

# Five Steps to Enhance Patient Participation in Cancer Clinical Trials

## Guide and Workbook

1.  
Building Relationships

2.  
Identifying Patients

3.  
Approaching Patients

4.  
Enrolling Interested Patients

5.  
Retaining Patients

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*Some material adapted from Committee to Optimize Recruitment, Retention and Adherence, Division of Cancer Prevention, National Cancer Institute, 2004.*

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# Five Steps to Enhance Patient Participation in Cancer Clinical Trials

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## Guide and Workbook

### **PART I: THE FIVE STEPS**

*It is important to note that there are several steps along the cancer clinical trials pathway that are essential to optimizing patient trial awareness, access and enrollment.*

*This section will provide an overview of the 5 steps, with specific tips and strategies on how to successfully execute each step.*

# SUMMARY CHECKLIST

<p><b>1.</b> Building Relationships</p>	<p><b>2.</b> Identifying Patients</p>	<p><b>3.</b> Approaching Patients</p>	<p><b>4.</b> Enrolling Interested Patients</p>	<p><b>5.</b> Retaining Patients</p>
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Step	Questions to Ask Yourself	Potential Successful Strategies
<p><b>1.</b> <b>Building Relationships</b></p>	<p>How can we get a more diverse population to come to our practice?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> How do we get primary care providers and other referring physicians more engaged in making referrals to our practice?</li> <li><input type="checkbox"/> How can we work with community organizations and leaders to educate potential patients about the quality care we offer through clinical trials?</li> </ul>	<ul style="list-style-type: none"> <li>■ Reach out to physicians where relationships are already established</li> <li>■ Develop local in-service presentations at physician offices                             <ul style="list-style-type: none"> <li>- Have discussion when physician has time available (breakfast, lunch, etc.)</li> <li>- Keep to a brief 20-30 minute presentation</li> <li>- Address whole staff, not just physician</li> </ul> </li> <li>■ Publish reports, a newsletter, or letters outlining of research activities and periodically disseminate them to local providers</li> <li>■ Hire navigators or translators to work at referring sites</li> <li>■ Arrange to make presentations before local physician groups, medical societies, etc.</li> <li>■ Develop new relationships with potential referring physicians doing some of these same activities</li> <li>■ Develop a clear policy to maintain communication with the referring providers to keep them informed about their patients</li> <li>■ Develop new relationships with community-based organizations</li> <li>■ Examples of community outreach activities include targeted media campaigns (print, radio, etc) in coordination with public relations and marketing staff, newsletters and community presentations at churches, town hall meetings, health fairs, etc</li> <li>■ Explain potential benefits of participation, but do not overlook the risks</li> <li>■ Use easy-to-understand language</li> <li>■ Avoid disrupting home and work schedules; hold meetings after church or other social activities</li> <li>■ Bring easy-to-understand flyers or brochures with phone numbers that are enduring</li> </ul>

Step	Questions to Ask Yourself	Potential Successful Strategies
<p><b>2.</b> Identifying Patients and Assessing Eligibility</p>	<p>How are we communicating as a team to ensure all patients are considered as potential candidates for trial enrollment?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Are all patients screened systematically for eligibility?</li> <li><input type="checkbox"/> Are all eligible patients approached?</li> <li><input type="checkbox"/> What are my/our own cultural values, biases and beliefs that might inhibit our approaching all eligible patients?</li> <li><input type="checkbox"/> What are the cultural values, experiences and beliefs of the patient?</li> <li><input type="checkbox"/> Do we document the percentage of our patients ineligible, and how is that information fed back to the administration?</li> <li><input type="checkbox"/> Do we have a way of documenting the approach and the response?</li> </ul>	<ul style="list-style-type: none"> <li>■ Ensure all patient charts are screened for eligibility</li> <li>■ Send potential cancer diagnosis reports for review by research nurses who determine available studies patient eligibility <ul style="list-style-type: none"> <li>- Nurses communicate with physicians who inform patients about trial opportunities</li> <li>- Develop policies or procedures to ensure that physicians are willing to approach all eligible patients</li> </ul> </li> <li>■ Hold weekly team meetings to discuss patients in-between point of diagnosis and initial treatment</li> <li>■ Track screening rates, eligibility rates, approach rates (and reasons not approached) and reasons for decline</li> </ul>

Step	Questions to Ask Yourself	Potential Successful Strategies
<p><b>3.</b> Approaching Eligible Patients</p>	<p>How can I discuss cancer clinical trials with patients in a way that optimizes understanding, BEFORE presenting the form?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> How do I accommodate for a patient's emotional state?</li> <li><input type="checkbox"/> What are my own attitudes toward the trial's design, clinical integrity, and feasibility?</li> <li><input type="checkbox"/> Have I checked what my personal feelings are toward participation in this type of study?</li> <li><input type="checkbox"/> Am I prepared to discuss the trial with the patient? Do I understand the study objectives and eligibility requirements?</li> <li><input type="checkbox"/> Am I making assumptions on interest based on a general characteristic? Or am I making an assessment on an individual basis?</li> <li><input type="checkbox"/> Have I adequately discussed <ul style="list-style-type: none"> <li>- the benefits, risks, and uncertainties of participation?</li> <li>- the voluntary nature of participation?</li> <li>- that clinical trials are offered for many patients, for first line treatment, localized and advanced disease?</li> <li>- the extra monitoring in a CCT?</li> <li>- the potential costs?</li> </ul> </li> <li><input type="checkbox"/> Have I discussed options for standard treatment to this patient?</li> <li><input type="checkbox"/> What choices for treatment can the patient and I agree upon that respect their cultural beliefs/practices?</li> <li><input type="checkbox"/> Do I know about the family's role in his/her decision making process? Did I acknowledge and discuss the role of family to this patient?</li> <li><input type="checkbox"/> Did I acknowledge and discuss the role of faith and spirituality to this patient?</li> <li><input type="checkbox"/> Have I assessed the need for an interpreter?</li> </ul>	<ul style="list-style-type: none"> <li>■ Provide patients with generic CCT educational material to enhance patient understanding</li> <li>■ Provide patients with welcome letter signed by program leader and patient's oncologist letting them know clinical trials may be mentioned during visits <ul style="list-style-type: none"> <li>- Minimize cost and effort by streamlining the process: including the letter in existing new patient packet, having a template letter and electronic signatures on file, etc.</li> </ul> </li> </ul>

