Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy
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Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy.

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Communities as Partners in Cancer Clinical Trials

Executive Summary

[Public] distrust of medical research is firmly entrenched and is a significant obstacle to clinical trials participation... involving the community... in assessing the need for specific studies and in planning and conducting the research itself, has proven effective in overcoming distrust. Specifically, communities must be involved early in research protocol development, and researchers must ensure that the community benefits from participation and receives research results. Further, the expertise of cancer advocates and survivors, who can help maintain a patient-centered focus on research projects, could be utilized more fully. Community involvement and support is particularly crucial to ensure the sustainability of interventions shown to be of benefit.*

President’s Cancer Panel

Translating Research into Cancer Care: Delivering on the Promise

June 2005

Introduction

Less than three percent of all adult cancer patients participate in clinical trials. The accrual rate is even lower among people of color, older people, and the medically underserved, who tend to have higher cancer mortality rates than the population as a whole. These low numbers compromise the value of clinical research and raise important questions about access to quality care and social justice for all communities affected by cancer.

In recent years, a number of reports have called for the inclusion of public representatives in research design and implementation to address low accrual and improve research outcomes. Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy, a national initiative spearheaded by the Education Network to Advance Cancer Clinical Trials (ENACT) and Community-Campus Partnerships for Health (CCPH) with core funding from the Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute (NCI), is exploring the potential for improving multi-site, therapeutic phase III cancer clinical trials through the use of community-based participatory research principles and approaches. Communities as Partners is the first national report to detail why and how the cancer clinical trial process can involve communities affected by cancer — from trial design to implementation to dissemination of results — with a focus on community engagement strategies.

Over a two year period, ENACT and CCPH assembled a diverse group of stakeholders – including Federal agencies, patient advocates and community-based organizations, cancer centers, oncology practices, health professional schools, the pharmaceutical industry and health care professional societies – to develop recommendations for improving accrual rates and addressing persistent disparities in phase III therapeutic cancer clinical trials. Phase III trials are designed nationally and implemented locally, providing opportunities for community engagement at both national and local levels.

The Promise of Community-Based Participatory Research Approaches to Addressing Clinical Trials Disparities and Accrual Challenges

Central to many successful initiatives that seek to understand and improve the health of underserved groups – especially people from racial and ethnic minority groups and those with low socioeconomic status – are participatory models in which communities are actively engaged in the research process through partnerships with researchers.† Community-based participatory research (CBPR) can be defined as an approach to "scientific inquiry conducted in communities in which community members, persons affected by the condition or issue under study and other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work, including conception, design, conduct, analysis, interpretation, conclusions and communication of results."‡

A 2004 AHRQ Evidence Report suggests that the utilization of CBPR can improve research quality, enhance intervention quality, improve outcomes, and enhance research recruitment efforts. ‡ Although CBPR has been more often utilized in public health research, we believe that the principles and approaches of CBPR can be systematically and integrally incorporated into many aspects of clinical research design and implementation. A CBPR approach to cancer clinical trials holds the potential for ensuring:

- Well-designed, high quality, cost-effective trials that will accrue, in a timely manner, sufficient numbers and diversity of patients
- Trials that are more universally relevant to the real lives of patients
- Enhanced community trust of researchers, research institutions and the research process
- Enhanced dissemination of research findings to the public and community clinicians

The Definition of “Community” in the Context of this Report

For the purposes of this report, we adopt the definition of community advanced by the Centers for Disease Control and Prevention: those whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the conduct of the research. ‡ Although cancer treatment trials solely enroll patients with cancer, there are many “communities” affected by cancer. Those groups that are disproportionately affected by cancer morbidity and mortality should be well represented in each component of phase III cancer clinical trial design and implementation.

Currently, many cancer patient advocates provide critical input into the design and implementation of clinical trials at both national and local levels, and their work is essential to the success of cancer research. However, we believe that to reap the full benefits of community engagement in phase III cancer clinical trials, we need to increase their numbers, strengthen their roles and be more inclusive of all communities whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the research itself.

When considering who best represents the community perspective in multi-site therapeutic phase III cancer clinical trials, we recommend that the cancer clinical trial research system strive to include both community representatives and patient advocates, recognizing that both are essential to the research process.

- Community representatives have experience with the healthy population at risk and ideally are affiliated with a community-based organization or group whose constituency is disproportionately affected by cancer.
- Patient advocates have experience as a patient with cancer, caregiver or family member and ideally are affiliated with a cancer advocacy organization or group.§

Throughout the document, we refer to them collectively as “community representatives/patient advocates” or “CR/PAs.”

Challenges to Implementing the Communities as Partners Recommendations

Funding. We recognize that lack of funding is a critical barrier to implementing certain recommendations, and are cognizant of concerns about “unfunded mandates.” However, these recommendations should be viewed as goals to be achieved over time. They are intended to serve as a strategic plan for key stakeholder discussion and implementation. Some recommendations are quite ambitious, requiring a realization of resources. Others can be implemented relatively quickly, with little or no need for

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† The National Community-Based Organization Research defines community-based organizations as groups that are “operated by individuals who are directly impacted by the community level problem or issue and who traditionally have had no say in the decisions that govern their lives.” http://www.ncri.org/ncri/docs/ncbo/definition.html

‡ As example would be a representative from a group involved in cancer care, but whose mission includes improving the health of the community. These would include: community-based groups such as unions and religious organizations, K-12 schools, faith-based groups, housing organizations, representatives from local chapters or affiliates of national groups such as the NAACP.

§ An example in an individual affiliated with a national or local cancer service group or advocacy organization such as the American Cancer Society, National Network, National Breast Cancer Coalition and academic lymphoma society (See Appendix B).
Communities as Partners in Cancer Clinical Trials

Additional funding. We suggest that stakeholders consider our recommendations in their efforts to enhance trial design and accrual.

Evidence: In the course of this project, some have suggested that in the absence of strong evidence that CBPR can improve the quality of cancer research, accelerate protocol development and review, or increase the rate of accrual, such approaches should not be implemented. However, national groups and reports have repeatedly called for the inclusion of public representatives in the design and implementation of clinical research based on the evidence from CBPR approaches in other health areas, which demonstrates its promise in addressing accrual challenges currently faced by cancer clinical trial sponsors and investigators. The Communities as Partners initiative has heeded these calls for action, and sets forth specific recommendations for including public representatives throughout the cancer clinical research continuum.

Additional time requirements: Concern has been expressed that the expanded use of patient advocates and community representatives throughout the clinical trial enterprise will slow down a system already overburdened with regulation and bureaucracy. It is important to note that concurrent to this project, NCI, through its Coordinating Center for Clinical Trials (CCCT), is spearheading efforts to address systemic challenges within the clinical trials system. Moreover, while initial implementation and set-up of the more ambitious recommendations in this report may be time-consuming, we believe that with careful implementation, they will not add to time burden, and can ultimately address accrual challenges currently faced by cancer clinical trials sponsors and investigators.

Recommendations for Community Engagement in Multi-site Therapeutic Phase III Cancer Clinical Trials

Our 58 recommendations center around seven broad themes, which help to define the involvement of communities in the development and implementation of phase III cancer clinical trials. The complete report details these recommendations with a full rationale, as well as an extensive appendix, with strategies and resources for implementation.

I. Ensuring a Meaningful Role for Community Representatives/Patient Advocates (CR/PAs) in Phase III Cancer Clinical Trials (11 recommendations)

The vital role of patient advocates in clinical research design and implementation is well documented, and it is important that we continue to broaden existing advocate involvement in clinical research through expanded opportunities for both community representatives and patient advocates. However, if CR/PAs are to be ethically and meaningfully involved in the research process, the system itself must ensure fairness, transparency, training, clear role definition, and meaningful integration into the larger research process.

II. Ensuring Community Perspectives in the Institutional Review Board (IRB) Review Process (7 recommendations)

Although phase III trials are designed nationally, IRBs play an important role not only in approving the study from an ethical perspective, but also in ensuring locally appropriate consent and recruitment activities. IRBs present an important and often overlooked opportunity for community participation.

III. Improving the Informed Consent Process (12 recommendations)

The complexity of the informed consent process presents a formidable barrier to clinical trial entry, particularly for underserved populations. Existing tools that may improve the informed consent process - including the OHRP-approved “short form” and patient navigation – are underutilized in the cancer clinical trial system. Moreover, additional approaches to address the needs of non-English speaking, Limited English Proficiency (LEP) and low-literacy individuals in the informed consent process are sorely needed.

IV. Ensuring Community Perspectives in Protocol Development, Trial Design and Implementation (6 recommendations)

At the national level, trained CR/PAs should be actively involved in protocol development and trial design. By contributing their perspectives to decisions in such areas as eligibility criteria, informed consent and site selection, CR/PAs can improve trial design and implementation. At the local level, community engagement in trial implementation requires partnership building between investigators and communities, and the development of reliable mechanisms for community feedback on proposed trials. One effective approach utilized in health research is the Community Advisory Board (CAB).

V. Improving Trial Participant Recruitment, Accrual and Retention (11 recommendations)

Accrual of patients to trials remains an enormous challenge for sponsors and investigators; moreover, substantial uncertainty exists about effective approaches for cancer clinical trial recruitment, especially among minority populations. Clearly defined recruitment and retention plans, though rare in treatment trials, may increase the likelihood of recruitment success, particularly with diverse populations. Additional community engagement approaches for improving participant recruitment and retention include cultural competency training for research staff; adoption of the National Standards on Culturally and Linguistically Appropriate Services (CLAS) within the research setting; ongoing collaboration with primary care providers in communication of trial availability; and acknowledgement and appreciation for trial participants.

VI. Enhancing Local Community Support for Cancer Research (5 recommendations)

Increasingly, partnerships between researchers and local communities are seen as an essential ingredient in efforts to improve research outcomes and eliminate health disparities. Partnerships help to build trust in the clinical research process and increase the likelihood that affected communities are invested in and supportive of the research being done. By enhancing community literacy about clinical trials, it is possible to change social norms, so that when a community member receives a cancer diagnosis, s/he is more likely to inquire about clinical trials as an option for treatment.

VII. Enhancing Community Interpretation, Dissemination and Implementation of Trial Outcomes (6 recommendations)

Although traditionally focused on data analysis, conference presentations and peer reviewed publications, there are distinct opportunities for community engagement in the final stage of a Phase III cancer clinical trial. These include better communication of trial results to trial participants, as well as broader use of CR/PAs in the interpretation and dissemination of trial outcomes to the larger community.

Implementing and Disseminating the Recommendations

The next phase of the Communities as Partners project includes broadly disseminating and communicating these recommendations to stakeholders within the clinical trial system, including:

- Sponsors of phase III cancer clinical trials: NCI and the pharmaceutical industry
- Those responsible for the design and implementation of phase III trials: the National Cooperative Groups, industry, and local clinical research sites
- Oversight and quality improvement agencies: The Food and Drug Administration, Office for Human Research Protections, AHRQ, and local Institutional Review Boards
- Accreditation Organizations: The Association for the Accreditation of Human Research Protection Programs and the American College of Surgeons' Commission on Cancer

For cancer clinical research to achieve its full potential in reducing deaths and disparities, we must explore new approaches to make trials more "accruable" and help communities become more involved in research activities. Indeed, as suggested by experts from the NCI, success in clinical trial accrual "will require sustained, aggressive action, and new partnerships between policymakers, healthcare professionals, professional societies, and underserved communities." We believe the recommendations advanced in this report, for the first time, effectively guide each of these groups in forging these new partnerships.
Introduction

Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy is a national initiative of the Education Network to Advance Cancer Clinical Trials (ENACCT) and Community-Campus Partnerships for Health (CCPH), with core funding from the Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute (NCI). This three-year (2006-2009) effort is exploring the potential of employing community-based participatory research (CBPR) principles and approaches to improve multi-site, therapeutic phase III cancer clinical trials, and to develop a strategic plan to shape research, practice and policy for this field. The initiative was guided by a national planning committee, whose composition reflects key stakeholders in CBPR and cancer clinical research.

After developing a background paper, involving Communities as Partners in Cancer Clinical Trials, and inviting expert commentaries, we held our first of two in-person invitational working meetings with representatives from community-based organizations, patient advocacy groups, cancer centers, health professional schools, the pharmaceutical industry, Federal health agencies, and local oncology practices in September 2007. Subsequently, participants were organized into workgroups that were charged with developing specific recommendations for employing CBPR principles and approaches in multi-site therapeutic phase III cancer clinical trials. An initial set of preliminary draft recommendations was completed in February 2008 and circulated widely for comment.

At the second meeting in March 2008, workgroups reconvened to review the many comments received on the preliminary draft recommendations and to advance those deemed most feasible and impactful.

A strategic implementation committee helped to refine the recommendations, which were circulated again for comment in the summer of 2008. In the project's final year, we will further engage key stakeholders, including the national cancer Cooperative Groups and the NCI, the pharmaceutical industry, Institutional Review Board (IRB) oversight and accrediting bodies, clinical professional societies, patient advocacy and cancer health disparities groups and others, in the report's dissemination and implementation.

Why Multi-site Therapeutic Phase III Cancer Clinical Trials?

Multi-site therapeutic phase III cancer clinical trials are the focus of this initiative for a number of reasons:

- They are designed nationally by public or private sponsors but implemented locally, providing opportunities for community engagement at both national and local levels.
- More than 20,000 people with cancer participate each year in NCI-sponsored phase III trials, making them the most common type of trial in which cancer patients participate.
- Community engagement strategies have not yet been implemented systematically in cancer treatment trials, as they have to some degree in large cancer screening and prevention trials.

Although the focus of this initiative is on phase III trials, it is important to note that all cancer clinical trials, regardless of phase or type, can benefit from the strategies recommended in this report.

Why Apply Community-Based Approaches to Cancer Clinical Research?

Although an estimated 20 percent of adult cancer patients are medically eligible for a cancer clinical trial, adult trial participation in the U.S. remains under three percent.1 2 3 4 This accrual rate is even lower among people of color, older people and the medically underserved, who tend to have higher cancer mortality rates than the population as a whole.5 6 7 8 9 These low numbers compromise the quality of clinical research and raise important concerns about access to care and social justice.

Numerous government-sponsored reports and investigator-authored journal articles have recommended community-based approaches to reduce public distrust of clinical research and enhance accrual and accrual efforts in cancer clinical trials. Community-based participatory research (CBPR) can be defined as an approach to "scientific inquiry conducted in communities in which community members, persons affected by the condition or issue under study and other key stakeholders in the community's health have the opportunity to be full participants in each phase of the work, including conception, design, conduct, analysis, interpretation, conclusions and communication of results."10 11 12 13

This initiative seeks to build upon a growing body of evidence from CBPR in other areas of health research to address persistent challenges in multi-site phase III cancer clinical trials. While applying "pure" CBPR principles and approaches in every component of these trials may not always be possible, we have taken a strategic approach by focusing on the most feasible and impactful recommendations for engaging communities as partners in the design and implementation of these trials. In using the term "CBPR principles and approaches," we have deliberately sought to include a continuum of strategies for engaging communities in each phase of clinical research.

Our Role as Conveners

The Education Network to Advance Cancer Clinical Trials (ENACCT) is the only national organization devoted solely to implementing and evaluating cancer clinical trial educational efforts. Community-Campus Partnerships for Health (CCPH) is the only national organization devoted solely to promoting health through partnerships between communities and higher educational institutions, including CBPR. Together, we sought funding for this important initiative from both public and private partners and were charged with:

- Developing a background paper
- Synthesizing and consolidating the information received
- Identifying stakeholders
- Planning and convening two national meetings to develop recommendations
- Vetting public feedback on the recommendations
- Disseminating the report and encouraging implementation by stakeholder groups
Although an estimated 20 percent of adult cancer patients are medically eligible for a cancer clinical trial, adult trial participation in the U.S. remains under three percent. This accrual rate is even lower among people of color, older people, and the medically underserved, who tend to have higher cancer mortality rates than the population as a whole. These low numbers compromise the quality of clinical research and raise important concerns about access to care and social justice.

The low accrual rate in therapeutic cancer clinical trials has a significant effect on both the quality of research and the rate at which new scientific discoveries are made. Better representation of all those affected by cancer - including different races, ethnicities and age groups - is critical to producing more generalizable findings to the population as a whole. Slow or insufficient patient enrollment in clinical trials significantly hampers trial completion and frequently results in the early closure of clinical trials. In a recent preliminary analysis of therapeutic phase III cancer clinical trials led by two national Cooperative Groups, 15-30% of these trials were closed due to poor accrual.

The low accrual rate in therapeutic cancer clinical trials, especially among racial and ethnic minorities, older adults and other medically underserved groups, is also a matter of social justice. Access to cancer clinical trials is a key quality measure for the delivery of health care services, and it is one of the established standards for the delivery of quality comprehensive cancer care. However, not all who are eligible to participate in cancer clinical trials are offered the opportunity. Studies have found that minority patients, as well as older cancer patients, are less likely to be offered participation in a cancer clinical trial, patients enrolled in cancer clinical trials are significantly more likely to be insured, and geographic areas with higher socioeconomic levels have higher levels of cancer clinical trial accrual. A large meta-analysis recently found that certain minority groups may be as willing to participate in health research studies as whites, but are less likely to be invited to participate.

The principles of social justice demand better representation of all populations in cancer clinical trials in order to ensure the just distribution of the benefits and burdens of research participation and address the impact of cancer health disparities. A number of researchers have suggested that trial participation is associated with improved clinical outcomes, and may be considered a means to better treatment. Indeed, some cancer patient advocates have suggested that one way to ensure receipt of standard care is through improved access to cancer clinical trials.

There are a number of structural, cultural, and linguistic barriers that negatively affect participation in clinical cancer research; many are clearly related to lack of knowledge and to underlying attitudes and beliefs on the part of the public as well as those of health care providers, as summarized in the chart in Appendix F.

A 2005 AHRQ Evidence Report concluded that:

1) there is substantial uncertainty about effective approaches for cancer clinical trials recruitment, especially among minority populations; and

2) there is a need for further investigation of effective communication and trust-building strategies, including research on the best approaches to disseminating information about clinical trials, both at community levels and at points of interaction with potential participants.

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* As described in the Belmont Report, justice “means the sense of ‘fairness in distribution’ or ‘what is deserved.’ An injustice occurs when a benefit to which a person is entitled is denied without good reason or when a burden is imposed unduly. Questions of justice have long been associated with social practices such as punishment, taxation and political representation, and have not generally been associated with scientific research. However, conceptions of justice are relevant to research involving human subjects. http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm

† As described in the Belmont Report, social justice “demands better representation of all populations in cancer clinical trials in order to ensure the just distribution of the benefits and burdens of research participation and address the impact of cancer health disparities.”
Prior Recommendations to Address Clinical Trials Disparities and Accrual Challenges

Numerous government-sponsored reports and investigator-authored journal articles have recently recommended new approaches to involving members of the public in clinical research design, implementation, outreach, and accrual. Some notable examples include the following:

- Experts from the NCI have stated that “success [in clinical trials accrual] will require sustained, aggressive action, and new partnerships between policymakers, healthcare professionals, professional societies, and underserved communities.”

- Prominent leaders in academic medicine have cautioned that the state of clinical research today “may hinge on the willingness and ability of the scientific community to actively engage study participants in every stage of research.”

- In a 2004 report, Public Trust in Clinical Research, the National Institutes of Health (NIH) Director’s Council of Public Representatives recommended the consistent and systematic engagement of researchers in incorporating the public’s perspective in both the conduct of clinical research and the publication of findings from that research.

- The Clinical Research Roundtable of the Institute of Medicine (IOM), in its 2003 report, indicated that community engagement in research requires “making a seat at the table for not just one but for several nonscientists,” and that community input “should inform and saturate every aspect of research, from formulating a research agenda to study design, to study review, to oversight at all levels, to dissemination and to translation to practice.”

- In its 2008 report on enhancing the quality of peer review, the NIH recommended piloting the wider use of patients and/or their advocates on reviews of clinical research studies.

- Among the recommendations in its 2005 report, the President’s Cancer Panel recommended that research funders require community participation early in protocol design and in research implementation.

- In its 1999 report, The Unequal Burden, the IOM warned that “…without a concerted effort to enhance the [the links between medically underserved individuals and clinical research, these] communities will continue to lag behind the American majority in benefiting from the tremendous recent scientific achievements and medical breakthroughs in cancer…”

- The 2003 AHRQ evidence report on cancer clinical trial recruitment recommended that research efforts to improve participation of underrepresented populations in cancer clinical trials should be developed within the framework of community-based participatory research, with community involvement through all phases of the research.

Despite these repeated calls for action, none of these recommendations have yet been optimally defined or implemented and are largely absent from national policy forums and efforts to reform the cancer clinical trial enterprise.

