Communities as Partners in Cancer Clinical Trials:

A Draft Strategic Plan for Changing Research, Practice and Policy

February 2008
Note: Currently, all phase III trials are designed nationally but implemented locally, whether at a cancer center, a community hospital, or within a physician practice.
Introduction

Cancer clinical trials help to move basic scientific research from the laboratory into treatments for people with cancer. By evaluating the results of these trials, scientists can find better treatments and ways to prevent, detect, and treat cancer. Although about 20 percent of cancer patients are medically eligible for a phase III therapeutic cancer clinical trial,\(^1\)\(^2\) trial participation among adult cancer patients remains at two and a half to three percent.\(^3\) This rate is even lower among people of color and the medically underserved,\(^4\) who tend to have higher cancer mortality rates than the population as a whole.

Numerous structural, cultural, and linguistic factors negatively affect participation in therapeutic cancer clinical trials. Many of these factors are clearly related to lack of knowledge and underlying attitudes and beliefs on the part of the public as well as health care providers. According to one national survey, 75% of people with cancer would have been interested in participating in a trial, had they known it was available.\(^5\) Moreover, clinical trial investigators also report great difficulty in identifying appropriate patients for their trials. A recent AHRQ report on cancer clinical trial recruitment confirmed that there is substantial uncertainty about effective approaches for cancer clinical trials recruitment, especially among minority populations.\(^6\)

The low accrual rate in therapeutic cancer clinical trials, especially among racial and ethnic minorities, the elderly and other medically underserved groups, has a significant effect on both the quality of research and the rate at which new scientific discoveries are made.\(^7\)\(^8\)\(^9\) Cooperative group trials often struggle to accrue patients; in phase III studies of ECOG and CALGB, preliminary data has shown that about 15-30% were closed due to poor accruals.\(^10\)

Despite NIH guidelines on inclusion of women and minorities as subjects in clinical research, only 11% of cancer patients enrolled in national publicly funded treatment trials are ethnic/cultural minorities.\(^11\) As Corbie-Smith and others point out, there are scientific imperatives that underscore the importance of better representation of the racial/ethnic minorities in clinical trials: a) to test specific hypotheses about differences by race and ethnicity (mandating appropriate statistical power to detect those differences); b) to generate hypotheses about possible differences by race and ethnicity (with new targeted therapies, studying populations with different prevalence of relevant genotypic variants are increasingly important); and c) to overcome the inability to generalize findings to the greater population.\(^12\)\(^13\)\(^14\)\(^15\)\(^16\) Moreover, strict eligibility criteria often 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.\(^17\)\(^18\)

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The low accrual rate in therapeutic cancer clinical trials – also has a profound effect on quality of care provided to all patients with cancer. Access to cancer clinical trials is a key quality measure for delivery of health care services; it is one of the established standards for the delivery of quality comprehensive cancer care.19 Yet all who are eligible are not offered this opportunity. Other studies have 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.20,2122

The low accrual rate in therapeutic cancer clinical trials is simply a matter of social justice. Principles of social justice demand better representation of all groups in cancer clinical trials to: a) ensure equal access to clinical trials;23 24 b) ensure the just distribution of the benefits and burdens of participation in research;25 and/or c) address the impact of cancer health disparities.26

Experts continually recommend community-based approaches to enhance accrual, noting that “success [in clinical trials accrual] will require sustained, aggressive action, and new partnerships between policymakers, healthcare professionals, professional societies, and underserved communities.” In its 2005 report, the President’s Cancer Panel emphasized that “both trust … and community participation are essential” to the success of clinical research.27 The Clinical Research Roundtable at the Institute of Medicine acknowledged 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, implanting a community based participatory research model.” 28

Community-based participatory research (CBPR) offers the potential for improving research quality and outcomes, and enhancing research recruitment efforts,29 and has been recommended as a way to improve the state of clinical research participation.30 The intent in CBPR is to transform research from a relationship where researchers act upon a community to answer a research question to one where researchers work side by side with community members to define the questions and methods, implement the research, disseminate the findings and apply them. Community members become part of the research team and researchers become engaged in the activities of the community. CBPR approaches have been utilized in public health research since the 1980s and notably in clinical research in HIV/AIDS since the mid-1990s.

Communities as Partners in Cancer Clinical Trials: Changing Research, Practice and Policy is a joint initiative of ENACCT (The Education Network to Advance Cancer Clinical Trials) and CCPH (Community-Campus Partnerships for Health), with core funding from the Agency for Healthcare Research and Quality (AHRQ) and the National Cancer Institute (NCI). This three-year national effort is exploring the potential of

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employing CBPR principles and approaches in phase III therapeutic cancer clinical trials. Guided by a diverse national planning committee, whose composition reflects key stakeholders in the CBPR and cancer clinical research fields, the initiative is developing a strategic plan for research, practice and policy.

In September 2007, seventy representatives from community-based organizations, patient advocacy groups, cancer centers, schools of medicine and public health, the pharmaceutical industry, Federal health agencies and local oncology practices convened in the DC area for the first of three invitational meetings, to lay the groundwork for a strategic plan for strengthening community engagement in Phase III cancer clinical trials.

At the meeting, participants discussed the issues and challenges facing the U.S. cancer clinical trial enterprise; the opportunities presented by CBPR; and models of community engagement in other areas of therapeutic clinical research. Participants worked in small and large groups to identify institutional and system barriers that inhibit greater community engagement in therapeutic cancer clinical trials and to explore the application of CBPR principles to key areas of the clinical research process. A framing background paper and invited commentaries sent to participants prior to the meeting helped to inform the deliberations.

Building on the foundation established at the meeting, participants in the Communities as Partners project were organized into three distinct workgroups: a) National Level Trial Design and Implementation; Local Level Trial Implementation; and National and Local Data Analysis, Interpretation and Dissemination. These workgroups were charged with developing specific recommendations for community engagement in phase III cancer treatment trials.