Step	Questions to Ask Yourself	Potential Successful Strategies
<p><b>4.</b> Enrolling Interested Patients</p>	<p>How do we initiate/ implement a consent process that is well understood?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Did I discuss the major details of the study before showing the consent form? Did I review the differences between receiving care off or on study?</li> <li><input type="checkbox"/> Will you be able to do provide detailed discussion on standard treatment as well as treatment on a clinical trial?</li> <li><input type="checkbox"/> Have I reminded the patient that trial participation is voluntary?</li> <li><input type="checkbox"/> How is consent form presented, considering culture and language and understandability?</li> <li><input type="checkbox"/> How do I know the consent process was well understood? <ul style="list-style-type: none"> <li>- What procedures are in place to ensure comprehension and understanding? (e.g. chunk and check)</li> <li>- Is there use of flow charts or calendars to explain what will happen?</li> </ul> </li> <li><input type="checkbox"/> Am I able to use the “short form” to consent the patient?</li> <li><input type="checkbox"/> Do I need an interpreter?</li> <li><input type="checkbox"/> Did I explain the concept of randomization in simple terms? Did I explain placebo if applicable?</li> <li><input type="checkbox"/> Have I listened to patient concerns about joining a study.</li> <li><input type="checkbox"/> Am I addressing concerns accurately and respectfully?</li> <li><input type="checkbox"/> Do I know about the family’s role in his/her decision making process? Have I talked with the patient about the family’s role in decision-making?</li> </ul> <p>How do we explain need for other tests to ensure eligibility?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Did I explain what the additional screening involves?</li> <li><input type="checkbox"/> Did I clarify then the option of receiving standard treatment?</li> </ul>	<ul style="list-style-type: none"> <li>■ Anticipate which trials might have non-English speaking patients and build that into the budget of the study</li> <li>■ Find out whether staff honorariums could be voluntarily donated to institutional fund to address translation services not covered by trial sponsors</li> <li>■ Explore whether the OHRP-approved “short form” for consent is viable for your institution</li> <li>■ Use graphics to illustrate randomization (e.g. NCI brochure or drawing out the schema in front of patient) <a href="http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies">http://www.cancer.gov/clinicaltrials/Taking-Part-in-Cancer-Treatment-Research-Studies</a></li> <li>■ Use a simple chart to illustrate the differences of treatment off and on a trial</li> <li>■ Use calendars and flow charts to illustrate what will happen when on a trial</li> <li>■ Use professional interpreters (in person or by phone) as a communication bridge</li> <li>■ Provide “CLAS Standards” training for clinical trial staff (<a href="http://thinkculturalhealth.org">thinkculturalhealth.org</a>)</li> <li>■ Provide ENACCT on line training for clinical trial staff (<a href="http://www.enacct.org/yourrole">www.enacct.org/yourrole</a>)</li> </ul>

Step	Questions to Ask Yourself	Potential Successful Strategies
<p><b>5.</b> Retaining Patients in Study</p>	<p>What do we do to help patients stay on study?</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> How are patients greeted, by whom and in which locations? How are their doctors informed?</li> <li><input type="checkbox"/> How do they get back and forth to the clinic?</li> <li><input type="checkbox"/> Does every staff member acknowledge and appreciate the patient's participation in the study (e.g. I see you're on a research study. How is that going for you? Can I get someone to answer any questions for you today?)</li> <li><input type="checkbox"/> How are we addressing childcare?</li> <li><input type="checkbox"/> How are they approached regarding additional data collection, such as questionnaires?</li> <li><input type="checkbox"/> What phone numbers are available for adverse effects or other problems? How are those phone calls handled in a systematic way?</li> <li><input type="checkbox"/> Do we have a systematic way to keep the referring physician "in the loop?"</li> </ul>	<ul style="list-style-type: none"> <li>■ Train all staff—even front desk staff—about the importance of clinical trials, and encourage them to acknowledge participation with the patients</li> <li>■ Maintain regular phone contact with patients between in person visits to monitor compliance</li> <li>■ Give patients treatment calendars to assist their planning</li> <li>■ Make free parking available</li> <li>■ Post signs with directions to the study site office. Be sure the signs are easy to read, large, and bold</li> <li>■ Have a well-organized clinic flow</li> <li>■ Encourage family members to accompany the patients</li> <li>■ Provide flexible appointment times, and try to consolidate visits</li> <li>■ Allow ample time for patients with the clinical trial staff</li> <li>■ Remind patients of upcoming appointments via postcards and/or telephone calls</li> <li>■ Address barriers, such as transportation or compliance difficulty</li> <li>■ Establish a schedule for contact with patient</li> <li>■ Implement retention tools/give-aways</li> <li>■ Send anniversary or birthday cards</li> <li>■ Establish and maintain rapport among all staff during follow-up</li> </ul>



# **STEP 1. Building External Relationships to Enhance Diverse Trial Participation**



*Because research shows that most participants will join a trial if recommended by their health provider or someone they trust, it is critical that research teams reach out to community health care providers (e.g., doctors, physicians' assistants, nurses, and nurse practitioners).*

It is important to consider these activities as an ongoing effort to enhance access to clinical trials, rather than as an approach to enhance recruitment to a particular trial.

## Common Questions from Community Physicians

Below are common concerns community health care providers/referring clinicians may have about cancer clinical trial participation, as well as suggestions for how to respond to these concerns. **Be sure to address all concerns in a frank, open, and honest manner.**

### Why should I refer patients to your institution/this trial?

Although about 20 percent of cancer patients are medically eligible for a treatment clinical trial<sup>8</sup>, **trial participation among adult cancer patients remains at about two and a half to three percent.**<sup>9,10,11,12</sup> This rate is even lower among people of color and the medically underserved,<sup>13,14,15</sup> who tend to have higher cancer mortality rates than the population as a whole.

- **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<sup>16</sup>. A number of studies have suggested that trial participation is associated with improved clinical outcomes, and is a means to better treatment.<sup>17,18,19,20,21,22,23,24</sup>
- **Only 15% of all cancer patients are told about the option of receiving treatment through a cancer clinical trial.**<sup>25,26</sup> Patients receiving a cancer diagnosis have the right to consider all possible approaches for treatment, including clinical trials. Referring people to our institution ensures that your patients will be screened for clinical trials eligibility and receive the most options for care.
- **Most patients would consider a clinical trial if their doctors recommended they do so.**<sup>27</sup> One study showed that recommendation by their physician was the primary factor influencing patients' decisions to enroll in a trial.<sup>28,29</sup>
- Because of the often long-term relationships primary care providers have with their patients, the message about clinical trial participation might be more readily accepted and heard by patients if their primary care physician introduces the subject.<sup>30</sup>
- Despite their influence, **only 2% of primary care physicians polled routinely discuss oncology clinical trials**, while 41% prefer to leave these discussions to oncologists.<sup>31</sup> Thirty-seven percent were unaware of clinical trials that might be available for their patients.<sup>32</sup>

## How do I begin to discuss clinical trials with my patients who I am sending out for referral?

For primary care providers and other referrers, we think it is critical to mention clinical trials as a viable treatment option. The following is an example of how you could bring this up:

“We’ve just found something that concerns me. Here is some general information for you about cancer—what it is and how it is treated. If this does turn out to be cancer, you may want to talk to the oncologist I will refer you to about clinical trials, because a trial may be appropriate for you.”<sup>33</sup>

## I think it would be reckless for me to refer to a trial when I am not sure what is clinically appropriate.

- Not knowing what is clinically appropriate is the precise reason for recommending a clinical trial. In fact, the ethics of clinical research require equipoise—a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a trial. If the best clinical intervention were known, there would be no need for the trial.