The Promise of Community-Based Participatory Research (CBPR) Approaches to Addressing Clinical Trials Disparities and Accrual Challenges

Central to many successful initiatives that seek to understand and improve the health of communities – in particular, racial and ethnic minorities and low income people – are participatory models in which communities are actively engaged in the research process through partnerships with researchers. The term “community-based participatory research” (CBPR) may be defined as “scientific inquiry conducted in communities in which community members, persons affected by the condition or issue under study and other key stakeholders in the community’s health have the opportunity to be full participants in each phase of the work – conception, design, conduct, analysis, interpretation, conclusions and communication of results.” CBPR is not a research method but rather an orientation to research that emphasizes engaging those who are affected by the issue or condition under study and seeking knowledge for a purpose, be it changes in practice or policy.

There are many important reasons why Federal agencies, private research funders, communities, and researchers today are increasingly turning to CBPR approaches:

- There is a growing recognition that “traditional” research approaches have failed to solve complex health disparities. Many research designs fail to incorporate multi-level explanations of health and researchers themselves do not understand many of the social and economic complexities motivating individual and family behavior.

- Significant community involvement can lead to scientifically sound research. Researchers using participatory methods have found community input invaluable in the design and adaptation of research instruments that make the tools user friendly, applicable and culturally appropriate.

- Research findings can be applied directly to develop interventions specific for communities. The intended outcome of CBPR is not simply to find answers to complex social questions but to have those results provide information that can be used by the community to develop its own solutions.

- Community members, wary of being “guinea pigs,” are increasingly demanding that research address their locally identified needs. Traditional researchers often complain about the challenges in recruiting “research subjects.” These challenges are often a result of community members’ feelings that the benefits of research are solely provided to the researcher (e.g., scholarly papers, promotion and tenure), while the community is left with no direct or sustained benefit.
Communities as Partners in Cancer Clinical Trials

CBPR approaches to research have the potential to enhance community interest in research by building greater trust and respect between researchers and communities. A number of peer-reviewed journal articles have reported on the contribution CBPR can make in building trust and greater satisfaction among study participants, including within randomized control trial settings.11, 16

There is growing evidence that participatory models of health research are effective in bridging the gap that often exists between research and practice.11, 17 Indeed, these models are essential to achieving the nation’s health agenda, as articulated by the NCI, NIH, Centers for Disease Control and Prevention (CDC), the National Institute of Environmental Health Sciences, the National Institute of Nursing Research, the American Public Health Association, the Kellogg Foundation, and the Robert Wood Johnson Foundation, among others.15, 16, 17

Underscoring the importance of the CBPR principles in clinical research, the NIH has recently funded a number of Clinical and Translational Science Awards (CTSAs) in its effort to transform how clinical and translational research is conducted. One of the nine CTSAs components is community engagement, the intent of which is to foster collaborative partnerships and enhance public trust in clinical and translational research.81

An AHRQ evidence report suggested that CBPR can enhance recruitment and retention of study participants and improve research quality and outcomes.82 The report cited application of CBPR across a wide range of clinical and behavioral research, including cancer, substance abuse, hypertension, heart disease, diabetes, and HIV/AIDS. The report also found examples of community involvement in every phase of research, with the greatest community involvement in participant recruitment and retention, development of instruments and data collection.

Although there are few reported applications of CBPR throughout all aspects of a clinical trial,13, 14 a number of groups have implemented community engagement strategies in therapeutic clinical research (see Appendix A). Perhaps the best example of comprehensive and systematic implementation of CBPR principles and approaches in clinical research is in HIV/AIDS. The National Institute of Allergy and Infectious Diseases (NIAID) has seven clinical research networks that require the involvement of community members, with specific guidelines for membership, responsibilities and how investigators must interface with them.85

Who is “the community” in multi-site therapeutic phase III cancer clinical trials?

There is no single definition of “community.” Indeed, other initiatives and working groups that have examined community engagement in clinical research have concluded that the term and concept of “community” can include a broad range of definitions.86-88 Community, for example, can refer to a group that self-identifies:

- By affinity, such as geography, disability, illness, or health condition
- By background or culture, such as race, ethnicity, gender, sexual orientation, or religion
- By common interest or cause, such as a sense of identification or shared emotional connection, shared values or norms, mutual influence, common interest, or commitment to meeting a shared need78

For the purposes of this report, we adopt the definition of community in the context of research that has been advanced by the CDC: those whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the conduct of the research.89 Although cancer treatment trials solely involve patients with cancer, there are many “communities” affected by cancer. Those groups that are disproportionately affected by cancer morbidity and mortality should be well represented in each component of phase III cancer clinical trial design and implementation.

Who represents “the community” in multi-site therapeutic phase III cancer clinical trials?

As we pursue a definition of community representation in the cancer clinical trials arena, addressing such questions as “Who is the community?” “Who represents the community?” and “Who speaks for the community?” are critically important.

Currently, many cancer patient advocates provide input and advice in cancer clinical research studies at both the national level - within the Cooperative Groups, various NCI committees, and the peer review process, for example - as well as the local level - such as within cancer centers, Specialized Programs of Research Excellence (SPORES), and Institutional Review Boards (IRBs). Their work is essential to the success of cancer research. However, we believe that to reap the full benefit of community engagement in phase III cancer clinical trials, we need to increase their numbers, strengthen their roles and be more inclusive of all communities whose participation is necessary for the implementation of the research and whose well-being is likely to be affected by the conduct of the research.
Communities as Partners in Cancer Clinical Trials

When considering who may best represent the community perspective in multi-site therapeutic phase III cancer clinical trials, we recommend that the cancer clinical trial research system strive to include both community representatives and patient advocates:

- Community representatives have experience with the healthy population at risk and ideally are affiliated with a community-based organization†† or group whose constituency is disproportionately affected by cancer.†††
- Patient advocates have experience as a patient with cancer, caregiver or family member and ideally are affiliated with a cancer advocacy organization or group.‡‡

Both community representatives and patient advocates are essential to the cancer clinical research process. There may be overlap between these types of individuals; however, one is not necessarily inclusive of the other. Both types of individuals must have a meaningful connection to a specific constituency affected by cancer, with whom they maintain ongoing communication and feedback. Training, appropriate to the activity they are to undertake (see appendix B), is paramount for both types of individuals. Throughout this document, we refer to them collectively as “community representatives/patient advocates” or “CR/PAs.”

Who are the key stakeholders in multi-site therapeutic phase III cancer clinical trials?

The following terms are used frequently in the report to distinguish among the key stakeholders in the cancer clinical trial system:

- Sponsors are the entities that fund the research and decide how and where clinical trials will be carried out. Examples of these are the NCI, pharmaceutical and biotechnology companies (which can include Contract Research Organizations acting on their behalf) and private funders. Through their cooperative agreements with the NCI, the national Cooperative Groups take a lead role in developing, implementing and analyzing these trials, they may also be considered a type of sponsor.
- Research sites are the institutions whose staff implements clinical trials. They may include large institutions, such as NCI-designated cancer centers, academic health centers, Community Clinical Oncology Programs (CCOPs)§§, and community hospitals. They may also include individual medical practices.
- Research teams are located within research sites and typically include oncologists, research nurses - who are often oncology trained nurses - and clinical research associates.
- Local investigators are members of the research team who serve as the principal investigator for the local trial.
- Those affected or at risk of being affected by cancer.

†† The National Community-based Organization Research defines community-based organizations as groups which are “organized by individuals who are directly impacted by the community level problem or issue and who traditionally have had to say in the decisions that govern their lives.” See: http://www.cph-un.ch/docs/healthaccess/1text.html
‡‡ An example would be a representation from a group unrelated to cancer, but whose mission includes improving the health of the community. These would include: community-based groups such as voluntary and professional organizations, schools, women’s health groups, faith-based groups, or housing organizations; or a representative from a local chapter or affiliate of a national voluntary group such as the NAACP Black Women’s Health Imperative, etc. (see appendix E).
§§ An example is an individual affiliated with a national or local cancer service group or advocacy organization such as the National Breast Cancer Coalition or Leukemia/Lymphoma Society (see Appendix E).

††† CBPR approaches in trial design at the national level can help to:
- Ensure well-designed, high quality, cost-effective trials that will accrue, in a timely manner, sufficient numbers of patients and patients from diverse backgrounds
- Ensure that trials are more universally relevant to the real lives of patients
- Increase participation of underrepresented populations in trials
- Enhance community awareness of and trust in clinical research

CBPR approaches in trial implementation at the local level can help to:
- Ensure that clinical trials opened for local accrual can more readily accrue patients
- Enhance community comfort with and trust of researchers, research institutions and the research process
- Enhance community member understanding of clinical research, enabling them to make more informed decisions about whether to participate in a trial
- Increase the rigor and validity of the research
- Encourage researchers to think of community involvement/engagement as a benefit, not a burden

CBPR approaches in the interpretation and dissemination of cancer research studies can help to:
- Promote the early adoption of safe and effective therapies at the community level
- Increase equitable access to state-of-the-art care and reduce cancer health disparities
- Improve health literacy
- Build greater trust in the clinical trials system
- Build greater public awareness about the importance of cancer clinical trials
- Generate stronger participation in cancer clinical trials
- Identify issues that should be addressed in phase IV effectiveness studies
- Enhance dissemination of research findings to the public and community clinicians

Cancer research provides hope and contributes to quality care for current and future cancer patients and communities at risk. Cancer research also offers local health care providers the promise of improved therapies for their patients. Therefore, each of these groups may benefit from research that incorporates CBPR approaches in the design, implementation and dissemination of clinical trials, as noted below:
Communities as Partners in Cancer Clinical Trials

As we consider new ways to involve communities in the development and implementation of multi-site therapeutic phase III cancer clinical trials, we must recognize the significant challenges faced by the current cancer clinical trials structure.

Challenges for National Study Sponsors

Most phase III cancer clinical trials are sponsored nationally by government agencies (principally the NCI, through its Cooperative Group Program) and pharmaceutical and biotechnology companies (which can include Contracts Research Organizations acting on their behalf). Although developed and managed at the national level, trials are implemented locally in a number of settings, including individual medical practices.

Challenges for the NCI Cooperative Group Program

- The NCI Cooperative Group Program faces severe funding challenges. A recent report has noted that funding for the Cooperative Group Program has declined since 2002, from $160 million to less than $150 million annually; and, in 2007, the number of patients participating in Cooperative Group clinical trials fell by 2,000 - the first time there has been a reduction in accrual.
- Each Cooperative Group has its own structure, organizational culture and operational systems. Advocates now serve in a number of committees within these groups, and are increasingly visible throughout the Cooperative Group system. Each group has its own approach for selecting and involving community representatives/patient advocates (CR/PAs) in the clinical trial concept and protocol development process.
- The NCI review process for new concepts and protocols includes a myriad of different scientific review committees, charged with approval of those trials developed through the Cooperative Groups; however, several recent studies have documented that it can take longer to approve a trial than to actually conduct it.

Challenges for Research Institutions and Individual Investigators

- Researchers in government-supported cancer clinical trials find it difficult to devote time and resources to engaging community representatives in their work, particularly for recruitment efforts.
- Similar to study sponsors, research teams and/or their institutions seldom use a formal assessment process to select appropriate trials for their community.
- Many researchers experience difficulty in clinical trial recruitment, leading to poor accrual and questionable quality of informed consent.
- Researchers in government-supported cancer clinical trials find it difficult to devote time and resources to engaging community representatives in their work, particularly for recruitment efforts.

Challenges for the Pharmaceutical Industry

- Today, a slight majority of cancer clinical trials are funded by the pharmaceutical industry. Industry conducts its own phase III trials, often contracting with individual investigators. Pharmaceutical companies often collaborate with the NCI and the Cooperative Groups on studies. In addition to patient enrollment, major industry challenges include research site identification, competition for sites among companies and investigator interest.
- Each company has its own internal process for developing and approving concepts and protocols for new trials. Some companies have utilized CR/PAs within these early review processes, but the extent of their involvement is unclear.

Challenges for all National Sponsors

It is clear that all study sponsors face accrual challenges. As stated earlier, overall adult accrual rates are less than three percent, with certain populations, such as those that are low income, elderly, racial/ethnic minorities or those who live in rural areas, being even less likely to participate. For Cooperative Group studies, 15-20% of sites never enroll a single patient, and 30% of sites enroll 75% of evaluable patients. Others have estimated the non-accrual rate in Cooperative Group national studies to be from 15-40%.

Challenges for Research Institutions and Individual Investigators

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Cross-Cutting Challenges to Utilizing CBPR Approaches in Cancer Clinical Trials

As we vetted draft recommendations with key stakeholders, it quickly became apparent that there are significant challenges to implementing CBPR approaches in multi-site phase III cancer clinical trials that cut across the system.

- **Concerns about additional time requirements**
  
  During our deliberations, many people expressed concern that the expanded use of CR/PAs throughout the clinical trial process will slow a system already overburdened with regulation and bureaucracy. The time range for designing and activating Phase III clinical trials varies widely, but the median time is approximately 80 days for a Phase III clinical trial to be activated.**††††** Similarly, at the local level, developing community partnerships takes time, patience and ongoing commitment to the process. In one study, for example, developing and submitting a grant proposal to NCI using CBPR approaches took 10 to 12 months.**‡‡‡‡**

- **Concerns about implementing participatory approaches without a strong evidence base**
  
  During our deliberations, many people observed that because there is no strong evidence that CBPR approaches can improve the quality of research, accelerate the protocol development and review process, or increase the rate of protocol accrual, such approaches should not be implemented. Rather, they suggested that each approach be appropriately evaluated in a controlled research study. We concur with prominent national groups that have called for the inclusion of public representatives in designing clinical research to improve the entire research process, even in the absence of strong evidence.**‡‡‡‡**

- **Concerns about compensation for community representatives/patient advocates**
  
  Clinical researchers receive both tangible (e.g., salary, publications) and intangible (e.g., prestige, career advancement) rewards from their participation in trial design and implementation. In contrast, most CR/PAs who participate in research activities are not otherwise working in the research setting and often are required to take time away from paid employment and other responsibilities. Our deliberations have emphasized the importance of maximizing the participation of CR/PAs through appropriate recognition, support and/or compensation. However, as noted above, many people have pointed out that cancer research dollars are diminishing, and that any compensation for CR/PAs would further reduce the amount of funding available to conduct trials overall. Reduced funding for clinical research affects the number of new trials opening, the number of patients participating, and the number of staff attending Cooperative Group meetings. In addition, lower patient reimbursement rates for NCI-funded trials have made accrual challenges currently faced by clinical trials sponsors and investigators.

- **Concerns about participation across disease sites and diseases**
  
  While we agree that additional research in this area is critical (and a number of the recommendations below make the case for more research), we believe that the evidence from CBPR in other health issues shows that these approaches hold much promise in addressing clinical trials disparities and accrual challenges currently faced by clinical trials sponsors and investigators.

- **Concerns about compensation for community representatives/patient advocates**
  
  Clinical researchers receive both tangible (e.g., salary, publications) and intangible (e.g., prestige, career advancement) rewards from their participation in trial design and implementation. In contrast, most CR/PAs who participate in research activities are not otherwise working in the research setting and often are required to take time away from paid employment and other responsibilities. Our deliberations have emphasized the importance of maximizing the participation of CR/PAs through appropriate recognition, support and/or compensation. However, as noted above, many people have pointed out that cancer research dollars are diminishing, and that any compensation for CR/PAs would further reduce the amount of funding available to conduct trials overall. Reduced funding for clinical research affects the number of new trials opening, the number of patients participating, and the number of staff attending Cooperative Group meetings. In addition, lower patient reimbursement rates for NCI-funded trials have made it difficult for smaller oncology practices to participate in clinical research.

- **A clinical trial workforce without CBPR training or experience**
  
  An important barrier to implementing CBPR approaches is the knowledge, skills and attitudes of a clinical trial workforce that was trained in the conventional investigator-initiated, hypothesis-driven model of research. Very few clinical researchers have undergone formal training to conduct CBPR.**‡‡‡‡**

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**††††**Includes Cooperative Group and CTEP review/approval of the trial, Central IRB review/approval, and local IRB review/approval.

**‡‡‡‡**Change. (2005). A Guidance Document for Implementing Effective Cancer Clinical Trials: Executive Summary 2005. The report states "government-sponsored studies are generally under-funded. Government-sponsored studies involve at approximately $2,000 per study subject. The randomized Phase II government-sponsored study median cost was $5,000, whereas for Phase II median cost was $3,427.

**§§§§**While we are challenging the cancer clinical trial system to change, we must also work within the system. While we recognize that the cancer clinical trial system (with a strong focus on NCI-funded Cooperative Group and industry-sponsored studies) is not perfect, we must engage these involved in it as partners in this effort. While there can be merit in envisioning an entirely new system built with communities as partners from the start, we believe this is neither realistic nor feasible. We are invested in making the current system more accessible to and involving of communities, and we see ourselves as partners with the clinical trial system.

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From Deliberations to Recommendations

Considering the challenges described above, applying CBPR principles and approaches consistently in every component of multi-site phase III cancer clinical trials may not always be possible. In this report, we have taken a strategic approach by focusing on the most feasible and impactful recommendations for engaging communities as partners in the design and implementation of these trials.

The recommendations that follow are intended to serve as a strategic plan for key stakeholder discussion and implementation. They have been informed by our understanding of the following:

- While we are challenging the cancer clinical trial system to change, we must also work within the system. While we recognize that the cancer clinical trial system (with a strong focus on NCI-funded Cooperative Group and industry-sponsored studies) is not perfect, we must engage those involved in it as partners in this effort. While there can be merit in envisioning an entirely new system built with communities as partners from the start, we believe this is neither realistic nor feasible. We are invested in making the current system more accessible to and involving of communities, and we see ourselves as partners with the clinical trial system.

- There are many study sponsors, researchers and patient advocates in the cancer clinical trial system currently working to engage communities in clinical trials, and we seek to build upon their efforts. We are aware that we are building on the great strides already made in bringing research systems, individual researchers and patient advocates together. However, we also acknowledge that such work is undervalued, under-funded and not consistently practiced across the cancer clinical trial system.

- There are numerous access barriers to clinical trials that will not be addressed by these recommendations. While we expect that community engagement strategies will reduce barriers and enhance accrual, we recognize that there are many more problems that need to be addressed, which are beyond the scope of this project.

- Federal research priority setting and the current funding climate (see challenges listed above) will naturally impact these recommendations. Although research priorities and funding are often disease-specific, not tied to the population burden of the disease, and driven by political factors, we must remain focused on our charge to improve the process and outcomes of phase III cancer clinical trials.
Recommendations for Community Engagement in Multi-Site Therapeutic Phase III Cancer Clinical Trials

I. Ensuring a Meaningful Role for Community Representatives/Patient Advocates (CR/PAs) in Phase III Cancer Clinical Trials

We recommend that public and private sponsors of phase III cancer clinical trials:

1. Ensure that the application and selection process for community representatives/patient advocates (CR/PAs) serving at the national level is open and transparent. Opportunities to serve should be widely communicated both to traditional and non-traditional sources of potential candidates.
2. Ensure that the roles, responsibilities, expectations and length of service of CR/PAs serving at the national level are explicit, well-defined and adequately communicated to all parties involved.
3. Ensure appropriate training for CR/PAs serving at the national level to prepare them sufficiently for the activities they will undertake.
4. Support appropriate training for CR/PAs at the local level, to prepare them sufficiently for the activities they will undertake.
5. Support training for individual investigators on optimal ways to integrate CR/PAs into research activities at both the national and local levels.
6. Implement specific approaches to appropriately recognize, support and compensate CR/PAs serving at the national level for the services they provide.
7. Acknowledge, promote and publicize the ongoing important role of CR/PAs in the national research process.

We recommend that local research sites implementing phase III cancer clinical trials:

8. Implement training for local level CR/PAs to prepare them sufficiently for the activities they will undertake.
9. Implement training for individual investigators and research teams on optimal ways to integrate CR/PAs into local level research activities.
10. Implement specific approaches to appropriately recognize, support and compensate CR/PAs serving at the local level for the services they provide.
11. Acknowledge, promote and publicize the ongoing important role of CR/PAs in the local research process.

Rationale

Mostly volunteers affected by a disease, “patient advocates” working in the research setting seek not only to change how research is conducted, but also to influence research funding decisions.118 In its 2003 report, the Clinical Research Roundtable of the IOM indicated that [trial] participants and community representatives have a great deal to contribute to the design, review, and conduct of projects and should be energetically recruited.119 The literature has documented the important role of these advocates in clinical research study development and implementation, especially in HIV/AIDS and cancer research.119, 120, 121, 122, 123, 124, 125, 126 As noted in the introduction, it is important that we continue to broaden existing advocate involvement in clinical research through both community representatives and patient advocates.

If members of the public are to be ethically and meaningfully involved in the research process, the system itself must ensure fairness, transparency, training, clear definition of role, and meaningful integration into the larger research process. A research system that seeks to include members of the public in its work should therefore include:

- A fair and open recruitment and selection process
- Clearly defined, meaningful roles and responsibilities that are universally accepted and implemented
- Training to empower advocates to ask critical questions and make sound judgments about research studies

Selection criteria: Trial sponsors and research institutions should have a process in place for selecting CR/PAs to serve in research activities. Each should set minimum qualifications and skills to serve, depending on the activities with which the person will be involved, and articulate them clearly and prominently. (See Appendix C for suggested criteria.)

