and Drug Information. (2000). [Online], Available: <http://www.health.org/features/multicultural>

Paskett, E. D., DeGraffinreid, C., Tatum, C. M., & Margitic, S. E. (1996). The recruitment of African-Americans to cancer prevention and control studies. *Preventive Medicine*, 25, 547-553.

Shinagawa, S. M., Kagawa-Singer, M., Chen, M., Tsark, J., Palafox, N., & Mackura, G. (1999). Cancer registries and data for "Asian Americans" and "Native Hawaiians and Pacific Islanders": What registrars need to know. *Journal of Registry Management*, 26(4), 128-141.

Susan G. Komen Breast Cancer Foundation. (1999). Suggestions to enhance the participation of women of color in breast cancer prevention trials. In *Clinical Trial Community Outreach Efforts*. Dallas, TX: Author.

The Mautner Project for Lesbians with Cancer. (2001). [Online], Available: <http://www.mautnerproject.org/>

Thomas, S. B., Quinn, S. C., Billingsley, A., & Caldwell, C. (1994). The characteristics of Northern Black churches with community health outreach programs. *American Journal of Public Health*, 84(4), 575-579.

Underwood, S. (2000). Minorities, women and clinical cancer research: The charge, promise, and challenge. *Annals of Epidemiology*, 10(8), S3-S12.

## **2. Ways to Educate Yourself**



## 2

# Ways to Educate Yourself

### **What You Can Do**

- Use NCI resources to keep up-to-date with new clinical trial information, including *www.cancer.gov*
- Find local clinical trials in your community
- Attend conferences, meetings, and workshops

### **Why?**

- To continue to learn about developments in cancer clinical trials
- To be an informed community educator

### **Introduction**

One of the most important ways to get started in clinical trial outreach and education is to make sure you learn as much as you can about clinical trials. This section provides resources that you can use to learn more about clinical trials.

### **Education and Outreach in Action**

A 60-year-old insurance salesman was treated for prostate cancer 2 years ago. He recently decided that he wanted to learn more about clinical trials after he saw a TV special about them. "I'm amazed about what I don't know about what clinical trials are going on right here in (my community). I want to make sure that men who go to my support group understand information about clinical trials."

# 1. Use NCI Resources

The NCI Web site, *www.cancer.gov*, contains information from PDQ®, including the latest information about cancer treatment, screening, prevention, genetics, supportive care, and complementary and alternative medicine, as well as a registry of cancer clinical trials. Clinical oncology specialists review current literature from more than 70 medical journals, evaluate its relevance, and synthesize it into clear summaries, which are then reviewed monthly and updated as needed based on new information. Most cancer information summaries appear in two versions: a technical version for the health professional and a nontechnical version for patients, their families, and the public. Many of the summaries are also available in Spanish.

The NCI Web site also includes approximately 100 fact sheets on various cancer-related topics and information on ordering NCI publications, as well as educational features and news summaries concerning the latest results from cancer clinical trials.

The clinical trials registry (PDQ) contains more than 1,800 ongoing clinical trials, with information about studies around the world. All clinical trials undergo review prior to inclusion. Although no single resource lists every cancer clinical trial being conducted in the United States and abroad, PDQ is the most comprehensive cancer clinical trials registry, and contains information about trials sponsored by NCI, the pharmaceutical industry, and some international groups. Users can narrow their retrieval by multiple parameters, such as stage of disease, phase of trial, treatment modality, and geographic location. PDQ also contains an archival file of more than 11,000 clinical trials that are no longer accepting patients, including contact information for the principal investigators of trials that may not yet be published in the biomedical literature.



## **Accessing Information from NCI**

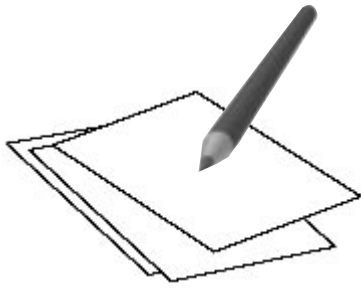
### **NCI's Cancer Information Service**

NCI's Cancer Information Service (CIS) is a national information and education network for patients, the public, and health professionals. From regional offices covering the entire United States, Puerto Rico, and the U.S. Virgin Islands, trained staff provide the latest cancer information through a toll-free telephone service. Staff can respond to calls in either English or Spanish.

#### *How to Reach the CIS*

The toll-free number is 1-800-4-CANCER (1-800-422-6237). For deaf and hard of hearing callers with TTY equipment, the number is 1-800-332-8615. Hours of operation are Monday through Friday, 9:00 a.m. to 4:30 p.m., local time. Callers also have the option of listening to recorded information about cancer 24 hours a day, 7 days a week.

See the guide to clinical trial resources on page 52 for other sources of clinical trial information.



## 2. Find Local Clinical Trials in Your Community

A good way to educate yourself about clinical trials is to become familiar with both the local institutions conducting clinical trials and the clinical trials themselves. As you begin to think about ways you would like to take action, it will be important for you to understand where clinical trials are taking place.

### Creating a List

You may want to create a list that identifies cancer clinical trials in your community. Collecting this information using the “Clinical Trial Community Resource Sheet” provided on the next page can help you direct interested community members to the best clinical trial resources available.

This information can help you:

- Understand clinical research in your community
- Understand some of the barriers to participating in clinical trials in your community
- Provide local clinical trial resources to the organizations or individuals with whom you are working

# Clinical Trial Community Resource Sheet

You may use this sheet as a reference for yourself or your organization, or you may develop it into a local fact sheet for distribution. Remember that clinical trial information becomes out of date very quickly, so you will need to update this sheet at least every 3 months. To locate information needed to complete this worksheet, you can:

- Call the National Cancer Institute’s (NCI’s) Cancer Information Service at 1-800-4-CANCER. Trained information specialists can search the NCI clinical trial database, PDQ, and provide contact information for local trials.
- Visit the Web site *www.cancer.gov*, to search the PDQ database on your own.
- Use the clinical trial resources sheet that follows for other ways to find local trials.

Type of Trial/ Type of Cancer	Phase	Protocol ID#	Institution	Point of contact	Phone number

## Guide To Finding Clinical Trial Resources

	<b>What is it?</b>	<b>How do I access it?</b>	<b>What will it provide?</b>
<b>National Cancer Institute's PDQ</b>	<p>Database produced by NCI</p> <p>Registry of approximately 1,800 active cancer clinical trials</p>	<p>Go to <a href="http://www.cancer.gov">www.cancer.gov</a></p> <p>Go to the clinical trials area and follow the search directions</p> <p>OR</p> <p>Call 1-800-4-CANCER</p>	<p>Summaries about clinical trials conducted by NCI-sponsored researchers, the pharmaceutical industry, and some international groups</p>
<b>National Library of Medicine</b>	<p>Database produced by NIH</p> <p>Registry now lists 4,000 primarily NIH-supported clinical studies on many conditions, and more will be added</p> <p>All trials on PDQ are listed in this database</p>	<p>Go to <a href="http://www.clinicaltrials.gov">www.clinicaltrials.gov</a></p> <p>Can browse by disease or sponsor or insert key words</p>	<p>Summaries about clinical trials for a wide range of conditions—most of the trials listed are sponsored by NIH</p>
<b>Food and Drug Administration's Cancer Clinical Trials Directory</b>	<p>A list of sources prepared by FDA's Office of Special Health Issues</p> <p>Guides user to other Web locations for institutions that conduct or list cancer clinical trials</p>	<p>Go to <a href="http://www.fda.gov/oashi/cancer/trials.html#table">www.fda.gov/oashi/cancer/trials.html#table</a></p> <p>Can browse by disease for different sources</p>	<p>Web addresses and telephone numbers</p> <p>Information listed on the Web sites in this directory varies widely</p>
<b>Local Cancer Center Web Sites</b>	<p>Locally produced Web sites that include listings for trials sponsored by NCI and some pharmaceutical companies</p> <p>Good supplementary resources for locating clinical trials; a cancer center may begin participating in an NCI-sponsored trial before the center's information is listed in CancerNet/PDQ</p>	<p>Different sites can be found through:</p> <ul style="list-style-type: none"> <li>• <a href="http://www.cancer.gov">www.cancer.gov</a></li> <li>• Local institutions</li> <li>• Call 1-800-4-CANCER for a center near you</li> </ul> <p>Information on trials taking place at NCI's Clinical Center in Bethesda, Maryland, is available at <a href="http://ccr.nci.nih.gov">http://ccr.nci.nih.gov</a></p> <p>Some centers may also have telephone information centers</p>	<p>Information that varies from center to center</p> <p><a href="http://www.cancer.gov">www.cancer.gov</a></p>
<b>Examples of Pharmaceutical Resources/ Internet Clinical Trial Matching Sites</b>	<p>Pharmaceutical Research and Manufacturers of America (PhRMA) publishes a list of new cancer drugs in development</p> <p>CenterWatch's Clinical Trials Listing Service and EmergingMed.com list many industry- and Government-sponsored trials</p>	<p><b>PhRMA</b> Go to <a href="http://www.phrma.org">http://www.phrma.org</a></p> <p>Click on "New Medicines in Development" and search by disease. The drugs are listed by cancer type or call 202-835-3400.</p> <p><b>CenterWatch</b> Go to <a href="http://www.centerwatch.com">www.centerwatch.com</a></p> <p>Click on "Trial Listings"</p> <p><b>EmergingMed.com</b> Go to <a href="http://www.emergingmed.com/">http://www.emergingmed.com/</a></p>	<p>Descriptions, sites, telephone numbers, and investigator names by State</p>

### **3. Attend Conferences, Meetings, and Workshops**

Some people find that attending scientific meetings keeps them up to date, helping them become better educators.

#### **Attending Local Meetings and Courses**

Many local hospitals and cancer centers hold public events, educational workshops, and lectures on a variety of topics related to clinical trials. Contact your local institution's community relations department to find out if it holds such events and when they are scheduled.

#### **Learning through the Internet**

Many of the large cancer centers have free online courses for the public, some of which may be related to clinical trials. See the Web site *www.cancer.gov* for a list of NCI-designated cancer centers and their Web sites to learn more about specific online courses.

#### **Attending National Meetings**

Scientists present the results of their research at large meetings before the results are published in the literature. Two annual meetings of importance to cancer research are:

1. American Association of Cancer Research in March of each year (Web site is *www.aacr.org*)
2. American Society of Clinical Oncology in May of each year (Web site is *www.asco.org*)

Both feature daily meeting updates on their Web sites.

Many scientific meetings are open and free to the public. Others have reduced fees for survivors or advocates.

The NCI event calendar provides a centralized and easily accessible place to obtain information about many cancer-related scientific meetings and events nationwide. The calendar can be found on the Web at *www.cancer.gov*. You can also call 1-800-4-CANCER to get information about these meetings.

To help you plan educating yourself, see the Plan for Action in the Appendix.