## Trial Specific Questions

Community health care providers may also have specific questions about a particular clinical trial that your research team will need to address. Examples of these questions include:

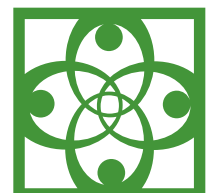
- What are the trial objectives and eligibility criteria?
- Will patients be randomized?
- What are the benefits and risks for this particular trial?
- Why should I refer my patients? My patients wouldn't be interested in participating in this study because they...
  - Are over 65
  - Are mostly minority
  - Are mostly uninsured
  - Do not want to travel
  - Do not speak English well



## Sending Information and Making Presentations to Community Physicians

It is important that your research team develop ongoing relationships with community health providers. While in-person connections are optimal, developing these connections can begin with ongoing correspondence such as newsletters. **(Please note, ENACCT does not recommend use of trial-specific letters to local doctors or use of paid advertising as a way to do outreach about particular studies due to very low yield. However, they may be used in raising awareness about trials in general.)**

1. Identify local health care providers you may want to contact to inform about your trials. Think about local chapters of associations and societies, community hospitals, local health clinics, and public health departments.
2. Tailor correspondence to fit the services available at your site, and if necessary, a particular clinical trial. Personalize the letter, include contact information for follow-up.
3. Send out correspondence and prepare to follow-up within a week of mailing.
4. When you follow-up, offer to meet with professional staff (including nurses and front desk staff) to explain the particulars of the treatment services you offer as well as current clinical trials. Scheduling a “detailing” visit discussing your services can be particularly helpful.
5. If referrals are a success, make time to say “thank you” and keep the practice abreast of patient progress.



## Building Relationships with Community-Based Organizations

Although research teams may choose to rely only on their own site for recruitment contacts, community organizations and community leaders may also help in recruiting patients. Therefore, it is important that your research team build collaborative relationships with community groups and their leadership.

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

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

### Lessons from the Field: *Referring Provider Engagement*



Susan Walsh, BS, MT (ASCP), CCRP  
Clinical Research Associate  
Decatur Memorial Hospital

As part of ENACCT's Pilot Education Program, the community site in Decatur Illinois conducted a series of Provider "Lunch and Learn" Sessions to raise awareness of trials and the role providers can play in education and referral. Susan Walsh, Clinical Research Associate at Decatur Memorial Hospital worked on this initiative as a Physician Educator.

*“We said, ‘We’ll provide lunch. We’ll do it over your lunch time. We’re going to market this kind of like a pharmaceutical rep does, come in and talk to you and we don’t want to talk just to the doctor; we want to talk to the whole staff, because all the staff in that office may have contact with patients or have an opportunity to discuss clinical trials with a patient at any point in time during their office visit.’”*

## What Are Other Resources For Cancer Clinical Trials Information?

The National Cancer Institute, drug companies, medical institutions, and other organizations sponsor clinical trials. Clinical trials take place in many settings, such as cancer centers, large medical centers, small hospitals, and doctors' offices. Unfortunately, there is no comprehensive national database that lists all available cancer clinical trials. The three services listed below are likely to contain the same clinical trials, but vary in the ease of the search and the intensity of service delivered through the phone line.

### National Cancer Institute Cancer Information Service

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The National Cancer Institute maintains the most complete database of cancer clinical trials in the country. This database is called PDQ®. The following resources from the National Cancer Institute can help you search PDQ® and see if there is a trial for your type and stage of cancer, free of charge.

Toll-free: 1-800-4-CANCER (1-800-422-6237)

TTY: 1-800-332-8615

Answers questions about cancer clinical trials and cancer-related services and helps users find information on the NCI Web site.  
Provides NCI printed materials.

Online: <http://www.cancer.gov/clinicaltrials>

Chat online: [www.cancer.gov/help](http://www.cancer.gov/help)

### American Cancer Society Clinical Trials Matching Service

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The American Cancer Society Clinical Trials matching Service is a free, confidential program that helps patients, their families and health care workers find cancer clinical trials most appropriate to a patient's medical and personal situation. The TrialCheck® database, developed and maintained by the Coalition of Cancer Cooperative Groups, is a comprehensive database that includes the Coalition, National Cancer Institute, and industry trials.

The American Cancer Society also has clinical trial specialists who are trained to answer questions about clinical trial participation, and to open the door to treatment options available through research studies. If you have questions about clinical trials or need help completing the questionnaire, please call 1-800-303-5691 to speak with one of our specialists.

Access the TrialCheck system:

Online: [www.cancer.org](http://www.cancer.org) (click on "Find a Clinical Trial")

Toll-free: 1-800-303-5691

## EMERGING MED

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Emerging Med, a commercial clinical trial matching service, has a highly personalized free phone and web-based service that increases patient and physician access to clinical trial information. Cancer patients, family members, and/or health care professionals complete a questionnaire online or over the phone with a trained Clinical Trial Navigator. This profile is matched against a comprehensive national clinical trial database, identifying studies that match the patient's specific diagnosis and treatment history.

Emerging Med's Clinical Trial Navigators are available to provide basic information and education about clinical trials and empower patients to discuss cancer study options with their health care providers. A special feature of this service is continued follow-up with individuals (with their permission) by the Clinical Trial Navigators to update match results and provide logistical guidance. The goal is to ensure patients recognize that clinical trials may be an option at any point throughout the course of their illness.