Length of Service: In order to maximize the role of the public in the research process, we believe that “term limits,” as instituted in many leadership positions in the nonprofit and medical arenas, should be implemented in all research efforts involving CR/PAs.

Clarity of Role: While the role of CR/PAs is growing in cancer research, through our project deliberations, it has become clear that both researchers and CR/PAs would benefit from a more clearly defined role in the cancer clinical research process. In most instances, the role is self-defined. Despite the benefits of such flexibility, many advocates serving on committees seek clearer role definition and greater support.116 This clarity can help to ensure that CR/PA inclusion is not viewed as auxiliary, but as integral to the scientific process;116 it is one of the benefits of such flexibility. In many instances, researchers or committees seek clearer role definition and greater support.116

Rationale

- National research activities include, but are not limited to: development of research question(s) and trial concept; design of trial (i.e., rationale, objectives, endpoints, eligibility, schema); development of consent forms; development of recruitment and accrual plans; development of requirements for local research team; participation in Data Safety Monitoring Board (DSMB) activities; participation in data analysis and interpretation; and participation in dissemination of findings through community networks.

- Local research activities include, but are not limited to: participation in decision of which trials local investigators choose to open; participation in creation of recruitment and retention plans; participation in community education activities; participation in IRB activities; advisement on trial implementation activities (such as data collection protocols; communication of trial availability, outreach, patient navigation design); advisement on ongoing communication activities (to enhance retention and promote translation of research results for patients and the public).
II. Ensuring Community Perspectives in the Institutional Review Board (IRB)

Review Process

We recommend that IRBs that review phase III cancer clinical trials, including the VCI Central IRB:

1. Be comprised of 25% community IRB members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.
2. Ensure that all members are trained in strategies for community engagement in research, and oriented to community member roles on the IRB.
3. Consider evidence of community engagement in and community support for studies seeking IRB approval.

We recommend that investigators submitting phase III cancer clinical trial protocols to IRBs:

4. Include evidence of community engagement in and community support for the study.

We recommend that the Association for the Accreditation of Human Research Protection Programs include in its accreditation standards that IRBs:

5. Be comprised of 25% community IRB members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.
6. Ensure that all members are trained in strategies for community engagement in research, and oriented to community member roles on the IRB.
7. Consider evidence of community engagement in and support for studies seeking IRB approval.

Rationale

Although phase III trials are designed nationally, local IRBs play an important role not only in approving the study from an ethical perspective, but also in ensuring locally appropriate consent and recruitment activities. IRBs present an important and often overlooked opportunity for community participation.

25% community IRB members who are properly oriented, trained, mentored and compensated: Federal human subjects regulations require that all IRBs must have at least one member “whose primary concerns are in non-scientific areas” (non-scientific) and at least one member “who is not otherwise affiliated with the institution” (non-affiliated). Often referred to as “community members,” non-scientific and non-affiliated IRB members can help to ensure that language and other aspects of a research study make sense to the layperson. They can bring unique viewpoints to the IRB; non-affiliated members are not biased by employment, and non-scientific members are not biased toward the research question. They can play an important role in evaluating the benefits and risks to research participants, reviewing the informed consent process to ensure participant protection, reviewing protocols, and making presentations to community groups about the role of IRBs and the importance of human subjects research.

Both the National Bioethics Advisory Committee and the IOM have recommended that IRBs be comprised of 25% community IRB members. Most IRBs do not have such composition. There are a number of barriers to community members’ participation on IRBs, including not having a clear definition and understanding of their role, the complexity and amount of information reviewed, and most community IRB members, for example, view their role solely as simplifying consent forms.

IRB member training: Orientation and training help to ensure that community members are competent in their roles on IRBs. Further, respect, recognition and feedback are critical for retaining community members. The largest study to date of non-scientific and non-affiliated IRB community members, for example, found that although 94% of participants had positive experiences working with scientist IRB members, 88% occasionally had been intimidated and felt disrespected by them. 45% identified lack of education and training as a problem, and 76% wanted more intensive education and training for new members.

In order to competently review IRB applications for cancer clinical trials, all IRB members should also be familiar with approaches to community engagement in research, including CBPR principles and approaches. This could be accomplished through informal (e.g., self-study of published articles) and formal (e.g., educational workshops) training (see Appendix B).

Evidence of community engagement and support for the study: While IRBs do consider the local context in which research is conducted, IRBs are neither expected nor required to assess the risks and benefits of a given study to participants’ communities or the broader community, and must do not make this assessment. Similarly, IRBs are neither expected nor required to assess the nature and extent of community support for the study. Native American communities are at the forefront in devising methods for ensuring community engagement, support and consent in research through tribal IRBs. IRBs can and should ask questions that are intended to determine the extent of community engagement and support for the study.

Investigators can demonstrate community engagement in and support for the proposed phase III trial by documenting and describing the activities conducted to engage the community, and the responses to these activities. For example:

• How they have involved CR/PAs in decisions leading up to their IRB application (e.g., deciding to participate as a study site, developing plans for recruiting and retaining study participants)
• How they plan to involve CR/PAs in subsequent phases of the research (e.g., recruiting and retaining study participants, disseminating study findings). Investigators could include in their application memoranda of understanding between researchers and community partners and letters from CR/PAs that speak to their involvement in and support for the study.
II. Improving the Informed Consent Process

We recommend that the Office for Human Research Protections (OHRP) and the U.S. Food and Drug Administration (FDA) adhere to the following recommendations:

1. Provide guidance on and encourage use of the OHRP-approved “short form” and its accompanying procedures with IRBs and investigators.
2. Monitor and manage quality improvement efforts to address ongoing challenges to the consent process.

We recommend that IRBs reviewing phase III cancer clinical trials:

3. Ensure that all members are trained in approaches to address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process.
4. Permit use of the OHRP-approved “short form” and its accompanying procedures, if submitted by an investigator.

We recommend that public and private sponsors of phase III cancer clinical trials:

5. Promote and encourage the appropriate use of the OHRP-approved “short form” and its accompanying procedures, with specific recommendations for its use in the field.

We recommend that local research sites enrolling patients in phase III cancer clinical trials:

6. Consider using the OHRP-approved “short form” and its accompanying procedures in the consent process.
7. Implement the consent process through trained staff, including, when available, patient navigators who can assist in the consent process at the patient’s request.
8. Utilize trained medical interpreters or a telephone language line* for LEP individuals, throughout the informed consent process and when consent forms are not available in the individual’s native language.

As the leader of the National Cancer Program, we recommend that the National Cancer Institute:

9. Develop policies for optimal ways to use the OHRP-approved “short form” for Cooperative Group trials, complementary to the existing template.
10. Develop policies and procedures for improving the consent process for LEP populations participating in Cooperative Group trials, including translation of forms and questionnaires.
11. Conduct research on optimal ways to implement the informed consent process beyond the written page, allowing for differences in learning styles (e.g., the use of pictures and videos), which will provide replicable practices for local research sites.
12. Expand funding for patient navigation programs, to include assisting in the informed consent process.

*If an accessible interpretation service, available in many health care institutions.

Rationale

Use of the OHRP-approved “short form” and alternatives to written informed consent: IRBs require the use of a written consent form during the consent process. Consent forms from clinical oncology protocols are written at a level that is difficult for most patients to read (an 11th or 14th grade level in many cases) and are between 20-40 pages in length. The IOM estimates that 90 million adults in the United States may have trouble understanding and acting on health information, and although the average American adult has achieved at least a twelfth grade education, the average reading level for American adults is estimated to be at the 8th or 9th grade.145 As summarized in a 2002 policy statement from the American Society of Clinical Oncology, “...the language used in informed consent documents is increasingly legal and scientific in nature. Experts agree that the documents are difficult for potential trial participants to comprehend because of this complex, legalistic language, where possible, the consent form should be simplified to optimize comprehensibility and clarity, reduce intimidating language, and place potential benefits and risks in a proper context.”146 Studies have documented the value of shorter, more comprehensible informed consent forms.147 In addition, many researchers experience difficulties in clinical trial recruitment, leading to questionable quality of informed consent.148

In 1995, the OHRP in the U.S. Department of Health and Human Services approved the use of a “short form” as a way to comply with the Code of Federal Regulations requirement that informed consent information is to be presented “in language understandable to the subject.” It clarified the procedures used with subjects who do not speak English, and specific roles for the IRB. In 1998, the FDA issued additional guidance for LEP populations. Neither agency has provided additional guidance for consent for people with low literacy skills. The short form may be a viable alternative for many people wishing to participate in clinical trials and may reduce barriers to access and to understandability. Unfortunately, few investigators are familiar with this option, and IRBs are fearful of approving its use. A concerted effort to educate study sponsors, IRBs and investigators about the “short form” and its associated processes for consent may lead to its greater use.

Beyond simplifying informed consent forms and making them available in multiple languages and literacy levels, new and creative methods are needed for informed consent that allow for differences in learning styles (e.g., the use of pictures and videos).149

IRB member training: As discussed in Section II, training for IRB members is critical. In order to competently review IRB applications for clinical trials, all IRB members must be familiar with approaches to informed consent in low literacy and LEP populations.150 These individuals have roles to play in the research process as well, particularly within the informed consent process.151 Research sites that use patient navigators are well-positioned to train them for roles in the informed consent process.
IV. Ensuring Community Perspectives in Protocol Development, Trial Design and Implementation

We recommend that public and private sponsors of phase III cancer clinical trials:

1. Develop explicit system-wide procedures to ensure that all concepts and proposed study protocols are appropriately and sufficiently reviewed by trained CR/PAs before the study is submitted for final approval, and ideally throughout the development process.
2. Encourage and permit funding for local research sites to develop mechanisms, such as community advisory boards (CABs), for ongoing community participation in study implementation.
3. Expand site selection criteria to include demonstrated local community engagement and cultural competence, as a means of ensuring community perspective.

We recommend that local research sites implementing phase III cancer clinical trials:

4. Develop mechanisms for ongoing community participation in trial implementation.
5. Develop specific criteria for selection of clinical trials in which they will participate.
6. Expand its support for research that aims to document the impact of community participation in the design and implementation of cancer clinical trials.

Rationale

System-wide procedures in protocol review: A number of national reports have called for the systematic inclusion of trained members of the public in designing clinical research to improve the entire research process. 176-178,179,180 As we consider how cancer clinical research can become more inclusive of CR/PAs, it is important to recognize that a defining characteristic of CBPR is that community members have the opportunity to be full participants in each phase of research. 181,182,183 As we consider implementation of this principle in clinical trial design, we must consider that optimal involvement of CR/PAs means both:

- A clarity of role 184 in protocol or concept review, as discussed in Section I.
- A clear understanding of where and how the CR/PA voice is being heard throughout the entire system (i.e. different levels of influence in core committees as well as steering committees).

Currently, advocates serve in a number of committees within the Cooperative Group system, providing feedback on trial design and recruitment concerns. While systemic involvement may well exist to those “in the know,” such clarity can assist the CR/PA currently serving, as well as the public at large, in understanding how research sponsors value the role of the public in research.

Support mechanisms for ongoing community participation in local study implementation: Partnerships between the community and investigators are a means for enhancing community participation in research study implementation. Community partnerships have the potential to enhance community interest in research by building greater trust and respect between researchers and communities, as well as greater satisfaction among study participants. 185,186 Such partnerships can be sought with key community-based institutions, as well as community stakeholders that are a part of the local infrastructure (e.g., primary care clinics, primary care clinicians, community oncologists, religious institutions, and community-based organizations). As a study progresses, key ongoing discussions between investigators and the community should include recruitment and retention progress, community trial promotion, and enhancing access to the trial.

One useful approach for ensuring ongoing community input into trial implementation is a Community Advisory Board (CAB). CABs are typically composed of community members who share a common identity, history, symbols and language, and culture. 187-190 They may include representatives of non-governmental and community-based organizations, members of patient advocacy groups, health care workers, trial participants, family members, and others. 191-194 CABs can provide a context for researchers and community members to discuss the intent, risks, benefits, and implications of research projects in a culturally appropriate manner: 195-198 CAB members are people who can effectively express community needs and concerns to researchers and communicate with other community members about clinical research studies. 199-201 CAB members may also influence the informed consent process. Traditionally, the informed consent process focuses on the relationship between the researcher and the participant, each expecting that the decision about enrollment in clinical trials is an individual choice. Yet, community perceptions of research may guide individual action. 202,203

Additionally, while volunteer recruitment and retention are not typically the responsibility of CAB members, their knowledge of how to best reach the community - where and how - can be of significant help to research staff as they seek to inform the community about upcoming and ongoing trials and recruit potential study volunteers. 204 If a CAB has authentic connections to its community, its members can also transform community attitudes about research. 205,206

Currently, Federally-funded clinical trials in HIV/AIDS have a number of policies that mandate the inclusion of public advocates in designing clinical research to improve the entire research process. For example, in order to receive funding through the National Institute of Allergy and Infectious Diseases (NIAID) HIV/AIDS Clinical Trials Networks (similar to the Cooperative Group system), researchers must document meaningful community partnerships. Investigator applications must include the establishment and maintenance of one or more CABs to represent the local population(s) impacted or threatened by HIV/AIDS at the clinical research site(s) and present the proposed research to the community. 207-209 The CDC also requires that its Prevention Research Centers have CABs. 209-211

Expand site selection criteria/develop local criteria for participation: Private sponsors need better guidance in selecting sites, and local institutions, whether participating in public or privately-funded trials, need better guidance in choosing trials in which to participate. Appropriate selection of trials to match local population needs is important. For example, consistent selection of trials with strict eligibility criteria may unintentionally and yet systematically exclude patients with chronic conditions, which, in turn, exclude the elderly, members of minority groups, and patients with lower socioeconomic status from participating in trials. 212 By considering other criteria, such as those related to cancer burden and community engagement, we may be able to increase the efficiency with which sites accrue all patients.

NCI expansion of support for research to document the impact of community participation in the design and implementation of cancer clinical trials: The 2005 AHRQ evidence report on cancer clinical trial recruitment suggested that “research efforts to improve participation of underrepresented populations in cancer clinical trials should be developed within the framework of CBPR, with community involvement, through all phases of the research.” Such research, with a focus on all levels of community involvement would help to provide evidence of the benefits of community participation, as well as improve ongoing initiatives that seek to include community members in research. The NCI is in a unique position to undertake such research efforts.
V. Improving Trial Participant Recruitment, Accrual and Retention

*Appropriate grouping may be done by institution or research group; may be classified by disease site, disease stage, type of treatment (i.e. adjuvant, surgical) etc.

We recommend that public and private sponsors of phase III cancer clinical trials:

1. Facilitate the development of national recruitment and retention plans to assist local investigators in optimally identifying potentially appropriate research participants, with additional focus on reaching minority and non-English speaking populations.
2. Clearly articulate funding consequences if trial recruitment and retention targets and/or substantive progress towards achieving them are not demonstrated.
3. Expand site selection criteria to include those who have adopted relevant National Standards on Culturally and linguistically Appropriate Services (CLAS), as a means of enhancing optimal recruitment and retention.
4. Expand patient navigator programs to include responsibilities related to discussion of clinical trial opportunities with eligible cancer patients.

We recommend that local research sites implementing phase III cancer clinical trials:

5. Ensure that each research team is trained in cultural competency, as it relates to clinical trials access, recruitment, and retention.
6. Establish an explicit and standardized approach for discussing clinical trials with all eligible patients at the time of initial treatment consultation.
7. Collaborate with primary care providers, patient navigators and other professionals involved in patient care, in order to encourage communication of trial availability to individuals recently diagnosed with cancer.
8. Develop participant recruitment and retention plans for groups of trials and ensure they are reviewed by community partners and/or existing CABs, prior to or concurrent with local IRB submission.
9. Demonstrate respect, acknowledgement and appreciation of trial participants through a variety of means, such as periodic correspondence about the trial, newsletters, cards, and special events.

At the Federal level we recommend:

10. NCI expand research funding to document and demonstrate promising practices in cancer clinical trial recruitment and retention efforts, and in particular, on efforts to involve members of underserved minority, non-English speaking, poor and elderly communities.
11. AHRQ commission an update of its 2005 “Evidence Report/Technology Assessment on Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials.”

Rationale

Recruitment and retention plans: Such plans have traditionally been used in cancer prevention and screening trials with some degree of success;218, 219 a multi-component plan with community input has been recognized as the most successful strategy to recruit diverse populations for research.220 Yet such plans are rare in therapeutic cancer clinical research, and most trials have few resources to devote to recruitment and retention efforts. However, even simple, systematic outreach efforts to referring physicians can have an impact. Two studies found that a lack of dissemination of study opportunities to providers made it difficult for the success of potentially eligible patients to cancer clinical trials.221, 222 Key reasons for recruitment problems include: inappropriate match between a trial and a community; inadequate planning at all levels of the trial; overestimation of the yield from a particular patient source; and an inability to alter existing plans rapidly and to implement other recruiting strategies if recruitment is lagging.223

We believe that the development of recruitment and retention plans, based on target population characteristics at the national level, and adaptable at the local level, can increase the likelihood of recruitment success. Recruitment practices can be optimized by: a) sponsors facilitating and organizing the development of a national outreach plan; and b) local investigators’ adapting such a plan for their own use and vetting it with a community partner or CAB.

Recruitment and retention planning, coupled with community review, should be done as trials are being considered at the local site, and, if possible, prior or concurrent to local IRB submission. This same review group should also review yearly updates on trial recruitment and retention plans to ensure targets are being met and/or substantive progress towards them is being made. Similar approaches assisting in recruitment and retention have been used at Siteman Cancer Center224 and at Fox Chase Cancer Center.225

Articulation of funding policy regarding trial recruitment and retention targets: While the NIH Revitalization Act of 1993 requires investigators to formulate a plan to include people of diverse racial and ethnic origins and women into NCI-sponsored clinical trials, recent data show that most clinical trials are still falling short of their target inclusion percentages and that submitted plans are not always followed after their initial approval.226 We believe that clear consequences, as are being implemented at Siteman Cancer Center (see Appendix A), and Helen F. Graham Cancer Center at Christiana Care,227 should be articulated by sponsors if overall trial recruitment and retention targets and/or substantive progress towards achieving them are not demonstrated.

Implementation of “standard” patient approach to discussing treatment options: Data have shown that not all eligible patients are approached to participate in cancer clinical trials. In a nationwide study with cancer patients, about 85% were either unaware or unsure that participation in clinical trials was an option, although about 75% said they would have been willing to enroll had they known it was possible.228, 229 A recent meta-analysis of numerous health research studies found that minority groups appear to be as willing to participate in research as whites, but are less likely to be invited to participate.230 Other studies have similarly found that minorities with cancer are less likely to be offered participation in a cancer clinical trial, that patients enrolled in cancer clinical trials are significantly more likely to be insured, and that geographic areas with higher socioeconomic levels have higher levels of cancer clinical trial accrual.231, 232, 233 Finally, researchers who do not value the inclusion of minorities in their research may demonstrate less commitment to ensuring their participation.234 Local research institutions’ universal implementation of a “uniform” policy to inform eligible patients of the option to receive treatment through a clinical trial may help to eliminate these disparities.

Acknowledgment of participation: Even though many cancer patients are receiving care through a clinical trial, they are also volunteering their time to participate in research, and, as such, should receive ongoing acknowledgment, as is done in many prevention studies. This is particularly important once the trial is completed and follow-up begins. Such acknowledgment should be standard procedure for all those conducting clinical research. One national group, the Center for Information & Study on Clinical Research Participation (CISCRP), has launched its “Medical Heroes - National Public Education Media Campaign,” to acknowledge the contributions of those who participate in research.

Cultural competency training of research teams: There is a growing awareness of racial and ethnic disparities in health and the need for health care systems to accommodate increasingly diverse patient populations. The same
is true for clinical research systems and institutions. Despite NIH guidelines on inclusion of women and minorities as subjects in clinical research, only 15% of cancer patients enrolled in national publicly-funded treatment trials are ethnic/cultural minorities. It has been documented that lack of cultural competence among clinical trial staff makes it more difficult to accrue patients to particular trials. Recently, Federal officials have underscored the need for cultural competency training in the research setting, supporting researchers to apply CIAS to the clinical trials process. Community members and institutional staff who share the same ethnic background as the target group have been successfully employed in community outreach, community education, recruitment, and data collection efforts. Those conducting clinical research in minority communities should strive to ensure that research teams include people with the same cultural, racial/ethnic, and language backgrounds as prospective research participants. Individuals should have familiarity with particular community customs, patterns, and values; rare racial or ethnic concordance is insufficient.

As mentioned above, many researchers experience difficulties when discussing trial participation, leading to poor accrual to trials and questionable quality of informed consent. Researchers are further challenged when recruiting and consenting ethnically diverse populations to clinical trials and may lack the skills necessary for conducting culturally sensitive community outreach and education programs on clinical trials. Several authors have called for the need to change the behaviors of research staff to increase minority access to research participation, suggesting that these efforts should include informing minority groups of specific trials and inviting them to participate, involving sites that are accessible to minority groups, and identifying and attempting to address factors that may undermine minority groups’ participation.