A set of guiding principles has informed the workgroups’ efforts. These principles helped to ensure that the recommendations reflect:

- An appreciation for the commitment of both researchers and patient advocates in the cancer clinical trial system who are currently working to engage communities in clinical trials and a desire to build upon their efforts. We acknowledge that we are not “starting from scratch” and that great work is already going on, but it is undervalued, under-funded and not consistently practiced across the cancer clinical trial system.

- An understanding that 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

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system built with communities as partners from the start, we believe this is
either realistic nor feasible. We are invested in making the current system more
accessible to and involving of communities.

• An understanding that there are numerous access barriers to clinical trials. While
we expect that community engagement strategies will reduce barriers and
enhance accrual, we recognize that there are many more problems that require
fixing, which is beyond the scope of this project.

• An understanding that federal research priority setting and funding will 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.

• An understanding that while there are genuine problems with our health care
system, including 47 million people without health insurance, the focus of our
work is on improving the process and outcomes of phase III cancer clinical trials.

• An acknowledgement that CBPR in therapeutic cancer clinical trials may not
always be possible or feasible. Therefore, the recommendations will not focus
exclusively on CBPR, but will also include other community engagement
strategies.

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Request for Public Input

This document is a compilation of the workgroup draft recommendations. **Between now and March 3, 2008, we are seeking public comment on these recommendations.** The workgroups will reconvene March 11-13, 2008 to review all comments received, finalize the recommendations and develop plans for dissemination. The third and final invitational meeting in September 2008 will focus on implementing the strategic plan, with particular emphasis on engaging policymakers and funding entities.

Please send your comments to Project Coordinator, Stacy Collins, at stacy.collins@enacct.org. When applicable, please reference the recommendation number (e.g., A1, B2, C13, etc.) or line number (see left margin) in your commentary. (Please note that all draft recommendations within this report are highlighted in green.)

If you do not plan to submit comments but would like to receive a copy of the final strategic plan, please complete this online form: [https://catalysttools.washington.edu/webq/survey/ccphuw/47602](https://catalysttools.washington.edu/webq/survey/ccphuw/47602)

Also, please visit the Communities as Partners website at: [http://www.enacct.org/conference/conference.php](http://www.enacct.org/conference/conference.php)

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Overview - Draft Workgroup Recommendations

The Communities as Partners workgroups envision a coordinated national-local system that includes trained community/patient representatives, involved in each component of the national research system supporting phase III cancer treatment trials.

- **At the national level**, where trial design and approval take place, the number of trained community/patient representatives serving on cooperative group protocol and disease committees would be increased, their roles/responsibilities clearly defined, and a transparent recruitment and application process established.

- **At the local level**, where patient enrollment and the study actually take place, community endorsement of the study and community/patient involvement in study implementation would be ensured by linking the local site investigators and research team to a community advisory board and increasing the number of trained community/patient representatives on institutional review boards (IRBs).

The following draft recommendations reflect the full spectrum of the Phase III clinical research system, subdivided into three main areas:

A. National Level Trial Design and Implementation
B. Local Level Trial Implementation
C. National and Local Data Analysis, Interpretation and Dissemination

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contains all FDA required elements of the informed consent. It is updated with study specifics and given to participating investigational sites to submit to their IRBs.

In 1995, the HHS Office of Human Research Protections (OHRP) approved the use of a “short form” as a way to implement the Common Rule’s mandate 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. However, no cooperative group educates its members in use of the short form, nor does the CIRB permit its use.

Recommendations for NCI and Cooperative Groups:

A1. As a part of the U10 cooperative agreement, NCI should require each cooperative group to have trained community/patient representatives on concept AND protocol design and review. This may be accomplished through one or both of the following approaches:

- Modify each standing committee’s membership, so that it includes at least 10% or two community/patient representatives, whichever is greater; or

- Establish a National Community Advisory Board (CAB) for feasibility review, separate from scientific review but required for concept or protocol approval. The National CAB for each cooperative group should be made up of at least 20 trained community/patient representatives nationwide.

A2. Cooperative groups should establish an open, transparent process with specific criteria for recruiting community/patient representatives. The opportunity to serve should be widely communicated both to traditional and non-traditional sources of potential representatives, with local cancer experience.

A3. Cooperative groups should establish specific and meaningful roles, responsibilities and expectations for its community/patient representatives, which are universally accepted and enforced by group and committee leadership.

A4. Cooperative groups should properly orient and prepare community/patient representatives for their role. (Possible resources for this training are listed at the end of this document.)

A5. Cooperative groups should appropriately compensate community/patient representatives for their role.

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1 For greater detail on skills, responsibilities and training of community/patient representatives, see page 27.

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A6. NCI's CTEP should only approve Group concepts or protocols containing evidence of community/patient review and endorsement.

A7. NCI's Central Institutional Review Board (CIRB) should only approve applications with consent forms containing evidence of community/patient review and endorsement. In addition, the CIRB should permit and encourage cooperative groups to utilize the OHRP approved "short form," with specifically directions for its use.

Recommendations for All Public and Private Study Sponsors:

A8. All study sponsors should have appropriate community representation at the national level, as outlined above.

A9. All study sponsors should have appropriate community representation in developing informed consent forms, as outlined above.

A10. All study sponsors should establish specific criteria and guidance for use of the "short form," and assist local study teams and IRBs in their approval.