Search by Phone: 1-877-601-8601.  
8:30 AM-6:00 PM EST (M-F)

Web search: [www.emergingmed.com](http://www.emergingmed.com)

## What Are Other Resources For Clinical Trial Costs And Coverage Assistance?

ASCO, Managing the Costs of Cancer Care

<http://www.cancer.net/managingcostofcare>

This is a 24 page booklet describing common costs associated with cancer care, including clinical trials, and lists national organizations that provide financial information and assistance to cover care expenses. Examples of such organizations are listed below:

**CancerCare Co-Payment Assistance Foundation**

[www.cancercarecopay.org](http://www.cancercarecopay.org)

866-552-6729

**Chronic Disease Fund**

[www.cdfund.org](http://www.cdfund.org)

877-968-7233

**Partnership for Prescription Assistance**

[www.pparx.org](http://www.pparx.org)

888-477-2669

**Patient Advocate Foundation**

[www.copays.org](http://www.copays.org)

866-512-3861

**Together Rx Access Card**

[www.together-rxaccess.com](http://www.together-rxaccess.com)

800-444-4106

**Cancer Financial Assistance Coalition**

[www.cancerfac.org](http://www.cancerfac.org)

**NeedyMeds, Inc.**

[www.needymeds.com](http://www.needymeds.com)

215-625-9609

**Patient Access Network Foundation**

[www.patientaccessnetwork.org](http://www.patientaccessnetwork.org)

866-316-7263

**Patient Services Inc.**

[www.uneedpsi.org](http://www.uneedpsi.org)

800-366-7741



## Lessons from the Field: *Best Practices for Community Outreach*



### **Debra Wujcik, RN, PhD**

Director of Clinical Trials at Meharry  
Associate Professor of Nursing  
Vanderbilt University School of Nursing, Nashville, TN

Debra coordinates clinical trial community awareness activities as part of a Meharry/Vanderbilt-Ingram Cancer Partnership grant funded by NCI with the goal of fostering research that addresses disparities in minority and medically underserved populations.

“*In my research office, I have a community outreach research nurse. She goes to four of our community safety net providers, these are community health centers, twice a month, and sets up an educational table in the lobby or the waiting area of those clinics. She uses an educational approach to reach out to folks not only about clinical trials, but cancer prevention, cancer screening information. In addition, we’ve had some of our clinical trials that she’s been able to recruit from the community.*”

In fall 2010, Vanderbilt expanded its efforts further by bringing together its clinical research staff and surrounding community partners to participate in ENACCT’s train-the-trainer program, fostering greater community understanding and trust, particularly among local African American and Latino populations.

### **Sending Information and Making Presentations to Community Groups**

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The following five steps were designed to help your research team connect with community and advocacy groups to help strengthen your relationships and eventually assist in referrals to particularly trials.

1. Identify community and advocacy groups, as well as specific community leaders and decision-makers, that you may want to contact to get assistance with recruitment efforts
2. Tailor letters to fit your site, the quality services you provide the community and if necessary particular clinical trials.
3. Send out materials and prepare to follow up within a week of mailing
4. When you follow-up, offer to meet with groups to explain the particulars of the services that you offer, and if necessary, particular clinical trials
5. If referrals are a success, make time to say “thank you”.

## **STEP 2: Identifying Patients and Assessing Eligibility**



### **Screening All Eligible Patients**

The next key step is to adopt the practice of screening all patients for eligibility to trials. This requires a systematic and consistent process for documenting the identification of all patients who might be eligible to participate in studies, and documenting whether the patient ends up going on to trial or declining. Gathering such data allows institutions to analyze trends in recruitment and screening practices, and how this potentially impacts on patient accrual.

Sites should ask themselves 3 critical questions related to screening:

1. What is the percentage of patients screened for eligibility to participate in a clinical trial?
2. Of those eligible, what percentage are actually approached to participate?
3. What percentage decline-and why?

Knowing your sites statistics for each of these metrics is important. Screening numbers offer a good picture of how many individuals are potentially eligible to participate in a study. But this piece of data should then be compared with the rates of how many patients are in fact approached about the possibility of participating. A final useful piece of information for sites to document is whether there is a percent decline in these metrics over time. Imagine if two cancer centers for example annual document their accrual rates, both currently experiencing a rate of 2%. But if one of those sites collected the additional data as described on the slide-screening and approach data, that site has more information to work with in determining where the gaps are in the trial access for patients.



**Debra Wujcik, RN, PhD**

Director of Clinical Trials at Meharry  
Associate Professor of Nursing  
Vanderbilt University School of Nursing, Nashville, TN

*“We diagnose about 300 patients per year with cancer at Nashville General Hospital, and every patient is screened for potential participation in a clinical trial.... every pathology report is sent to our research office and our research nurses look at those pathology reports and then begin to, what we call, ‘case manage’ or ‘navigate’ our patients through the system. So if a patient has been seen by a surgeon, for example, and had a biopsy of tissue that revealed cancer, then our nurses are communicating immediately with that surgeon to say, “We see that your pathology report has indicated a cancer. How can we help get your patient into our system and keep them in the system?”*

A competitive spirit is also fostered among investigators to incentivize the approach of all eligible patients about trials.

*“There definitely is some peer pressure in that we have a weekly team meeting where every patient who is in that period between initial diagnosis and start of treatment is discussed. ...if a patient is eligible for a trial and has been offered the trial, but does not go on the trial, then we ask for the reason why that person did not participate. We actually record that in our database... we do think that that peer pressure does turn out to hold people accountable for being a research advocate and offering those trials to their patients.”*

## **STEPS 3 AND 4: Approaching Eligible Patients and Enrolling Interested Patients**



### **Your Own Preparation for Clinical Trials Discussions**

Before beginning a discussion with patients about clinical trials participation, your research team needs to prepare how the clinical trial will be explained. Points to be aware of include:

- Understanding the study objectives and eligibility requirements and determining whether the patient meets the criteria
- Knowing the therapeutic options in general for this patient, and specifically which clinical trial(s) may be relevant
- Familiarity with (and comfort explaining) the benefits, risks, and uncertainties of participation and addressing them in a frank, open and honest way<sup>34</sup>
- Comfort level with the trial design, clinical integrity, and feasibility
- Personal feeling toward participation in a study of this nature
- Understanding of and comfort with the concept of equipoise and being able to explain it <sup>35,36,37, 38</sup>
  - **Equipoise:** Not knowing what is clinically appropriate is a precise reason for recommending a clinical trial. In fact, the ethics of clinical research require equipoise – a state of genuine uncertainty on the part of the clinical investigator regarding the comparative therapeutic merits of each arm in a clinical trial. If the best clinical intervention were known, there would be no need for the trial.
- Personal feeling about effort required to accrue different types of patients

## Eight Tips for Cancer Clinical Trial Discussions with Patients<sup>35</sup>

1. Begin with discussing standard treatment options that are available to the patient. “This is how we treat your condition today.”
2. Discuss how approaches to cancer treatment have changed over time and the evolution of the standard of care—the message is that all new approaches for cancer treatment have been developed through clinical trials.
3. Discuss how science and clinical research, in particular, is leading us toward even better approaches to treatment, with fewer side effects.
4. Explain how patient participation is needed to realize the promise of improved cancer treatment options.
5. Do not say “**randomized**”. Do not define randomization as a “flip of a coin” or assignment “by chance”. Say “Patients who agree to be in this clinical trial are assigned to different groups; this selection is done by computer. Although we know what medicine each group of patients will be given, neither doctors nor patients can choose the group they are assigned to.”
6. Address the myth of placebo. Say “Everyone is treated; no one in a cancer treatment clinical trial receives placebo instead of treatment they need.”
7. Talk about the importance of the informed consent process.
8. Talk about the role of the patient’s family in decision making and encourage the patient to take the informed consent home and allow the family to read.