Research team collaboration with community providers and patient navigators: A trusted physician’s recommendation is often the primary factor influencing patients’ decisions to enroll in a trial. Primary care providers are often in the best position to find the most opportune moments—before or when a definitive cancer diagnosis is made and before making a referral to an oncology specialist for treatment—to bring up the subject of clinical trials with their patients. By identifying ways to work collaboratively with these providers, we believe that referral sources can be enhanced and overall accrual and retention increased.

Patient navigators represent another opportunity to enhance recruitment and retention. Patient navigation “can make substantial contributions to health care access, improve the timeliness of cancer care, especially in patients who are not familiar with or distrustful of the health care system, and reduce inefficiencies in a fragmented health care system,” and may be essential to ameliorating disparities in clinical trials. Their role in clinical trials has had some success in the NCI-funded Cancer Disparities Research Program, expanding this role in all patient navigation programs has important potential. By identifying ways to work with these navigators, we believe that both the consent process can be enhanced and overall accrual and retention increased.

Expand NCI research funding to document and demonstrate promising practices in cancer clinical trial recruitment and retention efforts, and in particular efforts to involve members of underserved minority, non-English speaking, poor and elderly communities: As described previously, the AHRQ Evidence Report on cancer clinical trials concluded that: 1) there is substantial uncertainty about effective approaches for cancer clinical trials recruitment, especially among minority populations; and 2) there is a need for further investigation of effective communication and trust-building strategies, including research on the best approaches to disseminating information about clinical trials, both at community levels and at points of interaction with potential participants. We believe that NCI is in a unique position to undertake such research efforts, with a focus on implementable and transferable practices.

An update of the AHRQ 2005 Evidence Report/Technology Assessment on Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials: The AHRQ Evidence-Based Practice Centers (EPCCs) develop evidence reports and technology assessments on various topics; the clinical trials recruitment report was commissioned by the NCI in 2002. This report was released over three years later, with data from studies published over four years ago, and should be update to reflect new research.

VI. Enhancing Local Community Support for Cancer Research

We recommend that public and private sponsors of phase III cancer clinical trials:

1. Ensure that the institutions/investigators implementing their research protocols have documented: a) ongoing community education about clinical trials beyond any particular trial; and b) outreach activities with community groups, particularly those working to reduce health disparities.

2. Provide technical assistance to facilitate the ability of research sites to successfully implement community partnerships, outreach and engagement activities.

3. Demonstrate mutually beneficial, sustained partnerships with existing community infrastructure, such as primary care providers and community-based organizations. These partnerships should engage in outreach and education efforts that inform the community about clinical trials beyond any particular trial. Whenever possible, research sites located in the same geographic area should collaborate in these efforts.

4. Engage in outreach activities with community groups, particularly those working to reduce health disparities, to educate the broader community about cancer clinical trials beyond any particular trial. Whenever possible, research sites located in the same geographic area should collaborate in these efforts.

5. Expand existing standards for community outreach and research to include community-based education and partnerships around clinical trials.

Rationale

Ensure that the institutions and/or investigators have documented partnerships, community education and outreach activities, and provide assistance in helping them do so: As described elsewhere in this document, sustainable partnerships between research sites and local communities have long been considered vehicles for advancing public health. Increasingly, these partnerships are a requirement for private and Federal funding and are seen as essential in the effort to eliminate health disparities. Partnerships help to build trust in the clinical research process and increase the likelihood that affected communities are invested in and supportive of the research being done. Several experts have noted the harm in the common assumption that the public, especially people of color, are “distrustful” of research and research institutions, and therefore uninterested in participating in research. Rather, they note that it is the institutions” responsibility to engage in ongoing activities to gain people’s trust. As a prerequisite for participation in research, we believe strongly that research sites implementing phase III cancer clinical trials should cultivate community partnerships and that research sponsors should help them do so.

Community education must be a key component of any community-research site partnership. Specifically, community education on cancer clinical trials can enhance awareness of treatment options, address community distrust and may reduce barriers to clinical trial access. By enhancing community literacy about clinical trials, it is possible to change social norms, so that when a community member is diagnosed, his/her loved ones, friends and social networks may encourage that person to inquire about clinical trials as an option for treatment.

Other national initiatives include similar partnership-building recommendations. The EDICT project recommends that public and private clinical trial sponsors require researchers to demonstrate “methods and measures to ensure...
Communities as Partners in Cancer Clinical Trials

VII. Enhancing Community Interpretation, Dissemination and Implementation of Trial Outcomes

We recommend that public and private sponsors of phase III cancer clinical trials:

1. Support studies to identify the most effective strategies for community involvement in interpretation, dissemination and implementation of phase III cancer study results, measured in terms of changes in practice and policy.
2. Partner with private sector organizations, foundations and advocacy groups for the services they provide in interpretation, dissemination and implementation of phase III study results.
3. Partner with advocacy and community-based groups to set priorities for interpretation, broad dissemination, and implementation of study results, based on importance and applicability. There should be particular emphasis on reaching underserved, minority, LEP, low-literate, poor and elderly populations.
4. Explore appropriate ways to assist local research sites/local investigators in notifying clinical trial participants about trial results, in lay language and in a timely manner.
5. Conduct research on best practices to communicate aggregate trial results to participants.
6. Conduct an assessment of the ways in which CR/PAs are currently involved in the interpretation, dissemination and implementation of phase III study findings.

As the leader of the National Cancer Program, we recommend that the National Cancer Institute:

Rationale

Although data from phase III cancer treatment trials are analyzed at a central location and the results typically disseminated through publications in peer-reviewed journals and presentations at professional conferences, there can be distinct roles for CR/PAs to play in these activities at both the local and national levels.

Support studies to identify the most effective strategies for community involvement in study interpretation, dissemination and implementation: With so few studies documenting the contributions that community members make in data analysis and interpretation, our understanding of the rationale and mechanisms for engaging communities in these components of the phase III cancer clinical trials process would benefit from additional research and demonstration projects.

Partner with advocacy organizations and community groups to disseminate and implement study results: The more obvious opportunity to engage communities upon trial completion is in the dissemination and implementation of trial results - to ensure that study participants, patients, their caregivers, and those at risk for the cancer under study can access the results in understandable language and in a timely manner. Although conferences and peer review journals are important mechanisms for reaching professional audiences, they do not by themselves lead to changes in clinical practice. Furthermore, in many cases, these vehicles for dissemination are not readily accessible or understandable to non-scientists. Partnerships with patient advocacy organizations and community-based organizations are especially promising for ensuring that trial results are widely disseminated in accessible language and formats.

There are a number of national efforts that seek to inform the public about the results of clinical trials. The FDA Amendments Act of 2007 requires most clinical trials involving drugs, biological products and devices regulated by FDA to be registered on Clinical Trials.gov, providing penalties for those not listed. The Act also requires the reporting of results and adverse events, as well as basic results for these trials. NIH’s Public Access Policy requires that scientists submit journal articles that arise from NIH funds to the public digital archive, PubMed Central. The open-access Public Library of Science (PLoS) is committed to publishing peer-reviewed articles from clinical trials regardless of the study outcomes, and its new “Hub for Clinical Trials” includes articles from all the PLoS titles that publish clinical trials. The ClinicalTrialsResults.org site, sponsored by PHRMA, is a web-based repository for clinical study results, with the expressed purpose of making clinical trial results for many marketed pharmaceuticals more transparent. PatientInform.com provides patients and their caregivers access to selected research available about the diagnosis and treatment of specific diseases.

Other efforts are also underway to ensure that members of the public have access to clinical trial results in easily understanding language and formats. The Cochrane Collaboration publishes annual reviews on published studies. The Research Advocacy Network’s online fact sheets, “What it Means for You,” relay research results in various types of cancer in lay language and are intended to improve communications between patients and their clinicians. The John M. Eisenberg Clinical Decisions and Communications Science Center translates knowledge about effective health care into short, plain language materials that can be used to assess treatments, medications and technologies. Some journals are experimenting with creative formats, such as policy briefs and podcasts, which help to translate research findings into lay language. Collectively, these efforts represent a promising start, but are not consistently utilized by phase III cancer clinical trial study sponsors, researchers, study participants, patients, their caregivers, or the broader community. In addition, many patients are not aware of their availability.

meaningful community participation throughout the clinical trial process" and to include in their proposals “a detailed plan to build community capacity for understanding and supporting clinical research.”

Expansion of existing guidelines and standards: Accreditation requirements are an important leverage point for change. The American College of Surgeons’ Commission on Cancer has accreditation requirements for assuring access to cancer clinical trials and about community outreach on cancer issues. We believe there should be explicit requirements combining the two, such that community education and outreach on clinical trials becomes its own standard.

Although data from phase III cancer treatment trials are analyzed at a central location and the results typically disseminated through publications in peer-reviewed journals and presentations at professional conferences, there can be distinct roles for CR/PAs to play in these activities at both the local and national levels. Support studies to identify the most effective strategies for community involvement in interpretation, dissemination and implementation of phase III cancer study results, measured in terms of changes in practice and policy. Partnership with private sector organizations, foundations and advocacy groups for the services they provide in interpretation, dissemination and implementation of phase III study results. Partnership with advocacy and community-based groups to set priorities for interpretation, broad dissemination, and implementation of study results, based on importance and applicability. There should be particular emphasis on reaching underserved, minority, LEP, low-literate, poor and elderly populations. Explore appropriate ways to assist local research sites/local investigators in notifying clinical trial participants about trial results, in lay language and in a timely manner. As the leader of the National Cancer Program, we recommend that the National Cancer Institute: Conduct research on best practices to communicate aggregate trial results to participants. Conduct an assessment of the ways in which CR/PAs are currently involved in the interpretation, dissemination and implementation of phase III study findings.

Rationale

Although data from phase III cancer treatment trials are analyzed at a central location and the results typically disseminated through publications in peer-reviewed journals and presentations at professional conferences, there can be distinct roles for CR/PAs to play in these activities at both the local and national levels. Support studies to identify the most effective strategies for community involvement in study interpretation, dissemination and implementation: With so few studies documenting the contributions that community members make in data analysis and interpretation, our understanding of the rationale and mechanisms for engaging communities in these components of the phase III cancer clinical trials process would benefit from additional research and demonstration projects. Partner with advocacy organizations and community groups to disseminate and implement study results: The more obvious opportunity to engage communities upon trial completion is in the dissemination and implementation of trial results - to ensure that study participants, patients, their caregivers, and those at risk for the cancer under study can access the results in understandable language and in a timely manner. Although conferences and peer review journals are important mechanisms for reaching professional audiences, they do not by themselves lead to changes in clinical practice. Furthermore, in many cases, these vehicles for dissemination are not readily accessible or understandable to non-scientists. Partnerships with patient advocacy organizations and community-based organizations are especially promising for ensuring that trial results are widely disseminated in accessible language and formats.

Such partnerships are warranted for a number of reasons. A recent study found that 26% of large randomized oncology trials had not been published five years after their presentation at the annual meeting of the American Society of Clinical Oncology (ASCO), suggesting that some trials are never published. As Dickersin and Rennie observe, “Patients who agree to participate in clinical research do so with the understanding that they are contributing to medical knowledge. If the knowledge gained in a trial is never communicated to others, then their contribution is unrealized and the covenant between researcher and patient is broken.”

There are a number of national efforts that seek to inform the public about the results of clinical trials. The FDA Amendments Act of 2007 requires most clinical trials involving drugs, biological products and devices regulated by FDA to be registered on Clinical Trials.gov, providing penalties for those not listed. The Act also requires the reporting of results and adverse events, as well as basic results for these trials. NIH’s Public Access Policy requires that scientists submit journal articles that arise from NIH funds to the public digital archive, PubMed Central. The open-access Public Library of Science (PLoS) is committed to publishing peer-reviewed articles from clinical trials regardless of the study outcomes, and its new “Hub for Clinical Trials” includes articles from all the PLoS titles that publish clinical trials. The ClinicalTrialsResults.org site, sponsored by PHRMA, is a web-based repository for clinical study results, with the expressed purpose of making clinical trial results for many marketed pharmaceuticals more transparent. PatientInform.com provides patients and their caregivers access to selected research available about the diagnosis and treatment of specific diseases.

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Disseminating aggregate study results to trial participants: A recent narrative review of studies concerning communication of research results to participants found that available data consistently indicate that research participants want aggregate and clinically significant individual study results made available to them. The review also found that participants tend to be grateful when they receive study results, suggesting that such communication may bolster public opinion of investigators and the research they conduct. It is standard operating procedure within the AIDS Clinical Trials Group to distribute a letter to study participants, describing the study results and implications to them, prior to presentation or publishing. No such policy or routine mechanism is in place to share aggregate study results with participants in phase III cancer clinical trials. The Patient Advisory Board of the Coalition of National Cancer Cooperative Groups recommends that disclosure to participants of the results of clinical trials, including early disclosure, should be the norm. However, this policy is not consistently applied throughout the Cooperative Groups. Moreover, a national survey of IRBs in the United States found that the majority of IRBs had no policy regarding the return of research results to participants.

Sponsors should explore the development of procedures for their sites to disclose aggregate trial results to participants as an acknowledgment of their involvement in research. Sharing results might also lead to patients having a better understanding of clinical trials, thereby bolstering clinical trials accrual and ultimately leading to improvements in patient care. If study results are to be offered, patients should be notified through the informed consent process so that they are aware of the procedures and have the opportunity to decline future contact with the investigators. At a minimum, informed consent documents should help remind participants about the available, public listings of results and adverse events under the FDA Amendment Act of 2007. In addition, it is critical that the NCI conduct research on best practices to communicate aggregate trial results to participants.

NCI assessment of CR/PA involvement in interpretation, dissemination and implementation of phase III study findings:

The NCI is in a unique position to undertake such an assessment. Such research would help to document and understand the nature, extent and value of CR/PA involvement in these phases of the research process and identify promising practices.

From Recommendations to Implementation

The recommendations in this report are intended to serve as a strategic plan for key stakeholder discussion and implementation. Change is often incremental. Some recommendations are quite ambitious, requiring a reallocation of resources. Others can be implemented relatively quickly with little or no need for additional funding. This report includes appendices of action steps and resources, to support the implementation of each recommendation.

There are a number of tangible and practical ways that readers can immediately respond to this report:

If you are affiliated with a public or private national clinical trial sponsor:

- Forward the report to the organization’s leadership, staff and advisory councils, and encourage them to discuss it at their next meeting
- Consider the potential for incorporating report recommendations into forthcoming funding announcements or site selection criteria

If you are active in a Cooperative Group:

- Forward the report to the Cooperative Group leadership and committee chairs, and propose specific recommendations be discussed at the next meeting
- Convene a meeting of community representatives and patient advocates who are active in the Cooperative Group to specifically engage them in implementing the recommendations
- List your patient advocate opportunities prominently on your website, including a contact for interested CR/PAs to learn more about the process of applying for these positions

If you are from a research site:

- Forward the report to the site’s leadership and encourage them to discuss specific recommendations at their next meeting
- Convene a meeting of investigators and research teams from your site to discuss the potential for implementing the recommendations
- Convene a meeting of research sites in your geographic area to explore the potential for collaboration in implementing the recommendations
- Invite local CBPR researchers, representatives of patient advocacy organizations and representatives of community organizations to serve as speakers, trainers and consultants
- List opportunities for involvement prominently on your website, including a contact for interested CR/PAs to learn more about the process of applying for these positions
If you are a local investigator or other member of a research team:
 Forward the report to your research team and propose specific recommendations be discussed at the next team meeting
 Consider advocating for specific recommendations that may be appropriate in your work at this time
 Invite local CBPR researchers, representatives of patient advocacy organizations and representatives of community organizations to serve as speakers, trainers and consultants
 List opportunities for involvement prominently on your website, including a contact for interested CR/PAs to learn more about the process of applying for these positions

If you are an IRB administrator, chair or member:
 Forward the report to IRB members and propose specific recommendations be discussed at the next IRB meeting
 View your involvement with the IRB as a critical opportunity to ensure that more community members are recruited and retained on the IRB, and that community-level considerations be taken into account during IRB review
 List new membership opportunities prominently on your website, including a contact for interested CR/PAs to learn more about the process of applying for these positions

If you are a CBPR researcher:
 Forward the report to colleagues who are involved in cancer clinical research and encourage them to read it
 Offer to serve as a CBPR speaker, trainer or consultant to cancer clinical researchers who are working to implement the report’s recommendations
 Encourage your community partners to share their community knowledge and CBPR expertise and pursue leadership development by applying for CR/PA opportunities with cancer clinical trials and IRBs

If you are a community representative or patient advocate involved in cancer clinical trials:
 Forward the report to your colleagues and peers involved in cancer clinical trials and encourage them to read it
 Consider advocating for specific recommendations that may be appropriate in your work at this time
 For related committees and boards that you serve on, propose the report be discussed at the next meeting

If you are a community member, cancer survivor or caregiver who wants to help improve the cancer clinical trial system:
 Contact one of the cancer advocacy organizations in Appendix D about opportunities for involvement

We end this report as we began, by considering these sobering statistics about the cancer clinical trial system:
Adult trial participation in the U.S. remains under three percent; accrual rates are even lower among people of color, older people, and the medically underserved, who tend to have higher cancer mortality rates than the population as a whole; and, up to 30% of national Cooperative Group trials are closed due to poor accrual. For cancer clinical research to achieve its full potential in reducing cancer deaths and cancer disparities, we must explore new approaches to make trials more “accruable” and help communities become more involved in research activities. Indeed, “success (in clinical trials accrual) will require sustained, aggressive action, and new partnerships between policymakers, healthcare professionals, professional societies, and underserved communities.”266 We believe the recommendations outlined in this report can, for the first time, effectively guide each of these groups in forging these new partnerships.
## APPENDIX A: Action Guide for Implementing the Communities as Partners Recommendations

### I. Ensuring a Meaningful Role for Community Representatives/Patient Advocates in Phase III Cancer Clinical Trials

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Target Audience</th>
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<tbody>
<tr>
<td>1. Ensure that the application and selection process for CR/PAs serving at the national level is open and transparent, with opportunities to serve widely communicated both to traditional and non-traditional sources of potential candidates.</td>
<td>National Cooperative Groups and/or Coalition of National Cancer Cooperative Groups Patient Advisory Board</td>
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<tr>
<th>Implementation Steps</th>
<th>Implementation Resources &amp; Examples</th>
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<tbody>
<tr>
<td>1. Develop a specific application process, outlining selection criteria.</td>
<td>• Models for a systematic approach to advocate recruitment - The Department of Defense (DOD) Congressionally Directed Medical Research Programs has a Consumer Working Group (CWG), which addresses program improvements, recruitment activities, and promotes the benefits of consumer involvement. The application process for consumers serving on DOD research programs can be found at: <a href="http://cdmrp.army.mil/cwg/default.htm">http://cdmrp.army.mil/cwg/default.htm</a></td>
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<tr>
<td>2. Display application prominently on each group’s website.</td>
<td>• NCI’s CARRA (Consumers in Research and Related Activities), as described below.</td>
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<tr>
<td>3. Develop specific communication strategies to promote these opportunities through the organizations listed here.</td>
<td>• American Cancer Society’s Peer Review Stakeholder Program: The purpose of stakeholder participation in the ACS Peer Review process is to assure input from the stakeholder perspective in evaluating the relevance of research applications to the advancement of cancer control. Stakeholders receive peer review training from ACS and commit to a two-year participation term. <a href="http://www.cancer.org">http://www.cancer.org</a></td>
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<tr>
<td>4. Create a national pool of trained CR/PAs, who can be enlisted to participate in the design, implementation and dissemination of Phase III cancer treatment trials.</td>
<td>• NCI’s Cancer Information Service Partnership Program: <a href="http://cis.nci.nih.gov/community/community.htm">http://cis.nci.nih.gov/community/community.htm</a></td>
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<tr>
<td>5. Establish a local → national feeder system, by developing a web-based database system for local qualified CR/PAs who are eligible for service at the national level.</td>
<td>• Contacts for a local to national feeder system: - At the National level, the AIDS Clinical Trial Group (ACTG) sponsors the Network Community Advisory Board (NCAB), which provides broad community input into the scientific efforts, operations and activities of the ACTG. Members of NCAB are drawn from community advisory boards through the U.S., which provide input to local ACTG research sites. See: <a href="http://actg.org/about_main.asp">http://actg.org/about_main.asp</a> - NCI’s CARRA Program could be expanded to service the Cooperative Groups and local researchers through a web-based system to which CARRA members could opt-in. <a href="http://carra.cancer.gov">http://carra.cancer.gov</a></td>
</tr>
<tr>
<td>6. Document the role of advocates in research industry-wide.</td>
<td>• Models for a local to national feeder system: - At the National level, the AIDS Clinical Trial Group (ACTG) sponsors the Network Community Advisory Board (NCAB), which provides broad community input into the scientific efforts, operations and activities of the ACTG. Members of NCAB are drawn from community advisory boards through the U.S., which provide input to local ACTG research sites. See: <a href="http://actg.org/about_main.asp">http://actg.org/about_main.asp</a> - NCI’s CARRA Program could be expanded to service the Cooperative Groups and local researchers through a web-based system to which CARRA members could opt-in. <a href="http://carra.cancer.gov">http://carra.cancer.gov</a></td>
</tr>
<tr>
<td>7. Develop a specific application process, outlining selection criteria, which is displayed prominently on each company’s website.</td>
<td>• Project Blueprint, a United Way local leadership development program designed to prepare emerging leaders of ethic communities for leadership positions on nonprofit boards. <a href="http://www.uwsummit.org/ProjectBlueprint/Project_Blueprint.htm">http://www.uwsummit.org/ProjectBlueprint/Project_Blueprint.htm</a></td>
</tr>
<tr>
<td>8. Develop specific communication strategies to promote these opportunities through the organizations listed here.</td>
<td>• Board RecruitmentUSA, a website linking nonprofit boards and new leaders interested in serving. <a href="http://www.boardrecruitmentusa.org/public/home.asp">http://www.boardrecruitmentusa.org/public/home.asp</a></td>
</tr>
<tr>
<td>9. Create a national pool of trained CR/PAs who can be enlisted to participate in the design, implementation and dissemination of Phase III cancer treatment trials.</td>
<td>• Those trained by PMR, RAN, and Project LEAD</td>
</tr>
<tr>
<td>10. Establish a local → national feeder system, by developing a web-based database system for local qualified CR/PAs, eligible for service at the national level.</td>
<td>• CCPH electronic discussion groups, made up of academic and community partners interested in CBPR: <a href="http://depts.washington.edu/ccph/faq.html#Listserv">http://depts.washington.edu/ccph/faq.html#Listserv</a></td>
</tr>
</tbody>
</table>