### **3. Ways to Educate Others, One-on-One**

# 3

## Ways to Educate Others, One-on-One

### ***What You Can Do***

- Find opportunities to talk to others—neighbors, friends, and coworkers—about clinical trials, common myths surrounding clinical trials, and where to find more information on clinical trials
- Help others understand how to evaluate research in the news

### ***Why?***

- To address the many misconceptions that exist about clinical trial treatment options
- To provide clinical trial information to individuals making treatment or prevention decisions

### ***Introduction***

As someone who knows a lot about clinical trials, you will often be given the opportunity to talk to individuals about their cancer, cancer of a loved one, or being at high risk for cancer. One of the best ways to educate other people is to talk informally about what you are learning about clinical trials.

As you seek opportunities to speak to others, keep in mind that it's important to be able to answer common questions about clinical trials. But it's also important to admit when you don't know the answers, and to seek other resources for information.

This section will guide you through some ideas to talk to others about clinical trials.

For more information on strategies for clinical trial education, and working with ethnically diverse populations, see section 1.



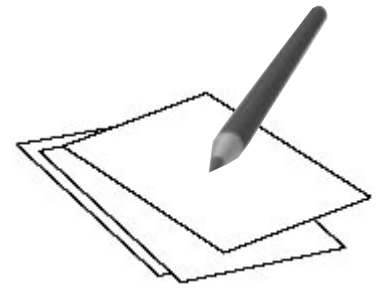
## ***Education and Outreach in Action***

A high school teacher who is a cancer survivor is finding ways to spread the word about clinical trials.

Because she is active in her church, she finds herself talking to many people whose lives have been touched by cancer. She says, “People call me the cancer lady, but I don’t care.” She is often asked to talk to fellow church members about her experience with cancer and her treatment on a clinical trial.

She says, “I used to think that clinical trials treated people like guinea pigs—a lot of folks do. I think people need to know the facts about clinical trials. No one likes to hear their own name associated with the word ‘cancer.’ But, how many times does someone hear about a co-worker, a friend, or a neighbor who was just diagnosed with cancer? That’s how I approach other people. I tell them that it’s important that cancer patients talk to their doctor about all their options. That’s the best help that I can provide someone.”

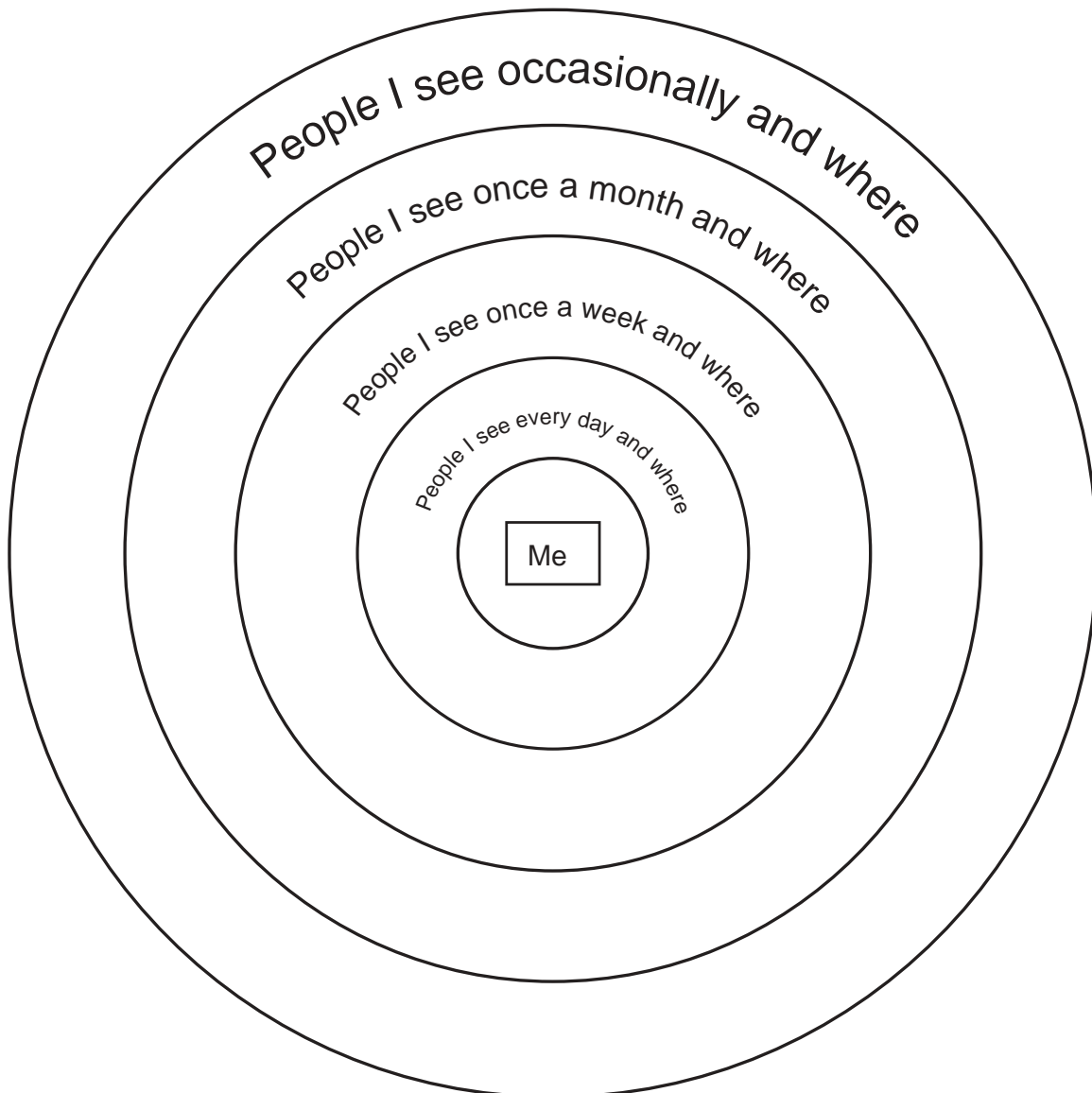
# 1. Get Started—Circle of Connections With Individuals



## Finding Opportunities to Talk to Others

You may be active within one specific organization or have connections with many different community groups. As you think about the importance of clinical trials, think about where and how you can become a clinical trial resource to people you know. How can you help other people learn about clinical trials?

In the circles below, write down the names of at least four people with whom you feel you can discuss clinical trials. Think about these people as you work through this section.



## 2. Talk to Others—Tips

One way to provide support to others is to help those diagnosed with cancer, and those at high risk for developing cancer, to learn more about the option of participating in a clinical trial. Equally important is explaining clinical trials to those who are not facing a cancer diagnosis, but who are interested in why they are important.

Here are some tips to get you started on this conversation; keep in mind that conversations need only be a few minutes long:

1. Express empathy for the person's situation.
2. Use active listening skills.
3. Ask whether the person would like to hear some information about cancer clinical trials.
4. In your own words, talk about why clinical trials are important.

If relevant:

5. Discuss clinical trials as an option for treatment and prevention. Remember that clinical trials are not the right option for everyone.
6. Review some of the benefits and risks to participating in clinical trials.
7. Respond to common myths associated with clinical trials.
8. Explain some key ways that participants' safety is protected in clinical trials.
9. Explain some of the barriers associated with clinical trials for patients.
10. Know how to answer common questions about clinical trials. But, admit when you don't know the answers. Have resources available (such as those in this series) and the Cancer Information Service's 1-800-4-CANCER.
11. Be aware of cultural sensitivities around clinical trial issues. (See section 1.)
12. Understand the local clinical trial resources in your community.

### 3. Help Others Understand How to Evaluate Research in the News

People often hear about the results of clinical trials from overly positive or overly negative media reports. These reports often influence the way they think about clinical trials and can help to reinforce common myths. When you find yourself talking to others about clinical trials, it will be important for you to respond to these reports in a thoughtful way. Here are some questions to consider as you help others evaluate these types of media reports.

Some of these questions will not be answered by a short article in a newspaper. You may need to locate the original research article by using PubMed or another medical library database.

#### 1. Who wrote this article?

Any good news article should list the author, his or her institution, and if the author is not a reporter, his or her background. Reporters are trained to be objective, but they often report on what seems newsworthy and may miss key facts. Some institutions may not list the author of an article, in which case the institution itself should be considered the author. Newspapers often use “wire reports,” such as the Associated Press (AP), and often include materials excerpted directly from press releases.

#### 2. What is the basis of the information in the article?

In addition to identifying who wrote the article you are reading, the evidence that material is based on should be provided. Medical facts and figures should have references (such as an article in a medical journal or the consensus of a meeting of experts reviewing research evidence); anecdotal evidence, opinions, or advice should be clearly set apart from information that is “evidence-based” (that is, based on research results).

**3. Does the article say if the study involved people, animals, or cells in the laboratory?**

In early cancer research or preclinical testing, scientists test promising new cancer treatments in the laboratory and in animal models. This is done to find out if the treatment has an anticancer effect and if it is safely tolerated in animals. Only if a new drug proves promising in the lab does it move to testing in humans. Clearly, preclinical research only suggests future direction, and cannot be applied directly to all people with a particular type of cancer.

**4. Does the article include information on the phase of the study and number of participants?**

Clinical research is generally conducted in three different types of studies called phase 1, 2, and 3 studies, reflecting the order in which they take place. Each phase of a study has a different goal and, although they are often conducted separately, they can be conducted as part of the same study.

News articles may not mention the study phase. However, if an article refers to an “early” study, it generally refers to a phase 1 or 2 study. If an article discusses different groups of patients getting different types of treatment or different doses of a drug, or mentions that a study was “randomized,” it usually means the study was a phase 3 study. Occasionally, phase 2 studies may be randomized.

**5. If the study includes a new agent or device, has it been approved by FDA?**

The Food and Drug Administration (FDA), an agency of the U.S. Department of Health and Human Services, must review all test results for new agents to ensure that products are safe and effective for specific uses.

FDA applies two key questions to each application for drug approval:

- Do the results of well-controlled studies provide substantial evidence of effectiveness?
- Do the results show the product is safe under the conditions of use in the proposed labeling? (In this context, “safe” means that potential benefits have been determined to outweigh any risks.)

Only when FDA makes the approval does it allow the drug to be “labeled” for a specific use. This label includes information on what kinds of people should be given the drug, the dosage of the drug, and information on safety and adverse effects. It is only at this time that the new drug can be given to people outside of a clinical trial.

**6. What were the characteristics of the people who participated in the study?**

Sometimes, studies are done only in specific groups of people—for example, people in a particular age group, or those whose cancer is at a particular stage. This may mean that the study results may not apply to those who are not members of these specific groups.