Rationale for community involvement in trial design at the national level:

A number of national reports have called for the inclusion of public representatives in designing clinical research to improve the entire research process;34,35,36,37,38 There are several national initiatives that illustrate the feasibility of implementing a group such as a national community advisory board for clinical research39. Currently, federally funded clinical trials in HIV/AIDS have a number of policies that mandate the inclusion of public representatives in designing clinical research. For example, in order to receive funding announced through NIAID HIV/AIDS Clinical Trials Networks (similar to the cooperative group system), researchers must document meaningful community partnerships; their 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 research to be conducted to the community. Other policies are listed at the end of this document.40,41,42

In cancer clinical research, there is an increasingly visible role of advocates within: a) NCI-funded Cancer Cooperative Groups43, b) Specialized Programs of Research Excellence (SPORE) projects and cores;44,45 c) U.S. Department of Defense Research Programs;46 and d) the California Breast Cancer Research Program. The literature has documented the important role of patient advocates in clinical research study development and implementation, especially in HIV/AIDS, and cancer research.47,48,49,50

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Despite these reports and ongoing recognition of the important involvement of patient advocates in the cancer clinical research system, there is no official process through which patient advocates are selected to serve within the cooperative group committees or within private sponsors. They have no official responsibilities nor is their participation mandated. Finally, their limited numbers, their homogeneity, and their length of service suggest that more diverse representation would help inform the development of more “accrueable” studies.

Rationale for community involvement in trial implementation at the national level:

On informed consent: Despite extensive national, cooperative group, institutional, and departmental reviews, consent forms from clinical oncology protocols are written at a level that is difficult for most patients to read (written at an 11th or 14th grade level) and are between 20-40 pages in length. The Institute of Medicine 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 eighth or ninth grade.

As summarized by ASCO: “The informed consent process has real potential to overwhelm patients. This is especially true because the evolving environment of clinical research seems to place emphasis on the informed consent document as a regulatory or legal protection for the institution and investigator. As a result, 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…”

Despite the use of the NCI template in the cooperative group system, nationally developed consent forms still need improvement.

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Draft recommendations A11 – A19 concern the following components of the national system:

- Development of trial communication plan
- Receipt and distribution of funds to research entities
- Development of qualifications/eligibility criteria for local research teams
- Data Safety Monitoring Board (DSMB) oversight

**Background**

**Development of trial communication plan – How this works currently:**

National communication or recruitment plans are written in a general manner; recruitment and retention are usually considered only after a study is open for accrual.

**Funding received/funds distributed to research entities – How this works currently:**

For cooperative groups, the NCI grants five-year U10 cooperative agreements from the 12 national cooperative groups. This funding supports the cooperative group infrastructure and reimburses approximately 60% of research costs to individual investigators. Remaining costs are offset through agreements with pharmaceutical companies. It is unclear if there is community participation in the NCI cooperative agreement application process. Regarding which trials are ultimately approved for implementation by CTEP, it is unclear if the number or types of clinical trials opened for a particular cancer are proportionate to cancer incidence, mortality, or burden to a particular population.

Within industry, study teams are required to assemble annual proposals that include strategy and proposed budgets for further study of investigational drugs. A team will review and determine what studies will be implemented in the following year.

**Development of qualifications/eligibility criteria for local research teams – How this works currently:**

Currently, qualifications are solely related to capacity to a) identify and consent patients, and b) appropriately manage patient data. Sites often experience difficulty accruing adequate numbers of patients.

**Data safety monitoring board (DSMB) oversight – How this works currently:**

An independent committee made up of statisticians, physicians, and in certain cases, patient advocates, this group ensures that the risks of participation are minimized, makes sure the data are complete, and stops a trial if safety concerns arise or when the trial's objectives have been met. DSMB reports are typically not made public.

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Recommendations for NCI and Cooperative Groups:

A11. As a part of the U10 cooperative agreement, NCI should require that cooperative groups include national communication plans, templates and guidelines for each protocol, which are informed by national community/patient representatives, with a focus on local customization and implementation.

A12. NCI should include trained community/patient representatives in its review of all U10 cooperative agreement applications, renewable every five years.

A13. As a part of the U10 cooperative agreement, NCI should require that all participating investigators within each cooperative group document meaningful connections with local communities, which should advise on the appropriateness of implementation of a trial at the local level. This may be accomplished through either: 1) utilization of a local community advisory board (CAB); and/or, 2) meaningful partnerships with community organizations (as detailed in the Local Implementation Section of the document).

A14. As a part of the U10 cooperative agreement, NCI should require that each cooperative group document how its members demonstrate cultural competency in the research setting. This may be indicated by: 1) yearly clinical research cultural competency programs; 2) the use of patient navigators or outreach workers; or 3) the hiring of local staff that can relate to the participants, have similar backgrounds, understand the participants’ experiences, speak their language and are respectful of community structures.

A15. As a part of the U10 cooperative agreement, NCI should require that each cooperative group DSMB modify its membership to include at least 10% trained community/patient representatives or two people, whichever is greater. All cooperative group DSMBs should prepare an annual progress/safety report for each trial, which should be written lay language and should include information above and beyond serious adverse events. The local investigator should distribute the report to all study participants and a summary of the report should be simultaneously posted on the cooperative group’s website.

Recommendations for All Public and Private Study Sponsors:

A16. All groups responsible for developing and approving new trials are required, as a condition of funding, to have appropriate community representation in developing communication plans, as outlined above.

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A17. All groups responsible for developing and approving new trials are required, as a condition of funding, to have appropriate community representation in approving funding of new clinical trials.

A18. All groups responsible for developing and approving new trials should allocate funds for local community education on clinical trials, which are not study specific.

A19. All groups responsible for developing and approving new trials should require proof of ongoing communication between DSMB and investigators, local IRBs, the public, and trial participants.

Rationale for community involvement in trial implementation at the national level:

On recruitment: While individual research teams have little time for recruitment and retention planning, the development of national recruitment strategies, based on target population characteristics at the national level, may increase the likelihood of recruitment success. It is erroneous to assume that all trial participants will come from passive recruitment efforts, such as flagging charts. Key reasons for recruitment problems are: 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.

On approval of funding: A number of initiatives include public representatives in the funding approval process for clinical research. These include the following:

- DOD Congressionally-Directed Medical Research Programs: In order to ensure that research funding decisions reflect the concerns and needs of patients, the clinicians who treat them, and survivors and their families, the U.S. Department of Defense’s Congressionally-Directed Medical Research Programs mandates inclusion of consumers as full members on all review and advisory panels to make recommendations for funding. Its Breast Cancer Research Program was the first to include consumer reviewers on every review and advisory panel, including those reviewing basic science proposals.