### What are Racial/Ethnic Minority Groups?

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

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

It is important to note that while these are how various populations are categorized per OMB guidelines, these terms may not necessarily be how individuals define themselves. Further, attitudes and beliefs related to cancer and medical research may vary across groups.

## Working with Patients from Ethnic/Racial Minority Groups

For racial and ethnic minority group members, it is also important to consider the following:

- 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; mere racial or ethnic concordance is not sufficient. Identifying members of the community or institutional staff who share the same ethnic background as the target group has been a very successful strategy for community outreach, community education, recruitment, and data collection <sup>39,40,41,42,43,44,45,46,47,48</sup> and may also maximize study participation.
- Stress the importance of enrollment in trials in impacting the future health of the family and future generations.
- Stress the importance of high quality care, of which clinical trials are a part.
- Emphasize the fact that because people are monitored closely under clinical trial protocols, they may a higher quality of medical care and follow up than do those who are not enrolled in clinical trials.
- Promote the balance of spirituality, faith, medicine, and science.



## Addressing Common Concerns Patients/Families May Have about Clinical Trial Participation

To begin this conversation, consider asking, “What concerns do you have about the possibility of joining this study?” Below are common questions families may have about cancer clinical trial participation, as well as suggestions for how to respond to these concerns. **Be sure to address all concerns in a frank, open, and honest manner.**

### What are cancer clinical trials?

- Cancer treatment clinical trials are research studies with people that seek to find new ways to treat cancer. These trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer.
- The treatments tested may include new drugs or new combinations of currently used drugs, new surgery or radiation therapy techniques, and vaccines or other treatments that stimulate a person’s immune system to fight cancer. Combinations of different treatment types may also be tested in these trials.



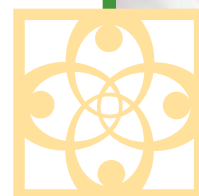
## What are the types of clinical trials?

Clinical trials differ by type and phase, but they all involve rigorous scientific testing. Each type of clinical trial attempts to answer different research questions:

- **Treatment.** These trials test the effectiveness of new treatments or new ways of using current treatments in people who have cancer, as noted above.
- **Prevention.** While most cancer prevention trials involve healthy people who have not had cancer, some trials involve people who have had cancer in the past; these trials test new approaches that may help prevent the return (recurrence) of the original cancer or reduce the chance of developing a new type of cancer.
- **Quality of life or supportive care.** These trials focus on the comfort and quality of life of cancer patients.
- **Screening and early detection trials** aim to discover new ways of finding cancer in people before they have any cancer symptoms.
- **Diagnostic trials** aim to develop better tools for classifying types and stages of cancer, and managing patient care.
- **Genetics trials** aim to determine how one's genetic makeup can influence detection, diagnosis, prognosis, and treatment.

## If a patient agreed to join a cancer clinical trial is there a chance she/he will receive a “placebo” (e.g., sugar pill) instead of a therapy that could treat their cancer?

- This is a common misunderstanding and why some cancer patients are reluctant to enter cancer clinical trials. Placebos (also called sugar pills) are rarely used in cancer clinical trials and **are never used in place of appropriate treatment.**





## I've always heard bad things about clinical trials. Aren't clinical trials just experimenting with people?

- Many people think that participant rights are not protected in clinical trials because of past abuses of research participants. However, **all patients who participate in clinical trials have rights that are protected under the law**. Under the informed consent process, you would have the right to know everything that is going to happen in a study. You also have the right to leave a clinical trial at any time and for any reason.
- **Patients who participate in clinical trials have both rights and protections to make sure their privacy and well being are maintained:**
  - One of the most important protections is **informed consent**. Informed consent is a process where someone from the research team, explains in clear and understandable language the purpose of the trial what will happen during the trial, and the trials' potential risks and benefits. This person must also explain that patients have the right to make an independent decision about participating and have a right to leave the study at any time.
  - The informed consent process continues by the patient signing a written document stating that he or she entered the trial of his or her own free will, without being pressured, and that he or she has full knowledge and understanding of the clinical trials and possible benefits. The informed consent process does not end once the form is signed. If new benefits, risks, or side effects are discovered during a study, the researchers must inform study participants.

## Would patients have costs to pay if they were on a clinical trial?

**Participating in a clinical trial does not guarantee free medical treatment and care** and there may be limitations to what costs are covered. It is important to ask your doctor or research team about their experiences with medical plan coverage for the trial you are considering.

There are three kinds of costs associated with clinical trials:

- **Patient care** costs fall into two categories:
  - Usual care costs, such as doctor visits, hospital stays, clinical laboratory tests, x-rays, etc., which occur whether a patient is participating in a trial or receiving standard care. These may or may not be covered by a third-party health plan, such as Medicare or private insurance.

- Extra care costs are a second category of costs associated with clinical trial participation, such as additional tests required. These may or may not be fully covered by the clinical trial sponsor and/or research institution, and they may or may not be covered by a third-party health plan, such as Medicare or private insurance.
- **Research costs** are those associated with conducting the trial, such as data collection and management, research physician and nurse time, analysis of results, and tests purely performed for research purposes. Such costs are usually covered by the sponsoring organization, such as a pharmaceutical company or the NCI.

Depending on the type of trial, the insurance company may be willing to pay for some or all costs of treatment. Health plans may specify other criteria a trial must meet to be covered. The trial might have to be sponsored by a specified organization, be judged “medically necessary” by the health plan, not be significantly more expensive than treatments the health plan considers standard, or focus on types of cancer for which no standard treatments are available. **Currently a majority of states require that insurance plans pay for the costs of certain clinical trials, including routine expenses, such as doctor visits, hospital stays, laboratory tests and x-rays. See <http://www.cancer.gov/clinicaltrials/ctlaws-home>.**

- **Medicare** will pay for the routine costs for some government sponsored clinical trials.
- **TRICARE**, the Department of Defense’s military defense system, will pay for the medical costs phase II and phase III cancer prevention (including screening and early detection) and treatment trials sponsored by the National Cancer Institute (NCI).
- **The Department of Veterans Affairs (VA)** will pay for medical costs for eligible veterans participating in prevention, diagnosis, and treatment clinical trials sponsored by the NCI.