Additional contacts in Appendix D
## Communities as Partners in Cancer Clinical Trials

### I. Ensuring a Meaningful Role for Community Representatives/Patient Advocates in Phase III Cancer Clinical Trials

<table>
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<tr>
<th>Recommendation</th>
<th>Target Audience</th>
<th>Implementation Steps</th>
<th>Implementation Resources &amp; Examples</th>
</tr>
</thead>
</table>
| **2. Ensure that the roles, responsibilities, expectations and length of service of CR/PAs serving at the national level are explicit, well-defined and adequately communicated to all parties involved.** | National Cooperative Groups | 1. Develop a specific list of roles, responsibilities, expectations and length of service | See Appendix C for suggested roles and responsibilities for CR/PAs. The following groups have also drafted such a list:  
- Coalition of Cancer Cooperative Groups Patient Advisory Board  
- NCI Clinical Trials Operating Committee (Task Forces and steering Committees)  
- NCI Advocates in Research Working Group  
**EXAMPLES:**  
ACRIN has developed the IMPACT review form for all of its patient advocates reviewing concepts and/or protocols.  
The National Institute of Allergy and Infectious Diseases (NIAID) has seven clinical research networks involving community members, with specific guidelines about membership, responsibilities, and how principal investigators must interface with community members.** |
| | Industry | 2. Ensure all group leadership commitment to implementation |  |
| | | 3. Develop material providing specific guidance for advocates to use in review |  |
| | | **Implementation Resources & Examples** |  |
| **3. Ensure appropriate training for CR/PAs serving at the national level to prepare them sufficiently for the activities they will undertake.** | NCI | 1. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better understand needs of individuals currently serving. Several groups, such as C3 and RAN, have already developed such assessments | See Appendix B for training resources for CR/PAs  
Several grant making organizations (Susan G. Komen for the Cure, American Cancer Society, and the Lance Armstrong Foundation) have training programs for their peer reviewers.  
- The FDA Cancer Liaison Program in the Office of Special Health Issues has training for those selected to take part in its Cancer Drug Development Patient Consultant Program and in its Patient Representative Program.  
- NCI has training for those selected to be part of its (CARRA) Program.  
- The DOD Congressionally Directed Medical Research Programs (CDMRP) prepares consumers for peer review with a “buddy” program, orientation materials and an orientation session on peer review. |
<p>| | National Cooperative Groups | 2. Inventory publicly available training programs and identify any gaps where new material must be developed |  |
| | Industry | 3. Develop new materials to meet unmet needs |  |
| | | 4. Initiate and/or expand partnerships with existing cancer education and advocacy organizations, in support of training opportunities for CR/PAs at both the local and national levels |  |
| | | 5. Ensure web-based programming, such as the Cancer Research: A Guide to Cancer Clinical Trials (Coalition of Cancer Cooperative Groups), is widely promoted to local and national entities seeking use of CR/PAs |  |
| | | 6. Require that appropriate training is successfully completed by each individual |  |
| | | 7. Conduct evaluation to ensure that training has assisted the person in completing activities asked of her/him |  |
| <strong>4. Support appropriate training for CR/PAs at the local level, to prepare them sufficiently for the activities they will undertake.</strong> | NCI | 1. Seek alternative funding for training from industry, foundations and other cancer research organizations |  |
| | National Cooperative Groups | 2. Encourage local investigators to use funding for this purpose |  |
| | (in support of local research sites) | 3. Encourage local investigators to use funding for this purpose |  |
| | Industry (in support of local research sites) | |  |</p>
<table>
<thead>
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<tbody>
<tr>
<td><strong>5. Support training for individual investigators on optimal ways to integrate CR/PAs into research activities at both the national and local levels</strong></td>
<td>NCI National Cooperative Groups Industry Local research sites</td>
<td>1. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better understand needs of investigators working with advocates 2. Develop appropriate mechanisms, such as web courses, expert speakers at meetings, or training sessions that can help enhance the skills of busy investigators and research teams</td>
<td>EXAMPLE: CCPFR’s “Developing and Sustaining CBPR Partnerships: A Skill-Building Curriculum” is an evidence-based curriculum intended as a tool for community-institutional partnerships that are using or planning to use a CBPR approach to improving health. <a href="http://www.cbprcurriculum.info">www.cbprcurriculum.info</a></td>
</tr>
<tr>
<td><strong>6. Implement specific approaches to appropriately recognize, support and compensate CR/PAs serving at the national level for the services they provide.</strong></td>
<td>NCI National Cooperative Groups Industry</td>
<td>1. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better understand the support, recognition and compensation needs of individuals serving, including those who are being recruited 2. Explore alternative mechanisms such as industry support to provide stipends that can help to offset financial burden</td>
<td>EXAMPLE: The FDA Cancer Liaison Program in the Office of Special Health Issues “hires” and pays its patient representatives as Special Government Employees for those selected to take part in its Cancer Drug Development Patient Consultant Program and in its Patient Representative Program. All DOD CDMRP consumer representatives on peer review panels receive a standard honorarium that covers their time spent to prepare for and attending meetings. In addition, all expenses are covered.</td>
</tr>
<tr>
<td><strong>7. Acknowledge, promote and publicize the ongoing important role of CR/PAs in the national research process</strong></td>
<td>NCI National Cooperative Groups Industry</td>
<td>1. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better plan acknowledgement and promotion activities 2. Use lessons learned from the DOD CDMRP in their efforts to promote benefits</td>
<td>EXAMPLE: DOD CDMRP has a Consumer Working Group (CWG), which concerns program improvements and recruitment activities, and promotes the benefits of consumer involvement. See I-3 above See Appendix B for existing training programs.</td>
</tr>
<tr>
<td><strong>8. Implement training for local-level CR/PAs to prepare them sufficiently for the activities they will undertake</strong></td>
<td>Local research sites Industry</td>
<td>1. Explore the development of such programs at local community colleges</td>
<td>SEE I-5 above</td>
</tr>
<tr>
<td><strong>9. Implement training for individual investigators and research teams on optimal ways to integrate CR/PAs into local level research activities</strong></td>
<td>Local research sites</td>
<td>1. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better understand the support, recognition and compensation needs of individuals serving, including those who are being recruited 2. Seek alternative funding for training from trial sponsor, foundations and other cancer research organizations 3. Insert request in budget submitted to sponsor</td>
<td>EXAMPLE: CCPFR’s “Developing and Sustaining CBPR Partnerships: A Skill-Building Curriculum” is an evidence-based curriculum intended as a tool for community-institutional partnerships that are using or planning to use a CBPR approach to improving health. <a href="http://www.cbprcurriculum.info">www.cbprcurriculum.info</a>.</td>
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II. Ensuring that Community Perspectives are Considered in the IRB Process

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<th>Recommendation</th>
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<tr>
<td>1. IRBs be comprised of 25% community members who are properly oriented, trained, mentored and compensated by the IRB sponsoring institution</td>
<td>Local IRBs, NCI Central IRB, Commercial IRBs</td>
<td>1. Assess knowledge and orientation, training, &amp; mentoring needs of current community IRB members&lt;br&gt;2. Assess compensation &amp; recognition preferences of current community IRB members&lt;br&gt;3. Pilot training/mentoring program with current IRB members - Explore the development of such programs at local community colleges&lt;br&gt;4. Pilot compensation &amp; recognition program with current IRB members&lt;br&gt;5. Develop recruitment materials and application for new community IRB members&lt;br&gt;6. Develop list of prospective new community members (see possible sources at right)&lt;br&gt;7. Invite prospects to apply&lt;br&gt;8. Review applications and make offers&lt;br&gt;9. Develop and implement orientation for new community IRB members&lt;br&gt;10. Match new community IRB members with experienced members as mentors&lt;br&gt;11. Provide ongoing training to IRB members</td>
<td>Sources for potential community members who can serve on IRBs include: Community partners of community-based research projects that have been previously approved by the IRB&lt;br&gt;- NCI’s CARRA (Consumers in Research and Related Activities) Program could be expanded to service IRBs through a web-based system to which CARRA members could opt-in. <a href="http://carra.cancer.gov">http://carra.cancer.gov</a>&lt;br&gt;- Cancer advocacy and support organizations; CCPh: <a href="http://www.ccph.info">http://www.ccph.info</a>&lt;br&gt;- Community-Based Public Health Caucus of the American Public Health Association (APHA)&lt;br&gt;- National Community Committee (NCC) of the Centers for Disease Control (CDC) Prevention&lt;br&gt;- Board members from Local Community Health Centers&lt;br&gt;Educational resources for community IRB members include:&lt;br&gt;- “You Want to be an IRB Community Member...Now What?” is a publication of the University of Southern California Office for the Protection of Research Subjects. It will be available on-line in December 2008: <a href="http://www.usc.edu/admin/provost/ops">http://www.usc.edu/admin/provost/ops</a>&lt;br&gt;- Community IRB Website and Listserv: Sponsored by the Human Subjects Research Program at the U.S. Department of Energy, the goal of this website is to enhance communications between Community IRB Members and provide resources for and about Community IRB Members: <a href="http://www.ornl.gov/commirb/default.htm">http://www.ornl.gov/commirb/default.htm</a>&lt;br&gt;- Audio-files, handouts and proceedings from the CCPh and Tuskegee Bioethics Center’s Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research: <a href="http://depts.washington.edu/ccph/irbcalls2.htm">http://depts.washington.edu/ccph/irbcalls2.htm</a>&lt;br&gt;- Public Responsibility in Medicine &amp; Research (PRIM&amp;R): <a href="http://www.primr.org">http://www.primr.org</a>&lt;br&gt;- Online research ethics curriculum for community health workers, promotores and others working in culturally diverse communities: <a href="http://projecttmes.sdsu.edu/eres/">http://projecttmes.sdsu.edu/eres/</a>&lt;br&gt;- Online research ethics curriculum for community representatives: <a href="http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm">http://www.fhi.org/en/RH/Training/trainmat/ethicscurr/retccr.htm</a>&lt;br&gt;EXAMPLE: Papa Ola Lokahi (POL), a community-based healthcare consortium, developed and administers the Native Hawaiian Health Care Systems IRB (NHHC IRB), a community IRB that approves all research for POL and five partnering Native Hawaiian Health Care Systems (NHHCs). The NHHC IRB assures that research is targeted to community priorities, is culturally sensitive, has tangible benefits for the community, and is attentive to group harm. The NHHC IRB has 21 members, of which 25% (5) are community members and 50% (11) are scientific members. The remainder brings expertise in nursing, social work, law and evaluation. Of the total membership, 17 (81%) are of Native Hawaiian ancestry. Community members are equal contributors and bring expertise on Hawaiian culture, beliefs and practices, as well as sensitivity to potential “group harm.” Ongoing IRB training is provided for all IRB members. The majority of protocols reviewed have been in the area of behavioral research, but with the expansion of cancer health disparities research and new clinical partnerships, the NHHC IRB anticipates future opportunities to review Phase III treatment trials. <a href="http://www.papaoalokahi.org/hoe2/index.cfm?wwa_ID=93B99296-EF41-4D27-9ECEB62C082DD382&amp;sub=yes">http://www.papaoalokahi.org/hoe2/index.cfm?wwa_ID=93B99296-EF41-4D27-9ECEB62C082DD382&amp;sub=yes</a></td>
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II. Ensuring that Community Perspectives are Considered in the IRB Process

### Recommendation
2. IRBs ensure that all members are trained in strategies for community engagement in research, and oriented to community member roles on the IRB

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<tr>
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</table>
| Local IRBs      | 1. Assess knowledge of community-engaged research and community IRB roles and preferred training options among current IRB members | Educational resources include: Classic texts on CBPR:  
  • June 2008 issue of the Journal of Empirical Research on Human Research Ethics, focused on ethical considerations in CBPR: http://www.csueastbay.edu/jerhre/  
  • Audio-files, handouts and proceedings from the CCPH and Tuskegee Bioethics Center’s Educational Conference Call Series on Institutional Review Boards and Ethical Issues in Research: http://depts.washington.edu/ccph/irbcalls2.htm  
  • Public Responsibility in Medicine & Research (PRIMR): http://www.primr.org  
  Sources for possible trainers include:  
  • Local CBPR experts, including leaders from community-based research projects that have been previously approved by the IRB  
  • CCPH Consultancy Network: http://depts.washington.edu/ccph/mentor.htm |
| NCI Central IRB | 2. Determine minimum knowledge/competence to be expected of IRB members |  |
| Commercial IRBs | 3. Develop, implement and evaluate training program |  |
|                 | 4. Review and respond to training needs annually and when new members join the IRB |  |

3. IRBs consider evidence of community engagement in and community support for studies they review

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<tbody>
<tr>
<td>Local IRBs</td>
<td>1. Review IRB instructions and forms in light of this report</td>
<td></td>
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<tr>
<td>NCI Central IRB</td>
<td>2. Review questions suggested by Flicker, et. al., in Journal of Urban Health, July 2007, for possible revisions to IRB application and review forms</td>
<td></td>
</tr>
<tr>
<td>Commercial IRBs</td>
<td>3. Invite public input on proposed revisions to IRB application and review forms</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Conduct “mock reviews” of research protocols using the new forms to ensure IRB members have shared understanding of what is being asked for and how it is being assessed</td>
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CBPR resources page on the CCPH website that includes examples of MOUs: http://depts.washington.edu/ccph/commbas.htm |

4. IRB accreditation standards include the above expectations

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</tr>
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<tbody>
<tr>
<td>AAHRPP</td>
<td>1. Review and respond to accreditation standards in light of this report</td>
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</table>

5. Investigators include evidence of community engagement in and support for the study in the protocols they submit to IRBs

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</table>
| National and local investigators | 1. Document and describe how CR/PAs have been involved in decision making leading up to the IRB application (e.g., advisement on deciding to participate as a study site, developing plans for recruiting and retaining trial participants) | CBPR resources page on the CCPH website that includes examples of CR/PAs: http://depts.washington.edu/ccph/commbas.htm  
EXAMPLE: In 2000, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) developed the Health Partnership Program, which involves community partners representing various sectors of the African American and Hispanic/Latino communities of Washington, DC. A trained core group of partners meets regularly to review research proposals before they are submitted to the IRB. The contributions and comments of this care group have led to substantive changes in NIAMS research protocols.** |
|                 | 2. Document and describe how CR/PAs will be involved in subsequent phases of the research (e.g., advisement on recruiting and retaining study participants, disseminating trial findings) |  |
|                 | 3. Include memorandum of understanding (MOU) between researchers and community partners, and/or letters from CR/PAs that speak to their involvement in and support for the trial |  |
### III. Improving the Informed Consent Process

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</thead>
<tbody>
<tr>
<td>2. Monitor and manage quality improvement efforts to address ongoing challenges to the consent process</td>
<td>OHRP, FDA</td>
<td>2. Sponsor presentations on use of the “short form” at PRIM&amp;R and other clinical research conferences</td>
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<tr>
<td>3. Ensure that all members are trained in approaches to address the needs of minority, low-literacy, poor and elderly, underserved, and Limited English Proficiency (LEP) populations in the informed consent process</td>
<td>All IRBs, including NCI Central IRB</td>
<td>3. Collect case examples of studies that have used the “short form” and post them online</td>
<td>See citations in the recommendations section</td>
</tr>
<tr>
<td>4. Permit use of the OHRP-approved “short form” and its accompanying procedures if submitted by an investigator</td>
<td>All IRBs, including NCI Central IRB</td>
<td>4. Review and respond to training needs annually and when new members join the IRB</td>
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<tr>
<td>5. Promote and encourage the appropriate use of the OHRP-approved “short form” and its accompanying procedures, with specific recommendations for its use in the field</td>
<td>Public and private trial sponsors</td>
<td>5. Identify and publicize innovative and promising practices for informed consent</td>
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<tr>
<td>6. Consider using the OHRP-approved “short form” and its accompanying procedures in the consent process</td>
<td>Local research sites</td>
<td>6. Develop, implement and evaluate training program</td>
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<tr>
<td>7. Implement the consent process through trained staff, including, when available, patient navigators who can assist in the consent process at the patient’s request</td>
<td>Local research sites</td>
<td>7. Consider using the OHRP-approved “short form”</td>
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**Examples of policies:**
- Cross-Cultural Health Care Program: [http://www.ucalifornia.org](http://www.ucalifornia.org)
- The Eliminating Disparities in Clinical Trials (EDICT) Project produced the CLAS-ACT Self-Assessment Handbook, which helps researchers and organizations assess how well they implement standards for Culturally and Linguistically Appropriate Services (CLAS) in clinical trials: [http://www.bcm.edu/edict/clas-act/index.html](http://www.bcm.edu/edict/clas-act/index.html)
- The citations included in the recommendations section (EDICT) Project produced the CLAS-ACT Self-Assessment Handbook, which helps researchers and organizations assess how well they implement standards for Culturally and Linguistically Appropriate Services (CLAS) in clinical trials: [http://www.bcm.edu/edict/clas-act/index.html](http://www.bcm.edu/edict/clas-act/index.html)
- Harold P. Freeman Patient Navigation Institute at the Ralph Lauren Center has an extensive certification program. See: [http://www.research.umn.edu/consent/](http://www.research.umn.edu/consent/)
### III. Improving the Informed Consent Process

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| 8. Utilize trained medical interpreters or a telephone language line for LEP individuals, throughout the informed consent process and when consent forms are not available in the individual’s native language | Local research sites | Prepare resource list for investigators that includes contact information for medical interpretation and telephone language line services | FDA: A Guide to Informed Consent, Non-English Speaking Subjects: [http://www.fda.gov/orc/ohrt/irbs/informedconsent.html](http://www.fda.gov/orc/ohrt/irbs/informedconsent.html)  
OHRP: Short Form Guidance: [http://www.hhs.gov/ohrp/humansubjects/guidance/irb-non-e.htm](http://www.hhs.gov/ohrp/humansubjects/guidance/irb-non-e.htm)  
Examples of policies:  
- UC Irvine Policy for Consenting Subjects Who Do Not Read, Speak or Understand English: [http://www.research.ucl.edu/ora/hrpp/nonenglishspeakingparticipants.htm](http://www.research.ucl.edu/ora/hrpp/nonenglishspeakingparticipants.htm)  
- Short form” consent forms are available in a number of languages: [http://www.cumc.columbia.edu/dept/irb/policies/index.htm](http://www.cumc.columbia.edu/dept/irb/policies/index.htm) and [http://healthcare.partners.org/phsirb/nonengco.htm](http://healthcare.partners.org/phsirb/nonengco.htm)  
- Other:  
  - IOM Roundtable on Health Literacy Meeting 3 Informed Consent for Populations with Low Health Literacy  
  - Background information: [http://www.iom.edu/CMS/3793/31487/36698.asp](http://www.iom.edu/CMS/3793/31487/36698.asp)  
  - International Medical Interpreters Association: [http://www.imiaweb.org/default.asp](http://www.imiaweb.org/default.asp) |
| 9. Develop policies for optimal ways to use the OHRP-approved “short form” for Cooperative Group trials, complementary to the existing template | NCI | Inform the policy development process by assessing the extent to which Cooperative Group trials use the “short form” and the facilitators/barriers to its use | Inform the policy and procedure development process by assessing the extent to which Cooperative Group trials have policies and procedures in place for improving the consent process for LEP populations and the extent to which their forms and questionnaires are available in appropriate languages |
| 10. Develop policies and procedures for improving the consent process for LEP populations participating in Cooperative Group trials, including translation of forms and questionnaires | NCI | Inform the policy and procedure development process by assessing the extent to which Cooperative Group trials have policies and procedures in place for improving the consent process for LEP populations and the extent to which their forms and questionnaires are available in appropriate languages | Assess the extent to which cancer clinical trials utilize alternative informed consent processes and evaluate the impact of those processes on patient understanding, recruitment and retention |
| 11. Conduct research on optimal ways to implement the informed consent process beyond the written page, allowing for differences in learning styles (e.g., the use of pictures and videos), which will provide replicable practices for local research sites | NCI | Assess the extent to which cancer clinical trials utilize alternative informed consent processes and evaluate the impact of those processes on patient understanding, recruitment and retention | Consider including in RFPs for patient navigator programs |
| 12. Expand funding for patient navigation programs to include assisting in the informed consent process | NCI | Consider including in RFPs for patient navigator programs | Several of the NCI-funded Cancer Disparities Research Program sites have implemented training programs for this purpose (Centinela, McKeesport)  
- C-Change has outlined optimal components of Patient Navigation in its patient navigation tool kit: See: [www.cancerpatientnavigation.org](http://www.cancerpatientnavigation.org)  
- Harold P. Freeman Patient Navigation Institute at the Ralph Lauren Center has an extensive certification program. See: [http://www.hpfreemanpni.org](http://www.hpfreemanpni.org) |
IV. Ensuring the Community Perspective in Protocol Development, Trial Design and Implementation