- California Breast Cancer Research Program (CBCRP): With the CBCRP, collaboration among scientists, breast cancer organizations and individuals involved in breast cancer issues was mandated by legislation. Each of the CBCRP’s peer review committees includes two community advocates who serve as voting members and a nonvoting observer who provides feedback on the process. The CBCRP council, which includes five breast cancer advocates, provides vision, sets research priorities, and determines how funds are invested.

On cultural competency: Many researchers experience difficulties when discussing trial participation, leading to poor trial accrual and questionable quality of informed consent.

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Researchers are further challenged when recruiting and consenting ethnically diverse populations to clinical trials. Many investigators and their staff lack the skills necessary for conducting culturally sensitive community outreach and education programs about clinical trials. Recently, federal officials have underscored the need for cultural competency training in the research setting, convening a national research team to apply National Standards on Culturally and Linguistically Appropriate Services (CLAS) to the clinical trials process.\(^3\)

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\(^3\) CLAS-ACT (Culturally and Linguistically Appropriate Standards And Clinical Trials) 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=5046

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LOCAL IMPLEMENTATION OF PHASE III TRIALS

Draft recommendations B1 – B9 concern the following components of the national system, as implemented locally:

- Seeking local community input and endorsement of Phase III studies
- Establishing the Local Research Team
- Obtaining Institutional Review Board (IRB) approval

Background

Seeking local community input and endorsement of Phase III studies - How this works currently:

Study sponsors find qualified investigators, provide investigators with the information and drugs needed to properly conduct the trial, monitor progress, ensure compliance with government regulations, and file appropriate reports with the FDA. Individual investigators must consider whether and if the trial is appropriate for their communities. Few investigators actively seek community endorsement of specific studies or seek input on the study’s relevance within the local community.

Establishing the Local Research Team - How this works currently:

Local investigators assemble their research teams based on the capacity to identify and consent patients, as well as manage patient data. Local sites often are unable to accrue adequate numbers of patients.

Obtaining Institutional Review Board (IRB) approval - How this works currently:

All clinical trials must be reviewed and approved by an IRB. Federal regulations require that an IRB include at least five people of diverse occupations and backgrounds; at least one member must have primarily scientific interests, and another member must have primarily non-scientific interests. The IRB reviews the protocol to ensure the study is conducted fairly and participants are not likely to be harmed. The IRB also decides how often to review the trial once it has begun. An ad hoc IRB member may be used for specific types of research.

Recommendations for All Public and Private Sponsors:

B1. To participate in a phase III cancer clinical trial, local investigators should be required to present the proposed research study to an institutional CAB or a centralized CAB (serving a regional consortium or multiple institutions). No trial can be approved by the local IRB without CAB endorsement. NOTE: It is understood that for geographic or other reasons, not all local researchers will have immediate access to a CAB. In such cases, interim proxies, such as a community organization or a community committee affiliated with a local IRB, may be acceptable. However, local CAB approval for all phase III studies should be the ultimate goal.

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B2. Entities that sponsor trials should provide funding for the operation of local CABs, including compensation for CAB members. Possible sources of funding include institutional indirect reimbursement; public-private partnerships; and direct grant funding.

B3. National standards should be established for local cancer research CABs. (Draft standards are listed at the end of the document).

B4. Local research teams should include members of the affected community in a voluntary or staff capacity. Such individuals should have similar backgrounds to potential study participants, understand the participants' experiences, speak their language and be familiar with community structures.

B5. Research is needed to document and demonstrate the value of community members serving on local CCT research teams.

Recommendations for OHRP and FDA:

B6. For all Phase III CCT studies, an investigator application to the local IRB should include evidence of CAB endorsement of the study. In the absence of CAB endorsement, investigators should document local community organization endorsement.

B7. Local IRB composition should be 20% community (non-scientific, unaffiliated) members, or four individuals, whichever is greater. All community IRB members are properly oriented, trained, mentored and compensated by the IRB sponsoring institution.

B8. Community IRB members should be involved in all aspects of the consent form review process. All IRB members should receive training on alternative ways to address the needs of low literacy and LEP populations in the clinical research consent process.

B9. Both agencies should provide guidance on and encourage use of the "short form." Local IRBs should permit use of the "short form" by local investigators.

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Draft recommendations B10 – B19 concern the following components of the national system, as implemented locally:

- Communicating trial availability
- Recruiting and identifying potential participants
- Screening, consenting and accruing study participants
- Enhancing participant retention
- Filing and obtaining periodic IRB review

Background

Communicating trial availability - How this works currently:

Trial communication is generally a passive endeavor, conducted primarily through letters to local doctors, postings on the research institution website, or print advertisements.

Recruiting and identifying potential participants - How this works currently:

Approaches to recruitment and retention are based on statistical power. This is not part of the protocol development and is usually considered only after a study is open for accrual. (For industry-funded trials, statistical powering is considered on a study basis, including number of allowed patients per site and region.) Recruitment plans are rare. Unlike peer-review funded behavioral or cancer control trials, many cancer clinical trials generally lack direct funding for recruitment activities.

Screening, consenting and accruing study participants - How this works currently:

MDs often serve as the “investigator,” advising patients on treatment decisions and presenting clinical trial opportunities to the patient. A nurse or clinical research associate (CRA) explains the details of the trial to prospective study participants and, as part of the consent process, reviews the consent form. While patients are enrolled in the trial, they interact with other members of the research team.

Enhancing participant retention - How this works currently:

Retention plans are also rare. Unlike peer-review funded behavioral or cancer control trials, many treatment clinical trials generally lack direct funding for retention activities.