**7. Does the article discuss the benefits and risks for those participating in the study in a balanced way?**

Just as there are potential side effects to all medications, there are benefits and risks to all clinical trials. The article should fully describe the known benefits and risks, as well as note that there may be side effects or risks that are unknown. If the article appears to be one-sided or overtly positive, you may be justified in having some skepticism about the author’s motives.

**8. Who funded the study?**

Studies can be funded from many sources. The most common sources in the United States are the Federal Government, universities, private foundations, or industry (such as pharmaceutical companies or companies making a device that is being tested). If a researcher has received funding from a source, such as the Federal Government, that uses a peer review process for evaluating and awarding research funds, the research findings will be more credible and less subject to bias than if the sponsor has a vested interest in the results.

**9. Who conducted the study?**

It is important that research studies have scientific review and ongoing oversight. Studies that have been through this level of scrutiny are more likely to produce high quality results than those that have not been reviewed.

**10. Were the study results “peer reviewed” or just announced at a meeting or through a press release?**

If the news article was based on a published article in a peer-reviewed journal, it means that other experts have examined and critiqued the researchers’ methods and findings.

To help you plan to educate others, see the Plan for Action in the Appendix.

## **4. Ways to Conduct Community Outreach and Education**



# 4

## Ways to Conduct Community Outreach and Education

### ***What You Can Do***

- Find opportunities and develop a strategy to speak about clinical trials and/or:
  - Present NCI Clinical Trials Education Series slide programs or the awareness video, “Cancer Trials...Because Lives Depend on It”
  - Distribute educational booklets and brochures (see the complete list of materials at the front of this guide):
    - At meetings or events
    - Through doctors’ offices
    - Through a booth at health fairs or events for local research institution(s)
- Write articles for newsletters; post articles on Web sites
- Host an information session or community forum on clinical trials
- Form a clinical trial advocacy coalition

### ***Why?***

- To provide information to people about cancer clinical trials before they are faced with a cancer diagnosis
- To provide information about a specific cancer trial to members of your community
- To provide people with the tools they need to find out about trials in your community
- To educate interested members of the public about the importance of cancer clinical trials
- To help debunk myths about clinical trials in the community
- To develop a community strategy for clinical trial outreach

## **Introduction**

This section provides ideas for educating your community about clinical trials. Whether you use personal contacts, community organizations, or health-related organizations, remember that combining strategies to get clinical trial messages out to your community will make your outreach more successful. Using different ways to get out critical messages about clinical trials increases the chance that people in your community will absorb and remember them.

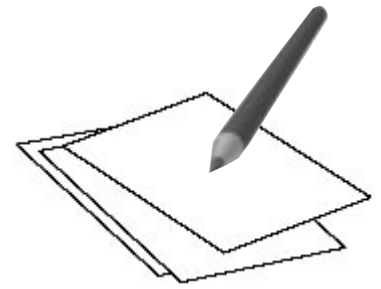
See the NCI *Trainer's Guide for Cancer Education* for ways to teach others about these issues. Information about ordering can be found at the front of this guide.

## **Education and Outreach in Action**

A chapter of a local cancer advocacy organization had been trained about clinical trials. Several members organized a community forum, inviting the local researchers on a breast cancer prevention trial to speak. They also invited several women who considered participating in the trial. More than 75 people attended the forum at the local YMCA.

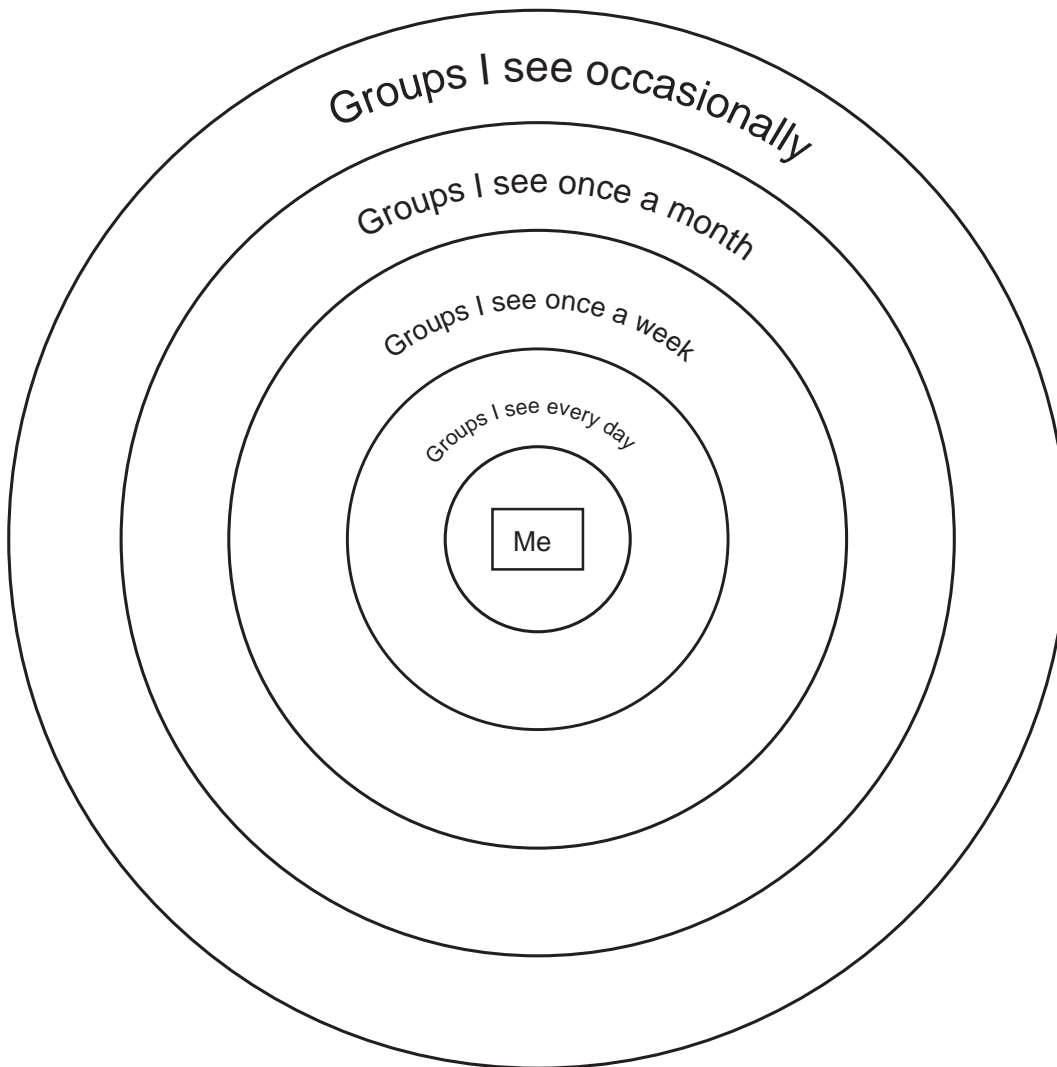
A local cancer support group has a Web site and a quarterly newsletter. The group's education committee copied the articles included here and put them on its Web site and in its newsletter. At the next meeting, the group decided that all of its members should learn about clinical trials.

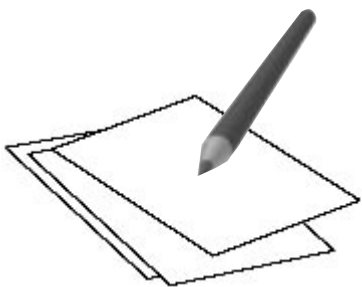
# 1. Get Started—Circle of Connections With Groups



Everyone has connections with different groups in his or her community. Some people represent a specific organization. Others may have connections with many different community groups. As you think about the importance of clinical trials, think about where and how you can become a clinical trial resource to these groups. How can you help engage the organization in this issue?

In the circles below, write down at least five groups or organizations you feel you can educate. The groups don't need to be cancer-related, but should have a health focus. Keep these groups in mind as you complete this section.





## 2. Expand Your Organization's "Community"

It is important to think broadly about other organizations with which you can partner, whether you are part of a group or organization that already has a clinical trial agenda, or if you want your group to develop one.

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 are likely to share clinical trial priorities
- Partnering with organizations with which you haven't yet worked
- 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 will be important to consider balancing your efforts between groups that are easy to reach with others that will take more effort.

For more information on working with different ethnic/minority groups, see section 1.

## Organization Contact Worksheet

Organization Type	Examples in My Community	Contact People in Community
Advocacy organizations		
African American, Asian American, Latino, and Native American-based organizations		
Cancer-oriented nonprofit organizations		
Cancer support groups		
CDC Breast and Cervical Cancer Early Detection Program coalition members (Hint: check with your State health department)		
Chambers of commerce		
Community cancer centers		
Community health centers / public health clinics		
Employee associations of large companies		
Health care professional associations (doctors, nurses, social workers, health educators, etc.)		
Hospital education departments		

Organization Type	Examples in My Community	Contact People in Community
Hospitals and research institutions		
Housing organizations		
Labor union locals		
Lesbian/gay organizations		
Men's organizations		
Religious organizations/houses of worship		
Senior citizens' organizations		
Service organizations, such as Rotary, Lions, Kiwanis, Jaycees, Junior League		
State cancer control committees		
Veterans' groups		
Women's organizations		

### **3. Prioritize—Develop a Strategy and Philosophy for Outreach and Education**

As you begin to consider different outreach and education activities, you'll need to think strategically. Answering the following questions can help ensure the success of your outreach and education efforts.

#### **Setting Objectives**

- Why should we get involved with clinical trial outreach and education?
- What is the problem we want to address? (Be realistic!)
- What is the goal or expected outcome of our efforts?

#### **Conducting Research**

- Is our clinical trial advocacy goal clear and realistically attainable?
- Who are our primary allies?
- Have similar clinical trial education efforts been attempted in the past, either in our community or elsewhere? What lessons can be learned from them?
- What is the most compelling information that we can use to make our case? (Think about your targets as you answer this question.)

#### **Considering “Targets”**

In figuring out who your audience is, keep in mind that the “general public” is not specific enough to be a target audience. Ask:

- Who are the key targets for our efforts?
- Are there key people who can help our efforts in reaching these audiences? Leaders of professional organizations? Community leaders?
- Who is our “community,” and how can it be expanded? (Use your sheet on page 67.)

## Considering a Philosophy

The questions that follow represent a simplified framework for outreach and education efforts that could be large and complex. The more complete your initial answers, the more likely it is that your efforts will proceed smoothly and successfully. Consider the following:

- What are the most appropriate ways for our community to learn about clinical trials?
- Do we want to simply inform people? Or do we want to influence attitudes and change behavior?
- Which channels best fit our message about clinical trials?
- What avenues are most likely to be credible to and accessible by our community or our “targets”? Meetings? Trainings? The media? Mail? Networks of contacts? Doctors’ offices? Community races?
- How can we complement existing cancer awareness activities, such as national theme months (e.g., October is Breast Cancer Awareness Month), local health fairs, and local hospital events, in our efforts?
- Who are our best spokespeople? How can we use community leaders in our outreach efforts?
- Does timing play an important role in some of our planned activities? Will other pending issues claim our targets’ attention?