**With the enactment of the Patient Protection and Affordable Care Act in 2010, the US will soon require all health insurers to pay for routine costs of care delivered in phase I through phase IV clinical trials, including trials focused on prevention and early diagnosis. In 2014, insurers will be prohibited from denying coverage for routine care that they would otherwise provide just because an individual is enrolled in a clinical trial. They will also be prohibited from dropping coverage because an individual chooses to participate in a clinical trial.**

## What are the possible benefits and risks of participating in a clinical trial?

Every clinical trial has both benefits and risks. Possible benefits may include:

- Participants have access to promising new treatments or approaches that are often not available outside the clinical trial setting.
- The treatment being studied may be more effective than the current standard treatment.
- Participants receive regular and careful medical attention from a research team that includes doctors and other health professionals.
- Participants may be the first to benefit from the new treatment under study.
- Results from the study may help others in the future.

Risk is dependent on the type and phase of trial. Possible risks may include:

- New treatments or procedures under study are not always better than the standard care to which they are being compared.
- New treatments may have side effects or risks that doctors do not expect or that are worse than those resulting from standard care.
- Participants in randomized trials will not be able to choose the treatment they receive.
- Health insurance and managed care providers may not cover all clinical trials costs.
- Participants may be required to make more visits to the doctor than they would if they were not in the clinical trial.

## Are cancer clinical trials the treatment of “last resort?”

- Clinical trials are not only for those with the most advanced disease. Many patients with many different types of cancer receive their first treatment as part of a clinical trial. Other patients participate in clinical trials after they have already been treated with one or more standard treatments.

### **If someone is in a phase III trial and it is found that there is a clear advantage for the participants in the other group, what happens?**

- If early results show that there is a clear advantage for one of the study groups, the sponsor of the study may choose to end the trial early. At this time, patients have the option to “cross over” to the group receiving the more beneficial treatment.

### **Can a person be put in a clinical trial without his or her knowledge?**

- No. The law requires that the health care team overseeing the trial explain all information about the trial, so that patients can make an informed decision about participating in a trial. The healthcare team must also explain that patients have the right to leave the study at any time.

### **Why are patients assigned to groups? Why can't they choose the group they want to be in?**

- Patients who agree to be in many clinical trials are assigned to different groups; this selection is done by a computer. Although we know what medicines each group of patients will be given, neither doctors nor patients can choose the group they are assigned to. This process is called “**randomization.**”
- Randomization helps avoid what is called bias: having a study's results affected by a doctor's beliefs or choices and, therefore, unevenly slanted toward one side or the other.
- Randomization also ensures that the groups of patients being compared (those who receive the treatment under study compared with those who receive the standard treatment) are as similar as possible and, therefore, comparable. At the end of the trial, if one group has a better outcome than the other, researchers will be able to conclude with some confidence that one treatment is better than the other.

### What will happen if the treatment the patient gets in a trial doesn't work for the patient?

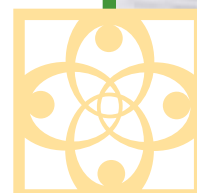
- **Clinical trial participants are monitored closely** and are kept informed of the treatment's effect and disease progression. **It is not ethical to keep patients who are responding poorly in the clinical trial.** Clinical trial participants are monitored closely and will be taken off the clinical trial if they are doing poorly or if their side effects cannot be managed.

### What about side effects?

- All cancer treatments may have side effects. The treatment studied in the clinical trial may have side effects that are unknown or worse than those caused by the standard the treatment for the disease. Clinical trial participants are monitored closely and will be taken off the clinical trial if they are doing poorly or if their side effects cannot be managed.

### Why are there so many restrictions about who can join each clinical trial?

- Clinical trials are conducted under strict criteria to protect patient's safety, while allowing researchers to answer the question that is being studied. For example, some patients have health problems that could be made worse by the treatment under study; in this case, they would not meet certain criteria and, therefore, would be excluded from a trial. Eligibility criteria that are frequently evaluated include age, gender, the specific kind or duration of the disease, what prior treatments been received, or what other medical conditions a patient may have.



## Enrolling Patients onto a Trial: Maximizing the Effectiveness of the Consent Process

Patients enrolling onto a clinical trial need to be able to offer an informed consent, meaning the information about the trial has been presented both verbally and in writing in a manner that allows the potential participants to understand the various aspects of the study, its risks and benefits, expectation of study participants, etc. It is thus important for clinical trial teams to use tools and resources available to optimize patients' enrollment experience. The following are a few examples of effective strategies and instruments to use.

### Approaches to enhance literacy

#### ■ Improve Verbal Communication

- Focus on the discussion more than the form.
- Speak slowly and use simple language.
- Use the teach back technique—ask the patient to repeat in their own words their understanding of the purpose and procedures and rights outlined in the consent document.
- Use “chunks and checks” technique—provide the patient with only two or three concepts a time and check for understanding of information through teach back.

#### ■ Complement and Modify Written Language—even beyond the consent form

- Simplify language, use common words and an active voice.
- Write simple instructions for the patient to take home. Number the steps to be taken.
- Read and review instructions with the patient. Underline or circle key points.
- Use translated/transcreated materials.
- Use pictures and diagrams to supplement written information. Consider use of flow chart to explain protocol, illustrating what happens on day one, day ten, month 3, etc.

## ■ Create a Shame-Free Environment

- Involve all staff in the effort to simplify and clarify written and oral communication.
- Identify those with low literacy skills. Some of the clues you might look for to assess low literacy are: comments that they left their glasses home today, taking a long time to complete forms, incomplete forms, information revealed during the social history, inability to tell you what meds they are taking, how they take them and what they are for.
- Give permission to ask questions by saying something like, “Many people have difficulty reading and understanding the medical information I give them so please feel comfortable asking questions if there’s something you don’t understand.”

## ■ Use Available Resources

- Ask the patient if he or she would like to invite a family member or friend to accompany him/her to the counseling and planning portion of the visit. Do not use the family member or friend to interpret, however.
- Use language line or interpreters to interpret the process, not translate the form.



## **STEP 5: Retaining Patients in a Study**



*The participant's comfort level while at the study site is of significant importance. Make the participant as comfortable as possible by presenting yourself, the study site offices, and waiting room as welcoming and accommodating as possible.*

### **Recruitment and Retention Planning**

Most research teams have minimal time and resources for recruitment, outreach, and retention planning, but planning ahead increases the likelihood of recruitment success. Clinical trials implemented within your research team's practice should include a detailed recruitment plan by site that includes contingency planning. Research teams should not assume that all trial participants will come from passive efforts.