Filing and obtaining periodic IRB review - How this works currently:

During the study’s annual review, the IRB examines a progress report and decides whether or not the project should continue as described in the original research plan. An IRB can suspend or terminate approval if the study appears to be causing unexpected serious harm to participants. Researchers are required to keep participants up-to-date on any new information that may impact their decision to remain enrolled in the trial, but there is no requirement for ongoing communication with study participants.

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Recommendations for All Public and Private Sponsors:

B10. Institutions in which research is being conducted should collaborate with the existing community infrastructure (e.g., primary care clinics, churches, and neighborhood associations), to communicate information about trial availability, beyond any particular trial. The institution should also engage in outreach activities with community groups, particularly those working to reduce health disparities, to educate the broader community about cancer clinical trials in general.

B11. The local research team should collaborate with patient navigators and other paraprofessionals involved in patient care, to encourage communication of trial availability to individuals recently diagnosed with cancer. Navigators are trained about the clinical trial process and how to approach patients who have received a recent cancer diagnosis.

B12. All sponsors should require local investigators to develop a recruitment and retention plan for CAB review. Investigators will provide recruitment and retention plan updates to the local IRB, as part of the IRB annual review.

B13. National study sponsors should require that at the institution where research is conducted, all patients are informed about clinical trial availability at time of initial consultation with the oncologist and the cancer treatment team. Patient advocates/navigators are available -- on-site, or at a minimum, by phone -- to speak with candidates considering participation in a clinical trial and help them understand the details of a proposed study.

B14. Study sponsors should require that consent is done by trained staff. A navigator should also be available at the patient’s request, to assist in the consent process. In the case of LEP individuals, when consent forms are not available in the individual’s language, special emphasis should be placed on use of the phone language line during the consent process.

B15. To optimize retention, the local research team should 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. Trial participants should be given the opportunity to discuss their experiences with those considering participation.

B16. NCI should fund research on promising practices in CCT recruitment and retention efforts.

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Recommendations for OHRP and/or FDA:

B17. Local IRBs should require that annual study progress reports are “translated” into lay language and sent to all trial participants. Investigator must provide proof of ongoing communication with trial participants.

B18. Local IRBs should review investigator updates on the trial recruitment and retention plan, to ensure targets are being met.

B19. Local IRBs should require researchers to keep participants up-to-date on any new study-related information, including adverse reactions, in written and oral forms.

Rationale for community involvement in trial implementation at the local level:

Community advisory boards (CABs) offer a vital link between local investigators and the communities in which research takes place. CAB members act as advocates for the community and as “translators” between the community and research scientists. Moreover, CABs are a promising vehicle for community endorsement of cancer clinical research studies. Partnerships between CABs and local investigators have operated successfully since the early 1990’s within the HIV/AIDS clinical trials system, as well as prevention-related public health research programs. If a CAB has authentic connections to its community, its members can transform attitudes about research. Indeed, some have posited that the focus of the principles of ethical research outlined in the Belmont Report needs to be expanded to include an explicit respect for communities—perhaps through a CAB or other manner of gaining “community consent”—to supplement the individually-focused informed consent process.

While recognizing that local IRBs are typically underfunded and overworked, improvements are needed to make IRBs more responsive to community concerns regarding clinical research. Currently, IRBs are focused primarily on assessing risk to individuals. They are not expected or required to assess the benefits of the research to the broader community (rather than to an individual patient) and most IRBs do not make such assessments.

Community education is an important part of reducing barriers to clinical trial access and enhancing awareness of treatment options. The only nationwide study conducted to date on cancer clinical trials awareness confirmed that the majority of the public knows little about cancer clinical trials. Findings showed that about 85% of people with cancer 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. At the moment of diagnosis and treatment decision making, the presentation of a clinical trial as a high quality treatment option can be both alienating and
frightening. Therefore, the optimal “educable” moment to learn about cancer clinical trials may not be at the moment of diagnosis. 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 will encourage him or her to inquire about clinical trials as an option for treatment – either to the trusted primary care provider or to the oncologist.

Note: Currently, all phase III trials are designed nationally but implemented locally, whether at a cancer center, a community hospital, or within a physician practice.
DATA ANALYSIS, INTERPRETATION AND DISSEMINATION OF PHASE III TRIALS

Draft recommendations C1 – C17 concern the following components of the national system:

- Data analysis and interpretation
- Dissemination of research findings
- Encouragement of application of positive findings into standard care provision

Background

Data analysis and interpretation Dissemination - How this works currently:

Upon completion of the study, the data are analyzed and interpreted by the sponsor and study team. Researchers report the findings from statistical analysis, publish in peer-reviewed journals, and present at professional meetings. Negative findings are typically not published. Subsequent to release of the results, the standard of care may change and new agents may be approved by the FDA. There is currently no systematic way to determine if all oncologists apply the new knowledge in their practices.

Recommendations for Federal agencies and study sponsors:

C1. NIH, CDC and AHRQ should jointly fund a systematic study of community involvement in data analysis and interpretation. Study components should include a literature review and follow-up with authors of papers that report on community-based research to specifically identify the extent and value of community involvement in data analysis and interpretation and how community members can best be prepared for these roles.

C2. Investigators should provide trained community/patient representatives involved in the study (e.g., those serving on their national cancer cooperative group or local site community advisory board) with the opportunity to participate in the team that analyzes and interprets the data. These individuals should be properly prepared and compensated for these roles.

C4. As part of the U10 agreement, NCI should require national cooperative groups and local investigators to articulate plans (including a timeline and budget) for disseminating their study findings (positive, negative and null results) to study participants, patients, their caregivers and the broader community.

C5. As part of the U10 agreement, NCI should require phase III cancer clinical trials to report on study progress and study results in written lay language to all participants as soon as the study is concluded (or halted), and before publication.

Note: Currently, all phase III trials are designed nationally but implemented locally, whether at a cancer center, a community hospital, or within a physician practice.
C6. As part of the U10 agreement, NCI should require that completed phase III cancer clinical trials provide a lay summary of the major findings and their implications for inclusion in online clinical trial registries. Such summaries should be co-authored with trained community/patient representatives involved in the study, and should follow easy-to-understand templates.