### Tip

**If you are not from the population(s) you seek to work with, it is critical that you or your organization develop partnerships with organizations from those communities.** Keep in mind that different communities find different information sources credible and may respond better to certain outreach strategies. Forming partnerships with these organizations, rather than simply asking them to join existing efforts, can help ensure that your educational and outreach efforts will be successful.



## **4. Use NCI Audiovisual Materials to Make Presentations**

You can present clear information about clinical trials to local groups by using one of NCI's three slide programs in the Clinical Trials Education Series or the awareness video, "Cancer Trials...Because Lives Depend on It." Most of these materials are geared to the general public and feature interactive discussion guides or talking points. By showing these materials at a meeting or as part of a larger program, you can generate discussion on the importance of clinical trials in your community. (See ordering information at the front of this guide.)

## **5. Distribute Materials**

Distributing materials is more than putting brochures out on a display table. Consider the following ideas.

### **At Events or Meetings**

- At meetings in which everyone receives a packet of material, target educational materials by inserting a cover letter about clinical trials signed by an influential person in your community.
- At events, such as health fairs or lectures, place materials out on a table. Offer candy or water and cups. Instead of standing behind a table, think about standing in front, to make your table look more inviting. Greet people warmly.

### **Through Doctors' Offices**

Partnerships may be developed with health care providers to educate their patients about clinical trials. Primary care providers may be willing to discuss prevention trials with their healthy patients. Some may be willing to send out materials to their patients.

### **Through a Booth at Health Fairs or Events for Local Research Institution(s)**

Often local institutions will be eager to host a booth to discuss the clinical trials they offer. These booths can also enhance community awareness around clinical trials.

## 6. Write Articles for Local Newsletters and Web Sites

Local organizations' Web sites, listservs, and newsletters can be targeted and effective ways to reach community members. Use the sample newsletter articles provided here to submit to organizational newsletters and Web sites.

Your organizations' own publications are one likely avenue. Other organizations may also be eager to publish information. Review each organization's media to understand better what they are likely to publish:

- Who is the target audience?
- What types of articles are currently available?
- Who can help get this article published/online?

### The Pros and Cons of Using Newsletters

#### Pros

- Newsletters are tools for intra- or interorganization communication.
- Newsletters help show how organized your group is and help keep your members and colleagues current on your activities.
- Newsletters have a very broad audience.

#### Cons

- Newsletters take time, money, and skill to produce.
- Newsletters are not well suited for publishing late-breaking news.

## Sample Newsletter Article 1

# Newsletter

## Clinical Trials: An Important Part of Our Mission

*[Insert how clinical trials relate to your organization's mission, and why you are getting involved with clinical trial outreach and education.]*

Just as there are misconceptions about cancer screening tests, there are misconceptions about clinical trials. When people think about clinical trials, many imagine “guinea pigs”— participants getting inferior treatment or a sugar pill (placebo) instead of actual medical treatment. Many people also think that clinical trials are for only the people who have no other treatment options available to them. This article provides an overview of why clinical trials are important, what they do, and why they are a critical part of our work.

### Why Clinical Trials Are Important

Clinical trials are a critical part of the research process. Clinical trials help to translate basic scientific research into new treatments. By evaluating the results of these trials, researchers are finding better treatments for cancer and ways to prevent cancer. The more people that participate in clinical trials, the faster we can answer the critical

research questions that will lead us to better treatment and prevention options for all cancers. Doctors will never know the true effectiveness of a cancer treatment, or a way to prevent cancer, unless they are able to involve more people in clinical trials. And, research shows that few of us really understand what clinical trials are.

### Cancer Treatment Trials

Most cancer clinical trials are treatment studies. These clinical trials involve people who have cancer. These studies try to answer specific questions about and evaluate the effectiveness of a new treatment or a new way of using an old treatment. Treatment trials seek to find out:

- What new treatment approaches can help people who have cancer?
- What is the most effective treatment for people who have cancer?

In most cancer treatment trials, in which one treatment is compared with another, people receive either the most advanced and accepted treatment for the kind of cancer they have—known as the “standard” treatment—or a new treatment that

has shown promise of being at least as beneficial as the standard treatment, if not better. People in these trials do not receive a placebo for their treatment.

In the past, clinical trials were sometimes seen as a last resort for people who had no other treatment choices. Today, many people with cancer, even those whose cancers have not spread, get their first treatment in a clinical trial. All people with cancer can benefit from learning about all their treatment options, which include participating in appropriate clinical trials.

### **Cancer Prevention Trials**

Unlike treatment trials, cancer prevention clinical trials are studies involving healthy people who are at high risk for developing cancer. These studies try to answer specific questions about and evaluate the effectiveness of ways to reduce the risk of cancer. Prevention trials seek to find out:

- What approaches can prevent a specific type of cancer from developing in people who have not previously had cancer?

### **Risks and Benefits**

Clinical trials have both benefits and risks, and they are not the right option for everyone.

#### *Possible Benefits*

- Participants have an opportunity to make a valuable contribution to cancer research.
- Participants have access to new anticancer approaches before they are widely available.

#### *Possible Risks*

- New approaches may have side effects or risks that are unknown.
- Even if a new treatment under study has benefits, it may not work for every participant.
- Participants may have to pay for the costs of travel, childcare, lost work hours, and meals.

[Discuss your community's education and outreach efforts.]

### **How to Learn More about Clinical Trials**

Call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) and ask for a customized search of the PDQ database, which provides information on current studies. Ask for the following pamphlets:

- "Taking Part in Clinical Trials: What Cancer Patients Need To Know"\*
- "Taking Part in Clinical Trials: Cancer Prevention Studies"\*
- "If You Have Cancer... What You Should Know about Clinical Trials"\* (easy to read)
- "If You Have Cancer and Have Medicare... You Should Know About Clinical Trials"

Or you can visit the clinical trials area of the NCI Web site at [www.cancer.gov](http://www.cancer.gov).

\* Also available in Spanish

## Sample Newsletter Article 2

# Newsletter

### **Key Facts about Cancer Clinical Trials**

Cancer clinical trials are research studies in which people help doctors find ways to improve health and cancer care. Each study tries to answer scientific questions and find better ways to prevent, diagnose, or treat cancer. These studies are the final step in the process of developing new drugs and other means to fight disease. Clinical trials are the way we make progress against cancer.

### **Understanding that Cancer Affects All of Us**

- Cancer affects us all—whether we have it, care about someone who does, or worry about getting it in the future.
- Consider the impact of cancer in the United States\* in 2002:
  - Each year, about 555,550 people are expected to die of cancer—more than 1,520 people a day.
  - Cancer is the second leading cause of death, exceeded only by heart disease.
  - 1 of 4 deaths is from cancer.
- About 1,284,900 new cancer cases are expected to be diagnosed each year.
- Research has shown that there are many differences in who

develops cancer and who dies from cancer among men and women, and among people of different races, ethnicities, and socioeconomic backgrounds. Differences in cancer screening and treatment have also been documented for people of different ages, incomes, educational, and racial/ethnic backgrounds.

### **Understanding What Clinical Trials Do to Fight Cancer**

- Clinical trials are a critical part of the research process. Clinical trials help to translate basic scientific research into practical treatments. By evaluating the results of these trials, we can find better treatments for cancer and ways to prevent cancer.
- Clinical trials contribute to knowledge and progress against cancer. Many of today's most effective cancer treatments are based on previous study results. Because of progress made through clinical trials, many people treated for cancer are now living longer.
- The more people that participate in clinical trials, the faster we can answer the critical research questions that will lead us to

\*American Cancer Society (2002). *Cancer Facts and Figures*.

better treatment and prevention options for all cancers. We will never know the true effectiveness of a cancer treatment, or a way to prevent cancer, unless we are able to involve more people in clinical trials.

- In the past, clinical trials were sometimes seen as a last resort for people who had no other treatment choices. Today, many people with cancer, even those whose cancers have not spread, get their first treatment in a clinical trial.

#### **Understanding How Few People with Cancer Take Part in Clinical Trials**

- Enormous improvements in treating childhood cancers have come about as the direct result of clinical trials; more than 60 percent of U.S. children with cancer participate in clinical trials. In 2000, more than 70 percent of children with cancer are alive 5 years after diagnosis, compared with only 55 percent in the mid-1970s.
- In contrast, only 3 percent of U.S. adults with cancer participate in clinical trials—far fewer than the number needed to answer the most pressing cancer questions quickly.
- According to a survey in 2000, most people with cancer were either unaware or unsure that participation in clinical trials was an option for their treatment, and most of them said they would have been willing to enroll had they known it was possible.

#### **How to Learn More about Clinical Trials**

Call NCI's Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) and ask for a customized search of the PDQ database, which provides information on current studies. Ask for the following pamphlets:

- "Taking Part in Clinical Trials: What Cancer Patients Need To Know"\*\*\*
- "Taking Part in Clinical Trials: Cancer Prevention Studies"\*\*\*
- "If You Have Cancer... What You Should Know about Clinical Trials"\*\*\* (easy to read)
- "If You Have Cancer and Have Medicare... You Should Know About Clinical Trials"

Or you can visit the clinical trials area of the NCI Web site at [www.cancer.gov](http://www.cancer.gov).

\*\* Also available in Spanish

## **7. Hosting an Information Session/ Community Forum—A Step-by-Step Planning Guide**

Many organizations choose to hold community events on clinical trials, which can be an effective way to reach community members. Careful planning is required to ensure your event is a success.

### **Step 1. Establish a Community Forum Organizing Committee If You Are Planning a Large Event**

The organizing committee could include members from your group's education committee or your board. You will need to determine a budget for the project that includes costs of meeting room rental, printing flyers or invitations, advertisements, and postage.

Involve other parts of your community—such as the leadership of other nonprofit or advocacy organizations—in the planning process.

The entire committee may need to meet only a few times to discuss presentation goals and outreach strategies. A timeline and specific “job responsibilities” can be discussed at the first meeting.

### **Step 2. To Focus Your Information Session, Clarify Your Goals**

It is important to answer the following question before beginning to plan the event. Potential answers are provided here, but you should answer this question for yourself: *What is our goal in hosting this forum?* □

You should aim for goals that are clearly expressible. Try not to be overly ambitious for one community presentation. Getting community leaders involved with clinical trials and educating community members about clinical trials should be among your primary goals.

Specific goals of the meeting/forum might be to:

- Provide information about a specific cancer trial to members of your community.
- Develop a community strategy for clinical trial outreach.
- Provide people with the tools they need to find out about trials in your community.
- Educate the public about the importance of cancer clinical trials.
- Help debunk myths about clinical trials.
- Make clinical trial information more accessible.
- Share information with local organizations, compare strategies, and unify positions on common issues.
- Encourage people to inform others about clinical trials.
- Begin to build links between local researchers with community members.