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<tr>
<td>1. Develop explicit system-wide procedures to ensure that all concepts and</td>
<td>National Cooperative Groups</td>
<td>1. Where it exists, document its existence, how “appropriate and sufficient” review is defined by the entity, and promote it through websites and other materials.</td>
</tr>
<tr>
<td>proposed study protocols are appropriately and sufficiently reviewed by trained</td>
<td>NCI Clinical Trials Operations Committee, Steering Committees and Task Forces</td>
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<tr>
<td>CR/PAs before the study is submitted for final approval, and ideally throughout</td>
<td>Industry</td>
<td>2. Where it does not exist, develop a plan to implement such procedures.</td>
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<td>the development process.</td>
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<td>Examples of systematic and explicit consumer involvement can be found in at least four programs:</td>
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<td>- The Department of Defense Congressionally Directed Medical Research Programs includes consumers as full members on peer review, its Integration Panel discussions on program priorities and funding recommendations, and its Consumer Working Group (CWO), which considers program improvements, recruitment activities, and promotes the benefits of consumer involvement. The CWO maintains advocate involvement in each of its research programs, further illustrating the agency’s ongoing commitment to their participation.</td>
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<td></td>
<td>- The California Breast Cancer Research Program includes advocates on each of its peer review committees and includes them on its council, which provides vision, sets research priorities, and determines how funds are invested. Further, the program awards grants to specifically support community-research collaborations in the design and conduct of breast cancer research.</td>
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<td>- In its “Clinical Trials Initiative,” the National Breast Cancer Coalition works with sponsors of clinical research willing to meet specific criteria for its members’ systematic involvement in study design and implementation.</td>
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<td></td>
<td>- ACRIN has developed the IMPACT review form for all of its patient advocates reviewing concepts and/or protocols.</td>
</tr>
<tr>
<td>2. Encourage and permit funding for local research sites to develop mechanisms,</td>
<td>NCI</td>
<td>1. Seek alternative funding for training from industry, foundations and other cancer research organizations.</td>
</tr>
<tr>
<td>such as community advisory boards (CABs), for ongoing community participation</td>
<td>National Cooperative Groups</td>
<td>2. Encourage local investigators to seek funding for this purpose.</td>
</tr>
<tr>
<td>in study implementation</td>
<td>Industry</td>
<td>Examples:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- ACRIN has developed the IMPACT review form for all of its patient advocates reviewing concepts and/or protocols.</td>
</tr>
<tr>
<td>3. Expand site selection criteria to include demonstrated local community</td>
<td>National Cooperative Groups</td>
<td>1. Create clear expectations of sites, utilizing a checklist or similar approach to determining completion of training or attempts at community engagement.</td>
</tr>
<tr>
<td>engagement and cultural competence, as a means of ensuring community</td>
<td>Industry</td>
<td>2. Document/describe how CR/PAs have been involved in advising on past trials (e.g. advisement on decision to participate as a study site, advisement on recruitment and retention, dissemination of study findings, etc.)</td>
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<td>perspective</td>
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<td>3. Document MOUs between research sites and community partners and/or letters of support from CR/PAs that speak to their support of the site’s participation.</td>
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### IV. Ensuring the Community Perspective in Protocol Development, Trial Design and Implementation

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| 4. **Develop mechanisms for ongoing community participation in trial implementation** | Local research sites | 1. Seek alternative funding for training from industry, foundations and other cancer research organizations  
2. Encourage local investigators to use funding for this purpose | • See NCI’s Cancer Clinical Trials: A Guide For Outreach and Advocacy to help plan community engagement efforts: [http://www.cancer.gov/clinicaltrials/resources/outreach-education-advocacy](http://www.cancer.gov/clinicaltrials/resources/outreach-education-advocacy)  
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**EXAMPLE:** In 2000, the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) developed the Health Partnership Program, which involves community partners representing various sectors of the African American and Hispanic/Latino communities of Washington, DC.  

A trained core group of partners meets regularly to review research proposals before they are submitted to the IRB. The contributions and comments of this core group have led to substantive changes in NIAMS research protocols.**[1](#)  
**2.** Systematic data collection about barriers and promoters of trial participation should be linked to concrete plans for designing interventions to address such barriers. Moreover, the next generation of studies of barriers and promoters of accrual should be multidisciplinary, including the involvement of community-based participatory researchers, social and behavioral scientists, as well as health economists.  
**3.** Different types of intervention approaches should be considered to promote accrual to cancer therapeutic trials and cancer prevention trials. Research and evaluation of recruitment strategies may yield stronger evidence about ways to improve participation of underrepresented populations in cancer clinical trials. The principal need is for hypothesis-driven research and, ultimately, randomized controlled trials to evaluate the most promising strategies for recruiting underrepresented populations into cancer treatment and prevention trials.**[2](#)  

**EXAMPLE:** The Eliminating Disparities in Clinical Trials (EDICT) Project produced the CLAS-ACT Self-Assessment Handbook, which helps researchers and organizations assess how well they implement standards for Culturally and Linguistically Appropriate Services (CLAS) in clinical trials: [see http://www.trim.edu/instit/CLAS/index.html](http://www.trim.edu/instit/CLAS/index.html)  

**1.** Consider community disease burden, epidemiologic data, eligibility restriction criteria on all available trials within disease (i.e., all breast cancer trials open within a site shouldn’t restrict on hypertension)  
**2.** Develop research initiatives to document this impact, starting with the Cooperative Groups  
**3.** Develop an adaptable plan that would include the following:  
• Plans and templates for accrual and retention planning  
• Materials for use in accrual and retention  
• Identification of potential partners’ for outreach and identification of patients  
• Tips to address i) concerns of specific ethnic or racial minority groups that may be particularly appropriate for the site/trials; ii) concerns of particular age groups; and iii) concerns regarding insurance  
• Include downloadable forms and tools for local customization  
**4.** Evaluate its use in real trial settings and report on results |  
**EXAMPLE:** See The Program for the Elimination of Cancer Disparities (PECaD) at the Siteman Cancer Center above.  

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### V. Improving Trial Participant Recruitment, Accrual and Retention

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| **1. Facilitate the development of national recruitment and retention plans to assist local investigators in optimally identifying potentially appropriate research participants, with additional focus on reaching minority and non-English speaking populations** | NCI Industry | 1. Identity best known practices for recruitment, and standardization in approach, starting with high accruing sites and ASCO awardees. 2. Develop adaptable plan that would include the following:  a. Plans and templates for accrual and retention planning  b. Materials for use in accrual and retention  c. Identification of potential partners for outreach and identification of patients  d. Tips to address i) concerns of specific ethnic or racial minority groups that may be particularly appropriate for the site/trial; ii) concerns of particular age groups; and iii) concerns regarding insurance  e. Include downloadable forms and tools for local customization 3. Evaluate its use in real trial settings and report on results |  a. ASCO Clinical Trials Participation Awards  b. Form letters and fact sheets (NCI's Clinical Trials Support Unit)  c. Study-specific patient "Fact Fact" sheets as an education tool for clinical trials recruitment (NCI's Cancer Disparities Research Program, Singing River).  d. NCI’s Division of Cancer Prevention has useful tools.  A Recruitment Action Plan and Recruitment Strategy Log that can be adapted for trial recruitment: http://prevention.cancer.gov/files/clinical-trials/recruitment_manual.pdf  EXAMPLES:  
1. The Program for the Elimination of Cancer Disparities (PECaD) at the Siteman Cancer Center works with the Protocol Review and Monitoring Committee (PRMC) to evaluate accrual of minority patients in the institution’s clinical studies (any investigator initiated trial or trial projected to recruit at least 25 patients) and to help investigators achieve appropriate representation by gender, race and ethnicity. All investigators are required to give trial accrual by gender, race and ethnicity. To better guide its researchers, Siteman has developed web-based tables on Incidence Cancer Cases by Disease Site and Demographic Information for their Primary Catchment Area. See: http://www.siteman.wustl.edu/final.aspx?id=1450&content=444  
2. The Recruitment, Retention and Outreach Core (RROC) facility at the Abramson Cancer Center facilitates recruitment efforts for investigators by providing them access to a collaborative team of recruitment, marketing, communication, education, and outreach specialists, as well as patient and community advocates. RROC provides a number of services including consultations with investigators to assist with recruitment planning, recruitment resource development, and coordination of community outreach activities. For additional information, contact the RROC Associate Director, Kia Kerrin, MWH, at wilsonk@mail.med.upenn.edu | |

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<tr>
<th><strong>2. Clearly articulate funding consequences if trial recruitment and retention targets and/or substantive progress towards achieving them are not demonstrated</strong></th>
<th>NCI Industry</th>
<th>1. Develop new or pilot procedures on funding impact if goals not met, or rewards if goals are met 2. Explore appropriate timing for reviewing recruitment goals 3. Implement policy and evaluate its impact</th>
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| **3. Expand site selection criteria to include those who have adopted relevant National Standards on Culturally and Linguistically Appropriate Services (CLAS), as a means of enhancing optimal recruitment and retention** | National Cooperative Groups Industry | 1. Develop new or pilot procedures on funding impact if goals not met, or rewards if goals are met 2. Explore appropriate timing for reviewing recruitment goals 3. Implement policy and evaluate its impact |  a. The HHS Office of Minority Health has funded CLAS-ACT (Culturally and Linguistically Appropriate Standards And Clinical Trials), which will guide scientists and health professionals in utilizing CLAS standards when designing and recruiting minority patients into new clinical trials. See: http://www.omhrc.gov/templates/content.aspx?ID=504  b. ASCO Clinical Trials Participation Awards  c. The EDICT Project™ produced the CLAS-ACT Self-Assessment Handbook, which helps researchers and organizations assess how well they implement standards for CLAS in clinical trials. See: http://www.hcm.stanford.edu/education/edict/clas-act/index.html  d. EDICT recommendations state that investigators should be trained on both the existence and current problems regarding disproportionate representation of underserved populations in clinical trials, as well as practical strategies for recruiting and retaining members of underrepresented populations in clinical trials.  EXAMPLE: See Siteman, above  
EXAMPLE: ENACT has implemented cultural competency in clinical trials training programs since 2006 |  |
### V. Improving Trial Participant Recruitment, Accrual and Retention

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| 4. Expand patient navigator programs to include responsibilities related to discussion of clinical trial opportunities with eligible cancer patients | NCI and other funders of patient navigation programs, Local research sites with patient navigators | 1. Expand training to include clinical trials information and practice in discussions
2. Modify position descriptions
3. Develop new approach
4. Implement new approach and evaluate its impact | Several of the NCI-funded Cancer Disparity Research Program sites have implemented training programs for this purpose (Centinela, McKeesport).

**EXAMPLE:** ENACT has a curriculum it has used with patient navigators to discuss cancer clinical trials. |

| 5. Ensure that each research team is trained in cultural competency, as it relates to clinical trials access, recruitment and retention | Local research sites | 1. Identify appropriate training programs to meet this purpose
2. Require that appropriate training is successfully completed by each individual
3. Conduct evaluation to ensure that training has assisted the person in completing activities asked of him/her | The Eliminating Disparities in Clinical Trials (EDICT) Project produced the CLAS-ACT Self-Assessment Handbook, which helps researchers and organizations assess how well they implement standards for Culturally and Linguistically Appropriate Services (CLAS) in clinical trials. See http://www.bcm.edu/edict/clas-act/index.html.

**EXAMPLE:** ENACT has implemented cultural competency in clinical trials training programs since 2006. |

| 6. Establish an explicit and standardized approach for discussing clinical trials with all eligible patients at the time of initial treatment consultation | Local research sites | 1. Identify best known practices on standardization or, in its absence, develop a process on standardizing approach
2. Develop registration and feedback interventions where all patients being treated in a clinical setting are interviewed to determine eligibility, interest and reasons for ineligibility or lack of interest
3. Develop new or pilot procedures on additional criteria for site selection
4. Implement procedure and evaluate its impact | ASCO's Annual Clinical Trials Participation Awards

**EXAMPLES:**
- Although there are many such practices and procedures, such as flagging charts, one in use at H. Lee Moffitt Cancer Center and Research Institute in 2007 is of interest: The Center sent a letter to all new lung cancer patients before their first appointment, explaining that offering a clinical trial at this hospital was the norm, to expect this discussion, and the option of standard treatment was always available. A year after the letter process was initiated, accrual rates increased 18%.  

- The Vanderbilt-Ingram Cancer Center has a “Clinical Trials Mentor Program,” in which advocates (all former trial participants) mentor patients considering enrolling in clinical trials.

- The North Central Cancer Treatment Group created a core group of community advocates who are available to talk to candidates considering participation in a clinical trial. Advocates are trained about the clinical trial process and how to approach patients who have received a recent cancer diagnosis. |
### Recommendation

**Collaborate with primary care providers, patient navigators and other professionals involved in patient care to encourage communication of trial availability to individuals recently diagnosed with cancer**

**Target Audience:** Local research sites

**Implementation Steps**

1. If patient navigators are available, train them in how to optimally discuss CCT with newly diagnosed patients
2. Develop new or pilot procedures on incorporating patient navigators into the research team
3. Implement policy and evaluate its impact

**Implementation Resources & Examples**

- Several of the NCI-funded Cancer Disparity Research Program sites have implemented training programs for this purpose (Centinela, McKeesport)
- C-Change has outlined optimal components of Patient Navigation in its patient navigation tool kit. See: [www.cancerpatientnavigation.org](http://www.cancerpatientnavigation.org)
- NCI and ACS have partnered to implement a training program for its funded Patient Navigator Programs.
- Harold P. Freeman Patient Navigation Institute at the Ralph Lauren Center has an extensive certification program. See: [http://www.hpfreemanpn.org](http://www.hpfreemanpn.org)
- The North Central Cancer Treatment Group created a core group of community advocates who are available to talk to candidates considering participation in a clinical trial. Advocates are trained about the clinical trial process and how to approach patients who have received a recent cancer diagnosis.
- The Vanderbilt-Ingram Cancer Center has a “Clinical Trials Mentor Program,” in which advocates (all former trial participants) mentor patients considering enrolling in clinical trials.

**Local research sites**

**Develop participant recruitment and retention plans for groups of trials and ensure they are reviewed by community partners and/or existing CABs prior to or concurrent with local IRB submission**

**Target Audience:** Local research sites

**Implementation Steps**

1. Assemble community review process, either by establishing a new committee or identifying appropriate groups that can serve as key reviewers
2. Determine the most appropriate grouping for trial review (may be done by institution or research group; may be classified by disease site, disease stage, or type of treatment (i.e. adjuvant, surgical), etc.)
3. Review the CBPR curriculum to begin to plan ways to seek local partners
4. Implement and incorporate “Principles of Good Community-Campus Partnerships”

**Implementation Resources & Examples**

- Evidence-based curriculum for community-institutional partnerships that are using or planning to use a CBPR approach to improving health. It can be used by partnerships that are just forming as well as mature partnerships. [http://www.cbpcurriculum.info/](http://www.cbpcurriculum.info/)
- Principles of Good Community Campus Partnerships can help clarify terms of engagement and expectations between partners (CCPH).

Several of the NCI-funded CDRP sites have implemented training programs for this purpose (Centinela, McKeesport).

**EXAMPLE:**

The Fred Hutchinson Cancer Research Center in Seattle coordinates the HIV Vaccine Trials Network (one of the seven NIAID-funded HIV/AIDS clinical research networks). Each of the 27 research sites within the network administers a Community Advisory Board (CAB), which provides community input into study design and local procedures.

**Demonstrate respect, acknowledgement and appreciation of trial participants through a variety of means, such as periodic correspondence on the trial, newsletters, cards, and special events**

**Target Audience:** Local research sites

**Implementation Steps**

1. Use correspondence, as done in longitudinal and prevention trials, to enhance retention for those in long term follow up trials
2. Develop and conduct needs assessment (through web surveys, focus groups or interviews) to better plan acknowledgement and appreciation activities

**Implementation Resources & Examples**

- CISCRP has materials and PSAs that acknowledge and express appreciation for research participants: [http://www.ciscrp.org](http://www.ciscrp.org)
- ACRIN is utilizing thank-you notes to summarize trial results.

**EXAMPLE:**

The Fred Hutchinson Cancer Research Center in Seattle coordinates the HIV Vaccine Trials Network (one of the seven NIAID-funded HIV/AIDS clinical research networks). Each of the 27 research sites within the network administers a Community Advisory Board (CAB), which provides community input into study design and local procedures.
Recommendation | Target Audience
---|---
10. **Expand research funding to document and demonstrate promising practices in cancer clinical trial recruitment and retention efforts, and in particular, on efforts to involve members of underserved minority, non-English speaking, poor and elderly communities** | NCI

11. **Commission an update of the 2005 evidence report on “Knowledge and Access to Information on Recruitment of Underrepresented Populations to Cancer Clinical Trials”** | AHRQ

| Implementation Steps | Implementation Resources & Examples |
---|---|
1. Develop and release RFA for this purpose 2. Consider supplemental funding to the CCOPs or Cooperative Groups | As suggested in the AHRQ Evidence report:
1. Systematic data collection about barriers and promoters of trial participation should be linked to concrete plans for designing interventions to address such barriers. Moreover, the next generation of studies of barriers and promoters of accrual should be multidisciplinary, including the involvement of community-based participatory researchers, social and behavioral scientists, as well as health economists.
2. Different types of intervention approaches should be considered to promote accrual to cancer therapeutic trials and cancer prevention trials. Research and evaluation of recruitment strategies may yield stronger evidence about ways to improve participation of underrepresented populations in cancer clinical trials. The principal need is for hypothesis-driven research, and, ultimately, randomized controlled trials to evaluate the most promising strategies for recruiting underrepresented populations into cancer treatment and prevention trials.