C7. All national study sponsors should support pilot studies intended to determine the most effective mechanisms for disseminating phase III cancer clinical trial results to study participants, patients, their caregivers and the broader community.

C8. All national study sponsors should support mechanisms for disseminating phase III cancer clinical trials results to study participants, patients, their caregivers and the broader community (e.g., video and web conferences).

Recommendations for Cooperative Groups:

C9. In their consent forms to participate in Phase III cancer clinical trials, cooperative groups should explicitly indicate that study participants will receive study results prior to publication in a form they can understand and act upon.

C10. Cooperative groups should determine if a given Phase III cancer clinical trial has potential policy implications and if so, disseminate findings to relevant policy groups (e.g., health insurers, Centers for Medicare and Medicaid Services, state and federal legislators).

Recommendations for Investigators:

C11. Investigators should invite and include trained community/patient representatives involved in the study (e.g., those serving on their national cancer cooperative group or local site community advisory board) to participate in the team that writes manuscripts, gives presentations and responds to media requests on the study. These individuals should be properly prepared and compensated for these roles.

Recommendations for Publishers (e.g., Journals, Clinical Trial Registries, Popular Media):

C12. When journals review manuscripts that report on findings from phase III cancer clinical trials, they should include in their review criteria an assessment of community/patient representative involvement in the study.

Note: Currently, all phase III trials are designed nationally but implemented locally, whether at a cancer center, a community hospital, or within a physician practice.
C13. When journals review manuscripts that report on findings from phase III cancer clinical trials, they should include trained community/patient representatives as manuscript reviewers. These reviewers could be drawn from already trained community/patient representatives who serve on national cancer cooperative groups, local community advisory boards and IRBs. These individuals should be properly prepared and compensated for these roles.

C14. When journals publish the results of phase III cancer clinical trials, they should publish invited commentaries on the study authored by trained community/patient representatives in the same journal issue. These authors could be drawn from community/patient representatives who serve on national cancer cooperative groups, local site community advisory boards and IRBs. These individuals should be properly prepared and compensated for these roles.

C15. Clinical trial registries, such as [http://www.clinicalstudyresults.org](http://www.clinicalstudyresults.org), should publish lay summaries of phase III cancer clinical trial findings and their implications.

Recommendations for Cancer-Focused Organizations:

C16. Cancer-focused organizations (e.g., American Cancer Society) should widely disseminate findings from Phase III cancer clinical trials to their constituencies through previously established mechanisms (e.g., newsletters, conferences, patient support programs).

Recommendations for Community/Patient Representatives Serving on National Cancer Cooperative Groups and/or Local Site Community Advisory Boards:

C17. Patient/community representatives who serve on national cancer cooperative groups and/or local site community advisory boards should widely disseminate findings from Phase III cancer clinical trials to their constituencies through previously established mechanisms (e.g., newsletters, conferences, patient support programs).

Rationale for Recommendations in Data Analysis, Interpretation and Dissemination

CBPR practitioners point to the value of community member involvement in data analysis and interpretation from a number of standpoints: community members can situate the data within their local social and cultural context; contribute to culturally relevant interpretations; and, understanding what the data shows, are more likely than academic researchers to apply the findings in their communities. As there are no published reports of non-scientists involved in analyzing or interpreting data from Phase III cancer clinical trials, this is an area that is ripe for research and development.

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Cancer clinical trial researchers routinely disseminate positive study findings through publications in peer-reviewed journals and presentations at conferences that reach research and clinical oncologists. Although these are important mechanisms for reaching professional audiences, there is ample evidence to support that journal articles and conference presentations 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 study participants, patients, their caregivers or the broader community. A related concern is the bias toward publishing and presenting study findings only when they are positive.

There are a number of efforts underway that are intended to disseminate clinical research findings to the public. These are 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. As patients and the broader community are informed about the results of phase III cancer clinical trials and their implications for patient care, they may increase their level of health literacy and be empowered to ask questions about the standard of health care they receive and the evidence base that underlies decisions being made about their health care. Further, they may be more supportive of clinical trials and more likely to participate in them.
Local and National Community Representation Definitions

Experts agree there is no singular definition of “community.” Community can refer to a group that self-identifies:

- By affinity, such as geography, disability, illness, or health condition; or
- By background or culture, such as race, ethnicity, gender, sexual orientation or religion; or
- Through a 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 need.

For our purposes, we define “community” as “those whose well-being is likely to be affected by the conduct of the research.” 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 all aspects of the cancer clinical research process.

As we pursue a definition of community representation in the cancer clinical trials arena, questions such as “who is the community?” “Who represents the community?” and “Who speaks for the community?” are all critically important. Currently, many cancer advocates and survivors serve at national and local levels. We believe their work is essential to the success of cancer research; however, their community representation is unclear.

Community/patient advocate representative definitions

- A community representative should ideally come from a recognized community-based organization whose constituency is disproportionately affected by cancer.
- A patient advocate should have first-hand experience as a patient or caregiver.

There may be overlap between these roles; however, one may not necessarily be representative of the other.