### **Step 3. Determine Your Target Audience**

Think about who and why. Develop a target audience list. Be sure to involve community leaders.

Possible audiences include those listed on page 64: “Expanding Your Organization’s Community.”

For ideas in reaching cancer-related organizations in your community, use the following sources from the National Cancer Institute’s Cancer Information Service:

- “Cancer Facts: National Organizations That Offer Services to People with Cancer and Their Families” is available on the Web at [www.cancer.gov/cis](http://www.cancer.gov/cis) or by calling 1-800-4-CANCER. This listing features dozens of organizations, many of which have local chapters, members, or affiliates.
- Your regional Partnership Program manager (who can be reached at 1-800-4-CANCER) can provide a list of local organizations that may have an interest in participating in your educational efforts.



## **Step 4. Choose an Interesting Theme With a Catchy Title**

The theme should combine your organization's goals with what you believe your target audience will find of interest. Some ideas are given here.

### **General Information on Clinical Trials**

- What are clinical trials and why should we care about them?
- How are cancer prevention clinical trials different from other studies?
- What are the myths and facts about clinical trials?
- How are people protected in clinical trials?
- How does cancer research in our community address the concerns of people living with the disease?
- How can someone decide whether to participate in a clinical trial?
- What are the barriers to accessing clinical trials?

### **Specific Information on a Particular Trial**

Provide information about a specific prevention or treatment trial that may be having problems accruing patients. The presentation can explain why it is important, including the risks and benefits. If possible, give the locations of the trial sites in your area.

### **Community Advocacy for Clinical Trials**

- How can we help reduce the barriers to participation in clinical trials in our community?
- How can we advocate for third-party payers to cover clinical trial costs?
- How can we develop a community strategy for clinical trial outreach?
- How can we make clinical trial information accessible to those who need it in our community?
- How can we find ways to help people understand that clinical trials can be a viable treatment option?
- How can people newly diagnosed with cancer learn about clinical trials in the community?

## Step 5. Choose the Forum Speaker(s), Format, and Date

Be sure to invite people who:

- Can speak to lay audiences without using a lot of technical information
- Have a good rapport with the audience
- Live in the area
- Present information that people can use

### Tip

When planning a special event, keep in mind that many audiences are unfamiliar with scientific terms. Strive to make information presented at your special event easy to understand and creative.

For speaker ideas, contact principal investigators from the list of cancer trials in your community. (See page 111 for more information.) Consider inviting speakers who have actually participated in a trial. You can also contact your local cancer center, hospital, or medical center or the Cancer Information Service for help in finding speakers who will appeal to your audience.

Choose your date carefully. Make sure it is a time when most people can attend and that it doesn't conflict with another large community event or a holiday.

### Tip

If your speakers are your "big draw," you may want to offer several dates to accommodate their schedules before the date is confirmed.

## **Step 6. Decide on the Best Way to Inform the Target Audience About the Event**

Your message should reflect the theme you've chosen. The cost, timing, and available person-power will affect the method you choose to publicize your event. Consider the following methods:

- Mailing invitations or flyers to organizational mailing lists
- E-mailing event announcements to organizations and individuals
- Posting on Web sites
- Advertising in local media, such as radio stations and newspapers
- Distributing flyers or posters in the community
- Contacting cancer centers, hospitals, support groups, and patient groups

## **Step 7. Obtain Educational Materials**

At the event, provide participants with handouts on the benefits of cancer research (e.g., handouts in this series). Encourage them to share information with friends, relatives, and other people in their lives.

## **Step 8. Arrange for a Location**

Choose a location that is accessible by various modes of transportation.

## **Step 9. Select an Event Format**

Research has shown that adults strongly prefer interactive delivery methods, which allow them to learn new information by:

- Seeing
- Experiencing
- Discussing

Many scientists do not use these delivery methods, but you can encourage their use to promote effective discussions in community presentations. Remember that you want to advocate for people to take action after they leave the forum.

Be creative in your format. Adults often gain the most out of presentations by figuring out how they can apply the information

in their lives immediately. Possible formats include:

- **Single speaker format.** An easy option is a presentation that includes an expert speaking and answering questions about cancer research. For example, a doctor, research scientist, or outreach coordinator who is involved in a cancer clinical trial could speak about the work he or she is doing in the community.
- **Panel discussion.** A small group of experts (usually between three and five) discuss a topic among themselves in front of an audience. Panel participants don't make formal presentations. They exchange ideas through conversation. Panels can expose the audience to different points of view about a single subject. Audience members ask questions or comment on the subject after a panel discussion. Usually, a time limit is set for each question and for the entire question-and-answer period. Cancer trial panels might include:
  - Survivors who reflect the diversity of your community who can discuss their decisions about trial participation (survivors who are community leaders or otherwise well known in your community might be of particular interest to your target audience)
  - Cancer researchers who can discuss their work
  - Survivors and scientists who can discuss both the personal decisions and the science behind trials
- **Symposium.** A small number of experts make short presentations in succession. Presentations usually range from 5 to 15 minutes each.
- **Open forum.** Members of the audience may participate at any time during the meeting.
- **Colloquy.** During a panel discussion, audience members may be invited to comment or ask questions if a panel member or the chair perceives a need to clarify points, raise an issue, or ensure that a misperception doesn't stand. Any interruptions of the panel discussion must focus on the point at hand. When the matter has been resolved, the organized discussion among panel members resumes.

- **Buzz session.** The audience is divided into groups of six to eight people for discussion of questions posed by the leader. One person from each group may be asked to summarize the group's discussion and report to the entire audience.
- **Audience reaction team.** Three to five members of the audience are pre-selected to respond to a presentation by offering a brief summary and interpretation of information presented. This discussion method can be used effectively in large-group settings and when time is limited.
- **Question period.** Members of the audience have an opportunity to ask questions of a presenter once the formal presentation is completed. Usually, a time limit is set for each question and for the entire question-and-answer period.
- **Workshop.** A small group of people (up to 25) with a common interest meet to study, research, and discuss a specific subject or to enhance their individual knowledge and proficiency.
- **Seminar.** A group of people who are studying a specific subject meet for a discussion led by a recognized authority.

### **Tip**

No matter what format you choose, make sure you allow plenty of time for questions and answers.

## Working with Presenters

### Preparation

- Interview potential presenters in advance! You need to assess a presenter's ability to discuss areas related to clinical trials, and any personal experience he or she may have. Ask potential presenters about their willingness to participate in an event. Provide information about the date, time, and focus of the event. Discuss any concerns about anonymity (e.g., picture-taking or media presence).
- Budget for honoraria and expenses. Whenever possible, pay presenters an honorarium and offer food, mileage, parking, and childcare reimbursement. If possible, plan to pay in cash the day of the workshop (and get a signed receipt).
- Send a confirmation letter. Make sure it includes date, time, and focus of the event, details about honorarium, travel to the site, parking, and a telephone number of a contact person at the training site.
- Call presenters 3 to 7 days before the event. Ask whether they have questions. Discuss plans for focusing on specific issues. Ask how they wish to be introduced. It may be easiest for presenters to introduce themselves, so they can disclose as much or as little identifying information as they like.
- Obtain a facilitator/moderator. The facilitator's role is critical to the event's success. A facilitator manages the discussion. Presenters need support from the facilitator, who should:
  - Assure them that they can refuse to respond to any question for any reason
  - Monitor time carefully and gently, so everyone gets a chance to speak
  - Help with questions and answers
  - Be available after the event to assist presenters and offer feedback

- Arrange to meet with all panelists before the presentation. This will help alleviate their anxiety and provide a chance to discuss any last-minute issues.
- Review the format for the panel. Look at time allowed for each presentation and when/how questions will be taken from the audience.

### **At the Event**

- Explain why you are holding a panel discussion. (Hint: Distribute an information sheet listing panelists and their affiliations. Then you won't have to spend a lot of time on introductions.)
- Review the ground rules. Tell the audience how much time each panelist will have to speak. Explain when audience members will be able to ask questions or offer comments.
- Show courtesy and respect for differing points of view.
- Pay careful attention to respecting limits on time.
- Summarize in the last 5 minutes. This is important, even if you have to say, "This discussion left many of us with more questions than answers!"

## **Plan Your Community Events—A Sample Timeline**

Whether you plan to host a forum or run a video presentation, this checklist can help you plan.

### **6-8 Weeks in Advance**

- Identify target audience
- Identify and reserve site for meeting and ensure video equipment is available—will it be a part of a regular organizational meeting, a visit to someone's home, a special event?

### **4 Weeks in Advance**

- Refine target audience
- Review audience needs
- Develop and send e-mail/flyer
- Order supplies, copies, and educational materials
- Confirm site reservation, video equipment

### **2 Weeks in Advance**

- Check in with onsite coordinator on number of participants and any changes anticipated
- Get flip charts and markers (if needed)
- Get nametags (if needed)
- Organize handouts
- Make sure any videotape works/CD-ROM works

### **1 Week in Advance**

- Prepare supplies and materials for presentation, place in boxes

### **Day of Session**

- Arrive at least 30 minutes before scheduled start time
- Check set-up and comfort of room
- Place welcome and directional signs in the facility
- Make sure you know how to work video equipment

### **1 Week After Session**

- Send thank-you letter to on-site coordinator and participants



## 8. Form an Advocacy Coalition

A coalition is a group of organizations and individuals working together for a common purpose. There are two types of coalitions or partnerships:

1. Single-issue or event coalitions need to agree only on one particular issue or event. The coalition dissolves when the issue is resolved or the event takes place.
2. Multi-issue coalitions focus on a set of related issues, such as clinical trial access, health care for all, or quality of cancer care. This more permanent type of coalition recognizes the value of mobilizing together for action over a longer time. To be effective, a multi-issue coalition should set a date for its work to be completed. The coalition can always be reorganized if needed.

### Why Form an Advocacy Coalition?

- To build important links among community-based organizations and clinical trial sites
- To share information with local organizations, compare strategies, and unify positions on common issues
- To help:
  - Set priorities for action or funding
  - Carry out an educational or outreach plan
  - Broaden the development of new constituencies

## **The Value of a Coalition or Partnership**

Coalition building is needed when one organization recognizes that it alone does not have the capability or people-power to have a real impact on an issue.

Clinical trial outreach is complex. Think of innovative ways to reach underserved communities with clinical trial information. You can be a catalyst for building important links among community-based organizations and clinical trial sites.

## **Getting Started**

### **Analyze Your Organization**

Analyze your interests before asking other groups to join in your efforts. Ask yourself:

- What can be gained from joining with others?
- Will the advantages outweigh the disadvantages?
- How can we best communicate the demands of other groups to our organization?