1. Invite Evidence-Based Practice Centers to develop proposal for this review 2. Encourage individuals and groups to nominate this topic at: [http://www.ahrq.gov/clinic/epic/reptopic.htm](http://www.ahrq.gov/clinic/epic/reptopic.htm)
VI. Enhancing Local Community Support for Cancer Research

Recommendation | Target Audience | Implementation Steps | Implementation Resources & Examples |
--- | --- | --- | --- |
1. Ensure that the institutions/investigators implementing research protocols have documented a) ongoing community education about clinical trials beyond any particular trial; b) outreach activities with community groups, particularly those working to reduce health disparities. | NCI National Cooperative Groups (in support of local study sites) | 1. Seek alternative funding for training from industry, foundations and other cancer research organizations. 2. Encourage local investigators to use funding for this purpose. | See Cancer Center guidelines listed below. |
2. Provide technical assistance to facilitate the ability of research sites to successfully implement community partnership, outreach and engagement activities. | National Cooperative Groups Industry | Provide experts speakers at national meetings and webinars on community outreach and engagement. | CCPP Consultancy Network.  
http://depts.washington.edu/ccph/mentortext.html  
NCI Cancer Information Service Partnership Program.  
www.cancer.gov/cis |
3. Demonstrate mutually beneficial, sustained partnerships with existing community infrastructure, such as primary care providers and community-based organizations. These partnerships should engage in outreach and education efforts that inform the community about clinical trials beyond any particular trial. Whenever possible, research sites located in the same geographic area should collaborate in these efforts. | Local research sites | Identify resources for ongoing collaboration and education. | Ideas for collaboration include:  
- Organizations could include state or county primary care professional organizations; community health centers; community-based organizations; and faith-based organizations. (also see Appendix D)  
- See NCI’s Cancer Trials: A Guide For Outreach and Advocacy, to help plan these efforts.  
http://www.cancer.gov/ClinicalTrials/resources/outreach-education-advocacy  
- NCI’s Cancer Information Service Partnership Program:  
http://cis.cancer.gov/community/community.htm  
- An evidence-based curriculum is intended as a tool for community-institutional partnerships that are using or planning to use a CBPR approach to improving health. It can be used by partnerships that are just forming as well as mature partnerships:  
http://www.cbprcurriculum.info/  
- Principles of Good Community-Campus Partnerships can help clarify terms of engagement and expectations between partners:  
http://depts.washington.edu/ccph/commbe.html  
- Community Tool Box:  
http://csh.harvard.edu/index.html  
http://www.hpai.org/  
- Slide programs from Cancer Clinical Trials Education Series (National Cancer Institute, which can be delivered by the NCI Cancer Information Service); Material used in the NCI SPORE PART:  
http://cancer.gov/cis/community/index.jsp  
- See NCI’s Cancer Clinical Trials: A Guide For Outreach and Advocacy, to help plan these efforts.  
http://www.cancer.gov/cis/community/index.jsp  
- NCI’s Cancer Information Service Partnership Program:  
http://cis.cancer.gov/community/community.htm |
4. Engage in outreach activities with community groups, particularly those working to reduce health disparities, to educate the broader community about cancer clinical trials, beyond any particular trial. Whenever possible, research sites located in the same geographic area should collaborate in these efforts. | American College of Surgeons’ Commission on Cancer | In its next iteration of standards, include minimum standards for community outreach and research. | EXAMPLE:  
As part of its criteria for approval, NCI requires designated cancer centers to demonstrate community service, outreach and dissemination efforts. Criteria is based on adequacy of the center’s:  
- Awareness of the cancer problem in the community it serves, including cancer incidence and mortality rates associated with both majority and special populations (e.g., minorities, people over age 65)  
- Collaboration with other centers, when their service regions are overlapping, in developing complementary outreach efforts to maximally benefit the community  
- Outreach activities, including plans for those that address the special problems of the community, as well as collaborations with not-for-profit or for-profit outreach programs  
- Priority setting and use of available expertise and resources to serve the community in ways that will reduce cancer incidence and mortality  
- Efforts to evaluate the impact of development to delivery activities on clinical and public health systems within the center’s catchment area:  
5. Expand existing standards for community outreach and research to include community-based education and partnerships around clinical trials. | American College of Surgeons’ Commission on Cancer |  |  |
### VII. Enhancing Community Interpretation, Dissemination and Implementation of Trial Outcomes

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<td>Public and private trial sponsors</td>
</tr>
<tr>
<td>2. Partner with private sector organizations, foundations and advocacy groups for the services they provide in interpretation, dissemination and implementation of Phase III study results</td>
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<tr>
<td>3. Partner with advocacy organizations and other community-based groups to set priorities for interpretation, broad dissemination and implementation of study results based on importance and applicability. There should be particular emphasis on reaching underserved minority, non-English speaking populations, poor and elderly populations</td>
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<tr>
<td>4. Explore appropriate ways to assist local research sites/local investigators in notifying clinical trial participants about trial results in lay language and in a timely manner</td>
<td>Public and private trial sponsors</td>
</tr>
<tr>
<td>5. Conduct research on best practices to communicate aggregate trial results to participants</td>
<td>NCI</td>
</tr>
<tr>
<td>6. Conduct an assessment of the ways in which CR/PAs are currently involved in the interpretation, dissemination and implementation of Phase III study findings</td>
<td>NCI</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Implementation Steps</th>
<th>Implementation Resources &amp; Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assess the extent to which currently supported studies are investigating these issues</td>
<td>Center for AIDS Prevention Studies’ guidelines for dissemination: <a href="http://www.chsrf.ca/kte_docs/CABDisseminationGuidelines.pdf">http://www.chsrf.ca/kte_docs/CABDisseminationGuidelines.pdf</a></td>
</tr>
<tr>
<td>3. Develop program announcement to specifically support such studies</td>
<td></td>
</tr>
<tr>
<td>1. Convene representatives of these groups to discuss this recommendation and develop collaborative strategies for implementing it</td>
<td>&quot;Motivating, recognizing and celebrating partners&quot; unit in the online curriculum on Developing and Sustaining CBPR Partnerships: <a href="http://depts.washington.edu/cbpr/cbpr/u4/u4b.php">http://depts.washington.edu/cbpr/cbpr/u4/u4b.php</a></td>
</tr>
<tr>
<td>2. Include questions asking for description of notification plan in trial proposals</td>
<td>See Appendix D for list of organizations</td>
</tr>
<tr>
<td>3. Collect and disseminate sample notification plans and communications with study participants</td>
<td></td>
</tr>
<tr>
<td>1. Include questions asking about the existence, process and outcomes of community involvement in trial interpretation, dissemination and implementation in reports submitted by funded trials</td>
<td>Center for AIDS Prevention Studies’ guidelines for dissemination: <a href="http://www.chsrf.ca/kte_docs/CABDisseminationGuidelines.pdf">http://www.chsrf.ca/kte_docs/CABDisseminationGuidelines.pdf</a></td>
</tr>
<tr>
<td>2. Commission study on best practices</td>
<td>See Appendix D for list of organizations</td>
</tr>
<tr>
<td>1. Commission study</td>
<td>See citations in recommendations section</td>
</tr>
<tr>
<td>2. Include questions asking for this information in the reports submitted by NCI-funded trials</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX B: Training Resources for Community Representatives/Patient Advocates Involved in Cancer Clinical Research

Please note: this is not meant to be an exhaustive list. If you have suggestions to add, please email them to Project Coordinator Stacy Collins at stacy.collins@enactc.org.

**NCI’s CARRA Training Program**

This NCI training program helps patient advocates become effective participants in the NCI peer review process. The 2 1/2 day workshop curriculum is for members of its Consumer Advocates in Research and Related Activities (CARRA) program. Entitled “Preparing Consumer Advocates to Participate in Peer Review,” the training program focuses on the scientific, technical, and cultural aspects of NCI peer review and how advocates can more effectively represent the collective views of survivors, patients and family members during the grant review process. Each workshop is conducted by a multidisciplinary training team, which includes consumer advocates, university scientists, NCI staff, and training facilitators. Mock peer reviews are also conducted to demonstrate how grant applications are reviewed and scored, and how advocates address human subjects concerns during the peer review process. The NCI website includes a downloadable version of the CARRA training curriculum, as well as a host of additional training resources for community representatives/patient advocates.

[http://carracancer.gov/members/training/overview](http://carracancer.gov/members/training/overview)

**Coalition of Cancer Cooperative Groups’ Patient Advocacy Training**

The Coalition of Cancer Cooperative Groups’ self-study training program, Cancer Research: A Guide to Cancer Clinical Trials, was developed for patient advocates nationwide. The goal of the training program is to provide education, training and ongoing professional support that will enable advocates to: effectively inform and influence the cancer clinical trial research process; stay current with issues and aspects of clinical research; and increase patient accrual to clinical trials. The training program includes six individual modules: Cooperative Groups; Cancer Clinical Trials; Drug Development; Surgical and Radiation Therapies; Protecting Research Participants; and Tissue and its Use. The training program is available on-line and in CD format. The coalition also sponsors an annual Patient Advocate Training and is a national co-convener of the annual “Summit Series on Cancer Clinical Trials.”


**The Research Advocacy Network “Advocate Institute”**

The Research Advocacy Network’s (RAN) Advocate Institute provides advocates with multiple learning modalities so they can better understand the medical research system, participate in discussions and other interactions that provide a solid background in cancer research. Through the program, patient advocates develop stronger backgrounds in cancer research and related issues; keep abreast of recent advances in drug development and basic, clinical and translational cancer research; and interface with cancer scientists.

[http://www.ran.org/home/survivors-advocates/scientisthrar;survivor-program.aspx](http://www.ran.org/home/survivors-advocates/scientisthrar;survivor-program.aspx)

**American Association for Cancer Research Scientist Survivor Program**

The AACR Scientist Survivor Program is designed to build partnerships between the scientific and cancer survivor/patient advocacy communities. The program exposes advocates to special lay-language lectures, small group discussions and other interactions that provide a solid background in cancer research. Through the program, patient advocates develop stronger backgrounds in cancer research and related issues; keep abreast of recent advances in drug development and basic, clinical and translational cancer research; and interface with cancer scientists.

[http://www.aacr.org/home/survivors-advocates/scientisthrar;survivor-program.aspx](http://www.aacr.org/home/survivors-advocates/scientisthrar;survivor-program.aspx)

**Project LEAD**

Developed by the National Breast Cancer Coalition (NBCC), Project LEAD® is a science training course designed to help breast cancer activists influence research and public policy processes. As an extensive, four-day program, Project LEAD® prepares advocates for participation in the wide range of forums where breast cancer research decisions are made. Through the training of Project LEAD®, NBCC has created an innovative model for consumer influence marked by open communication and an exchange of information among scientists, researchers, policy-makers, and consumers nationwide. Project LEAD graduates are eligible to take the advanced course: Clinical Trials Project LEAD.


**C3 Research Advocacy Training Program**

Colonial Cancer Coalition (C3) sponsors an annual Gastrointestinal (GI) Research Advocacy Training. The goal of the training is to improve the ability of advocates to effectively participate in the research process. The GI Research Advocacy training is open to all advocates with a focus on GI cancers, who are currently serving as patient representatives for the FDA, NCI, Cooperative Groups, Specialized Programs of Research Excellence (SPORES), and local IRBs or DSMBs.

[http://fightcolonetcancer.org/research/training](http://fightcolonetcancer.org/research/training)

**NCI’s Cancer Information Service Partnership Program**

NCI’s Cancer Information Service has established partnerships with nonprofit, private and other government organizations at the national, regional and state levels to develop and implement training programs on cancer-related topics, including clinical trials. The CIS works with partners who have an established presence, are trusted within their communities and are dedicated to serving minority and medically-underserved populations.


**Project TRES**

Project TRES (Training in Research Ethics and Standards), funded by NIH, is a culturally-tailored, content-appropriate, Spanish-translated research ethics curriculum that targets community health workers who assist with community-based research in Hispanic/Latino communities. Community health workers are respected members of the target community and are often involved in conducting complex research protocols. The web-based curriculum is divided into three sessions that address the purpose of research, the roles and responsibilities of those involved in research (e.g., institution, IRB, investigator, and research team), risk and benefits, confidentiality of information; and the components of the informed consent process (e.g., recruitment, enrollment and participation).

[http://projecttres.sdu.edu/tres/about.jsp](http://projecttres.sdu.edu/tres/about.jsp)

**NCTCG Patient Advocate Symposium**

The patient advocate committee of the North Central Cancer Treatment Group (NCTCG) hosts an annual training symposium for cancer research advocates, especially those interested in working within the cooperative group structure. The symposium seeks to develop a network of community patient advocates who are knowledgeable about cancer research and clinical trials.

[http://nctcgpatientadvocates.org/home.html](http://nctcgpatientadvocates.org/home.html)

**United States Cochrane Center: Understanding Evidence-based Healthcare**

The U.S. Cochrane Center is a non-profit organization, which produces and disseminates reviews of healthcare interventions and promotes clinical trials. The organization offers a free web-based course that is designed to help consumer advocates understand the fundamentals of evidence-based healthcare concepts and skills. The objectives of the course are to provide consumer advocates with the tools they need to successfully navigate the world of medical information, critically appraise research studies, influence the creation of responsible public policy in healthcare, and help the people they serve to make healthcare choices based on the best available evidence.


**SPORE Patient Advocate Research Team (PART) Program**

Although the grant that funded the SPORE (Specialized Programs of Research Excellence) PART Program has ended, training materials developed through the program are available on the web, including the Clinical Trials and People Workshop, as well as other resources for developing research advocacy skills.

[http://www.sporadvocates.net/content/index.php?option=com_frontpage&Itemid=149](http://www.sporadvocates.net/content/index.php?option=com_frontpage&Itemid=149)
In addition, community representatives/patient advocates can contact Deborah Collyar, president of PAIR: Patient Advocates In Research and former SPORE PART program director, at collyar@att.net, for other training resources.

**Cancer Information and Support Network (CISN)**

CISN is a grassroots organization that fosters public awareness and literacy about the importance of clinical research. It offers a variety of trainings for community representatives/patient advocates, including:

- “Clinical Trials 101”
- “How to Read and Review a Clinical Trial Protocol”
- “Effective Advocate Participation in the Clinical Trial process”
- “How to help write good consent forms”

http://cisncancer.org/

**Family Health International’s Research Ethics Training Curriculum**

Family Health international’s (FHI) Office of International Research Ethics (OIRE) has developed a curriculum to empower community representatives to participate effectively in research activities. Developed and field-tested in eight countries, the Research Ethics Training Curriculum for Community Representatives (RETC-CR) helps community representatives to understand the research process and their roles and responsibilities as partners of the research team. The curriculum also explains the corresponding roles and responsibilities of ethics committees/IRBs and researchers. The RETC-CR addresses universal principles of research ethics, informed consent, ethics committees, and other important issues. Components include:

- Slides and text
- Real-life case studies
- Learning activities
- Facilitator notes
- References
- Additional resources
- Certificates of completion from OIRE

The curriculum is available in an on-line, self-study version, as well as in print and CD-ROM format. Available languages include English, French, Spanish and Portuguese.


**APPENDIX C: Suggested Roles, Qualifications and Expectations for Community Representatives/ Patient Advocates**

Skills/Qualifications¹ for Serving as a Community Representative/Patient Advocate

<table>
<thead>
<tr>
<th>To serve on a National Cooperative Group, an individual must demonstrate.</th>
<th>To work with local investigator(s)/institutions, such as within a Community Advisory Board (CAB), an individual must demonstrate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local experience related to clinical research (consider the use of a “feeder system”⁴)</td>
<td>Being directly affected by cancer (personally, as a caregiver, or as a member of community disproportionately affected), AND</td>
</tr>
<tr>
<td>Meaningful connection with a specific constituency affected by cancer with which he/she is able to have ongoing communication and feedback</td>
<td>Experience with cancer advocacy through activities/organizations⁵ that go beyond a personal experience, AND</td>
</tr>
<tr>
<td>Genuine understanding of the specific community(s)/constituency’s needs</td>
<td>Willing to learn more about cancer, cancer research, and how cancer affects the community</td>
</tr>
<tr>
<td>Interest and ability to network with other organizations with an interest in cancer</td>
<td>Ability to interact effectively with clinical and laboratory researchers</td>
</tr>
<tr>
<td>Level of comfort articulating opinions assertively and professionally among persons of all types of educational and professional backgrounds</td>
<td>Willingness to learn more about cancer research and the research development process, including concept and protocol development</td>
</tr>
<tr>
<td>Interest/ability to listen, reflect, question, and respond without becoming defensive or confrontational</td>
<td>Ability to discern the needs of the community from which they came and the needs of local research studies</td>
</tr>
<tr>
<td>Interest in gaining self-confidence to ask questions of physicians/scientists, and to disagree with them when necessary</td>
<td>Ability to discern the needs of the community from which they came and the needs of research nationally</td>
</tr>
<tr>
<td>Ability to interact effectively with clinical and laboratory researchers</td>
<td>Ability to apply scientific concepts and knowledge in analyzing complicated proposals, in both written and verbal forms</td>
</tr>
</tbody>
</table>

¹ Qualifications are not limited to educational achievement, as measured by an academic degree.

⁴ “Feeder system” refers to a system where local investigators or institutions refer patients to larger cooperative groups for more advanced or specialized treatments.

⁵ Organizations that go beyond a personal experience include but are not limited to local support groups, community organizations, and advocacy groups.

⁶ “Discerning the needs of the community” refers to the ability to understand and prioritize the needs of the community from which they come, compared to the needs of research at the national level.
Competencies/Knowledge Needed for Community Representatives/Patient Advocates

To serve on a National Cooperative Group, an individual must have knowledge in these areas:

- Basic understanding of the disease being studied, including standard of care
- Basic understanding of the cancer clinical research process
- Key aspects of community outreach and accessible communication and education strategies
- Key aspects of health literacy and discerning readability of written documents
- The cancer clinical research system in the United States
- Belmont Report and ethical requirements for research
- The informed consent process

To work with local investigator(s)/ institutions, such as within a CAB or IRB, an individual must have knowledge in these areas:

- Basic understanding of the disease being studied, including standard of care
- Basic understanding of the cancer clinical research process
- Key aspects of community outreach and accessible communication and education strategies
- Key aspects of health literacy and discerning readability of written documents
- The cancer clinical research system in the United States
- Belmont Report and ethical requirements for research
- The informed consent process

Responsibilities and Expectations for Community Representatives/Patient Advocates Serving on National Cooperative Groups

<table>
<thead>
<tr>
<th>Responsibilities (for Review of Both Concepts and Protocols)</th>
<th>Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Judge the feasibility of trial concept (i.e., Is this something that will be of interest to patients?)</td>
<td>• Attend orientation and training</td>
</tr>
<tr>
<td>• Evaluate the relative priority of the trial with respect to other research questions (i.e., How important will the results be to patients?)</td>
<td>• Use formal criteria and standard forms, such PROJECT INFORM (used in ACRIN)</td>
</tr>
<tr>
<td>• Consider potential patient experience in trial (i.e., How does the trial experience compare to standard care?)</td>
<td>• Invest time reviewing protocols/concepts</td>
</tr>
<tr>
<td>• Consider eligibility criteria that can best meet the needs of those disproportionately impacted by the disease</td>
<td>• Invest time attending meetings</td>
</tr>
<tr>
<td>• Review the consent form, to ensure comprehensibility and clarity in a number of areas</td>
<td>• Participate and vote in calls and in-person review meetings</td>
</tr>
<tr>
<td>• Consider review of all patient documents, with an understanding of basic concepts in addressing health literacy</td>
<td>• Adhere to specific term limits</td>
</tr>
</tbody>
</table>

Sample Cancer Clinical Trial Community Advisory Board Standards

CAB Membership

- Advocates in local communities disproportionately impacted by cancer morbidity or mortality
- Survivors and family members who have experience with different types of cancer
- Clinical trial participants
- Religious leaders
- Primary health care providers

Roles and Responsibilities of CAB Members

- Review study concepts and protocols for community relevance
- Pre-test study materials, particularly for cultural sensitivity
- Review recruitment and retention plan
- Evaluate the study’s accessibility to underserved populations, including low literacy and LEP (limited English proficiency) individuals, racial and ethnic minorities, and people living with disabilities
- Assist investigators in implementing outreach and recruitment efforts

Informational Needs regarding CAB Operations

- Establishing and funding CABs
- Building CAB-investigator relationships
- CAB member training
- Local and national CAB interface
- A CAB review checklist, for scoring prospective studies
- Best practices for CAB involvement in recruitment efforts
APPENDIX D: Resources for Identifying Community Partners to Participate in Clinical Trial Activities

- The Intercultural Cancer Council (ICC)
The Intercultural Cancer Council (ICC), based at Baylor College of Medicine, (ICC) promotes policies, programs, partnerships, and research to eliminate the unequal burden of cancer among racial and ethnic minorities and medically underserved populations in the United States and its associated territories. The ICC hosts a network of regional and local cancer control organizations:


ICC Regional Network: http://iccnetwork.org/who/regionalnetwork.htm

- The NCI CARRA Program
The NCI CARRA Program is administered by the NCI Office of Advocacy Relations (OAR). The program consists of approximately 200 consumer advocates from many different cancer types, age groups, and ethnic groups across the nation. As a highly qualified, pre-screened group of volunteers, CARRA members can strengthen and enrich research activities by providing the perspective of patients, survivors, family members, and caregivers. Although CARRA members are primarily engaged in NCI activities, investigators can request their participation in other cancer research projects as well. Contact Elizabeth Nelson, CARRA Program Manager, at 301-451-3321 or via email at nci-carra@mail.nih.gov

- NCI Grantees Working on Health Disparities
Three NCI health disparities initiatives include community partners at the grantee level:

The Cancer Disparities Research Partnership Program (CDRP) supports the planning, development, and conduct of radiation oncology clinical trials in institutions that care for a disproportionate number of medically underserved, low-income, ethnic and minority populations that have not been traditionally involved in NCI-sponsored research. The CDRP grant also includes support for patient navigation. See http://wwwj.cancer.gov/rmp/cdrp/funded.html

The Community Networks Program (CNP) is designed to reach communities and populations that experience a disproportionate share of the cancer burden: African Americans, American Indians/Alaska Natives, Hawaiian Natives and other Pacific Islanders, Asians, Hispanics/Latinos, and underserved rural populations. The overall goal of the program is to improve access to and utilization of -beneficial cancer interventions and treatments in communities experiencing cancer health disparities, through community-based participatory education, training, and research. See http://crcht.cancer.gov/cnp/cnp-project-listing.html

The NCI Community Cancer Centers Program (NC3P) is a three-year pilot program to test the concept of a national network of community cancer centers to expand cancer research and deliver advanced cancer care to a greater number of Americans in the communities in which they live. The NC3P seeks to:

- Bring more Americans into a system of high-quality cancer care
- Increase participation in clinical trials
- Reduce cancer healthcare disparities
- Improve information sharing among community cancer centers

http://nc3p.cancer.gov/

- CANCER Control P.L.A.N.E.T
The CANCER Control P.L.A.N.E.T. is an NCI-sponsored web portal that features state and regional “program partners,” including the NCI Cancer Information Service Partnership Program, who can be contacted to participate in clinical trial activities.

http://cancercontrolplanet.cancer.gov/

- Sisters Network (SN)
Sister Network, Inc. is a national African American breast cancer survivorship organization. It has a membership base of 3000, which includes more than 40 affiliate survivor-run chapters nationwide.

http://www.sisternetworkinc.org/default.asp

- Native American Cancer Research (NACR)
Native American Cancer Research (NACR) is an education and support organization for Native American cancer patients, survivors and caregivers. The organization actively participates in cancer research studies, including clinical trials, within the Native American community.

http://natamcancer.org/index.html

- Research Advocacy Network (RAN)
The Research Advocacy Network (RAN) maintains a database of cancer clinical research advocates nationwide:

http://www.researchadvocacy.org/about/contact.php

- Coalition of Cancer Cooperative Groups
The Coalition of Cancer Cooperative Groups maintains a database of national and state-level cancer patient advocacy organizations with experience in cancer clinical trials:

http://www.cancertrialshelp.org/patient_content/pdMainContent.aspx?intAppMode=2

- The American Association for Cancer Research (AACR)
The American Association for Cancer Research (AACR) maintains an extensive list of U.S. and Canadian cancer advocacy organizations, dedicated to specific types of cancer:


NOTE: Although the following entities are not cancer-specific, they have local constituencies and/or affiliates. We suggest that researchers first contact the national office (web addresses provided below) and request information on local members/chapters that can be contacted for cancer research projects.