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Qualifications\(^5\) for Serving as a Community/patient advocate representative

<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, an individual must demonstrate...</th>
</tr>
</thead>
</table>
| 1. Local experience related to clinical research (consider the use of a “feeder system”\(^6\)) | 1. a) being directly affected by cancer (personally, as a caregiver, or as a member of community disproportionately affected); AND  
   b) having experience with cancer advocacy through activities/organizations\(^5\) that go beyond a personal experience AND  
   c) willing to learn more about cancer, cancer research, and how cancer affects the community |
| 2. having a meaningful connection with a specific constituency affected by cancer with which he/she is able to have ongoing communication and feedback |  |
| 3. having a genuine understanding of the communities’ needs |  |
| 4. interest and ability to network with other organizations with an interest in cancer |  |
| 5. a level of comfort articulating personal opinions assertively and professionally among persons of all types of educational and professional backgrounds |  |
| 6. an interest/ability to listen, reflect, question, and respond without becoming defensive or confrontational |  |
| 7. An interest in gaining self-confidence to ask questions of physicians and scientists, and to disagree with them when necessary |  |
| 8. A willingness to learn more about cancer research, research development process, including concept and protocol development | 8. An ability to discern the needs of the community from which they came and the needs of local research studies |
| 9. An ability to discern the needs of the community from which they came and the needs of research nationally |  |

\(^5\) Qualifications are NOT limited to educational achievement, as measured by an academic degree  
\(^6\) Other models of local ↔ national community representation on research panels, such as the CDC Prevention Research Centers (PRCs) and HIV/AIDS Community Advisory Boards for clinical research. With AIDS, there is a built-in mechanism (i.e., feeder system) for moving people from local community advisory boards to the national level board.  
\(^7\) As may be demonstrated by * Geographic residence or place of work; * Connection to the disease * Trial participation * Use of a particular health service

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### Skills needed for Community/patient advocate representatives

<table>
<thead>
<tr>
<th>To effectively serve on a National Cooperative Group, an individual must demonstrate the following skills</th>
<th>To effectively work with Local Investigator(s)/Institutions, such as within a Community Advisory Board, an individual must demonstrate the following skills</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Interest and ability to network with other organizations with an interest in cancer</td>
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</tr>
<tr>
<td>2. A level of comfort articulating personal opinion assertively and professionally among persons of all types of educational and professional backgrounds</td>
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</tr>
<tr>
<td>3. Self-confidence to ask questions of physicians and scientists, and to disagree with them when necessary</td>
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</tr>
<tr>
<td>4. The ability to interact effectively with clinical and laboratory researchers</td>
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</tr>
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</table>

### Competencies/knowledge needed for Community/patient advocate representatives

<table>
<thead>
<tr>
<th>To serve on a National Cooperative Group, an individual must have knowledge in these areas...</th>
<th>To work with Local Investigator(s)/Institutions, such as within a CAB, an individual must have knowledge in these areas...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. A basic understanding of the disease being studied, including standard of care</td>
<td>1. A basic understanding of the disease being studied, including standard of care</td>
</tr>
<tr>
<td>2. A basic understanding of the cancer clinical research process</td>
<td>2. A basic understanding of the cancer clinical research process</td>
</tr>
<tr>
<td>3. Key aspects of community outreach and accessible communication and education strategies</td>
<td>3. Key aspects of community outreach and accessible communication and education strategies</td>
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<tr>
<td>4. Key aspects of health literacy and discerning readability of written documents</td>
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</tr>
<tr>
<td>5. The cancer clinical research system in the United States;</td>
<td>5. The cancer clinical research system in the United States;</td>
</tr>
<tr>
<td>6. Belmont Report and ethical requirements for research</td>
<td>6. Belmont Report and ethical requirements for research</td>
</tr>
<tr>
<td>7. Informed consent process</td>
<td>7. Informed consent process</td>
</tr>
<tr>
<td>8. Ability to apply scientific concepts and knowledge to analyze complicated proposals in both written and verbal forms.</td>
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<tr>
<td>10. Basic science concepts (cellular behavior, genetics)</td>
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</tr>
<tr>
<td>11. Epidemiological concepts (incidence and prevalence, risk, study design, randomization)</td>
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</tr>
<tr>
<td>12. Basic statistics (p-value, confidence interval, odds ratio, risk ratio)</td>
<td>12. Basic statistics (p-value, confidence interval, odds ratio, risk ratio)</td>
</tr>
<tr>
<td>13. Ethical principles of research as outlined in the Belmont report</td>
<td>13. Ethical principles of research as outlined in the Belmont report</td>
</tr>
<tr>
<td>14. How new cancer treatments are developed (from laboratory to phase 3 study to FDA approval)</td>
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</tr>
<tr>
<td>15. The culture, function and procedures of the peer review process</td>
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Community/Patient Representatives Serving on National Cooperative Groups

<table>
<thead>
<tr>
<th>Responsibilities (for review of both concepts and protocols)</th>
<th>Expectations</th>
<th>Training Resources</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>
<td>SPORE &quot;PART&quot; Program</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 as PROJECT INFORM (used in ACRIN).</td>
<td>NBCC’s Project LEAD</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>
<td>NCI’s CARRA training program</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>
<td>NCI’s Cancer Information Service Partnership Program</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>
<td>Genetic Alliance</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>
<td>CISN</td>
</tr>
</tbody>
</table>

Draft Local CAB (Community Advisory Board) Standards

<table>
<thead>
<tr>
<th>CAB Membership</th>
<th>Roles and responsibilities of CAB members</th>
<th>Informational needs re: CAB operations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representatives of local communities disproportionately impacted by cancer morbidity or mortality at the clinical research site</td>
<td>Review study concepts and protocols for community relevance</td>
<td>Establishing and funding CABs</td>
</tr>
<tr>
<td>Survivors and family members who have experience with different types of cancer</td>
<td>Pre-test study materials; particularly for cultural sensitivity</td>
<td>Building CAB-investigator relationships</td>
</tr>
<tr>
<td>Clinical trial participants</td>
<td>Review recruitment and retention plan</td>
<td>CAB member training</td>
</tr>
<tr>
<td>Religious leaders</td>
<td>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.</td>
<td>Local and national CAB interface</td>
</tr>
<tr>
<td>Primary health care providers</td>
<td>Assist investigators in implementing outreach and recruitment efforts</td>
<td>A CAB review checklist, for scoring prospective studies</td>
</tr>
</tbody>
</table>

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Endnotes


4 Brawley, O. The study of accrual to clinical trials: Can we learn from studying who enters our studies? Journal of Clinical Oncology, 2004. 22(11), 2039-2040.