## **Forming an Advocacy Coalition—A Planning Guide**

### **Step 1. Establish a Partnership Organizing Committee**

The committee can be made up of leaders in your organization. The committee manages the formation of the entire partnership. Specific job responsibilities can be divided at the first meeting.

### **Step 2. With the Group, Clarify Your Organization’s Interest in Developing a Community Partnership**

- Why do you want to advocate for access to clinical trials? Why is it important?
- Which issues, questions, and behaviors around clinical trials are of particular interest to you, and why? Do you need more information on these topics?
- What don’t you know about these issues, questions, and behaviors around clinical trials? What questions do you need to have answered?
- What outside resources can you tap to help you understand the issues?

Identifying what you know about an issue also helps highlight what you don’t know—issues you can ask about when you get other organizations involved.

### **Step 3. Identify Current Needs and Resources**

When you start looking closely at clinical trial issues in your community, you need detailed information about the needs of individuals and the organizations that serve them, as well as the resources that your community has available to solve those needs.

Needs can be defined as the gap between what a situation is and what it should be. A need can be felt by an individual, a group, or an entire community. It can be as concrete as the need for more clinical trials or as abstract as improved community understanding of clinical trials. Examining needs can help you discover what is lacking, and point you in the direction of future improvement.

Resources or assets can be used to improve quality of life. They can be anything from people to places to organizations. Everyone is an asset, and everyone has assets that can be used for community building.

Identifying current needs and resources can help you:

- Understand the environment where you'll be working.
- Know how the community feels about an issue and what members think needs to be done about it. Getting the opinions of community members, identifying both the resources and limitations of your area, will give you a holistic view of the issue.
- Make decisions about priorities for program or system improvement. Once you assess the community, it is much easier to make improvements that community members will notice and benefit from.

This needs assessment process will be an ongoing part of forming your coalition.

#### **Step 4. Start With What You Know**

After choosing an issue to focus on, you may find possible solutions. Ask yourself:

- What do we already know about the needs and resources for clinical trials in our community?
- Has anyone else researched this topic in our community? Can we rely on this other work to give us insight and answers?
- Are there experts in the community who can answer some questions before we get started in forming the coalition? (Their input may narrow the remaining questions you need to ask other community members.)

**Step 5. Identify the Key Organizations With Which You May Be Working**

Develop a list of organizations likely to want to participate in the project. Be sure to include the institutions conducting clinical research in your community. Possible participants may include those listed on page 63.

Remember that this project presents an opportunity for you to build important links among people with cancer, researchers, doctors, and advocates.

**Step 6. Determine What You Will Ask of Groups Who Join Your Efforts**

For example, each organization must be committed to:

- Addressing clinical trial barriers in the community
- Coordinating to solve the problem, not just to gain public recognition
- The right of every other organization to be involved
- Open communication

**Step 7. Write a Letter or E-mail Inviting Organizations to a “Brainstorming” and Planning Session**

The goal of this meeting is to figure out how community groups can address local concerns associated with clinical trials. This initiative may focus on collaboration among the groups. Keep in mind that priorities may be different among the groups. This could be an open meeting for discussion among interested parties. Publicize the event through the media and at meetings.

**Step 8. To Followup With All Participating Organizations, Provide an Outline of Your Plans**

Ongoing communication is critical to gaining community ownership of this project.

## **Hold a Coalition Planning Meeting**

### **Requirements for a Successful Meeting**

Key requirements for a successful meeting include:

- An accessible location and time
- A good facilitator, if possible from outside the coalition, to help make sure all ideas are heard
- A good notetaker to record minutes, along with action steps, and distribute them to attendees

The following are possible tasks for the first meeting.

### **Goal Setting**

The meeting should have a goal. One example would be: “This meeting will determine how community groups can collaborate on addressing local concerns associated with clinical trials.”

### **Team Building**

Open the meeting with a team-building exercise. Pair people with someone they don't know. Ask them to introduce themselves by telling the other person about groups they belong to, as well as a skill or talent they have. Ask people to introduce their partners by giving their names, where they're from, groups they belong to, and a skill or talent. Comment on the number of groups mentioned, the various skills named, and how this is a beginning to building an effective coalition/partnership.

### **Information Overview**

Be prepared to:

- Share clinical trials educational materials
- Discuss your goal in getting involved with advocacy
- Ask people to think about ways to spread the word

### **Brainstorming**

In a brainstorming session, participants share their ideas or suggestions for solving a problem. Discussion of each point occurs after all ideas have been expressed. The atmosphere should be open and encouraging.

Use a newsprint pad and marker and ask for a volunteer “recorder.” In the groups:

1. Discuss community perspectives on barriers to clinical trials. How do they differ from the information presented? What other concerns do members of the community have? Focus discussion on barriers in the community, in institutions, and among potential participants.
2. Next, discuss possible solutions. Explain that this is a participatory goal-setting process. Discuss potential projects to let more people know about clinical trials.

### **Tip**

You can use a buzz session in a coalition-building meeting as well as for a community meeting. If you use a buzz session instead of brainstorming, you may want to have the groups use worksheets to discuss the issues. The worksheets will help to determine community priorities for this project.

### **Mission Statement**

Meeting attendees should work to develop a mission statement for the partnership. Examples of mission statements are:

- To determine the issues of importance related to clinical trials in our community, in order to develop a community-based advocacy initiative
- To work together to reduce the barriers to clinical trials in our community

The facilitator may need to further develop the statement and send it to attendees for comment at the second meeting.

### **Finding Other Partners**

Brainstorm to decide on other groups to invite to the next meeting. List the following organization types and examples on separate sheets of a newsprint pad:

- Service
- Religious
- Issue-oriented
- Social
- Educational
- Local or statewide councils and boards

When inviting groups to join the coalition, define the issue in a way that appeals to their self-interest.

### **Followup Steps**

Participants should resolve the following before the meeting ends:

- How to continue communication among coalition members
- Who will facilitate future meetings (The facilitator should invite other organizations to join the coalition's next meeting. The group can elect someone to this position.)
- Who will coordinate an agenda for the next meeting (Committee assignments are one way to develop different parts of the agenda.)
- How additional input will be incorporated in the coalition's plans

To help you plan conducting community outreach and education, see the Plan for Action in the Appendix.



## 5. Ways to Work With the Media



# 5

## Ways to Work With the Media

### ***What You Can Do***

- Develop a media campaign
- Contact local media outlets about running a story related to clinical trials
- Write a letter to the editor or an op-ed piece for your local newspaper

### ***Why?***

- To educate the public about clinical trials
- To encourage people to find out about trials
- To encourage local doctors to refer people to trials

### ***Introduction***

Media advocacy is the use of television, radio, newspapers, magazines, or other media to help promote your mission. The media are a primary source of health information. Using the media can help your organization:

- Change the way community members look at clinical trials
- Create a reliable, consistent stream of publicity for your organization's activities
- Motivate community members and policymakers to get involved and learn more about clinical trials

Keep in mind that newspapers, television stations, and radio stations have different audiences. Messages that work for one audience may not work for another.

## ***Education and Outreach in Action***

A woman with colon cancer was very active in the local PTA in her community. Many of the parents were surprised when she told them about her decision to join a clinical trial. One of the parents said, “I didn’t know a lot about clinical trials, but I saw how much the trial is helping our friend. I figured that we had to let other people know about it.” The PTA approached the local community newspaper to do a story on her experience in the trial, which resulted in a five-part series.

### **1. Work With Mass Media—Goals, Timing, and Process**

#### **Goals**

Goals in using the mass media include:

- Informing the public about issues related to clinical trials in your community
- Recasting clinical trial barriers as concerns that affect everyone, not just individuals
- Encouraging people to find out more about clinical trials and to get involved

#### **Timing**

Good times to focus extra energy on the media include when:

- Announcing a new project (for example, a new clinical trial outreach plan)
- You have information that can be tied to a community event
- The public or government officials are debating or considering laws or activities that affect clinical trials

## The Process

There are three different activities in media advocacy: Agenda setting, shaping the debate, and advancing a policy.

Agenda setting is what you accomplish when you influence:

1. What the media cover (media agenda)
2. What people talk about (public agenda)
3. How policymakers think about or act upon issues during legislative sessions or in committee (policy or political agenda)

Agenda setting helps you make connections with the media and their audiences. It also sets the stage for your next trick, shaping the debate. To set an agenda:

- Let the media and public know your concerns
- Get the public talking about what is important to you
- Generate some sort of action (e.g., aim to influence policy or get more people involved)

Shaping the debate is trying to change the way people talk about clinical trials. The media often give tidbits of information about clinical trial problems and then provide quick-fix solutions.

Traditionally, the media tell an audience:

- “This is what the problem is”—providing information about a problem
- “This is the solution”—usually summed up in a quick health message such as, “Just say no.”

Once you help to shape the way clinical trials are reported by the media, then the community can work for better access to clinical trials. Advancing a policy is a way to use the media to inform policymakers about an issue. Media coverage created by advocates can educate policymakers before they take action.

## 2. Develop a Media Campaign

A media advocacy campaign is similar to a political campaign in that you need to plan it carefully—identifying specific strategies and tools to use—before taking any action. You need to understand how you want the media to help you advance your goals.

Use the following steps to set up a media campaign:

- 1. Prepare your organization or your members.** You will need to designate a spokesperson to work with the media. Spokespeople need to be prepared to speak with media representatives, using extra caution with words and language that might be manipulated.
- 2. Select your objectives.** Ask yourself why you need to set up a media campaign. Is a campaign the best way to meet your needs? What are you going to use the media for? Do you want to inform the people of important facts or do you want to get them involved? Do you want to change policies or create new ones? Do you want to build support for your goals and objectives?
- 3. Identify your target audience.** Anyone involved in health issues can make a difference. Because people who live in one community can have many different opinions and preferences, you can't reach everyone with just one message. You will need to narrow your audience and decide who you want to target:
  - Policymakers?
  - People who are facing a decision about treatment or prevention options?
  - Groups who are undecided about supporting clinical trials?
  - The general public, who doesn't know about clinical trials?
- 4. Make a plan.** Because media advocacy activities consume time and money, it's important to put your best foot forward when you begin. Carefully consider when to start your campaign, who you will contact first, what issues you will tackle, and how you will present them. What media would you like to use? Television, print media (such as magazines, newspapers, and newsletters), radio, or billboards?

- 5. Review your goals.** Even though you put a lot of thought into your media advocacy plan, be prepared to modify your goals. Remember, the news can change quickly, and you need to be ready to react to an opportunity, even one that doesn't fall under your organization's typical scope of activities. Are your goals feasible?
- 6. Keep your ear to the ground.** Ask yourself what people talk about, in your community and nationwide. What can polls and surveys tell you about the hot topics? How much do people know about your issues? What kinds of misconceptions or prejudices can you find in public opinion?