## Recruitment and Retention Plan Outline

This outline provides an overview of the phase and steps in an effective recruitment and retention plan.

### Phase I: Pre-Initiation—Strategy Development

This phase should begin several months before actively recruiting.

- **Step 1:** Determine protocol staff assignments
- **Step 2:** Assess protocol design and implications for recruitment
- **Step 3:** Identify referral sources and plan frequency of contact
- **Step 4:** Determine and document metrics for continuous evaluation of recruitment and retention performance
- **Step 5:** Develop staff training plans and materials
- **Step 6:** Determine how you will acknowledge the efforts of recruiters and consortium staff
- **Step 7:** Plan to ensure a comfortable and pleasant clinic environment/experience
- **Step 8:** Plan for retention “gifts”
- **Step 9:** Develop recruitment budget

### Phase II: Active Recruitment—Implementation of Strategies

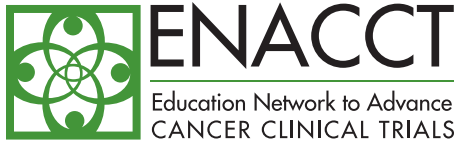
- **Step 1:** Implement recruitment and retention plans
- **Step 2:** Assess eligibility of potential participants
- **Step 3:** Implement consistent approach in consenting patients
- **Step 4:** Implement continuous evaluation strategies as planned during pre-initiation phase

### Phase III: Retention and Compliance

- **Step 1:** Implement system to maintain contact with and provide support to staff, referring physician, and participants
- **Step 2:** Implement systems that will ensure ongoing pleasant clinic visits
- **Step 3:** Continue tracking systems and implement alternate plans, if necessary

### Phase IV: Evaluation—Documentation of Outcome of Strategies

- **Step 1:** Implement periodic (monthly) monitoring system that provides rapid feedback regarding efficacy and costs



# Five Steps to Enhance Patient Participation in Cancer Clinical Trials

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## Guide and Workbook

### **PART II: SAMPLE PLANS AND FORMS**

# Clinical Trials Screening and Accrual Log



**Patient Identification Number:** xxxxxxxx  
*Record the Patient ID for your records*



1. **Date of patient screening:** (ex. MM/DD/YYYY)

## PATIENT DEMOGRAPHICS

2. **Ethnicity** (select only one):  Hispanic or Latino  Non-Hispanic/Latino  Unknown

3. **Race:**

<input type="checkbox"/> American Indian or Alaska Native	<input type="checkbox"/> Native Hawaiian or Other Pacific Islander	<input type="checkbox"/> Asian
<input type="checkbox"/> Black or African American	<input type="checkbox"/> White	<input type="checkbox"/> More Than One Race
<input type="checkbox"/> Not Reported, Patient Refused	<input type="checkbox"/> Not Reported, Data Not Available	<input type="checkbox"/> Unknown, Patient Unsure of Race

4. **Gender** (select only one):  Male  Female

5. **Age** (ex.43):

## PROTOCOL SCREENING METHODS

6. **Protocol for which the patient was screened** (select only one):

<input type="checkbox"/> ECOG E1505 (Lung)	<input type="checkbox"/> CALGB 50303 (Lymphoma) Tissue Procurement
<input type="checkbox"/> ECOG E2804 (Renal Cell) Phase II	<input type="checkbox"/> CALGB C80405 (Colorectal)
<input type="checkbox"/> ECOG E2805 (Adjuvant Renal)	<input type="checkbox"/> NCCTG N0147 (Adjuvant Colon)
<input type="checkbox"/> ECOG E5202 (Adjuvant Colon)	<input type="checkbox"/> NSABP B-42 (Breast)
<input type="checkbox"/> PACCT-1 (TailorX)	<input type="checkbox"/> NSABP C-10 (Colon) Phase II

7. **What method(s) were used to identify this patient for protocol screening** (select all that apply):

<input type="checkbox"/> Chart review	<input type="checkbox"/> Patient self referral
<input type="checkbox"/> Tumor Board	<input type="checkbox"/> Physician referral: NCCCP Investigator
<input type="checkbox"/> Cancer/Tumor Registry	<input type="checkbox"/> Physician referral: within institution
<input type="checkbox"/> Patient care rounds	<input type="checkbox"/> Physician referral: outside institution
<input type="checkbox"/> Multidisciplinary/disease site conferences	<input type="checkbox"/> Patient Navigator
<input type="checkbox"/> Review of surgical schedule	<input type="checkbox"/> Response to advertisement

8. **Was the patient navigator used in identifying the patient for screening:**  Yes  No

9. **If the patient navigator was involved, indicate how they were involved** (select all that apply):

Navigator obtained consent for treatment  Navigator referred patient to the research team



## PROTOCOL SCREENING

10. Did the patient enroll in the protocol:  Yes  No

11. If the patient did not enroll in the protocol, indicate the reason why (select only one):

- |  |  |
|--|--|
| <input type="checkbox"/> Patient did not meet trial eligibility criteria (skip to question 13) | <input type="checkbox"/> Patient was eligible but MD declined to offer participation (skip to question 15)                 |
| <input type="checkbox"/> Patient was eligible but declined participation (skip to question 14) | <input type="checkbox"/> Patient was eligible but started treatment prior to completion of screening (skip to question 12) |

12. If the patient was not captured prior to starting treatment, indicate reason why (select only one):

- |  |  |
|--|--|
| <input type="checkbox"/> Urgency to initiate treatment             | <input type="checkbox"/> Insufficient medical records at time of screening |
| <input type="checkbox"/> Patient not referred to the research team | <input type="checkbox"/> Other (Text): _____                               |
| <input type="checkbox"/> Recurring patient/ not new patient        |  |

13. If the patient did not meet trial eligibility criteria, indicate the reason why (select all that apply):

- |   |   |
|---|---|
| <input type="checkbox"/> Performance status                       | <input type="checkbox"/> Co-morbidities   |
| <input type="checkbox"/> Abnormal labs                            | <input type="checkbox"/> Insufficient or unavailable pathologic samples for study (including unclear margins) |
| <input type="checkbox"/> Abnormal organ function                  | <input type="checkbox"/> Does not meet genetic testing criteria   |
| <input type="checkbox"/> Prior therapy                            | <input type="checkbox"/> Patient had progressive disease  |
| <input type="checkbox"/> Time requirement from surgery or therapy | <input type="checkbox"/> Other (Text): _____  |

14. If the patient was eligible but the patient declined participation, indicate the patient-related reason why (select all that apply):