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"The inclusion of ethnic minority and medically underserved individuals in clinical trials and the dissemination of information to their community and health care providers are critical links connecting scientific innovation with improvements in health and health care delivery. Enhancement of these links is clearly within the purview of NCI and NIH. Although many factors pose challenges to such improvements (e.g., mistrust of the scientific establishment among many members of ethnic minority communities), without a concerted effort to enhance this process, ethnic minority and medically underserved communities will continue to lag behind the American majority in benefiting from the tremendous recent scientific achievements and medical breakthroughs in cancer prevention, treatment, and control." Institute of Medicine, The Unequal Burden of Cancer: An Assessment of NIH Research and Programs for Ethnic Minorities and the Medically Underserved. Washington, DC: National Academic Press. 1999.

In its 2005 report, Translating Research into Cancer Care: Delivering on the Promise, the President’s Cancer Panel made the following recommendations:

(Rec 17) Clinical and prevention research funders should require community participation early in protocol design and in research implementation.
(Rec 18) Research results must be shared with the individuals and communities that participate in clinical trials and other studies.
(Rec 19) Clinical and prevention research grantees should be required to include as part of the grant application a plan for disseminating and sustaining new interventions into the community.
(Rec 20) Existing community-based participatory research models should be evaluated to determine the potential for adopting them in other geographic areas and populations.


AHRQ has stated“…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.”


In a 2000 National Institute of General Medical Sciences Report recommended that researchers: 1) Obtain broad community input for all phases of research; 2) Respect communities as full partners in research; 3) Facilitate the return of benefits to communities; 4) Ensure dissemination of accurate information.

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A 2007 Secretary’s Advisory Panel Report recommended that an assessment of the public’s willingness to participate be made before any funding decision is made and that public engagement occur throughout all aspects and stages of the research process. Secretary’s Advisory Committee on Genetics Health and Society. (2007). Policy Issues Associated with Undertaking a New Large US Population Cohort Study of Genes, Environment and Disease. Washington, DC: US Department of Health and Human Services.

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31 The framing background paper and invited commentaries are available at http://www.enact.org/conference/conference.php

32 For example: A-Essential components of a system that seeks to include research advocates include the following characteristics: 1) it is systematic and required by the study sponsor(s); 2) the identification of appropriate community representatives is transparent; 3) the role and influence of the community members is meaningful and clear to avoid tokenism; and 3) includes appropriate training to help lay people make ethical judgments about research studies. Dresser, R. (1999). Public advocacy and allocation of federal funds for biomedical research. Milbank Quarterly, 77, 257-274.

B-In the Department of Defense, Congressionally Directed Medical Research Programs, Consumer Reviewer is mandated, Selection is accomplished through a three-step process. First, nominations are solicited from disease-related advocacy organizations across the country. Nominees are screened based on a letter of support, a resume or CV, and a personal essay detailing the nominee’s involvement in advocacy and efforts to increase their own scientific understanding of their disease. Applications are reviewed by senior program staff and evaluated in the following areas: advocacy, interest in science, communication skills, participatory skills, and vision. The final step involves a short telephone call to ascertain a nominee’s understanding of the peer review process and willingness to serve as a Consumer Reviewer. Department of Defense, Congressionally Directed Medical Research Programs. (2008). http://cdmrp.army.mil/

33 Sample sources include:
NCI trained Consumer Advocates in Research and Related Activities (CARRA) members
NCI and ACS-funded Patient Navigator Programs
NCI’s Cancer Information Service (CIS) Partnership Program
Intercultural Cancer Council
Local cancer support groups

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Local community advisory boards

Local community health workers, which can be reached through a number of associations

Members of the National Health Council

NAACP; National Council of La Raza; Asian Pacific Islander American Health Forum

34 2005 Agency for Healthcare Research and Quality (AHRQ) Evidence Report/ Technology Assessment on cancer clinical trial recruitment 34 states, “…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.”


35 The Clinical Research Roundtable at the Institute of Medicine states 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, implanting a community based participatory research model.”


36 In a 2000 National Institute of General Medical Sciences Report 36 recommended that researchers: 1) Obtain broad community input for all phases of research; 2) Respect communities as full partners in research; 3) Facilitate the return of benefits to communities; 4) Ensure dissemination of accurate information to the media and the public; and 5) Provide sufficient funds for research and encourage community–researcher partnerships.


37 A 2007 Secretary’s Advisory Panel Report 37 recommended that an assessment of the public’s willingness to participate be made before any funding decision is made and that public engagement occur throughout all aspects and stages of the research process.


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39 Vaccine Trial Advisory Board (has a national and local focus): http://gateway.nlm.nih.gov/MeetingAbstracts/102253013.html; SELECT National Participant Advisory Board: http://www.crab.org/select/npab.asp. There is a also NCAB (the HIV national CAB) whose mission is to:
Ensure the groups scientific priorities reflect the pressing needs of the entire spectrum of people with cancer;
Protect the interests of research subjects;
Represent the interests of the diverse communities impacted by the HIV epidemic;
Advocate for as broad inclusion as possible into the full range of clinical trials;
Advocate for innovative solutions to include traditionally under-represented populations


42 Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS clinical trials group (PACTG), the HIV Prevention trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN) each have Community Constituency Groups, which actively participate in network scientific committees and protocol teams, and have input in setting research agenda and scientific priorities Add Your Voice (2007)


46 Since its inception, and due to the efforts of breast cancer advocates, the Department of Defense (DOD) Breast Cancer Research Program (BCRP) has included consumers as full members on all review and advisory panels and today remains the only Federal agency to mandate consumer involvement. DOD has now incorporated advocates into each of its research programs, further illustrating the agency’s ongoing commitment to their participation. They provide “a perspective that is complementary to the scientific expertise. . . . [It] helps the scientists understand the human side of how the research will impact the community, and allows for funding decisions that will reflect the concerns and needs of patients, the clinicians who treat them” (DOD BCRP Website: http://cdmrp.army.mil/pubs/pips/bcpip.pdf)


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