### **Tips**

- Review local publications to understand better what information each is likely to publish. Who is the target audience? What types of articles are currently available?
- Find out who reports on health and community issues and go directly to him or her.
- Remember that reporters are always looking for good news stories and you can serve as a resource to them. Developing media opportunities is a challenging job, but with the right preparation, you can soon become an expert.
- Always be ready to arrange an interview with a health care provider and a person with cancer. Factual stories need a human-interest angle.
- Pitch stories in relation to health awareness months.
- Ask producers of radio call-in shows to feature clinical trials on one of their programs. Offer to provide background information, sample questions and answers, and people to interview.
- Use local organizations' media (e.g., newsletters, Web sites, and listservs).

## **3. Use Media Tools**

### **Press Releases**

Press releases are one-page write-ups about your organization's news. To be effective, they should be used sparingly. Press releases are best used to announce an event, a coalition meeting, or other strategy your group is employing to spread the word about clinical trials.

Typically, press releases are faxed to the appropriate reporter or editor.

The press release should be double-spaced and no more than a page long.

## Sample Press Release Format

Contact—  
Be sure to include a  
telephone number

Headline—  
When possible include  
link to local event

1st paragraph—  
Interesting lead  
sentence, general  
description of event,  
date, or place

2nd and succeeding  
paragraphs—  
More description and  
background. When  
possible, obtain a  
direct quote, local  
interest angle

For more information  
provide a Web address  
or telephone number



**National Institutes of Health**

**EMBARGOED FOR RELEASE**

1 p.m. EDT  
Friday, November 01, 2002  
NCI Press Office  
(301) 496-6641

### **National Cancer Institute Hosts Lecture, "Poor Whites and Health"**

J. Wayne Flynt, Ph.D., distinguished professor, Auburn University, Auburn, Ala., will discuss the impoverishment of whites in America and the effect of poverty on their medical care.

Flynt received his Ph.D. from Florida State University in 1965, specializing in Southern political history. His research interests subsequently turned to poverty and religion. He has lectured at universities across America and abroad.

Flynt is a community activist, serving on the American Cancer Society's Committee for the Socioeconomically Disadvantaged. He is co-founder of the Alabama Poverty Project and Sowing Seeds of Hope, an initiative to overcome poverty in Perry County, Ala.

Flynt is the author of 10 books, two of which have been nominated for Pulitzer Prizes. In 2003-2004 he will serve as president of the Southern Historical Association, the largest professional organization devoted to the study of Southern history and culture.

This lecture is the second in a series presented by the National Cancer Institute's Center to Reduce Cancer Health Disparities. This lecture series explores issues related to health disparities and the unequal burden of disease in American society.

**WHEN:** Tuesday, Nov. 5, 2002, 2 p.m.

**WHERE:** The lecture will take place in Masur Auditorium at the Warren G. Magnuson Clinical Center on the National Institutes of Health (NIH) campus in Bethesda, MD.

If you are interested in attending this lecture or require further information, please contact (301) 496-6641.



Most media outlets are deluged with press releases. Consider alternatives to the press release format:

- Fact sheets—who, what, when, where, and why
- Position statements—a brief explanation of an issue and why your group cares about it

### **Pros**

Most nonprofit organizations rely on the news media to reach the largest audience possible. Press releases:

- Provide an excellent way to tip off journalists and editors to your organization's news or upcoming activities
- Can be produced quickly in the event of breaking news
- Allow you to frame the issues
- Are easily distributed by mail, fax, or e-mail
- Encourage credible, objective journalists to report on your activities

### **Cons**

Press releases require skill to do well. Writing and distributing a press release isn't enough. You have to work hard to form good relationships with the media to make journalists more receptive to your press releases and other efforts. And once you establish ties, you have to work hard to maintain them. Remember that the attention span of the news media is generally very short and that your story has to compete with many others for attention.

## Public Service Announcements

Public service announcements (PSAs) may be used to solicit membership or to provide general information about your group and its mission to spread the word about clinical trials. They are more likely to be broadcast or printed if they announce a meeting or public event.

### Tip

Many media outlets run community calendar segments during newsbreaks or talk programs. Call outlets and ask to insert an item in their community calendar segments. They will either take down the information over the phone or ask that you provide it in writing.

When distributing your PSA, include a letter that sums up your group's mission and why your PSA is important to your community. You can also provide the public service director at the news outlet with a press kit that includes more extensive information on your group.

### Radio

Radio PSAs should be submitted in a written script format or on a professionally-produced tape. Written copies are often less expensive and more effective, because they will be read by the radio announcer, who is an experienced and familiar voice to the public ear.

### Television

Keep in mind that television production can be very expensive and requires experienced technicians and extensive camera equipment. Don't forget about public access cable—more and more people are using it. Using public access, you are most likely to get your message broadcast without changes—a rare case where you have complete control over your message.

**Pros**

PSAs:

- Can give you free air time
- Can help long-range advocacy goals by helping to maintain name recognition for your organization
- Are an easy way to spread information

**Cons**

You can't control the placement of your PSA, and competition for "good airspace" can be fierce. In addition, PSAs:

- Are labor intensive
- Offer less flexibility than paid advertisements (radio and television stations may pick and choose which PSAs they wish to use)
- Don't allow you to react quickly to breaking news because they are hard to revise

## Sample PSA Format

Usually it is best to simply provide the information for a PSA to a media outlet, in a clearly readable format. In many cases a radio or TV station will run a PSA exactly as you submit it.

Time of spot

Title of PSA

Interesting lead sentence

General description of topic or event or who is invited. You may want to include a sentence on history or a local-interest angle.

Final sentence—  
Where to go for more information



### 30-second spot

Sam Donaldson on Melanoma for NCI

HI, I'M SAM DONALDSON. YOU MAY KNOW ME AS A NEWS ANCHOR, BUT I'M ALSO A MELANOMA SURVIVOR. MELANOMA – THE MOST SERIOUS TYPE OF SKIN CANCER – CAN BE CURABLE IF CAUGHT AND TREATED EARLY. SO YOU AND YOUR DOCTOR SHOULD EXAMINE YOUR SKIN REGULARLY. OFTEN, THE FIRST SIGN OF MELANOMA IS A CHANGE IN SIZE, SHAPE, COLOR OR FEEL OF AN EXISTING MOLE.

FOR MORE INFORMATION, CALL THE NATIONAL CANCER INSTITUTE'S CANCER INFORMATION SERVICE AT 1-800-4-CANCER OR VISIT NCI'S WEB SITE AT CANCER-DOT-GOV.

### Tip

Remember to Keep It Short and Simple!

## Letters to the Editor

The philosophy behind your local newspapers' letters-to-the-editor pages can differ dramatically. The key variable is the size of the paper's circulation.

Some editors of the letters page see it as a community bulletin board where all sorts of opinions ought to be posted. This wide-open policy typically is found at smaller papers, where they might be struggling to fill the space they've allotted for letters. These papers are a perfect opportunity for those interested in clinical trial outreach and education.

In the midsize to large suburban and urban daily newspaper, hundreds of letters may come in each day. For the editors of larger papers, relevance is the key consideration. They want to print feedback/criticism/praise for stories and opinion columns that have appeared in their paper quite recently.

When you have evaluated the newspaper you are writing to and have an idea of its circulation, you should begin to outline your topic. First and foremost, know what you're writing about. Don't criticize a newspaper's overall coverage of an issue unless you have truly read every inch of coverage. Don't embarrass yourself and your organization by claiming that a newspaper doesn't cover cancer issues, for example, only to be presented with 30 clips of stories printed over the past 2 years. If you're going to use the media, you must first be a smart, consistent consumer of their products.

Keeping this in mind, it is best to focus your piece on a particular story the paper has published:

- Always quote the headline and date in your first or second sentence.
- Stick to the facts and keep it dignified.
- Keep it brief, for the reader's sake. Four to six paragraphs is the rule, with paragraphs consisting of only one or two sentences each (generally 250-500 words max).

- If you can't make your point within these constraints, consider writing a full-blown opinion column for the page, often called the op-ed because it is published opposite the newspaper's editorials. An op-ed column should consist of no more than 15 paragraphs, and 10 is a better length (500-800 words). Op-eds should be signed by a prominent person in your community.

If possible, fax your letter or column to the editorial page. You should identify a specific person to whom your letter should be sent. The letter will get there more quickly, and 70 percent of editors say they prefer faxes. You must sign your letter and include a daytime telephone number.

If you have not seen your letter printed within a few days, followup to inquire, politely. The answers you get will help you the next time you write. Remember that no newspaper is obligated to print your letter, but newspaper editors consider themselves obligated to fairly and accurately present all sides of the issues. Use this ethic to your advantage.

To help you plan ways to work with the media, see the Plan for Action in the Appendix.

## Sample Letter to the Editor

Dear Editor:

Your most recent coverage of cancer in our community [April 11—Cancer Clinical Trials: False Promises] was an earnest attempt to address the issues surrounding this topic. However, some important facts about clinical trials were lost in the process. As [insert what you are], I share the authors' concern about the potential abuses in the clinical trials system and appreciate their commitment to bring attention to this problem. But this year alone, it is estimated that 553,400 people will die of cancer in the United States—more than 1,500 people a day. By providing a one-sided and sensationalistic view of a highly complex subject, you do a great disservice to the important contributions of thousands of hard-working and ethical researchers, as well as to clinical trial participants.

The public's confidence in clinical research is seriously shaken by stories like yours that report inadequacies in participant protection without discussing the benefits of clinical trials. Considering the thousands of people who take part in clinical trials each year, breaches in protection are rare.

It is important to note that the number of studies executed efficiently and ethically far outweighs these tragedies resulting from clinical trials. We will never be able to answer the most pressing questions about the causes of and treatments for cancer without the scientific evidence produced through well-designed and ethically executed clinical trials. Your readers should know that many Federal regulations enforce participant protection rules. In addition, in 2000, the U.S. Department of Health and Human Services took additional steps to strengthen government oversight of medical research and to reinforce clinical researchers' responsibility to follow federal guidelines.

Only 3 percent of adults with cancer currently participate in clinical trials. How will we ever answer the most pressing questions about the causes of and treatments for cancer without the scientific evidence produced through well-designed and ethically executed clinical trials?

I firmly believe that people with cancer should have access to the best treatments and be given the best possible chance for survival. Clinical trials ultimately offer the best hope for many people, and all must be offered the opportunity to participate. Participant protection must be enforced in clinical research, and all participants need to be appraised of the risks and benefits of participating through existing informed consent laws.

We all need to know the facts about clinical trials. To learn more about clinical trials, call NCI's Cancer Information Service at 1-800-4-CANCER or log on to the Web site at [www.cancer.gov](http://www.cancer.gov).

Sincerely,

**1st paragraph—**  
Begin by connecting to a timely event, previous article, or statement. When possible, tie national events into relevant stories or information about your community.