- |   |  |
|---|--|
| <input type="checkbox"/> No desire to participate in research           | <input type="checkbox"/> Social issues (Housing, childcare)                      |
| <input type="checkbox"/> Preference for standard treatment              | <input type="checkbox"/> Mistrust of research                                    |
| <input type="checkbox"/> Patient preferred another trial                | <input type="checkbox"/> Family member influenced against trial participation    |
| <input type="checkbox"/> Lack of awareness/education about trials       | <input type="checkbox"/> Language barrier/lack of access to interpreter          |
| <input type="checkbox"/> Perceived side effects / toxicities too great  | <input type="checkbox"/> Patient declined to be retested per protocol            |
| <input type="checkbox"/> Cultural / religious issues                    | <input type="checkbox"/> Refused to have re-biopsy or further tissue collection  |
| <input type="checkbox"/> No insurance coverage                          | <input type="checkbox"/> Insurance company refused to pay for additional testing |
| <input type="checkbox"/> Financial concerns/ indirect costs (work, etc) | <input type="checkbox"/> Insurance company denied coverage                       |
| <input type="checkbox"/> Travel & transportation issues                 | <input type="checkbox"/> Other (Text): _____                                     |

15. If the patient was eligible but the MD declined to offer participation, indicate the physician-related reason why (select all that apply):

- |   |  |
|---|--|
| <input type="checkbox"/> Preferred to offer standard of care                                  | <input type="checkbox"/> Lack of knowledge/awareness of the trial by MD/research staff |
| <input type="checkbox"/> Preferred to offer a different trial                                 | <input type="checkbox"/> Lack of adequate reimbursement                                |
| <input type="checkbox"/> Medical concerns re: age/frailty of patient                          | <input type="checkbox"/> Physician declined to have patient retested per protocol      |
| <input type="checkbox"/> Medical concerns re: patient tolerating treatment/performance status | <input type="checkbox"/> Insurance company refused to pay for additional testing       |
| <input type="checkbox"/> Concerns over patient non-compliance/lack of social support          | <input type="checkbox"/> Insurance company denied coverage                             |
| <input type="checkbox"/> Lack of time for MD/research staff to offer patient the trial        | <input type="checkbox"/> Refused to have re-biopsy or further tissue collection        |
| <input type="checkbox"/> Lack of MD/research staff time/support to administer the trial       | <input type="checkbox"/> Language barrier/lack of access to interpreter                |
|   | <input type="checkbox"/> Other (Text): _____   |

16. If there was a language barrier, indicate the language spoken (select only one):

- Spanish  French  Chinese  Korean  Vietnamese  Other  N/A

## Recruitment Strategies Log



Date of Project (month ____ year ____ )				
Recruitment Strategy (list activity)	Try Strategy Again (Y/N)	Number of Potential Participants		
		Number Contacted? (Actual/Estimate)	Number Who Visited Clinic/Site	Number Accrued/ Enrolled?
<b>Month/Week 1</b>				
1.				
2.				
3.				
4.				
<b>Month/Week 2</b>				
1.				
2.				
3.				
4.				

Site name: \_\_\_\_\_ Date: \_\_\_\_\_

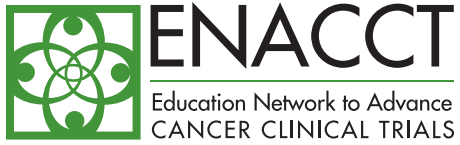
Staff member name: \_\_\_\_\_



## Sample Screening Log Summary



Site 1	
Patients Screened	
Patients Enrolled	
Withdrawals	
• Treatment Failure	
• Adverse Event	
• Progression of Disease	
• WD Consent	
• Other	
# Queries Outstandin	
CRFs received to date	
CRFs entered to date	
Site 2	
Patients Screened	
Patients Enrolled	
Patients Completed	
Withdrawals	
• Treatment Failure	
• Adverse Event	
• Progression of Disease	
• WD Consent	
• Other	
# Queries Outstanding	
CRFs received to date	
CRFs entered to date	



# Five Steps to Enhance Patient Participation in Cancer Clinical Trials

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## Guide and Workbook

### **PART III: Additional Resources**



# ADDITIONAL RESOURCES

## Cultural Competency in Cancer Clinical Trials

ENACCT- *Your Role in Cancer Clinical Trials* -Level 1 and *Your Role in Action* -Level 2 (Online Courses)

[www.enacct.org/yourrole](http://www.enacct.org/yourrole)

Eliminating Disparities in Cancer Clinical Trials-*Culturally and Linguistically Appropriate Services And Clinical Trials (CLAS-ACT) SELF-STUDY Handbook*

<http://www.bcm.edu/edict/clas-act/handbook.cfm>

Department of Health and Human Services, Office of Minority Health- *Think Cultural Health* (Online Courses)

<http://www.thinkculturalhealth.hhs.gov>

## Language Access and Health Literacy

Department of Health and Human Services, Office of Minority Health- *National Standards for Culturally and Linguistically Appropriate Services in Health Care-Final Report*.

<http://minorityhealth.hhs.gov/assets/pdf/checked/finalreport.pdf>

Joint Commission-*Patient Centered Communication Standards for Hospitals*

[http://www.jointcommission.org/PatientSafety/HLC/HLC\\_Joint\\_Commission\\_Standards.htm](http://www.jointcommission.org/PatientSafety/HLC/HLC_Joint_Commission_Standards.htm)

American Medical Association-Health Literacy and Patients Safety: Help Patients Understand

<http://www.ama-assn.org/ama/no-index/about-ama/8035.shtml>

Cross Cultural Health Care Program DVD “Communicating Effectively Through an Interpreter”

<http://www.xculture.org/catalog/index.php?cPath=22>

## Informed Consent Short Form-Institutional Policies

Dana Farber Cancer Institute “*OHRS Information Sheet Instructions for Obtaining and Documenting Informed Consent of Non-English-Speaking Participants*”.

[http://www.dfhcc.harvard.edu/fileadmin/DFHCC\\_Admin/Clinical\\_Trials/OPRS/Investigator\\_Resources/Information\\_Sheets/IS\\_-\\_Non\\_English\\_Speaking\\_Subjects.pdf](http://www.dfhcc.harvard.edu/fileadmin/DFHCC_Admin/Clinical_Trials/OPRS/Investigator_Resources/Information_Sheets/IS_-_Non_English_Speaking_Subjects.pdf)

University of California-Irvine, Research Administration “*Consenting Subjects Who Do Not Read, Speak or Understand English*”

<http://www.research.uci.edu/ora/hrpp/non-englishspeakingparticipants.htm>

University of Minnesota, Institutional Review Board “*Guidance and FAQ’s*” Consent Short Forms & FAQs”

<http://www.research.umn.edu/irb/guidance/short-forms.html>

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