- U.S. Department of Health and Human Services Office of Minority Health (OMH)
The Office of Minority Health (OMH) has Minority and Multicultural Health Liaison Representatives in each state that may assist in connections with grassroots organizations in their areas:


OMH also maintains minority health consultants in each of the 10 HHS Regional Offices, to facilitate a network of consumers and professionals working on minority health issues:

http://www.omhrc.gov/images/usa-regions.html

OMH grantees are community organizations throughout the US, working locally to eliminate health disparities:


- CCPH Community-Based Participatory Research and Community Partner Listserv
Community-Campus Partnerships for Health sponsors two electronic discussion groups that are potential sources of community partners already involved in collaborative research.
The Community-Based Participatory Research (CBPR) Listserv, with over 3000 subscribers is a resource for the growing network of people involved and interested in CBPR and other types of community-academic research partnerships, including those from community-based organizations.

To subscribe, send an email request to ccph@mcw.edu

The Community Partner Listserv was established to help build the capacity of community partners involved in community-academic partnerships (including CBPR) through information-sharing, collaborative problem-solving and advocacy.

To subscribe, send an email request to ccph@mcw.edu

- **National Association of Community Health Centers (NACHC)**
  Spread across 50 states and all U.S. territories, more than 1150 community health centers organizations provide primary care to more than 17 million Americans with limited financial resources. Each community health center is directed by a board with majority consumer membership.
  http://www.nachc.com/about-our-health-centers.cfm
  http://findahealthcenter.hrsa.gov/

- **The Center for Sustainable Health Outreach (CSHO)**
  The Center serves as a national point of contact for community health workers (CHWs), who, as members of the communities they serve, provide culturally and linguistically appropriate outreach, prevention, intervention, and treatment services. CHWs also educate providers and health care systems and help craft services that are more responsive to the communities being served.
  http://www.usm.edu/csho/general_information2.htm

- **National Council of La Raza – Affiliate Network**
  NCLR's Affiliate Network includes nearly 300 community-based organizations. Located throughout the US, these organizations provide services to approximately four million Hispanic Americans. These organizations deal on a day-to-day basis with all aspects of serving the Latino population.
  http://www.nctr.org/section/network/

- **Consumers United for Evidence-based Healthcare (CUE)**
  Consumers United for Evidence-based Healthcare (CUE), based at Johns Hopkins University, is a partnership between consumer health advocacy groups and scientists involved in evidence-based healthcare (EBHC). A coalition of 27 health and consumer advocacy organizations, CUE seeks to empower consumers, public health policy makers, and healthcare providers in making informed decisions based on the best current evidence through research, education, and advocacy.
  http://apps1.jhsph.edu/cochrane/usccce.htm

- **Centers for Disease Control (CDC) Prevention Research Centers (PRCs)**
  The PRCs are a network of academic researchers, public health agencies, and community members that conducts applied research in disease prevention and control. Community members at each PRC site have formed a National Community Committee to support community-based prevention research.

  National Community Committee (NCC)
  http://www.hdpd.unc.edu/ncc/

  CDC Prevention Research Centers Local Programs
  http://www.cdc.gov/prc/index.htm

- **National Health Council**
  The National Health Council includes more than 155 member organizations representing many areas of health care, such as voluntary health agencies, professional and membership associations and non-profit organizations with an interest in health.
  http://www.nationalhealthcouncil.org/aboutus/membership/index.htm

- **Other national organizations with state and local level affiliates/members: Community-Based Public Health Caucus of the American Public Health Association (APHA)**
  http://www.sph.umich.edu/cbphcaucus/

  CCPH
  Community-Campus Partnerships for Health
  http://www.ccpp.info

  National Community-Based Organization Network
  http://www.sph.umich.edu/cbphcaucus/ncbon.html

  AARP
  http://www.aarp.org

  National Council on Aging (NCOA)
  http://www.ncoa.org/

  National Association for the Advancement of Colored People (NAACP)
  http://www.naaccp.org/uniformindex/index.htm

  Black Women's Health Imperative
  http://www.blackwomenshhealth.org/site/c.eerIPWOC/n/b.3082485k.3082485/

  AAPI Health Forum
  http://www.apahl.org/programs/apahin/index.htm

  Hadassah
  http://www.hadassah.org/pageframe.asp?section=about&page=locations/locations.html#header+locations&size=50

  National Asian Women's Health Organization
  http://www.nawho.org/site/c.ipILKTOCJsG/b.4089873/k.7F6D/NAWHO_Home_page.htm
APPENDIX E: How to Get Started in Finding Community Groups with Which to Collaborate

Excerpted from the NCI publication: Cancer Clinical Trials: A Resource Guide for Outreach, Education, and Advocacy

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.

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 chart below 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.

<table>
<thead>
<tr>
<th>Organization Type</th>
<th>Examples in My Community</th>
<th>Contact People in Community</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advocacy organizations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>African-American, Asian American, Latino, and Native American-based organizations</td>
<td></td>
<td></td>
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<tr>
<td>Cancer-oriented nonprofit organizations</td>
<td></td>
<td></td>
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<tr>
<td>Cancer support groups</td>
<td></td>
<td></td>
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<tr>
<td>CDC Breast and Cervical Cancer Early Detection Program coalition members (check with your State health department)</td>
<td></td>
<td></td>
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<tr>
<td>Chambers of commerce</td>
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<td></td>
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<tr>
<td>Community cancer centers</td>
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<td></td>
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<tr>
<td>Community health centers/public health clinics</td>
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<td></td>
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<tr>
<td>Employee associations of large companies</td>
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<td></td>
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<tr>
<td>Health care professional associations (doctors, nurses, social workers, health educators, etc.)</td>
<td></td>
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<tr>
<td>Hospital education departments</td>
<td></td>
<td></td>
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<tr>
<td>Hospitals and research institutions</td>
<td></td>
<td></td>
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<tr>
<td>Housing organizations</td>
<td></td>
<td></td>
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<tr>
<td>Labor union locals</td>
<td></td>
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<tr>
<td>LGBT organizations</td>
<td></td>
<td></td>
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<tr>
<td>Men’s organizations</td>
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<tr>
<td>Religious organizations/houses of worship</td>
<td></td>
<td></td>
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<tr>
<td>Senior citizens’ organizations</td>
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<td></td>
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<tr>
<td>Service organizations, such as Rotary, Lions, Kiwanis, Jaycees, Junior League</td>
<td></td>
<td></td>
</tr>
<tr>
<td>State cancer control committees</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Veterans’ groups</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women’s organizations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX F: Patient and Physician Barriers to Clinical Trial Access

Physician, Patient and Environmental Barriers to Clinical Trial Access
(Source: NCI Outreach Guide unless otherwise noted)

<table>
<thead>
<tr>
<th>Physician Barriers</th>
<th>Patient and Environmental Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>A physician’s recommendation is often the primary factor influencing patients’ decisions to enroll in a trial. Yet, each group of providers involved in diagnosis and treatment face unique barriers to facilitating patient access to clinical trials.</td>
<td>For all Patients</td>
</tr>
<tr>
<td>Participating Oncologists</td>
<td>For Medically Underserved Groups in Particular*</td>
</tr>
<tr>
<td>Non-Participating Oncologists/ Surgical Oncologists</td>
<td>May lack awareness</td>
</tr>
<tr>
<td>Primary Care Providers Doing Diagnostic Workup Prior to Referral</td>
<td>May lack access</td>
</tr>
<tr>
<td>May not offer treatment through a clinical trial to all that would otherwise qualify by:</td>
<td>May face payment or other logistical barriers</td>
</tr>
<tr>
<td>- Assuming disinterest on the part of their patients</td>
<td>May not meet eligibility criteria</td>
</tr>
<tr>
<td>- Inadvertently discriminating against older people or the medically underserved**</td>
<td>May be fearful, distrustful or suspicious of research</td>
</tr>
<tr>
<td>- Avoiding the subject out of concern they would be seen as insensitive</td>
<td>May believe common myths</td>
</tr>
<tr>
<td>- May not have the skills, ability or resources to conduct appropriate recruitment within the community**</td>
<td></td>
</tr>
<tr>
<td>- May feel the extra effort required to consent minority patients or the medically underserved is not important for their research**</td>
<td>May have long-standing fear, apprehension and skepticism about medical research because of past abuses (and not simply from the legacy of the U.S. Public Health Service Syphilis Study in African Americans)**</td>
</tr>
</tbody>
</table>

*These groups comprise government-designated ethnic and racial groups, including American Indian/Alaska Natives, Asians, African Americans, Hispanics/Latinos, and Native Hawaiian and other Pacific Islanders. They also include rural residents and people of low income and low literacy.

**Concerns about health insurance (e.g., denial of coverage and increased out-of-pocket costs) are other known deterrents to participation in cancer clinical trials. Studies have shown that patients in NCI clinical trials were significantly less likely to be uninsured than the U.S. population in general. Medicare did not cover participation in clinical trials until 2000.
APPENDIX G: SAMPLE RECRUITMENT AND RETENTION MATERIAL

(Nota: This resource was adapted from work initiated by the Committee to Optimize Recruitment, Retention and Adherence (CORRA), Division of Cancer Prevention, National Cancer Institute, 2004.)

Form to Identify Referral Sources and Plan Frequency of Contact
Use the thermometer tool to evaluate protocol, target population, clinic, and referral sources. Then, determine the most appropriate recruitment and retention strategies.

<table>
<thead>
<tr>
<th>Approach</th>
<th>Referral Source</th>
<th>How</th>
<th>Start</th>
<th>End</th>
</tr>
</thead>
</table>

Forms to Plan Your Recruitment and Retention Performance
A suggestion for monitoring recruitment is to assign a number to each referral source. If using more than one recruitment strategy for a single source, assign each strategy a unique number. For example, assign two referral source numbers to a referral source for which you do two mailings - one for the first mailing and a different number for the second mailing.

Recruitment Strategies Log
The purpose of the Strategies Log is to document the effectiveness of your recruitment methods. Strategies Logs should be completed by the end of each month, and the information recorded should reflect recruitment efforts from the first to the last day of the month.

The following describes how each of the log’s sections should be completed:

**Recruitment strategies:** Summarize in a few short words the type of recruitment strategies implemented. This description should be general; for example, if someone at your site is speaking with church groups, then you might write, “meet with church groups”

**Try strategy again:** The purpose of this section is to state whether or not your site would try the strategy listed in the previous column again. Think about how successful this strategy was in your community and how feasible it was to implement. A “yes” or “no” in this column is all that is necessary

**Number contacted:** Record the actual number or an estimate of participants who were initially introduced to the trial by the strategy implemented

**Number who visited the clinic site:** Record the number of potential participants who visited a clinic site as a result of the strategy implemented

**Number accrued:** Record the actual number of individuals accrued to the study

**Site name, staff member name, phone number, and date:** Record site information and the name of the person completing the form should questions arise in the future
### Sample Recruitment Strategies Log

<table>
<thead>
<tr>
<th>Recruitment Strategy (list activity)</th>
<th>Try Strategy Again? (Y/N)</th>
<th>Number of Potential Participants</th>
<th>Number Contacted? (Actual/Estimate)</th>
<th>Number Who Visited Clinic/ Site?</th>
<th>Number Accrued/ Enrolled?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Month/Week 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month/Week 2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Sample Screening Log

Sample screening log form with attribution to specific strategy and reasons for ineligibility, or non-enrollment.
## Sample Screening Log Summary

<table>
<thead>
<tr>
<th>Site 1</th>
<th>Site 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Screened</td>
<td>Patients Screened</td>
</tr>
<tr>
<td>Patients Enrolled</td>
<td>Patients Enrolled</td>
</tr>
<tr>
<td>Patients Completed</td>
<td>Patients Completed</td>
</tr>
<tr>
<td>Withdrawals</td>
<td>Withdrawals</td>
</tr>
<tr>
<td>Treatment Failure</td>
<td>Treatment Failure</td>
</tr>
<tr>
<td>Adverse Event</td>
<td>Adverse Event</td>
</tr>
<tr>
<td>Progression of Disease</td>
<td>Progression of Disease</td>
</tr>
<tr>
<td>WD Consent</td>
<td>WD Consent</td>
</tr>
<tr>
<td>Other</td>
<td>Other</td>
</tr>
<tr>
<td># Queries Outstanding</td>
<td># Queries Outstanding</td>
</tr>
<tr>
<td>CRFs received to date</td>
<td>CRFs received to date</td>
</tr>
<tr>
<td>CRFs entered to date</td>
<td>CRFs entered to date</td>
</tr>
</tbody>
</table>

## Sample Patient Scheduling Form

<table>
<thead>
<tr>
<th>Patient Listing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wd. for progression of disease</td>
</tr>
<tr>
<td>Wd. for AE</td>
</tr>
<tr>
<td>Wd. For other reason</td>
</tr>
<tr>
<td>Wd. Consent</td>
</tr>
<tr>
<td>Wd. for Treat. Fail</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for WD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Last Visit</td>
</tr>
<tr>
<td>Month 1 Visit Date</td>
</tr>
<tr>
<td>Week 2 Visit Date</td>
</tr>
<tr>
<td>Date of First Dose</td>
</tr>
<tr>
<td>Random Date</td>
</tr>
<tr>
<td>Screening Date</td>
</tr>
<tr>
<td>Reason for Screen Failure</td>
</tr>
<tr>
<td>Random Number</td>
</tr>
<tr>
<td>Subject Number</td>
</tr>
<tr>
<td>PATIENT INITIALS</td>
</tr>
</tbody>
</table>
## APPENDIX H: Frequently Used Acronyms

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAHRPP</td>
<td>Association for the Accreditation of Human Research Protection Programs</td>
</tr>
<tr>
<td>ACOSCoC</td>
<td>American College of Surgeons’ Commission on Cancer</td>
</tr>
<tr>
<td>AHRQ</td>
<td>Agency for Healthcare Research and Quality</td>
</tr>
<tr>
<td>ASCO</td>
<td>American Society of Clinical Oncology</td>
</tr>
<tr>
<td>CAB</td>
<td>Community Advisory Board</td>
</tr>
<tr>
<td>CARRA</td>
<td>Consumer Advocates in Research and Related Activities</td>
</tr>
<tr>
<td>CBO</td>
<td>Community-Based Organization</td>
</tr>
<tr>
<td>CBPR</td>
<td>Community-Based Participatory Research</td>
</tr>
<tr>
<td>CCOP</td>
<td>Community Clinical Oncology Program</td>
</tr>
<tr>
<td>CCPH</td>
<td>Community-Campus Partnerships for Health</td>
</tr>
<tr>
<td>CCT</td>
<td>Cancer Clinical Trial</td>
</tr>
<tr>
<td>CDC</td>
<td>Centers for Disease Control and Prevention</td>
</tr>
<tr>
<td>CIBB</td>
<td>Central Institutional Review Board</td>
</tr>
<tr>
<td>CISCRP</td>
<td>Center for Information and Study on Clinical Research Participation</td>
</tr>
<tr>
<td>CLAS-ACT</td>
<td>Culturally and Linguistically Appropriate Standards and Clinical Trials</td>
</tr>
<tr>
<td>CRA</td>
<td>Clinical Research Associate</td>
</tr>
<tr>
<td>CRO</td>
<td>Contract Research Organization</td>
</tr>
<tr>
<td>CTEP</td>
<td>Cancer Therapy Evaluation Program</td>
</tr>
<tr>
<td>DSMB</td>
<td>Data and Safety Monitoring Board</td>
</tr>
<tr>
<td>EdCT</td>
<td>Eliminating Disparities in Clinical Trials Project</td>
</tr>
<tr>
<td>ENACT</td>
<td>Education Network to Advance Cancer Clinical Trials</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>ICC</td>
<td>Intercultural Cancer Council</td>
</tr>
<tr>
<td>IND</td>
<td>Investigational New Drug</td>
</tr>
<tr>
<td>IRB</td>
<td>Institutional Review Board</td>
</tr>
<tr>
<td>LEP</td>
<td>Limited English Proficiency</td>
</tr>
<tr>
<td>NCI</td>
<td>National Cancer Institute</td>
</tr>
<tr>
<td>NIAID</td>
<td>National Institute of Allergy and Infectious Diseases</td>
</tr>
<tr>
<td>NIH</td>
<td>National Institutes of Health</td>
</tr>
<tr>
<td>OHRP</td>
<td>Office for Human Research Protections</td>
</tr>
<tr>
<td>PLoS</td>
<td>Public Library of Science</td>
</tr>
<tr>
<td>SPORE</td>
<td>Specialized Program of Research Excellence</td>
</tr>
</tbody>
</table>

### Sample Summary Report Form

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients Screened</td>
<td>45</td>
<td>46</td>
<td>47</td>
</tr>
<tr>
<td>Patients Enrolled</td>
<td>22</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Patients Completed</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Withdrawals</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment Failure</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Adverse Event</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Progression of Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WD Consent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td># Queries Outstanding</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CRFs received to date</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CRFs entered to date</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX I: Project Participants

Any opinions, findings, conclusions, or recommendations expressed in this publication do not necessarily reflect the views of the individuals or organizations that provided support for this project.

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Endnotes


28 Stewart, W. et al. (2002).


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83 Viswanathan et al. (2003). Overcoming Barriers to Effective Community-Based Participatory Research in U.S. Medical Education. Education for Health. 17(3): 141-151.


96 A Guidance Document for Implementing Effective Cancer Clinical Trials Version 1.2; June 2005.


100 National Institute of General Medical Sciences


112 President’s Cancer Panel. (2005).

113 Vaccine Trial Advisory Board: http://www.osap.org/reports/vcavtrial.html


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Patridge AH & Winer EP. (2002). Factors Associated With Failure to Publish Large Randomized Trials Presented at an Oncology Meeting.


About Us

The Education Network to Advance Cancer Clinical Trials’ (ENACCT) is the only national organization devoted solely to implementing and evaluating clinical trial educational efforts. ENACCT’s mission is to identify, implement and validate innovative community centered approaches to cancer clinical trials education. In its work, ENACCT: Develops and delivers the highest quality, evidence-based, community-focused clinical trials education programs for health care providers, patients, and the public; offers high quality, fee-based services that enhance the capacity of organizations conducting cancer clinical trials outreach, education and recruitment; and advocates for the inclusion of appropriate cancer clinical trials education as a top national priority. For more information, visit www.enacct.org.

Community-Campus Partnerships for Health (CCPH) is a nonprofit organization that promotes health (broadly defined) through partnerships between communities and higher educational institutions. Founded in 1996, CCPH is a growing network of over 1,800 communities and campuses across North America and increasingly the world that are collaborating to promote health through service-learning, community-based participatory research, broad-based coalitions and other partnership strategies. These partnerships are powerful tools for improving higher education, civic engagement and the overall health of communities. CCPH advance its mission by disseminating information, providing training and technical assistance, conducting research and evaluations, developing and influencing policies, and building coalitions. For more information, visit www.ccph.info.