**2nd paragraph—**  
Make your point upfront.

**3rd paragraph—**  
Use facts to support your point. Make sure you get your facts from a reliable source.

**4th paragraph—**  
Be persuasive; appeal to readers' sense of justice, decency, or empathy to strengthen your argument. Don't be afraid to use a personal example as a way to support your point of view.

**5th and 6th paragraphs—**  
Say what readers should do, for your organization, for your community, in support of clinical trials.

## **6. Ways to Work With Hospitals, Medical Centers, and Universities**



# 6

## Ways to Work With Hospitals, Medical Centers, and Universities

### ***What You Can Do***

- Help researchers design and conduct clinical trial recruitment efforts
- Find ways to get primary care doctors, oncologists, and oncology nurses to understand local clinical trial resources and to refer people to trials
- Find out how you can serve on a local institutional review board (IRB)

### ***Why?***

To help increase access and accrual to cancer clinical trials

### ***Introduction***

Many public institutions recognize the importance of including nonscientists in the clinical trial review process and are including patients and advocates as members of advisory committees and planning/oversight groups that have a focus on clinical trials.

People from outside the research community play an important role in program planning and implementation, and help to set priorities and research agendas for clinical trials.

## ***Education and Outreach in Action***

A retired mail carrier helped her significant other through cancer treatment. She read everything that she got her hands on about chemotherapy and learned a lot about cancer treatment.

Now that the cancer is in remission, she still logs onto the National Cancer Institute's Web site for new information. As a part of the local cancer support group, she attended a local cancer conference. One of the presenters discussed new medicine being studied in phase 3 trials, but mentioned in passing that the researchers are having trouble getting patients to consider participating in the trial.

During the "Q and A," she asked the presenter, "How can patient groups help you get the word out about this trial?" The group made a plan to meet with the researchers to figure out how they could work together.

Of the experience, the mail carrier says, "If I hadn't made contact at that meeting, they would still be having the same problems getting patients to consider participating in this trial. Experts don't realize the scope of patient organizations and all of the services we have to assist them with their trials and any other projects."

"I work in a breast cancer screening program," said a nurse from a Midwest health department. "Some women are really worried about getting breast cancer—they've lost a sister, a mother, an aunt to breast cancer. Once they've gotten a normal mammogram report, I tell them that they need to take care of themselves by getting annual mammograms and clinical breast exams, and I train them how to do breast self-exams. But, I also tell them that they may want to think about participating in a breast cancer prevention trial." The health department works with local physicians, the local medical center, and some churches to let community members know about opportunities to participate in breast cancer prevention trials.

# 1. Work with Researchers and Health Care Professionals

In addition to sponsoring community forums and information sessions as outlined in other sections of this guide, many laypeople have worked alongside researchers to advise them in their clinical trial outreach and education efforts.

Points to keep in mind when assisting researchers with community outreach include the following:

- Community members who are known, trusted, and accountable may be more effective and more believable to other community members than a researcher.
- Community members can help advise researchers on ways to present clinical trial information that complements the values people in the community hold.
- Community members can help foster the development of partnerships with organizations and the research institutions.

## Tips to Find Out How You Can Help Researchers

Contact principal investigators or research nurses of local institutions. To find out the kind of research being conducted in your community:

- Contact the research office of the institution.
- Use the NCI Research Portfolio to find out about research going on in your community. The portfolio allows users to browse and explore active NCI-supported research, including extramural and intramural projects, by type of cancer or by type of cancer research. Research projects (including treatment, prevention, and cancer control studies) can also be sorted by research project title, principal investigator, State, and institution. Visit the Web site <http://researchportfolio.cancer.gov>.

For more information on strategies for clinical trial education and working with different ethnic/minority groups, see section 1.

## Tips to Find Out How You Can Help Health Care Professionals

Find ways to get primary care doctors, oncologists, and oncology nurses to understand local clinical trial resources and to refer people to trials:

- Talk to your own primary care physician, oncologist and nurse about resources available to them from NCI, such as:
  - *The PDQ Clinical Trials Registry*, discussed on page 43. PDQ can be accessed by [www.cancer.gov](http://www.cancer.gov) and through 1-800-4-CANCER.
  - *The Cancer Information Service's Partnership Program*. Through this program, the Cancer Information Service reaches the medically underserved, including minority groups and people with limited access to health information and services, with cancer information. The program can provide clinical trials training to state and regional organizations working with these populations. Call the Cancer Information Service at 1-800-4-CANCER or visit the National Cancer Institute's Web site at [www.cancer.gov/cis](http://www.cancer.gov/cis).
  - *The Cancer Trials Support Unit (CTSU)*. This is a pilot project sponsored by NCI that supports a national network of physicians and patients to participate in NCI-sponsored phase III cancer treatment trials. For more information about joining, log on at [www.ctsu.org](http://www.ctsu.org) or call 1-888-823-5923.
  - *The NCI Research Portfolio* (see previous page).
- Find an oncologist who can present information on clinical trials to primary care physicians and nurses in your community.
- Contact local chapters of the American Academy of Family Physicians ([www.aafp.org](http://www.aafp.org)) and/or the Oncology Nurses Society ([www.ons.org](http://www.ons.org)) to explore their knowledge of cancer clinical trials in your community.

## 2. Serve on an Institutional Review Board (IRB)

IRBs are made up of people who are qualified to evaluate new and ongoing clinical trials on the basis of scientific, legal, and ethical merit. The IRB determines whether the risks involved in a study are reasonable with respect to the potential benefits. IRBs also monitor the ongoing progress of the trial—from when it begins to when it ends.

Federal regulations require that each IRB is made up of at least five people; one member must be from outside the institution. IRBs usually are made up of a mix of medical specialists and lay members of the community. Many IRBs include members from diverse occupations and backgrounds.

In most cases, IRBs are located where the study is to take place. Most institutions that carry out clinical trials have their own IRBs.

### Typical Questions Addressed by an IRB

- Are the risks to participants minimized as much as possible through sound research design and the use of safety-focused procedures?
- Are the risks reasonable in relation to the anticipated benefits and the importance of the knowledge that may result?
- Are participants selected fairly?
- Is a plan in place for seeking and documenting participants' informed consent?
- Is the informed consent document both legally and ethically sound?
- Have provisions been made for monitoring the data collected to ensure the safety of participants as the trial progresses?
- Have provisions been made to protect the privacy of participants and the confidentiality of data collected during the study?

To find out how you can serve on an IRB:

- Contact administrators of local hospitals, cancer centers, or universities (researcher or grant departments are good places to start) to learn about vacancies.
- Ask your doctor or nurse.

To help you plan for work with hospitals, medical centers, and universities, see the Plan for Action in the Appendix.

# Appendix

Clinical Trials & Cancer Clinical Trials

# Appendix

## Plan for Action

This worksheet is to help you determine how to accomplish your goals for clinical trial outreach and education. We hope that this planning will inspire you to take realistic steps towards your goals.

Please be realistic in planning; you do not need to fill out every page.

1. Remind yourself why you/your organization want(s) to get involved in clinical trial outreach and education. Sometimes it can be helpful to list these reasons before you plan your efforts.

List five reasons here:

- 

- 

- 

- 

-



2. Given your interest in the above topic areas, which of the following activities do you feel ready to undertake during the next 6 months or next year?

---

---

---

---

---

---

---

Read through the entire action plan before you begin to check your interests. Be realistic about your other commitments!

#### **Ways to Educate Yourself**

- Use NCI resources to keep up-to-date with new clinical trial information, including *www.cancer.gov*
- Find local clinical trials in your community
- Attend conferences, meetings, and workshops

#### **Ways to Educate Others, One-on-One**

- Find opportunities to talk to others—neighbors, friends, and coworkers—about clinical trials, and about the common myths surrounding clinical trials, and where to find more information on clinical trials
- Help others understand how to evaluate research in the news

### **Ways to Conduct Community Outreach and Education**

- Find opportunities and develop a strategy to speak about clinical trials and/or:
  - Present NCI slide programs or the awareness video “Cancer Trials...Because Lives Depend on It”
  - Distribute educational materials such as those in this series:
    - At meetings or events
    - Through doctors’ offices
    - Through a booth for local research institution(s) at events
- Write articles for newsletters; post articles on Web sites
- Host an information session or community forum on clinical trials
- Form a clinical trial advocacy coalition

### **Ways to Work with the Media**

- Develop a media campaign
- Contact local media outlets about running a story related to clinical trials
- Write a letter to the editor or an op-ed piece for your local newspaper

### **Ways to Work with Hospitals, Medical Centers, and Universities**

- Help researchers design and conduct clinical trial recruitment efforts
- Find ways to get primary care doctors, oncologists, and oncology nurses to understand local clinical trial resources and to refer people to trials
- Find out how you can serve on a local institutional review board (IRB)

3. What resources will you need to get these activities accomplished? (Think about time, organizations, and individuals.)

---

---

---

---

---

---

---

4. Name five steps you will take to begin planning these activities. Be as specific as possible.

- 
- 
- 
- 
-

5. What challenges do you see standing in your way of accomplishing these activities?

---

---

---

---

---

---

---

6. How can you address these challenges? If you are working as a part of a larger organizational effort, how can you get support from your organization?

---

---

---

---

---

---

---

## Resources

Education and Training. (2000). North Carolina State University College of Agriculture and Life Sciences: North Carolina Cooperative Extension Service. [Online], Available: <http://www.ces.ncsu.edu/resources/education/>

How You Can be an Advocate for Change: Action Against Cancer. (1997). Washington, DC: Center for the Advancement of Health.

KU Work Group on Health Promotion and Community Development. (2000). Community Tool Box. Lawrence, KS: University of Kansas. [Online], Available: [http://ctb.ukans.edu/tools/EN/section\\_1045.htm](http://ctb.ukans.edu/tools/EN/section_1045.htm).

Stevens, G.L. (1990). A Process for Building Coalitions. Lincoln, NE: Cooperative Extension, Institute of Agriculture and Natural Resources, University of Nebraska. [Online], Available: <http://ianrwww.unl.edu/pubs/family/g988.htm>

Susan G. Komen Breast Cancer Foundation. (1999). Educational materials for affiliate distribution. Clinical Research Affiliates Funding Trials (CRAFT).



The Susan G. Komen  
Breast Cancer Foundation

*The printing of this publication was supported by an educational gift from the Susan G. Komen Breast Cancer Foundation.*

*This booklet was written and published by the National Cancer Institute (NCI),  
9000 Rockville Pike, Bethesda, Maryland 20892.*

*NCI is the U.S. Government's main agency for cancer research and information about cancer. To inquire about copyright and use of NCI materials contact Clearance Officer,  
National Cancer Institute.*

NATIONAL  
CANCER  
INSTITUTE



Public Health Service  
National Institutes of Health  
NIH Publication No. 02-5053  
Printed October 2001  
Reprinted September 2002

